

# PHARMACY LAWS OF NORTH CAROLINA

**This compilation of some of the Pharmacy Laws of North Carolina is provided by the Board of Pharmacy for the convenience of its licensees and the public. It is not guaranteed to be a complete collection of all of the relevant laws, nor to be correct or updated. For complete guidance, you must refer to the official North Carolina General Statutes and Session Laws or consult an attorney.**

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**CHAPTER 90**  
**MEDICINE AND ALLIED OCCUPATIONS**  
**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.

**§ 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.
    - (11) "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.
- (12) "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.

#### **§ 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.

#### **§ 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.

#### **§ 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.

#### **§ 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.

#### **§ 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.

#### **§ 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.

#### **§ 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.

#### **§ 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.

#### **§ 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.

#### **§ 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.

**§ 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.

**§ 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.

**§ 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.

**§ 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.

**§ 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.

#### **§ 90-85.15B. Immunizing pharmacists.**

(a) Except as provided 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.

(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 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.

(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.

NOTE: On August 19, 2020, the U.S. Department of Health and Human Services issued an amendment to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) that preempts state law and allows licensed pharmacists and supervised pharmacy interns to administer certain vaccines to individuals ages three through eighteen, but only if they meet the following requirements:

- The vaccine must be FDA-authorized or FDA-licensed.
- The vaccination must be ordered and administered according to ACIP's standard immunization schedule.
- The pharmacist must complete a practical training program of at least 20 hours that is approved by ACPE and contains certain enumerated subjects, and the intern must complete a practical training program approved by the ACPE.
- The pharmacist and intern must have a current certificate in basic CPR.
- The pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing education during each State licensing period.
- The pharmacist must comply with all state recordkeeping and reporting requirements.
- The pharmacist must inform all childhood-vaccination patients and their adult caregivers of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.

Note that: (1) in order to be eligible to administer vaccines to younger patients than permitted by state law, the pharmacist and intern must comply with all of the requirements of this federal amendment, and (2) the federal amendment imposes additional continuing education requirements beyond that of state law. Pharmacists and interns who do not comply with the terms of this amendment must continue to follow state law.

The Declaration states that it is effective through December 31, 2024, though it may be amended or terminated sooner. See the current version of the declaration here: <https://www.federalregister.gov/documents/2023/05/12/2023-10216/eleventh-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for>

See the NCBOP's guidance: <http://ncbop.org/faqs/ExpandedVaccineAuthorityFAQ.pdf>

#### **§ 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.

#### **§ 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.

#### **§ 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.

**§ 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.

**§ 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.

...

**§ 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

**§ 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.

#### **§ 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.

#### **§ 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.

**§ 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.

**§ 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.

**§ 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.

**§ 90-85.24. Fees collectible by Board. [version effective until March 1, 2024]**

- (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).

(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.

**§ 90-85.24. Fees collectible by Board. [version effective on and after March 1, 2024]**

- (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.

**§ 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.

**§ 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.

**§ 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.

**§ 90-85.26B. Registration of dispensing optometrists. [effective March 1, 2024]**

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.

**§ 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.

**§ 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.

(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.

#### **§ 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.

#### **§ 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.

#### **§ 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.

#### **§ 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.

**§ 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.

**§ 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.

**§ 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.

**§ 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.

**§ 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.

**§ 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.

**§ 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, delivery, 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.

**§ 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.

**§ 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.

**§ 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.

## **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.



**CHAPTER 90**

**MEDICINE AND ALLIED OCCUPATIONS**

***OTHER SELECTED PROVISIONS***

**Article 1.  
Practice of Medicine.**

***Selected Provisions***

\* \* \* \* \*

**§ 90-1.1. Definitions.**

The following definitions apply in this Article:

- (1) Board. – The North Carolina Medical Board.  
...
- (4) License. – An authorization issued by the Board to a physician, physician assistant, or anesthesiologist assistant to perform medical acts, tasks, or functions.  
...
- (5) The practice of medicine or surgery. – Except as otherwise provided by this subdivision, the practice of medicine or surgery, for purposes of this Article, includes any of the following acts:
  - a. Advertising, holding out to the public, or representing in any manner that the individual is authorized to practice medicine in this State.
  - b. Offering or undertaking to prescribe, order, give, or administer any drug or medicine for the use of any other individual.
  - c. Offering or undertaking to prevent or diagnose, correct, prescribe for, administer to, or treat in any manner or by any means, methods, or devices any disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of any individual, including the management of pregnancy or parturition.
  - d. Offering or undertaking to perform any surgical procedure on any individual.
  - e. Using the designation "Doctor," "Doctor of Medicine," "Doctor of Osteopathy," "Doctor of Osteopathic Medicine," "Physician," "Surgeon," "Physician and Surgeon," "Dr.," "M.D.," "D.O.," or any combination thereof in the conduct of any occupation or profession pertaining to the prevention, diagnosis, or treatment of human disease or condition, unless the designation additionally contains the description of or reference to another branch of the healing arts for which the individual holds a valid license in this State or the use of the designation "Doctor" or "Physician" is otherwise specifically permitted by law.
  - f. The performance of any act, within or without this State, described in this subdivision by use of any electronic or other means, including the Internet or telephone.

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 medicine or surgery.

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**§ 90-8.2. Appointment of subcommittees.**

- ...
- (b) The North Carolina Medical Board shall appoint and maintain a subcommittee of four licensed physicians to work jointly with a subcommittee of the North Carolina Board of Pharmacy to develop rules to govern the performance of medical acts by clinical pharmacist practitioners, including the determination of reasonable fees to accompany an application for approval not to exceed one hundred dollars (\$100.00) and for renewal of approval not to exceed fifty dollars (\$50.00). Rules recommended by the subcommittee shall be adopted in accordance with Chapter 150B of the General Statutes by both the North Carolina Medical Board and the North Carolina Board of

Pharmacy and shall not become effective until adopted by both Boards. The North Carolina Medical Board shall have responsibility for ensuring compliance with these rules.

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**§ 90-12.7. Treatment of overdose with opioid antagonist; immunity.**

(a) As used in this section, "opioid antagonist" means an opioid antagonist that is approved by the federal Food and Drug Administration for the treatment of a drug overdose.

(b) The following individuals may prescribe an opioid antagonist in the manner prescribed by this subsection:

- (1) A practitioner acting in good faith and exercising reasonable care may directly or by standing order prescribe an opioid antagonist to (i) a person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose. As an indicator of good faith, the practitioner, prior to prescribing an opioid under this subsection, may require receipt of a written communication that provides a factual basis for a reasonable conclusion as to either of the following:
  - a. The person seeking the opioid antagonist is at risk of experiencing an opiate-related overdose.
  - b. The person other than the person who is at risk of experiencing an opiate-related overdose, and who is seeking the opioid antagonist, is in relation to the person at risk of experiencing an opiate-related overdose:
    1. A family member, friend, or other person.
    2. In the position to assist a person at risk of experiencing an opiate-related overdose.
- (2) The State Health Director or a designee may prescribe an opioid antagonist pursuant to subdivision (1) of this subsection by means of a statewide standing order.
- (3) A practitioner acting in good faith and exercising reasonable care may directly or by standing order prescribe an opioid antagonist to any governmental or nongovernmental organization, including a local health department, a law enforcement agency, or an organization that promotes scientifically proven ways of mitigating health risks associated with substance use disorders and other high-risk behaviors, for the purpose of distributing, through its agents, the opioid antagonist to (i) a person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose.

(c) A pharmacist may dispense an opioid antagonist to a person or organization pursuant to a prescription issued in accordance with subsection (b) of this section. For purposes of this section, the term "pharmacist" is as defined in G.S. 90-85.3.

(c1) A governmental or nongovernmental organization, including a local health department, a law enforcement agency, or an organization that promotes scientifically proven ways of mitigating health risks associated with substance use disorders and other high-risk behaviors may, through its agents, distribute an opioid antagonist obtained pursuant to a prescription issued in accordance with subdivision (3) of subsection (b) of this section or obtained over-the-counter to (i) a person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose. An organization, through its agents, shall include with any distribution of an opioid antagonist pursuant to this subsection basic instruction and information on how to administer the opioid antagonist.

(d) A person who receives an opioid antagonist that was prescribed pursuant to subsection (b) of this section or distributed pursuant to subsection (c1) of this section or obtained over-the-counter may administer an opioid antagonist to another person if (i) the person has a good faith belief that the other person is experiencing a drug-related overdose and (ii) the person exercises reasonable care in administering the drug to the other person. Evidence of the use of reasonable care in administering the drug shall include the receipt of basic instruction and information on how to administer the opioid antagonist.

(e) All of the following individuals are immune from any civil or criminal liability for actions authorized by this section:

- (1) Any practitioner who prescribes an opioid antagonist pursuant to subsection (b) of this section.
- (2) Any pharmacist who dispenses an opioid antagonist pursuant to subsection (c) of this section.
- (3) Any person who administers an opioid antagonist pursuant to subsection (d) of this section.

- (4) The State Health Director acting pursuant to subsection (b) of this section.
- (5) Any organization, or agent of the organization, that distributes an opioid antagonist pursuant to subsection (c1) of this section.

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**§ 90-18. Practicing without license; penalties.**

(a) No person shall perform any act constituting the practice of medicine or surgery, as defined in this Article, or any of the branches thereof, unless the person shall have been first licensed and registered so to do in the manner provided in this Article. Any person who practices medicine or surgery without being duly licensed and registered, as provided in this Article, shall not be allowed to maintain any action to collect any fee for such services. Any person so practicing without being duly licensed and registered in this State shall be guilty of a Class 1 misdemeanor. Any person so practicing without being duly licensed and registered in this State and who is falsely representing himself or herself in a manner as being licensed or registered under this Article or any Article of this Chapter shall be guilty of a Class I felony. Any person so practicing without being duly licensed and registered in this State and who is an out-of-state practitioner shall be guilty of a Class I felony. Any person who has a license or approval under this Article that is inactive due solely to the failure to complete annual registration in a timely fashion as required by this Article or any person who is licensed, registered, and practicing under any other Article of this Chapter shall be guilty of a Class 1 misdemeanor.

...  
 (c) The following shall not constitute practicing medicine or surgery as defined in this Article:

- ...  
 (3) The practice of pharmacy by any legally licensed pharmacist engaged in the practice of pharmacy.
- (3a) The provision of drug therapy management by a licensed pharmacist engaged in the practice of pharmacy pursuant to an agreement that is physician, pharmacist, patient, and disease specific when performed in accordance with rules and rules developed by a joint subcommittee of the North Carolina Medical Board and the North Carolina Board of Pharmacy and approved by both Boards. Drug therapy management shall be defined as: (i) the implementation of predetermined drug therapy which includes diagnosis and product selection by the patient's physician; (ii) modification of prescribed drug dosages, dosage forms, and dosage schedules; and (iii) ordering tests; (i), (ii), and (iii) shall be pursuant to an agreement that is physician, pharmacist, patient, and disease specific.

...

**§ 90-18.1. Limitations on physician assistants.**

(a) Any person who is licensed under the provisions of G.S. 90-9.3 to perform medical acts, tasks, and functions as a physician assistant may use the title "physician assistant" or "P.A." Any other person who uses the title in any form or holds out to be a physician assistant or to be so licensed, shall be deemed to be in violation of this Article.

- (b) Physician assistants are authorized to write prescriptions for drugs under the following conditions:
  - (1) The North Carolina Medical Board has adopted regulations governing the approval of individual physician assistants to write prescriptions with such limitations as the Board may determine to be in the best interest of patient health and safety.
  - (2) The physician assistant holds a current license issued by the Board.
  - (4) The supervising physician has provided to the physician assistant written instructions about indications and contraindications for prescribing drugs and a written policy for periodic review by the physician of the drugs prescribed.
  - (5) A physician assistant shall personally consult with the supervising physician prior to prescribing a targeted controlled substance as defined in Article 5 of this Chapter when all of the following conditions apply:
    - a. The patient is being treated by a facility that primarily engages in the treatment of pain by prescribing narcotic medications.
    - b. The therapeutic use of the targeted controlled substance will or is expected to exceed a period of 30 days.

When a targeted controlled substance prescribed in accordance with this subdivision is continuously prescribed to the same patient, the physician assistant shall consult with the supervising physician at least once every 90 days to verify that the prescription remains medically appropriate for the patient.

- (c) Physician assistants are authorized to compound and dispense drugs under the following conditions:
  - (1) The function is performed under the supervision of a licensed pharmacist.
  - (2) Rules and regulations of the North Carolina Board of Pharmacy governing this function are complied with.
  - (3) The physician assistant holds a current license issued by the Board.
- (d) Physician assistants are authorized to order medications, tests and treatments in hospitals, clinics, nursing homes, and other health facilities under the following conditions:
  - (1) The North Carolina Medical Board has adopted regulations governing the approval of individual physician assistants to order medications, tests, and treatments with such limitations as the Board may determine to be in the best interest of patient health and safety.
  - (2) The physician assistant holds a current license issued by the Board.
  - (3) The supervising physician has provided to the physician assistant written instructions about ordering medications, tests, and treatments, and when appropriate, specific oral or written instructions for an individual patient, with provision for review by the physician of the order within a reasonable time, as determined by the Board, after the medication, test, or treatment is ordered.
  - (4) The hospital or other health facility has adopted a written policy about ordering medications, tests, and treatments, including procedures for verification of the physician assistants' orders by nurses and other facility employees and such other procedures as are in the interest of patient health and safety.
- (e) Any prescription written by a physician assistant or order given by a physician assistant for medications, tests, or treatments shall be deemed to have been authorized by the physician approved by the Board as the supervisor of the physician assistant and the supervising physician shall be responsible for authorizing the prescription or order.  
...
- (g) Any person who is licensed under G.S. 90-9.3 to perform medical acts, tasks, and functions as a physician assistant shall comply with each of the following:
  - (1) Maintain a current and active license to practice in this State.
  - (2) Maintain an active registration with the Board.
  - (3) Have a current Intent to Practice form filed with the Board.
- (h) A physician assistant serving active duty in the Armed Forces of the United States is exempt from the requirements of subdivision (g)(3) of this section.
- (i) A physician assistant's license shall become inactive any time the holder fails to comply with the requirements of subsection (g) of this section. A physician assistant with an inactive license shall not practice medical acts, tasks, or functions. The Board shall retain jurisdiction over the holder of the inactive license.

**§ 90-18.2. Limitations on nurse practitioners.**

- (a) Any nurse approved under the provisions of G.S. 90-18(c)(14) to perform medical acts, tasks or functions may use the title "nurse practitioner." Any other person who uses the title in any form or holds out to be a nurse practitioner or to be so approved, shall be deemed to be in violation of this Article.
- (b) Nurse practitioners are authorized to write prescriptions for drugs under all of the following conditions:
  - (1) The North Carolina Medical Board and Board of Nursing have adopted regulations developed by a joint subcommittee governing the approval of individual nurse practitioners to write prescriptions with such limitations as the boards may determine to be in the best interest of patient health and safety.
  - (2) The nurse practitioner has current approval from the boards.
  - (4) The supervising physician has provided to the nurse practitioner written instructions about indications and contraindications for prescribing drugs and a written policy for periodic review by the physician of the drugs prescribed.
  - (5) A nurse practitioner shall personally consult with the supervising physician prior to prescribing a targeted controlled substance as defined in Article 5 of this Chapter when all of the following conditions apply:
    - a. The patient is being treated by a facility that primarily engages in the treatment of pain by prescribing narcotic medications.

b. The therapeutic use of the targeted controlled substance will or is expected to exceed a period of 30 days.

When a targeted controlled substance prescribed in accordance with this subdivision is continuously prescribed to the same patient, the nurse practitioner shall consult with the supervising physician at least once every 90 days to verify that the prescription remains medically appropriate for the patient.

- (c) Nurse practitioners are authorized to compound and dispense drugs under the following conditions:
- (1) The function is performed under the supervision of a licensed pharmacist; and
  - (2) Rules and regulations of the North Carolina Board of Pharmacy governing this function are complied with.
- (d) Nurse practitioners are authorized to order medications, tests and treatments in hospitals, clinics, nursing homes and other health facilities under all of the following conditions:
- (1) The North Carolina Medical Board and Board of Nursing have adopted regulations developed by a joint subcommittee governing the approval of individual nurse practitioners to order medications, tests and treatments with such limitations as the boards may determine to be in the best interest of patient health and safety.
  - (2) The nurse practitioner has current approval from the boards.
  - (3) The supervising physician has provided to the nurse practitioner written instructions about ordering medications, tests and treatments, and when appropriate, specific oral or written instructions for an individual patient, with provision for review by the physician of the order within a reasonable time, as determined by the Board, after the medication, test or treatment is ordered.
  - (4) The hospital or other health facility has adopted a written policy, approved by the medical staff after consultation with the nursing administration, about ordering medications, tests and treatments, including procedures for verification of the nurse practitioners' orders by nurses and other facility employees and such other procedures as are in the interest of patient health and safety.
- (e) Any prescription written by a nurse practitioner or order given by a nurse practitioner for medications, tests or treatments shall be deemed to have been authorized by the physician approved by the boards as the supervisor of the nurse practitioner and such supervising physician shall be responsible for authorizing such prescription or order.

...

**§ 90-18.2A. Physician assistants receiving, prescribing, or dispensing prescription drugs without charge or fee.**

The North Carolina Medical Board shall have sole jurisdiction to regulate and license physician assistants receiving, prescribing, or dispensing prescription drugs under the supervision of a licensed physician without charge or fee to the patient. The provisions of G.S. 90-18.1(c)(1), (c)(2), and G.S. 90-85.21(b), shall not apply to the receiving, prescribing, or dispensing of prescription drugs without charge or fee to the patient.

\* \* \* \* \*

**§ 90-18.4. Limitations on clinical pharmacist practitioners.**

(a) Any pharmacist who is approved under the provisions of G.S. 90-18(c)(3a) to perform medical acts, tasks, and functions may use the title "clinical pharmacist practitioner". Any other person who uses the title in any form or holds himself or herself out to be a clinical pharmacist practitioner or to be so licensed shall be deemed to be in violation of this Article.

(b) Clinical pharmacist practitioners are authorized to implement predetermined drug therapy, which includes diagnosis and product selection by the patient's physician, modify prescribed drug dosages, dosage forms, and dosage schedules, and to order laboratory tests pursuant to a drug therapy management agreement that is physician, pharmacist, patient, and disease specific under the following conditions:

- (1) The North Carolina Medical Board and the North Carolina Board of Pharmacy have adopted rules developed by a joint subcommittee governing the approval of individual clinical pharmacist practitioners to practice drug therapy management with such limitations that the Boards determine to be in the best interest of patient health and safety.
- (2) The clinical pharmacist practitioner has current approval from both Boards.

- (3) The North Carolina Medical Board has assigned an identification number to the clinical pharmacist practitioner which is shown on written prescriptions written by the clinical pharmacist practitioner.
  - (4) The drug therapy management agreement prohibits the substitution of a chemically dissimilar drug product by the pharmacist for the product prescribed by the physician without the explicit consent of the physician and includes a policy for periodic review by the physician of the drugs modified pursuant to the agreement or changed with the consent of the physician.
- (c) Clinical pharmacist practitioners in hospitals and other health facilities that have an established pharmacy and therapeutics committee or similar group that determines the prescription drug formulary or other list of drugs to be utilized in the facility and determines procedures to be followed when considering a drug for inclusion on the formulary and procedures to acquire a nonformulary drug for a patient may order medications and tests under the following conditions:
- (1) The North Carolina Medical Board and the North Carolina Board of Pharmacy have adopted rules governing the approval of individual clinical pharmacist practitioners to order medications and tests with such limitations as the Boards determine to be in the best interest of patient health and safety.
  - (2) The clinical pharmacist practitioner has current approval from both Boards.
  - (3) The supervising physician has provided to the clinical pharmacist practitioner written instructions for ordering, changing, or substituting drugs, or ordering tests with provision for review of the order by the physician within a reasonable time, as determined by the Boards, after the medication or tests are ordered.
  - (4) The hospital or health facility has adopted a written policy, approved by the medical staff after consultation with nursing administrators, concerning the ordering of medications and tests, including procedures for verification of the clinical pharmacist practitioner's orders by nurses and other facility employees and such other procedures that are in the best interest of patient health and safety.
  - (5) Any drug therapy order written by a clinical pharmacist practitioner or order for medications or tests shall be deemed to have been authorized by the physician approved by the Boards as the supervisor of the clinical pharmacist practitioner and the supervising physician shall be responsible for authorizing the prescription order.
- (d) Any registered nurse or licensed practical nurse who receives a drug therapy order from a clinical pharmacist practitioner for medications or tests is authorized to perform that order in the same manner as if the order was received from a licensed physician.

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**Article 1A.  
Treatment of Minors.**

*Selected Provisions*

**§ 90-21.1. When physician may treat minor without consent of parent, guardian or person in loco parentis.**

It shall be lawful for any physician licensed to practice medicine in North Carolina to render treatment to any minor without first obtaining the consent and approval of either the father or mother of said child, or any person acting as guardian, or any person standing in loco parentis to said child where:

- (1) The parent or parents, the guardian, or a person standing in loco parentis to said child cannot be located or contacted with reasonable diligence during the time within which said minor needs to receive the treatment herein authorized, or
- (2) Where the identity of the child is unknown, or where the necessity for immediate treatment is so apparent that any effort to secure approval would delay the treatment so long as to endanger the life of said minor, or
- (3) Where an effort to contact a parent, guardian, or person standing in loco parentis would result in a delay that would seriously worsen the physical condition of said minor, or
- (4) Where the parents refuse to consent to a procedure, and the necessity for immediate treatment is so apparent that the delay required to obtain a court order would endanger the life or seriously worsen the physical condition of the child. No treatment shall be administered to a

child over the parent's objection as herein authorized unless the physician shall first obtain the opinion of another physician licensed to practice medicine in the State of North Carolina that such procedure is necessary to prevent immediate harm to the child.

Provided, however, that the refusal of a physician to use, perform or render treatment to a minor without the consent of the minor's parent, guardian, or person standing in the position of loco parentis, in accordance with this Article, shall not constitute grounds for a civil action or criminal proceedings against such physician.

**§ 90-21.2. "Treatment" defined.**

The word "treatment" as used in G.S. 90-21.1 is hereby defined to mean any medical procedure or treatment, including X rays, the administration of drugs, blood transfusions, use of anesthetics, and laboratory or other diagnostic procedures employed by or ordered by a physician licensed to practice medicine in the State of North Carolina that is used, employed, or ordered to be used or employed commensurate with the exercise of reasonable care and equal to the standards of medical practice normally employed in the community where said physician administers treatment to said minor.

\* \* \* \* \*

**§ 90-21.4. Responsibility, liability and immunity of physicians.**

(a) Any physician licensed to practice medicine in North Carolina providing health services to a minor under the terms, conditions and circumstances of this Article shall not be held liable in any civil or criminal action for providing such services without having obtained permission from the minor's parent, legal guardian, person standing in loco parentis, or a legal custodian other than a parent when granted specific authority in a custody order to consent to medical or psychiatric treatment. The physician shall not be relieved on the basis of this Article from liability for negligence in the diagnosis and treatment of a minor.

(b) The physician shall not notify a parent, legal guardian, person standing in loco parentis, or a legal custodian other than a parent when granted specific authority in a custody order to consent to medical or psychiatric treatment, without the permission of the minor, concerning the medical health services set out in G.S. 90-21.5(a), unless the situation in the opinion of the attending physician indicates that notification is essential to the life or health of the minor. If a parent, legal guardian[,] person standing in loco parentis, or a legal custodian other than a parent when granted specific authority in a custody order to consent to medical or psychiatric treatment contacts the physician concerning the treatment or medical services being provided to the minor, the physician may give information.

**§ 90-21.5. Minor's consent sufficient for certain medical health services.**

(a) Subject to subsection (a1) of this section, any minor may give effective consent to a physician licensed to practice medicine in North Carolina for medical health services for the prevention, diagnosis and treatment of (i) venereal disease and other diseases reportable under G.S. 130A-135, (ii) pregnancy, (iii) abuse of controlled substances or alcohol, and (iv) emotional disturbance. This section does not authorize the inducing of an abortion, performance of a sterilization operation, or admission to a 24-hour facility licensed under Article 2 of Chapter 122C of the General Statutes except as provided in G.S. 122C-223. This section does not prohibit the admission of a minor to a treatment facility upon his own written application in an emergency situation as authorized by G.S. 122C-223.

(a1) Notwithstanding any other provision of law to the contrary, a health care provider shall obtain written consent from a parent or legal guardian prior to administering any vaccine that has been granted emergency use authorization and is not yet fully approved by the United States Food and Drug Administration to an individual under 18 years of age.

(b) Any minor who is emancipated may consent to any medical treatment, dental and health services for himself or for his child.

**Article 1B.**

**Medical Malpractice Actions.**

*Selected Provisions*

**§ 90-21.11. Definitions.**

The following definitions apply in this Article:

- (1) Health care provider. – Without limitation, any of the following:

- a. A person who pursuant to the provisions of Chapter 90 of the General Statutes is licensed, or is otherwise registered or certified to engage in the practice of or otherwise performs duties associated with any of the following: medicine, surgery, dentistry, pharmacy, optometry, midwifery, osteopathy, podiatry, chiropractic, radiology, nursing, physiotherapy, pathology, anesthesiology, anesthesia, laboratory analysis, rendering assistance to a physician, dental hygiene, psychiatry, or psychology.
  - b. A hospital, a nursing home licensed under Chapter 131E of the General Statutes, or an adult care home licensed under Chapter 131D of the General Statutes.
  - c. Any other person who is legally responsible for the negligence of a person described by sub-subdivision a. of this subdivision, a hospital, a nursing home licensed under Chapter 131E of the General Statutes, or an adult care home licensed under Chapter 131D of the General Statutes.
  - d. Any other person acting at the direction or under the supervision of a person described by sub-subdivision a. of this subdivision, a hospital, a nursing home licensed under Chapter 131E of the General Statutes, or an adult care home licensed under Chapter 131D of the General Statutes.
  - e. Any paramedic, as defined in G.S. 131E-155(15a).
- (2) Medical malpractice action. – Either of the following:
- a. A civil action for damages for personal injury or death arising out of the furnishing or failure to furnish professional services in the performance of medical, dental, or other health care by a health care provider.
  - b. A civil action against a hospital, a nursing home licensed under Chapter 131E of the General Statutes, or an adult care home licensed under Chapter 131D of the General Statutes for damages for personal injury or death, when the civil action (i) alleges a breach of administrative or corporate duties to the patient, including, but not limited to, allegations of negligent credentialing or negligent monitoring and supervision and (ii) arises from the same facts or circumstances as a claim under sub-subdivision a. of this subdivision.

**§ 90-21.12. Standard of health care.**

(a) Except as provided in subsection (b) of this section, in any medical malpractice action as defined in G.S. 90-21.11(2)(a), the defendant health care provider shall not be liable for the payment of damages unless the trier of fact finds by the greater weight of the evidence that the care of such health care provider was not in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities under the same or similar circumstances at the time of the alleged act giving rise to the cause of action; or in the case of a medical malpractice action as defined in G.S. 90-21.11(2)(b), the defendant health care provider shall not be liable for the payment of damages unless the trier of fact finds by the greater weight of the evidence that the action or inaction of such health care provider was not in accordance with the standards of practice among similar health care providers situated in the same or similar communities under the same or similar circumstances at the time of the alleged act giving rise to the cause of action.

(b) In any medical malpractice action arising out of the furnishing or the failure to furnish professional services in the treatment of an emergency medical condition, as the term "emergency medical condition" is defined in 42 U.S.C. § 1395dd(e)(1)(A), the claimant must prove a violation of the standards of practice set forth in subsection (a) of this section by clear and convincing evidence.

\* \* \* \* \*

**§ 90-21.13. Informed consent to health care treatment or procedure.**

(a) No recovery shall be allowed against any health care provider upon the grounds that the health care treatment was rendered without the informed consent of the patient or other person authorized to give consent for the patient where:

- (1) The action of the health care provider in obtaining the consent of the patient or other person authorized to give consent for the patient was in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities; and



- (2) A reasonable person, from the information provided by the health care provider under the circumstances, would have a general understanding of the procedures or treatments and of the usual and most frequent risks and hazards inherent in the proposed procedures or treatments which are recognized and followed by other health care providers engaged in the same field of practice in the same or similar communities; or
  - (3) A reasonable person, under all the surrounding circumstances, would have undergone such treatment or procedure had he been advised by the health care provider in accordance with the provisions of subdivisions (1) and (2) of this subsection.
- (b) A consent which is evidenced in writing and which meets the foregoing standards, and which is signed by the patient or other authorized person, shall be presumed to be a valid consent. This presumption, however, may be subject to rebuttal only upon proof that such consent was obtained by fraud, deception or misrepresentation of a material fact. A consent that meets the foregoing standards, that is given by a patient, or other authorized person, who under all the surrounding circumstances has capacity to make and communicate health care decisions, is a valid consent.
- (c) The following persons, in the order indicated, are authorized to consent to medical treatment on behalf of a patient who is comatose or otherwise lacks capacity to make or communicate health care decisions:
- (1) A guardian of the patient's person, or a general guardian with powers over the patient's person, appointed by a court of competent jurisdiction pursuant to Article 5 of Chapter 35A of the General Statutes; provided that, if the patient has a health care agent appointed pursuant to a valid health care power of attorney, the health care agent shall have the right to exercise the authority to the extent granted in the health care power of attorney and to the extent provided in G.S. 32A-19(a) unless the Clerk has suspended the authority of that health care agent in accordance with G.S. 35A-1208(a).
  - (2) A health care agent appointed pursuant to a valid health care power of attorney, to the extent of the authority granted.
  - (3) An agent, with powers to make health care decisions for the patient, appointed by the patient pursuant to Chapter 32C of the General Statutes, to the extent of the authority granted.
  - (4) The patient's spouse.
  - (5) A majority of the patient's reasonably available parents and children who are at least 18 years of age.
  - (6) A majority of the patient's reasonably available siblings who are at least 18 years of age.
  - (7) An individual who has an established relationship with the patient, who is acting in good faith on behalf of the patient, and who can reliably convey the patient's wishes.
- (c1) If none of the persons listed under subsection (c) of this section is reasonably available, then the patient's attending physician, in the attending physician's discretion, may provide health care treatment without the consent of the patient or other person authorized to consent for the patient if there is confirmation by a physician other than the patient's attending physician of the patient's condition and the necessity for treatment; provided, however, that confirmation of the patient's condition and the necessity for treatment are not required if the delay in obtaining the confirmation would endanger the life or seriously worsen the condition of the patient.
- (d) No action may be maintained against any health care provider upon any guarantee, warranty or assurance as to the result of any medical, surgical or diagnostic procedure or treatment unless the guarantee, warranty or assurance, or some note or memorandum thereof, shall be in writing and signed by the provider or by some other person authorized to act for or on behalf of such provider.
- (e) In the event of any conflict between the provisions of this section and those of G.S. 35A-1245, 90-21.17, and 90-322, Articles 1A and 19 of Chapter 90, and Article 3 of Chapter 122C of the General Statutes, the provisions of those sections and Articles shall control and continue in full force and effect.

**§ 90-21.14. First aid or emergency treatment; liability limitation.**

- (a) Any person, including a volunteer medical or health care provider at a facility of a local health department as defined in G.S. 130A-2 or at a nonprofit community health center or a volunteer member of a rescue squad, who voluntarily and without expectation of compensation renders first aid or emergency health care treatment to a person who is unconscious, ill or injured,
- (1) When the reasonably apparent circumstances require prompt decisions and actions in medical or other health care, and

- (2) When the necessity of immediate health care treatment is so reasonably apparent that any delay in the rendering of the treatment would seriously worsen the physical condition or endanger the life of the person,

shall not be liable for damages for injuries alleged to have been sustained by the person or for damages for the death of the person alleged to have occurred by reason of an act or omission in the rendering of the treatment unless it is established that the injuries were or the death was caused by gross negligence, wanton conduct or intentional wrongdoing on the part of the person rendering the treatment. The immunity conferred in this section also applies to any person who uses an automated external defibrillator (AED) and otherwise meets the requirements of this section.

...

(b) Nothing in this section shall be deemed or construed to relieve any person from liability for damages for injury or death caused by an act or omission on the part of such person while rendering health care services in the normal and ordinary course of his business or profession. Services provided by a volunteer health care provider who receives no compensation for his services and who renders first aid or emergency treatment to members of athletic teams are deemed not to be in the normal and ordinary course of the volunteer health care provider's business or profession.

(c) In the event of any conflict between the provisions of this section and those of G.S. 20-166(d), the provisions of G.S. 20-166(d) shall control and continue in full force and effect.

**§ 90-21.15. Emergency treatment using automated external defibrillator; immunity.**

(a) It is the intent of the General Assembly that, when used in accordance with this section, an automated external defibrillator may be used during an emergency for the purpose of attempting to save the life of another person who is in or who appears to be in cardiac arrest.

(b) For purposes of this section:

(1) "Automated external defibrillator" means a device, heart monitor, and defibrillator that meets all of the following requirements:

- a. The device has received approval from the United States Food and Drug Administration of its premarket notification filed pursuant to 21 U.S.C. § 360(k), as amended.
- b. The device is capable of recognizing the presence or absence of ventricular fibrillation or rapid ventricular tachycardia and is capable of determining, without intervention by an operator, whether defibrillation should be performed.
- c. Upon determining that defibrillation should be performed, the device automatically charges and requests delivery of, or delivers, an electrical impulse to an individual's heart.

(2) "Person" means an individual, corporation, limited liability company, partnership, association, unit of government, or other legal entity.

(3) "Training" means a nationally recognized course or training program in cardiopulmonary resuscitation (CPR) and automated external defibrillator use including the programs approved and provided by the:

- a. American Heart Association.
- b. American Red Cross.

(c) The use of an automated external defibrillator when used to attempt to save or to save a life shall constitute "first-aid or emergency health care treatment" under G.S. 90-21.14(a).

(d) The person who provides the cardiopulmonary resuscitation and automated external defibrillator training to a person using an automated external defibrillator, the person responsible for the site where the automated external defibrillator is located when the person has provided for a program of training, and a North Carolina licensed physician writing a prescription without compensation for an automated external defibrillator whether or not required by any federal or state law, shall be immune from civil liability arising from the use of an automated external defibrillator used in accordance with subsection (c) of this section.

(e) The immunity from civil liability otherwise existing under law shall not be diminished by the provisions of this section.

(f) Nothing in this section requires the purchase, placement, or use of automated external defibrillators by any person, entity, or agency of State, county, or local government. Nothing in this section applies to a product's liability claim against a manufacturer or seller as defined in G.S. 99B-1.

(g) In order to enhance public health and safety, a seller of an automated external defibrillator shall notify the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Office of Emergency Medical Services of the existence, location, and type of automated external defibrillator.

**§ 90-21.15A. Emergency treatment using epinephrine auto-injector; immunity.**

(a) Definitions. – The following definitions apply in this section:

- (1) Administer. – The direct application of an epinephrine auto-injector to the body of an individual.
- (2) Authorized entity. – Any entity or organization, other than a school described in G.S. 115C-375.2A, at which allergens capable of causing anaphylaxis may be present, including, but not limited to, recreation camps, colleges, universities, day care facilities, youth sports leagues, amusement parks, restaurants, places of employment, and sports arenas. An authorized entity shall also include any person, corporation, or other entity that owns or operates any entity or organization listed.
- (3) Epinephrine auto-injector. – A single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body.
- (4) Health care provider. – A health care provider licensed to prescribe drugs under the laws of this State.
- (5) Provide. – To supply one or more epinephrine auto-injectors to an individual.

(b) Prescribing to Authorized Entities Permitted. – A health care provider may prescribe epinephrine auto-injectors in the name of an authorized entity for use in accordance with this section, and pharmacists and health care providers may dispense epinephrine auto-injectors pursuant to a prescription issued in the name of an authorized entity. A prescription issued pursuant to this section shall be valid for no more than two years.

(c) Authorized Entities Permitted to Maintain Supply. – An authorized entity may acquire and stock a supply of epinephrine auto-injectors pursuant to a prescription issued in accordance with this section. An authorized entity that acquires and stocks epinephrine auto-injectors shall make a good-faith effort to store the supply of epinephrine auto-injectors in accordance with the epinephrine auto-injector manufacturer's instructions for use and any additional requirements that may be established by the Department of Health and Human Services. An authorized entity that acquires and stocks a supply of epinephrine auto-injectors pursuant to a prescription issued in accordance with this section shall designate employees or agents to be responsible for the storage, maintenance, control, and general oversight of epinephrine auto-injectors acquired by the authorized entity.

(d) Use of Epinephrine Auto-Injectors by Authorized Entities. – An employee or agent of an authorized entity or other individual who has completed the training required by subsection (e) of this section may use epinephrine auto-injectors prescribed pursuant to G.S. 90-726.1 to do any of the following:

- (1) Provide an epinephrine auto-injector to any individual who the employee, agent, or other individual believes in good faith is experiencing anaphylaxis, or a person believed in good faith to be the parent, guardian, or caregiver of such individual, for immediate administration, regardless of whether the individual has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy.
- (2) Administer an epinephrine auto-injector to any individual who the employee, agent, or other individual believes in good faith is experiencing anaphylaxis, regardless of whether the individual has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy.

(e) Mandatory Training Program. – An authorized entity that elects to acquire and stock a supply of epinephrine auto-injectors as described in subsection (c) of this section shall designate employees or agents to complete an anaphylaxis training program. The training may be conducted online or in person and shall, at a minimum, include all of the following components:

- (1) How to recognize signs and symptoms of severe allergic reactions, including anaphylaxis.
- (2) Standards and procedures for the storage and administration of an epinephrine auto-injector.
- (3) Emergency follow-up procedures.

In-person training shall cover the three components listed in this subsection and be conducted by (i) a physician, physician assistant, or registered nurse licensed to practice in this State; (ii) a nationally recognized organization experienced in training laypersons in emergency health treatment; or (iii) an entity or individual approved by the Department of Health and Human Services.

Online training shall cover the three components listed in this subsection and be offered (i) by a nationally recognized organization experienced in training laypersons in emergency health treatment; (ii) by an entity or

individual approved by the Department of Health and Human Services; or (iii) by means of an online training course that has been approved by another state.

(f) Immunity. –

- (1) The following persons are immune from criminal liability and from suit in any civil action brought by any person for injuries or related damages that result from any act or omission taken pursuant to this section:
  - a. Any authorized entity that voluntarily and without expectation of payment possesses and makes available epinephrine auto-injectors.
  - b. Any employee or agent of an authorized entity, or any other individual, who provides or administers an epinephrine auto-injector to an individual whom the employee, agent, or other individual believes in good faith is experiencing symptoms of anaphylaxis and has completed the required training set forth in subsection (e) of this section.
  - c. A health care provider that prescribes epinephrine auto-injectors to an authorized entity.
  - d. A pharmacist or health care provider that dispenses epinephrine auto-injectors to an authorized entity.
  - e. Any individual or entity that conducts the training mandated by subsection (e) of this section.
- (2) The immunity conferred by this section does not apply to acts or omissions constituting willful or wanton conduct as defined in G.S. 1D-5(7) or intentional wrongdoing.
- (3) Nothing in this section creates or imposes any duty, obligation, or basis for liability on any authorized entity, any employee or agent of an authorized entity, or any other individual to acquire, possess, store, make available, or administer an epinephrine auto-injector.
- (4) This section does not eliminate, limit, or reduce any other immunity or defense that may be available under State law, including the protections set forth in G.S. 90-21.14.

(g) Liability for Acts Outside of This State. – An authorized entity located in this State shall not be liable under the laws of this State for any injuries or related damages resulting from the provision or administration of an epinephrine auto-injector outside of this State under either of the following circumstances:

- (1) If the authorized entity would not have been liable for such injuries or related damages if the epinephrine auto-injector had been provided or administered within this State.
- (2) If the authorized entity is not liable for such injuries or related damages under the laws of the state in which the epinephrine auto-injector was provided or administered.

(h) Does Not Constitute Practice of Medicine. – The administration of an epinephrine auto-injector in accordance with this section is not the practice of medicine or any other profession that otherwise requires licensure.

**§ 90-21.16. Volunteer health care professionals; liability limitation.**

(a) This section applies as follows:

- (1) Any volunteer medical or health care provider at a facility of a local health department or at a nonprofit community health center,
- (2) Any volunteer medical or health care provider rendering services to a patient referred by a local health department as defined in G.S. 130A-2(5), nonprofit community health center, or nonprofit community health referral service at the provider's place of employment,
- (3) Any volunteer medical or health care provider serving as medical director of an emergency medical services (EMS) agency, or
- ...
- (5) Any volunteer medical or health care provider licensed or certified in this State who provides services within the scope of the provider's license or certification at a free clinic facility, who receives no compensation for medical services or other related services rendered at the facility, center, agency, or clinic, or who neither charges nor receives a fee for medical services rendered to the patient referred by a local health department, nonprofit community health center, or nonprofit community health referral service at the provider's place of employment shall not be liable for damages for injuries or death alleged to have occurred by reason of an act or omission in the rendering of the services unless it is established that the injuries or death were caused by gross negligence, wanton conduct, or intentional wrongdoing on the part of the person rendering the services. The free clinic, local health department facility, nonprofit

community health center, nonprofit community health referral service, or agency shall use due care in the selection of volunteer medical or health care providers, and this subsection shall not excuse the free clinic, health department facility, community health center, or agency for the failure of the volunteer medical or health care provider to use ordinary care in the provision of medical services to its patients.

(b) Nothing in this section shall be deemed or construed to relieve any person from liability for damages for injury or death caused by an act or omission on the part of such person while rendering health care services in the normal and ordinary course of his or her business or profession. Services provided by a medical or health care provider who receives no compensation for his or her services and who voluntarily renders such services at the provider's place of employment, facilities of free clinics, local health departments as defined in G.S. 130A-2, nonprofit community health centers, or as a volunteer medical director of an emergency medical services (EMS) agency, are deemed not to be in the normal and ordinary course of the volunteer medical or health care provider's business or profession.

(c) As used in this section, a "free clinic" is a nonprofit, 501(c)(3) tax-exempt organization organized for the purpose of providing health care services without charge or for a minimum fee to cover administrative costs.

(c1) For a volunteer medical or health care provider who provides services at a free clinic to receive the protection from liability provided in this section, the free clinic shall provide the following notice to the patient, or person authorized to give consent for treatment, for the patient's retention prior to the delivery of health care services:

**"NOTICE**

Under North Carolina law, a volunteer medical or health care provider shall not be liable for damages for injuries or death alleged to have occurred by reason of an act or omission in the medical or health care provider's voluntary provision of health care services unless it is established that the injuries or death were caused by gross negligence, wanton conduct, or intentional wrongdoing on the part of the volunteer medical or health care provider."

(d) A nonprofit community health referral service that refers low-income patients to medical or health care providers for free services is not liable for the acts or omissions of the medical or health care providers in rendering service to that patient if the nonprofit community health referral service maintains liability insurance covering the acts and omissions of the nonprofit health referral service and any liability pursuant to subsection (a) of this section.

(e) As used in this section, a "nonprofit community health referral service" is a nonprofit, 501(c)(3) tax-exempt organization organized to provide for no charge the referral of low-income, uninsured patients to volunteer health care providers who provide health care services without charge to patients.

**§ 90-21.17. Portable do not resuscitate order and Medical Order for Scope of Treatment.**

(a) It is the intent of this section to recognize a patient's desire and right to withhold cardiopulmonary resuscitation and other life-prolonging measures to avoid loss of dignity and unnecessary pain and suffering through the use of a portable do not resuscitate ("DNR") order or a Medical Order for Scope of Treatment (MOST).

This section establishes an optional and nonexclusive procedure by which a patient or the patient's representative may exercise this right.

(b) A physician may issue a portable DNR order or MOST for a patient:

- (1) With the consent of the patient;
- (2) If the patient is a minor, with the consent of the patient's parent or guardian; or
- (3) If the patient is not a minor but is incapable of making an informed decision regarding consent for the order, with the consent of the patient's representative.

The physician shall document the basis for the DNR order or MOST in the patient's medical record. When the order is a MOST, the patient or the patient's representative must sign the form, provided, however, that if it is not practicable for the patient's representative to sign the original MOST form, the patient's representative shall sign a copy of the completed form and return it to the health care professional completing the form. The copy of the form with the signature of the patient's representative, whether in paper or electronic form, shall be placed in the patient's medical record. When the signature of the patient's representative is on a separate copy of the MOST form, the original MOST form must indicate in the appropriate signature field that the signature is "on file".

(c) The Department of Health and Human Services shall develop a portable DNR order form and a MOST form. The official DNR form shall include fields for the name of the patient; the name, address, and telephone number of the physician; the signature of the physician; and other relevant information. At a minimum, the official MOST form shall include fields for: the name of the patient; an advisory that a patient is not required to have a MOST; the name, telephone number, and signature of the physician, physician assistant, or nurse practitioner authorizing the order; the name and contact information of the health care professional who prepared the form with the patient or the patient's representative; information on who agreed (i.e., the patient or the patient's representative) to the options

selected on the MOST form; a range of options for cardiopulmonary resuscitation, medical interventions, antibiotics, medically administered fluids and nutrition; patient or patient representative's name, contact information, and signature; effective date of the form and review dates; a prominent advisory that directions in a MOST form may suspend, while those MOST directions are in effect, any conflicting directions in a patient's previously executed declaration of an advance directive for a natural death ("living will"), health care power of attorney, or other legally authorized instrument; and an advisory that the MOST may be revoked by the patient or the patient's representative. The official MOST form shall also include the following statement written in boldface type directly above the signature line: "You are not required to sign this form to receive treatment." The form may be approved by reference to a standard form that meets the requirements of this subsection. For purposes of this section, the "patient's representative" means an individual from the list of persons authorized to consent to the withholding of life-prolonging measures pursuant to G.S. 90-322.

(d) No physician, emergency medical professional, hospice provider, or other health care provider shall be subject to criminal prosecution, civil liability, or disciplinary action by any professional licensing or certification agency for withholding cardiopulmonary resuscitation or other life-prolonging measures from a patient in good faith reliance on an original DNR order or MOST form adopted pursuant to subsection (c) of this section, provided that (i) there are no reasonable grounds for doubting the validity of the order or the identity of the patient, and (ii) the provider does not have actual knowledge of the revocation of the portable DNR order or MOST. No physician, emergency medical professional, hospice provider, or other health care provider shall be subject to criminal prosecution, civil liability, or disciplinary action by any professional licensing or certification agency for failure to follow a DNR order or MOST form adopted pursuant to subsection (c) of this section if the provider had no actual knowledge of the existence of the DNR order or MOST.

(e) A health care facility may develop policies and procedures that authorize the facility's provider to accept a portable DNR order or MOST as if it were an order of the medical staff of that facility. This section does not prohibit a physician in a health care facility from issuing a written order, other than a portable DNR order or MOST not to resuscitate a patient in the event of cardiac or respiratory arrest, or to use, withhold, or withdraw additional medical interventions as provided in the MOST, in accordance with acceptable medical practice and the facility's policies.

(f) Nothing in this section shall affect the validity of portable DNR order or MOST forms in existence prior to the effective date of this section.

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**§ 90-21.19. Liability limit for noneconomic damages.**

(a) Except as otherwise provided in subsection (b) of this section, in any medical malpractice action in which the plaintiff is entitled to an award of noneconomic damages, the total amount of noneconomic damages for which judgment is entered against all defendants shall not exceed five hundred thousand dollars (\$500,000). Judgment shall not be entered against any defendant for noneconomic damages in excess of five hundred thousand dollars (\$500,000) for all claims brought by all parties arising out of the same professional services. On January 1 of every third year, beginning with January 1, 2014, the Office of State Budget and Management shall reset the limitation on damages for noneconomic loss set forth in this subsection to be equal to five hundred thousand dollars (\$500,000) times the ratio of the Consumer Price Index for November of the prior year to the Consumer Price Index for November 2011. The Office of State Budget and Management shall inform the Revisor of Statutes of the reset limitation. The Revisor of Statutes shall publish this reset limitation as an editor's note to this section. In the event that any verdict or award of noneconomic damages stated pursuant to G.S. 90-21.19B exceeds these limits, the court shall modify the judgment as necessary to conform to the requirements of this subsection.

(b) Notwithstanding subsection (a) of this section, there shall be no limit on the amount of noneconomic damages for which judgment may be entered against a defendant if the trier of fact finds both of the following:

- (1) The plaintiff suffered disfigurement, loss of use of part of the body, permanent injury or death.
- (2) The defendant's acts or failures, which are the proximate cause of the plaintiff's injuries, were committed in reckless disregard of the rights of others, grossly negligent, fraudulent, intentional or with malice.

(c) The following definitions apply in this section:

- (1) Consumer Price Index. – The Consumer Price Index – All Urban Consumers, for the South urban area, as published by the Bureau of Labor Statistics of the United States Department of Labor.

- (2) Noneconomic damages. – Damages to compensate for pain, suffering, emotional distress, loss of consortium, inconvenience, and any other nonpecuniary compensatory damage. "Noneconomic damages" does not include punitive damages as defined in G.S. 1D-5.
- (3) Same professional services. – The transactions, occurrences, or series of transactions or occurrences alleged to have caused injury to the health care provider's patient.

(d) Any award of damages in a medical malpractice action shall be stated in accordance with G.S. 90-21.19B. If a jury is determining the facts, the court shall not instruct the jury with respect to the limit of noneconomic damages under subsection (a) of this section, and neither the attorney for any party nor a witness shall inform the jury or potential members of the jury panel of that limit.

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**§ 90-21.19B. Verdicts and awards of damages in medical malpractice actions; form.**

In any malpractice action, any verdict or award of damages, if supported by the evidence, shall indicate specifically what amount, if any, is awarded for noneconomic damages. If applicable, the court shall instruct the jury on the definition of noneconomic damages under G.S. 90-21.19(b).

**Article 11.  
Abortion Laws.**

**§ 90-21.80. Short title.**

This act may be cited as "Abortion Laws."

**§ 90-21.81. Definitions.**

The following definitions apply in this Article:

- (1) Abortion. – A surgical abortion or a medical abortion, as those terms are defined in this section, respectively.
- (1a) Abortion-inducing drug. – A medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination will, with reasonable likelihood, cause the death of the unborn child. This includes the off-label use of drugs such as mifepristone (Mifeprex), misoprostol (Cytotec), and methotrexate, approved by the United States Food and Drug Administration to induce abortions or known to have abortion-inducing properties, prescribed specifically with the intent of causing an abortion, whether or not there exists a diagnosed pregnancy at the time of prescription or dispensing, for the purposes of the woman taking the drugs at a later date to cause an abortion rather than contemporaneously with a clinically diagnosed pregnancy. This definition shall not include drugs that may be known to cause an abortion but are prescribed for other medical indications, such as chemotherapeutic agents and diagnostic drugs.
- (1b) Adverse event. – Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.
- ...
  - (2a) Complication. – Any physical or psychological conditions which, in the reasonable medical judgment of a licensed health care professional, arise as a primary or secondary result of an induced abortion, including:
    - a. Uterine perforation.
    - b. Cervical laceration.
    - c. Infection.
    - d. Bleeding or vaginal bleeding that qualifies as a Grade 2 or higher adverse event according to the Common Terminology Criteria for Adverse Events.
    - e. Pulmonary embolism.
    - f. Deep vein thrombosis.
    - g. Failure to actually terminate the pregnancy.
    - h. Incomplete abortion due to retained tissue.
    - i. Pelvic inflammatory disease.
    - j. Endometritis.

- k. Missed ectopic pregnancy.
  - l. Cardiac arrest.
  - m. Respiratory arrest.
  - n. Renal failure.
  - o. Shock.
  - p. Amniotic fluid embolism.
  - q. Coma.
  - r. Free fluid in abdomen.
  - s. Allergic reactions to anesthesia and abortion-inducing drugs.
  - t. Psychological complications as described by the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM).
- (3) Department. - The Department of Health and Human Services.
  - (4) Display a real-time view of the unborn child. - An ultrasound or any more scientifically advanced means of viewing the unborn child in real time.
  - (4a) Health care provider. – As defined in G.S. 90-410.
  - (4b) Hospital. – As defined in G.S. 131E-76.
  - ...
  - (4d) Life-limiting anomaly. – The diagnosis by a qualified physician of a physical or genetic condition that (i) is defined as a life-limiting disorder by current medical evidence and (ii) is uniformly diagnosable.
  - (4e) Medical abortion. – The use of any medicine, drug, or other substance intentionally to terminate the pregnancy of a woman known to be pregnant with an intention other than to do any of the following:
    - a. Increase the probability of a live birth.
    - b. Preserve the life or health of the child.
    - c. Remove a dead, unborn child who died as a result of (i) natural causes in utero, (ii) accidental trauma, or (iii) a criminal assault of the pregnant woman or her unborn child which causes the premature termination of the pregnancy.
    - d. Remove an ectopic pregnancy.
  - (5) Medical emergency. - A condition which, in reasonable medical judgment, so complicates the medical condition of the pregnant woman as to necessitate the immediate abortion of her pregnancy to avert her death or for which a delay will create serious risk of substantial and irreversible physical impairment of a major bodily function, not including any psychological or emotional conditions. For purposes of this definition, no condition shall be deemed a medical emergency if based on a claim or diagnosis that the woman will engage in conduct which would result in her death or in substantial and irreversible physical impairment of a major bodily function.
  - (5a) Partial-birth abortion. – As defined in 18 U.S.C. § 1531(b)(1) as it exists on January 1, 2023.
  - (6) Physician. - An individual licensed to practice medicine in accordance with this Chapter.
  - (7) Probable gestational age. - What, in the judgment of the physician, will, with reasonable probability, be the gestational age of the unborn child at the time the abortion is planned to be performed.
  - (7a) Qualified physician. – Any of the following: (i) a physician who possesses, or is eligible to possess, board certification in obstetrics or gynecology, (ii) a physician who possesses sufficient training based on established medical standards in safe abortion care, abortion complications, and miscarriage management, or (iii) a physician who performs an abortion in a medical emergency as defined by this Article
  - (8) Qualified professional. - An individual who is a registered nurse, nurse practitioner, or physician assistant licensed in accordance with Article 1 of this Chapter, or a qualified technician acting within the scope of the qualified technician's authority as provided by North Carolina law and under the supervision of a physician.
  - (9) Qualified technician. - A registered diagnostic medical sonographer who is certified in obstetrics and gynecology by the American Registry for Diagnostic Medical Sonography (ARDMS) or a nurse midwife or advanced practice nurse practitioner in obstetrics with certification in obstetrical ultrasonography.



- (9a) Rape. – The criminally injurious conduct in the nature of the conduct described in G.S. 14-27.21, 14-27.22, 14-27.23, 14-27.24, and 14-27.25.
- (10) Website. - A website that, to the extent reasonably practicable, is safeguarded from having its content altered other than by the Department.
- (10a) Unborn child. – As defined in G.S. 14-23.1.
- (11) Woman. - A female human, whether or not she is an adult.

**§ 90-21.81A. Abortion.**

(a) Abortion. – It shall be unlawful after the twelfth week of a woman's pregnancy to procure or cause a miscarriage or abortion in the State of North Carolina.

(b) Partial-Birth Abortion Prohibited. – It shall be unlawful for a qualified physician, any health care provider, or any person to perform a partial-birth abortion at any time.

**§ 90-21.81B. When abortion is lawful.**

Notwithstanding any of the provisions of G.S. 14-44 and G.S. 14-45, and subject to the provisions of this Article, it shall not be unlawful to procure, or cause a miscarriage or an abortion in the State of North Carolina in the following circumstances:

- (1) When a qualified physician determines there exists a medical emergency.
- (2) During the first 12 weeks of a woman's pregnancy . . . when a medical abortion is procured.
- ...
- (4) During the first 24 weeks of a woman's pregnancy, if a qualified physician determines there exists a life-limiting anomaly in accordance with this Article.

**§ 90-21.81C. Abortion reporting, objection, and inspection requirements.**

...

(d) Fetal Death Reporting. – The requirements of G.S. 130A-114 are not applicable to abortions performed pursuant to this section.

(e) Medical Personnel Objection. – No physician, nurse, or any other health care provider who shall state an objection to abortion on moral, ethical, or religious grounds shall be required to perform or participate in medical procedures which result in an abortion. The refusal of a physician, nurse, or health care provider to perform or participate in these medical procedures shall not be a basis for damages for the refusal or for any disciplinary or any other recriminatory action against the physician, nurse, or health care provider.

(f) Requirement of Services. – Nothing in this section shall require a hospital, other health care institution, or other health care provider to perform an abortion or to provide abortion services.

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**§ 90-21.83. Printed information required.**

(a) Within 90 days after this Article becomes effective, the Department shall publish in English and in each language that is the primary language of at least two percent (2%) of the State's population and shall cause to be available on the State website established under G.S. 90-21.84, the following printed materials in a manner that ensures that the information is comprehensible to a person of ordinary intelligence:

- (1) Geographically indexed materials designed to inform a woman of public and private agencies and services available to assist her through pregnancy, upon childbirth, and while the child is dependent, including adoption agencies. The information shall include a comprehensive list of the agencies available, a description of the services they offer, including which agencies offer, at no cost to the woman, imaging that enables the woman to view the unborn child or heart tone monitoring that enables the woman to listen to the heartbeat of the unborn child, and a description of the manner, including telephone numbers, in which they might be contacted. In the alternative, in the discretion of the Department, the printed materials may contain a toll-free, 24-hour-a-day telephone number that may be called to obtain, orally or by tape recorded message tailored to the zip code entered by the caller, a list of these agencies in the locality of the caller and of the services they offer.
- (2) Materials designed to inform the woman of the probable anatomical and physiological characteristics of the unborn child at two-week gestational increments from the time a woman

can be known to be pregnant until full term, including pictures or drawings representing the development of the unborn child at two-week gestational increments. The pictures shall contain the dimensions of the unborn child, information about brain and heart functions, the presence of external members and internal organs, and be realistic and appropriate for the stage of pregnancy depicted. The materials shall be objective, nonjudgmental, and designed to convey only accurate scientific information about the unborn child at the various gestational ages. The material shall contain objective information describing the methods of abortion procedures employed, the medical risks associated with each procedure, the possible adverse psychological effects of abortion, as well as the medical risks associated with carrying an unborn child to term.

(b) The materials referred to in subsection (a) of this section shall be printed in a typeface large enough to be clearly legible. The website provided for in G.S. 90-21.84 shall be maintained at a minimum resolution of 70 DPI (dots per inch). All pictures appearing on the website site shall be a minimum of 200x300 pixels. All letters on the Web site shall be a minimum of 12-point font. All information and pictures shall be accessible with an industry-standard browser requiring no additional plug-ins.

(c) The materials required under this section shall be available at no cost from the Department upon request and in appropriate numbers to any physician, person, health facility, hospital, or qualified professional. The Department shall create the consent forms described in this section to be used by qualified physicians for the purposes of obtaining informed consent for surgical and medical abortions.

(d) The Department shall cause to be available on the State website a list of resources the woman may contact for assistance upon receiving information from the physician performing the ultrasound that the unborn child may have a disability or serious abnormality and shall do so in a manner prescribed by subsection (b) of this section.

#### **§ 90-21.83A. Informed consent to medical abortion.**

(a) No medical abortion shall be performed upon a woman in this State without her voluntary and informed consent as described in this section.

(b) Except in the case of a medical emergency, consent to a medical abortion is voluntary and informed only if all of the following conditions are satisfied:

- (1) At least 72 hours prior to the medical abortion, a qualified physician or qualified professional has orally informed the woman, in person, of the information contained in the consent form.
- (2) The consent form shall include, at a minimum, all of the following:
  - a. The name of the physician who will prescribe, dispense, or otherwise provide the abortion-inducing drugs to ensure the safety of the procedure and prompt medical attention to any complications that may arise, specific information for the physician's hospital admitting privileges, and whether the physician accepts the pregnant woman's insurance. The physician prescribing, dispensing, or otherwise providing any drug or chemical for the purpose of inducing an abortion shall be physically present in the same room as the woman when the first drug or chemical is administered to the woman.
  - b. The probable gestational age of the unborn child as determined by both patient history and by ultrasound results used to confirm gestational age.
  - c. A detailed description of the steps to complete the medical abortion.
  - d. A detailed list of the risks related to the specific abortion-inducing drug or drugs to be used, including hemorrhage, failure to remove all tissue of the unborn child which may require an additional procedure, sepsis, sterility, and possible continuation of the pregnancy.
  - e. The medical risks associated with carrying the child to term.
  - f. The display of a real-time view of the unborn child and heart tone monitoring that enable the pregnant woman to view her unborn child or listen to the heartbeat of the unborn child are available to the woman. The physician performing the abortion, qualified technician, or referring physician shall inform the woman that the printed materials and website described in G.S. 90-21.83 and G.S. 90-21.84 contain phone numbers and addresses for facilities that offer the services free of charge. If requested by the woman, the physician or qualified professional shall provide to the woman the list as compiled by the Department.

- g. Information about Rh incompatibility, including that if the woman has an Rh-negative blood type, she could receive an injection of Rh immunoglobulin at the time of the medical abortion to prevent Rh incompatibility in future pregnancies.
- h. Information about the risks of complications from a medical abortion, including incomplete abortion, increase with advancing gestational age, and that infection and hemorrhage are the most common causes of deaths related to medical abortions.
- i. Notice that the woman may see the remains of her unborn child in the process of completing the abortion.
- j. Notice that the physician who is to perform the medical abortion has no liability insurance for malpractice in the performance or attempted performance of an abortion, if applicable.
- k. The location of the hospital that offers obstetrical or gynecological care located within 30 miles of the location where the medical abortion is performed or induced and at which the physician performing or inducing the medical abortion has clinical privileges. If the physician who will perform the medical abortion has no local hospital admitting privileges, that information shall be communicated.

If the physician or qualified professional does not know the information required in sub-subdivision a., j., or k. of this subdivision, the woman shall be advised that this information will be directly available from the physician who is to perform the medical abortion. However, the fact that the physician or qualified professional does not know the information required in sub-subdivision a., j., or k. shall not restart the 72-hour period. The information required by this subdivision shall be provided in English and in each language that is the primary language of at least two percent (2%) of the State's population. The information shall be provided orally in person, by the physician or qualified professional, in which case the required information may be based on facts supplied by the woman to the physician and whatever other relevant information is reasonably available. The information required by this subdivision shall not be provided by a tape recording but shall be provided during an in-person consultation conducted by a qualified professional or a qualified physician. A physician must be available to ask and answer questions within the statutory time frame upon request of the patient or the qualified professional. If, in the medical judgment of the physician, a physical examination, tests, or the availability of other information to the physician subsequently indicates a revision of the information previously supplied to the patient, then that revised information may be communicated to the patient at any time before the performance of the medical abortion. Nothing in this section may be construed to preclude provision of required information in a language understood by the patient through a translator.

- (3) A consent form shall not be considered valid, and informed consent not obtained from the woman, unless all of the following conditions are satisfied:
  - a. The woman signs and initials each entry, list, description, or declaration required to be on the consent form described in subdivision (2) of this subsection.
  - b. The woman signs and initials each entry, list, description, or declaration required to be on the acknowledgment of risks and consent statement described in subdivision (4) of this subsection.
  - c. The physician signs the qualified physician declaration described in subdivision (5) of this subsection.
  - d. The physician uses the consent form created by the Department for the purposes of this section.
- (4) Prior to the medical abortion, an acknowledgment of risks and consent statement must be signed and initialed by the woman with a physical or electronic signature attesting she has received all of the following information at least 72 hours before the medical abortion. The acknowledgment of risks and consent statement shall include, at a minimum, all of the following:
  - a. That medical assistance benefits may be available for prenatal care, childbirth, and neonatal care.
  - b. That public assistance programs under Chapter 108A of the General Statutes may or may not be available as benefits under federal and State assistance programs.

- c. That the father is liable to assist in the support of the child, even if the father has offered to pay for the abortion.
- d. That the woman has other alternatives to abortion, including keeping the baby or placing the baby for adoption.
- e. That the woman has been told about the printed materials described in G.S. 90-21.83, and that she has been told that these materials are available on a State-sponsored website, and she has been given the address of the State-sponsored website. The physician or a qualified professional shall orally inform the woman that the materials have been provided by the Department and that they describe the unborn child and list agencies that offer alternatives to abortion. If the woman chooses to view the materials other than on the website, the materials shall be given to her at least 72 hours before the medical abortion.
- f. Attestation that the woman (i) is not being forced to have a medical abortion, (ii) has a choice to not have the medical abortion, and (iii) is free to withhold or withdraw her consent to the abortion-inducing drug regimen even after she has begun the abortion-inducing drug regimen.
- g. Attestation that the woman understands that the medical abortion is intended to end her pregnancy.
- h. Attestation that the woman understands the medical abortion regimen has specific risks and may result in specific complications.
- i. Attestation that the woman has been given the opportunity to ask questions about her pregnancy, the development of her unborn child, and alternatives to medical abortion.
- j. Confirmation that the woman has been provided access to State-prepared, printed materials on informed consent for abortion and the State-prepared and maintained website on informed consent for a medical abortion.
- k. If applicable, that the woman has been given the name and phone number of a qualified physician who has agreed to provide medical care and treatment in the event of complications associated with the abortion-inducing drug regimen.
- l. Notice that the physician will schedule an in-person follow-up visit for the woman at approximately seven to 14 days after providing the abortion-inducing drug or drugs to confirm that the pregnancy is completely terminated and to assess the degree of bleeding and other complications.
- m. That the woman has received or been given sufficient information to give her informed consent to the abortion-inducing drug regimen or procedure.
- n. That the woman has a private right of action to sue the qualified physician under the laws of this State if she feels she has been coerced or misled prior to obtaining an abortion, and how to access State resources regarding her legal right to obtain relief.
- o. A statement that she will be given a copy of the forms and materials with all signatures and initials required under this Article, and all other informed consent forms required by this State.

The information required by this subdivision shall be provided in English and in each language that is the primary language of at least two percent (2%) of the State's population.

- (5) The physician has signed a physician declaration form stating that prior to the medical abortion procedure, the qualified physician has (i) explained in person the medical abortion procedure to be used, (ii) provided all of the information required in this section, and (iii) answered all of the woman's questions regarding the medical abortion.

**§ 90-21.83B. Distribution of abortion-inducing drugs and duties of physician.**

(a) A physician prescribing, administering, or dispensing an abortion-inducing drug must examine the woman in person and, prior to providing an abortion-inducing drug, shall do all of the following:

- (1) Independently verify that the pregnancy exists.
- (2) Determine the woman's blood type; offer necessary medical services, treatment, and advice, based on the physician's reasonable medical judgment of any medical risks associated with the woman's blood type, including whether the woman's blood type is Rh negative; and be able to administer Rh immunoglobulin at the time of the abortion, if medically necessary.

- (3) Provide any other medically indicated diagnostic tests, including iron or hemoglobin/hematocrit tests, to determine whether the woman has a heightened risk of complications.
- (4) Screen the woman for coercion, abuse, comply with G.S. 90-21.91, and refer the woman to the appropriate health care provider for appropriate treatment, if medically necessary.
- (5) Inform the patient that she may see the remains of her unborn child in the process of completing the abortion.
- (6) Verify the probable gestational age of the unborn child.
- (7) Document in the woman's medical chart the probable gestational age and existence of an intrauterine pregnancy, and whether the woman received treatment for an Rh negative condition or any other diagnostic tests.
- (8) Comply with all provisions of this Article and laws of this State as applicable.

(b) The physician providing any abortion-inducing drug, or an agent of the physician, shall schedule a follow-up visit for the woman at approximately seven to 14 days after administration of the abortion-inducing drug to confirm that the pregnancy is completely terminated and to assess the degree of bleeding. The physician shall make all reasonable efforts to ensure that the woman returns for the scheduled appointment. A brief description of the efforts made to comply with this subsection, including the date, time, and identification by name of the person making these efforts, shall be included in the woman's medical records.

**§ 90-21.84. Internet website.**

The Department shall develop and maintain a stable Internet website to provide the information described in this Article. No information regarding who accesses the website shall be collected or maintained. The Department shall monitor the Web site on a regular basis to prevent and correct tampering.

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**§ 90-21.86. Procedure in case of medical emergency.**

When a medical emergency compels the performance of an abortion, the physician shall inform the woman, before the abortion if possible, of the medical indications supporting the physician's judgment that an abortion is necessary to avert her death or that a 72-hour delay will create a serious risk of substantial and irreversible impairment of a major bodily function, not including psychological or emotional conditions. As soon as feasible, the physician shall document in writing the medical indications upon which the physician relied and shall cause the original of the writing to be maintained in the woman's medical records and a copy given to her.

**§ 90-21.87. Informed consent for a minor.**

If the woman upon whom an abortion is to be performed is an unemancipated minor, the voluntary and informed written consent required under G.S. 90-21.82 or 90-21.83A shall be obtained from the minor and from the adult individual who gives consent pursuant to G.S. 90-21.7(a).

**§ 90-21.88. Civil remedies.**

(a) Any person upon whom an abortion has been performed, her personal representative in the event of a wrongful death action in accordance with G.S. 28A-18-1, and any father of an unborn child that was the subject of an abortion may maintain an action for damages against the person who performed the abortion in knowing or reckless violation of this Article. Any person upon whom an abortion has been attempted may maintain an action for damages against the person who performed the abortion in willful violation of this Article.

(a1) Notwithstanding any other provision of law, (i) a woman upon whom the abortion has been attempted, induced, or performed or (ii) her parent or guardian, if she is a minor at the time of the attempted or completed abortion, may bring an action under this section within three years from the date of the alleged violation or from the date of the initial discovery of harm from an alleged violation. If at the time of the alleged violation the woman is a minor, then the minor shall have three years from the date the minor attains the age of majority to bring an action under this section

(b) Injunctive relief against any person who has willfully violated this Article may be sought by and granted to (i) the woman upon whom an abortion was performed or attempted to be performed in violation of this Article, (ii) any person who is the spouse, parent, sibling, or guardian of, or a current or former licensed health care provider of, the woman upon whom an abortion has been performed or attempted to be performed in violation of this Article, or

(iii) the Attorney General. The injunction shall prevent the abortion provider from performing or inducing further abortions in this State in violation of this Article.

(c) If judgment is rendered in favor of the plaintiff in any action authorized under this section, the court shall also tax as part of the costs reasonable attorneys' fees in favor of the plaintiff against the defendant. If judgment is rendered in favor of the defendant and the court finds that the plaintiff's suit was frivolous or brought in bad faith, then the court shall tax as part of the costs reasonable attorneys' fees in favor of the defendant against the plaintiff.

**§ 90-21.88A. Violation of this Article.**

A physician who violates any provision of this Article shall be subject to discipline by the North Carolina Medical Board under G.S. 90-14(a)(2) and any other applicable law or rule. Any licensed pharmacist who violates any provision of this Article shall be subject to discipline by the North Carolina Board of Pharmacy under Article 4A of this Chapter. Any other licensed health care provider who violates any provision of this Article shall be subject to discipline under their respective licensing agency or board. No pregnant woman seeking to obtain an abortion in accordance with this Article shall be subject to professional discipline for attempting to do so.

\* \* \* \* \*

**§ 90-21.90. Assurance of informed consent.**

(a) All information required to be provided under G.S. 90-21.82 and 21.83A to a woman considering abortion shall be presented to the woman individually and in the physical presence of the woman and in a language the woman understands to ensure that the woman has adequate opportunity to ask questions and to ensure the woman is not the victim of a coerced abortion.

(b) Should a woman be unable to read the materials provided to the woman pursuant to this section, a physician or qualified professional shall read the materials to the woman in a language the woman understands before the abortion.

**§ 90-21.91. Assurance that consent is freely given.**

If a physician acting pursuant to this Article has reason to believe that a woman is being coerced into having an abortion, the physician or qualified professional shall inform the woman that services are available for the woman and shall provide the woman with private access to a telephone and information about, but not limited to, each of the following services:

- (1) Rape crisis centers.
- (2) Shelters for victims of domestic violence.
- (3) Restraining orders.
- (4) Pregnancy care centers.

\* \* \* \* \*

**§ 90-21.93. Reporting requirements.**

(a) Report. – After a surgical or medical abortion is performed, the physician or health care provider that conducted the surgical or medical abortion shall complete and transmit a report to the Department in compliance with the requirements of this section. The report shall be completed by either the hospital, clinic, or health care provider in which the surgical or medical abortion was completed and signed by the physician who dispensed, administered, prescribed, or otherwise provided the abortion-inducing drug or performed the procedure or treatment to the woman. Any physician or health care provider shall make reasonable efforts to include all of the required information in this section in the report without violating the privacy of the woman. The report shall be transmitted to the Department within 15 days after either the (i) date of the follow-up appointment following a medical abortion, (ii) date of the last patient encounter for treatment directly related to a surgical abortion, or (iii) end of the month in which the last scheduled appointment occurred, whichever is later. A report completed under this section for a minor shall be sent to the Department and the Division of Social Services within 30 days of the surgical or medical abortion.

(b) Contents. – Each report completed in accordance with this section shall contain, at a minimum, all of the following:

- (1) Identifying information of the (i) physician who provided the abortion-inducing drug or performed the surgical abortion and (ii) referring physician, agency, or service, if applicable.
- (2) The location, date, and type of the surgical abortion, or the location of where any abortion-inducing drug was administered or dispensed, including any health care provider facility, at the home of the pregnant woman, or other location.
- (3) The woman's county, state, and country of residence; age; and race.

- (4) The woman's number of live births, previous pregnancies, and number of previous abortions.
- (5) The woman's preexisting medical conditions, which could complicate her pregnancy.
- (6) The probable gestational age of the unborn child, as determined by both patient history and ultrasound, and the date of the ultrasound used to estimate gestational age.
- (7) The abortion-inducing drugs used, and the date in which the abortion-inducing drugs were dispensed, administered, and used.
- (8) Whether the woman returned for the scheduled follow-up appointment or examination to determine the completion of the abortion procedure and to assess bleeding, the results of the follow-up appointment or examination, and the date of any follow-up appointment or examination of the abortion procedure.
- (9) The reasonable efforts of the physician to encourage the woman to attend the follow-up appointment or examination if the woman did not attend.
- (10) Any specific complications the woman suffered from the abortion procedure.
- (11) The amount of money billed to cover the treatment for specific complications, including whether the treatment was billed to Medicaid, private insurance, private pay, or any other method, including ICD-10 diagnosis codes reported, any other codes reported, any charges for hospitals, emergency departments, physicians, prescriptions or other drugs, laboratory tests, and any other costs for treatment.

...

(g) Identifying Information. – A report completed under this section shall not contain the woman's name, any common identifiers of the woman, or any other information that would make it possible to identify the woman subject to a report under this section, including the woman's social security number or drivers license identification number. The Department and any State agency or any contractor thereof shall not maintain statistical information that may reveal the identity of a woman obtaining or seeking to obtain a surgical or medical abortion. Absent a court order, the Department and any State agency or any contractor thereof shall not compare data concerning surgical or medical abortions or resulting complications maintained in an electronic or other information system file or format with data in any other format or information system in an effort to identify a woman obtaining or seeking to obtain a drug-induced abortion.

## **Article 1J. Voluntary Health Care Services Act.**

### **§ 90-21.100. Short title.**

This Article shall be known and may be cited as the Volunteer Health Care Services Act.

### **§ 90-21.101. Findings.**

- (a) The General Assembly makes the following findings:
  - (1) Access to high-quality health care services is a concern of all persons.
  - (2) Access to high-quality health care services may be limited for some residents of this State, particularly those who reside in remote, rural areas or in the inner city.
  - (3) Physicians and other health care providers have traditionally worked to ensure broad access to health care services.
  - (4) Many health care providers from North Carolina and elsewhere are willing to volunteer their services to address the health care needs of North Carolinians who may otherwise not be able to obtain high-quality health care services.
- (b) The General Assembly further finds that it is the public policy of this State to encourage and facilitate the voluntary provision of health care services.

### **§ 90-21.102. Definitions.**

The following definitions apply in this Article:

- (1) Department. – The North Carolina Department of Health and Human Services.
- (2) Free clinic. – A nonprofit, 501(c)(3) tax-exempt organization organized for the purpose of providing health care services without charge or for a minimum fee to cover administrative costs.
- (3) Health care provider. – Any person who:

- a. Is licensed to practice as a physician or a physician assistant under Article 1 of this Chapter.
  - b. Holds a limited volunteer license under G.S. 90-12.1A.
  - c. Holds a retired limited volunteer license under G.S. 90-12.1B.
  - d. Holds a physician assistant limited volunteer license under G.S. 90-12.4.
  - e. Holds a physician assistant retired limited volunteer license under 90-12.4B.
  - f. Is a volunteer health care professional to whom G.S. 90-21.16 applies.
  - g. Is licensed to practice dentistry under Article 2 of this Chapter.
  - h. Is licensed to practice pharmacy under Article 4A of this Chapter.
  - i. Is licensed to practice optometry under Article 6 of this Chapter.
  - j. Is licensed to practice as a registered nurse or licensed practical nurse under Article 9A of this Chapter.
  - k. Is licensed to practice as a dental hygienist under Article 16 of this Chapter.
  - l. Holds a license as a registered licensed optician under Article 17 of this Chapter.
  - m. Is licensed to practice as a physician, physician assistant, dentist, pharmacist, optometrist, registered nurse, licensed practical nurse, dental hygienist, or optician under provisions of law of another state of the United States comparable to the provisions referenced in sub-subdivisions a. through l. of this subdivision.
- (4) Sponsoring organization. – Any nonprofit organization that organizes or arranges for the voluntary provision of health care services pursuant to this Article.
- (5) Voluntary provision of health care services. – The provision of health care services by a health care provider in association with a sponsoring organization in which both of the following circumstances exist:
- a. The health care services are provided without charge to the recipient of the services or to a third party on behalf of the recipient.
  - b. The health care provider receives no compensation or other consideration in exchange for the health care services provided.

For the purposes of this Article, the provision of health care services in nonprofit community health centers, local health department facilities, free clinic facilities, or at a provider's place of employment when the patient is referred by a nonprofit community health referral service shall not be considered the voluntary provision of health care.

**§ 90-21.103. Limitation on duration of voluntary health care services.**

A sponsoring organization duly registered in accordance with G.S. 90-21.104 may organize or arrange for the voluntary provision of health care services at a location in this State for a period not to exceed seven calendar days in any calendar year.

**§ 90-21.104. Registration, reporting, and record-keeping requirements.**

(a) A sponsoring organization shall not organize or arrange for the voluntary provision of health care services in this State without first registering with the Department on a form prescribed by the Department. The registration form shall contain all of the following information:

- (1) The name of the sponsoring organization.
- (2) The name of the principal individuals who are the officers or organizational officials responsible for the operation of the sponsoring organization.
- (3) The street address, city, zip code, and county of the sponsoring organization's principal office and each of the principal individuals described in subdivision (2) of this subsection.
- (4) Telephone numbers for the principal office of the sponsoring organization and for each of the principal individuals described in subdivision (2) of this subsection.
- (5) Any additional information requested by the Department.

(b) Each sponsoring organization that applies for registration under this Article shall pay a one-time registration fee in the amount of fifty dollars (\$50.00), which it shall submit to the Department along with the completed registration form required by subsection (a) of this section. Upon approval by the Department, a sponsoring organization's registration remains valid unless revoked by the Department pursuant to subsection (f) of this section.



(c) Upon any change in the information required under subsection (a) of this section, the sponsoring organization shall notify the Department of the change, in writing, within 30 days after the effective date of the change.

(d) Each registered sponsoring organization has the duty and responsibility to do all of the following:

(1) Except as provided in this subdivision, by no later than 14 days before a sponsoring organization initiates voluntary health care services in this State, the sponsoring organization shall submit to the Department a list containing the following information regarding each health care provider who is to provide voluntary health care services on behalf of the sponsoring organization during any part of the time period in which the sponsoring organization is authorized to provide voluntary health care services in the State:

- a. Name.
- b. Date of birth.
- c. State of licensure.
- d. License number.
- e. Area of practice.
- f. Practice address.

By no later than 3 days prior to voluntary health care services being rendered, a sponsoring organization may amend the list to add health care providers defined in G.S. 90-21.102(3)a. through G.S. 90-21.102(3)l.

(2) Beginning April 1, 2013, submit quarterly reports to the Department identifying all health care providers who engaged in the provision of voluntary health care services in association with the sponsoring organization in this State during the preceding calendar quarter. The quarterly report must include the date, place, and type of voluntary health care services provided by each health care provider.

(3) Maintain a list of health care providers associated with its provision of voluntary health care services in this State. For each health care provider listed, the sponsoring organization shall maintain a copy of a current license or statement of exemption from licensure or certification. For health care providers currently licensed or certified under this Chapter, the sponsoring organization may maintain a copy of the health care provider's license or certification verification obtained from a State-sponsored Internet Web site.

(4) Maintain records of the quarterly reports and records required under this subsection for a period of five years from the date of voluntary service and make these records available upon request to any State licensing board established under this Chapter.

(e) Compliance with subsections (a) through (d) of this section is prima facie evidence that the sponsoring organization has exercised due care in its selection of health care providers.

(f) The Department may revoke the registration of any sponsoring organization that fails to comply with the requirements of this Article. A sponsoring organization may challenge the Department's decision to revoke its registration by filing a contested case under Article 3 of Chapter 150B of the General Statutes.

(g) The Department may waive any of the requirements of this section during a natural disaster or other emergency circumstance.

#### **§ 90-21.105. Department and licensure boards to review licensure status of volunteers.**

The Department shall forward the information received from a sponsoring organization under G.S. 90-21.104(d)(1) to the appropriate licensure board within seven days after receipt. Upon receipt of any information or notice from a licensure board that a health care provider on the list submitted by the sponsoring organization pursuant to G.S. 90-21.104(d)(1) is not licensed, authorized, or in good standing, or is the subject of an investigation or pending disciplinary action, the Department shall immediately notify the sponsoring organization that the health care provider is not permitted to engage in the voluntary provision of health care services on behalf of the sponsoring organization.

#### **§ 90-21.106. On-site requirements.**

A sponsoring organization that organizes or arranges for the provision of voluntary health care services at a location in this State shall ensure that at least one health care provider licensed to practice in this State, with access to the controlled substances reporting system established under G.S. 90-113.73, is located on the premises where the provision of voluntary health care services is occurring. In addition, every sponsoring organization shall post in a

clear and conspicuous manner the following notice in the premises where the provision of voluntary health care services is occurring:

**"NOTICE**

Under North Carolina law, there is no liability for damages for injuries or death alleged to have occurred by reason of an act or omission in the health care provider's voluntary provision of health care services, unless it is established that the injuries or death were caused by gross negligence, wanton conduct, or intentional wrongdoing on the part of the health care provider."

**§ 90-21.107. Additional licensure not required for certain volunteers.**

(a) A health care provider who engages in the voluntary provision of health care services in association with a sponsoring organization for no more than seven days during any calendar year shall not be required to obtain additional licensure or authorization in connection therewith if the health care provider meets any of the following criteria:

- (1) The health care provider is duly licensed or authorized under the laws of this State to practice in the area in which the health care provider is providing voluntary health care services and is in good standing with the applicable licensing board.
- (2) The health care provider lawfully practices in another state or district in the area in which the health care provider is providing voluntary health care services and is in good standing with the applicable licensing board.

(b) This exemption from additional licensure or authorization requirements does not apply if any of the following circumstances exist:

- (1) The health care provider has been subjected to public disciplinary action or is the subject of a pending disciplinary proceeding in any state in which the health care provider is or ever has been licensed.
- (2) The health care provider's license has been suspended or revoked pursuant to disciplinary proceedings in any state in which the health care provider is or ever has been licensed.
- (3) The health care provider renders services outside the scope of practice authorized by the health care provider's license or authorization.

**§ 90-21.108. Immunity from civil liability for acts or omissions.**

(a) Subject to subsection (b) of this section, a health care provider who engages in the voluntary provision of health care services at any location in this State in association with a sponsoring organization shall not be liable for damages for injuries or death alleged to have occurred by reason of an act or omission in the health care provider's voluntary provision of health care services, unless it is established that the injuries or death were caused by gross negligence, wanton conduct, or intentional wrongdoing on the part of the health care provider.

(b) The immunity from civil liability provided by subsection (a) of this section does not apply if any of the following circumstances exist:

- (1) The health care provider receives, directly or indirectly, any type of compensation, benefits, or other consideration of any nature from any person for the health care services provided.
- (2) The health care services provided are not part of the health care provider's training or assignment.
- (3) The health care services provided are not within the scope of the health care provider's license or authority.
- (4) The health care services provided are not authorized by the appropriate authorities to be performed at the location.

**Article 1L.**

**Emergency or Disaster Treatment Protection Act.**

**§ 90-21.130. Short title.**

This Article shall be known and may be cited as the Emergency or Disaster Treatment Protection Act.

**§ 90-21.131. Purpose.**

It is the purpose of this Article to promote the public health, safety, and welfare of all citizens by broadly protecting the health care facilities and health care providers in this State from liability that may result from treatment of individuals during the COVID-19 public health emergency under conditions resulting from circumstances

associated with the COVID-19 public health emergency. A public health emergency that occurs on a statewide basis requires an enormous response from State, federal, and local governments working in concert with private and public health care providers in the community. The rendering of treatment to patients during such a public health emergency is a matter of vital State concern affecting the public health, safety, and welfare of all citizens.

**§ 90-21.132. Definitions.**

The following definitions apply in this Article:

- (1) COVID-19. – Coronavirus disease 2019.
- (2) COVID-19 emergency declaration. – Executive Order No. 116 issued March 10, 2020, by Governor Roy A. Cooper, including any amendments issued by executive order, subject to extensions under Chapter 166A of the General Statutes.
- (3) COVID-19 emergency rule. – Any executive order, declaration, directive, request, or other State or federal authorization, policy statement, rule making, or regulation that waives, suspends, or modifies applicable State or federal law regarding scope of practice, including modifications authorizing health care providers licensed in another state to practice in this State, or the delivery of care, including those regarding the facility space in which care is delivered and which equipment is used during the COVID-19 emergency declaration.
- (4) Damages. – Economic or noneconomic losses for harm to an individual.
- (5) Harm. – Physical and nonphysical contact that results in injury to or death of an individual.
- (6) Health care facility. – Any entity licensed pursuant to Chapter 122C, 131D, or 131E of the General Statutes or Article 64 of Chapter 58 of the General Statutes, and any clinical laboratory certified under the federal Clinical Laboratory Improvement Amendments in section 353 of the Public Health Service Act (42 U.S.C. § 263a).
- (7) Health care provider. –
  - a. An individual who is licensed, certified, or otherwise authorized under Chapter 90 or 90B of the General Statutes to provide health care services in the ordinary course of business or practice of a profession or in an approved education or training program.
  - b. A health care facility where health care services are provided to patients, residents, or others to whom such services are provided as allowed by law.
  - c. Individuals licensed under Chapter 90 of the General Statutes or practicing under a waiver in accordance with G.S. 90-12.5.
  - d. Any emergency medical services personnel as defined in G.S. 131E-155(7).
  - e. Any individual providing health care services within the scope of authority permitted by a COVID-19 emergency rule.
  - f. Any individual who is employed as a health care facility administrator, executive, supervisor, board member, trustee, or other person in a managerial position or comparable role at a health care facility.
  - g. An agent or employee of a health care facility that is licensed, certified, or otherwise authorized to provide health care services.
  - h. An officer or director of a health care facility.
  - i. An agent or employee of a health care provider who is licensed, certified, or otherwise authorized to provide health care services.
  - j. An individual who volunteers to assist a State agency, department, or approved organization in the administration of COVID-19 vaccinations, including clinical, clinical support, and nonclinical support activities.
- (8) Health care service. – Treatment, clinical direction, supervision, management, or administrative or corporate service, provided by a health care facility or a health care provider during the period of the COVID-19 emergency declaration, regardless of the location in this State where the service is rendered:
  - a. To provide testing, diagnosis, or treatment of a health condition, illness, injury, or disease related to a confirmed or suspected case of COVID-19.
  - b. To dispense drugs, medical devices, medical appliances, or medical goods for the treatment of a health condition, illness, injury, or disease related to a confirmed or suspected case of COVID-19.

- c. To provide care to any other individual who presents or otherwise seeks care at or from a health care facility or to a health care provider during the period of the COVID-19 emergency declaration.
- (9) Volunteer organization. – Any medical organization, company, or institution that has made its facility or facilities available to support the State's response and activities under the COVID-19 emergency declaration and in accordance with any applicable COVID-19 emergency rule.

**§ 90-21.133. Immunity.**

(a) Notwithstanding any law to the contrary, except as provided in subsection (b) of this section, any health care facility, health care provider, or entity that has legal responsibility for the acts or omissions of a health care provider shall have immunity from any civil liability for any harm or damages alleged to have been sustained as a result of an act or omission in the course of arranging for or providing health care services only if all of the following apply:

- (1) The health care facility, health care provider, or entity is arranging for or providing health care services during the period of the COVID-19 emergency declaration, including, but not limited to, the arrangement or provision of those services pursuant to a COVID-19 emergency rule.
- (2) The arrangement or provision of health care services is impacted, directly or indirectly:
  - a. By a health care facility, health care provider, or entity's decisions or activities in response to or as a result of the COVID-19 pandemic; or
  - b. By the decisions or activities, in response to or as a result of the COVID-19 pandemic, of a health care facility or entity where a health care provider provides health care services.
- (3) The health care facility, health care provider, or entity is arranging for or providing health care services in good faith.

(b) The immunity from any civil liability provided in subsection (a) of this section shall not apply if the harm or damages were caused by an act or omission constituting gross negligence, reckless misconduct, or intentional infliction of harm by the health care facility or health care provider providing health care services; provided that the acts, omissions, or decisions resulting from a resource or staffing shortage shall not be considered to be gross negligence, reckless misconduct, or intentional infliction of harm.

(c) Notwithstanding any law to the contrary, a volunteer organization shall have immunity from any civil liability for any harm or damages occurring in or at its facility or facilities arising from the State's response and activities under the COVID-19 emergency declaration and in accordance with any applicable COVID-19 emergency rule, unless it is established that such harm or damages were caused by the gross negligence, reckless misconduct, or intentional infliction of harm by the volunteer organization.

**§ 90-21.134. Severability.**

This Article shall be liberally construed to effectuate its public health emergency purpose as outlined in G.S. 90-121.131. The provisions of this Article are severable. If any part of this Article is declared to be invalid by a court, the invalidity does not affect other parts of this Article that can be given effect without the invalid provision.

**Article 1M.  
Born-Alive Abortion Survivors Protection Act.**

**§ 90-21.140. Definitions.**

As used in this Article, the following definitions apply:

- (1) Abortion. – As defined in G.S. 90-21.81.
- (2) Attempt to perform an abortion. – As defined in G.S. 90-21.81.
- (3) Born alive. – With respect to a member of the species *Homo sapiens*, this term means the complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion.

\* \* \* \* \*

**§ 90-21.142. Requirements for health care practitioners.**

In the case of an abortion or an attempt to perform an abortion that results in a child born alive, any health care practitioner present at the time the child is born alive shall do all of the following:

- (1) Exercise the same degree of professional skill, care, and diligence to preserve the life and health of the child as a reasonably diligent and conscientious health care practitioner would render to any other child born alive at the same gestational age.
- (2) Following the exercise of skill, care, and diligence required under subdivision (1) of this section, ensure that the child born alive is immediately transported and admitted to a hospital.

**§ 90-21.143. Mandatory reporting of noncompliance.**

A health care practitioner or any employee of a hospital, a physician's office, or an abortion clinic who has knowledge of a failure to comply with the requirements of G.S. 90-21.142 shall immediately report the failure to comply to an appropriate State or federal law enforcement agency, or both.

\* \* \* \* \*

**§ 90-21.145. Penalties.**

(a) In General. – Except as provided in subsection (b) of this section, unless the conduct is covered under some other provision of law providing greater punishment, a person who violates G.S. 90-21.142 or G.S. 90-21.143 is guilty of a Class D felony, which shall include a fine of not more than two hundred fifty thousand dollars (\$250,000).

(b) Unlawful Killing of Child Born Alive. – Any person who intentionally performs or attempts to perform an overt act that kills a child born alive shall be punished as under G.S. 14-17(c) for murder.

**§ 90-21.146. Civil remedies; attorneys' fees.**

(a) Civil Remedies. – If a child is born alive and there is a violation of this Article, a claim for damages against any person who has violated a provision of this Article may be sought by the woman upon whom an abortion was performed or attempted in violation of this Article. A claim for damages may include any one or more of the following:

- (1) Objectively verifiable money damage for all injuries, psychological and physical, occasioned by the violation of this Article.
- (2) Statutory damages equal to three times the cost of the abortion or attempted abortion.
- (3) Punitive damages pursuant to Chapter 1D of the General Statutes.

(b) Attorneys' Fees. – If judgment is rendered in favor of the plaintiff in any action authorized under this section, the court shall also tax as part of the costs reasonable attorneys' fees in favor of the plaintiff against the defendant. If judgment is rendered in favor of the defendant and the court finds that the plaintiff's suit was frivolous or brought in bad faith, then the court shall tax as part of the costs reasonable attorneys' fees in favor of the defendant against the plaintiff.

**Article 4B.**

**Pharmacy Quality Assurance Protection Act.**

**§ 90-85.45. Legislative intent.**

It is the intent of the General Assembly to require pharmacy quality assurance programs to further contribute to and enhance the quality of health care and reduce medication errors in this State by facilitating a process for the continuous review of the practice of pharmacy.

**§ 90-85.46. Definitions.**

The following definitions shall apply in this Article:

- (1) Board. – The North Carolina Board of Pharmacy.
- (2) Pharmacy quality assurance program. – A program pertaining to one of the following:
  - a. A pharmacy association created under G.S. 90-85.4 or incorporated under Chapter 55A of the General Statutes that evaluates the quality of pharmacy services and

- alleged medication errors and incidents and makes recommendations to improve the quality of pharmacy services.
- b. A program established by a person or entity holding a valid pharmacy permit pursuant to G.S. 90-85.21 or G.S. 90-85.21A to evaluate the quality of pharmacy services and alleged medication errors and incidents and make recommendations to improve the quality of pharmacy services.
  - c. A quality assurance committee or medical or peer review committee established by a health care provider licensed under this Chapter or a health care facility licensed under Chapter 122C, 131D, or 131E of the General Statutes that includes evaluation of the quality of pharmacy services and alleged medication errors and incidents and makes recommendations to improve the quality of pharmacy services.

**§ 90-85.47. Pharmacy quality assurance program required; limited liability; discovery.**

(a) Every person or entity holding a valid pharmacy permit pursuant to G.S. 90-85.21 or G.S. 90-85.21A shall establish or participate in a pharmacy quality assurance program as defined under G.S. 90-85.46(2), to evaluate the following:

- (1) The quality of the practice of pharmacy.
- (2) The cause of alleged medication errors and incidents.
- (3) Pharmaceutical care outcomes.
- (4) Possible improvements for the practice of pharmacy.
- (5) Methods to reduce alleged medication errors and incidents.

(b) There shall be no monetary liability on the part of, or no cause of action for damages arising against, any member of a duly appointed pharmacy quality assurance program or any pharmacy or pharmacist furnishing information to a pharmacy quality assurance program or any person, including a person acting as a witness or incident reporter to or investigator for a pharmacy quality assurance program, for any act or proceeding undertaken or performed within the scope of the functions of the pharmacy quality assurance program.

(c) This section shall not be construed to confer immunity from liability on any professional association, pharmacy or pharmacist, or health care provider while performing services other than as a member of a pharmacy quality assurance program or upon any person, including a person acting as a witness or incident reporter to or investigator for a pharmacy quality assurance program, for any act or proceeding undertaken or performed outside the scope of the functions of the pharmacy quality assurance program. Except as provided in subsection (a) or (b) of this section, where a cause of action would arise against a pharmacy, pharmacist, or an individual health care provider, the cause of action shall remain in effect.

(d) The proceedings of a pharmacy quality assurance program, the records and materials it produces, and the materials it considers shall be confidential and not considered public records within the meaning of G.S. 132-1 or G.S. 58-2-100 and shall not be subject to discovery or introduction into evidence in any civil action, administrative hearing or Board investigation against a pharmacy, pharmacist, pharmacy technician, a pharmacist manager or a permittee or a hospital licensed under Chapter 122C or Chapter 131E of the General Statutes or that is owned or operated by the State, which civil action, administrative hearing or Board Investigation results from matters that are the subject of evaluation and review by the pharmacy quality assurance program. No person who was in attendance at a meeting of the pharmacy quality assurance program shall be required to testify in any civil action, administrative hearing or Board investigation as to any evidence or other matters produced or presented during the proceedings of the pharmacy quality assurance program or as to any findings, recommendations, evaluations, opinions, or other actions of the pharmacy quality assurance program or its members. However, information, documents, or records otherwise available are not immune from discovery or use in a civil action merely because they were presented during proceedings of the pharmacy quality assurance program. Documents otherwise available as public records within the meaning of G.S. 132-1 do not lose their status as public records merely because they were presented or considered during proceedings of the pharmacy quality assurance program. A member of the pharmacy quality assurance program may testify in a civil or administrative action but cannot be asked about the person's testimony before the pharmacy quality assurance program or any opinions formed as a result of the pharmacy quality assurance program. Nothing in this subsection shall preclude:

- (1) A pharmacy, pharmacist, pharmacy technician, or other person or any agent or representative of a pharmacy, pharmacist, pharmacy technician or other person participating on a pharmacy quality assurance program may use otherwise privileged, confidential information for legitimate internal business or professional purposes of the pharmacy quality assurance program.

- (2) A pharmacy, pharmacist, pharmacy technician, other person participating on the committee, or any person or organization named as a defendant in a civil action, a respondent in an administrative proceeding, or a pharmacy, pharmacist, or pharmacy technician subject to a Board investigation as a result of participation in the pharmacy quality assurance program may use otherwise privileged, confidential information in the pharmacy quality assurance program or person's own defense. A plaintiff in the civil action or the agency in the administrative proceeding may disclose records or determinations of or communications to the pharmacy quality assurance program in rebuttal to information given by the defendant, respondent, or pharmacist subject to Board investigation.

(e) Upon the Board providing written notice to the pharmacy permittee's designated agent under G.S. 90-85.21(a) and pharmacist of an investigation against the pharmacist, including the specific reason for the Board investigation, the pharmacy permittee's designated agent shall compile and provide documentation within 10 days of the receipt of the notice of any alleged medication error or incident committed by the pharmacist in the 12 months preceding the receipt of the notice, that the pharmacy permittee has knowledge of, when:

- (1) The alleged medication error or incident resulted in any of the following:
  - a. A visit to a physician or an emergency room attributed to the alleged medication incident or error.
  - b. Hospitalization requiring an overnight stay or longer.
  - c. A fatality.
- (2) The Board has initiated a disciplinary proceeding against the pharmacist as a result of the investigation. Unless the documentation relates to an alleged medication error or incident that was specifically the cause of the investigation, the Board may review the documentation only after the Board has made findings of fact and conclusions of law pursuant to G.S. 150B-42(a) and may use the documentation in determining the remedial action the pharmacist shall undergo as part of the disciplinary action imposed by the Board. The documentation shall be released only to the Board or its designated employees pursuant to this subsection and shall not otherwise be released except as required by law.

The documentation provided to the Board shall not include the proceedings and records of a pharmacy quality assurance program or information prepared by the pharmacy solely for consideration by or upon request of a pharmacy quality assurance program.

(f) Nothing in this section shall preclude the Board from obtaining information concerning a specific alleged medication error or incident that is the subject of a Board investigation resulting from a complaint to the Board.

#### **Article 4C. Pharmacy Audit Rights.**

##### **§ 90-85.50. Declaration of pharmacy rights during audit.**

- (a) The following definitions apply in this Article:
  - (1) "Pharmacy" means a person or entity holding a valid pharmacy permit pursuant to G.S. 90-85.21 or G.S. 90-85.21A.
  - (2) "Responsible party" means the entity responsible for payment of claims for health care services other than (i) the individual to whom the health care services were rendered or (ii) that individual's guardian or legal representative.
- (b) Notwithstanding any other provision of law, whenever a managed care company, insurance company, third-party payer, or any entity that represents a responsible party conducts an audit of the records of a pharmacy, the pharmacy has a right to all of the following:
  - (1) To have at least 14 days' advance notice of the initial on-site audit for each audit cycle.
  - (2) To have any audit that involves clinical judgment be done with a pharmacist who is licensed, and is employed or working under contract with the auditing entity.
  - (3) Not to have clerical or record-keeping errors, including typographical errors, scrivener's errors, and computer errors, on a required document or record, in the absence of any other evidence, deemed fraudulent. This subdivision does not prohibit recoupment of fraudulent payments.
  - (4) If required under the terms of the contract, to have the auditing entity provide a pharmacy, upon request, all records related to the audit in an electronic format or contained in digital media.

- (5) To have the properly documented records of a hospital or any person authorized to prescribe controlled substances for the purpose of providing medical or pharmaceutical care for their patients transmitted by any means of communication in order to validate a pharmacy record with respect to a prescription or refill for a controlled substance or narcotic drug.
- (6) To have a projection of an overpayment or underpayment based on either the number of patients served with a similar diagnosis or the number of similar prescription orders or refills for similar drugs. This subdivision does not prohibit recoupments of actual overpayments, unless the projection for overpayment or underpayment is part of a settlement by the pharmacy.
- (7) Prior to the initiation of an audit, if the audit is conducted for an identified problem, the audit is limited to claims that are identified by prescription number.
- (8) If an audit is conducted for a reason other than described in subdivision (6) of this subsection, the audit is limited to 100 selected prescriptions.
- (9) If an audit reveals the necessity for a review of additional claims, to have the audit conducted on site.
- (10) Except for audits initiated for the reason described in subdivision (6) of this subsection, to be subject to no more than one audit in one calendar year, unless fraud or misrepresentation is reasonably suspected.
- (11) Except for cases of Food and Drug Administration regulation or drug manufacturer safety programs, to be free of recoupments based on any of the following unless defined within the billing requirements set forth in the pharmacy provider manual not inconsistent with current North Carolina Board of Pharmacy Regulations:
  - a. Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the State Board of Pharmacy.
  - b. A requirement that a pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the State Board of Pharmacy.
- (12) To be subject to recoupment only following the correction of a claim and to have recoupment limited to amounts paid in excess of amounts payable under the corrected claim.
- (13) Except for Medicare claims, to be subject to reversals of approval for drug, prescriber, or patient eligibility upon adjudication of a claim only in cases in which the pharmacy obtained the adjudication by fraud or misrepresentation of claim elements.
- (14) To be audited under the same standards and parameters as other similarly situated pharmacies audited by the same entity.
- (15) To have at least 30 days following receipt of the preliminary audit report to produce documentation to address any discrepancy found during an audit.
- (16) To have the period covered by an audit limited to 24 months from the date a claim was submitted to, or adjudicated by, a managed care company, an insurance company, a third-party payer, or any entity that represents responsible parties, unless a longer period is permitted by a federal plan under federal law.
- (17) Not to be subject to the initiation or scheduling of audits during the first five calendar days of any month due to the high volume of prescriptions filled during that time, without the express consent of the pharmacy. The pharmacy shall cooperate with the auditor to establish an alternate date should the audit fall within the days excluded.
- (18) To have the preliminary audit report delivered to the pharmacy within 120 days after conclusion of the audit.
- (19) To have a final audit report delivered to the pharmacy within 90 days after the end of the appeals period, as provided for in G.S. 90-85.51.
- (20) Not to have the accounting practice of extrapolation used in calculating recoupments or penalties for audits, unless otherwise required by federal requirements or federal plans.
- (21) Not to be subject to recoupment on any portion of the reimbursement for the dispensed product of a prescription, unless otherwise provided in this subdivision:
  - a. Recoupment of reimbursement, or a portion of reimbursement, for the dispensed product of a prescription may be had in the following cases:
    1. Fraud or other intentional and willful misrepresentation evidenced by a review of the claims data, statements, physical review, or other investigative methods.



2. Dispensing in excess of the benefit design, as established by the plan sponsor.
  3. Prescriptions not filled in accordance with the prescriber's order.
  4. Actual overpayment to the pharmacy.
- b. Recoupment of claims in cases set out in sub-subdivision a. of this subdivision shall be based on the actual financial harm to the entity or the actual underpayment or overpayment. Calculations of overpayments shall not include dispensing fees unless one of the following conditions is present:
1. A prescription was not actually dispensed.
  2. The prescriber denied authorization.
  3. The prescription dispensed was a medication error by the pharmacy. For purposes of this subdivision, a medication error is a dispensing of the wrong drug or dispensing to the wrong patient or dispensing with the wrong directions.
  4. The identified overpayment is based solely on an extra dispensing fee.
  5. The pharmacy was noncompliant with Risk Evaluation and Mitigation Strategies (REMS) program guidelines.
  6. There was insufficient documentation, including electronically stored information, as described in this subsection.
  7. Fraud or other intentional and willful misrepresentation by the pharmacy.
- (22) To have an audit based only on information obtained by the entity conducting the audit and not based on any audit report or other information gained from an audit conducted by a different auditing entity. This subdivision does not prohibit an auditing entity from using an earlier audit report prepared by that auditing entity for the same pharmacy. Except as required by State or federal law, an entity conducting an audit may have access to a pharmacy's previous audit report only if the previous report was prepared by that entity.
- (23) If the audit is conducted by a vendor or subcontractor, that entity is required to identify the responsible party on whose behalf the audit is being conducted without having this information being requested.
- (24) To use any prescription that complies with federal or State laws and regulations at the time of dispensing to validate a claim in connection with a prescription, prescription refill, or a change in a prescription.

**§ 90-85.51. Mandatory appeals process.**

- (a) Each entity that conducts an audit of a pharmacy shall establish an appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.
- (b) If, following the appeal, the entity finds that an unfavorable audit report or any portion of the unfavorable audit report is unsubstantiated, the entity shall dismiss the unsubstantiated portion of the audit report without any further proceedings.
- (c) Each entity conducting an audit shall provide a copy, if required under contractual terms, of the audit findings to the plan sponsor after completion of any appeals process.

**§ 90-85.52. Pharmacy audit recoupments.**

- (a) The entity conducting an audit shall not recoup any disputed funds, charges, or other penalties from a pharmacy until (i) the deadline for initiating the appeals process established pursuant to G.S. 90-85.51 has elapsed or (ii) after the final internal disposition of an audit, including the appeals process as set forth in G.S. 90-85.51, whichever is later, unless fraud or misrepresentation is reasonably suspected.
- (b) Recoupment on an audit shall be refunded to the responsible party as contractually agreed upon by the parties.
- (c) The entity conducting the audit may charge or assess the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:
  - (1) The responsible party and the entity conducting the audit have entered into a contract that explicitly states the percentage charge or assessment to the responsible party.
  - (2) A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

**§ 90-85.53. Applicability.**

This Article does not apply to any audit, review, or investigation that involves alleged Medicaid fraud, Medicaid abuse, insurance fraud, or other criminal fraud or misrepresentation.

**Article 5.  
North Carolina Controlled Substances Act.**

*Selected Provisions*

**§ 90-86. Title of Article.**

This Article shall be known and may be cited as the "North Carolina Controlled Substances Act."

**§ 90-87. Definitions.**

As used in this Article:

- (1) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means to the body of a patient or research subject by:
  - a. A practitioner (or, in his presence, by his authorized agent), or
  - b. The patient or research subject at the direction and in the presence of the practitioner.
- (2) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser but does not include a common or contract carrier, public warehouseman, or employee thereof.
- (3) "Bureau" means the Bureau of Narcotics and Dangerous Drugs, United States Department of Justice or its successor agency.
- (3a) "Commission" means the Commission for Mental Health, Developmental Disabilities, and Substance Use Services established under Part 4 of Article 3 of Chapter 143B of the General Statutes.
- (4) "Control" means to add, remove, or change the placement of a drug, substance, or immediate precursor included in Schedules I through VI of this Article.
- (5) "Controlled substance" means a drug, substance, or immediate precursor included in Schedules I through VI of this Article.
- (5a) "Controlled substance analogue" means a substance (i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II; (ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II; or (iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II; and does not include (i) a controlled substance; (ii) any substance for which there is an approved new drug application; (iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under § 355 of Title 21 of the United States Code to the extent conduct with respect to such substance is pursuant to such exemption; or (iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance. The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to subdivision 802(34) or 802(35) of Title 21 of the United States Code does not preclude a finding pursuant to this subdivision that the chemical is a controlled substance analogue.
- (6) "Counterfeit controlled substance" means:
  - a. A controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports, or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser; or

- b. Any substance which is by any means intentionally represented as a controlled substance. It is evidence that the substance has been intentionally misrepresented as a controlled substance if the following factors are established:
  - 1. The substance was packaged or delivered in a manner normally used for the illegal delivery of controlled substances.
  - 2. Money or other valuable property has been exchanged or requested for the substance, and the amount of that consideration was substantially in excess of the reasonable value of the substance.
  - 3. The physical appearance of the tablets, capsules or other finished product containing the substance is substantially identical to a specified controlled substance.
- (7) "Deliver" or "delivery" means the actual constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship.
- (8) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.
- (9) "Dispenser" means a practitioner who dispenses.
- (10) "Distribute" means to deliver other than by administering or dispensing a controlled substance.
- (11) "Distributor" means a person who distributes.
- (12) "Drug" means a. substances recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; b. substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; c. substances (other than food) intended to affect the structure or any function of the body of man or other animals; and d. substances intended for use as a component of any article specified in a, b, or c of this subdivision; but does not include devices or their components, parts, or accessories.
- (13) "Drug dependent person" means a person who is using a controlled substance and who is in a state of psychic or physical dependence, or both, arising from use of that controlled substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects, or to avoid the discomfort of its absence.
- (13a) "Hemp" means the plant *Cannabis sativa* (L.) and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) on a dry weight basis.
- (13b) "Hemp products" means all products made from hemp, including, but not limited to, cloth, cordage, fiber, food, fuel, paint, paper, particleboard, plastics, seed, seed meal and seed oil for consumption, and verified propagules for cultivation if the seeds originate from hemp varieties.
- (14) "Immediate precursor" means a substance which the Commission has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit such manufacture.
- (14a) The term "isomer" means the optical isomer, unless otherwise specified.
- (15) "Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance by any means, whether directly or indirectly, artificially or naturally, or by extraction from substances of a natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and "manufacture" further includes any packaging or repackaging of the substance or labeling or relabeling of its container except that this term does not include the preparation or compounding of a controlled substance by an individual for his own use or the preparation, compounding, packaging, or labeling of a controlled substance:
  - a. By a practitioner as an incident to his administering or dispensing of a controlled substance in the course of his professional practice, or

- b. By a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to research, teaching, or chemical analysis and not for sale.
- (16) "Marijuana" means all parts of the plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin, but shall not include the mature stalks of such plant, fiber produced from such stalks, oil, or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination. The term does not include hemp or hemp products.
- (17) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
- a. Opium, opiate and opioid, and any salt, compound, derivative, or preparation of opium, opiate, or opioid.
  - b. Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause a, but not including the isoquinoline alkaloids of opium.
  - c. Opium poppy and poppy straw.
  - d. Cocaine and any salt, isomer (whether optical or geometric), salts of isomers, compound, derivative, or preparation thereof, or coca leaves and any salt, isomer, salts of isomers, compound, derivative or preparation of coca leaves, or any salt, isomer, salts of isomers, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocanized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.
- (18) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under G.S. 90-88, the dextrorotatory isomer of 3-methoxy-n-methyl-morphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.
- (18a) "Opioid" means any synthetic narcotic drug having opiate-like activities but is not derived from opium.
- (19) "Opium poppy" means the plant of the species *Papaver somniferum* L., except its seeds.
- (20) "Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.
- (21) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.
- (22) "Practitioner" means:
- a. A physician, dentist, optometrist, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance so long as such activity is within the normal course of professional practice or research in this State.
  - b. A pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance so long as such activity is within the normal course of professional practice or research in this State.
- (23) "Prescription" means:
- a. A written order or other order which is promptly reduced to writing for a controlled substance as defined in this Article, or for a preparation, combination, or mixture thereof, issued by a practitioner who is licensed in this State to administer or prescribe drugs in the course of his professional practice; or issued by a practitioner serving on active duty with the Armed Forces of the United States or the United States Veterans Administration who is licensed in this or another state or Puerto Rico, provided the order is written for the benefit of eligible beneficiaries of armed services medical care; a prescription does not include an order entered in a chart or other medical record of a patient by a practitioner for the administration of a drug; or

- b. A drug or preparation, or combination, or mixture thereof furnished pursuant to a prescription order.
- (24) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.
- (25) "Registrant" means a person registered by the Commission to manufacture, distribute, or dispense any controlled substance as required by this Article.
- (26) "State" means the State of North Carolina.
- (26a) "Targeted controlled substance" means any controlled substance included in G.S. 90-90(1) or (2) or G.S. 90-91(d).
- (27) "Ultimate user" means a person who lawfully possesses a controlled substance for his own use, or for the use of a member of his household, or for administration to an animal owned by him or by a member of his household.

**§ 90-88. Authority to control.**

(a) The Commission may add, delete, or reschedule substances within Schedules I through VI of this Article on the petition of any interested party, or its own motion. In every case the Commission shall give notice of and hold a public hearing pursuant to Chapter 150B of the General Statutes prior to adding, deleting or rescheduling a controlled substance within Schedules I through VI of this Article, except as provided in subsection (d) of this section. A petition by the Commission, the North Carolina Department of Justice, or the North Carolina Board of Pharmacy to add, delete, or reschedule a controlled substance within Schedules I through VI of this Article shall be placed on the agenda, for consideration, at the next regularly scheduled meeting of the Commission, as a matter of right.

(a1) In making a determination regarding a substance, the Commission shall consider the following:

- (1) The actual or relative potential for abuse;
- (2) The scientific evidence of its pharmacological effect, if known;
- (3) The state of current scientific knowledge regarding the substance;
- (4) The history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) The risk to the public health;
- (7) The potential of the substance to produce psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under this Article.

(b) After considering the required factors, the Commission shall make findings with respect thereto and shall issue an order adding, deleting or rescheduling the substance within Schedules I through VI of this Article.

(c) If the Commission designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

(d) If any substance is designated, rescheduled or deleted as a controlled substance under federal law, the Commission shall similarly control or cease control of, the substance under this Article unless the Commission objects to such inclusion. The Commission, at its next regularly scheduled meeting that takes place 30 days after publication in the Federal Register of a final order scheduling a substance, shall determine either to adopt a rule to similarly control the substance under this Article or to object to such action. No rule-making notice or hearing as specified by Chapter 150B of the General Statutes is required if the Commission makes a decision to similarly control a substance. However, if the Commission makes a decision to object to adoption of the federal action, it shall initiate rule-making procedures pursuant to Chapter 150B of the General Statutes within 180 days of its decision to object.

(e) The Commission shall exclude any nonnarcotic substance from the provisions of this Article if such substance may, under the federal Food, Drug and Cosmetic Act, lawfully be sold over-the-counter without prescription.

(f) Authority to control under this Article does not include distilled spirits, wine, malt beverages, or tobacco.

(g) The Commission shall similarly exempt from the provisions of this Article any chemical agents and diagnostic reagents not intended for administration to humans or other animals, containing controlled substances which either (i) contain additional adulterant or denaturing agents so that the resulting mixture has no significant abuse potential, or (ii) are packaged in such a form or concentration that the particular form as packaged has no significant abuse potential, where such substance was exempted by the Federal Bureau of Narcotics and Dangerous Drugs.

...  
(i) The North Carolina Department of Health and Human Services shall maintain a list of all preparations, compounds, or mixtures which are excluded, exempted and excepted from control under any schedule of this Article by the United States Drug Enforcement Administration and/or the Commission. This list and any changes to this list shall be mailed to the North Carolina Board of Pharmacy, the State Bureau of Investigation and each district attorney of this State.

**§ 90-89. Schedule I controlled substances.**

This schedule includes the controlled substances listed or to be listed by whatever official name, common or usual name, chemical name, or trade name designated. In determining that a substance comes within this schedule, the Commission shall find: a high potential for abuse, no currently accepted medical use in the United States, or a lack of accepted safety for use in treatment under medical supervision. The following controlled substances are included in this schedule:

- (1) Opiates. – Any of the following opiates or opioids, including the isomers, esters, ethers, salts and salts of isomers, esters, and ethers, unless specifically excepted, or listed in another schedule, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:
  - a. Acetyl-alpha-methylfentanyl  
(N-[1-(1-methyl-2-phenethyl)-4/y-piperidinyl]-N-phenylacet amide).
  - b. Acetylmethadol.
  - c. Repealed by Session Laws 1987, c. 412, s. 2.
  - d. Alpha-methylthiofentanyl  
(N-[1-methyl-2-(2-thienyl)ethyl]-4/y-piperidinyl]-N-phenylpropanamide).
  - e. Allylprodine.
  - f. Alphacetylmethadol (except levo-alphacetylmethadol, also known as levomethadyl acetate and LAAM).
  - g. Alphameprodine.
  - h. Alphamethadol.
  - i. Alpha-methylfentanyl (N-(1-(alpha-methyl-beta-phenyl) ethyl-4-piperidyl) propionalilide; 1(1-methyl-2-phenyl-ethyl)-4-(N-propanilido) piperidine).
  - j. Benzethidine.
  - k. Betacetylmethadol.
  - l. Beta-hydroxfentanyl  
(N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamid).
  - m. Beta-hydroxy-3-methylfentanyl  
(N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide).
  - n. Betameprodine.
  - o. Betamethadol.
  - p. Betaprodine.
  - q. Clonitazene.
  - r. Dextromoramide.
  - s. Diampromide.
  - t. Diethylthiambutene.
  - u. Difenoxin.
  - v. Dimenoxadol.
  - w. Dimepheptanol.
  - x. Dimethylthiambutene.
  - y. Dioxaphetyl butyrate.
  - z. Dipipanone.
  - aa. Ethylmethylthiambutene.
  - bb. Etonitazene.
  - cc. Etoxidine.
  - dd. Furethidine.
  - ee. Hydroxypethidine.
  - ff. Ketobemidone.
  - gg. Levomoramide.

- hh. Levophenacymorphan. For purposes of this sub-subdivision only, the term "isomer" includes the optical and geometric isomers.
  - ii. 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP).
  - jj. 3-Methylfentanyl  
(N-[3-methyl-1-(2-Phenylethyl)-4-Pi-peridyl]-N-Phenylpropanamide).
  - kk. 3-Methylthiofentanyl  
(N-[3-methyl-1-(2-thienyl)ethyl/y-4-piperidinyl]-N-phenylpropanamide).
  - ll. Morpheridine.
  - mm. Noracymethadol.
  - nn. Norlevorphanol.
  - oo. Normethadone.
  - pp. Norpipanone.
  - qq. Para-fluorofentanyl  
(N-(4-fluorophenyl)-N-[1-(2-phen-ethyl)-4-piperidinyl]-propanamide).
  - rr. Phenadoxone.
  - ss. Phenampromide.
  - tt. 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP).
  - uu. Phenomorphan.
  - vv. Phenoperidine.
  - ww. Piritramide.
  - xx. Proheptazine.
  - yy. Properidine.
  - zz. Propiram.
  - aaa. Racemoramide.
  - bbb. Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide).
  - ccc. Tilidine.
  - ddd. Trimeperidine.
  - eee. Acetyl Fentanyl.
  - fff. Trans-3,4-dichloro-N-(2(dimethylamino)cyclohexyl)-N-methyl-benzamide (U47700).
  - ggg. 3,4-dichloro-N([1(dimethylamino)cyclohexyl)methyl]benzamide;  
1-(3,4-dichlorobenzamidomethyl)cyclohexyldimethylamine) (also known as AH-7921).
  - hhh. 3,4-dichloro-N-[(diethylamino)cyclohexyl]-N-methylbenzamide (also known as U-49900).
  - iii. U-77891.
  - jjj. 1-phenylethylpiperidylidene-2-(4-chlorophenyl)sulfonamide;  
1-(4-nitrophenylethyl)piperidylidene-2-(4-chlorophenyl)sulfonamide;  
4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]-2-piperidinylidene]/y-benzenesulfonamide (also known as W-18).
  - kkk. 1-phenylethylpiperidylidene-2-(4-chlorophenyl)sulfonamide;  
4-chloro-N-[1-(2-phenylethyl)-2-piperidinylidene]-benzenesulfonamide (also known as W-15).
  - lll. 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (also known as MT-45).
  - mmm. 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-isopropylbenz amide (also known as Isopropyl-U-47700).
  - nnn. 2-(3,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methylacetamide (also known as U-51754).
  - ooo. 2-(2,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methylacetamide (also known as U-48800).
  - ppp. Isotonitazene.
  - qqq. Metonitazene.
  - rrr. Brophine.
- (1a) Fentanyl derivatives. – Unless specifically excepted, listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any compound structurally derived from

N-[1-(2-phenylethyl)-4-piperidinyl]-N-phenylpropanamide (Fentanyl) by any substitution on or replacement of the phenethyl group, any substitution on the piperidine ring, any substitution on or replacement of the propanamide group, any substitution on the anilido phenyl group, or any combination of the above unless specifically excepted or listed in another schedule to include their salts, isomers, and salts of isomers. Fentanyl derivatives include, but are not limited to, the following:

- a. N-(1-phenylethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide (also known as Furanyl Fentanyl).
- b. N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide;  
N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide (also known as Butyryl Fentanyl).
- c. N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide;  
N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]N-phenylpropanamide (also known as Beta-Hydroxythiofentanyl).
- d. N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]-2propenamide (also known as Acrylfentanyl).
- e. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (also known as Valeryl Fentanyl).
- f. N-(2-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (also known as 2-fluorofentanyl).
- g. N-(3-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (also known as 3-fluorofentanyl).
- h. N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (also known as tetrahydrofuran fentanyl).
- i. N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (also known as 4-fluoroisobutyryl fentanyl, 4-FIBF).
- j. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (also known as 4-fluorobutyryl fentanyl, 4-FBF).

(2) Opium derivatives. – Any of the following opium derivatives, including their salts, isomers, and salts of isomers (whether optical, positional, or geometric), unless specifically excepted, or listed in another schedule, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- a. Acetorphine.
- b. Acetyldihydrocodeine.
- c. Benzylmorphine.
- d. Codeine methylbromide.
- e. Codeine-N-Oxide.
- f. Cyprenorphine.
- g. Desomorphine.
- h. Dihydromorphine.
- i. Etorphine (except hydrochloride salt).
- j. Heroin.
- k. Hydromorphanol.
- l. Methyl-desorphine.
- m. Methyl-dihydromorphine.
- n. Morphine methylbromide.
- o. Morphine methylsulfonate.
- p. Morphine-N-Oxide.
- q. Myrophine.
- r. Nicocodeine.
- s. Nicomorphine.
- t. Normorphine.
- u. Pholcodine.
- v. Thebacon.
- w. Drotebanol.



- (3) Hallucinogenic substances. – Any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, including their salts, isomers (whether optical, positional, or geometric), and salts of isomers, unless specifically excepted, or listed in another schedule, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
- a. 3, 4-methylenedioxyamphetamine.
  - b. 5-methoxy-3, 4-methylenedioxyamphetamine.
  - c. 3, 4-Methylenedioxymethamphetamine (MDMA).
  - d. 3, 4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3, 4-(methylenedioxy) phenethylamine, N-ethyl MDA, MDE, and MDEA).
  - e. N-hydroxy-3, 4-methylenedioxyamphetamine (also known as N-hydroxy/y-alpha-methyl-3, 4-(methylenedioxy) phenethylamine, and N-hydroxy MDA).
  - f. 3, 4, 5-trimethoxyamphetamine.
  - g. Alpha-ethyltryptamine. Some trade or other names: etryptamine, Monase, alpha-ethyl-1H-indole-3-ethanamine, 3-(2-aminobutyl) indole, alpha-ET, and AET.
  - h. Bufotenine.
  - i. Diethyltryptamine.
  - j. Dimethyltryptamine.
  - k. 4-methyl-2, 5-dimethoxyamphetamine.
  - l. Ibogaine.
  - m. Lysergic acid diethylamide.
  - n. Mescaline.
  - o. Peyote, meaning all parts of the plant presently classified botanically as *Lophophora Williamsii* Lemaire, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seed or extracts.
  - p. N-ethyl-3-piperidyl benzilate.
  - q. N-methyl-3-piperidyl benzilate.
  - r. Psilocybin.
  - s. Psilocin.
  - t. 2, 5-dimethoxyamphetamine.
  - u. 2, 5-dimethoxy-4-ethylamphetamine. Some trade or other names: DOET.
  - v. 4-bromo-2, 5-dimethoxyamphetamine.
  - w. 4-methoxyamphetamine.
  - x. Ethylamine analog of phencyclidine. Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE.
  - y. Pyrrolidine analog of phencyclidine. Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP.
  - z. Thiophene analog of phencyclidine. Some trade or other names: 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP.
  - aa. 1-[1-(2-thienyl)cyclohexyl]pyrrolidine; Some other names: TCPy.
  - bb. Parahexyl.
  - cc. 4-Bromo-2, 5-Dimethoxyphenethylamine.
  - dd. Alpha-Methyltryptamine.
  - ee. 5-Methoxy-N,N-diisopropyltryptamine.
  - ff. Methoxetamine (other names: MXE, 3-MeO-2-Oxo-PCE).
  - gg. BTCP (Benzothiophenylcyclohexylpiperidine).
  - hh. Deschloroketamine.
  - jj. 3-MeO-PCP (3-methoxyphencyclidine).
  - kk. 4-hydroxy-MET.
  - ll. 4-OH-MiPT (4-hydroxy-N-methyl-N-isopropyltryptamine).
  - mm. 5-methoxy-N-methyl-N-propyltryptamine (5-MeO-MiPT).

- nn. Substituted tryptamines. – Any compound, unless specifically excepted, specifically named in this schedule, or listed under a different schedule, structurally derived from 2-(1H-indol-3-yl)ethanamine (i.e., tryptamine) by mono- or di-substitution of the amine nitrogen with alkyl or alkenyl groups or by inclusion of the amino nitrogen atom in a cyclic structure whether or not the compound is further substituted at the alpha position with Senate Bill 321 Session Law 2021-155 Page 3 an alkyl group or whether or not further substituted on the indole ring to any extent with any alkyl, alkoxy, halo, hydroxyl, or acetoxy groups. Substances in this class include, but are not limited to: 4-AcO-DiPT (4-acetoxy-N,N-diisopropyltryptamine), 4-HO-MPMI ((R)-3-(N-methylpyrrolidin-2-ylmethyl)-4-hydroxyindole), and DALT (N,N-diallyltryptamine).
- oo. Substituted phenylcyclohexylamines. – Any compound, unless specifically excepted or unless listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation containing a phenylcyclohexylamine structure, with or without any substitution on the phenyl ring, any substitution on the cyclohexyl ring, any replacement of the phenyl ring with a thiophenyl or benzothiophenyl ring, with or without substitution on the amine with alkyl, dialkyl, or alkoxy substituents, inclusion of the nitrogen in a cyclic structure, or any combination of the above. Substances in this class include, but are not limited to: BCP (benocyclidine), PCMPA ((phenylcyclohexyl(methoxypropylamine)), and Hydroxy-PCP ((hydroxyphenyl)cyclohexylpiperidine).
- (4) Systemic depressants. – Any material compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, unless specifically excepted or unless listed in another schedule:
- a. Mecloqualone.
  - b. Methaqualone.
  - c. Gamma hydroxybutyric acid; Some other names: GHB, gamma-hydroxybutyrate, 4-hydroxybutyrate, 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate.
  - d. Etizolam.
  - e. Flubromazepam.
  - f. Phenazepam.
  - g. Clonazolam.
  - h. Flualprazolam.
  - i. Flubromazolam.
- (5) Stimulants. – Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:
- a. Aminorex. Some trade or other names: aminoxaphen; 2-amino-5-phenyl-2-oxazoline; or 4,5-dihydro-5-phenyl-2-oxazolamine.
  - b. Cathinone. Some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone.
  - c. Fenethylamine.
  - d. Methcathinone. Some trade or other names: 2-(methylamino)-propionophenone, alpha-(methylamino)propionophenone, 2-(methylamino)-1-phenylpropan-1-one, alpha-N-methylamino-propionophenone, monomethylpropion, ephedrone, N-methylcathinone, methylcathinone, AL-464, AL-422, AL-463, and UR1432.
  - e. (+)-cis-4-methylaminorex [(+)-cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine] (also known as 2-amino-4-methyl-5-phenyl-2-oxazoline).
  - f. N,N-dimethylamphetamine. Some other names: N,N,alpha-tri-methylbenzeneethanamine; N,N,alpha-trimethylphenethylamine.
  - g. N-ethylamphetamine.
  - h. 4-methylmethcathinone (also known as mephedrone). For this compound, the term "isomer" includes the optical, positional, or geometric isomer.

- i. 3,4-Methylenedioxypropylvalerone (also known as MDPV). For this compound, the term "isomer" includes the optical, positional, or geometric isomer.
  - j. Substituted cathinones. A compound, other than bupropion, that is structurally derived from 2-amino-1-phenyl-1-propanone by modification in any of the following ways: (i) by substitution in the phenyl ring to any extent with alkyl, alkoxy, alkylendioxy, haloalkyl, or halide substituents, whether or not further substituted in the phenyl ring by one or more other univalent substituents; (ii) by substitution at the 3-position to any extent; or (iii) by substitution at the nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups or by inclusion of the nitrogen atom in a cyclic structure. For this compound, the term "isomer" includes the optical, positional, or geometric isomer.
  - k. N-Benzylpiperazine.
  - l. 2,5 – Dimethoxy-4-(n)-propylthiophenethylamine.
- (6) NBOMe compounds. – Any material compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, positional, or geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation unless specifically excepted or unless listed in another schedule:
- a. 25B-NBOMe (2C-B-NBOMe)  
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine.
  - b. 25C-NBOMe (2C-C-NBOMe)  
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine.
  - c. 25D-NBOMe (2C-D-NBOMe)  
2-(2,5-dimethoxy-4-methylphenyl)-N-(2-methoxybenzyl)ethanamine.
  - d. 25E-NBOMe (2C-E-NBOMe)  
2-(4-Ethyl-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine.
  - e. 25G-NBOMe (2C-G-NBOMe)  
2-(2,5-dimethoxy-3,4-dimethylphenyl)-N-(2-methoxybenzyl)ethanamine.
  - f. 25H-NBOMe (2C-H-NBOMe)  
2-(2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine.
  - g. 25I-NBOMe (2C-I-NBOMe)  
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine.
  - h. 25N-NBOMe (2C-N-NBOMe)  
2-(2,5-dimethoxy-4-nitrophenyl)-N-(2-methoxybenzyl)ethanamine.
  - i. 25P-NBOMe (2C-P-NBOMe)  
2-(4-Propyl-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine.
  - j. 25T2-NBOMe (2C-T2-NBOMe)  
2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-4-(methylthio)-benzeneethanamine.
  - k. 25T4-NBOMe (2C-T4-NBOMe)  
2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-4-[(1-methylethyl)thio]- benzeneethanamine.
  - l. 25T7-NBOMe (2C-T7-NBOMe)  
2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-4-(propylthio)-benzeneethanamine.
- (7) Synthetic cannabinoids. – Any quantity of any synthetic chemical compound that (i) is a cannabinoid receptor agonist and mimics the pharmacological effect of naturally occurring substances or (ii) has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is not listed as a controlled substance in Schedules I through V, and is not an FDA-approved drug. Synthetic cannabinoids include, but are not limited to, the substances listed in sub-subdivisions a. through p. of this subdivision and any substance that contains any quantity of their salts, isomers (whether optical, positional, or geometric), homologues, and salts of isomers and homologues, unless specifically excepted, whenever the existence of these salts, isomers, homologues, and salts of isomers and homologues is possible within the specific chemical designation. The following substances are examples of synthetic cannabinoids and are not intended to be inclusive of the substances included in this Schedule:
- a. Naphthylindoles. Any compound containing a 3-(1-naphthyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl,

- cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Some trade or other names: JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, JWH-398, AM-2201, and WIN 55-212.
- b. Naphthylmethylindoles. Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent.
  - c. Naphthoylpyrroles. Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Another name: JWH-307.
  - d. Naphthylmethylindenes. Any compound containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent.
  - e. Phenylacetylindoles. Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Some trade or other names: SR-18, RCS-8, JWH-250, and JWH-203.
  - f. Cyclohexylphenols. Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not substituted in the cyclohexyl ring to any extent. Some trade or other names: CP 47,497 (and homologues), cannabicyclohexanol.
  - g. Benzoylindoles. Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Some trade or other names: AM-694, Pravadoline (WIN 48,098), and RCS-4.
  - h. 2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-naphthalenylmethanone. Some trade or other name: WIN 55,212-2.
  - i. (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol 7370. Some trade or other name: HU-210.
  - j. 3-(cyclopropylmethanone) indole or 3-(cyclobutylmethanone) indole or 3-(cyclopentylmethanone) indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not further substituted on the cyclopropyl, cyclobutyl, or cyclopentyl rings to any extent. Substances in this class include, but are not limited to: UR-144, fluoro-UR-144, XLR-11, A-796,260, and A-834,735.
  - k. Indole carboxaldehydes. Any compound structurally derived from 1H-indole-3-carboxaldehyde or 1H-indole-2-carboxaldehyde substituted in both of the following ways:

1. At the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, tetrahydropyranylmethyl, benzyl, or halo benzyl group; and
  2. At the carbon of the carboxaldehyde by a phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group;
- whether or not the compound is further modified to any extent in the following ways: (i) substitution to the indole ring to any extent, (ii) substitution to the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group to any extent, (iii) a nitrogen heterocyclic analog of the indole ring, or (iv) anitrogen heterocyclic analog of the phenyl, benzyl, naphthyl, adamantyl, or cyclopropyl ring. Substances in this class include, but are not limited to: AB-001.
- l.* Indole carboxamides. Any compound structurally derived from 1H-indole-3-carboxamide or 1H-indole-2-carboxamide substituted in both of the following ways:
1. At the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, tetrahydropyranylmethyl, benzyl, or halo benzyl group; and
  2. At the nitrogen of the carboxamide by a phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group;
- whether or not the compound is further modified to any extent in the following ways: (i) substitution to the indole ring to any extent, (ii) substitution to the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group to any extent, (iii) a nitrogen heterocyclic analog of the indole ring, or (iv) a nitrogen heterocyclic analog of the phenyl, benzyl, naphthyl, adamantyl, or cyclopropyl ring. Substances in this class include, but are not limited to: SDB-001 and STS-135.
- m.* Indole carboxylic acids. Any compound structurally derived from 1H-indole-3-carboxylic acid or 1H-indole-2-carboxylic acid substituted in both of the following ways:
1. At the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, tetrahydropyranylmethyl, benzyl, or halo benzyl group; and
  2. At the nitrogen of the carboxamide by a phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group;
- whether or not the compound is further modified to any extent in the following ways: (i) substitution to the indole ring to any extent, (ii) substitution to the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group to any extent, (iii) a nitrogen heterocyclic analog of the indole ring, or (iv) a nitrogen heterocyclic analog of the phenyl, benzyl, naphthyl, adamantyl, or cyclopropyl ring. Substances in this class include, but are not limited to: SDB-001 and STS-135.
- whether or not the compound is further modified to any extent in the following ways: (i) substitution to the indole ring to any extent, (ii) substitution to the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group to any extent, (iii) a nitrogen heterocyclic analog of the indole ring, or (iv) a nitrogen heterocyclic analog of the phenyl, benzyl, naphthyl, adamantyl, or cyclopropyl ring. Substances in this class include, but are not limited to: PB-22 and fluoro-PB-22.
- n.* Indazole carboxaldehydes. Any compound structurally derived from 1H-indazole-3-carboxaldehyde or 1H-indazole-2-carboxaldehyde substituted in both of the following ways:

1. At the nitrogen atom of the indazole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, tetrahydropyranylmethyl, benzyl, or halo benzyl group; and
  2. At the carbon of the carboxaldehyde by a phenyl, benzyl, whether or not the compound is further modified to any extent in the following ways: (i) substitution to the indazole ring to any extent, (ii) substitution to the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group to any extent, (iii) a nitrogen heterocyclic analog of the indazole ring, or (iv) a nitrogen heterocyclic analog of the phenyl, benzyl, naphthyl, adamantyl, or cyclopropyl ring.
- o. Indazole carboxamides. Any compound structurally derived from 1H-indazole-3-carboxamide or 1H-indazole-2-carboxamide substituted in both of the following ways:
1. At the nitrogen atom of the indazole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, tetrahydropyranylmethyl, benzyl, or halo benzyl group; and
  2. At the nitrogen of the carboxamide by a phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group; whether or not the compound is further modified to any extent in the following ways: (i) substitution to the indazole ring to any extent, (ii) substitution to the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group to any extent, (iii) a nitrogen heterocyclic analog of the indazole ring, or (iv) a nitrogen heterocyclic analog of the phenyl, benzyl, naphthyl, adamantyl, or cyclopropyl ring. Substances in this class include, but are not limited to: AKB-48, fluoro-AKB-48, APINCACA, AB-PINACA, AB-FUBINACA, ADB-FUBINACA, and ADB-PINACA.
- p. Indazole carboxylic acids. Any compound structurally derived from 1H-indazole-3-carboxylic acid or 1H-indazole-2-carboxylic acid substituted in both of the following ways:
1. At the nitrogen atom of the indazole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, tetrahydropyranylmethyl, benzyl, or halo benzyl group; and
  2. At the hydroxyl group of the carboxylic acid by a phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group; whether or not the compound is further modified to any extent in the following ways: (i) substitution to the indazole ring to any extent, (ii) substitution to the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group to any extent, (iii) a nitrogen heterocyclic analog of the indazole ring, or (iv) a nitrogen heterocyclic analog of the phenyl, benzyl, naphthyl, adamantyl, or cyclopropyl ring.
- q. Carbazoles. Any compound containing a carbazole ring system with a substituent on the nitrogen atom and bearing an additional substituent at the 1, 2, or 3 position of the carbazole ring system, with a linkage connecting the ring system to the substituent:
1. Where the linkage connecting the carbazole ring system to the substituent if its 1, 2, or 3 position is any of the following: Alkyl, Carbonyl, Ester, Thione, Thioester, Amino, Alkylamino, Amido, or Alkylamido.
  2. Where the substituent at the 1, 2, or 3 position of the carbazole ring system, disregarding the linkage, is any of the following groups: Naphthyl, Quinoliny, Adamantyl, Phenyl, Cycloalkyl (limited to cyclopropyl, cyclobutyl, cyclopentyl, or cyclohexyl), Biphenyl, Alkylamido (limited to ethylamido, propylamido, butanamido, pentamido), Benzyl, Carboxylic

acid, Ester, Ether, Phenylpropylamido, or Phenylpropylamino; whether or not further substituted in either of the following ways: (i) the substituent at the 1, 2, or 3 position of the carbazole ring system, disregarding the linkage, is further substituted to any extent (ii) further substitution on the carbazole ring system to any extent. This class includes, but is not limited to, the following: MDMB CHMCZCA, EG-018, and EG-2201.

- r. Naphthoynaphthalenes. Any compound structurally derived from naphthalene-1-yl-(naphthalene-1-yl) methanone with substitutions on either of the naphthalene rings to any extent. Substances in this class include, but are not limited to: CB-13.
- (8) Substituted phenethylamines. – This includes any compound, unless specifically excepted, specifically named or included in another subset in this schedule, or listed under a different schedule, structurally derived from phenylethan-2-amine by substitution on the phenyl ring in any of the following ways, that is to say, by substitution with a fused methylenedioxy ring, fused furan ring, or fused tetrahydrofuran ring; by substitution with two alkoxy groups; by substitution with one alkoxy and either one fused furan, tetrahydrofuran, or tetrahydropyran ring system; or by substitution with two fused ring systems from any combination of the furan, tetrahydrofuran, or tetrahydropyran ring systems. Whether or not the compound is further modified in any of the following ways, that is to say: (i) by substitution of phenyl ring by any halo, hydroxyl, alkyl, trifluoromethyl, alkoxy, or alkythio groups, (ii) by substitution at the 2-position by any alkyl groups, or (iii) by substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, hydroxybenzyl, methylenedioxybenzyl, or methoxybenzyl groups. Substances in this class include, but are not limited to: 2C-I (4-Iodo-2,5-dimethoxyphenethylamine), APDB ((2-aminopropyl)-2,3-dihydrobenzofuran), MBDB (3,4-methylenedioxy-N-methylbutanamine), and 2C-I-NBOH (N-(2-hydroxybenzyl)-4-iodo-2,5-dimethoxyphenethylamine).
- (9) N-Benzyl phenethylamines. – Unless specifically excepted or listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation, including its salts, isomers (whether optical, geometric, or positional), esters, or ethers, and salts of isomers, esters, or ethers, whenever the existence of such salts is possible within any of the following specific chemical designations, any compound containing a phenethylamine structure without a beta-keto group, with substitution on the nitrogen atom of the amino group with a benzyl substituent, with or without substitution on the phenyl or benzyl ring to any extent with alkyl, alkoxy, thio, alkylthio, halide, fused alkylendioxy, fused furan, fused benzofuran, or fused tetrahydropyran substituents, whether or not further substituted on a ring to any extent, with or without substitution at the alpha position by any alkyl substituent. Substances in this class include, but are not limited to: 25B-NBOH (4-bromo-2,5-dimethoxy-[N-(2-hydroxybenzyl)]phenethylamine), 25I-NBF (4-iodo-2,5-dimethoxy-[N-(2-fluorobenzyl)]phenethylamine), and 25C-NBMD (4-chloro-2,5-dimethoxy-[N-(2,3-methylenedioxybenzyl)]phenethylamine).

#### § 90-89.1. Treatment of controlled substance analogues.

A controlled substance analogue shall, to the extent intended for human consumption, be treated for the purposes of any State law as a controlled substance in Schedule I.

#### § 90-90. Schedule II controlled substances.

This schedule includes the controlled substances listed or to be listed by whatever official name, common or usual name, chemical name, or trade name designated. In determining that a substance comes within this schedule, the Commission shall find: a high potential for abuse; currently accepted medical use in the United States, or currently accepted medical use with severe restrictions; and the abuse of the substance may lead to severe psychic or physical dependence. The following controlled substances are included in this schedule:

- (1) Any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, unless specifically excepted or unless listed in another schedule:

- a. Opium, opiate, or opioid and any salt, compound, derivative, or preparation of opium and opiate, excluding apomorphine, nalbuphine, dextropropofol, naloxone, naltrexone and nalmefene, and their respective salts, but including the following:
    - 1. Raw opium.
    - 2. Opium extracts.
    - 3. Opium fluid extracts.
    - 4. Powdered opium.
    - 5. Granulated opium.
    - 6. Tincture of opium.
    - 7. Codeine.
    - 8. Ethylmorphine.
    - 9. Etorphine hydrochloride.
    - 10. Any material, compound, mixture, or preparation which contains any quantity of hydrocodone.
    - 11. Hydromorphone.
    - 12. Metopon.
    - 13. Morphine.
    - 14. Oxycodone.
    - 15. Oxymorphone.
    - 16. Thebaine.
    - 17. Dihydroetorphine.
  - b. Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph 1 of this subdivision, except that these substances shall not include the isoquinoline alkaloids of opium.
  - c. Opium poppy and poppy straw.
  - d. Cocaine and any salt, isomer (whether optical or geometric), salts of isomers, compound, derivative, or preparation thereof, or coca leaves and any salt, isomer, salts of isomers, compound, derivative, or preparation of coca leaves, or any salt, isomer, salts of isomers, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.
  - e. Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrine alkaloids of the opium poppy).
- (2) Any of the following opiates or opioids, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation unless specifically exempted or listed in other schedules:
- a. Alfentanil.
  - b. Alphaprodine.
  - c. Anileridine.
  - d. Bezitramide.
  - e. Carfentanil.
  - f. Dihydrocodeine.
  - g. Diphenoxylate.
  - h. Fentanyl.
  - h1. Fentanyl immediate precursor chemical, 4-anilino-N-phenethyl-4-piperidine (ANPP).
  - h2. Norfentanyl (N-phenyl-N-(piperidin-4-yl) propionamide).
  - i. Isomethadone.
  - j. Levo-alpha-acetylmethadol. Some trade or other names: levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM.
  - k. Levomethorphan.
  - l. Levorphanol.
  - m. Metazocine.
  - n. Methadone.



- o. Methadone – Intermediate, 4-cyano-2-dimethylamino-4, 4/y-diphenyl butane.
  - p. Moramide – Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid.
  - q. Pethidine.
  - r. Pethidine – Intermediate – A, 4-cyano-1-methyl-4/y-phenylpiperidine.
  - s. Pethidine – Intermediate – B, ethyl-4-phenylpiperidine-4-carboxylate.
  - t. Pethidine – Intermediate – C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
  - u. Phenazocine.
  - v. Piminodine.
  - w. Racemethorphan.
  - x. Racemorphan.
  - y. Remifentanil.
  - z. Sufentanil.
  - aa. Tapentadol.
- (3) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system unless specifically exempted or listed in another schedule:
- a. Amphetamine, its salts, optical isomers, and salts of its optical isomers.
  - b. Phenmetrazine and its salts.
  - c. Methamphetamine, including its salts, isomers, and salts of isomers.
  - d. Methylphenidate, including its salts, isomers, and salts of its isomers.
  - e. Phenylacetone. Some trade or other names: Phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone.
  - f. Lisdexamfetamine, including its salts, isomers, and salts of isomers.
- (4) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, unless specifically exempted by the Commission or listed in another schedule:
- a. Amobarbital
  - b. Glutethimide
  - ...
  - d. Pentobarbital
  - e. Phencyclidine
  - f. Phencyclidine immediate precursors:
    - 1. 1-Phenylcyclohexylamine
    - 2. 1-Piperidinocyclohexanecarbonitrile (PCC)
  - g. Secobarbital.
- (5) Any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, including their salts, isomers, and salts of isomers, unless specifically excepted, or listed in another schedule, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
- ...
  - b. Nabilone [Another name for nabilone: (+/-)-trans-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl/y-9H-dibenzo[b,d]pyran-9-one].

**§ 90-91. Schedule III controlled substances.**

This schedule includes the controlled substances listed or to be listed by whatever official name, common or usual name, chemical name, or trade name designated. In determining that a substance comes within this schedule, the Commission shall find: a potential for abuse less than the substances listed in Schedules I and II; currently accepted medical use in the United States; and abuse may lead to moderate or low physical dependence or high psychological dependence. The following controlled substances are included in this schedule:

...

(b) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system unless specifically exempted or listed in another schedule:

1. Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.
2. Chlorhexadol.
- ...
4. Lysergic acid.
5. Lysergic acid amide.
6. Methyprylon.
7. Sulfondiethylmethane.
8. Sulfonethylmethane.
9. Sulfonmethane.
- 9a. Tiletamine and zolazepam or any salt thereof. Some trade or other names for tiletamine-zolazepam combination product: Telazol. Some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl)-cyclohexanone. Some trade or other names for zolazepam: 4-(2-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo-[3,4-e][1,4]y-diazepin-7(1H)-one. flupyrazapon.
10. Any compound, mixture or preparation containing
  - (i) Amobarbital.
  - (ii) Secobarbital.
  - (iii) Pentobarbital.or any salt thereof and one or more active ingredients which are not included in any other schedule.
11. Any suppository dosage form containing
  - (i) Amobarbital.
  - (ii) Secobarbital.
  - (iii) Pentobarbital.or any salt of any of these drugs and approved by the federal Food and Drug Administration for marketing as a suppository.
12. Ketamine.

(c) Nalorphine.

(d) Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof unless specifically exempted or listed in another schedule:

1. Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit with an equal or greater quantity of an isoquinoline alkaloid of opium.
2. Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- ...
5. Not more than 1.80 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
6. Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
7. Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
8. Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
9. Buprenorphine.

(e) Any compound, mixture or preparation containing limited quantities of the following narcotic drugs, which shall include one or more active, nonnarcotic, medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

1. Paregoric, U.S.P.; provided, that no person shall purchase or receive by any means whatsoever more than one fluid ounce of paregoric within a consecutive 24-hour period, except on prescription issued by a duly licensed physician.

(f) Paregoric, U.S.P., may be dispensed at retail as permitted by federal law or administrative regulation without a prescription only by a registered pharmacist and no other person, agency or employee may dispense paregoric, U.S.P., even if under the direct supervision of a pharmacist.

(g) Notwithstanding the provisions of G.S. 90-91(f), after the pharmacist has fulfilled his professional responsibilities and legal responsibilities required of him in this Article, the actual cash transaction, credit transaction, or delivery of paregoric, U.S.P., may be completed by a nonpharmacist. A pharmacist may refuse to dispense a paregoric, U.S.P., substance until he is satisfied that the product is being obtained for medicinal purposes only.

(h) Paregoric, U.S.P., may only be sold at retail without a prescription to a person at least 18 years of age. A pharmacist must require every retail purchaser of a paregoric, U.S.P., substance to furnish suitable identification, including proof of age when appropriate, in order to purchase paregoric, U.S.P. The name and address obtained from such identification shall be entered in the record of disposition to consumers.

(i) The Commission may by regulation except any compound, mixture, or preparation containing any stimulant or depressant substance listed in paragraphs (a)1 and (a)2 of this schedule from the application of all or any part of this Article if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system; and if the ingredients are included therein in such combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system.

(j) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, positional or geometric), and salts of said isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, unless specifically excluded or listed in some other schedule.

1. Benzphetamine.
2. Chlorphentermine.
3. Clortermine.
- ...
5. Phendimetrazine.

(k) Anabolic steroids. The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, including, but not limited to, the following:

1. Methandrostenolone,
2. Stanozolol,
3. Ethylestrenol,
4. Nandrolone phenpropionate,
5. Nandrolone decanoate,
6. Testosterone propionate,
7. Chorionic gonadotropin,
8. Boldenone,
- 8a. Boldione,
9. Chlorotestosterone (4-chlorotestosterone),
10. Clostebol,
11. Dehydrochlormethyltestosterone,
- 11a. Desoxymethyltestosterone (17[alpha]-methyl-5[alpha]-androst-2-en-17[beta]-ol) (also known as madol),
12. Dibydrotestosterone (4-dihydrotestosterone),
13. Drostanolone,
14. Fluoxymesterone,
15. Formebolone (formebolone),
16. Mesterolene,
17. Methandienone,
18. Methandranone,
19. Methandriol,
- 19a. Methasterone,
20. Methenolene,

21. Methyltestosterone,
22. Mibolerone,
23. Nandrolene,
24. Norethandrolene,
25. Oxandrolone,
26. Oxymesterone,
27. Oxymetholone,
28. Stanolone,
29. Testolactone,
30. Testosterone,
31. Trenbolone,
- 31a. 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione), and
32. Any salt, ester, or isomer of a drug or substance described or listed in this subsection, if that salt, ester, or isomer promotes muscle growth. Except such term does not include (i) an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration or (ii) chorionic gonadotropin when administered by injection for veterinary use by a licensed veterinarian or the veterinarian's designated agent. If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this subsection.

...

(m) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

(n) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved drug product. [Some other names: (6aR-trans), -6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol or (-)-delta-9-(trans)-tetrahydrocannabinol].

**§ 90-92. Schedule IV controlled substances.**

(a) This schedule includes the controlled substances listed or to be listed by whatever official name, common or usual name, chemical name, or trade name designated. In determining that a substance comes within this schedule, the Commission shall find: a low potential for abuse relative to the substances listed in Schedule III of this Article; currently accepted medical use in the United States; and limited physical or psychological dependence relative to the substances listed in Schedule III of this Article. The following controlled substances are included in this schedule:

- (1) Depressants. – Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
  - a. Alprazolam.
  - b. Barbital.
  - c. Bromazepam.
  - d. Camazepam.
  - d1. Carisoprodol.
  - e. Chloral betaine.
  - f. Chloral hydrate.
  - g. Chlordiazepoxide.
  - h. Clobazam.
  - i. Clonazepam.
  - j. Clorazepate.
  - k. Clotiazepam.
  - l. Cloxazolam.
  - m. Delorazepam.
  - m1. Desalkylflurazepam.
  - n. Diazepam.

- n1. Dichloralphenazone.
- n2. Diclazepam.
- o. Estazolam.
- p. Ethchlorvynol.
- q. Ethinamate.
- r. Ethyl loflazepate.
- s. Fludiazepam.
- t. Flunitrazepam.
- u. Flurazepam.
- u1. Fospropol.
- . . .
- w. Halazepam.
- x. Haloxazolam.
- y. Ketazolam.
- z. Loprazolam.
- aa. Lorazepam.
- bb. Lormetazepam.
- cc. Mebutamate.
- dd. Medazepam.
- ee. Meprobamate.
- ff. Methohexital.
- gg. Methylphenobarbital (mephobarbital).
- hh. Midazolam.
- ii. Nimetazepam.
- jj. Nitrazepam.
- kk. Nordiazepam.
- ll. Oxazepam.
- mm. Oxazolam.
- nn. Paraldehyde.
- oo. Petrichloral.
- pp. Phenobarbital.
- qq. Pinazepam.
- rr. Prazepam.
- ss. Quazepam.
- tt. Temazepam.
- uu. Tetrazepam.
- vv. Triazolam.
- ww. Zolpidem.
- xx. Zaleplon.
- yy. Zopiclone.
- zz. Designer benzodiazepines. – Unless specifically excepted or listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, derivative, mixture, or preparation, including its salts, isomers, salts of isomers, halogen analogues, or homologues, whenever the existence of such salts, isomers, or salts of isomers, halogen analogues, or homologues is possible within the specific chemical designation, structurally derived from 1,4 benzodiazepine by substitution at the 5 position with a phenyl ring system (which may be further substituted), whether or not the compound is further modified in any of the following ways:
  1. By substitution at the 2 position with a ketone;
  2. By substitution at the 3 position with a hydroxyl group or ester group, which itself may be further substituted;
  3. By a fused triazole ring at the 1,2 position, which itself may be further substituted;
  4. By a fused imidazole ring at the 1,2 position, which itself may be further substituted;

5. By a fused oxazolidine ring at the 4,5 position, which itself may be further substituted;
  6. By a fused oxazine ring at the 4,5 position, which itself may be further substituted;
  7. By substitution at the 7 position with a nitro group;
  8. By substitution at the 7 position with a halogen group; or
  9. By substitution at the 1 position with an alkyl group, which itself may be further substituted.
- (2) Any material, compound, mixture, or preparation which contains any of the following substances, including its salts, or isomers and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:
- a. Fenfluramine. For this compound, the term "isomer" includes the optical, positional, or geometric isomer.
  - b. Pentazocine.
- (3) Stimulants. – Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
- a. Diethylpropion.
  - b. Mazindol.
  - c. Pemoline (including organometallic complexes and chelates thereof).
  - d. Phentermine.
  - e. Cathine.
  - f. Fencamfamin.
  - g. Fenproporex.
  - h. Mefenorex.
  - i. Sibutramine.
  - j. Modafinil.
- (4) Other Substances. – Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:
- a. Dextropropoxyphene (Alpha-(plus)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxybutane).
  - b. Pipradrol.
  - c. SPA ((-)-1-dimethylamino-1, 2-diphenylethane).
  - d. Butorphanol.
- (5) Narcotic Drugs. – Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:
- a. Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.
  - ...
  - c. 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers, and salts of these isomers (including tramadol).

(b) The Commission may by regulation except any compound, mixture, or preparation containing any stimulant or depressant substance listed in this schedule from the application of all or any part of this Article if the compound, mixture, or preparation contains one or more active, nonnarcotic, medicinal ingredients not having a stimulant or depressant effect on the central nervous system; provided, that such admixtures shall be included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a stimulant or depressant effect on the central nervous system.

**§ 90-93. Schedule V controlled substances.**

(a) This schedule includes the controlled substances listed or to be listed by whatever official name, common or usual name, chemical name, or trade name designated. In determining that a substance comes within this schedule, the Commission shall find: a low potential for abuse relative to the substances listed in Schedule IV of this

Article; currently accepted medical use in the United States; and limited physical or psychological dependence relative to the substances listed in Schedule IV of this Article. The following controlled substances are included in this schedule:

- (1) Any compound, mixture or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic alone:
  - a. Not more than 200 milligrams of codeine or any of its salts per 100 milliliters or per 100 grams.
  - b. Not more than 100 milligrams of dihydrocodeine or any of its salts per 100 milliliters or per 100 grams.
  - c. Not more than 100 milligrams of ethylmorphine or any of its salts per 100 milliliters or per 100 grams.
  - d. Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
  - e. Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.
  - f. Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

...

- (3) Stimulants. – Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

...

b. Pyrovalerone.

- (4) Anticonvulsants. – Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:
  - a. Ezogabine.
  - b. Lacosamide.
  - c. Brivaracetam.
  - d. Pregabalin.
  - e. Cenobamate.
  - f. Lasmiditan.

(b) A Schedule V substance may be sold at retail without a prescription only by a registered pharmacist and no other person, agent or employee may sell a Schedule V substance even if under the direct supervision of a pharmacist.

(c) Notwithstanding the provisions of G.S. 90-93(b), after the pharmacist has fulfilled the responsibilities required of him in this Article, the actual cash transaction, credit transaction, or delivery of a Schedule V substance, may be completed by a nonpharmacist. A pharmacist may refuse to sell a Schedule V substance until he is satisfied that the product is being obtained for medicinal purposes only.

(d) A Schedule V substance may be sold at retail without a prescription only to a person at least 18 years of age. The pharmacist must require every retail purchaser of a Schedule V substance to furnish suitable identification, including proof of age when appropriate, in order to purchase a Schedule V substance. The name and address obtained from such identification shall be entered in the record of disposition to consumers.

#### **§ 90-94. Schedule VI controlled substances.**

(a) This schedule includes the controlled substances listed or to be listed by whatever official name, common or usual name, chemical name, or trade name designated. In determining that such substance comes within this schedule, the Commission shall find: no currently accepted medical use in the United States, or a relatively low potential for abuse in terms of risk to public health and potential to produce psychic or physiological dependence liability based upon present medical knowledge, or a need for further and continuing study to develop scientific evidence of its pharmacological effects.

(b) The following controlled substances are included in this schedule:

- (1) Marijuana.

- (2) Tetrahydrocannabinols, except for tetrahydrocannabinols found in a product delta-9 tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) on a dry weight basis.

...

(c) Notwithstanding the provisions of this section, any prescription drug approved by the federal Food and Drug Administration under Section 505 of the federal Food, Drug, and Cosmetic Act that is designated, rescheduled, or deleted as a controlled substance under federal law by the United States Drug Enforcement Administration shall be excluded from Schedule VI and may be prescribed, distributed, dispensed, and used in accordance with federal law upon the issuance of a notice, final rule, or interim final rule by the United States Drug Enforcement Administration that designates, reschedules, or deletes such prescription drug as a controlled substance under federal law, unless the Commission objects to such action as provided under G.S. 90-88(d). If the Commission does not object as provided under G.S. 90-88(d), the prescription drug shall be deemed to be designated, rescheduled, or deleted as a controlled substance in accordance with federal law and in compliance with this Chapter.

**§ 90-94.1. Exemption for use or possession of hemp extract.**

(a) As used in this section, "hemp extract" means an extract from a cannabis plant, or a mixture or preparation containing cannabis plant material, that has all of the following characteristics:

- (1) Is composed of less than nine-tenths of one percent (0.9%) tetrahydrocannabinol by weight.
- (2) Is composed of at least five percent (5%) cannabidiol by weight.
- (3) Contains no other psychoactive substance.

(b) Notwithstanding any other provision of this Chapter, an individual may possess or use hemp extract, and is not subject to the penalties described in this Chapter, if the individual satisfies all of the following criteria:

- (1) Possesses or uses the hemp extract only to treat intractable epilepsy, as defined in G.S. 90-113.101.
- (2) Possesses, in close proximity to the hemp extract, a certificate of analysis that indicates the hemp extract's ingredients, including its percentages of tetrahydrocannabinol and cannabidiol by weight.
- (3) Is a caregiver, as defined in G.S. 90-113.101.

(c) Notwithstanding any other provision of this Chapter, an individual who possesses hemp extract lawfully under this section may administer hemp extract to another person under the individual's care and is not subject to the penalties described in this Chapter for administering the hemp extract to the person if the individual is the person's caregiver, as defined in G.S. 90-113.101.

(d) Any individual who possesses or uses hemp extract, as defined under this section, shall dispose of all residual oil from the extract at a secure collection box managed by a law enforcement agency. No criminal penalty shall attach for any violation of this subsection.

**§ 90-95. Violations; penalties.**

(a) Except as authorized by this Article, it is unlawful for any person:

- (1) To manufacture, sell or deliver, or possess with intent to manufacture, sell or deliver, a controlled substance;
- (2) To create, sell or deliver, or possess with intent to sell or deliver, a counterfeit controlled substance;
- (3) To possess a controlled substance.

...

(d1) (1) Except as authorized by this Article, it is unlawful for any person to:

- a. Possess an immediate precursor chemical with intent to manufacture a controlled substance; or
- b. Possess or distribute an immediate precursor chemical knowing, or having reasonable cause to believe, that the immediate precursor chemical will be used to manufacture a controlled substance; or
- c. Possess a pseudoephedrine product if the person has a prior conviction for the possession of methamphetamine, possession with the intent to sell or deliver methamphetamine, sell or deliver methamphetamine, trafficking methamphetamine, possession of an immediate precursor chemical, or manufacture of methamphetamine. The prior conviction may be from any jurisdiction within the United States.



Except where the conduct is covered under subdivision (2) of this subsection, any person who violates this subdivision shall be punished as a Class H felon.

- (2) Except as authorized by this Article, it is unlawful for any person to:
- a. Possess an immediate precursor chemical with intent to manufacture methamphetamine; or
  - b. Possess or distribute an immediate precursor chemical knowing, or having reasonable cause to believe, that the immediate precursor chemical will be used to manufacture methamphetamine.

Any person who violates this subdivision shall be punished as a Class F felon.

(d2) The immediate precursor chemicals to which subsection (d1) of this section applies are those immediate precursor chemicals designated by the Commission pursuant to its authority under G.S. 90-88, and the following (until otherwise specified by the Commission):

- (1) Acetic anhydride.
- (2) Acetone.
- (2a) Ammonium nitrate.
- (2b) Ammonium sulfate.
- (3) Anhydrous ammonia.
- (4) Anthranilic acid.
- (5) Benzyl chloride.
- (6) Benzyl cyanide.
- (7) 2-Butanone (Methyl Ethyl Ketone).
- (8) Chloroephedrine.
- (9) Chlorpseudoephedrine.
- (10) D-lysergic acid.
- (11) Ephedrine.
- (12) Ergonovine maleate.
- (13) Ergotamine tartrate.
- (13a) Ether based starting fluids.
- (14) Ethyl ether.
- (15) Ethyl Malonate.
- (16) Ethylamine.
- (17) Gamma-butyrolactone.
- (18) Hydrochloric Acid. (Muriatic Acid).
- (19) Iodine.
- (20) Isosafrole.
- (21) Sources of lithium metal.
- (22) Malonic acid.
- (23) Methylamine.
- (24) Methyl Isobutyl Ketone.
- (25) N-acetylanthranilic acid.
- (26) N-ethylephedrine.
- (27) N-ethylepseudoephedrine.
- (28) N-methylephedrine.
- (29) N-methylpseudoephedrine.
- (29a) N-phenethyl-4-piperidinone (NPP).
- (30) Norpseudoephedrine.
- (30a) Petroleum based organic solvents such as camping fuels and lighter fluids.
- (31) Phenyl-2-propanone.
- (32) Phenylacetic acid.
- (33) Phenylpropanolamine.
- (34) Piperidine.
- (35) Piperonal.
- (36) Propionic anhydride.
- (37) Pseudoephedrine.
- (38) Pyrrolidine.
- (39) Red phosphorous.

- (40) Safrole.
- (40a) Sodium hydroxide (Lye).
- (41) Sources of sodium metal.
- (42) Sulfuric Acid.
- (43) Tetrachloroethylene.
- (44) Thionylchloride.
- (45) Toluene.
- ...

\* \* \* \* \*

**§ 90-95.2. Cooperation between law-enforcement agencies.**

(a) The head of any law-enforcement agency may temporarily provide assistance to another agency in enforcing the provisions of this Article if so requested in writing by the head of the other agency. The assistance may comprise allowing officers of the agency to work temporarily with officers of the other agency (including in an undercover capacity) and lending equipment and supplies. While working with another agency under the authority of this section, an officer shall have the same jurisdiction, powers, rights, privileges, and immunities (including those relating to the defense of civil actions and payment of judgments) as the officers of the requesting agency in addition to those he normally possesses. While on duty with the other agency, he shall be subject to the lawful operational commands of his superior officers in the other agency, but he shall for personnel and administrative purposes remain under the control of his own agency, including for purposes of pay. He shall furthermore be entitled to workers' compensation when acting pursuant to this section to the same extent as though he were functioning within the normal scope of his duties.

(b) As used in this section:

- (1) "Head" means any director or chief officer of a law-enforcement agency, including the chief of police of a local police department and the sheriff of a county, or an officer of the agency to whom the head of the agency has delegated authority to make or grant requests under this section, but only one officer in the agency shall have this delegated authority at any time.
- (2) "Law-enforcement agency" means any State or local agency, force, department, or unit responsible for enforcing criminal laws in this State, including any local police department or sheriff's office.

(c) This section in no way reduces the jurisdiction or authority of State law-enforcement officers.

\* \* \* \* \*

**§ 90-98. Attempt and conspiracy; penalties.**

Except as otherwise provided in this Article, any person who attempts or conspires to commit any offense defined in this Article is guilty of an offense that is the same class as the offense which was the object of the attempt or conspiracy and is punishable as specified for that class of offense and prior record or conviction level in Article 81B of Chapter 15A of the General Statutes.

**§ 90-99. Republishing of schedules.**

The North Carolina Department of Health and Human Services shall update and republish the schedules established by this Article on a semiannual basis for two years from January 1, 1972, and thereafter on an annual basis.

**§ 90-100. Rules.**

The Commission may adopt rules relating to the registration and control of the manufacture, distribution, security, and dispensing of controlled substances within this State.

**§ 90-101. Annual registration and fee to engage in listed activities with controlled substances; effect of registration; exceptions; waiver; inspection.**

(a) Every person who manufactures, distributes, dispenses, or conducts research with any controlled substance within this State or who proposes to engage in any of these activities shall annually register with the North Carolina Department of Health and Human Services, in accordance with rules adopted by the Commission, and shall

pay the registration fee set by the Commission for the category to which the applicant belongs. An applicant for registration shall file an application for registration with the Department of Health and Human Services and submit the required fee with the application. The categories of applicants and the maximum fee for each category are as follows:

<u>CATEGORY</u> .....	<u>MAXIMUM FEE</u>
Clinic.....	\$150.00
Animal Shelter .....	150.00
Hospital.....	350.00
Nursing Home .....	150.00
Teaching Institution .....	150.00
Researcher.....	150.00
Analytical Laboratory .....	150.00
Dog Handler.....	150.00
Distributor.....	600.00
Manufacturer.....	700.00

...

(b) Persons registered by the North Carolina Department of Health and Human Services under this Article (including research facilities) to manufacture, distribute, dispense or conduct research with controlled substances may possess, manufacture, distribute, dispense or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this Article.

(c) The following persons shall not be required to register and may lawfully possess controlled substances under the provisions of this Article:

- (1) An agent, or an employee thereof, of any registered manufacturer, distributor, or dispenser of any controlled substance if such agent is acting in the usual course of his business or employment;
  - (2) The State courier service operated by the Department of Administration, a common or contract carrier, or a public warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of his business or employment;
  - (3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner;
- ...
- (5) Any law-enforcement officer acting within the course and scope of official duties, or any person employed in an official capacity by, or acting as an agent of, any law-enforcement agency or other agency charged with enforcing the provisions of this Article when acting within the course and scope of official duties; and
  - (6) A practitioner, as defined in G.S. 90-87(22)a., who is required to be licensed in North Carolina by his respective licensing board.

(d) The Commission may, by rule, waive the requirement for registration of certain classes of manufacturers, distributors, or dispensers if it finds it consistent with the public health and safety.

(e) A separate registration shall be required at each principal place of business, research or professional practice where the registrant manufactures, distributes, dispenses or uses controlled substances.

(f) The North Carolina Department of Health and Human Services is authorized to inspect the establishment of a registrant, applicant for registration, or practitioner in accordance with rules adopted by the Commission.

(g) Practitioners licensed in North Carolina by their respective licensing boards may possess, dispense or administer controlled substances to the extent authorized by law and by their boards.

...

**§ 90-102. Additional provisions as to registration.**

(a) The North Carolina Department of Health and Human Services shall register an applicant to manufacture or distribute controlled substances included in Schedules I through VI of this Article unless it determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) Maintenance of effective controls against diversion of any controlled substances and any substance compounded therefrom into other than legitimate medical, scientific, or industrial channels;

- (2) Compliance with applicable federal, State and local law;
  - (3) Prior conviction record of applicant, its agents or employees under federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
  - (4) Past experience in the manufacture of controlled substances, and the existence in the establishment or facility of effective controls against diversion; and
  - (5) Any factor relating to revocation, suspension, or denial of past registrations, licenses, or applications under this or any other State or federal law;
  - (6) Such other factors as may be relevant to and consistent with the public health and safety.
- (b) Registration granted under subsection (a) of this section shall not entitle a registrant to manufacture and distribute controlled substances included in Schedule I or II other than those specified in the registration.
- (c) Individual practitioners licensed to dispense and authorized to conduct research under federal law with Schedules II through V substances must be registered with the North Carolina Department of Health and Human Services to conduct such research.
- (d) Manufacturers and distributors registered or licensed under federal law to manufacture or distribute controlled substances included in Schedules I through VI of this Article are entitled to registration under this Article, but this registration is expressly made subject to the provisions of G.S. 90-103.
- (e) The North Carolina Department of Health and Human Services shall initially permit persons to register who own or operate any establishment engaged in the manufacture, distribution, or dispensing of any substances prior to January 1, 1972, and who are registered or licensed by the State.

\* \* \* \* \*

**§ 90-103. Revocation or suspension of registration.**

- (a) A registration under G.S. 90-102 to manufacture, distribute, or dispense a controlled substance, may be suspended or revoked by the Commission upon a finding that the registrant:
- (1) Has furnished false or fraudulent material information in any application filed under this Article;
  - (2) Has been convicted of a felony under any State or federal law relating to any controlled substance; or
  - (3) Has had his federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances.
- (b) The Commission may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.
- (c) Before denying, suspending, or revoking a registration or refusing a renewal of registration, the Commission shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended, or why the renewal should not be refused. The order to show cause shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before the Commission at a time and place not less than 30 days after the date of service of the order, but in the case of a denial or renewal of registration, the show cause order shall be served not later than 30 days before the expiration of the registration. These proceedings shall be conducted in accordance with rules and regulations of the Commission required by Chapter 150B of the General Statutes, and subject to judicial review as provided in Chapter 150B of the General Statutes. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this Article or any law of the State.
- (d) The Commission may suspend, without an order to show cause, any registration simultaneously with the institutions of proceedings under this section, or where renewal of registration is refused if it finds that there is an imminent danger to the public health or safety which warrants this action. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, unless sooner withdrawn by the Commission or dissolved by a court of competent jurisdiction.
- (e) In the event the Commission suspends or revokes a registration granted under G.S. 90-102, all controlled substances owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may in the discretion of the Commission be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances may be ordered forfeited to the State.
- (f) The Bureau shall promptly be notified of all orders suspending or revoking registration.

**§ 90-104. Records of registrants or practitioners.**

Each registrant or practitioner manufacturing, distributing, or dispensing controlled substances under this Article shall keep records and maintain inventories in conformance with the record-keeping and the inventory requirements of the federal law and shall conform to such rules and regulations as may be promulgated by the Commission.

**§ 90-105. Order forms.**

Controlled substances included in Schedules I and II of this Article shall be distributed only by a registrant or practitioner, pursuant to an order form. Compliance with the provisions of the Federal Controlled Substances Act or its successor respecting order forms shall be deemed compliance with this section.

**§ 90-106. Prescriptions and labeling.**

(a) Definitions. – As used in this section, the following terms have the following meanings:

- (1) Acute pain. – Pain, whether resulting from disease, accident, intentional trauma, or other cause, that the practitioner reasonably expects to last for three months or less. The term does not include chronic pain or pain being treated as part of cancer care, hospice care, palliative care, or medication-assisted treatment for a substance use disorder. The term does not include pain being treated as part of cancer care, hospice care, or palliative care provided by a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes.
- (2) Chronic pain. – Pain that typically lasts for longer than three months or that lasts beyond the time of normal tissue healing.
- (3) Surgical procedure. – A procedure that is performed for the purpose of structurally altering the human body by incision or destruction of tissues as part of the practice of medicine or a procedure that is performed for the purpose of structurally altering the animal body by incision or destruction of tissues as part of the practice of veterinary medicine. This term includes the diagnostic or therapeutic treatment of conditions or disease processes by use of instruments such as lasers, ultrasound, ionizing radiation, scalpels, probes, or needles that cause localized alteration or transportation of live human tissue, or live animal tissue in the practice of veterinary medicine, by cutting, burning, vaporizing, freezing, suturing, probing, or manipulating by closed reduction for major dislocations and fractures, or otherwise altering by any mechanical, thermal, light-based, electromagnetic, or chemical means.

(a1) Electronic Prescription Required; Exceptions. – Unless otherwise exempted by this subsection, a practitioner shall electronically prescribe all targeted controlled substances and all controlled substances included in G.S. 90-93(a)(1)a. This subsection does not apply to any product that is sold at retail without a prescription by a pharmacist under G.S. 90-93(b) through (d). This subsection does not apply to prescriptions for targeted controlled substances or any controlled substances included in G.S. 90-93(a)(1)a. issued by any of the following:

- (1) A practitioner, other than a pharmacist, who dispenses directly to an ultimate user.
- (2) A practitioner who orders a controlled substance to be administered in a hospital, nursing home, hospice facility, outpatient dialysis facility, or residential care facility, as defined in G.S. 14-32.2(i).
- (3) A practitioner who experiences temporary technological or electrical failure or other extenuating circumstance that prevents the prescription from being transmitted electronically. The practitioner, however, shall document the reason for this exception in the patient's medical record.
- (4) A practitioner who writes a prescription to be dispensed by a pharmacy located on federal property. The practitioner, however, shall document the reason for this exception in the patient's medical record.
- (5) A person licensed to practice veterinary medicine pursuant to Article 11 of this Chapter. A person licensed to practice veterinary medicine pursuant to Article 11 this Chapter may continue to prescribe targeted controlled substances from valid written, oral, or facsimile prescriptions that are otherwise consistent with applicable laws.

(a2) Verification by Dispenser Not Required. – A dispenser is not required to verify that a practitioner properly falls under one of the exceptions specified in subsection (a1) of this section prior to dispensing a targeted controlled substance or a controlled substance included in G.S. 90-93(a)(1)a. A dispenser may continue to dispense

targeted controlled substances and controlled substances included in G.S. 90-93(a)(1)a. from valid written, oral, or facsimile prescriptions that are otherwise consistent with applicable laws.

(a3) **Limitation on Prescriptions Upon Initial Consultation for Acute Pain.** – A practitioner may not prescribe more than a five-day supply of any targeted controlled substance upon the initial consultation and treatment of a patient for acute pain, unless the prescription is for post-operative acute pain relief for use immediately following a surgical procedure. A practitioner shall not prescribe more than a seven-day supply of any targeted controlled substance for post-operative acute pain relief immediately following a surgical procedure. Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill, or new prescription for a targeted controlled substance. This subsection does not apply to prescriptions for controlled substances issued by a practitioner who orders a controlled substance to be wholly administered in a hospital, nursing home licensed under Chapter 131E of the General Statutes, hospice facility, or residential care facility, as defined in G.S. 14-32.2(i). This subsection does not apply to prescriptions for controlled substances issued by a practitioner who orders a controlled substance to be wholly administered in an emergency facility, veterinary hospital, or animal hospital, as defined in G.S. 90-181.1. A practitioner who acts in accordance with the limitation on prescriptions as set forth in this subsection is immune from any civil liability or disciplinary action from the practitioner's occupational licensing agency for acting in accordance with this subsection.

(a4) **Repealed by Session Laws 2019-76, s. 12.(b), effective October 1, 2020, and applicable to services rendered on or after that date.**

(a5) **Dispenser Immunity.** – A dispenser is immune from any civil or criminal liability or disciplinary action from the Board of Pharmacy for dispensing a prescription written by a prescriber in violation of this section.

(b) **Dispensing of Schedule II Controlled Substances.** – No Schedule II substance shall be dispensed pursuant to a written or electronic prescription more than six months after the date it was prescribed. In emergency situations, as defined by rule of the Commission, Schedule II controlled substances may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed by the dispensing agent. Prescriptions shall be retained in conformity with the requirements of G.S. 90-104. No prescription for a Schedule II substance may be refilled.

(c) **Dispensing of Schedule III and IV Controlled Substances.** – Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance included in Schedules III or IV, except paregoric, U.S.P., as provided in G.S. 90-91(e)1., shall be dispensed without a prescription, and oral prescriptions shall be promptly reduced to writing and filed with the dispensing agent. The prescription shall not be filled or refilled more than six months after the date of the prescription or be refilled more than five times after the date of the prescription.

(d) **Dispensing of Schedule V Controlled Substances.** – No controlled substance included in Schedule V of this Article or paregoric, U.S.P., shall be distributed or dispensed other than for a medical purpose.

(e) **Dispensing of Schedule VI Controlled Substance.** – No controlled substance included in Schedule VI of this Article shall be distributed or dispensed other than for scientific or research purposes by persons registered under, or permitted by, this Article to engage in scientific or research projects.

(f) **Labeling Requirements.** – No controlled substance shall be dispensed or distributed in this State unless the substance is in a container clearly labeled in accord with regulations lawfully adopted and published by the federal government or the Commission.

(g) **Copies.** – When a copy of a prescription for a controlled substance under this Article is given as required by G.S. 90-70, the copy shall be plainly marked: "Copy – for information only." Copies of prescriptions for controlled substances shall not be filled or refilled.

(h) **Fill Date.** – A pharmacist dispensing a controlled substance under this Article shall enter the date of dispensing on the prescription order pursuant to which the controlled substance was dispensed.

(i) **Distribution of Complimentary Samples.** – A manufacturer's sales representative may distribute a controlled substance as a complimentary sample only upon the written request of a practitioner. The request must be made on each distribution and must contain the names and addresses of the supplier and the requester and the name and quantity of the specific controlled substance requested. The manufacturer shall maintain a record of each request for a period of two years.

#### **§ 90-106.1. Photo ID requirement for Schedule II controlled substances.**

(a) Immediately prior to dispensing a Schedule II controlled substance, or any of the Schedule III controlled substances listed in subdivisions 1. through 8. of G.S. 90-91(d), each pharmacy holding a valid permit pursuant to G.S. 90-85.21 shall require the person seeking the dispensation to present one of the following valid, unexpired forms of government-issued photographic identification: (i) a drivers license, (ii) a special identification card issued under

G.S. 20-37.7, (iii) a military identification card, or (iv) a passport. Upon presentation of the required photographic identification, the pharmacy shall document the name of the person seeking the dispensation, the type of photographic identification presented by the person seeking the dispensation, and the photographic identification number. The pharmacy shall retain this identifying information on the premises or at a central location apart from the premises as part of its business records for a period of three years following dispensation.

(b) The pharmacy shall make the identifying information available to any person authorized under G.S. 90-113.74 to receive prescription information data in the controlled substances reporting system within 72 hours after a request for the identifying information. A pharmacy that submits the identifying information required under this section to the controlled substances reporting system established and maintained pursuant to G.S. 90-113.73 is deemed in compliance with this subsection.

(c) Nothing in this section shall be deemed to require that the person seeking the dispensation and the person to whom the prescription is issued be the same person, and nothing in this section shall apply to the dispensation of controlled substances to employees of "health care facilities", as that term is defined in G.S. 131E-256(b), when the controlled substances are delivered to the health care facilities for the benefit of residents or patients of such health care facilities.

### **§ 90-106.3. Disposal of residual pain prescriptions following death of hospice or palliative care patient.**

Any hospice or palliative care provider who prescribes a targeted controlled substance to be administered to a patient in his or her home for the treatment of pain as part of in-home hospice or palliative care shall, at the commencement of treatment, provide oral and written information to the patient and his or her family regarding the proper disposal of such targeted controlled substances. This information shall include the availability of permanent drop boxes or periodic "drug take-back" events that allow for the safe disposal of controlled substances such as those permanent drop boxes and events that may be identified through North Carolina Operation Medicine Drop.

### **§ 90-107. Prescriptions, stocks, etc., open to inspection by officials.**

Prescriptions, order forms and records, required by this Article, and stocks of controlled substances included in Schedules I through VI of this Article shall be open for inspection only to federal and State officers, whose duty it is to enforce the laws of this State or of the United States relating to controlled substances included in Schedules I through VI of this Article, and to authorized employees of the North Carolina Department of Health and Human Services. No officer having knowledge by virtue of his office of any such prescription, order, or record shall divulge such knowledge other than to other law-enforcement officials or agencies, except in connection with a prosecution or proceeding in court or before a licensing board or officer to which prosecution or proceeding the person to whom such prescriptions, orders, or records relate is a party.

### **§ 90-107.1. Certified diversion investigator access to prescription records.**

(a) A certified diversion investigator associated with a qualified law enforcement agency, as those terms are defined in G.S. 90-113.74(i), shall request and receive from a pharmacy copies of prescriptions and records related to prescriptions in connection with a bona fide active investigation related to the enforcement of laws governing licit or illicit drugs by providing in writing or electronically all of the following:

- (1) The certified diversion investigator's name and certification number.
- (2) The name of the qualified law enforcement agency for whom the investigator works.
- (3) The case number associated with the request.
- (4) A description of the nature and purpose of the request.
- (5) The first name, last name, and date of birth of each individual whose prescription and records related to the prescription the investigator seeks, including, when appropriate, any alternative name, spelling, or date of birth associated with each such individual.

(b) When a certified diversion investigator transmits such a request to a pharmacy, the certified diversion investigator shall also transmit a copy of the request to the North Carolina State Bureau of Investigation, Diversion and Environmental Crimes Unit. The North Carolina State Bureau of Investigation shall conduct periodic audits of a random sample of these requests.

(c) A pharmacy shall provide copies of requested prescriptions and records related to prescriptions as soon as practicable and no later than two business days after receipt of the request from the certified diversion investigator.

(d) No certified diversion investigator having knowledge by virtue of his office of any such prescription or record related to prescriptions shall divulge such knowledge other than to other law enforcement officials or agencies involved in the bona fide active investigation, except in connection with a prosecution or proceeding in court or

before a licensing board or officer to which prosecution or proceeding the person to whom such prescriptions, orders, or records relate is a party, or as provided in G.S. 90-113.74 (i)(4), or as otherwise allowed by law.

(e) A pharmacy or pharmacist that in good faith complies with this section and provides copies of prescriptions and records related to prescriptions to a certified diversion investigator shall have no liability for improper use of information divulged to the certified diversion investigator.

**§ 90-108. Prohibited acts; penalties.**

- (a) It shall be unlawful for any person:
- (1) Other than practitioners licensed under Articles 1, 2, 4, 6, 11, 12A of this Chapter to represent to any registrant or practitioner who manufactures, distributes, or dispenses a controlled substance under the provision of this Article that he or she is a licensed practitioner in order to secure or attempt to secure any controlled substance as defined in this Article or to in any way impersonate a practitioner for the purpose of securing or attempting to secure any drug requiring a prescription from a practitioner as listed above and who is licensed by this State.
  - (2) Who is subject to the requirements of G.S. 90-101 or a practitioner to distribute or dispense a controlled substance in violation of G.S. 90-105 or 90-106.
  - (3) Who is a registrant to manufacture, distribute, or dispense a controlled substance not authorized by his or her registration to another registrant or other authorized person.
  - (4) To omit, remove, alter, or obliterate a symbol required by the Federal Controlled Substances Act or its successor.
  - (5) To refuse or fail to make, keep, or furnish any record, notification, order form, statement, invoice or information required under this Article.
  - (6) To refuse any entry into any premises or inspection authorized by this Article.
  - (7) To knowingly keep or maintain any store, shop, warehouse, dwelling house, building, vehicle, boat, aircraft, or any place whatever, which is resorted to by persons using controlled substances in violation of this Article for the purpose of using such substances, or which is used for the keeping or selling of the same in violation of this Article.
  - (8) Who is a registrant or a practitioner to distribute a controlled substance included in Schedule I or II of this Article in the course of his or her legitimate business, except pursuant to an order form as required by G.S. 90-105.
  - (9) To use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person.
  - (10) To acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.
  - (11) To furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this Article, or any record required to be kept by this Article.
  - (12) To do either of the following:
    - a. To possess, manufacture, distribute, export, or import any three-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material which may be used to create a counterfeit controlled substance, knowing, intending, or having reasonable cause to believe that it will be used to create a counterfeit controlled substance.
    - b. To make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit substance, knowing, intending, or having reasonable cause to believe that it will be used to create a counterfeit controlled substance.
  - (12a) To possess, manufacture, distribute, export, or import any three-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material which may be used to manufacture a controlled substance or listed chemical, knowing, intending, or having reasonable cause to believe that it will be used to manufacture a controlled substance. This subdivision shall not apply to a pharmacy, a pharmacist, a pharmacy technician, or a pharmacy intern licensed or permitted under Article 4A of Chapter 90 of the General Statutes possessing any item included in this subdivision



utilized in the compounding, dispensing, delivering, or administering of a controlled substance pursuant to a prescription.

- (13) To obtain controlled substances through the use of legal prescriptions which have been obtained by the knowing and willful misrepresentation to or by the intentional withholding of information from one or more practitioners.
- (14) Who is a registrant or practitioner or an employee of a registrant or practitioner and who is authorized to possess controlled substances or has access to controlled substances by virtue of employment, to embezzle or fraudulently or knowingly and willfully misapply or divert to his or her own use or other unauthorized or illegal use or to take, make away with or secrete, with intent to embezzle or fraudulently or knowingly and willfully misapply or divert to his or her own use or other unauthorized or illegal use any controlled substance which shall have come into his or her possession or under his or her care.
- (15) Who is not a registrant or practitioner nor an employee of a registrant or practitioner and who, by virtue of his or her occupation or profession, administers or provides medical care, aid, emergency treatment, or any combination of these to a person who is prescribed a controlled substance, to embezzle or fraudulently or knowingly and willfully misapply or divert to his or her own use or other unauthorized or illegal use or to take, make away with, or secrete, with intent to embezzle or fraudulently or knowingly and willfully misapply or divert to his or her own use or other unauthorized or illegal use any controlled substance that is prescribed to another.

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**§ 90-110. Injunctions.**

(a) The superior court of North Carolina shall have jurisdiction in proceedings in accordance with the rules of those courts to enjoin violations of this Article.

(b) In case of an alleged violation of an injunction or restraining order issued under this section, trial shall, upon demand of the accused, be by a jury in accordance with the rules of the superior courts of North Carolina.

**§ 90-111. Cooperative arrangements.**

The North Carolina Department of Health and Human Services and the Attorney General of North Carolina shall cooperate with federal and other State agencies in discharging their responsibilities concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, they are authorized to:

- (1) Arrange for the exchange of information between governmental officials concerning the use and abuse of controlled substances;
- (2) Coordinate and cooperate in training programs on controlled substances for law enforcement at the local and State levels;
- (3) Cooperate with the Bureau by establishing a centralized unit which will accept, catalogue, file, and collect statistics, including records of drug-dependent persons and other controlled substance law offenders within the State, and make such information available for federal, State, and local law-enforcement purposes. Provided that neither the Attorney General of North Carolina, the North Carolina Department of Health and Human Services nor any other State officer or agency shall be authorized to accept or file, or give out the names or other form of personal identification of drug-dependent persons who voluntarily seek treatment or assistance related to their drug dependency.

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**§ 90-113.1. Burden of proof; liabilities.**

(a) It shall not be necessary for the State to negate any exemption or exception set forth in this Article in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this Article, and the burden of proof of any such exemption or exception shall be upon the person claiming its benefit.

(b) In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this Article, he shall be presumed not to be the holder of such registration or form, and the burden of proof shall be upon him to rebut such presumption.

(c) No liability shall be imposed by virtue of this Article upon any duly authorized officer, engaged in the lawful enforcement of this Article.

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**§ 90-113.5. State Board of Pharmacy, State Bureau of Investigation and peace officers to enforce Article.**

It is hereby made the duty of the State Board of Pharmacy, its officers, agents, inspectors, and representatives, and all peace officers within the State, including agents of the State Bureau of Investigation, and all State's attorneys, to enforce all provisions of this Article, except those specifically delegated, and to cooperate with all agencies charged with the enforcement of the laws of the United States, of this State, and of all other states, relating to controlled substances. The State Bureau of Investigation is hereby authorized to make initial investigation of all violations of this Article, and is given original but not exclusive jurisdiction in respect thereto with all other law-enforcement officers of the State.

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**Article 5B.  
Drug Paraphernalia.**

*Selected Provisions*

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**§ 90-113.27. Needle and hypodermic syringe exchange programs authorized; limited immunity.**

(a) Any governmental or nongovernmental organization, including a local or district health department or an organization that promotes scientifically proven ways of mitigating health risks associated with drug use and other high-risk behaviors, may establish and operate a needle and hypodermic syringe exchange program. The objectives of the program shall be to do all of the following:

- (1) Reduce the spread of HIV, AIDS, viral hepatitis, and other bloodborne diseases in this State.
- (2) Reduce needle stick injuries to law enforcement officers and other emergency personnel.
- (3) Encourage individuals who use drugs illicitly to enroll in evidence-based treatment.
- (4) Reduce the number of drug overdoses in this State.

(b) Programs established pursuant to this section shall offer all of the following:

- (1) Disposal of used needles and hypodermic syringes.
- (2) Needles, hypodermic syringes, and other injection supplies at no cost and in quantities sufficient to ensure that needles, hypodermic syringes, and other injection supplies are not shared or reused.
- (3) Reasonable and adequate security of program sites, equipment, and personnel. Written plans for security shall be provided to the police and sheriff's offices with jurisdiction in the program location and shall be updated annually.
- (4) Educational materials on all of the following:
  - a. Overdose prevention.
  - b. The prevention of HIV, AIDS, and viral hepatitis transmission.
  - c. Drug abuse prevention.
  - d. Treatment for mental illness, including treatment referrals.
  - e. Treatment for substance abuse, including referrals for medication assisted treatment.
- (5) Access to opioid antagonist kits that contain an opioid antagonist that is approved by the federal Food and Drug Administration for the treatment of a drug overdose, or referrals to programs that provide access to an opioid antagonist that is approved by the federal Food and Drug Administration for the treatment of a drug overdose.
- (6) For each individual requesting services, personal consultations from a program employee or volunteer concerning mental health or addiction treatment as appropriate.

(c) Notwithstanding any provision of the Controlled Substances Act in Article 5 of Chapter 90 of the General Statutes or any other law, no employee, volunteer, or participant of a program established pursuant to this section shall be charged with or prosecuted for possession of any of the following:

- (1) Needles, hypodermic syringes, or other injection supplies obtained from or returned to a program established pursuant to this section.
- (2) Residual amounts of a controlled substance contained in a used needle, used hypodermic syringe, or used injection supplies obtained from or returned to a program established pursuant to this section.

The limited immunity provided in this subsection shall apply only if the person claiming immunity provides written verification that a needle, syringe, or other injection supplies were obtained from a needle and hypodermic syringe exchange program established pursuant to this section. In addition to any other applicable immunity or limitation on civil liability, a law enforcement officer who, acting on good faith, arrests or charges a person who is thereafter determined to be entitled to immunity from prosecution under this section shall not be subject to civil liability for the arrest or filing of charges.

(d) Prior to commencing operations of a program established pursuant to this section, the governmental or nongovernmental organization shall report to the North Carolina Department of Health and Human Services, Division of Public Health, all of the following information:

- (1) The legal name of the organization or agency operating the program.
- (2) The areas and populations to be served by the program.
- (3) The methods by which the program will meet the requirements of subsection (b) of this section.

(e) Not later than one year after commencing operations of a program established pursuant to this section, and every 12 months thereafter, each organization operating such a program shall report the following information to the North Carolina Department of Health and Human Services, Division of Public Health:

- (1) The number of individuals served by the program.
- (2) The number of needles, hypodermic syringes, and needle injection supplies dispensed by the program and returned to the program.
- (3) The number of opioid antagonist kits distributed by the program.
- (4) The number and type of treatment referrals provided to individuals served by the program, including a separate report of the number of individuals referred to programs that provide access to an opioid antagonist that is approved by the federal Food and Drug Administration for the treatment of a drug overdose.

#### **Article 5D.**

#### **Control of Methamphetamine Precursors.**

#### *Selected Provisions*

#### **§ 90-113.50. Title.**

This Article shall be known and may be cited as the "Methamphetamine Lab Prevention Act of 2005."

#### **§ 90-113.51. Definitions.**

- (a) For purposes of this Article, "pseudoephedrine product" means a product containing any detectable quantity of pseudoephedrine or ephedrine base, their salts or isomers, or salts of their isomers.
- (b) For purposes of this Article, a "retailer" means an individual or entity that is the general owner of an establishment where pseudoephedrine products are available for sale.
- (c) For purposes of this Article, the "Commission" means the Commission for Mental Health, Developmental Disabilities, and Substance Use Services.

#### **§ 90-113.52. Pseudoephedrine: restrictions on sales.**

- (a) A pseudoephedrine product in the form of a tablet, caplet, or gel cap shall not be offered for retail sale loose in bottles but shall be sold only in blister packages.
- (b) Pseudoephedrine products shall not be offered for retail sale by self-service, but shall be stored and sold in the following manner: Any pseudoephedrine product in the form of a tablet or caplet containing pseudoephedrine as the sole active ingredient or in combination with other active ingredients shall be stored and sold behind a pharmacy counter.
- (c) A pseudoephedrine product may be sold at retail without a prescription only to a person at least 18 years of age. The retailer shall require every retail purchaser of a pseudoephedrine product to furnish a valid, unexpired, government-issued photo identification and to provide, in print or orally, a current valid personal residential address. If the retailer has reasonable grounds to believe that the prospective purchaser is under 18 years of age, the retailer

shall require the prospective purchaser to furnish photo identification showing the date of birth of the person. The name and address of every purchaser shall be entered in a record of disposition of pseudoephedrine products to the consumer on a form approved by the Commission. The record of disposition shall also identify each pseudoephedrine product purchased, including the number of grams the product contains and the purchase date of the transaction. The retailer shall require that every purchaser sign the form attesting to the validity of the information. The form approved by the Commission shall be constructed so that it allows for entry of information in electronic format, including electronic signature. The form shall also be constructed and maintained so as to minimize disclosure of personal information to unauthorized persons.

(d) A retailer shall maintain a record of disposition of pseudoephedrine products to the consumer for a period of two years from the date of each transaction. A record shall be readily available within 48 hours of the time of the transaction for inspection by an authorized official of a federal, State, or local law enforcement agency. The records maintained by a retailer are privileged information and are not public records but are for the exclusive use of the retailer and law enforcement. The retailer may destroy the information after two years from the date of the transactions.

(e) This section does not apply to any pseudoephedrine product that is in the form of a liquid, liquid capsule, gel capsule, or pediatric product labeled pursuant to federal regulation primarily intended for administration to children under 12 years of age according to label instruction, except as to those specific products for which the Commission issues an order pursuant to G.S. 90-113.58 subjecting the product to requirements under this Article.

#### **§ 90-113.52A. Electronic record keeping.**

(a) A retailer shall, before completing a sale of a product containing a pseudoephedrine product, electronically submit the required information to the National Precursor Log Exchange (NPLEx) administered by the National Association of Drug Diversion Investigators (NADDI), provided that the NPLEx system is available to retailers in the State without a charge for accessing the system and the retailer has Internet access. The seller shall not complete the sale if the system generates a stop alert. Absent negligence, wantonness, recklessness, or deliberate misconduct, any retailer utilizing the electronic sales tracking system in accordance with this subsection shall not be civilly liable as a result of any act or omission in carrying out the duties required by this subsection and shall be immune from liability to any third party unless the retailer has violated any provision of this subsection in relation to a claim brought for such violation.

(b) If a pharmacy selling a product containing a pseudoephedrine product experiences mechanical or electronic failure of the electronic sales tracking system and is unable to comply with the electronic sales tracking requirement, the pharmacy or retail establishment shall record that the sale was made without submission to the NPLEx system in the record of disposition required under G.S. 90-113.52.

(c) The NADDI shall forward North Carolina transaction records in NPLEx to the State Bureau of Investigation weekly and provide real-time access to NPLEx information through the NPLEx online portal to law enforcement in the State as authorized by the SBI, provided that the SBI executes a memorandum of understanding with NADDI governing access.

(d) This system shall be capable of generating a stop sale alert, which shall be a notification that completion of the sale would result in the seller or purchaser violating the quantity limits set forth in G.S. 90-113.52. The system shall contain an override function that may be used by a dispenser of a pseudoephedrine product who has a reasonable fear of imminent bodily harm if the dispenser does not complete a sale. Each instance in which the override function is utilized shall be logged by the system.

#### **§ 90-113.53. Pseudoephedrine transaction limits.**

(a) No person shall deliver to any one person, attempt to deliver to any one person, purchase, or attempt to purchase at retail more than 3.6 grams of any pseudoephedrine products per calendar day. This limit does not apply if the product is dispensed under a valid prescription.

(b) No person shall purchase at retail more than 9 grams of pseudoephedrine products within any 30-day period. This limit does not apply if the product is dispensed under a valid prescription.

(c) This section does not apply to any pseudoephedrine products that are in the form of liquids, liquid capsules, gel capsules, or pediatric products labeled pursuant to federal regulation primarily intended for administration to children under 12 years of age according to label instruction, except as to those specific products for which the Commission issues an order pursuant to G.S. 90-113.58 subjecting the product to requirements under this Article.

**§ 90-113.54. Posting of signs.**

(a) A retailer shall post a sign or placard in a clear and conspicuous manner in the area of the premises where the pseudoephedrine products are offered for sale substantially similar to the following: "North Carolina law strictly prohibits the purchase of more than 3.6 grams total of certain products containing pseudoephedrine per day, and more than 9 grams total of certain products containing pseudoephedrine within a 30-day period. This store will maintain a record of all sales of these products which may be accessible to law enforcement officers.

(b) This section does not apply to any pseudoephedrine products that are in the form of liquids, liquid capsules, gel capsules, or pediatric products labeled pursuant to federal regulation primarily intended for administration to children under 12 years of age according to label instruction, except as to those specific products for which the Commission issues an order pursuant to G.S. 90-113.58 subjecting the product to requirements under this Article.

**§ 90-113.55. Training of employees.**

A retailer shall require that employees of the establishment involved in the sale of pseudoephedrine products in the form of tablets or caplets, and any other pseudoephedrine product for which the Commission issues an order pursuant to G.S. 90-113.58 to subject the product to requirements under this Article, be trained in a program conducted by or approved by the Commission pursuant to G.S. 90-113.59.

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**§ 90-113.57. Immunity.**

A retailer or an employee of the retailer who, reasonably and in good faith, reports to any law enforcement agency any alleged criminal activity related to the sale or purchase of pseudoephedrine products, or who refuses to sell a pseudoephedrine product to a person reasonably believed to be ineligible to purchase a pseudoephedrine product pursuant to this Article, is immune from civil liability for that conduct except in cases of willful misconduct. No retailer shall retaliate in any manner against any employee of the establishment for a report made in good faith to any law enforcement agency concerning alleged criminal activity related to the sale or purchase of pseudoephedrine products.

**§ 90-113.58. Commission authority to control pseudoephedrine products.**

(a) The Commission may add or delete a specific pseudoephedrine product from requirements of this Article on the petition of any interested party, or its own motion. In addition, the Commission may modify the specific storage, security, transaction limit, and record-keeping requirements applicable to a particular product upon such terms and conditions as they deem appropriate. In every case, the Commission shall give notice of and hold a public hearing pursuant to Chapter 150B of the General Statutes prior to adding or deleting a product. A petition by the Commission or the North Carolina Department of Justice to add or delete a specific product from requirements of this Article shall be placed on the agenda for consideration at the next regularly scheduled meeting of the Commission, as a matter of right. In making a determination regarding a specific product, the Commission shall consider whether or not there is substantial evidence that the specific product would be used to manufacture methamphetamine in the State.

(b) In making a determination, the Commission shall make findings with respect thereto and shall issue an order adding or deleting the specific product from requirements of this Article. The order shall be published in the North Carolina Register at least 60 days prior to the time that the addition or deletion of a specific product from the requirements of this Article becomes effective.

(c) The Commission may adopt temporary and permanent rules in accordance with this section.

**§ 90-113.59. Commission development of employee training programs.**

The Commission shall develop training and education programs targeted for employees of establishments where pseudoephedrine products are available for sale and shall approve such programs for implementation by retailers. The Commission may also conduct employee training programs for retail establishments. The Commission may adopt temporary and permanent rules in this regard.

**§ 90-113.60. Preemption.**

This Article shall preempt all local ordinances or regulations governing the sale by a retailer of over-the-counter products containing pseudoephedrine.

**§ 90-113.61. Regulation of pseudoephedrine products in the form of liquids, liquid capsules, gel capsules, and pediatric products.**

Except as to those specific products for which the Commission issues an order pursuant to G.S. 90-113.58 subjecting the product to requirements under this Article, any pseudoephedrine products that are in the form of liquids, liquid capsules, gel capsules, or pediatric products labeled pursuant to federal regulation primarily intended for administration to children under 12 years of age according to label instruction shall not be subject to requirements under this Article, but such products shall be subject to the requirements of the Combat Methamphetamine Act of 2005, Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177.

**§ 90-113.64. SBI annual report.**

Beginning with the 2011 calendar year, the State Bureau of Investigation shall determine the number of methamphetamine laboratories discovered in the State each calendar year and report its findings to the Joint Legislative Oversight Committee on Justice and Public Safety by March 1, 2012, for the 2011 calendar year and each March 1 thereafter for the preceding calendar year. The State Bureau of Investigation shall participate in the High Intensity Drug Trafficking Areas (HIDTA) program, assist in coordinating the drug control efforts between local and State law enforcement agencies, and monitor the implementation and effectiveness of the electronic record-keeping requirements included in G.S. 90-113.52A and G.S. 90-113.56. The SBI shall include its findings in the report to the Commission required by this section.

**Article 5E.**

**North Carolina Controlled Substances Reporting System Act.**

**§ 90-113.70. Short title.**

This Article shall be known and may be cited as the "North Carolina Controlled Substances Reporting System Act."

**§ 90-113.71. Legislative findings and purpose.**

- (a) The General Assembly makes the following findings:
- (1) North Carolina is experiencing an epidemic of poisoning deaths from unintentional drug overdoses.
  - (2) Since 1997, the number of deaths from unintentional drug overdoses has increased threefold, from 228 deaths in 1997 to 690 deaths in 2003.
  - (3) The number of unintentional deaths from illicit drugs in North Carolina has decreased since 1992 while unintentional deaths from licit drugs, primarily prescriptions, have increased.
  - (4) Licit drugs are now responsible for over half of the fatal unintentional poisonings in North Carolina.
  - (5) Over half of the prescription drugs associated with unintentional deaths are narcotics (opioids).
  - (6) Of these licit drugs, deaths from methadone, usually prescribed as an analgesic for severe pain, have increased sevenfold since 1997.
  - (7) Methadone from opioid treatment program clinics is a negligible source of the methadone that has contributed to the dramatic increase in unintentional methadone-related deaths in North Carolina.
  - (8) Review of the experience of the 19 states that have active controlled substances reporting systems clearly documents that implementation of these reporting systems do not create a "chilling" effect on prescribing.
  - (9) Review of data from controlled substances reporting systems help:
    - a. Support the legitimate medical use of controlled substances.
    - b. Identify and prevent diversion of prescribed controlled substances.
    - c. Reduce morbidity and mortality from unintentional drug overdoses.
    - d. Reduce the costs associated with the misuse and abuse of controlled substances.
    - e. Assist clinicians in identifying and referring for treatment patients misusing controlled substances.
    - f. Reduce the cost for law enforcement of investigating cases of diversion and misuse.
    - g. Inform the public, including health care professionals, of the use and abuse trends related to prescription drugs.

(b) This Article is intended to improve the State's ability to identify controlled substance abusers or misusers and refer them for treatment, and to identify and stop diversion of prescription drugs in an efficient and cost-effective manner that will not impede the appropriate medical utilization of licit controlled substances.

**§ 90-113.72. Definitions.**

The following definitions apply in this Article:

- (1) Commission. – The Commission for Mental Health, Developmental Disabilities, and Substance Use Services established under Part 4 of Article 3 of Chapter 143B of the General Statutes.
- (2) Controlled substance. – A controlled substance as defined in G.S. 90-87(5).
- (3) Department. – The Department of Health and Human Services.
- (4) Dispenser. – A person who delivers a Schedule II through V controlled substance to an ultimate user in North Carolina, but does not include any of the following:
  - a. A licensed hospital or long-term care pharmacy that dispenses such substances for the purpose of inpatient administration.
  - b. Repealed by Session Laws 2013-152, s. 1, effective January 1, 2014, and applicable to prescriptions delivered on or after that date.
  - c. A wholesale distributor of a Schedule II through V controlled substance.
  - d. A person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes.
- (4a) Pharmacy. – A person or entity holding a valid pharmacy permit pursuant to G.S. 90-85.21 or G.S. 90-85.21A.
- (5) Ultimate user. – A person who has lawfully obtained, and who possesses, a Schedule II through V controlled substance for the person's own use, for the use of a member of the person's household, or for the use of an animal owned or controlled by the person or by a member of the person's household.

**§ 90-113.73. Requirements for controlled substances reporting system; civil penalties for failure to properly report. [Version effective until March 1, 2024]**

(a) The Department shall establish and maintain a reporting system of prescriptions for all Schedule II through V controlled substances. Each dispenser shall submit the information in accordance with transmission methods and frequency established by rule by the Commission. The Department may issue a waiver to a dispenser who is unable to submit prescription information by electronic means. The waiver may permit the dispenser to submit prescription information by paper form or other means, provided all information required of electronically submitted data is submitted. The dispenser shall report the information required under this section no later than the close of the next business day after the prescription is delivered; however, dispensers are encouraged to report the information no later than 24 hours after the prescription was delivered. The information shall be submitted in a format as determined annually by the Department based on the format used in the majority of the states operating a controlled substances reporting system. In the event the dispenser is unable to report the information within the time frame required by this section because the system is not operational or there is some other temporary electrical or technological failure, this inability shall be documented in the dispenser's records. Once the electrical or technological failure has been resolved, the dispenser shall promptly report the information.

(b) The Commission shall adopt rules requiring dispensers to report the following information. The Commission may modify these requirements as necessary to carry out the purposes of this Article. The dispenser shall report:

- (1) The dispenser's DEA number.
- (2) The name of the patient for whom the controlled substance is being dispensed, and the patient's:
  - a. Full address, including city, state, and zip code.
  - b. Telephone number.
  - c. Date of birth.
- (3) The date the prescription was written.
- (4) The date the prescription was filled.
- (5) The prescription number.
- (6) Whether the prescription is new or a refill.
- (7) Metric quantity of the dispensed drug.

- (8) Estimated days of supply of dispensed drug, if provided to the dispenser.
  - (9) National Drug Code of dispensed drug.
  - (10) Prescriber's DEA number.
  - (10a) Prescriber's national provider identification number, for any prescriber that has a national provider identification number. A pharmacy shall not be subject to a civil penalty under subsection (e) of this section for failure to report the prescriber's national provider identification number when it is not received by the pharmacy.
  - (11) Method of payment for the prescription.
- (c) A dispenser shall not be required to report instances in which a controlled substance is provided directly to the ultimate user and the quantity provided does not exceed a 48-hour supply.
- (d) A dispenser shall not be required to report instances in which a Schedule V non-narcotic, non-anorectic Schedule V controlled substance is provided directly to the ultimate user for the purpose of assessing a therapeutic response when prescribed according to indications approved by the United States Food and Drug Administration.
- (e) The Department shall assess, against any pharmacy that employs dispensers found to have failed to report information in the manner required by this section within a reasonable period of time after being informed by the Department that the required information is missing or incomplete, a civil penalty of not more than one hundred dollars (\$100.00) for a first violation, two hundred fifty dollars (\$250.00) for a second violation, and five hundred dollars (\$500.00) for each subsequent violation if the pharmacy fails to report as required under this section, up to a maximum of five thousand dollars (\$5,000) per pharmacy per calendar year. Each day of a continuing violation shall constitute a separate violation. A pharmacy acting in good faith that attempts to report the information required by this section shall not be assessed any civil penalty. The clear proceeds of penalties assessed under this section shall be deposited to the Civil Penalty and Forfeiture Fund in accordance with Article 31A of Chapter 115C of the General Statutes. The Commission shall adopt rules to implement this subsection that include factors to be considered in determining the amount of the penalty to be assessed.
- (f) For purposes of this section, a "dispenser" includes a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes when that person dispenses any Schedule II through V controlled substances. Notwithstanding subsection (b) of this section, the Commission shall adopt rules requiring the information to be reported by a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes.
- (g) A person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes may submit prescription information by paper form or other means, provided all information required of electronically submitted data is submitted.

**§ 90-113.73. Requirements for controlled substances reporting system; civil penalties for failure to properly report. [Version effective on and after March 1, 2024 and until March 1, 2025]**

- (a) The Department shall establish and maintain a reporting system of prescriptions for all Schedule II through V controlled substances. Each dispenser shall submit the information in accordance with transmission methods and frequency established by rule by the Commission. The Department may issue a waiver to a dispenser who is unable to submit prescription information by electronic means. The waiver may permit the dispenser to submit prescription information by paper form or other means, provided all information required of electronically submitted data is submitted. The dispenser shall report the information required under this section no later than the close of the next business day after the prescription is delivered; however, dispensers are encouraged to report the information no later than 24 hours after the prescription was delivered. The information shall be submitted in a format as determined annually by the Department based on the format used in the majority of the states operating a controlled substances reporting system. In the event the dispenser is unable to report the information within the time frame required by this section because the system is not operational or there is some other temporary electrical or technological failure, this inability shall be documented in the dispenser's records. Once the electrical or technological failure has been resolved, the dispenser shall promptly report the information.
- (b) The Commission shall adopt rules requiring dispensers to report the following information. The Commission may modify these requirements as necessary to carry out the purposes of this Article. The dispenser shall report:
- (1) The dispenser's DEA number for prescriptions of controlled substances, and for prescriptions of gabaentin, whether the dispenser has a DEA number.
  - (2) The name of the patient for whom the controlled substance is being dispensed, and the patient's:
    - a. Full address, including city, state, and zip code.



- b. Telephone number.
- c. Date of birth.
- (3) The date the prescription was written.
- (4) The date the prescription was filled.
- (5) The prescription number.
- (6) Whether the prescription is new or a refill.
- (7) The metric quantity of the dispensed drug.
- (8) The estimated days of supply of dispensed drug, if provided to the dispenser.
- (9) The National Drug Code of dispensed drug.
- (10) The prescriber's DEA number for prescriptions of controlled substances, and for prescriptions of gabapentin, if the prescriber has a DEA number and the number is known by the dispenser.
- (10a) The prescriber's national provider identification number, for any prescriber that has a national provider identification number. A pharmacy shall not be subject to a civil penalty under subsection (e) of this section for failure to report the prescriber's national provider identification number when it is not received by the pharmacy.
- (11) The method of payment for the prescription.

(c) A dispenser shall not be required to report instances in which a controlled substance, or gabapentin, is provided directly to the ultimate user and the quantity provided does not exceed a 48-hour supply.

(c1) A dispenser shall not be required to report gabapentin to the controlled substances reporting system when gabapentin is a component of a compounded prescription that is dispensed in dosages of 100 milligrams or less.

(d) A dispenser shall not be required to report instances in which a Schedule V non-narcotic, non-anorectic Schedule V controlled substance is provided directly to the ultimate user for the purpose of assessing a therapeutic response when prescribed according to indications approved by the United States Food and Drug Administration.

(e) The Department shall assess, against any pharmacy that employs dispensers found to have failed to report information in the manner required by this section within a reasonable period of time after being informed by the Department that the required information is missing or incomplete, a civil penalty of not more than one hundred dollars (\$100.00) for a first violation, two hundred fifty dollars (\$250.00) for a second violation, and five hundred dollars (\$500.00) for each subsequent violation if the pharmacy fails to report as required under this section, up to a maximum of five thousand dollars (\$5,000) per pharmacy per calendar year. Each day of a continuing violation shall constitute a separate violation. A pharmacy acting in good faith that attempts to report the information required by this section shall not be assessed any civil penalty. The clear proceeds of penalties assessed under this section shall be deposited to the Civil Penalty and Forfeiture Fund in accordance with Article 31A of Chapter 115C of the General Statutes. The Commission shall adopt rules to implement this subsection that include factors to be considered in determining the amount of the penalty to be assessed.

(f) For purposes of this section, a "dispenser" includes a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes when that person dispenses any Schedule II through V controlled substances. Notwithstanding subsection (b) of this section, the Commission shall adopt rules requiring the information to be reported by a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes.

(g) A person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes may submit prescription information by paper form or other means, provided all information required of electronically submitted data is submitted.

**§ 90-113.73. Requirements for controlled substances reporting system; civil penalties for failure to properly report. [Version effective on and after March 1, 2025]**

(a) The Department shall establish and maintain a reporting system of prescriptions for all Schedule II through V controlled substances. Each dispenser shall submit the information in accordance with transmission methods and frequency established by rule by the Commission. The Department may issue a waiver to a dispenser who is unable to submit prescription information by electronic means. The waiver may permit the dispenser to submit prescription information by paper form or other means, provided all information required of electronically submitted data is submitted. The dispenser shall report the information required under this section no later than the close of the next business day after the prescription is delivered; however, dispensers are encouraged to report the information no later than 24 hours after the prescription was delivered. The information shall be submitted in a format as determined annually by the Department based on the format used in the majority of the states operating a controlled substances reporting system. In the event the dispenser is unable to report the information within the time frame

required by this section because the system is not operational or there is some other temporary electrical or technological failure, this inability shall be documented in the dispenser's records. Once the electrical or technological failure has been resolved, the dispenser shall promptly report the information.

(b) The Commission shall adopt rules requiring dispensers to report the following information. The Commission may modify these requirements as necessary to carry out the purposes of this Article. The dispenser shall report:

- (1) The dispenser's DEA number for prescriptions of controlled substances, and for prescriptions of gabapentin, whether the dispenser has a DEA number.
- (2) The name of the patient for whom the controlled substance is being dispensed, and the patient's:
  - a. Full address, including city, state, and zip code.
  - b. Telephone number.
  - c. Date of birth.
- (3) The date the prescription was written.
- (4) The date the prescription was filled.
- (5) The prescription number.
- (6) Whether the prescription is new or a refill.
- (7) The metric quantity of the dispensed drug.
- (8) The estimated days of supply of dispensed drug, if provided to the dispenser.
- (9) The National Drug Code of dispensed drug.
- (10) The prescriber's DEA number for prescriptions of controlled substances, and for prescriptions of gabapentin, if the prescriber has a DEA number and the number is known by the dispenser.
- (10a) The prescriber's national provider identification number, for any prescriber that has a national provider identification number. A pharmacy shall not be subject to a civil penalty under subsection (e) of this section for failure to report the prescriber's national provider identification number when it is not received by the pharmacy.
- (11) The method of payment for the prescription.

(c) A dispenser shall not be required to report instances in which a controlled substance, or gabapentin, is provided directly to the ultimate user and the quantity provided does not exceed a 48-hour supply.

(c1) A dispenser shall not be required to report gabapentin to the controlled substances reporting system when gabapentin is a component of a compounded prescription that is dispensed in dosages of 100 milligrams or less.

(d) A dispenser shall not be required to report instances in which a Schedule V non-narcotic, non-anorectic Schedule V controlled substance is provided directly to the ultimate user for the purpose of assessing a therapeutic response when prescribed according to indications approved by the United States Food and Drug Administration.

(e) The Department shall assess, against any pharmacy that employs dispensers found to have failed to report information in the manner required by this section within a reasonable period of time after being informed by the Department that the required information is missing or incomplete, a civil penalty of not more than one hundred dollars (\$100.00) for a first violation, two hundred fifty dollars (\$250.00) for a second violation, and five hundred dollars (\$500.00) for each subsequent violation if the pharmacy fails to report as required under this section, up to a maximum of five thousand dollars (\$5,000) per pharmacy per calendar year. Each day of a continuing violation shall constitute a separate violation. A pharmacy acting in good faith that attempts to report the information required by this section shall not be assessed any civil penalty. The clear proceeds of penalties assessed under this section shall be deposited to the Civil Penalty and Forfeiture Fund in accordance with Article 31A of Chapter 115C of the General Statutes. The Commission shall adopt rules to implement this subsection that include factors to be considered in determining the amount of the penalty to be assessed.

(f) For purposes of this section, a "dispenser" includes a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes when that person dispenses any Schedule II through V controlled substance or gabapentin. Notwithstanding subsection (b) of this section, the Commission shall adopt rules requiring the information to be reported by a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes.

(g) A person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes may submit prescription information by paper form or other means, provided all information required of electronically submitted data is submitted.

**§ 90-113.73A. Expand monitoring capacity; report.**

(a) The North Carolina Controlled Substances Reporting System shall expand its monitoring capacity by establishing data use agreements with the Prescription Behavior Surveillance System. In order to participate, the CSRS shall establish a data use agreement with the Center of Excellence at Brandeis University no later than January 1, 2016.

(b) Beginning September 1, 2016, and every two years thereafter, the Division of Mental Health, Developmental Disabilities, and Substance Use Services of the Department of Health and Human Services shall report on its participation with the Prescription Behavior Surveillance System to the Joint Legislative Oversight Committee on Health and Human Services and the Joint Legislative Oversight Committee on Justice and Public Safety.

**§ 90-113.74. Confidentiality.**

(a) Prescription information submitted to the Department is privileged and confidential, is not a public record pursuant to G.S. 132-1, is not subject to subpoena or discovery or any other use in civil proceedings, and except as otherwise provided below may only be used (i) for investigative or evidentiary purposes related to violations of State or federal law, (ii) for regulatory activities, or (iii) to inform medical records or clinical care. Except as otherwise provided by this section, prescription information shall not be disclosed or disseminated to any person or entity by any person or entity authorized to review prescription information.

(b) The Department may use prescription information data in the controlled substances reporting system only for purposes of implementing this Article in accordance with its provisions.

(b1) The Department may review the prescription information data in the controlled substances reporting system and upon review may:

- (1) Notify practitioners that a patient may have obtained prescriptions for controlled substances in a manner that may represent abuse, diversion of controlled substances, or an increased risk of harm to the patient.
- (1a) Notify practitioners and their respective licensing boards of prescribing behavior that (i) increases risk of diversion of controlled substances, (ii) increases risk of harm to the patient, or (iii) is an outlier among other practitioner behavior.
- (2) Report information regarding the prescribing practices of a practitioner to the agency responsible for licensing, registering, or certifying the practitioner pursuant to rules adopted by the agency as set forth below in subsection (b2) of this section.

(b2) In order to receive a report pursuant to subdivision (2) of subsection (b1) of this section, an agency responsible for licensing, registering, or certifying a practitioner with prescriptive or dispensing authority shall adopt rules setting the criteria by which the Department may report the information to the agency. The criteria for reporting established by rule shall not establish the standard of care for prescribing or dispensing, and it shall not be a basis for disciplinary action by an agency that the Department reported a practitioner to an agency based on the criteria.

(c) The Department shall release data in the controlled substances reporting system to the following persons only:

- (1) Persons authorized to prescribe or dispense controlled substances for the purpose of providing medical or pharmaceutical care for their patients. A person authorized to receive data pursuant to this paragraph may delegate the authority to receive the data to other persons working under his or her direction and supervision, provided the Department approves this delegation.

The administrator of a hospital emergency department or hospital acute care facility shall provide the Department with a list of prescribers who are authorized to prescribe controlled substances for the purpose of providing medical care for patients of the hospital emergency department or hospital acute care facility and a list of delegates who are authorized to receive data on behalf of the providers listed. The administrator acting under this paragraph shall submit the lists to the Department no later than December 1 of the calendar year preceding the year during which the delegates are to receive data and may provide updated lists at any time during the course of the year. Within one week of receiving the initial or updated lists described in this paragraph, the Department shall establish all of the delegate accounts necessary to enable each delegate listed by the administrator of the hospital emergency department or hospital acute care facility to receive data on behalf of the listed prescribers. Delegations made pursuant to this paragraph are valid during the calendar year for which submitted by the administrator.

- (2) An individual who requests the individual's own controlled substances reporting system information.
  - (3) Special agents of the North Carolina State Bureau of Investigation who are assigned to the Diversion & Environmental Crimes Unit and whose primary duties involve the investigation of diversion and illegal use of prescription medication. SBI agents assigned to the Diversion & Environmental Crimes Unit may then provide this information to other SBI agents who are engaged in a bona fide specific investigation related to enforcement of laws governing licit drugs. The Attorney General of North Carolina, or a designee who is a full-time employee in the North Carolina Department of Justice, shall have access to the system to monitor requests for inspection of records.
  - (4) Primary monitoring authorities for other states pursuant to a specific ongoing investigation involving a designated person, if information concerns the dispensing of a Schedule II through V controlled substance to an ultimate user who resides in the other state or the dispensing of a Schedule II through V controlled substance prescribed by a licensed health care practitioner whose principal place of business is located in the other state.
  - (5) To a sheriff or designated deputy sheriff or a police chief or a designated police investigator who is assigned to investigate the diversion and illegal use of prescription medication or pharmaceutical products identified in Article 5 of this Chapter of the General Statutes as Schedule II through V controlled substances and who is engaged in a bona fide specific investigation related to the enforcement of laws governing licit drugs pursuant to a lawful court order specifically issued for that purpose.
  - (5a) Local law enforcement officers pursuant to subsection (i) of this section.
  - (6) The Division of Medical Assistance for purposes of administering the State Medical Assistance Plan.
  - (7) Licensing boards with jurisdiction over health care disciplines pursuant to an ongoing investigation by the licensing board of a specific individual licensed by the board.
  - (8) Any county medical examiner appointed by the Chief Medical Examiner pursuant to G.S. 130A-382 and the Chief Medical Examiner, for the purpose of investigating the death of an individual.
  - (9) The federal Drug Enforcement Administration's Office of Diversion Control or Tactical Diversion Squad in North Carolina.
  - (10) The North Carolina Health Information Exchange Authority (NC HIE Authority), established under Article 29B of this Chapter, through Web-service calls.
- (d) The Department may provide data to public or private entities for statistical, research, or educational purposes only after removing information that could be used to identify individual patients who received prescription medications from dispensers.
- (e) In the event that the Department finds patterns of prescribing medications that are unusual, the Department shall inform the Attorney General's Office of its findings. The Office of the Attorney General shall review the Department's findings to determine if the findings should be reported to the SBI and the appropriate sheriff for investigation of possible violations of State or federal law relating to controlled substances.
- (f) The Department shall, on a quarterly basis, purge from the controlled substances reporting system database all information more than six years old. The Department shall maintain in a separate database all information purged from the controlled substances reporting system database pursuant to this subsection and may release data from that separate database only as provided in subsection (d) of this section.
- (g) Nothing in this Article shall prohibit a person authorized to prescribe or dispense controlled substances pursuant to Article 1 of Chapter 90 of the General Statutes from disclosing or disseminating data regarding a particular patient obtained under subsection (c) of this section to another person (i) authorized to prescribe or dispense controlled substances pursuant to Article 1 of Chapter 90 of the General Statutes and (ii) authorized to receive the same data from the Department under subsection (c) of this section.
- (h) Nothing in this Article shall prevent persons licensed or approved to practice medicine or perform medical acts, tasks, and functions pursuant to Article 1 of Chapter 90 of the General Statutes from retaining data received pursuant to subsection (c) of this section in a patient's confidential health care record.
- (i) Data released by the Department from the controlled substances reporting system to local law enforcement officers is subject to all of the following conditions and requirements:
- (1) The Department shall release data in the controlled substances reporting system to a local law enforcement officer only if all of the following conditions are satisfied:

- a. The local law enforcement officer is a certified diversion investigator.
  - b. The agency that supervises the investigator is a qualified law enforcement agency.
  - c. The request is reasonably related to a bona fide active investigation involving a specific violation of any State or federal law involving a controlled substance.
  - d. The request has been reviewed and approved by the State Bureau of Investigation, Diversion & Environmental Crimes Unit.
- (2) In the event a special agent of the State Bureau of Investigation, Diversion & Environmental Crimes Unit, takes action upon a request by a certified diversion investigator for access to data in the controlled substances reporting system, the special agent shall not incur criminal or civil liability for such action or for actions taken by the certified diversion investigator making the request.
- (3) The conditions outlined in this subsection shall create an audit trail that may be used to investigate or prosecute violations of this section. The Department shall grant access to the system to the Attorney General of North Carolina or a designee and Special Agents of the State Bureau of Investigation who are assigned to the Diversion & Environmental Crimes Unit for the purpose of reviewing the audit trail. The State Bureau of Investigation shall conduct periodic audits of a random sample of requests from certified diversion investigators for access to data in the controlled substances reporting system.
- (4) Data obtained by certified diversion investigators from the controlled substances reporting system in the manner prescribed by this subsection may be shared with other law enforcement personnel or prosecutorial officials (i) only upon the direction of the certified diversion investigator who originally requested the information and (ii) in the case of law enforcement personnel from other law enforcement agencies, only with law enforcement personnel who are directly participating in an official joint investigation or as provided in subdivision (5) of this subsection.
- (5) In the event the data provided to the local law enforcement officer indicates transactions solely outside of that local law enforcement officer's jurisdiction, the matter shall be referred to the State Bureau of Investigation, Diversion & Environmental Crimes Unit, or to a certified diversion investigator employed by a qualified law enforcement agency with jurisdiction over the transactions at issue.
- (6) Certified diversion investigators may not request or receive prescription data from other states through PMP Interconnect or any other mechanism established by the Department to facilitate interstate connectivity of the controlled substances reporting system.
- (7) As used in this subsection, the following terms have the following meanings:
- a. Bona fide active investigation. – An investigation of one or more specific persons conducted with a reasonable, good-faith belief based on specific facts and circumstances equivalent to those normally necessary for the issuance of a court order, as described in G.S. 90-113.74(c)(5).
  - a1. Certified diversion investigator. – An officer affiliated with a qualified law enforcement agency who is certified as a diversion investigator by either the North Carolina Sheriffs' Education and Training Standards Commission or the North Carolina Criminal Justice Education and Training Standards Commission. If for any reason a certified diversion investigator leaves a position involving diversion investigation, the qualified law enforcement agency shall notify the North Carolina Department of Health and Human Services Controlled Substance Reporting System and the State Bureau of Investigation, Diversion & Environmental Crimes Unit, within 72 hours after the effective date of the change.
  - b. Certified diversion supervisor. – The head of a municipal police department, a county police department, a sheriff's office, or the designee of the agency head with supervisory authority over that agency's diversion investigators who is certified as a diversion supervisor by either the North Carolina Sheriffs' Education and Training Standards Commission or the North Carolina Criminal Justice Education and Training Standards Commission.
  - c. Qualified law enforcement agency. – Any of the following entities whose head is a certified diversion investigator or that employs at least one certified diversion investigator and at least one certified diversion supervisor:

1. A municipal police department.
  2. A county police department.
  3. A sheriff's office.
- (j) The Department shall do all of the following:
- (1) Enable each certified diversion investigator associated with a qualified law enforcement agency to register with the controlled substances reporting system by providing, at a minimum, all of the following information:
    - a. The investigator's name and certification number.
    - b. The name of the qualified law enforcement agency for whom the investigator works.
    - c. The name and certification number of each certified diversion supervisor with whom the investigator works.
  - (2) Enable each certified diversion investigator associated with a qualified law enforcement agency to request and receive data in connection with a bona fide active investigation involving a specific violation of any state or federal law involving a controlled substance by providing, at a minimum, all of the following:
    - a. The case number associated with the request.
    - b. A description of the nature and purpose of the request.
    - c. The first name, last name, and date of birth of each individual whose prescription data the investigator seeks, including, when appropriate, any alternative name, spelling, or date of birth associated with each such individual.
    - d. An acknowledgement that the certified diversion investigator is aware of the penalties associated with improperly obtaining, disclosing, or disseminating data from the controlled substances reporting system.
  - (3) Enable the State Bureau of Investigation, Diversion & Environmental Crimes Unit, to review each request for data from a certified diversion investigator associated with a qualified law enforcement agency and, upon such review, to determine if the request is approved, denied, or delayed pending further review or investigation.
  - (4) Create an audit trail that may be used to investigate or prosecute violations of this Part and ensure that the Attorney General of North Carolina or a designee and Special Agents of the North Carolina State Bureau of Investigation who are assigned to the Diversion & Environmental Crimes Unit have access to the system to review the audit trail.
- (k) In addition to the civil penalties provided in G.S. 90-113.75(a) and any other applicable civil or criminal penalties, the following criminal penalties apply to any individual authorized to access data in the controlled substances reporting system when that access is authorized by subdivisions (3) through (10) of subsection (c) of this section:
- (1) An individual who knowingly and intentionally accesses prescription information in the controlled substances reporting system for a purpose not authorized by this section shall be guilty of a Class I felony.
  - (2) An individual who knowingly and intentionally discloses or disseminates prescription information from the system for a purpose not authorized by this section shall be guilty of a Class I felony.
  - (3) An individual who willfully and maliciously obtains, discloses, or disseminates prescription information for a purpose not authorized by this section and with the intent to use such information for commercial advantage or personal gain, or to maliciously harm any person, shall be guilty of a Class H felony.

Any person who is convicted of a criminal offense under this subsection is permanently barred from accessing the controlled substances reporting system.

(l) The State Bureau of Investigation, Diversion & Environmental Crimes Unit, may investigate suspected violations of this section and shall notify the Department of any charges or convictions pursuant to this section.

**§ 90-113.74A. Mandatory prescriber registration for access to controlled substances reporting system**

Within 30 days after obtaining an initial or renewal license that confers the authority to prescribe a controlled substance for the purpose of providing medical care for a patient, the licensee shall demonstrate to the satisfaction of the licensing board that he or she is registered for access to the controlled substances reporting system. A violation of this section may constitute cause for the licensing board having jurisdiction over the licensee to suspend or revoke the license.

**§ 90-113.74B. Mandatory dispenser registration for access to controlled substances reporting system; exception.**

(a) Within 30 days after obtaining an initial or renewal license to practice pharmacy, the licensee shall demonstrate to the satisfaction of the North Carolina Board of Pharmacy that he or she is registered for access to the controlled substances reporting system. A violation of this section may constitute cause for the Board of Pharmacy to suspend or revoke the license.

(b) This section does not apply to a licensee employed in a pharmacy practice setting where a Schedule II, III, or IV controlled substance will not be dispensed.

**§ 90-113.74C. Practitioner use of controlled substances reporting system; mandatory reporting of violations.**

(a) Prior to initially prescribing a targeted controlled substance to a patient, a practitioner shall review the information in the controlled substances reporting system pertaining to the patient for the 12-month period preceding the initial prescription. For every subsequent three-month period that the targeted controlled substance remains a part of the patient's medical care, the practitioner shall review the information in the controlled substances reporting system pertaining to the patient for the 12-month period preceding the determination that the targeted controlled substance should remain a part of the patient's medical care. Each instance in which the practitioner reviews the information in the controlled substances reporting system pertaining to the patient shall be documented in the patient's medical record. In the event the practitioner is unable to review the information in the controlled substances reporting system pertaining to the patient because the system is not operational or there is some other temporary electrical or technological failure, this inability shall be documented in the patient's medical record. Once the electrical or technological failure has been resolved, the practitioner shall review the information in the controlled substances reporting system pertaining to the patient and the review shall be documented in the patient's medical record.

(b) A practitioner may, but is not required to, review the information in the controlled substances reporting system pertaining to a patient prior to prescribing a targeted controlled substance to the patient in any of the following circumstances:

- (1) The controlled substance is to be administered to a patient in a health care setting, hospital, nursing home, outpatient dialysis facility, or residential care facility, as defined in G.S. 14-32.2.
- (2) The controlled substance is prescribed for the treatment of cancer or another condition associated with cancer.
- (3) The controlled substance is prescribed to a patient in hospice care or palliative care.

(c) The Department shall conduct periodic audits of the review of the controlled substances reporting system by prescribers. The Department shall determine a system for selecting a subset of prescriptions to examine during each auditing period. The Department shall report to the appropriate licensing board any prescriber found to be in violation of this section. A violation of this section may constitute cause for the licensing board to suspend or revoke a prescriber's license.

(d) For purposes of this section, a "practitioner" does not include a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes.

**§ 90-113.74D. Dispenser use of controlled substances reporting system.**

(a) Prior to dispensing a targeted controlled substance, a dispenser shall review the information in the controlled substances reporting system pertaining to the patient for the preceding 12-month period and document this review under any of the following circumstances:

- (1) The dispenser has a reasonable belief that the ultimate user may be seeking a targeted controlled substance for any reason other than the treatment of the ultimate user's existing medical condition.
- (2) The prescriber is located outside of the usual geographic area served by the dispenser.
- (3) The ultimate user resides outside of the usual geographic area served by the dispenser.
- (4) The ultimate user pays for the prescription with cash when the patient has prescription insurance on file with the dispenser.
- (5) The ultimate user demonstrates potential misuse of a controlled substance by any one or more of the following:
  - a. Over-utilization of the controlled substance.
  - b. Requests for early refills.
  - c. Utilization of multiple prescribers.

- d. An appearance of being overly sedated or intoxicated upon presenting a prescription.
- e. A request by an unfamiliar ultimate user for an opioid drug by a specific name, street name, color, or identifying marks.

(b) If a dispenser has reason to believe a prescription for a targeted controlled substance is fraudulent or duplicative, the dispenser shall withhold delivery of the prescription until the dispenser is able to contact the prescriber and verify that the prescription is medically appropriate.

(c) A dispenser shall be immune from any civil or criminal liability for actions authorized by this section. Failure to review the system in accordance with subsection (a) of this section shall not constitute medical negligence.

**§ 90-113.75. Civil penalties; other remedies; immunity from liability.**

(a) A person who intentionally, knowingly, or negligently releases, obtains, or attempts to obtain information from the system in violation of a provision of this Article or a rule adopted pursuant to this Article shall be assessed a civil penalty by the Department not to exceed ten thousand dollars (\$10,000) per violation and shall be temporarily barred from accessing the system until further findings by the Department. The clear proceeds of penalties assessed under this section shall be deposited to the Civil Penalty and Forfeiture Fund in accordance with Article 31A of Chapter 115C of the General Statutes. The Commission shall adopt rules establishing the factors to be considered in determining the amount of the penalty to be assessed.

(b) In addition to any other remedies available at law, an individual whose prescription information has been disclosed in violation of this Article or a rule adopted pursuant to this Article may bring an action against any person or entity who has intentionally, knowingly, or negligently released confidential information or records concerning the individual for either or both of the following:

- (1) Nominal damages of one thousand dollars (\$1,000). In order to recover damages under this subdivision, it shall not be necessary that the plaintiff suffered or was threatened with actual damages.
- (2) The amount of actual damages, if any, sustained by the individual.

(c) Notwithstanding the foregoing, G.S. 8-53, G.S. 75-65, or any other provision of international, federal, State, or local law, a practitioner as defined in G.S. 90-87, a dispenser, or other person or entity permitted access to or required or permitted to submit or transmit reports or other records, data, or information, including, without limitation, any protected health information or any other individually identifying or personal information, under this Article that, in good faith, submits or transmits such reports or other records, data, or information as required or allowed by this Article is immune from civil or criminal liability that might otherwise be incurred or imposed as a result of submitting or transmitting such reports or other records, data, or information, or as a result of any subsequent actual or attempted access to or use or disclosure of such reports or other records, data, or information, whether by the Department, any law enforcement officer or agency, or any other person or entity.

**§ 90-113.75A. Creation of Controlled Substances Reporting System Fund.**

(a) The Controlled Substances Reporting System Fund is created within the Department as a special revenue fund. The Department shall administer the Fund. The Department shall use the Fund only for operation of the controlled substances reporting system and to carry out the provisions of this Article.

(b) The Fund shall consist of the following:

- (1) Any moneys appropriated to the Fund by the General Assembly.
- (2) Any moneys received from State, federal, private, or other sources for deposit into the Fund.

(c) All interest that accrues to the Fund shall be credited to the Fund. Any balance remaining in the Fund at the end of any fiscal year shall remain in the Fund and shall not revert to the General Fund.

**§ 90-113.75B. Annual report to General Assembly and licensing boards.**

Annually on February 1, beginning February 1, 2019, the Department shall report to the Joint Legislative Oversight Committee on Health and Human Services, the North Carolina Medical Board, the North Carolina Board of Podiatry Examiners, the North Carolina Board of Nursing, the North Carolina Dental Board, the North Carolina Veterinary Medical Board, and the North Carolina Board of Pharmacy on data reported to the controlled substances reporting system. The report shall include at least all of the following information about targeted controlled substances reported to the system during the preceding calendar year:

- (1) The total number of prescriptions dispensed, broken down by Schedule.
- (2) Demographics about the ultimate users to whom prescriptions were dispensed.
- (3) Statistics regarding the number of pills dispensed per prescription.



- (4) The number of ultimate users who were prescribed a controlled substance by two or more practitioners.
- (5) The number of ultimate users to whom a prescription was dispensed in more than one county.
- (6) The categories of practitioners prescribing controlled substances and the number of prescriptions authorized by each category of practitioner. For the purpose of this subdivision, medical doctors, surgeons, palliative care practitioners, oncologists and other practitioners specializing in oncology, pain management practitioners, practitioners who specialize in hematology, including the treatment of sickle cell disease, and practitioners who specialize in treating substance use disorder shall be treated as distinct categories of practitioners.
- (7) Any other data deemed appropriate and requested by the Joint Legislative Oversight Committee on Health and Human Services, the North Carolina Medical Board, the North Carolina Board of Podiatry Examiners, the North Carolina Board of Nursing, the North Carolina Dental Board, the North Carolina Veterinary Medical Board, or the North Carolina Board of Pharmacy.

**§ 90-113.75E. Opioid and Prescription Drug Abuse Advisory Committee; statewide strategic plan.**

(a) There is hereby created the Opioid and Prescription Drug Abuse Advisory Committee, to be housed in and staffed by the Department. The Committee shall develop and, through its members, implement a statewide strategic plan to combat the problem of opioid and prescription drug abuse. The Committee shall include representatives from the following, as well as any other persons designated by the Secretary of Health and Human Services:

- (1) The Department's Division of Medical Assistance.
- (2) The Department's Division of Mental Health, Developmental Disabilities, and Substance Use Services.
- (3) The Department's Division of Public Health.
- (4) The Rural Health Section of the Department's Division of Public Health.
- (5) The Division of Juvenile Justice of the Department of Public Safety.
- (5a) The Division of Community Supervision and Reentry of the Department of Adult Correction.
- (5b) The Division of Prisons of the Department of Adult Correction.
- (6) The State Bureau of Investigation.
- (7) The Attorney General's Office.
- (8) The following health care regulatory boards with oversight of prescribers and dispensers of opioids and other prescription drugs:
  - a. North Carolina Board of Dental Examiners.
  - b. North Carolina Board of Nursing.
  - c. North Carolina Board of Podiatry Examiners.
  - d. North Carolina Medical Board.
  - e. North Carolina Board of Pharmacy.
- (9) The UNC Injury Prevention Research Center.
- (10) The substance abuse treatment community.
- (11) Governor's Institute on Substance Abuse, Inc.
- (12) The Department of Insurance's drug take-back program. After developing the strategic plan, the Committee shall be the State's steering committee to monitor achievement of strategic objectives and receive regular reports on progress made toward reducing opioid and prescription drug abuse in North Carolina.

(b) In developing the statewide strategic plan to combat the problem of opioid and prescription drug abuse, the Opioid and Prescription Drug Abuse Advisory Committee shall, at a minimum, complete the following steps:

- (1) Identify a mission and vision for North Carolina's system to reduce and prevent opioid and prescription drug abuse.
- (2) Scan the internal and external environment for the system's strengths, weaknesses, opportunities, and challenges (a SWOC analysis).
- (3) Compare threats and opportunities to the system's ability to meet challenges and seize opportunities (a GAP analysis).
- (4) Enforcement of State laws for the misuse and diversion of controlled substances.
- (5) Any other appropriate mechanism identified by the Committee.

(d) The Department, in consultation with the Opioid and Prescription Drug Abuse Advisory Committee, shall develop and implement a formalized performance management system that connects the goals and objectives identified in the statewide strategic plan to operations of the Controlled Substances Reporting System and Medicaid lock-in program, law enforcement activities, and oversight of prescribers and dispensers. The performance management system must be designed to monitor progress toward achieving goals and objectives and must recommend actions to be taken when performance falls short.

(e) Beginning on December 1, 2016, and annually thereafter, the Department shall submit an annual report on the performance of North Carolina's system for monitoring opioid and prescription drug abuse to the Joint Legislative Oversight Committee on Health and Human Services, the Joint Legislative Oversight Committee on Justice and Public Safety, and the Fiscal Research Division.

**§ 90-113.76. Commission for Mental Health, Developmental Disabilities, and Substance Use Services to adopt rules.**

The Commission for Mental Health, Developmental Disabilities, and Substance Use Services shall adopt rules necessary to implement this Article.

**Article 23A.  
Right to Try Act.**

*Selected Provisions*

Part 1. Experimental Treatments

**§ 90-325. Short title; purpose.**

- (a) This Article shall be known and may be cited as the Right to Try Act.
- (b) The purpose of Part 1 of this Article is to authorize access to and use of experimental treatments for patients with a terminal illness; to establish conditions for use of experimental treatment; to prohibit sanctions of health care providers solely for recommending or providing experimental treatment; to clarify duties of a health insurer with regard to experimental treatment authorized under this Part; to prohibit certain actions by State officials, employees, and agents; and to restrict certain causes of action arising from experimental treatment.

**§ 90-325.1. Definitions.**

The following definitions apply in this Part, unless the context requires otherwise:

- (1) Eligible patient. – An individual who meets all of the following criteria:
  - a. Has a terminal illness, attested to by a treating physician.
  - b. Has, in consultation with a treating physician, considered all other treatment options currently approved by the United States Food and Drug Administration.
  - c. Has received a recommendation from the treating physician for use of an investigational drug, biological product, or device for treatment of the terminal illness.
  - d. Has given informed consent in writing to use of the investigational drug, biological product, or device for treatment of the terminal illness or, if the individual is a minor or is otherwise incapable of providing informed consent, the parent or legal guardian has given informed consent in writing to use of the investigational drug, biological product, or device.
  - e. Has documentation from the treating physician that the individual meets all of the criteria for this definition. This documentation shall include an attestation from the treating physician that the treating physician was consulted in the creation of the written, informed consent required under this Part.
- (2) Investigational drug, biological product, or device. – A drug, biological product, or device that has successfully completed Phase I of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.
- (3) Terminal illness. – A progressive disease or medical or surgical condition that (i) entails significant functional impairment, (ii) is not considered by a treating physician to be reversible

even with administration of available treatments approved by the United States Food and Drug Administration, and (iii) will soon result in death without life-sustaining procedures.

(4) Written, informed consent. – A written document that is signed by an eligible patient; or if the patient is a minor, by a parent or legal guardian; or if the patient is incapacitated, by a designated health care agent pursuant to a health care power of attorney, that at a minimum includes all of the following:

- a. An explanation of the currently approved products and treatments for the eligible patient's terminal illness.
- b. An attestation that the eligible patient concurs with the treating physician in believing that all currently approved treatments are unlikely to prolong the eligible patient's life.
- c. Clear identification of the specific investigational drug, biological product, or device proposed for treatment of the eligible patient's terminal illness.
- d. A description of the potentially best and worst outcomes resulting from use of the investigational drug, biological product, or device to treat the eligible patient's terminal illness, along with a realistic description of the most likely outcome. The description shall be based on the treating physician's knowledge of the proposed treatment in conjunction with an awareness of the eligible patient's terminal illness and shall include a statement acknowledging that new, unanticipated, different, or worse symptoms might result from, and that death could be hastened by, the proposed treatment.
- e. A statement that eligibility for hospice care may be withdrawn if the eligible patient begins treatment of the terminal illness with an investigational drug, biological product, or device and that hospice care may be reinstated if such treatment ends and the eligible patient meets hospice eligibility requirements.
- f. A statement that the eligible patient's health benefit plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device, unless specifically required to do so by law or contract.
- g. A statement that the eligible patient understands that he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that this liability extends to the eligible patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.
- h. A statement that the eligible patient or, for an eligible patient who is a minor or lacks capacity to provide informed consent, that the parent or legal guardian consents to the use of the investigational drug, biological product, or device for treatment of the terminal condition.

**§ 90-325.2. Authorized access to and use of investigational drugs, biological products, and devices.**

(a) A manufacturer of an investigational drug, biological product, or device may make available to an eligible patient, and an eligible patient may request, the manufacturer's investigational drug, biological product, or device. However, nothing in this Part shall be construed to require a manufacturer of an investigational drug, biological product, or device to make such investigational drug, biological product, or device available to an eligible patient.

(b) A manufacturer of an investigational drug, biological product, or device may provide the investigational drug, biological product, or device to an eligible patient without receiving compensation or may require the eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

**§ 90-325.3. No liability to heirs for outstanding debt related to use of investigational drugs, biological products, or devices.**

If an eligible patient dies while being treated with an investigational drug, biological product, or device, the eligible patient's heirs are not liable for any outstanding debt related to the treatment, including any costs attributed to lack of insurance coverage for the treatment.

**§ 90-325.4. Sanctions against health care providers prohibited.**

(a) A licensing board shall not revoke, fail to renew, suspend, or take any other disciplinary action against a health care provider licensed under this Chapter, based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device.

(b) An entity responsible for Medicare certification shall not take action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device.

**§ 90-325.5. Prohibited conduct by State officials.**

No official, employee, or agent of this State shall block or attempt to block an eligible patient's access to an investigational drug, biological product, or device. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider does not constitute a violation of this section.

**§ 90-325.6. No private right of action against manufacturers of investigational drugs, biological products, or devices.**

No private right of action may be brought against a manufacturer of an investigational drug, biological product, or device, or against any other person or entity involved in the care of an eligible patient using an investigational drug, biological product, or device, for any harm caused to the eligible patient resulting from use of the investigational drug, biological product, or device as long as the manufacturer or other person or entity has made a good-faith effort to comply with the provisions of this Part and has exercised reasonable care in actions undertaken pursuant to this Part.

**§ 90-325.7. Insurance coverage of clinical trials.**

Nothing in this Part shall be construed to affect a health benefit plan's obligation to provide coverage for an insured's participation in a clinical trial pursuant to G.S. 58-3-255.

\* \* \* \* \*

**Article 27.**

**Referral Fees and Payment for Certain Solicitations Prohibited.**

**§ 90-400. Definition.**

As used in this Article, a health care provider is a person holding any license issued under this Chapter.

**§ 90-401. Referral fees and payment for certain solicitations prohibited.**

A health care provider shall not financially compensate in any manner a person, firm, or corporation for recommending or securing the health care provider's employment by a patient, or as a reward for having made a recommendation resulting in the health care provider's employment by a patient. No health care provider who refers a patient of that health care provider to another health care provider shall receive financial or other compensation from the health care provider receiving the referral as a payment solely or primarily for the referral. This section shall not be construed to prohibit a health care provider's purchase of advertising which does not entail direct personal contact or telephone contact of a potential patient.

**§ 90-401.1. Direct solicitation prohibited.**

It shall be unlawful for a health care provider or the provider's employee or agent to initiate direct personal contact or telephone contact with any injured, diseased, or infirmed person, or with any other person residing in the injured, diseased, or infirmed person's household, for a period of 90 days following the injury or the onset of the disease or infirmity, if the purpose of initiating the contact, in whole or in part, is to attempt to induce or persuade the injured, diseased, or infirmed person to become a patient of the health care provider. This section shall not be construed to prohibit a health care provider's use of posted letters, brochures, or information packages to solicit injured, diseased, or infirmed persons, so long as such use does not entail direct personal contact with the person.

**§ 90-402. Sanctions.**

Violation of the provisions of this Article shall be grounds for the offending health care provider's licensing board to suspend or revoke the health care provider's license, to refuse to renew the health care provider's license, or to take any other disciplinary action authorized by law.

**Article 29.**  
**Medical Records.**

**§ 90-410. Definitions.**

As used in this Article:

- (1) "Health care provider" means any person who is licensed or certified to practice a health profession or occupation under this Chapter or Chapters 90B or 90C of the General Statutes, a health care facility licensed under Chapters 131E or 122C of the General Statutes, and a representative or agent of a health care provider.
- (2) "Medical records" means personal information that relates to an individual's physical or mental condition, medical history, or medical treatment, excluding X rays and fetal monitor records.

**§ 90-411. Record copy fee.**

A health care provider may charge a reasonable fee to cover the costs incurred in searching, handling, copying, and mailing medical records to the patient or the patient's designated representative. The maximum fee for each request shall be seventy-five cents (75¢) per page for the first 25 pages, fifty cents (50¢) per page for pages 26 through 100, and twenty-five cents (25¢) for each page in excess of 100 pages, provided that the health care provider may impose a minimum fee of up to ten dollars (\$10.00), inclusive of copying costs. If requested by the patient or the patient's designated representative, nothing herein shall limit a reasonable professional fee charged by a physician for the review and preparation of a narrative summary of the patient's medical record. Charges for medical records and reports related to claims under Article 1 of Chapter 97 of the General Statutes shall be governed by the fees established by the North Carolina Industrial Commission pursuant to G.S. 97-26.1. This section shall not apply to Department of Health and Human Services Disability Determination Services requests for copies of medical records made on behalf of an applicant for Social Security or Supplemental Security Income disability.

**§ 90-412. Electronic medical records.**

(a) Notwithstanding any other provision of law, any health care provider or facility licensed, certified, or registered under the laws of this State or any unit of State or local government may create and maintain medical records in an electronic format. The health care provider, facility, or governmental unit shall not be required to maintain a separate paper copy of the electronic medical record. A health care provider, facility, or governmental unit shall maintain electronic medical records in a legible and retrievable form, including adequate data backup.

(b) Notwithstanding any other provision of law, any health care provider or facility licensed, certified, or registered under the laws of this State or any unit of State or local government may permit authorized individuals to authenticate orders and other medical record entries by written signature, or by electronic or digital signature in lieu of a signature in ink. Medical record entries shall be authenticated by the individual who made or authorized the entry. For purposes of this section, "authentication" means identification of the author of an entry by that author and confirmation that the contents of the entry are what the author intended.

(c) The legal rights and responsibilities of patients, health care providers, facilities, and governmental units shall apply to records created or maintained in electronic form to the same extent as those rights and responsibilities apply to medical records embodied in paper or other media. This subsection applies with respect to the security, confidentiality, accuracy, integrity, access to, and disclosure of medical records.

**Article 29B.**  
**Statewide Health Information Exchange Act.**

**§ 90-414.1. Title.**

This act shall be known and may be cited as the "Statewide Health Information Exchange Act."

**§ 90-414.2. Purpose.**

This Article is intended to improve the quality of health care delivery within this State by facilitating and regulating the use of a voluntary, statewide health information exchange network for the secure electronic transmission of individually identifiable health information among health care providers, health plans, and health care clearinghouses in a manner that is consistent with the Health Insurance Portability and Accountability Act, Privacy Rule and Security Rule, 45 C.F.R. §§ 160, 164.

**§ 90-414.3. Definitions.**

The following definitions apply in this Article:

- (1) Business associate. – As defined in 45 C.F.R. § 160.103.
- (2) Business associate contract. – The documentation required by 45 C.F.R. § 164.502(e)(2) that meets the applicable requirements of 45 C.F.R. § 164.504(e).
- (3) Covered entity. – Any entity described in 45 C.F.R. § 160.103 or any other facility or practitioner licensed by the State to provide health care services.
- (4) Department. – North Carolina Department of Health and Human Services.
- (5) Disclose or disclosure. – The release, transfer, provision of access to, or divulging in any other manner an individual's protected health information through the HIE Network.
- ...
- (7) GDAC. – The North Carolina Government Data Analytics Center.
- (8) HIE Network. – The voluntary, statewide health information exchange network overseen and administered by the Authority.
- (9) HIPAA. – Sections 261 through 264 of the federal Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, as amended, and any federal regulations adopted to implement these sections, as amended.
- (10) Individual. – As defined in 45 C.F.R. § 160.103.
- (11) North Carolina Health Information Exchange Advisory Board or Advisory Board. – The Advisory Board established under G.S. 90-414.8.
- (12) North Carolina Health Information Exchange Authority or Authority. – The entity established pursuant to G.S. 90-414.7.
- (13) Opt out. – An individual's affirmative decision communicated to the Authority in writing to disallow his or her protected health information from being disclosed by the Authority to covered entities or other persons or entities through the HIE Network.
- (14) Protected health information. – As defined in 45 C.F.R. § 160.103.
- (15) Public health purposes. – The public health activities and purposes described in 45 C.F.R. § 164.512(b).
- (16) Qualified organization. – An entity with which the Authority has contracted for the sole purpose of facilitating the exchange of data with or through the HIE Network.
- (17) Research purposes. – Research purposes referenced in and subject to the standards described in 45 C.F.R. § 164.512(i).
- (18) State CIO. – The State Chief Information Officer.

**§ 90-414.4. Required participation in HIE Network for some providers.**

- (a) Findings. – The General Assembly makes the following findings:
  - (1) That controlling escalating health care costs of the Medicaid program and other State-funded health care services is of significant importance to the State, its taxpayers, its Medicaid recipients, and other recipients of State-funded health care services.
  - (2) That the State and covered entities in North Carolina need timely access to certain demographic and clinical information pertaining to services rendered to Medicaid and other State-funded health care program beneficiaries and paid for with Medicaid or other State-funded health care funds in order to assess performance, improve health care outcomes, pinpoint medical expense trends, identify beneficiary health risks, and evaluate how the State is spending money on Medicaid and other State-funded health services. The Department of Information Technology, the Department of State Treasurer, State Health Plan Division, and the Department of Health and Human Services, Division of Health Benefits, have an affirmative duty to facilitate and support participation by covered entities in the statewide health information exchange network.
  - (3) That making demographic and clinical information available to the State and covered entities in North Carolina by secure electronic means as set forth in subsection (b) of this section will improve care coordination within and across health systems, increase care quality for such beneficiaries, enable more effective population health management, reduce duplication of medical services, augment syndromic surveillance, allow more accurate measurement of care services and outcomes, increase strategic knowledge about the health of the population, and facilitate health care cost containment.

(a1) Mandatory Connection to HIE Network. – Notwithstanding the voluntary nature of the HIE Network under G.S. 90-414.2, the following providers and entities shall be connected to the HIE Network and begin submitting data through the HIE Network pertaining to services rendered to Medicaid beneficiaries and to other State-funded health care program beneficiaries and paid for with Medicaid or other State-funded health care funds in accordance with the following time line:

(1) The following providers of Medicaid services licensed to operate in the State that have an electronic health record system shall begin submitting, at a minimum, demographic and clinical data by June 1, 2018:

a. Hospitals as defined in G.S. 131E-176(13).

...

(2) Except as provided in subdivisions (3), (4), and (5) of this subsection, all other providers of Medicaid and State-funded health care services and their affiliated entities shall begin submitting demographic and clinical data by January 1, 2023.

(3) The following entities shall submit encounter and claims data, as appropriate, in accordance with the following time line:

a. Prepaid Health Plans, as defined in G.S. 108D-1, by the commencement date of a capitated contract with the Division of Health Benefits for the delivery of Medicaid and NC Health Choice services as specified in Article 4 of Chapter 108D of the General Statutes.

b. Local management entities/managed care organizations, as defined in G.S. 122C-3, by June 1, 2020.

If authorized by the Authority in accordance with this Article, the Department of Health and Human Services may submit the data required by this subsection on behalf of the entities specified in this subdivision.

(4) The following entities shall begin submitting demographic and clinical data by January 1, 2023:

...

d. The State Laboratory of Public Health operated by the Department of Health and Human Services.

(5) The following entities shall begin submitting claims data by January 1, 2023:

a. Pharmacies registered with the North Carolina Board of Pharmacy under Article 4A of Chapter 90 of the General Statutes.

b. State health care facilities operated under the jurisdiction of the Secretary of the Department of Health and Human Services, including State psychiatric hospitals, developmental centers, alcohol and drug treatment centers, neuro-medical treatment centers, and residential programs for children such as the Wright School and the Whitaker Psychiatric Residential Treatment Facility.

(a2) Extensions of Time for Establishing Connection to the HIE Network. – The Department of Information Technology, in consultation with the Department of Health and Human Services and the State Health Plan for Teachers and State Employees, may establish a process to grant limited extensions of the time for providers and entities to connect to the HIE Network and begin submitting data as required by this section upon the request of a provider or entity that demonstrates an ongoing good-faith effort to take necessary steps to establish such connection and begin data submission as required by this section. The process for granting an extension of time must include a presentation by the provider or entity to the Department of Information Technology, the Department of Health and Human Services, and the State Health Plan for Teachers and State Employees on the expected time line for connecting to the HIE Network and commencing data submission as required by this section. Neither the Department of Information Technology, the Department of Health and Human Services nor the State Health Plan for Teachers and State Employees shall grant an extension of time (i) to any provider or entity that fails to provide this information to both Departments, and the State Health Plan for Teachers and State Employees, (ii) that would result in the provider or entity connecting to the HIE Network and commencing data submission as required by this section later than January 1, 2023. The Department of Information Technology shall consult with the Department of Health and Human Services and the State Health Plan for Teachers and State Employees to review and decide upon a request for an extension of time under this section within 30 days after receiving a request for an extension.

(a3) Exemptions from Connecting to the HIE Network. – The Secretary of Health and Human Services, or the Secretary's designee, shall have the authority to grant exemptions to classes of providers of Medicaid and other State-funded health care services for whom acquiring and implementing an electronic health record system and

connecting to the HIE Network as required by this section would constitute an undue hardship. The Secretary, or the Secretary's designee, shall promptly notify the Department of Information Technology of classes of providers granted hardship exemptions under this subsection. Neither the Secretary nor the Secretary's designee shall grant any hardship exemption that would result in any class of provider connecting to the HIE Network and submitting data later than December 31, 2022.

(b) **Mandatory Submission of Demographic and Clinical Data.** – Notwithstanding the voluntary nature of the HIE Network under G.S. 90-414.2 and, except as otherwise provided in subsection (c) of this section, as a condition of receiving State funds, including Medicaid funds, the following entities shall submit at least twice daily, through the HIE network, demographic and clinical information pertaining to services rendered to Medicaid and other State-funded health care program beneficiaries and paid for with Medicaid or other State-funded health care funds, solely for the purposes set forth in subsection (a) of this section:

- (1) Each hospital, as defined in G.S. 131E-176(13) that has an electronic health record system.
- (2) Each Medicaid provider, unless the provider is an ambulatory surgical center as defined in G.S. 131E-146, however, a physician who performs a procedure at the ambulatory surgical center must be connected to the HIE Network.
- (3) Each provider that receives State funds for the provision of health services, unless the provider is an ambulatory surgical center as defined in G.S. 131E-146, however, a physician who performs a procedure at the ambulatory surgical center must be connected to the HIE Network.
- (4) Each local management entity/managed care organization, as defined in G.S. 122C-3.

(b1) **Balance Billing Prohibition.** – An in-network provider or entity who renders health care services, including prescription drugs and durable medical equipment, under a contract with the State Health Plan for Teachers and State Employees and who is not connected to the HIE Network in accordance with this Article, is prohibited from billing the State Health Plan or a Plan member more than either party would be billed if the entity or provider was connected to the HIE Network. Balance billing because the provider or entity did not connect to the HIE Network is prohibited.

(c) **Exemption for Certain Records.** – Providers with patient records that are subject to the disclosure restrictions of 42 C.F.R. § 2 are exempt from the requirements of subsection (b) of this section but only with respect to the patient records subject to these disclosure restrictions. Providers shall comply with the requirements of subsection (b) of this section with respect to all other patient records. A pharmacy shall only be required to submit claims data pertaining to services rendered to Medicaid and other State-funded health care program beneficiaries and paid for with Medicaid or other State-funded health care funds.

(c1) **Exemption from Twice Daily Submission.** – A pharmacy shall only be required to submit claims data once daily through the HIE Network using pharmacy industry standardized formats.

(d) **Method of Data Submissions.** – The data submissions required under this section shall be by connection to the HIE Network periodic asynchronous secure structured file transfer or any other secure electronic means commonly used in the industry and consistent with document exchange and data submission standards established by the Office of the National Coordinator for Information Technology within the U.S. Department of Health and Human Services.

(e) **Voluntary Connection for Certain Providers.** – Notwithstanding the mandatory connection and data submission requirements in subsections (a1) and (b) of this section, the following providers of Medicaid services or other State-funded health care services are not required to connect to the HIE Network or submit data but may connect to the HIE Network and submit data voluntarily:

- (1) Community-based long-term services and supports providers, including personal care services, private duty nursing, home health, and hospice care providers.
- (2) Intellectual and developmental disability services and supports providers, such as day supports and supported living providers.
- (3) Community Alternatives Program waiver services (including CAP/DA, CAP/C, and Innovations) providers.
- ...
- (7) Durable medical equipment providers.
- ...
- (10) Local education agencies and school-based health providers.
- ...



(f) Confidentiality of Data. – All data submitted to or through the HIE Network containing protected health information, personally identifying information, or a combination of these, that are in the possession of the Department of Information Technology or any other agency of the State are confidential and shall not be defined as public records under G.S. 132-1. This subsection shall not be construed to prohibit the disclosure of any such data as otherwise permitted under federal law.

Session Law 2022-74 provides: “Notwithstanding any provision of Article 29B of Chapter 90 of the General Statutes or any other provision of law to the contrary, connecting to and submitting data through the HIE Network known as NC HealthConnex shall not be a condition precedent to the receipt of State funds, including Medicaid funds, by any provider or entity subject to subsection (b) of G.S. 90-414.4 until a bill designating a lead agency responsible for enforcement of the Statewide Health Information Exchange Act is enacted into law.”

**§ 90-414.5. State agency and legislative access to HIE Network data.**

(a) The Authority shall provide the Department and the State Health Plan for Teachers and State Employees secure, real-time access to data and information disclosed through the HIE Network, solely for the purposes set forth in G.S. 90-414.4(a) and in G.S. 90-414.2. The Authority shall limit access granted to the State Health Plan for Teachers and State Employees pursuant to this section to data and information disclosed through the HIE Network that pertains to services (i) rendered to teachers and State employees and (ii) paid for by the State Health Plan.

(b) At the written request of the Director of the Fiscal Research, Bill Drafting, Research, or Program Evaluation Division of the General Assembly for an aggregate analysis of the data and information disclosed through the HIE Network, the Authority shall provide the professional staff of these Divisions with such aggregated analysis responsive to the Director's request. Prior to providing the Director or General Assembly's staff with any aggregate data or information submitted through the HIE Network or with any analysis of this aggregate data or information, the Authority shall redact any personal identifying information in a manner consistent with the standards specified for de-identification of health information under the HIPAA Privacy Rule, 45 C.F.R. § 164.514, as amended.

**§ 90-414.6. State ownership of HIE Network data.**

Any data pertaining to services rendered to Medicaid and other State-funded health care program beneficiaries submitted through and stored by the HIE Network pursuant to G.S. 90-414.4 or any other provision of this Article shall be and will remain the sole property of the State. Any data or product derived from the aggregated, de-identified data submitted to and stored by the HIE Network pursuant to G.S. 90-414.4 or any other provision of this Article, shall be and will remain the sole property of the State. The Authority shall not allow data it receives pursuant to G.S. 90-414.4 or any other provision of this Article to be used or disclosed by or to any person or entity for commercial purposes or for any other purpose other than those set forth in G.S. 90-414.4(a) or G.S. 90-414.2. To the extent the Authority receives requests for electronic health information as the term is defined in 45 C.F.R. § 171.102, or other medical records from an individual, an individual's personal representative, or an individual or entity purporting to act on an individual's behalf, the Authority (i) shall not fulfill the request and (ii) shall make available to the requester and the public, via the Authority's website, educational materials about how to access such information from other sources. Patient identifiers created and utilized by the Authority to integrate identity data in the HIE Network, along with the minimum necessary required demographic information related to those patients, shall be released to the GDAC and the Department by the Authority for purposes of entity resolution and master data management. These identifiers shall not be considered public records pursuant to Chapter 132 of the General Statutes.

**§ 90-414.7. North Carolina Health Information Exchange Authority.**

(a) Creation. – There is hereby established the North Carolina Health Information Exchange Authority to oversee and administer the HIE Network in accordance with this Article. The Authority shall be located within the Department of Information Technology and shall be under the supervision, direction, and control of the State CIO. The State CIO shall employ an Authority Director and may delegate to the Authority Director all powers and duties associated with the daily operation of the Authority, its staff, and the performance of the powers and duties set forth in subsection (b) of this section. In making this delegation, however, the State CIO maintains the responsibility for the performance of these powers and duties.

(b) Powers and Duties. – The Authority has the following powers and duties:

- (1) Oversee and administer the HIE Network in a manner that ensures all of the following:
  - a. Compliance with this Article.

- b. Compliance with HIPAA and any rules adopted under HIPAA, including the Privacy Rule and Security Rule.
  - c. Compliance with the terms of any participation agreement, business associate agreement, or other agreement the Authority or qualified organization or other person or entity enters into with a covered entity participating in submission of data through or accessing the HIE Network.
  - d. Notice to the patient by the healthcare provider or other person or entity about the HIE Network, including information and education about the right of individuals on a continuing basis to opt out or rescind a decision to opt out.
  - e. Opportunity for all individuals whose data has been submitted to the HIE Network to exercise on a continuing basis the right to opt out or rescind a decision to opt out.
  - f. Nondiscriminatory treatment by covered entities of individuals who exercise the right to opt out.
  - g. Facilitation of HIE Network interoperability with electronic health record systems of all covered entities listed in G.S. 90-414.4(b).
  - h. Minimization of the amount of data required to be submitted under G.S. 90-414.4(b) and any use or disclosure of such data to what is determined by the Authority to be required in order to advance the purposes set forth in G.S. 90-414.2 and G.S. 90-414.4(a).
- (2) In consultation with the Advisory Board, set guiding principles for the development, implementation, and operation of the HIE Network.
  - (3) Employ staff necessary to carry out the provisions of this Article and determine the compensation, duties, and other terms and conditions of employment of hired staff.
  - (4) Enter into contracts pertaining to the oversight and administration of the HIE Network, including contracts of a consulting or advisory nature. G.S. 143-64.20 does not apply to this subdivision.
  - (5) Establish fees for participation in the HIE Network and report the established fees to the General Assembly, with an explanation of the fee determination process.
  - (6) Following consultation with the Advisory Board, develop, approve, and enter into, directly or through qualified organizations acting under the authority of the Authority, written participation agreements with persons or entities that participate in or are granted access or user rights to the HIE Network. The participation agreements shall set forth terms and conditions governing participation in, access to, or use of the HIE Network not less than those set forth in agreements already governing covered entities' participation in the federal eHealth Exchange. The agreement shall also require compliance with policies developed by the Authority pursuant to this Article or pursuant to applicable laws of the state of residence for entities located outside of North Carolina.
  - (7) Receive, access, add, and remove data submitted through and stored by the HIE Network in accordance with this Article.
  - (8) Following consultation with the Advisory Board, enter into, directly or through qualified organizations acting under the authority of the Authority, a HIPAA compliant business associate agreement with each of the persons or entities participating in or granted access or user rights to the HIE Network.
  - (9) Following consultation with the Advisory Board, grant user rights to the HIE Network to business associates of covered entities participating in the HIE Network (i) at the request of the covered entities and (ii) at the discretion of and subject to contractual, policy, and other requirements of the Authority upon consideration of and consistent with the business associates' legitimate need for utilizing the HIE Network and privacy and security concerns.
  - (10) Facilitate and promote use of the HIE Network by covered entities.
  - (11) Actively monitor compliance with this Article by the Department, covered entities, and any other persons or entities participating in or granted access or user rights to the HIE Network or any data submitted through or stored by the HIE Network.
  - (12) Collaborate with the State CIO to ensure that resources available through the GDAC are properly leveraged, assigned, or deployed to support the work of the Authority. The duty to collaborate under this subdivision includes collaboration on data hosting and development, implementation, operation, and maintenance of the HIE Network.

- (13) Initiate or direct expansion of existing public-private partnerships within the GDAC as necessary to meet the requirements, duties, and obligations of the Authority. Notwithstanding any other provision of law and subject to the availability of funds, the State CIO, at the request of the Authority, shall assist and facilitate expansion of existing contracts related to the HIE Network, provided that such request is made in writing by the Authority to the State CIO with reference to specific requirements set forth in this Article.
- (14) In consultation with the Advisory Board, develop a strategic plan for achieving statewide participation in the HIE Network by all hospitals and health care providers licensed in this State.
- (15) In consultation with the Advisory Board, define the following with respect to operation of the HIE Network:
  - a. Business policy.
  - b. Protocols for data integrity, data sharing, data security, HIPAA compliance, and business intelligence as defined in G.S. 143B-1381. To the extent permitted by HIPAA, protocols for data sharing shall allow for the disclosure of data for academic research.
  - c. Qualitative and quantitative performance measures.
  - d. An operational budget and assumptions.
- (16) Annually report to the Joint Legislative Oversight Committee on Health and Human Services and the Joint Legislative Oversight Committee on Information Technology on the following:
  - a. The operation of the HIE Network.
  - b. Any efforts or progress in expanding participation in the HIE Network.
  - c. Health care trends based on information disclosed through the HIE Network.
- (17) Ensure that the HIE Network interfaces with the federal level HIE, the eHealth Exchange.

**§ 90-414.8. North Carolina Health Information Exchange Advisory Board.**

(a) Creation and Membership. – There is hereby established the North Carolina Health Information Exchange Advisory Board within the Department of Information Technology. The Advisory Board shall consist of the following 12 members:

- (1) The following four members appointed by the President Pro Tempore of the Senate:
  - a. A licensed physician in good standing and actively practicing in this State.
  - b. A patient representative.
  - c. An individual with technical expertise in health data analytics.
  - d. A representative of a behavioral health provider.
- (2) The following four members appointed by the Speaker of the House of Representatives:
  - a. A representative of a critical access hospital.
  - b. A representative of a federally qualified health center.
  - c. An individual with technical expertise in health information technology.
  - d. A representative of a health system or integrated delivery network.
- (3) The following three ex officio, nonvoting members:
  - a. The State Chief Information Officer or a designee.
  - b. The Director of GDAC or a designee.
  - c. The Secretary of Health and Human Services, or a designee.
- (4) The following ex officio, voting member:
  - a. The Executive Administrator of the State Health Plan for Teachers and State Employees, or a designee.

(b) Chairperson. – A chairperson shall be elected from among the members. The chairperson shall organize and direct the work of the Advisory Board.

(c) Administrative Support. – The Department of Information Technology shall provide necessary clerical and administrative support to the Advisory Board.

(d) Meetings. – The Advisory Board shall meet at least quarterly and at the call of the chairperson. A majority of the Advisory Board constitutes a quorum for the transaction of business.

(e) Terms. – In order to stagger terms, in making initial appointments, the President Pro Tempore of the Senate shall designate two of the members appointed under subdivision (1) of subsection (a) of this section to serve for a one-year period from the date of appointment and, the Speaker of the House of Representatives shall designate two members appointed under subdivision (2) of subsection (a) of this section to serve for a one-year period from

the date of appointment. The remaining appointed voting members shall serve two-year periods. Future appointees who are voting members shall serve terms of two years, with staggered terms based on this subsection. Appointed voting members may serve up to two consecutive terms, not including the abbreviated two-year terms that establish staggered terms or terms of less than two years that result from the filling of a vacancy. Ex officio, nonvoting and voting members are not subject to these term limits. A vacancy other than by expiration of a term shall be filled by the appointing authority.

(f) Expenses. – Members of the Advisory Board who are State officers or employees shall receive no compensation for serving on the Advisory Board but may be reimbursed for their expenses in accordance with G.S. 138-6. Members of the Advisory Board who are full-time salaried public officers or employees other than State officers or employees shall receive no compensation for serving on the Advisory Board but may be reimbursed for their expenses in accordance with G.S. 138-5(b). All other members of the Advisory Board may receive compensation and reimbursement for expenses in accordance with G.S. 138-5.

(g) Duties. – The Advisory Board shall provide consultation to the Authority with respect to the advancement, administration, and operation of the HIE Network and on matters pertaining to health information technology and exchange, generally. In carrying out its responsibilities, the Advisory Board may form committees of the Advisory Board to examine particular issues related to the advancement, administration, or operation of the HIE Network.

#### **§ 90-414.9. Participation by covered entities.**

(a) Each covered entity that participates in the HIE Network shall enter into a HIPAA compliant business associate agreement described in G.S. 90-414.7(b)(8) and a written participation agreement described in G.S. 90-414.7(b)(6) with the Authority or qualified organization prior to submitting data through or in the HIE Network.

(b) Each covered entity that participates in the HIE Network may authorize its business associates on behalf of the covered entity to submit data through, or access data stored in, the HIE Network in accordance with this Article and at the discretion of the Authority, as provided in G.S. 90-414.7(b)(8).

(c) Notwithstanding any federal or State law or regulation to the contrary, each covered entity that participates in the HIE Network may disclose an individual's protected health information through the HIE Network to other covered entities for any purpose permitted by HIPAA.

#### **§ 90-414.10. Continuing right to opt out; effect of opt out.**

(a) Each individual has the right on a continuing basis to opt out or rescind a decision to opt out.

(b) The Authority or its designee shall enforce an individual's decision to opt out or rescind an opt out prospectively from the date the Authority or its designee receives written notice of the individual's decision to opt out or rescind an opt out in the manner prescribed by the Authority. An individual's decision to opt out or rescind an opt out does not affect any disclosures made by the Authority or covered entities through the HIE Network prior to receipt by the Authority or its designee of the individual's written notice to opt out or rescind an opt out.

(c) A covered entity shall not deny treatment, coverage, or benefits to an individual because of the individual's decision to opt out. However, nothing in this Article is intended to restrict a health care provider from otherwise appropriately terminating a relationship with an individual in accordance with applicable law and professional ethical standards.

(d) Except as otherwise permitted in G.S. 90-414.11(a)(3), or as required by law, the protected health information of an individual who has exercised the right to opt out may not be made accessible or disclosed to covered entities or any other person or entity through the HIE Network for any purpose.

...

#### **§ 90-414.11. Construction and applicability.**

(a) Nothing in this Article shall be construed to do any of the following:

- (1) Impair any rights conferred upon an individual under HIPAA, including all of the following rights related to an individual's protected health information:
  - a. The right to receive a notice of privacy practices.
  - b. The right to request restriction of use and disclosure.
  - c. The right of access to inspect and obtain copies.
  - d. The right to request amendment.
  - e. The right to request confidential forms of communication.
  - f. The right to receive an accounting of disclosures.

- (2) Authorize the disclosure of protected health information through the HIE Network to the extent that the disclosure is restricted by federal laws or regulations, including the federal drug and alcohol confidentiality regulations set forth in 42 C.F.R. Part 2.
- (3) Restrict the disclosure of protected health information through the HIE Network for public health purposes or research purposes, so long as disclosure is permitted by both HIPAA and State law.
- (4) Prohibit the Authority or any covered entity participating in the HIE Network from maintaining in the Authority's or qualified organization's computer system a copy of the protected health information of an individual who has exercised the right to opt out, as long as the Authority or the qualified organization does not access, use, or disclose the individual's protected health information for any purpose other than for necessary system maintenance or as required by federal or State law.

(b) This Article applies only to disclosures of protected health information made through the HIE Network, including disclosures made within qualified organizations. It does not apply to the use or disclosure of protected health information in any context outside of the HIE Network, including the redisclosure of protected health information obtained through the HIE Network.

**§ 90-414.12. Penalties and remedies; immunity for covered entities and business associates for good faith participation.**

(a) Except as provided in subsection (b) of this section, a covered entity that discloses protected health information in violation of this Article is subject to the following:

- (1) Any civil penalty or criminal penalty, or both, that may be imposed on the covered entity pursuant to the Health Information Technology for Economic and Clinical Health (HITECH) Act, P.L. 111-5, Div. A, Title XIII, section 13001, as amended, and any regulations adopted under the HITECH Act.
- (2) Any civil remedy under the HITECH Act or any regulations adopted under the HITECH Act that is available to the Attorney General or to an individual who has been harmed by a violation of this Article, including damages, penalties, attorneys' fees, and costs.
- (3) Disciplinary action by the respective licensing board or regulatory agency with jurisdiction over the covered entity.
- (4) Any penalty authorized under Article 2A of Chapter 75 of the General Statutes if the violation of this Article is also a violation of Article 2A of Chapter 75 of the General Statutes.
- (5) Any other civil or administrative remedy available to a plaintiff by State or federal law or equity.

(b) To the extent permitted under or consistent with federal law, a covered entity or its business associate that in good faith submits data through, accesses, uses, discloses, or relies upon data submitted through the HIE Network shall not be subject to criminal prosecution or civil liability for damages caused by such submission, access, use, disclosure, or reliance.

**Article 37.**

**Health Care Practitioner Identification.**

**§ 90-640. Identification badges required.**

(a) For purposes of this section, "health care practitioner" means an individual who is licensed, certified, or registered to engage in the practice of medicine, nursing, dentistry, pharmacy, or any related occupation involving the direct provision of health care to patients.

(b) When providing health care to a patient, a health care practitioner shall wear a badge or other form of identification displaying in readily visible type the individual's name and the license, certification, or registration held by the practitioner. If the identity of the individual's license, certification, or registration is commonly expressed by an abbreviation rather than by full title, that abbreviation may be used on the badge or other identification.

(c) The badge or other form of identification is not required to be worn if the patient is being seen in the health care practitioner's office and, the name and license of the practitioner can be readily determined by the patient from a posted license, a sign in the office, a brochure provided to patients, or otherwise.

(d) Each licensing board or other regulatory authority for health care practitioners may adopt rules for exemptions from wearing a badge or other form of identification, or for allowing use of the practitioner's first name only, when necessary for the health care practitioner's safety or for therapeutic concerns.

(e) Violation of this section is a ground for disciplinary action against the health care practitioner by the practitioner's licensing board or other regulatory authority.

**CHAPTER 14  
CRIMINAL LAW**

***SELECTED PROVISIONS***

\* \* \* \* \*

**§ 14-18.4. Death by distribution of certain controlled substances; aggravated death by distribution of certain controlled substances; penalties.**

(a) Legislative Intent. – The General Assembly recognizes that deaths due to the opioid epidemic are devastating families and communities across North Carolina. The General Assembly finds that the opioid crisis is overwhelming medical providers engaged in the lawful distribution of controlled substances and is straining prevention and treatment efforts. Therefore, the General Assembly enacts this law to encourage effective intervention by the criminal justice system to hold illegal drug dealers accountable for criminal conduct that results in death.

(a1) Death by Distribution Through Unlawful Delivery of Certain Controlled Substances. – A person is guilty of death by distribution through unlawful delivery of certain controlled substances if all of the following requirements are met:

- (1) The person unlawfully delivers at least one certain controlled substance.
- (2) The ingestion of the certain controlled substance or substances causes the death of the user.
- (3) The commission of the offense in subdivision (1) of this subsection was the proximate cause of the victim's death.

(a2) Death by Distribution Through Unlawful Delivery with Malice of Certain Controlled Substances. – A person is guilty of death by distribution through unlawful delivery with malice of certain controlled substances if all of the following requirements are met:

- (1) The person unlawfully delivers at least one certain controlled substance.
- (2) The person acted with malice.
- (3) The ingestion of the certain controlled substance or substances causes the death of the user.
- (4) The commission of the offense in subdivision (1) of this subsection was the proximate cause of the victim's death.

(b) Death by Distribution Through Unlawful Sale of Certain Controlled Substances. – A person is guilty of death by distribution through unlawful sale of certain controlled substances if all of the following requirements are met:

- (1) The person unlawfully sells at least one certain controlled substance.
- (2) The ingestion of the certain controlled substance or substances causes the death of the user.
- (3) The commission of the offense in subdivision (1) of this subsection was the proximate cause of the victim's death.

(c) Aggravated Death by Distribution Through Unlawful Sale of Certain Controlled Substances. – A person is guilty of aggravated death by distribution through unlawful sale of certain controlled substances if all of the following requirements are met:

- (1) The person unlawfully sells at least one certain controlled substance.
- (2) The ingestion of the certain controlled substance or substances causes the death of the user.
- (3) The commission of the offense in subdivision (1) of this subsection was the proximate cause of the victim's death.
- (4) Repealed.
- (5) The person has a previous conviction under this section, G.S. 90-95(a)(1), 90-95.1, 90-95.4, 90-95.6, or trafficking in violation of G.S. 90-95(h), or a prior conviction in any federal or state court in the United States that is substantially similar to an offense listed, within 10 years of the date of the offense. In calculating the 10-year period under this subdivision, any period of time during which the person was incarcerated in a local, state, or federal detention center, jail, or prison shall be excluded.

(d) Certain Controlled Substance. – For the purposes of this section, the term "certain controlled substance" includes any opium, opiate, or opioid; any synthetic or natural salt, compound, derivative, or preparation of opium, opiate, or opioid; cocaine or any other substance described in G.S. 90-90(1)(d); methamphetamine; a depressant described in G.S. 90-92(a)(1); or a mixture of one or more of these substances.

(e) Lesser Included Offense. – Death by distribution of through unlawful sale of certain controlled substances constitutes a lesser included offense of aggravated death by distribution through unlawful sale of certain controlled substances in violation of this section.

(f) Samaritan Protection. – Nothing in this section shall be construed to restrict or interfere with the rights and immunities provided under G.S. 90-96.2.

(g) Lawful Distribution. – This section shall not apply to any of the following:

- (1) Issuing a valid prescription for a controlled substance for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.
- (2) Dispensing, delivering, or administering a controlled substance pursuant to a prescription, by a pharmacy permitted under G.S. 90-85.21, a pharmacist, or an individual practitioner.

(h) Penalties. – Unless the conduct is covered under some other provision of law providing greater punishment, the following classifications apply to the offenses set forth in this section:

- (1) A violation of subsection (a1) of this section is a Class C felony.
- (2) A violation of subsection (c) of this section is a Class B1 felony.

...

#### **§ 14-44.1. Providing or advertising abortion-inducing drugs to pregnant woman.**

(a) Offense. – All of the following are unlawful:

- (1) For any individual within the State, including a physician, an employee or contractor of a physician's office or clinic, or other abortion provider, or organization within the State, including a physician's office or clinic or other abortion provider, to mail, provide, or supply an abortion-inducing drug directly to a pregnant woman in violation of G.S. 90-21.83A(b)(2)a. Lack of knowledge or intent that the abortion-inducing drug will be administered outside the physical presence of a physician shall not be a defense to a violation of this subdivision.
- (2) For any manufacturer or supplier of an abortion-inducing drug to ship or cause to be shipped any abortion-inducing drug directly to a pregnant woman in violation of G.S. 90-21.83A(b)(2)a. Lack of knowledge or intent that the abortion-inducing drug will be administered outside the physical presence of a physician shall not be a defense to a violation of this subdivision.
- (3) For any individual or organization to purchase or otherwise procure an advertisement, host or maintain an internet website, or provide an internet service purposefully directed to a pregnant woman who is a resident of this State when the individual or organization knows that the purpose of the advertisement, website, or internet service is solely to promote the sale of an abortion-inducing drug to be administered to a woman in violation of G.S. 90-21.83A(b)(2)a.

...

(c) Definitions. – The following definitions apply in this section:

- (1) Abortion-inducing drug. – As defined in G.S. 90-21.81(1a).
- (2) Organization. – As defined in G.S. 15A-773(c).

#### **§ 14-234. Public officers or employees benefiting from public contracts; exceptions.**

- (a)
  - (1) No public officer or employee who is involved in making or administering a contract on behalf of a public agency may derive a direct benefit from the contract except as provided in this section, or as otherwise allowed by law.
  - (2) A public officer or employee who will derive a direct benefit from a contract with the public agency he or she serves, but who is not involved in making or administering the contract, shall not attempt to influence any other person who is involved in making or administering the contract.
  - (3) No public officer or employee may solicit or receive any gift, favor, reward, service, or promise of reward, including a promise of future employment, in exchange for recommending, influencing, or attempting to influence the award of a contract by the public agency he or she serves.

(a1) For purposes of this section:



- (1) As used in this section, the term "public officer" means an individual who is elected or appointed to serve or represent a public agency, other than an employee or independent contractor of a public agency.
  - (2) A public officer or employee is involved in administering a contract if he or she oversees the performance of the contract or has authority to make decisions regarding the contract or to interpret the contract.
  - (3) A public officer or employee is involved in making a contract if he or she participates in the development of specifications or terms or in the preparation or award of the contract. A public officer is also involved in making a contract if the board, commission, or other body of which he or she is a member takes action on the contract, whether or not the public officer actually participates in that action, unless the contract is approved under an exception to this section under which the public officer is allowed to benefit and is prohibited from voting.
  - (4) A public officer or employee derives a direct benefit from a contract if the person or his or her spouse: (i) has more than a ten percent (10%) ownership or other interest in an entity that is a party to the contract; (ii) derives any income or commission directly from the contract; or (iii) acquires property under the contract.
  - (5) A public officer or employee is not involved in making or administering a contract solely because of the performance of ministerial duties related to the contract.
- (b) Subdivision (a)(1) of this section does not apply to any of the following:
- (1) Any contract between a public agency and a bank, banking institution, savings and loan association, or with a public utility regulated under the provisions of Chapter 62 of the General Statutes.
  - (2) An interest in property conveyed by an officer or employee of a public agency under a judgment, including a consent judgment, entered by a superior court judge in a condemnation proceeding initiated by the public agency.
  - (3) Any employment relationship between a public agency and the spouse of a public officer of the agency.
  - (3a) Any employment relationship between a local board of education and the spouse of the superintendent of that local school administrative unit, if that employment relationship has been approved by that board in an open session meeting pursuant to the board's policy adopted as provided in G.S. 115C-47(17a).
  - (4) Remuneration from a public agency for services, facilities, or supplies furnished directly to needy individuals by a public officer or employee of the agency under any program of direct public assistance being rendered under the laws of this State or the United States to needy persons administered in whole or in part by the agency if: (i) the programs of public assistance to needy persons are open to general participation on a nondiscriminatory basis to the practitioners of any given profession, professions or occupation; (ii) neither the agency nor any of its employees or agents, have control over who, among licensed or qualified providers, shall be selected by the beneficiaries of the assistance; (iii) the remuneration for the services, facilities or supplies are in the same amount as would be paid to any other provider; and (iv) although the public officer or employee may participate in making determinations of eligibility of needy persons to receive the assistance, he or she takes no part in approving his or her own bill or claim for remuneration.
- (b1) No public officer who will derive a direct benefit from a contract entered into under subsection (b) of this section may deliberate or vote on the contract or attempt to influence any other person who is involved in making or administering the contract.
- ...
- (d1) Subdivision (a)(1) of this section does not apply to . . . (v) any physician, pharmacist, dentist, optometrist, veterinarian, or nurse appointed to a county social services board, local health board, or area mental health, developmental disabilities, and substance use board serving one or more counties within which there is located no village, town, or city with a population of more than 20,000 according to the most recent official federal census .
- ..
- (d2) Subsection (d1) of this section does not apply to contracts that are subject to Article 8 of Chapter 143 of the General Statutes, Public Building Contracts.
- ...

(f) A contract entered into in violation of this section is void. A contract that is void under this section may continue in effect until an alternative can be arranged when: (i) immediate termination would result in harm to the public health or welfare, and (ii) the continuation is approved as provided in this subsection. A public agency that is a party to the contract may request approval to continue contracts under this subsection as follows:

(1) Local governments, as defined in G.S. 159-7(15), public authorities, as defined in G.S. 159-7(10), local school administrative units, and community colleges may request approval from the chair of the Local Government Commission.

(2) All other public agencies may request approval from the State Director of the Budget.

Approval of continuation of contracts under this subsection shall be given for the minimum period necessary to protect the public health or welfare.

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**CHAPTER 15  
CRIMINAL PROCEDURE**

**Article 19.  
Execution.**

*Selected Provisions*

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**§ 15-187. Death by administration of lethal drugs.**

Death by electrocution under sentence of law and death by the administration of lethal gas under sentence of law are abolished. Any person convicted of a criminal offense and sentenced to death shall be executed in accordance with G.S. 15-188 and the remainder of this Article. The warden of Central Prison may obtain and employ the drugs necessary to carry out the provisions of this Article, regardless of contrary provisions in Chapter 90 of the General Statutes.

\* \* \* \* \*

**§ 15-188.1. Health care professional assistance.**

(a) Any assistance rendered with an execution under this Article by any licensed health care professional, including, but not limited to, physicians, nurses, and pharmacists, shall not be cause for any disciplinary or corrective measures by any board, commission, or other authority created by the State or governed by State law which oversees or regulates the practice of health care professionals, including, but not limited to, the North Carolina Medical Board, the North Carolina Board of Nursing, and the North Carolina Board of Pharmacy.

(b) The infliction of the punishment of death by administration of the required lethal substances under this Article shall not be construed to be the practice of medicine.

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**CHAPTER 58  
INSURANCE**

***SELECTED PROVISIONS***

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**§ 58-1-5. Definitions.**

In this Chapter, unless the context clearly requires otherwise:

- ...
- (2) "Commissioner" means the Commissioner of Insurance of North Carolina or an authorized designee of the Commissioner.
  - (3) "Company" or "insurance company" or "insurer" includes any corporation, association, partnership, society, order, individual or aggregation of individuals engaging or proposing or attempting to engage as principals in any kind of insurance business, including the exchanging of reciprocal or interinsurance contracts between individuals, partnerships and corporations. "Company" or "insurance company" or "insurer" does not mean the State of North Carolina or any county, city, or other political subdivision of the State of North Carolina.
  - (4) "Department" means the Department of Insurance of North Carolina.

...

  - (9) "Person" means an individual, partnership, firm, association, corporation, joint-stock company, trust, any similar entity, or any combination of the foregoing acting in concert.
  - (10) The singular form includes the plural, and the masculine form includes the feminine wherever appropriate.

\* \* \* \* \*

**§ 58-2-161. False statement to procure or deny benefit of insurance policy or certificate.**

(a) Definitions. - For the purposes of this section:

- (1) "Insurer" has the same meaning as in G.S. 58-1-5(3) and also includes:
  - a. Any hull insurance and protection and indemnity club operating under Article 20 of this Chapter.
  - b. Any surplus lines insurer operating under Article 21 of this Chapter.
  - c. Any risk retention group or purchasing group operating under Article 22 of this Chapter.
  - d. Any local government risk pool operating under Article 23 of this Chapter.
  - e. Any risk-sharing plan operating under Article 42 of this Chapter.
  - f. The North Carolina Insurance Underwriting Association operating under Article 45 of this Chapter.
  - g. The North Carolina Joint Insurance Underwriting Association operating under Article 46 of this Chapter.
  - h. The North Carolina Insurance Guaranty Association operating under Article 48 of this Chapter.
  - i. Any multiple employer welfare arrangement operating under Article 49 of this Chapter.
  - j. The North Carolina Life and Health Insurance Guaranty Association operating under Article 62 of this Chapter.
  - k. Any service corporation operating under Article 65 of this Chapter.
  - l. Any health maintenance organization operating under Article 67 of this Chapter.
  - m. The State Health Plan for Teachers and State Employees and any optional plans or programs operating under Part 2 of Article 3 of Chapter 135 of the General Statutes.
  - n. A group of employers self-insuring their workers' compensation liabilities under Article 47 of this Chapter.
  - o. An employer self-insuring its workers' compensation liabilities under Article 5 of Chapter 97 of the General Statutes.

- p. The North Carolina Self-Insurance Security Association under Article 4 of Chapter 97 of the General Statutes.
- q. Any reinsurer licensed or accredited under this Chapter.
- (2) "Statement" includes any application, notice, statement, proof of loss, bill of lading, receipt for payment, invoice, account, estimate of property damages, bill for services, diagnosis, prescription, hospital or doctor records, X rays, test result, or other evidence of loss, injury, or expense.
- (b) Prohibited Act. – It is unlawful for a person to, with the intent to injure, defraud, or deceive an insurer or insurance claimant, do either of the following:
  - (1) Present or cause to be presented a written or oral statement, including computer-generated documents as part of, in support of, or in opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains false or misleading information concerning any fact or matter material to the claim.
  - (2) Assist, abet, solicit, or conspire with another person to prepare or make any written or oral statement that is intended to be presented to an insurer or insurance claimant in connection with, in support of, or in opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains false or misleading information concerning a fact or matter material to the claim. Each claim shall be considered a separate count. Upon conviction, if the court imposes probation, the court may order the defendant to pay restitution as a condition of probation. In determination of the amount of restitution pursuant to G.S. 15A-1343(d), the reasonable costs and attorneys' fees incurred by the victim in the investigation of, and efforts to recover damages arising from, the claim, may be considered part of the damage caused by the defendant arising out of the offense.

In a civil cause of action for recovery based upon a claim for which a defendant has been convicted under this section, the conviction may be entered into evidence against the defendant. The court may award the prevailing party compensatory damages, attorneys' fees, costs, and reasonable investigative costs. If the prevailing party can demonstrate that the defendant has engaged in a pattern of violations of this section, the court may award treble damages.

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**Article 3.  
General Regulations for Insurance.**

*Selected Provisions*

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**§ 58-3-177. Uniform prescription drug identification cards.**

(a) Every health benefit plan that provides coverage for prescription drugs or devices and that issues a prescription drug card, shall issue to its insureds a uniform prescription drug identification card. The uniform prescription drug identification card shall contain the information listed in subdivisions (1) through (7) of this subsection in the following order beginning at the top left margin of the card:

- (1) The health benefit plan's name and/or logo.
- (2) The American National Standards Institute assigned Issuer Identification Number.
- (3) The processor control number.
- (4) The insured's group number.
- (5) The health benefit plan's card issuer identifier.
- (6) The insured's identification number.
- (7) The insured's name.

(b) In addition to the information required under subsection (a), the uniform prescription drug card shall contain, in one of the lower-most elements on the back side of the card, the following information:

- (1) The health benefit plan's claims submission name and address.
- (2) The health benefit plan's help desk telephone number and name.

Nothing in this section shall require a health benefit plan to violate a contractual agreement, service mark agreement, or trademark agreement.

(c) A new uniform prescription drug identification card as required under subsection (a) of this section shall be issued annually by a health benefit plan if there has been any change in the insured's coverage in the previous 12 months. A change in the insured's coverage shall include, but is not limited to, the addition or deletion of a dependent of the insured covered by a health benefit plan.

(d) Not later than January 1, 2003, the uniform prescription drug identification card provided under subsection (a) of this section shall contain one of the following mediums capable of the processing or adjudicating of a claim through electronic verification:

- (1) A magnetic strip.
- (2) A bar code.
- (3) Any new technology available that is capable of processing or adjudicating a claim by electronic verification.

(e) As used in this section, "health benefit plan" means an accident and health insurance policy or certificate; a nonprofit hospital or medical service corporation contract; a health maintenance organization subscriber contract; a plan provided by a multiple employer welfare arrangement; or a plan provided by another benefit arrangement, to the extent permitted by the Employee Retirement Income Security Act of 1974, as amended, or by any waiver of or other exception to that Act provided under federal law or regulation. "Health benefit plan" does not mean any of the following kinds of insurance:

- (1) Accident.
- (2) Credit.
- (3) Disability income.
- (4) Long-term or nursing home care.
- (5) Medicare supplement.
- (6) Specified disease.
- (7) Dental or vision.
- (8) Coverage issued as a supplement to liability insurance.
- (9) Workers' compensation.
- (10) Medical payments under automobile or homeowners.
- (11) Insurance under which benefits are payable with or without regard to fault and that is statutorily required to be contained in any liability policy or equivalent self-insurance.
- (12) Hospital income or indemnity.

(f) This section shall not apply to an entity that has its own facility and employs or contracts with physicians, pharmacists, nurses, and other health care personnel, to the extent that the entity dispenses prescription drugs or devices from its own pharmacies to its employees and to enrollees of its health benefit plan. This section does not apply to a health benefit plan that issues a single identification card to its insureds for all services covered under the plan.

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**§ 58-3-228. Coverage for extra prescriptions during a state of emergency or disaster.**

(a) All health benefit plans as defined in G.S. 58-3-167, the State Health Plan for Teachers and State Employees, and any optional plans or programs operating under Part 2 of Article 3 of Chapter 135 of the General Statutes, and other stand-alone prescription medication plans issued by entities that are licensed by the Department shall have, when an event described in subdivision (b)(1) of this section occurs and the requirements of subdivisions (b)(2) and (b)(3) of this section are satisfied, a procedure in place to waive time restrictions on filling or refilling prescriptions for medication if requested by the covered person or subscriber. The procedure shall include waiver or override of electronic "refill too soon" edits to pharmacies and shall include provision for payment to the pharmacy in accordance with the prescription benefit plan and applicable pharmacy provider agreement. The procedure shall enable covered persons or subscribers to:

- (1) Obtain one refill on a prescription if there are authorized refills remaining, or
- (2) Fill one replacement prescription for one that was recently filled, as prescribed or approved by the prescriber of the prescription that is being replaced and not contrary to the dispensing authority of the dispensing pharmacy.

(b) All entities subject to this section shall authorize payment to pharmacies for any prescription dispensed in accordance with subsection (a) of this section regardless of the date upon which the prescription had most recently been filled by a pharmacist, if all of the following conditions apply:

- (1) The Commissioner issues a Bulletin Advisory notifying all insurance carriers licensed in this State of a declared state of disaster or state of emergency in North Carolina. The Department shall provide a copy of the Bulletin to the North Carolina Board of Pharmacy.
- (2) The covered person requesting coverage of the refill or replacement prescription resides in a county that:
  - a. Is covered under a state of emergency issued by the Governor or General Assembly under G.S. 166A-19.20, or a declaration of major disaster issued by the President of the United States under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. § 5121, et seq., as amended; . . .
- (3) The prescription medication is requested within 29 days after the origination date of the conditions stated in subdivision (b)(1) of this section.

(c) The time period for the waiver of prescription medication refills may be extended in 30-day increments by an order issued by the Commissioner. Additional refills still remaining on a prescription shall be covered by the insurer as long as consistent with the orders of the prescriber or authority of the dispensing pharmacy.

(d) This section does not excuse or exempt an insured or subscriber from any other terms of the policy or certificate providing coverage for prescription medications.

(e) Quantity limitations shall be consistent with the original prescription and the extra or replacement fill may recognize proportionate dosage use prior to the disaster.

(f) No requirements additional to those under the pharmacy provider agreement or the prescription benefit plan may be placed upon the provider for coverage of the replacement fill or extra fill.

(g) Nothing in this section is intended to affect the respective authority or scope of practice of prescribers or pharmacies.

\* \* \* \* \*

**§ 58-50-30. Right to choose services of certain providers.**

...  
(a1) Whenever any health benefit plan, subscriber contract, or policy of insurance issued by a health maintenance organization, hospital or medical service corporation, or insurer governed by Articles 1 through 67 of this Chapter provides for coverage for, payment of, or reimbursement for any service rendered in connection with a condition or complaint that is within the scope of practice of a provider listed in subsection (b) of this section, the insured or other persons entitled to benefits under the policy shall be entitled to coverage of, payment of, or reimbursement for the services, whether the services be performed by a duly licensed physician, or a provider listed in subsection (b) of this section, notwithstanding any provision contained in the plan or policy limiting access to the providers. The policyholder, insured, or beneficiary shall have the right to choose the provider of services notwithstanding any provision to the contrary in any other statute, subject to the utilization review, referral, and prior approval requirements of the plan that apply to all providers for that service; provided that:

- (1) In the case of plans that require the use of network providers as a condition of obtaining benefits under the plan or policy, the policyholder, insured, or beneficiary must choose a provider of the services within the network; and
- (2) In the case of plans that require the use of network providers as a condition of obtaining a higher level of benefits under the plan or policy, the policyholder, insured, or beneficiary must choose a provider of the services within the network in order to obtain the higher level of benefits.

(a2) Whenever any policy of insurance governed by Articles 1 through 64 of this Chapter provides for certification of disability that is within the scope of practice of a provider listed in subsection (b) of this section, the insured or other persons entitled to benefits under the policy shall be entitled to payment of or reimbursement for the disability whether the disability be certified by a duly licensed physician, or a provider listed in subsection (b) of this section, notwithstanding any provisions contained in the policy. The policyholder, insured, or beneficiary shall have the right to choose the provider of the services notwithstanding any provision to the contrary in any other statute; provided that for plans that require the use of network providers either as a condition of obtaining benefits under the plan or policy or to access a higher level of benefits under the plan or policy, the policyholder, insured, or beneficiary must choose a provider of the services within the network, subject to the requirements of the plan or policy.

(a3) Whenever any health benefit plan, subscriber contract, or policy of insurance issued by a health maintenance organization, hospital or medical service corporation, or insurer governed by Articles 1 through 67 of this Chapter provides coverage for medically necessary treatment, the insurer shall not impose any limitation on treatment or levels of coverage if performed by a duly licensed chiropractor acting within the scope of the chiropractor's practice as defined in G.S. 90-151 unless a comparable limitation is imposed on the medically necessary treatment if performed or authorized by any other duly licensed physician.

(b) This section applies to the following provider types:

...

(8) A duly licensed pharmacist, subject to the provisions of subsection (e) of this section.

...

(e) Payment or reimbursement is required by this section for a service performed by a duly licensed pharmacist only when:

- (1) The service performed is within the lawful scope of practice of the pharmacist;
- (2) The service performed is not initial counseling services required under State or federal law or regulation of the North Carolina Board of Pharmacy;
- (3) The policy currently provides reimbursement for identical services performed by other licensed health care providers; and
- (4) The service is identified as a separate service that is performed by other licensed health care providers and is reimbursed by identical payment methods.

Nothing in this subsection authorizes payment to more than one provider for the same service.

...

(g) A health maintenance organization, hospital or medical service corporation, or insurer governed by Articles 1 through 67 of this Chapter shall not exclude from participation in its provider network or from eligibility to provide particular covered services under the plan or policy any duly licensed physician or provider listed in subsection (b) of this section, acting within the scope of the provider's license or certification under North Carolina law, solely on the basis of the provider's license or certification. Any health maintenance organization, hospital or medical service corporation, or insurer governed by Articles 1 through 67 of this Chapter that offers coverage through a network plan may condition participation in the network on satisfying written participation criteria, including credentialing, quality, and accessibility criteria. The participation criteria shall be developed and applied in a like manner consistent with the licensure and scope of practice for each type of provider. Any health maintenance organization, hospital or medical service corporation, or insurer governed by Articles 1 through 67 of this Chapter that excludes a provider listed in subsection (b) of this section from participation in its network or from eligibility to provide particular covered services under the plan or policy shall provide the affected listed provider with a written explanation of the basis for its decision. A health maintenance organization, hospital or medical service corporation, or insurer governed by Articles 1 through 67 of this Chapter shall not exclude from participation in its provider network a provider listed in subsection (b) of this section acting within the scope of the provider's license or certification under North Carolina law solely on the basis that the provider lacks hospital privileges, unless use of hospital services by the provider on behalf of a policy holder, insured, or beneficiary reasonably could be expected.

(h) Nothing in this section shall be construed as expanding the scope of practice of any duly licensed physician or provider listed in subsection (b) of this section.

\* \* \* \* \*

**§ 58-51-37. Pharmacy of choice.**

(a) This section shall apply to all health benefit plans providing pharmaceutical services benefits, including prescription drugs, to any resident of North Carolina. This section shall also apply to insurance companies and health maintenance organizations that provide or administer coverages and benefits for prescription drugs. This section shall apply to pharmacy benefits managers with respect to 340B covered entities and 340B contract pharmacies, as defined in G.S. 58-56A-1. This section shall not apply to any entity that has its own facility, employs or contracts with physicians, pharmacists, nurses, and other health care personnel, and that dispenses prescription drugs from its own pharmacy to its employees and to enrollees of its health benefit plan; provided, however, this section shall apply to an entity otherwise excluded that contracts with an outside pharmacy or group of pharmacies to provide prescription drugs and services. This section shall not apply to any federal program, clinical trial program, hospital or other health care facility licensed pursuant to Chapter 131E or Chapter 122C of the General Statutes, when dispensing prescription drugs to its patients.

(b) As used in this section:



- (1) "Copayment" means a type of cost sharing whereby insured or covered persons pay a specified predetermined amount per unit of service with their insurer paying the remainder of the charge. The copayment is incurred at the time the service is used. The copayment may be a fixed or variable amount.
  - (2) "Contract provider" means a pharmacy granted the right to provide prescription drugs and pharmacy services according to the terms of the insurer.
  - (3) "Health benefit plan" is as that term is defined in G.S. 58-50-110(11).
  - (4) "Insurer" means any entity that provides or offers a health benefit plan.
  - (5) "Pharmacy" means a pharmacy registered with the North Carolina Board of Pharmacy.
- (c) The terms of a health benefit plan shall not:
- (1) Prohibit or limit a resident of this State, who is eligible for reimbursement for pharmacy services as a participant or beneficiary of a health benefit plan, from selecting a pharmacy of his or her choice when the pharmacy has agreed to participate in the health benefit plan according to the terms offered by the insurer;
  - (2) Deny a pharmacy the opportunity to participate as a contract provider under a health benefit plan if the pharmacy agrees to provide pharmacy services that meet the terms and requirements, including terms of reimbursement, of the insurer under a health benefit plan, provided that if the pharmacy is offered the opportunity to participate, it must participate or no provisions of G.S. 58-51-37 shall apply;
  - (3) Impose upon a beneficiary of pharmacy services under a health benefit plan any copayment, fee, or condition that is not equally imposed upon all beneficiaries in the same benefit category, class, or copayment level under the health benefit plan when receiving services from a contract provider;
  - (4) Impose a monetary advantage or penalty under a health benefit plan that would affect a beneficiary's choice of pharmacy. Monetary advantage or penalty includes higher copayment, a reduction in reimbursement for services, or promotion of one participating pharmacy over another by these methods.
  - (5) Reduce allowable reimbursement for pharmacy services to a beneficiary under a health benefit plan because the beneficiary selects a pharmacy of his or her choice, so long as that pharmacy has enrolled with the health benefit plan under the terms offered to all pharmacies in the plan coverage area; or
  - (6) Require a beneficiary, as a condition of payment or reimbursement, to purchase pharmacy services, including prescription drugs, exclusively through a mail-order pharmacy.
- (d) A pharmacy, by or through a pharmacist acting on its behalf as its employee, agent, or owner, may not waive, discount, rebate, or distort a copayment of any insurer, policy, or plan, or a beneficiary's coinsurance portion of a prescription drug coverage or reimbursement and if a pharmacy, by or through a pharmacist's acting on its behalf as its employee, agent or owner, provides a pharmacy service to an enrollee of a health benefit plan that meets the terms and requirements of the insurer under a health benefit plan, the pharmacy shall provide its pharmacy services to all enrollees of that health benefit plan on the same terms and requirements of the insurer. A violation of this subsection shall be a violation of the Pharmacy Practice Act subjecting the pharmacist as a licensee to disciplinary authority of the North Carolina Board of Pharmacy pursuant to G.S. 90-85.38.
- (e) At least 60 days before the effective date of any health benefit plan providing reimbursement to North Carolina residents for prescription drugs, which restricts pharmacy participation, the entity providing the health benefit plan shall notify, in writing, all pharmacies within the geographical coverage area of the health benefit plan, and offer to the pharmacies the opportunity to participate in the health benefit plan. All pharmacies in the geographical coverage area of the plan shall be eligible to participate under identical reimbursement terms for providing pharmacy services, including prescription drugs. The entity providing the health benefit plan shall, through reasonable means, on a timely basis, and on regular intervals in order to effectuate the purposes of this section, inform the beneficiaries of the plan of the names and locations of pharmacies that are participating in the plan as providers of pharmacy services and prescription drugs. Additionally, participating pharmacies shall be entitled to announce their participation to their customers through a means acceptable to the pharmacy and the entity providing the health benefit plans. The pharmacy notification provisions of this section shall not apply when an individual or group is enrolled, but when the plan enters a particular county of the State.
- (f) If rebates or marketing incentives are allowed to pharmacies or other dispensing entities providing services or benefits under a health benefit plan, these rebates or marketing incentives shall be offered on an equal basis to all pharmacies and other dispensing entities providing services or benefits under a health benefit plan when

pharmacy services, including prescription drugs, are purchased in the same volume and under the same terms of payment. Nothing in this section shall prevent a pharmaceutical manufacturer or wholesale distributor of pharmaceutical products from providing special prices, marketing incentives, rebates, or discounts to different purchasers not prohibited by federal and State antitrust laws.

(g) Any entity or insurer providing a health benefit plan is subject to G.S. 58-2-70. A violation of this section shall subject the entity providing a health benefit plan to the sanctions of revocation, suspension, or refusal to renew license in the discretion of the Commissioner pursuant to G.S. 58-3-100.

(h) A violation of this section creates a civil cause of action for damages or injunctive relief in favor of any person or pharmacy aggrieved by the violation.

(i) The Commissioner shall not approve any health benefit plan providing pharmaceutical services which does not conform to this section.

(j) Any provision in a health benefit plan which is executed, delivered, or renewed, or otherwise contracted for in this State that is contrary to any provision of this section shall, to the extent of the conflict, be void.

(k) It shall be a violation of this section for any insurer or any person to provide any health benefit plan providing for pharmaceutical services to residents of this State that does not conform to the provisions of this section.

(l) An insurer's use of a lock-in program developed pursuant G.S. 58-51-37 or G.S. 108A-68.2 is not a violation of this section.

\* \* \* \* \*

## **Article 56A. Pharmacy Benefits Management.**

### **§ 58-56A-1. Definitions.**

The following definitions apply in this Article:

- (1) 340B contract pharmacy. – Any pharmacy under contract with a 340B covered entity to dispense drugs on behalf of the 340B covered entity.
- (2) 340B covered entity. – Any entity defined in 42 U.S.C. § 256b(a)(4)(A), 42 U.S.C. § 256b(a)(4)(C), 42 U.S.C. § 256b(a)(4)(D), 42 U.S.C. § 256b(a)(4)(E), 42 U.S.C. § 256b(a)(4)(I), 42 U.S.C. § 256b(a)(4)(J), 42 U.S.C. § 256b(a)(4)(K), 42 U.S.C. § 256b(a)(4)(N), or 42 U.S.C. § 256b(a)(4)(O).
- (3) Claim. – A request from a pharmacy or pharmacist to be reimbursed for the cost of filling or refilling a prescription for a drug or for providing a medical supply or device.
- (4) Claims processing service. – The administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include either or both of the following activities:
  - a. Receiving payments for pharmacist services.
  - b. Making payments to pharmacists or pharmacies for pharmacist services.
- (5) Health benefit plan. – As defined in G.S. 58-3-167.
- (6) Insured. – An individual covered by a health benefit plan.
- (7) Insurer. – As defined in G.S. 58-3-167.
- (8) Maximum allowable cost list. – A listing of generic or multiple source drugs used by a pharmacy benefits manager to set the maximum allowable cost on which reimbursement of a pharmacy is made.
- (9) Maximum allowable cost price. – The maximum amount that a pharmacy benefits manager will reimburse a pharmacy for the cost of generic or multiple source prescription drugs, medical products, or devices.
- (10) Out-of-pocket costs. – With respect to the acquisition of a drug, the amount to be paid by the insured under the plan or coverage, including any cost-sharing, copayment, coinsurance, or deductible.
- (11) Pharmacist. – A person licensed to practice pharmacy under Article 4A of Chapter 90 of the General Statutes.
- (12) Pharmacist services. – Products, goods, or services provided as a part of the practice of pharmacy.
- (13) Pharmacy. – As defined in G.S. 90-85.3(q).

- (14) Pharmacy benefits manager. – An entity who contracts with a pharmacy on behalf of an insurer or third-party administrator to administer or manage prescription drug benefits to perform any of the following functions:
  - a. Negotiating rebates with manufacturers for drugs paid for or procured as described in this Article.
  - b. Processing claims for prescription drugs or medical supplies or providing retail network management for pharmacies or pharmacists.
  - c. Paying pharmacies or pharmacists for prescription drugs or medical supplies.
- (15) Pharmacy benefits manager affiliate. – A pharmacy or pharmacist that directly or indirectly, through one or more intermediaries, owns or controls or is owned or controlled by a pharmacy benefits manager.
- (16) Pharmacy service administrative organization (PSAO). – An organization that assists community pharmacies and pharmacy benefits managers or third-party payors in achieving administrative efficiencies, including contracting and payment efficiencies.
- (17) Third-party administrator. – As defined in G.S. 58-56-2.

**§ 58-56A-2. Licensure.**

(a) A person or organization may not establish or operate as a pharmacy benefits manager for health benefit plans in this State without obtaining a license from the Commissioner of the Department of Insurance.

(b) The Commissioner shall develop an application for licensure to operate in this State as a pharmacy benefits manager and may charge an initial application fee of two thousand dollars (\$2,000) and an annual renewal fee of one thousand five hundred dollars (\$1,500). The pharmacy benefits manager application form must collect only the following information:

- (1) The name, address, and telephone contact number of the pharmacy benefits manager.
- (2) The name and address of the pharmacy benefits manager's agent for service of process in this State.
- (3) The name and address of each person with management or control over the pharmacy benefits manager.
- (4) The name and address of each person with a beneficial ownership interest in the pharmacy benefits manager.
- (5) Either (i) a signed statement that, to the best of the applicant's knowledge, no officer with management or control of the pharmacy benefits manager has been convicted of a felony or has violated any requirement of State or federal law applicable to pharmacy benefits management or (ii) a description of any felony or any violation of any requirement of State or federal law applicable to pharmacy benefits management committed by any officer with management or control of the pharmacy benefits manager.

(c) Unless otherwise provided for in this Article, an applicant or a pharmacy benefits manager that is licensed to conduct business in the State shall file a notice describing any material modification of the information required under this section.

(d) The Commissioner shall adopt rules establishing the licensing and reporting requirements of pharmacy benefits managers consistent with the provisions of this Article.

**§ 58-56A-3. Consumer protections.**

(a) A pharmacy or pharmacist shall have the right to provide an insured information regarding the amount of the insured's cost share for a prescription drug. Neither a pharmacy nor a pharmacist shall be penalized by a pharmacy benefits manager for discussing any information described in this section or for selling a lower-priced drug to the insured if one is available.

(b) A pharmacy benefits manager shall not, through contract, prohibit a pharmacy from offering and providing direct and limited delivery services to an insured as an ancillary service of the pharmacy, as delineated in the contract between the pharmacy benefits manager and the pharmacy.

(b1) A pharmacy benefits manager shall not prohibit a pharmacist or pharmacy from charging a minimal shipping and handling fee to the insured for a mailed or delivered prescription if the pharmacist or pharmacy discloses all of the following to the insured before delivery:

- (1) The fee will be charged.
- (2) The fee may not be reimbursed by the health benefit plan, insurer, or pharmacy benefits manager.

- (3) The charge is specifically agreed to by the health benefit plan or pharmacy benefits manager.
- (c) A pharmacy benefits manager shall not charge, or attempt to collect from, an insured a copayment that exceeds the total submitted charges by the network pharmacy.
- (c1) When calculating an insured's contribution to any out-of-pocket maximum, deductible, copayment, coinsurance, or other applicable cost-sharing requirement, the insurer or pharmacy benefits manager shall include any amounts paid by the insured, or on the insured's behalf, for a prescription that is either:
- (1) Without an AB-rated generic equivalent.
  - (2) With an AB-rated generic equivalent if the insured has obtained authorization for the drug through any of the following:
    - a. Prior authorization from the insurer or pharmacy benefits manager.
    - b. A step therapy protocol.
    - c. The exception or appeal process of the insurer or pharmacy benefits manager.

This subsection shall not apply to an insured covered by a high deductible health plan, as that term is defined in section 223 of the Internal Revenue Code, if its application would render the insured ineligible for a health savings account under section 223 unless (i) the insured has satisfied the minimum deductible under section 223 or (ii) the prescription qualifies as preventive care under section 223.

(c2) For purposes of this section, the term "generic equivalent" means a drug that has an identical amount of the same active ingredients in the same dosage form; meets applicable standards of strength, quality, and purity according to the United States Pharmacopeia or other nationally recognized compendium; and which, if administered in the same amount, would provide comparable therapeutic effects. The term "generic equivalent" does not include a drug that is listed by the United States Food and Drug Administration as having unresolved bioequivalence concerns according to the Administration's most recent publication of approved drug products with therapeutic equivalence evaluations.

(d) Any contract for the provision of a network to deliver health care services between a pharmacy benefits manager and insurer shall be made available for review by the Department.

#### **§ 58-56A-4. Pharmacy and pharmacist protections.**

(a) A pharmacy benefits manager may only charge fees or otherwise hold a pharmacy responsible for a fee relating to the adjudication of a claim if the fee is reported on the remittance advice of the adjudicated claim or is set out in contract between the pharmacy benefits manager and the pharmacy. No fee or adjustment for the receipt and processing of a claim, or otherwise related to the adjudication of a claim, shall be charged without a justification on the remittance advice or as set out in contract and agreed upon by the pharmacy or pharmacist for each adjustment or fee. This section shall not apply with respect to claims under an employee benefit plan under the Employee Retirement Income Security Act of 1974 or Medicare Part D.

(b) Nothing in this Article shall abridge the right of a pharmacist to refuse to fill or refill a prescription if the pharmacist believes it would be harmful to the patient or is not in the patient's best interest, or if there is a question to the validity of the prescription.

(c) A pharmacy or pharmacist shall not be prohibited by a pharmacy benefits manager from dispensing any prescription drug, including specialty drugs dispensed by a credentialed and accredited pharmacy, allowed to be dispensed under a license to practice pharmacy under Article 4A of Chapter 90 of the General Statutes.

(d) A pharmacy benefits manager shall not penalize or retaliate against a pharmacist or pharmacy for exercising rights provided under this Article. This subsection does not apply to breach of contract between a pharmacy and a pharmacy benefits manager.

(e) A claim for pharmacist services may not be retroactively denied or reduced after adjudication of the claim unless any of the following apply:

- (1) The original claim was submitted fraudulently.
- (2) The original claim payment was incorrect because the pharmacy or pharmacist had already been paid for the pharmacist services.
- (3) The pharmacist services were not rendered by the pharmacy or pharmacist.
- (4) The adjustments were agreed to by the pharmacy or pharmacist.
- (5) The adjustments were part of an attempt to limit overpayment recovery efforts by a pharmacy benefits manager.

(f) Nothing in this section shall be construed to limit overpayment recovery efforts by a pharmacy benefits manager.

**§ 58-56A-5. Maximum allowable cost price.**

(a) In order to place a prescription drug on the maximum allowable cost price list, the drug must be available for purchase by pharmacies in North Carolina from national or regional wholesalers, must not be obsolete, and must meet one of the following conditions:

- (1) The drug is listed as "A" or "B" rated in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.
- (2) The drug has a "NR" or "NA" rating, or a similar rating, by a nationally recognized reference.

(b) A pharmacy benefits manager shall adjust or remove the maximum allowable cost price for a prescription drug to remain consistent with changes in the national marketplace for prescription drugs. A review of the maximum allowable cost prices for removal or modification shall be completed by the pharmacy benefits manager at least once every seven business days, and any removal or modification shall occur within seven business days of the review. A pharmacy benefits manager shall provide a means by which the contracted pharmacies may promptly review current prices in an electronic, print, or telephonic format within one business day of the removal or modification.

(c) A pharmacy benefits manager shall ensure that dispensing fees are not included in the calculation of maximum allowable cost price.

(d) A pharmacy benefits manager shall establish an administrative appeals procedure by which a contracted pharmacy or pharmacist, or a designee, may appeal the provider's reimbursement for a prescription drug subject to maximum allowable cost pricing if the amount of reimbursement for the drug is less than the net amount that the network provider paid to the suppliers of the drug. The reasonable administrative appeal procedure must include all of the following:

- (1) A dedicated telephone number and email address or website for the purpose of submitting administrative appeals.
- (2) The ability to submit an administrative appeal regarding the pharmacy benefits plan or program directly to the pharmacy benefits manager or through a pharmacy service administrative organization if the pharmacy service administrative organization has a contract with the pharmacy benefits manager that allows for the submission of appeals.
- (3) No less than 10 calendar days after the applicable prescription fill date to file an administrative appeal.
- (4) A period of no more than 10 calendar days after receipt of notice of the filing of the administrative appeal by the pharmacy benefits manager for a decision to be made on the appeal.
- (5) A requirement that if an appeal is upheld, then, within 10 calendar days of the decision, the pharmacy benefits manager shall take all of the following actions:
  - a. Notify the appellant of the decision.
  - b. Apply the change in the maximum allowable cost effective as of the date the appeal was resolved and make the change effective for all similarly situated pharmacies or pharmacists, as defined by the payor subject to the Maximum Allowable Cost list.
  - c. Permit the appellant to reverse and rebill the claim that was appealed.
- (6) A requirement that if the appeal is denied, then, within 10 calendar days of the decision, the pharmacy benefits manager shall notify the appellant of the decision and provide all of the following information:
  - a. The reason for denial.
  - b. The National Drug Code number for the prescription drug that is the subject of the appeal.
  - c. The names of the national or regional pharmaceutical wholesalers operating in the State.

**§ 58-56A-15. Pharmacy benefits manager networks.**

(a) A pharmacy benefits manager shall not deny the right to any properly licensed pharmacist or pharmacy to participate in a retail pharmacy network on the same terms and conditions of other similarly situated participants in the network.

(b) A pharmacist or pharmacy that is a member of a pharmacy service administrative organization that enters into a contract with a health benefit plan issuer or a pharmacy benefits manager on the pharmacy's behalf is

entitled to receive from the pharmacy service administrative organization a copy of the contract provisions applicable to the pharmacy, including each provision relating to the pharmacy's rights and obligations under the contract.

(c) Termination of a pharmacy or pharmacist from a pharmacy benefits manager network does not release the pharmacy benefits manager from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services properly rendered according to the contract. This subsection does not apply in cases of fraud, waste, and abuse.

**§ 58-56A-20. Pharmacy benefits manager affiliate disclosure; sharing of data.**

A pharmacy benefits manager shall not, in any way that is prohibited by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), transfer or share records relative to prescription information containing patient-identifiable and prescriber-identifiable data to a pharmacy benefits manager affiliate.

**§ 58-56A-21. Claims data provided to health benefit plan.**

Upon the request of an insurer offering a health benefit plan that contracts with a pharmacy benefits manager, the pharmacy benefits manager shall provide the insurer with claims data that reflects the total amount the insurer paid to the pharmacy benefits manager under the health benefit plan for a specified outpatient prescription drug, including the ingredient cost and the dispensing fee. The pharmacy benefits manager shall also provide the cost that it paid for the specified outpatient prescription drug, including the ingredient cost and the dispensing fee.

**§ 58-56A-25. Enforcement.**

(a) The Commissioner may make an examination of the affairs of any pharmacy benefits manager pursuant to the services that it provides for an insurer or a health benefit plan that are relevant to determining if the pharmacy benefits manager is in compliance with this Article. When making an examination, the Commissioner may retain attorneys, independent actuaries, independent certified public accountants, or other professionals and specialists as examiners. The pharmacy benefits manager shall bear the cost of retaining those persons.

(b) Pending, during, and after the examination of any pharmacy benefits manager, the Commissioner shall not make public the information or data acquired, and the information or data acquired during an examination is considered proprietary and confidential and is not a public record under Chapter 132 of the General Statutes.

(c) Violations of this Article are subject to the penalties under G.S. 58-56A-30. After notice and hearing, a pharmacy benefits manager may also be subject to revocation of, or a refusal to renew, a license to operate in this State as a result of violations of this Article.

**§ 58-56A-30. Civil Penalties for violations; administrative procedure.**

(a) Whenever the Commissioner has reason to believe that a pharmacy benefits manager has violated any of the provisions of this Article with such frequency as to indicate a general business practice, the Commissioner may, after notice and opportunity for a hearing, proceed under the appropriate subsections of this section.

(b) If, under subsection (a) of this section, the Commissioner finds a violation of this Article, the Commissioner may order the payment of a monetary penalty or petition the Superior Court of Wake County for an order directing payment of restitution as provided in subsections (d) and (e) of this section, or both. Each day during which a violation occurs constitutes a separate violation.

(c) If the Commissioner orders the payment of a monetary penalty pursuant to subsection (b) of this section, the penalty shall not be less than one hundred dollars (\$100.00) nor more than one thousand dollars (\$1,000) per day for each prescription drug resulting from the pharmacy benefit manager's failure to comply with G.S. 58-56A-5. In determining the amount of the penalty, the Commissioner shall consider the degree and extent of harm caused by the violation, the amount of money that inured to the benefit of the violator as a result of the violation, whether the violation was committed willfully, and the prior record of the violator in complying or failing to comply with laws, rules, or orders applicable to the violator. The clear proceeds of the penalty shall be remitted to the Civil Penalty and Forfeiture Fund in accordance with G.S. 115C-457.2. Payment of the civil penalty under this section shall be in addition to payment of any other penalty for a violation of the criminal laws of this State.

(d) Upon petition of the Commissioner to the court pursuant to subsection (b) of this section, the court may order the pharmacy benefits manager who committed a violation under this Article to make restitution in an amount that would make whole any pharmacist harmed by the violation. The petition may be made at any time and also in any appeal of the Commissioner's order.

(e) Upon petition of the Commissioner to the court pursuant to subsection (b) of this section, the court may order the pharmacy benefits manager who committed a violation under this Article to make restitution to the Department for expenses under subsection (f) of this section, incurred in the investigation, hearing, and any appeals

associated with the violation in such amount that would reimburse the agency for the expenses. The petition may be made at any time and also in any appeal of the Commissioner's order.

(f) The Commissioner may contract with consultants and other professionals with relevant expertise as necessary and appropriate to conduct investigation, hearing, and appeals activities as provided in this section. These contracts shall not be subject to G.S. 114-2.3, G.S. 147-17, or Articles 3, 3C, and 8 of Chapter 143 of the General Statutes, together with rules and procedures adopted under those Articles concerning procurement, contracting, and contract review.

(g) Nothing in this section prevents the Commissioner from negotiating a mutually acceptable agreement with any pharmacy benefits manager as to any civil penalty or restitution.

(h) Unless otherwise specifically provided for, all administrative proceedings under this Article are governed by Chapter 150B of the General Statutes. Appeals of the Commissioner's orders under this section shall be governed by G.S. 58-2-75.

**§ 58-56A-50. Contracts with 340B covered entities.**

(a) A contract entered into between a pharmacy benefits manager and a 340B covered entity's pharmacy or between a pharmacy benefits manager and a 340B contract pharmacy shall not do any of the following:

- (1) Restrict access to a pharmacy network or adjust 340B drug reimbursement rates based on whether a pharmacy dispenses drugs under the 340B drug discount program.
- (2) Assess any additional, or vary the amount of any, fees, chargebacks, or other adjustments on the basis of a drug being dispensed under the 340B drug discount program or a pharmacy's status as a 340B covered entity or a 340B contract pharmacy. This section does not prevent adjustments to correct errors or overpayments resulting from an adjudicated claim.

(b) No pharmacy benefits manager making payments pursuant to a health benefit plan shall discriminate against a 340B covered entity or a 340B contract pharmacy in a manner that prevents or interferes with an enrollee's choice to receive a prescription drug from an in-network 340B covered entity or an in-network 340B contract pharmacy.

(c) The provisions of G.S. 58-51-37 shall apply to pharmacy benefits managers with respect to 340B covered entities and 340B contract pharmacies.

(d) Any provision of a contract entered into between a pharmacy benefits manager and a 340B covered entity or 340B contract pharmacy that is contrary to this section is unenforceable.

\* \* \* \* \*

**CHAPTER 75**  
**MONOPOLIES, TRUSTS AND CONSUMER PROTECTION**  
***SELECTED PROVISIONS***

**Article 4.**  
**Telephone Solicitations.**  
***Selected Provisions***

\* \* \* \* \*

**§ 75-101. Definitions.**

The following definitions apply in this Article:

- ...
- (2) Automatic dialing and recorded message player. – Any automatic equipment that incorporates a storage capability of telephone numbers to be called or a random or a sequential number generator capable of producing numbers to be called that, working alone or in conjunction with other equipment, disseminates a prerecorded message to the telephone number called.
- ...
- (4) Doing business in this State. – To make or cause to be made any telephone solicitation to North Carolina telephone subscribers, whether the telephone solicitations are made from a location inside North Carolina or outside North Carolina.
- ...
- (6) Express invitation or permission. – Any invitation or permission that is registered by the telephone subscriber on an independent form and that contains the telephone number to which calls can be placed and the signature of the telephone subscriber. The form may be completed and signed electronically.
- (7) Person. – Any individual, business establishment, business, or other legal entity.
- (8) Telemarketing Sales Rule. – The federal regulation promulgated by the Federal Trade Commission, 16 C.F.R. Part 310 (January 29, 2003 Edition), as amended, to implement the Telemarketing and Consumer Fraud and Abuse Prevention Act, 15 U.S.C. §§ 6101-6108, as amended.
- (9) Telephone solicitation. – A voice or text communication, whether prerecorded, live, or a facsimile, over a telephone line or wireless telephone network or via a commercial mobile radio service that is made by a telephone solicitor to a telephone subscriber for the purpose of soliciting or encouraging the purchase or rental of, or investment in, property, goods, or services; obtaining or providing information that will or may be used for that purpose; soliciting or encouraging a telephone subscriber's participation in any contest, sweepstakes, raffle, or lottery, whether legal or illegal; or obtaining a charitable donation. "Telephone solicitation" also includes those transactions that are defined as "telemarketing" under the Telemarketing Sales Rule.
- (10) Telephone solicitor. – Any individual, business establishment, business, or other legal entity doing business in this State that, directly or through salespersons or agents, makes or attempts to make telephone solicitations or causes telephone solicitations to be made. "Telephone solicitor" also includes any party defined as a "telemarketer" under the Telemarketing Sales Rule.
- (11) Telephone subscriber. – An individual who subscribes to a residential telephone service from a local exchange company, a competing local provider certified to do business in North Carolina, or a wireless telephone company; or the individuals living or residing with that individual.
- (12) Unsolicited telephone call. – A voice or text communication, whether prerecorded, live, or a facsimile, over a telephone line or wireless telephone network or via a commercial mobile radio service that is made by a person to a telephone subscriber without prior express invitation or permission.

\* \* \* \* \*



**§ 75-104. Restrictions on use of automatic dialing and recorded message players.**

(a) Except as provided in this section, no person may use an automatic dialing and recorded message player to make an unsolicited telephone call.

(b) Notwithstanding subsection (a) of this section, a person may use an automatic dialing and recorded message player to make an unsolicited telephone call only under one or more of the following circumstances:

- ...
- (2) Prior to the playing of the recorded message, a live operator complies with G.S. 75-102(c), states the nature and length in minutes of the recorded message, and asks for and receives prior approval to play the recorded message from the person receiving the call.
  - (3) The unsolicited telephone call is in connection with an existing debt or contract for which payment or performance has not been completed at the time of the unsolicited telephone call, and both of the following are satisfied:
    - a. No part of the call is used to make a telephone solicitation.
    - b. The person making the call clearly identifies the person's name and contact information and the nature of the unsolicited telephone call.
  - (4) The unsolicited telephone call is placed by a person with whom the telephone subscriber has made an appointment, provided that the call is conveying information only about the appointment, or by a utility, telephone company, cable television company, satellite television company, or similar entity for the sole purpose of conveying information or news about network outages, repairs or service interruptions, and confirmation calls related to restoration of service, and both of the following are satisfied:
    - a. No part of the call is used to make a telephone solicitation.
    - b. The person making the call clearly identifies the person's name and contact information and the nature of the unsolicited telephone call.
  - (5) The person plays the recorded message in order to comply with section 16 C.F.R. Part 310.4(b)(4) of the Telemarketing Sales Rule.
- ...
- (7) No part of the call is used to make a telephone solicitation, the person making the call clearly identifies the person's contact information and the nature of the unsolicited telephone call, and the sole purpose of the unsolicited telephone call is to protect the public health, safety, or welfare, by informing the telephone subscriber of any of the following:
    - a. That the telephone subscriber has purchased a product that is subject to a recall by the product's manufacturer, distributor or retailer, or by the federal Consumer Product Safety Commission or another government agency or department with legal authority to recall the product which is the subject of the call, due to safety or health concerns, provided that (i) there is a reasonable basis to believe that the telephone subscriber has purchased the product, and (ii) the message complies with any requirements imposed by any government agency instituting the recall.
    - b. That the telephone subscriber may have received a prescription or over-the-counter medication that is subject to a recall by the product's manufacturer, distributor or retailer, or by the federal Food and Drug Administration or another government agency or department with legal authority to recall the product which is the subject of the call, due to safety or health concerns, provided that (i) the call and its message comply with the requirements of the Health Insurance Portability and Accountability Act (P.L. 104-191) (HIPAA) and any corresponding regulations pertaining to privacy, (ii) there is a reasonable basis to believe that the telephone subscriber has purchased or received the medication, and (iii) the message complies with any requirements imposed by the government agency or product manufacturer, distributor, or retailer instituting the recall.
    - c. That the telephone subscriber has not picked up a filled prescription drug for which a valid prescription is on file with a pharmacy licensed pursuant to G.S. 90-85.21 and the telephone subscriber requested that the prescription be filled, provided that the call and its message comply with the requirements of the Health Insurance Portability and Accountability Act (P.L. 104-191) (HIPAA) and any corresponding regulations pertaining to privacy.

\* \* \* \* \*

...

**CHAPTER 93B.**  
**OCCUPATIONAL LICENSING BOARDS.**  
***SELECTED PROVISIONS***

**§ 93B-1. Definitions.**

As used in this Chapter, the following definitions apply:

- (1) License. – Any license (other than a privilege license), certificate, or other evidence of qualification which an individual is required to obtain before he may engage in or represent himself to be a member of a particular profession or occupation.
- (2) Occupational licensing board. Any board, committee, commission, or other agency in North Carolina which is established for the primary purpose of regulating the entry of persons into, and the conduct of persons within, a particular profession or occupation, and which is authorized to issue licenses. The phrase "occupational licensing board" does not include State agencies, staffed by full-time State employees, which as a part of their regular functions may issue licenses.

...

**§ 93B-2. Annual reports required; contents; open to inspection; sanction for failure to report.**

(a) No later than October 31 of each year, each occupational licensing board shall file electronically with the Secretary of State, the Attorney General, and the Joint Legislative Administrative Procedure Oversight Committee an annual report containing all of the following information:

- (1) The address of the board, and the names of its members and officers.
- (1a) The total number of licensees supervised by the board.
- (2) The number of persons who applied to the board for examination.
- (3) The number who were refused examination.
- (4) The number who took the examination.
- (5) The number to whom initial licenses were issued.
- (5a) The number who failed the examination.
- (6) The number who applied for license by reciprocity or comity.
- (7) The number who were granted licenses by reciprocity or comity.
- (7a) The number of official complaints received involving licensed and unlicensed activities.
- (7b) The number of disciplinary actions taken against licensees, or other actions taken against nonlicensees, including injunctive relief.
- (8) The number of licenses suspended or revoked.
- (9) The number of licenses terminated for any reason other than failure to pay the required renewal fee.
- (9a) The number of applicants for a license and, of that number, the number granted a license.
- (9b) The number of applicants with a conviction record and, of that number granted a license, denied a license for any reason, and denied a license because of a conviction.
- (9c) The number of applicants who are active duty military or military veterans, the number granted a license, the number denied a license for any reason, and a summary of the reasons for denial. The information provided in accordance with this subdivision shall not disclose any identifying information of any applicant.
- (9d) The number of applicants who are military spouses, the number granted a license, the number denied a license for any reason, and a summary of the reasons for denial. The information provided in accordance with this subdivision shall not disclose any identifying information of any applicant.
- (10) The substance of any anticipated request by the occupational licensing board to the General Assembly to amend statutes related to the occupational licensing board.
- (11) The substance of any anticipated change in rules adopted by the occupational licensing board or the substance of any anticipated adoption of new rules by the occupational licensing board.

(b) No later than October 31 of each year, each occupational licensing board shall file electronically with the Secretary of State, the Attorney General, the Office of State Budget and Management, and the Joint Legislative Administrative Procedure Oversight Committee a financial report that includes the source and amount of all funds credited to the occupational licensing board and the purpose and amount of all funds disbursed by the occupational licensing board during the previous fiscal year.

(b1) No later than October 31 of each year, each occupational licensing board or State agency licensing board shall file electronically with the Secretary of the Department of Military and Veterans Affairs information collected pursuant to G.S. 93B-2(a)(9c) and (9d).

(c) The reports required by this section shall be open to public inspection.

(d) The Joint Legislative Administrative Procedure Oversight Committee shall notify any board that fails to file the reports required by this section. Failure of a board to comply with the reporting requirements of this section by October 31 of each year shall result in a suspension of the board's authority to expend any funds until such time as the board files the required reports. Suspension of a board's authority to expend funds under this subsection shall not affect the board's duty to issue and renew licenses or the validity of any application or license for which fees have been tendered in accordance with law. Each board shall adopt rules establishing a procedure for implementing this subsection and shall maintain an escrow account into which any fees tendered during a board's period of suspension under this subsection shall be deposited.

...

### **§ 93B-3. Register of persons licensed; information as to licensed status of individuals.**

Each occupational licensing board shall prepare a register of all persons currently licensed by the board and shall supplement said register annually by listing the changes made in it by reason of new licenses issued, licenses revoked or suspended, death, or any other cause. The board shall, upon request of any citizen of the State, inform the requesting person as to the licensed status of any individual.

### **§ 93B-4. Audit of Occupational Licensing Boards; payment of costs.**

(a) The State Auditor shall audit occupational licensing boards from time to time to ensure their proper operation. The books, records, and operations of each occupational licensing board shall be subject to the oversight of the State Auditor pursuant to Article 5A of Chapter 147 of the General Statutes. In accordance with G.S. 147-64.7(b), the State Auditor may contract with independent professionals to meet the requirements of this section.

(b) Each occupational licensing board with a budget of at least fifty thousand dollars (\$50,000) shall conduct an annual financial audit of its operations and provide a copy to the State Auditor.

### **§ 93B-5. Compensation, employment, and training of board members.**

(a) 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.

(b) Board members shall be reimbursed for all necessary travel expenses in an amount not to exceed that authorized under G.S. 138-6(a) for officers and employees of State departments. Actual expenditures of board members in excess of the maximum amounts set forth in G.S. 138-6(a) for travel and subsistence may be reimbursed if the prior approval of the State Director of Budget is obtained and such approved expenditures are within the established and published uniform standards and criteria of the State Director of Budget authorized under G.S. 138-7 for extraordinary charges for hotels, meals, and convention registration for State officers and employees, whenever such charges are the result of required official business of the Board.

...

(d) Except as provided herein board members shall not be paid a salary or receive any additional compensation for services rendered as members of the board.

(e) Board members shall not be permanent, salaried employees of said board.

...

(g) Within six months of a board member's initial appointment to the board, and at least once within every two calendar years thereafter, a board member shall receive training, either from the board's staff, including its legal advisor, or from an outside educational institution such as the School of Government of the University of North Carolina, on the statutes governing the board and rules adopted by the board, as well as the following State laws, in order to better understand the obligations and limitations of a State agency:

(1) Chapter 150B, The Administrative Procedure Act.

(2) Chapter 132, The Public Records Law.

(3) Article 33C of Chapter 143, The Open Meetings Act.

(4) Articles 31 and 31A of Chapter 143, The State Tort Claims Act and The Defense of State Employees Law.

(5) Subchapter II of Chapter 163A, Ethics and Lobbying.

...

Completion of the training requirements contained in Subchapter II of Chapter 163A of the General Statutes satisfies the requirements of subdivision (5) of this subsection.

**§ 93B-6. Use of funds for lobbying prohibited.**

Occupational licensing boards shall not use any funds to promote or oppose in any manner the passage by the General Assembly of any legislation.

**§ 93B-7. Rental of state-owned office space.**

Any occupational licensing board, which financially operates on the licensing fees charged and also occupies state-owned office space, shall pay rent, in a reasonable amount to be determined by the Governor, to the State for the occupancy of such space.

**§ 93B-8. Examination procedures.**

(a) Each applicant for an examination given by any occupational licensing board shall be informed in writing or print of the required grade for passing the examination prior to the taking of such examination.

(b) Each applicant for an examination given by any occupational licensing board shall be identified, for purposes of the examination, only by number rather than by name.

(c) Each applicant who takes an examination given by any occupational licensing board, and does not pass such examination, shall have the privilege to review his examination in the presence of the board or a representative of the board. Except as provided in this subsection, an occupational licensing board shall not be required to disclose the contents of any examination or of any questions which have appeared thereon, or which may appear thereon in the future.

(d) Notwithstanding the provisions of this section, under no circumstances shall an occupational licensing board be required to disclose to an applicant questions or answers to tests provided by recognized testing organizations pursuant to contracts which prohibit such disclosures.

**§ 93B-8.1. Use of criminal history records.**

(a) The following definitions apply in this section:

(1) Applicant. – An individual who makes application for licensure from a board.

(2) Board. – An occupational licensing board . . . as defined in G.S. 93B-1.

(3) Criminal history record. – A State or federal history of conviction of a crime, whether a misdemeanor or felony, that bears upon an applicant's or a licensee's fitness to be licensed or disciplined.

(4) Licensee. – An individual who has obtained a license to engage in or represent himself or herself to be a member of a particular profession or occupation.

(b) Unless federal law governing a particular board provides otherwise, a board may deny an applicant on the basis of a conviction of a crime only if the board finds that the applicant's criminal conviction history is directly related to the duties and responsibilities for the licensed occupation or the conviction is for a crime that is violent or sexual in nature. Notwithstanding any other provision of law, a board shall not automatically deny licensure on the basis of an applicant's criminal history, and no board shall deny an applicant a license based on a determination that a conviction is for a crime of moral turpitude. The board shall make its determination based on the factors specified in subsection (b1) of this section.

(b1) Before a board may deny an applicant a license due to a criminal conviction under subsection (b) of this section, the board must specifically consider all of the following factors:

(1) The level and seriousness of the crime.

(2) The date of the crime.

(3) The age of the individual at the time of the crime.

(4) The circumstances surrounding the commission of the crime, if known.

(5) The nexus between the criminal conduct and the prospective duties of the applicant as a licensee.

(6) The prison, jail, probation, parole, rehabilitation, and employment records of the applicant since the date the crime was committed.

(6a) The completion of, or active participation in, rehabilitative drug or alcohol treatment.

(6b) A Certificate of Relief granted pursuant to G.S. 15A-173.2.

(7) The subsequent commission of a crime by the applicant.

(8) Any affidavits or other written documents, including character references.

- (b2) If the board denies an applicant a license under this section, the board shall do all of the following:
- (1) Make written findings specifying the factors in subsection (b1) of this section the board deemed relevant to the applicant and explaining the reason for the denial. The board's presiding officer shall sign the findings.
  - (2) Provide or serve a signed copy of the written findings to the applicant within 60 days of the denial.
  - (3) Retain a signed copy of the written findings for no less than five years.
- (b3) Each board shall include in its application for licensure and on its public website all of the following information:
- (1) Whether the board requires applicants to consent to a criminal history record check.
  - (2) The factors considered by the board under subsection (b1) of this section when making a determination of licensure.
  - (3) The appeals process pursuant to Chapter 150B of the General Statutes if the board denies an applicant licensure in whole or in part because of a criminal conviction.
- (b4) If a board requires an applicant to submit a criminal history record, the board shall require the provider of the criminal history record to provide the applicant with access to the applicant's criminal history record or otherwise deliver a copy of the criminal history record to the applicant. If an applicant's criminal history includes matters that will or may prevent the board from issuing a license to the applicant, the board shall notify the applicant in writing of the specific issues in sufficient time for the applicant to provide additional documentation supporting the application for consideration by the board prior to any final decision to deny the application. After being notified of any potential issue with licensure due to one or more criminal convictions, an applicant shall have 30 days to respond by either correcting any inaccuracy in the criminal history record or submitting evidence of mitigation or rehabilitation for consideration by the board.
- (b5) If, following a hearing, a board denies an application for licensure, the board's written order shall include specific reference to any criminal conviction considered as part or all of any basis for the denial and the rationale for the denial, as well as a reference to the appeal process and the applicant's ability to reapply. No applicant shall be restricted from reapplying for licensure for more than two years from the date of the most recent application.
- (b6) Notwithstanding any other provisions in the law, an individual with a criminal history may petition a board at any time, including before the individual starts or completes any mandatory education or training requirements, for a predetermination of whether the individual's criminal history will likely disqualify the individual from obtaining a license. This petition shall include a criminal history record report obtained by the individual from a reporting service designated by the board, the cost of which shall be borne by the applicant. Criminal history records relating to a predetermination petition are not public records under Chapter 132 of the General Statutes. A board may predetermine that the petitioner's criminal history is likely grounds for denial of a license only after the board has applied the requirements of subsection (b) of this section. Each board shall delegate authority for the predetermination to its executive director or equivalent officer, or to a committee of the board, so that the predeterminations can be made in a timely manner. No board member having served on a predetermination committee for an individual shall be required to recuse in any later determinations or hearings involving the same applicant. The board shall inform the individual of the board's determination within 45 days of receiving the petition from the individual. The board may charge a fee to recoup its costs not to exceed forty-five dollars (\$45.00) for each petition. If the board determines an applicant would likely be denied licensure based on the individual's criminal history, the board shall notify the individual in writing of the following:
- (1) The grounds and reasons for the predetermination.
  - (2) That the petitioner has the right to complete any requirements for licensure, to apply to the board, and to have the petitioner's application considered by the board under its application process.
  - (3) That further evidence of rehabilitation will be considered upon application.
- (b7) A predetermination made under subsection (b6) this section that a petitioner's criminal history would likely prevent licensure is not a final agency decision and does not entitle the individual to any right to judicial review under Article 4 of Chapter 150B of the General Statutes.
- (b8) A predetermination made under subsection (b6) of this section that a petitioner is eligible for a license is binding if both of the following apply:
- (1) The petitioner applies for licensure and fulfills all other requirements for the occupational license.
  - (2) The applicant's submitted criminal history was correct and remains unchanged at the time of application for a license.

(c) If a board requires an applicant to consent to a criminal history record check or use of fingerprints or other identifying information required by the State or National Repositories of Criminal Histories, the board may deny licensure to an applicant who refuses to consent.

(c1) Nothing in this section or in G.S. 93B-1 authorizes a board to require an applicant to consent to a criminal history record check or use of fingerprints or other identifying information required by the State or National Repositories of Criminal Histories as a condition of granting or renewing a license.

...

**§ 93B-8.2. Prohibit licensees from serving as investigators.**

No occupational licensing board shall contract with or employ a person licensed by the board to serve as an investigator or inspector if the licensee is actively practicing in the profession or occupation and is in competition with other members of the profession or occupation over which the board has jurisdiction. Nothing in this section shall prevent a board from (i) employing licensees who are not otherwise employed in the same profession or occupation as investigators or inspectors or for other purposes or (ii) contracting with licensees of the board to serve as expert witnesses or consultants in cases where special knowledge and experience is required, provided that the board limits the duties and authority of the expert witness or consultant to serving as an information resource to the board and board personnel.

**§ 93B-8.6. Recognition of apprenticeships and training.**

(a) The following definitions shall apply in this section:

- (1) Apprenticeship. – A program that meets the federal guidelines for registered apprenticeships set out in 29 C.F.R. Part 29 and 29 U.S.C. § 50. An apprenticeship can be completed under a State-licensed practitioner of that occupation or at a State-licensed school.
- (2) Career technical education. – Programs of study, clusters, and pathways approved by the North Carolina State Board of Education or the State Board of Community Colleges.
- (3) Licensing. – Any required training, education, or fee to work in a specific profession.

(b) Unless otherwise required by federal law, including requirements pertaining to eligibility for federal grant funding, an occupational licensing board shall grant a license to any applicant who meets the following criteria:

- (1) Completed an apprenticeship approved by the North Carolina State Approving Agency or federal Department of Labor, or otherwise permitted under State or federal law.
- (2) Passed an examination, if one is deemed to be necessary by the licensing authority.
- (3) With the exception of any prelicensing education requirements, has met any other requirements for licensure set forth in the law or rules related to the particular board.

(b1) This section shall not apply to occupational licensing boards governing professions requiring advanced knowledge acquired by a prolonged course of specialized intellectual study, including those requiring a bachelor's or advanced degree.

(c) Each occupational licensing board shall establish a passing score for the board's examinations which shall not exceed the passing score that is required under the board's standard licensing processes. If the relevant law or rule does not require an examination for the standard licensing process, no examination may be required for applicants who complete an apprenticeship in that occupation. Except as otherwise required by federal law, apprenticeships for an occupation shall not be required to exceed the number of hours required by the relevant licensing authority or statute for that occupation.

(d) Applicants for licensure shall be permitted to apply training hours earned through career technical education provided by North Carolina public schools and colleges towards the requirements for licensure in the same occupation in accordance with the standards and procedures authorized in accordance with this Chapter.

(e) The State Board of Community Colleges and occupational licensing boards shall adopt rules for the implementation of this section.

**§ 93B-9. Age requirements.**

... [N]o occupational licensing board may require that an individual be more than 18 years of age as a requirement for receiving a license ...

**§ 93B-10. Expiration of term of appointment of board member.**

A board member serving on an occupational and professional licensing board whose term of appointment has expired shall continue to serve until a successor is appointed and qualified.

**§ 93B-11. Interest from State Treasurer's Investment Program.**

Any interest earned by an occupational licensing board under G.S. 147-69.3(d) may be used only for the following purposes:

- (1) To reduce fees;
- (2) Improve services offered to licensees and the public; or
- (3) For educational purposes to benefit licensees or the public.

\* \* \* \* \*

**§ 93B-13. Revocation when licensing privilege forfeited for nonpayment of child support or for failure to comply with subpoena.**

(a) Upon receipt of a court order, pursuant to G.S. 50-13.12 and G.S. 110-142.1, revoking the occupational license of a licensee under its jurisdiction, an occupational licensing board shall note the revocation in its records, report the action within 30 days to the Department of Health and Human Services, and follow the normal postrevocation rules and procedures of the board as if the revocation had been ordered by the board. The revocation shall remain in effect until the board receives certification by the clerk of superior court or the Department of Health and Human Services in an IV-D case that the licensee is no longer delinquent in child support payments, or, as applicable, that the licensee is in compliance with or is no longer subject to the subpoena that was the basis for the revocation.

(b) Upon receipt of notification from the Department of Health and Human Services that a licensee under an occupational licensing board's jurisdiction has forfeited the licensee's occupational license pursuant to G.S. 110-142.1, then the occupational licensing board shall send a notice of intent to revoke or suspend the occupational license of that licensee as provided by G.S. 110-142.1(d). If the license is revoked as provided by the provisions of G.S. 110-142.1, the revocation shall remain in effect until the board receives certification by the designated representative or the child support enforcement agency that the licensee is no longer delinquent in child support payments, or, as applicable, that the licensee is in compliance with or no longer subject to a subpoena that was the basis for the revocation.

(c) If at the time the court revokes a license pursuant to subsection (a) of this section, or if at the time the occupational licensing board revokes a license pursuant to subsection (b) of this section, the occupational licensing board has revoked the same license under the licensing board's disciplinary authority over licensees under its jurisdiction, and that revocation period is greater than the revocation period resulting from forfeiture pursuant to G.S. 50-13.12 or G.S. 110-142.1 then the revocation period imposed by the occupational licensing board applies.

(d) Immediately upon certification by the clerk of superior court or the child support enforcement agency that the licensee whose license was revoked pursuant to subsection (a) or (b) of this section is no longer delinquent in child support payments, the occupational licensing board shall reinstate the license. Immediately upon certification by the clerk of superior court or the child support enforcement agency that the licensee whose license was revoked because of failure to comply with a subpoena is in compliance with or no longer subject to the subpoena, the occupational licensing board shall reinstate the license. Reinstatement of a license pursuant to this section shall be made at no additional cost to the licensee.

**§ 93B-14. Information on applicants for licensure.**

Every occupational licensing board shall require applicants for licensure to provide to the Board the applicant's social security number. This information shall be treated as confidential and may be released only as follows:

- (1) To the State Child Support Enforcement Program of the Department of Health and Human Services upon its request and for the purpose of enforcing a child support order.
- (2) To the Department of Revenue for the purpose of administering the State's tax laws.

**§ 93B-15. Payment of license fees by members of the Armed Forces; board waiver rules.**

(a) An individual who is serving in the Armed Forces of the United States and to whom G.S. 105-249.2 grants an extension of time to file a tax return is granted an extension of time to pay any license fee charged by an occupational licensing board as a condition of retaining a license granted by the board. The extension is for the same period that would apply if the license fee were a tax.

(b) Occupational licensing boards shall adopt rules to postpone or waive continuing education, payment of renewal and other fees, and any other requirements or conditions relating to the maintenance of licensure by an individual who is currently licensed by and in good standing with the board, is serving in the Armed Forces of the United States, and to whom G.S. 105-249.2 grants an extension of time to file a tax return.

**§ 93B-15.1. Licensure for individuals with military training and experience; proficiency examination; licensure by endorsement for military spouses; temporary license.**

(a) Except as provided by subsection (a2) of this section, and notwithstanding any other provision of law, an occupational licensing board, or State agency licensing board, as defined in G.S. 93B-1, shall issue a license, certification, or registration to a military-trained applicant to allow the applicant to lawfully practice the applicant's occupation in this State if, upon application to an occupational licensing board or State agency licensing board, the military-trained applicant satisfies the following conditions:

- (1) Has been awarded a military occupational specialty and has done all of the following at a level that is substantially equivalent to or exceeds the requirements for licensure, certification, or registration of the occupational licensing board or State agency licensing board from which the applicant is seeking licensure, certification, or registration in this State: completed a military program of training, completed testing or equivalent training and experience, and performed in the occupational specialty.
- (2) Has engaged in the active practice of the occupation for which the person is seeking a license, certification, or permit from the occupational licensing board or State agency licensing board in this State for at least two of the five years preceding the date of the application under this section.
- (3) Has not committed any act in any jurisdiction that would have constituted grounds for refusal, suspension, or revocation of a license to practice that occupation in this State at the time the act was committed and has no pending complaints.

...

(a1) No later than 15 days following receipt of an application from a military-trained applicant, an occupational licensing board or State agency licensing board shall either issue a license, certification, or registration or notify an applicant when the applicant's military training or experience does not satisfy the requirements for licensure, certification, or registration and shall specify the criteria or requirements that the board determined that the applicant failed to meet and the basis for that determination. If a military-trained applicant has a pending complaint under subdivision (3) of subsection (a) of this section, an occupational licensing board or State agency licensing board shall notify the applicant no later than 15 days following the board receiving written notice of the disposition of the pending complaint.

(a2) An occupational licensing board or State agency licensing board, as defined in G.S. 93B-1, shall issue a license, certification, or registration to a military-trained applicant to allow the applicant to lawfully practice the applicant's occupation in this State if the military-trained applicant, upon application to the occupational licensing board or State agency licensing board, satisfies the following conditions:

- (1) Presents official, notarized documentation, such as a U.S. Department of Defense Form 214 (DD-214), or similar substantiation, attesting to the applicant's military occupational specialty certification and experience in an occupational field within the board's purview; and
- (2) Passes a proficiency examination offered by the board to military-trained applicants in lieu of satisfying the conditions set forth in subsection (a) of this section; however, if an applicant fails the proficiency examination, then the applicant may be required by the board to satisfy those conditions.

In any case where a proficiency examination is not offered routinely by an occupational licensing board or State agency licensing board, the board shall design a fair proficiency examination for military-trained applicants to obtain licensure, certification, or registration under this section. If a proficiency examination is offered routinely by an occupational licensing board or State agency licensing board, that examination shall satisfy the requirements of this section.

(b) Notwithstanding any other provision of law, an occupational licensing board, as defined in G.S. 93B-1, shall issue a license, certification, or registration to a military spouse to allow the military spouse to lawfully practice the military spouse's occupation in this State if, upon application to an occupational licensing board or State agency licensing board, the military spouse satisfies the following conditions:

- (1) Holds a current license, certification, or registration from another jurisdiction, and that jurisdiction's requirements for licensure, certification, or registration are substantially equivalent to or exceed the requirements for licensure, certification, or registration of the occupational licensing board or State agency licensing board for which the applicant is seeking licensure, certification, or registration in this State.



- (2) Can demonstrate competency in the occupation through methods as determined by the Board, such as having completed continuing education units or having had recent experience for at least two of the five years preceding the date of the application under this section.
- (3) Has not committed any act in any jurisdiction that would have constituted grounds for refusal, suspension, or revocation of a license to practice that occupation in this State at the time the act was committed.
- (4) Is in good standing; has not been disciplined by the agency that had jurisdiction to issue the license, certification, or permit; and has no pending complaints.

...

(b1) No later than 15 days following receipt of an application from a military spouse, an occupational licensing board or State agency licensing board shall either issue a license, certification, or registration or notify an applicant when the applicant's training or experience does not satisfy the requirements for licensure, certification, or registration and specify the criteria or requirements that the board determined that the applicant failed to meet and the basis for that determination. If an applicant who is a military spouse has a pending complaint under subdivision (4) of subsection (b) of this section, an occupational licensing board or State agency licensing board shall notify the applicant no later than 15 days following the board receiving written notice of the disposition of the pending complaint.

(c) All relevant experience of a military service member in the discharge of official duties or, for a military spouse, all relevant experience, including full-time and part-time experience, regardless of whether in a paid or volunteer capacity, shall be credited in the calculation of years of practice in an occupation as required under subsection (a) or (b) of this section.

(c1) Each occupational licensing board or State agency licensing board shall publish on its Web site all of the following:

- (1) A document that lists the specific criteria or requirements for licensure, registration, or certification by the board, with a description of the criteria or requirements that are satisfied by military training or experience as provided in this section, and any necessary documentation needed for obtaining the credit or satisfying the requirement.
- (2) A document that includes a summary of the opportunities available to veterans and military spouses under this section.

(c2) The Secretary of the Department of Military and Veterans Affairs shall publish on the Department's Web site the information required under subsection (c1) of this section.

(d) A nonresident licensed, certified, or registered under this section shall be entitled to the same rights and subject to the same obligations as required of a resident licensed, certified, or registered by an occupational licensing board or State agency licensing board in this State.

...

(f) An occupational licensing board or State agency licensing board shall issue a temporary practice permit to a military-trained applicant or military spouse licensed, certified, or registered in another jurisdiction while the military-trained applicant or military spouse is satisfying the requirements for licensure under subsection (a) or (b) of this section no later than 15 days following receipt of an application, if that jurisdiction has licensure, certification, or registration standards substantially equivalent to the standards for licensure, certification, or registration of an occupational licensing board or State agency licensing board in this State. The temporary practice permit shall be issued using the same information as provided by the applicant in the licensure application and remain valid for the later of one year or the required renewal date for the occupation the temporary practice permit was issued for or until a license, certification, or registration is granted by the occupational licensing board or State agency licensing board. A temporary practice permit may be denied or revoked for a pending complaint after notice is provided to the military-trained applicant or military spouse as set forth under subsection (a1) or (b1) of this section.

(g) An occupational licensing board or State agency licensing board may adopt rules necessary to implement this section.

(h) Nothing in this section shall be construed to prohibit a military-trained applicant or military spouse from proceeding under the existing licensure, certification, or registration requirements established by an occupational licensing board or State agency licensing board in this State.

...

(k) An occupational licensing board or State agency licensing board shall not charge a military-trained applicant or a military spouse an initial application fee for a license, certification, registration, or temporary practice permit issued pursuant to this section. Nothing in this subsection shall be construed to prohibit an occupational

licensing board or State agency licensing board from charging its ordinary fee for a renewal application or prohibit a third party from charging actual costs for a service such as a background check.

**§ 93B-16. Occupational board liability for negligent acts.**

(a) An occupational licensing board may purchase commercial insurance of any kind to cover all risks or potential liability of the board, its members, officers, employees, and agents, including the board's liability under Articles 31 and 31A of Chapter 143 of the General Statutes.

(b) Occupational licensing boards shall be deemed State agencies for purposes of Articles 31 and 31A of Chapter 143 of the General Statutes, and board members and employees of occupational licensing boards shall be considered State employees for purposes of Articles 31 and 31A of Chapter 143 of the General Statutes. To the extent an occupational licensing board purchases commercial liability insurance coverage in excess of one hundred fifty thousand dollars (\$150,000) per claim for liability arising under Article 31 or 31A of Chapter 143 of the General Statutes, the provisions of G.S. 143-299.4 shall not apply. To the extent that an occupational licensing board purchases commercial insurance coverage for liability arising under Article 31 or 31A of Chapter 143 of the General Statutes, the provisions of G.S. 143-300.6(c) shall not apply.

(c) The purchase of insurance by an occupational licensing board under this section shall not be construed to waive sovereign immunity or any other defense available to the board, its members, officers, employees, or agents in an action or contested matter in any court, agency, or tribunal. The purchase of insurance by an occupational licensing board shall not be construed to alter or expand the limitations on claims or payments established in G.S. 143-299.2 or limit the right of board members, officers, employees, or agents to defense by the State as provided by G.S. 143-300.3.

**CHAPTER 99B.  
PRODUCTS LIABILITY.**

***SELECTED PROVISIONS***

**§ 99B-1. Definitions.**

When used in this Chapter, unless the context otherwise requires:

- (1) "Claimant" means a person or other entity asserting a claim and, if said claim is asserted on behalf of an estate, an incompetent or a minor, "claimant" includes plaintiff's decedent, guardian, or guardian ad litem.
- (2) "Manufacturer" means a person or entity who designs, assembles, fabricates, produces, constructs or otherwise prepares a product or component part of a product prior to its sale to a user or consumer, including a seller owned in whole or significant part by the manufacturer or a seller owning the manufacturer in whole or significant part.
- (3) "Product liability action" includes any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling of any product.
- (4) "Seller" includes a retailer, wholesaler, or distributor, and means any individual or entity engaged in the business of selling a product, whether such sale is for resale or for use or consumption. "Seller" also includes a lessor or bailor engaged in the business of leasing or bailment of a product.

**§ 99B-1.1. Strict liability.**

There shall be no strict liability in tort in product liability actions.

**§ 99B-1.2. Breach of warranty.**

Nothing in this act shall preclude a product liability action that otherwise exists against a manufacturer or seller for breach of warranty. The defenses provided for in this Chapter shall apply to claims for breach of warranty unless expressly excluded under this Chapter.

**§ 99B-2. Seller's opportunity to inspect; privity requirements for warranty claims.**

(a) No product liability action, except an action for breach of express warranty, shall be commenced or maintained against any seller when the product was acquired and sold by the seller in a sealed container or when the product was acquired and sold by the seller under circumstances in which the seller was afforded no reasonable opportunity to inspect the product in such a manner that would have or should have, in the exercise of reasonable care, revealed the existence of the condition complained of, unless the seller damaged or mishandled the product while in his possession; provided, that the provisions of this section shall not apply if the manufacturer of the product is not subject to the jurisdiction of the courts of this State or if such manufacturer has been judicially declared insolvent.

(b) A claimant who is a buyer, as defined in the Uniform Commercial Code, of the product involved, or who is a member or a guest of a member of the family of the buyer, a guest of the buyer, or an employee of the buyer may bring a product liability action directly against the manufacturer of the product involved for breach of implied warranty; and the lack of privity of contract shall not be grounds for the dismissal of such action.

**§ 99B-3. Alteration or modification of product.**

(a) No manufacturer or seller of a product shall be held liable in any product liability action where a proximate cause of the personal injury, death, or damage to property was either an alteration or modification of the product by a party other than the manufacturer or seller, which alteration or modification occurred after the product left the control of such manufacturer or such seller unless:

- (1) The alteration or modification was in accordance with the instructions or specifications of such manufacturer or such seller; or
- (2) The alteration or modification was made with the express consent of such manufacturer or such seller.

(b) For the purposes of this section, alteration or modification includes changes in the design, formula, function, or use of the product from that originally designed, tested, or intended by the manufacturer. It includes failure to observe routine care and maintenance, but does not include ordinary wear and tear.

**§ 99B-4. Knowledge or reasonable care.**

No manufacturer or seller shall be held liable in any product liability action if:

- (1) The use of the product giving rise to the product liability action was contrary to any express and adequate instructions or warnings delivered with, appearing on, or attached to the product or on its original container or wrapping, if the user knew or with the exercise of reasonable and diligent care should have known of such instructions or warnings; or
- (2) The user knew of or discovered a defect or dangerous condition of the product that was inconsistent with the safe use of the product, and then unreasonably and voluntarily exposed himself or herself to the danger, and was injured by or caused injury with that product; or
- (3) The claimant failed to exercise reasonable care under the circumstances in the use of the product, and such failure was a proximate cause of the occurrence that caused the injury or damage complained of.

**§ 99B-5. Claims based on inadequate warning or instruction.**

(a) No manufacturer or seller of a product shall be held liable in any product liability action for a claim based upon inadequate warning or instruction unless the claimant proves that the manufacturer or seller acted unreasonably in failing to provide such warning or instruction, that the failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought, and also proves one of the following:

- (1) At the time the product left the control of the manufacturer or seller, the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer or seller knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant.
- (2) After the product left the control of the manufacturer or seller, the manufacturer or seller became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

(b) Notwithstanding subsection (a) of this section, no manufacturer or seller of a product shall be held liable in any product liability action for failing to warn about an open and obvious risk or a risk that is a matter of common knowledge.

(c) Notwithstanding subsection (a) of this section, no manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant unless the United States Food and Drug Administration requires such direct consumer warning or instruction to accompany the product.

**§ 99B-6. Claims based on inadequate design or formulation.**

(a) No manufacturer of a product shall be held liable in any product liability action for the inadequate design or formulation of the product unless the claimant proves that at the time of its manufacture the manufacturer acted unreasonably in designing or formulating the product, that this conduct was a proximate cause of the harm for which damages are sought, and also proves one of the following:

- (1) At the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.
- (2) At the time the product left the control of the manufacturer, the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design.

(b) In determining whether the manufacturer acted unreasonably under subsection (a) of this section, the factors to be considered shall include, but are not limited to, the following:

- (1) The nature and magnitude of the risks of harm associated with the design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product.
- (2) The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm.
- (3) The extent to which the design or formulation conformed to any applicable government standard that was in effect when the product left the control of its manufacturer.
- (4) The extent to which the labeling for a prescription or nonprescription drug approved by the United States Food and Drug Administration conformed to any applicable government or private standard that was in effect when the product left the control of its manufacturer.
- (5) The utility of the product, including the performance, safety, and other advantages associated with that design or formulation.
- (6) The technical, economic, and practical feasibility of using an alternative design or formulation at the time of manufacture.
- (7) The nature and magnitude of any foreseeable risks associated with the alternative design or formulation.

(c) No manufacturer of a product shall be held liable in any product liability action for a claim under this section to the extent that it is based upon an inherent characteristic of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability and that is recognized by the ordinary person with the ordinary knowledge common to the community.

(d) No manufacturer of a prescription drug shall be liable in a product liability action on account of some aspect of the prescription drug that is unavoidably unsafe, if an adequate warning and instruction has been provided pursuant to G.S. 99B-5(c). As used in this subsection, "unavoidably unsafe" means that, in the state of technical, scientific, and medical knowledge generally prevailing at the time the product left the control of its manufacturer, an aspect of that product that caused the claimant's harm was not reasonably capable of being made safe.

(e) Nothing in this section precludes an action against a manufacturer in accordance with the provisions of G.S. 99B-5. (1995, c. 522, s. 1.)

\* \* \* \* \*

**CHAPTER 106**  
**AGRICULTURE**

*SELECTED PROVISIONS*

**Article 12.**  
**Food, Drugs and Cosmetics.**

*Selected Provisions*

**§ 106-120. Title of Article.**

This Article may be cited as the North Carolina Food, Drug and Cosmetic Act.

**§ 106-121. Definitions and general consideration.**

For the purpose of this Article:

- (1) The term "advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purposes of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics.
- (1a) The term "color" includes black, white, and intermediate grays.
- (1b) The term "color additive" means a material which:
  - a. Is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source; or
  - b. When added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

Provided, that such term does not apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

- (2) The term "Commissioner" means the Commissioner of Agriculture; the term "Department" means the Department of Agriculture and Consumer Services, and the term "Board" means the Board of Agriculture.
- (2a) The term "consumer commodity" except as otherwise specifically provided by this subdivision means any food, drug, device, or cosmetic as those terms are defined by this Article. Such term does not include:
  - a. Any tobacco or tobacco product; or
  - b. Any commodity subject to packaging or labeling requirements imposed under the North Carolina Pesticide Law of 1971, Article 52, Chapter 143, of the General Statutes of North Carolina, or the provisions of the eighth paragraph under the heading "Bureau of Animal Industry" of the act of March 4, 1913 (37 Stat. 832-833; 21 U.S.C. 151-157) commonly known as the Virus-Serum Toxin Act; or
  - c. Any drug subject to the provisions of G.S. 106-134(13) or 106-134.1 of this Article or section 503(b)(1) or 506 of the federal act; or
  - d. Any beverage subject to or complying with packaging or labeling requirements imposed under the Federal Alcohol Administration Act (27 U.S.C., et seq.); or
  - e. Any commodity subject to the provisions of the North Carolina Seed Law, Article 31, Chapter 106 of the General Statutes of North Carolina.
- (3) The term "contaminated with filth" applies to any food, drug, device or cosmetic not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.
- (4) The term "cosmetic" means
  - a. Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and

- b. Articles intended for use as a component of any such articles, except that such terms shall not include soap.
- (4a) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer or distributor.
- (5) The term "device," except when used in subdivision (15) of this section and in G.S. 106-122, subdivision (10), 106-130, subdivision (6), 106-134, subdivision (3) and 106-137, subdivision (3) means instruments, apparatus and contrivances, including their components, parts and accessories, intended
  - a. For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or
  - b. To affect the structure or any function of the body of man or other animals.
- (6) The term "drug" means
  - a. Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
  - b. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and
  - c. Articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
  - d. Articles intended for use as a component of any article specified in paragraphs a, b or c; but does not include devices or their components, parts, or accessories.
- (7) The term "federal act" means the Federal Food, Drug and Cosmetic Act (Title 21 U.S.C. 301 et seq.; 52 Stat. 1040 et seq.).
- (8) The term "food" means
  - a. Articles used for food or drink for man or other animals,
  - b. Chewing gum, and
  - c. Articles used for components of any such article.
- (8a) The term "food additive" means any substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food; and including any source of radiation intended for any such use) if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in a food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include:
  - a. A pesticide chemical in or on a raw agricultural commodity; or
  - b. A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or
  - c. A color additive; or
  - d. Any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, pursuant to the federal act; the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 et seq.).
- (9) The term "immediate container" does not include package liners.
- (10) The term "label" means a display of written, printed or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Article that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside

- container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.
- (11) The term "labeling" means all labels and other written, printed, or graphic matter
- a. Upon an article or any of its containers or wrappers, or
  - b. Accompanying such article.
- ...
- (12) The term "new drug" means
- a. Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or
  - b. Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigation, been used to a material extent or for a material time under such conditions.
- ...
- (13) The term "official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.
- (13a) The term "package" means any container or wrapping in which any consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers, but does not include:
- a. Shipping containers or wrappings used solely for the transportation of any consumer commodity in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof; or
  - b. Shipping containers or outer wrappings used by retailers to ship or deliver any commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity.
- (14) The term "person" includes individual, partnership, corporation, and association.
- (14a) The term "pesticide chemical" means any substance which, alone, in chemical combination, or in formulation with one or more other substances is a "pesticide" within the meaning of the North Carolina Pesticide Law of 1971, Article 52, Chapter 143, of the General Statutes of North Carolina, or the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 135 et seq.), and which is used in the production, storage, or transportation of raw agricultural commodities.
- (14b) The term "practitioner" means a physician, dentist, veterinarian or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a drug so long as such activity is within the normal course of professional practice or research.
- (14c) The term "principal display panel" means that part of a label that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale.
- (14d) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.
- ...
- (15) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.



- (16) The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.
- (17) The provisions of this Article regarding the selling of food, drugs, devices, or cosmetics, shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article; and the supplying or applying of any such article in the conduct of any food, drug or cosmetic establishment.

**§ 106-122. Certain acts prohibited.**

The following acts and the causing thereof within the State of North Carolina are hereby prohibited:

- (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded.
- (2) The adulteration or misbranding of any food, drug, device, or cosmetic.
- (3) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
- (4) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of G.S. 106-131 or 106-135.
- (5) The dissemination of any false advertisement.
- (6) The refusal to permit entry or inspection, or to permit the taking of a sample, or to permit access to or copying of any record as authorized by G.S. 106-140.
- (7) The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in the State of North Carolina from whom he received in good faith the food, drug, device or cosmetic.
- (8) The removal or disposal of a detained or embargoed article in violation of G.S. 106-125.
- (9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded or adulterated.
- (10) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label or other identification device authorized or required by regulations promulgated under the provisions of this Article.
- (11) The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under G.S. 106-135, or that such drug complies with the provisions of such section.
- ...
- (13) The distribution in commerce of a consumer commodity, as defined in this Article, if such commodity is contained in a package, or if there is affixed to that commodity a label, which does not conform to the provisions of this Article and regulations promulgated under authority of this Article; provided, however, that this prohibition shall not apply to persons engaged in business as wholesale or retail distributors of consumer commodities except to the extent that such persons:
  - a. Are engaged in the packaging or labeling of such commodities; or
  - b. Prescribe or specify by any means the manner in which such commodities are packaged or labeled.
- (14) The using by any person to his own advantage, or revealing, other than to the Commissioner or authorized officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Article, any information acquired under authority of this Article concerning any method or process which as a trade secret is entitled to protection.
- (15) In the case of a prescription drug distributed or offered for sale in this State, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer such drug within the normal course of professional practice, who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which

that drug is distributed or sold, or such other printed matter as is approved under the federal act. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Article.

- (16) a. Placing or causing to be placed upon any drug or device or container thereof, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; or
  - b. Selling, dispensing, disposing of or causing to be sold, dispensed or disposed of, or concealing or keeping in possession, control or custody, with intent to sell, dispense or dispose of, any drug, device or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by subsection (a) of this section; or
  - c. Making, selling, or disposing of; causing to be made, sold or disposed of; keeping in possession, control or custody; or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.
- (17) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing of a counterfeit drug.
- (18) Dispensing or causing to be dispensed a different drug in place of the drug ordered or prescribed without the express permission of the person ordering or prescribing.
- (19) The acquiring or obtaining or attempting to acquire or obtain any drug subject to the provisions of G.S. 106-134.1(a)(3) or (4) by fraud, deceit, misrepresentation, or subterfuge, or by forgery or alteration of a prescription, or by the use of a false name, or the giving of a false address.

#### **§ 106-123. Injunctions restraining violations.**

In addition to the remedies hereinafter provided, the Commissioner of Agriculture is hereby authorized to apply to the superior court for, and such court shall have jurisdiction upon hearing and for cause shown to grant, a temporary or permanent injunction restraining any person from violating any provision of G.S. 106-122, irrespective of whether or not there exists an adequate remedy at law.

#### **§ 106-124. Violations made misdemeanor.**

(a) Any person, firm or corporation violating any provision of this Article, or any regulation of the Board adopted pursuant to this Article, shall be guilty of a Class 2 misdemeanor. In addition, if any person continues to violate or further violates any provision of this Article after written notice from the Commissioner, or his duly designated agent, the court may determine that each day during which the violation continued or is repeated constitutes a separate violation subject to the foregoing penalties.

(b) No person shall be subject to the penalties of subsection (a) of this section, for having violated G.S. 106-122, subdivision (1) or (3) if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the State of North Carolina from whom he received in good faith the article, to the effect that such article is not adulterated or misbranded within the meaning of this Article, designating this article.

(c) No publisher, radio-broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, shall be liable under this section by reason of the dissemination by him of such false advertisement, unless he has refused on the request of the Commissioner of Agriculture to furnish the Commissioner the name and post-office address of the manufacturer, packer, distributor, seller or advertising agency residing in the State of North Carolina who caused him to disseminate such advertisement.

#### **§ 106-124.1. Civil penalties.**

(a) The Commissioner may assess a civil penalty of not more than two thousand dollars (\$2,000) against any person who violates a provision of this Article or any rule adopted pursuant to this Article. In determining the amount of the penalty, the Commissioner shall consider the degree and extent of harm caused by the violation.

(b) Prior to assessing a civil penalty, the Commissioner shall give the person written notice of the violation and a reasonable period of time in which to correct the violation. However, the Commissioner shall not be required

to give a person time to correct a violation before assessing a penalty if the Commissioner determines the violation is likely to cause future physical injury or illness.

(c) The Commissioner shall consider the training and management practices implemented by the person for the purpose of complying with this Article as a mitigating factor when determining the amount of the civil penalty.

...

**§ 106-125. Detention of product or article suspected of being adulterated or misbranded.**

(a) Whenever a duly authorized agent of the Department of Agriculture and Consumer Services finds or has probable cause to believe, that any food, drug, device, cosmetic or consumer commodity is adulterated, or so misbranded as to be dangerous or fraudulent within the meaning of this Article or is in violation of G.S. 106-131 or 106-135 of this Article, he shall affix to such article a tag or other appropriate marking giving notice that such article is, or is suspected of being, adulterated or misbranded and has been detained or embargoed, and warning all persons not to remove or dispose of such article by sale or otherwise until permission for removal or disposal is given by such agent or the court. It shall be unlawful for any person to remove or dispose of such detained or embargoed article by sale or otherwise without such permission.

(b) When an article detained or embargoed under subsection (a) has been found by such agent to be adulterated, or misbranded or to be in violation of G.S. 106-131 or 106-135 of this Article, he shall petition a judge of the district, or superior court in whose jurisdiction the article is detained or embargoed for an order for condemnation of such article. When such agent has found that an article so detained or embargoed is not adulterated or misbranded, he shall remove the tag or other marking.

(c) If the court finds that a detained or embargoed article is adulterated or misbranded, such article shall, after entry of the decree, be destroyed at the expense of the claimant thereof, under the supervision of such agent; and all court costs and fees, and storage and other proper expenses, shall be taxed against the claimant of such article or his agent: Provided, that when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that such article shall be so labeled or processed, has been executed, may by order direct that such article be delivered to the claimant thereof for such labeling or processing under the supervision of an agent of the Department of Agriculture and Consumer Services. The expense of such supervision shall be paid by the claimant. Such bond shall be returned to the claimant of the article on representation to the court by the Department of Agriculture and Consumer Services that the article is no longer in violation of this Article, and that the expenses of such supervision have been paid.

(d) Whenever any duly authorized agent of the Department of Agriculture and Consumer Services shall find in any room, building, vehicle of transportation or other structure, any meat, seafood, poultry, vegetable, fruit or other perishable articles which are unsound, or contain any filthy, decomposed or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the agent shall forthwith condemn or destroy the same, or in any other manner render the same unsalable as human food.

**§ 106-126. Prosecutions of violations.**

It shall be the duty of the solicitors and district attorneys of this State to promptly prosecute all violations of this Article.

**§ 106-127. Report of minor violations in discretion of Commissioner.**

Nothing in this Article shall be construed as requiring the Commissioner of Agriculture to report for the institution of proceedings under this Article, minor violations of this Article, whenever the Commissioner believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

\* \* \* \* \*

**§ 106-132. Additives, etc., deemed unsafe.**

Any added poisonous or added deleterious substance, any food additive, any pesticide chemical in or on a raw agricultural commodity or any color additive, shall with respect to any particular use or intended use be deemed unsafe for the purpose of application of G.S. 106-129(1), paragraphs b and g and 106-129(4) with respect to any food, 106-133(1) with respect to any drug or device, or 106-136(1) and (5) with respect to any cosmetic, unless there is in effect a regulation pursuant to G.S. 106-139 of this Article limiting the quantity of substance, and the use or intended use of such substance conforms to the terms prescribed by such regulation. While such regulations relating to such substance are in effect, a food, drug, or cosmetic shall not, by reason of bearing or containing such substance

in accordance with the regulations be considered adulterated within the meaning of G.S. 106-129(1)a, 106-133(1) and 106-136(1).

**§ 106-133. Drugs deemed to be adulterated.**

A drug or device shall be deemed to be adulterated:

- (1)
  - a. If it consists in whole or in part of any filthy, putrid or decomposed substance; or
  - b. If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or
  - c. If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
  - d. If
    1. It is a drug and it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of G.S. 106-132, or
    2. If it is a color additive, the intended use of which in or on drugs is for purposes of coloring only, and is unsafe within the meaning of G.S. 106-132;
  - e. If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Article as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.
- (2) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those so prescribed under authority of the federal act. No drug defined in an official compendium shall be deemed to be adulterated under this subdivision because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.
- (3) If it is not subject to the provisions of subdivision (2) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.
- (4) If it is a drug and any substance has been
  - a. Mixed or packed therewith so as to reduce its quality or strength; or
  - b. Substituted wholly or in part therefor.

**§ 106-134. Drugs deemed misbranded.**

A drug or device shall be deemed to be misbranded:

- (1) If its labeling is false or misleading in any particular, or if its labeling or packaging fails to conform with the requirements of G.S. 106-139 or 106-139.1 of this Article.
- (2) If in package form unless it bears a label containing
  - a. The name and place of business of the manufacturer, packer, or distributor; and
  - b. An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, which statement shall be separately and accurately stated in a uniform location upon the principal display panel of the label, except as exempted with respect to this clause by G.S. 106-121(2a)c of this Article; provided, that under paragraph b of this subdivision reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Board of Agriculture.

- (3) If any word, statement, or other information required by or under authority of this Article to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- (4) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alphaeucaine, barbituric acid, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substances, which derivative has been by the Board after investigation, found to be, and by regulations under this Article, designated as, habit forming; unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning – May be habit forming."
- (5)
  - a. If it is a drug, unless:
    1. Its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula),
      - I. The established name (as defined in paragraph b of this subdivision) of the drug, if such there be, and
      - II. In case it is fabricated from two or more ingredients the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: Provided, that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subdivision, shall apply only to prescription drugs; and
    2. For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient; and provided, that to the extent that compliance with the requirements of 1 II or 2 of this subdivision is impracticable, exemptions shall be allowed under regulations promulgated by the Board.
  - b. As used in this subdivision (5), the term "established name," with respect to a drug or ingredient thereof, means:
    1. The applicable official name designated pursuant to section 508 of the federal act, or
    2. If there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof, in such compendium, or
    3. If neither 1 nor 2 of this paragraph applies, then the common or usual name, if any, of such drug or of such ingredient:

Provided further, that where 2 of this sub-subdivision applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply.
- (6) Unless its labeling bears
  - a. Adequate directions for use; and
  - b. Such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, that where any requirement of paragraph a of

this subdivision, as applied to any drug or device, is not necessary for the protection of the public health, the Board of Agriculture shall promulgate regulations exempting such drug or device from such requirements.

- (7) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: Provided, that the method of packing may be modified with the consent of the Board of Agriculture. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.
- (8) If it has been found by the Department of Agriculture and Consumer Services to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Board of Agriculture shall by regulations require as necessary for the protection of public health. No such regulation shall be established for any drug recognized in an official compendium until the Commissioner of Agriculture shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.
- (9)
  - a. If it is a drug and its container is so made, formed, or filled as to be misleading; or
  - b. If it is an imitation of another drug; or
  - c. If it is offered for sale under the name of another drug.
- (10) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.
- ...
- (13) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless:
  - a. It is from a batch with respect to which a certificate or release has been issued pursuant to section 506 of the federal act, and
  - b. Such certificate or release is in effect with respect to such drug.
- (14) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless
  - a. It is from a batch with respect to which a certificate or release has been issued pursuant to section 507 of the federal act, and
  - b. Such certificate or release is in effect with respect to such drug:Provided, that this subsection shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507(c) or (d) of the federal act. For the purpose of this subsection the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by microorganisms and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).
- (15) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, prescribed under the provisions of G.S. 106-132 of this Article.
- (16) In the case of any prescription drug distributed or offered for sale in this State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of
  - a. The established name, as defined in G.S. 106-134(5)b of this Article, printed prominently and in type at least half as large as that used for any trade or brand name thereof,
  - b. The formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e) of the federal act, and

- c. Such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations issued under the federal act.
- (17) If a trademark, trade name or other identifying mark, imprint or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.
- (18) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Federal Poison Prevention Packaging Act of 1970.

**§ 106-134.1. Prescriptions required; label requirements; removal of certain drugs from requirements of this section.**

(a) A drug intended for use by man which:

- (1) Is a habit-forming drug to which G.S. 106-134(4) applies; or
- (2) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug in the course of his normal practice; or
- (3) Is limited by an approved application under section 505 of the federal act to use under the professional supervision of a practitioner licensed by law to administer such drug; or
- (4) Is a drug the label of which bears the statement "Caution: Federal law prohibits dispensing without a prescription," shall be dispensed only
  - a. Upon a written prescription of a practitioner licensed by law to administer such drug, or authorized to issue orders pursuant to G.S. 90-87(23)(a), provided that the written prescription must bear the printed or stamped name, address, telephone number and DEA number of the prescriber in addition to his legal signature, or
  - b. Upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or
  - c. By refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. If any prescription for such drug does not indicate the times it may be refilled, if any, such prescription may not be refilled unless the pharmacist is subsequently authorized to do so by the practitioner.

The act of dispensing a drug contrary to the provisions of this subdivision shall be deemed to be an act which results in a drug being misbranded while held for sale.

(b) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of G.S. 106-134, except subsections (1), (9)b and c, (13) and (14), and the packaging requirements of subsections (7) and (8), if the drug bears an affixed label containing the name of the patient, the name and address of the pharmacy, the phrase "Filled by \_\_\_\_\_" or "Dispensed by \_\_\_\_\_," with the name of the practitioner who dispenses the prescription appearing in the blank, the serial number and date of the prescription or of its filling, the name of the prescriber, the directions for use, and unless otherwise directed by the prescriber of such drug, the name and strength of such drug. This exemption shall not apply to any drugs dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of subsection (a) of this section.

Any tranquilizer or sedative dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be labelled by the pharmacist, if the prescriber so directs on the prescription, with a warning that: "The consumption of alcoholic beverages while on this medication can be harmful to your health."

(c) The Board may, by regulation, remove drugs subject to G.S. 106-134(4) and G.S. 106-135 from the requirements of subsection (a) of this section when such requirements are not necessary for the protection of the public health. Drugs removed from the prescription requirements of the federal act by regulations issued thereunder shall also, by regulations issued by the Board, be removed from the requirement of subsection (a).

(d) A drug which is subject to subsection (a) of this section shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription." A drug to which subsection (a) of this section does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(e) Nothing in this section shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classification of "controlled substances" as this term is defined in applicable federal and State controlled substance acts.

**§ 106-135. Regulations for sale of new drugs.**

- (a) No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless:
- (1) An application with respect thereto has been approved and said approval has not been withdrawn under section 505 of the federal act, or
  - (2) When not subject to the federal act, by virtue of not being a drug in interstate commerce, unless such drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the Commissioner an application setting forth
    - a. Full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;
    - b. A full list of the articles used as components of such drug;
    - c. A full statement of the composition of such drug;
    - d. A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;
    - e. Such samples of such drug and of the articles used as components thereof as the Commissioner may require; and
    - f. Specimens of the labeling proposed to be used for such drug.
- (b) An application provided for in subdivision (a)(2) of this section shall become effective on the one hundred eightieth day after the filing thereof, except that if the Commissioner finds, after due notice to the applicant and giving him an opportunity for hearing,
- (1) That the drug is not safe or not effective for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof; or
  - (2) The methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug is inadequate to preserve its identity, strength, quality, and purity; or
  - (3) Based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.
- (c) An order refusing to permit an application under this section to become effective may be revoked by the Commissioner.
- (d) The Commissioner shall promulgate regulations for exempting from the operation of the foregoing subsections and subdivisions of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Commissioner among other conditions relating to the protection of the public health, provide for conditioning such exemption upon
- (1) The submission to the Commissioner, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;
  - (2) The manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and
  - (3) The establishment and maintenance of such records, and the making of such reports to the Commissioner, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Commissioner finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible, or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be



construed to require any clinical investigator to submit directly to the Commissioner reports on the investigational use of drugs; provided, that regulations adopted under section 505(i) of the federal act may be adopted by the Commissioner as the regulations in this State.

- (e) (1) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Commissioner, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Commissioner may by general regulation, or by order with respect to such application, prescribe: Provided, however, that regulations and orders issued under this subsection and under subsection (d) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Commissioner deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Commissioner.
- (2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Commissioner, permit such officer or employee at all reasonable times to have access to and copy and certify such records.
- (f) The Commissioner may, after affording an opportunity for public hearing, revoke an application approved pursuant to this section if he finds that the drug, based on evidence acquired after such approval, may not be safe or effective for its intended use, or that the facilities or controls used in the manufacture, processing, or labeling of such drug may present a hazard to the public health.
- (g) This section shall not apply:
  - (1) To a drug sold in this State or introduced into interstate commerce at any time prior to the enactment of the federal act, if its labeling contained the same representations concerning the conditions of its use; or
  - (2) To any drug which is licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.) or under the Animal Virus-Serum-Toxin Act of March 4, 1913 (13 Stat. 832; 21 U.S.C. 151 et seq.); or
  - (3) To any drug which is subject to G.S. 106-134 (14) of this Article.

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**§ 106-138. False advertising.**

- (a) An advertisement of a food, drug, device or cosmetic shall be deemed to be false if it is false or misleading in any particular.
- (b) For the purpose of this Article the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis, media, paralysis, pneumonia, poliomyelitis, (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis, tumors, typhoid, uremia, or venereal diseases, shall also be deemed to be false; except that no advertisement not in violation of subsection (a) shall be deemed to be false under this subsection if it is disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices: Provided, that whenever the Department of Agriculture and Consumer Services determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the Board shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the Board may deem necessary in the interest of public health: Provided, that this subsection shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

**§ 106-139. Regulations by Board of Agriculture.**

- (a) The authority to promulgate regulations for the efficient enforcement of this Article is hereby vested in the Board of Agriculture, except the Commissioner of Agriculture is hereby authorized to promulgate regulations under G.S. 106-131 and 106-135. The Board and Commissioner are hereby authorized to make the regulations promulgated under this Article conform, insofar as practicable, with those promulgated for foods, drugs, devices,

cosmetics and consumer commodities under the federal act, including but not limited to pesticide chemical residues on or in foods, food additives, color additives, special dietary foods, labeling of margarine for retail sale or distribution, nutritional labeling of foods, the fair packaging and labeling of consumer commodities and new drug clearance. Notwithstanding the provisions of subsection (e) of this section, a federal regulation adopted by the Board or Commissioner pursuant to this Article shall take effect in this State on the date it becomes effective as a federal regulation.

(b) The Board may promulgate regulations exempting from any affirmative labeling requirement of this Article consumer commodities which are, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such consumer commodities are not adulterated or misbranded under the provisions of this Article upon removal from such processing, labeling or repacking establishment. The Board may additionally promulgate regulations exempting from any labeling requirement of this Article foods packaged or dispensed at the direction of the retail purchaser at the time of sale, whether or not for immediate consumption by the purchaser on the premises of the seller.

(c) Whenever the Board determines that regulations containing prohibitions or requirements other than those prescribed by G.S. 106-139.1(a) are necessary to prevent the deception of consumers or to facilitate value comparisons as to any consumer commodity, the Board shall promulgate with respect to that commodity regulations effective to:

- (1) Establish and define standards for the characterization of the size of a package enclosing any consumer commodity, which may be used to supplement the label statement of net quantity of contents of packages containing such commodity, but this paragraph shall not be construed as authorizing any limitation of the size, shape, weight, dimensions, or number of packages which may be used to enclose any commodity;
- (2) Regulate the placement upon any package containing any commodity or upon any label affixed to such commodity, of any printed matter stating or representing by implication that such commodity is offered for retail sale at a price lower than the ordinary and customary retail sale price or that a retail sale price advantage is accorded to purchasers thereof by reason of the size of that package or the quantity of its contents;
- (3) Require that the label on each package of a consumer commodity bear
  - a. The common or usual name of such consumer commodity, if any, and
  - b. In case such consumer commodity consists of two or more ingredients, the common or usual name of each such ingredient listed in order of decreasing predominance, but nothing in this paragraph shall be deemed to require that any trade secret be divulged;or
- (4) Prevent the nonfunctional slack-fill of packages containing consumer commodities. For the purposes of subdivision (4) of this subsection, a package shall be deemed to be nonfunctionally slack-filled if it is filled of substantially less than its capacity for reasons other than
  - a. Protection of the contents of such package, or
  - b. The requirements of machines used for enclosing the contents in such package;provided, the Board may adopt any regulations promulgated pursuant to the Federal Fair Packaging and Labeling Act which shall have the force and effect of law in this State.

(d) Hearings authorized or required by G.S. 106-131 or G.S. 106-135 shall be conducted in accordance with Chapter 150B of the General Statutes.

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#### **§ 106-139.1. Declaration of net quantity of contents.**

(a) All labels of consumer commodities, as defined by this Article, shall conform with the requirement for the declaration of net quantity of contents of section 4 of the Federal Fair Packaging and Labeling Act (15 U.S.C. 1451, et seq.) and the regulations promulgated pursuant thereto: Provided, that consumer commodities exempted from such requirements of section 4 of the Federal Fair Packaging and Labeling Act shall also be exempt from this subsection.

(b) The label of any package of a consumer commodity which bears a representation as to the number of servings of such commodity contained in such package shall bear a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving.

(c) No person shall distribute or cause to be distributed in commerce any packaged consumer commodity if any qualifying words or phrases appear in conjunction with the separate statement of the net quantity of contents required by subsection (a) of this section, but nothing in this section shall prohibit supplemental statements, at other places on the package, describing in nondeceptive terms the net quantity of contents: Provided, that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the commodity contained in the package.

**§ 106-140. Further powers of Commissioner of Agriculture for enforcement of Article; report by inspector to owner of establishment.**

(a) For purposes of enforcement of this Article, the Commissioner or any of his authorized agents, are authorized upon presenting appropriate credentials and a written notice to the owner, operator or agent in charge,

- (1) To enter at reasonable times any factory, warehouse or establishment in which food, drugs, devices or cosmetics are manufactured, processed, or packed or held for introduction into commerce or after such introduction or to enter any vehicle being used to transport or hold such food, drugs, devices or cosmetics in commerce; and
- (2) To inspect at reasonable times and in a reasonable manner such factory, warehouse, establishment or vehicle and all pertinent equipment, finished or unfinished materials, containers and labeling therein, and to obtain samples necessary to the endorsement of this Article. In the case of any factory, warehouse, establishment, or consulting laboratory in which any food, drug, device or cosmetic is manufactured, processed, analyzed, packed or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls and facilities) bearing on whether any food, drug, device or cosmetic which is adulterated or misbranded within the meaning of this Article or which may not be manufactured, introduced into commerce or sold or offered for sale by reason of any provision of this Article, has been or is being manufactured, processed, packed, transported or held in any such place or otherwise bearing on violation of this Article. No inspection authorized by the preceding sentence shall extend to
  - a. Financial data,
  - b. Sales data other than shipment data,
  - c. Personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Article),
  - d. Pricing data, and
  - e. Research data (other than data relating to new drugs and antibiotic drugs, subject to reporting and inspection under lawful regulations issued pursuant to section 505(i) or (j) or section 507 (d) or (g) of the federal act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the federal act).

Such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to such classes of persons as the Board may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

- (3) To have access to and to copy all records of carriers in commerce showing the movement in commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper and consignee thereof: Provided, that evidence obtained under this subsection shall not be used in a criminal prosecution of the person from whom obtained; and provided further, that carriers shall not be subject to the other provisions of this Article by reason of their receipt, carriage, holding, or delivery of food, drugs, devices or cosmetics in the usual course of business as carriers.

(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory or other establishment and prior to leaving the premises, the authorized agent making the inspection shall give to the owner, operator, or agent-in-charge a report in writing setting forth any conditions or practices observed by him which in his judgment indicate that any food, drug, device or cosmetic in such establishment:

- (1) Consists in whole or in part of any filthy, putrid, or decomposed substance; or

- (2) Has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.
- (c) If the authorized agent making any such inspection of a factory, warehouse or other establishment has obtained any salable product samples in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall offer reasonable payment for any such product samples.
- (d) It shall be the duty of the Commissioner of Agriculture to make or cause to be made examination of samples secured under the provisions of this section to determine whether or not any provision of this Article is being violated.

**§ 106-140.1. Registration of producers of prescription drugs and devices.**

- (a) On or before December 31 of each year, every person doing business in North Carolina and operating as a wholesaler, manufacturer, outsourcing facility, or repackager, as those terms are defined in subsection (j) of this section, shall register with the Commissioner his name and business location(s) in North Carolina. If said person has no business locations in North Carolina, he shall register his name and location of his corporate offices.
- (b) Every person, upon first operating as a wholesaler, manufacturer, outsourcing facility, or repackager in North Carolina shall immediately register with the Commissioner his name, place of business, and such establishment. If said person has no business locations in North Carolina, he shall register his name and location of his corporate offices.
- (c) Every person duly registered in accordance with subsections (a) and (b) of this section shall register with the Commissioner any additional establishment that he owns or operates in the State of North Carolina prior to doing business as a manufacturer, wholesaler, outsourcing facility, or repackager.
- (d) The Commissioner may assign a registration number to any person or any establishment registered in accordance with this section.
- (e) The Commissioner shall make available for inspection to any person so requesting any registration filed pursuant to this section.
- (f) The following classes of people are exempt from the registration requirements of this section:
  - (1) Pharmacists as defined in G.S. 90-85.3(q) holding a valid permit as defined in G.S. 90-85.3(m).
  - (2) Practitioners licensed or registered by law to prescribe or administer drugs and who manufacture, prepare, compound, or process drugs or devices solely for use in the course of their professional practice.
  - (3) Persons who manufacture, prepare, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale.
  - (4) Other classes of persons the Commissioner may by rule exempt from the application of this section upon a finding that registration by these classes of persons in accordance with this section is not necessary for the protection of the public health.
  - (5) Wholesale distributors of prescription drugs licensed under G.S. 106-145.3.
- (g) Every establishment in the State of North Carolina registered with the Commissioner pursuant to this section shall be subject to inspection pursuant to G.S. 106-140.
- (h) The Commissioner shall adopt rules to implement the registration requirements of this section. These rules shall provide for an annual registration fee of one thousand dollars (\$1,000) for companies operating as manufacturers, outsourcing facilities, or repackagers and seven hundred dollars (\$700.00) for companies operating as wholesalers. The Department of Agriculture and Consumer Services shall use these funds for the implementation of the North Carolina Food, Drug and Cosmetic Act.
- (i) For the purposes of this act, name means the name of the partnership if a partnership and the name of the corporation if a corporation.
- (j) As used in this section:
  - (1) The term "manufacturer" means a person who prepares, derives, or produces a prescription drug. Pharmacists are specifically excluded from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it.
  - (1a) The term "outsourcing facility" means a manufacturer at a single geographic location or address that is engaged in the compounding of sterile drugs, has elected to register as an outsourcing facility with the Food and Drug Administration, and complies with the requirements as provided in 21 U.S.C. § 353b. Exemptions provided by 21 U.S.C. § 353b(a) with respect to labeling, new drug registration, and distribution supply chain requirements shall also apply to compounded drugs distributed in North Carolina by an outsourcing facility.

- (2) The term "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 a prescription."
- (3) The term "repackager" means a person who repacks, relabels, or manipulates a prescription drug which was in a unit packaged and sealed by a manufacturer. Pharmacists are specifically exempted from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it.
- (4) The term "wholesaler" means a person acting as a jobber, wholesale merchant, salvager, or broker, or agent thereof, who sells or distributes for resale a prescription drug. Pharmacists are specifically exempted from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it.

**§ 106-141. Examinations and investigations.**

...  
 (b) The Commissioner of Agriculture is authorized to conduct the examinations and investigations for the purposes of this Article through officers and employees of the Department or through any health, food or drug officer or employee of the State, or any political subdivision thereof: Provided, that when examinations and investigations are to be conducted through any officer or employee of any agency other than the Department of Agriculture and Consumer Services the arrangements for such examinations and investigations shall be approved by the directing head of such agency.

(c) The Commissioner of Agriculture is authorized to delegate embargo authority concerning food and drink pursuant to G.S. 106-125 to the Secretary of Health and Human Services and to local health directors.

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**§ 106-142. Publication of reports of judgments, decrees, etc.**

(a) The Commissioner of Agriculture may cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Article, including the nature of the charge and the disposition thereof.

(b) The Commissioner of Agriculture may also cause to be disseminated such information regarding food, drugs, devices, and cosmetics as he deems necessary in the interest of public health and the protection of the consumer against fraud. Nothing in this section shall be construed to prohibit the Commissioner of Agriculture from collecting, reporting, and illustrating the results of the investigations of the Department.

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**Article 12A.  
 Wholesale Prescription Drug Distributors.**

**§ 106-145.1. Purpose and interpretation of Article.**

This Article establishes a State licensing program for wholesale distributors to enable wholesale distributors to comply with federal law. This Article shall be construed to do only that required for compliance with 21 U.S.C. § 353(e) and 21 C.F.R. Part 205. This Article shall be interpreted to be consistent with 21 C.F.R. Part 205, Guidelines for State Licensing of Wholesale Prescription Drug Distributors. In the event of a conflict, the federal law controls.

**§ 106-145.2. Definitions.**

The following definitions apply in this Article:

- (1) Blood. – Whole blood collected from a single donor and processed either for transfusion or further manufacturing.
- (2) Blood component. – That part of blood separated by physical or mechanical means.
- (3) Commissioner. – The Commissioner of Agriculture.
- (4) Common control. – The power to direct or cause the direction of the management and policies of a person, whether by ownership of stock, by voting rights, by contract, or otherwise.
- (5) Department. – The Department of Agriculture and Consumer Services.
- (6) Drug sample. – A unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

- (7) Manufacturer. – A person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling a prescription drug.
- (8) Person. – An individual, a corporation, a partnership, or any other entity.
- (9) Prescription drug. – A human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to 21 U.S.C. § 353(b). Only for the purposes of the provisions of this Article, the term "prescription drug" shall include pseudoephedrine products as defined in G.S. 90-113.51 that may be dispensed without a prescription.
- (10) Wholesale distribution. – Distribution of a prescription drug to a person who is not a consumer or patient, other than any of the following types of distributions:
  - a. Intracompany sales. An intracompany sale is a transaction or transfer between any divisions, subsidiary and parent companies, or affiliated companies under common control of the same corporate entity.
  - b. The purchase or other acquisition of a prescription drug by a hospital or other health care entity that is a member of a group purchasing organization for its own use from the group purchasing organization or from other hospitals or other health care entities that are members of these organizations.
  - c. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code to a nonprofit affiliate of the organization to the extent otherwise permitted by law.
  - d. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control.
  - e. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons. Emergency medical reasons include transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage when the gross dollar value of the transfers does not exceed five percent (5%) of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any 12-consecutive-month period.
  - f. The sale, purchase, or trade of a prescription drug; an offer to sell, purchase, or trade a prescription drug; or the dispensing of a prescription drug pursuant to a prescription.
  - g. The distribution of drug samples by a representative of a manufacturer or a wholesale distributor.
  - h. The sale, purchase, or trade of blood and blood components intended for transfusion.
- (11) Wholesale distributor. – A person who is engaged in the wholesale distribution of prescription drugs. The term includes manufacturers, repackers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions. The term does not include a person who acquires prescription drugs commingled with other goods as part of a recovery operation and who disposes of such drugs under the supervision of the Department. A warehouse includes a warehouse of a manufacturer or wholesale distributor, a chain drug warehouse, and a wholesale drug warehouse.

**§ 106-145.3. Wholesale distributor must have license.**

(a) Requirement. – Every wholesale distributor engaged in the wholesale distribution of prescription drugs in interstate commerce in this State shall obtain a license from the Commissioner for each location from which prescription drugs are distributed and shall renew each license annually. A license may cover multiple buildings and multiple operations at a single location, at the wholesale distributor's discretion. A license expires on December 31 of the year in which it is issued. A wholesale distributor licensed under this section is not required to register under G.S. 106-140.1. In lieu of licensing under this section, a wholesale distributor who has no facilities in this State may register under G.S. 106-140.1 if the wholesale distributor possesses a valid license granted by another state that has requirements substantially similar to this Article.

(b) Reciprocity. – The Commissioner may license an out-of-State wholesale distributor on the basis of reciprocity with another state when the following conditions apply:

- (1) The out-of-State wholesale distributor possesses a valid license granted by another state pursuant to requirements substantially equivalent to the license requirements of this State.
- (2) The other state extends reciprocal treatment under its own laws to wholesale distributors licensed in this State.

**§ 106-145.4. Application and fee for license.**

(a) Application. – An application for a wholesale distributor license or for renewal of a wholesale distributor license shall be on a form prescribed by the Commissioner and shall include the following information:

- (1) The name, full business address, and telephone number of the applicant.
- (2) All trade or business names used by the applicant.
- (3) Addresses, telephone numbers, and names of contact persons for all facilities used by the applicant for the storage, handling, and distribution of prescription drugs.
- (4) The type of ownership or operation of the applicant, such as a partnership, a corporation, or a sole proprietorship.
- (5) The name of each owner and operator of the applicant, including:
  - a. If the applicant is an individual, the individual's name.
  - b. If the applicant is a partnership, the name of each partner and the name of the partnership.
  - c. If the applicant is a corporation, the name and title of each corporate officer and director, the corporate name of the corporation, and the state of incorporation.
  - d. If the applicant is a sole proprietorship, the full name of the sole proprietor and the name of the business entity.
- (6) Any other information required by the Commissioner to determine if the applicant is qualified to receive a license.

When a change occurs in any information listed in this subsection after a license is issued, the license holder shall report the change to the Commissioner within 90 days after the change.

(b) Fee. – An application for an initial license or a renewed license as a wholesale distributor shall be accompanied by a nonrefundable fee of one thousand dollars (\$1,000) for a manufacturer or seven hundred dollars (\$700.00) for any other person.

**§ 106-145.5. Review of application and qualifications of applicant.**

The Commissioner shall determine whether to issue or deny a wholesale distributor license within 90 days after an applicant files an application for a license with the Commissioner. The Commissioner shall have authority to review an application and issue or deny a license, grant reciprocity under G.S. 106-145.3(b), or accept registration under G.S. 106-140.1, that is conditioned upon approval of a prescription drug under section 505 of the Federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. § 301 et seq.; 52 Stat. 1040 et seq.) while the federal approval process is pending. In reviewing an application, the Commissioner shall consider the factors listed in this subsection. In the case of a partnership or corporation, the Commissioner shall consider the factors as applied to each individual whose name is required to be included in the license application.

The factors to be considered are:

- (1) Any convictions of the applicant under any federal, state, or local law relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances.
- (2) Any felony convictions of the applicant under federal, state, or local law.
- (3) The applicant's past experience in the manufacture or distribution of controlled substances and other prescription drugs.
- (4) Whether the applicant has previously given any false or fraudulent information in an application made in connection with drug manufacturing or distribution.
- (5) Suspension or revocation by the federal government or a state or local government of any license currently or previously held by the applicant for the manufacture or distribution of any controlled substances or other prescription drugs.
- (6) Compliance with the licensing requirements under any previously granted license.
- (7) Compliance with the requirements to maintain or make available to the Commissioner or to a federal, state, or local law enforcement official those records required under G.S. 106-145.8.
- (8) Whether the applicant requires employees of the applicant who are involved in any prescription drug wholesale distribution activity to have education, training, experience, or any combination of these factors sufficient to enable the employee to perform assigned

functions in a manner that ensures that prescription drug quality, safety, and security will be maintained at all times as required by law.

- (9) Any other factors or qualifications the Commissioner considers relevant to and consistent with the public health and safety.

The Commissioner shall inspect the facility of an applicant at which prescription drugs will be stored, handled, or distributed before issuing the applicant a license.

**§ 106-145.6. Denial, revocation, and suspension of license; penalties for violations.**

(a) Adverse Action. – The Commissioner may deny a license to an applicant if the Commissioner determines that granting the applicant a license would not be in the public interest. Public interest considerations shall be limited to factors and qualifications that are directly related to the protection of public health and safety. The Commissioner may deny, suspend, or revoke a license for substantial or repeated violations of this Article or for conviction of a violation of any other federal, state, or local prescription drug law or regulation. Chapter 150B of the General Statutes governs the denial, suspension, or revocation of a license under this Article.

(b) Criminal Sanctions. – It is unlawful to engage in wholesale distribution in this State without a wholesale distributor license or to violate any other provision of this Article. A person who violates this Article commits a Class H felony. A fine imposed for a violation of this Article may not exceed two hundred fifty thousand dollars (\$250,000).

(c) Civil Penalty. – The Commissioner may assess a civil penalty of not more than ten thousand dollars (\$10,000) against a person who violates any provision of this Article. In determining the amount of a civil penalty, the Commissioner shall consider the degree and extent of harm caused by the violation. Chapter 150B of the General Statutes governs the assessment of a civil penalty under this subsection. If a civil penalty is not paid within 30 days after the completion of judicial review of a final agency decision by the Commissioner, the penalty may be collected in any manner by which a debt may be collected. The clear proceeds of civil penalties assessed pursuant to this section shall be remitted to the Civil Penalty and Forfeiture Fund in accordance with G.S. 115C-457.2.

**§ 106-145.7. Storage, handling, and records of prescription drugs.**

(a) Facilities. – All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed for wholesale distribution shall meet the following requirements:

- (1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations.
- (2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.
- (3) Have a quarantine area for the storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.
- (4) Be maintained in a clean and orderly condition.
- (5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security. – All facilities used for wholesale distribution shall be secure from unauthorized entry. Access from outside the premises shall be kept to a minimum and be well-controlled. The outside perimeter of the premises shall be well-lighted. Entry into areas where prescription drugs are held shall be limited to authorized personnel. The facilities shall be equipped with the following:

- (1) An alarm system to detect entry after hours.
- (2) A security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Storage. – All prescription drugs for wholesale distribution shall be stored at appropriate temperatures and under appropriate conditions in accordance with any requirements stated in the labeling of the prescription drugs or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF). If the labeling of a prescription drug or a compendium do not establish storage requirements for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(d) Examination of Materials. – A wholesale distributor shall visually examine each outside shipping container upon receipt for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. The examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents. A wholesale distributor shall carefully inspect each outgoing shipment for identity of the prescription drugs and to ensure that no prescription drugs that have been damaged in storage or held under improper conditions are delivered.



(e) **Returned, Damaged, and Outdated Prescription Drugs.** – A wholesale distributor shall quarantine and physically separate prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated from other prescription drugs until their destruction or their return to their supplier. A prescription drug whose immediate or sealed outer or sealed secondary container has been opened or used shall be identified as having been opened or used and shall be treated in the same manner as outdated prescription drugs.

If the conditions under which a prescription drug has been returned to a wholesale distributor cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to its supplier unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.

**§ 106-145.8. Records of prescription drugs.**

(a) **Records.** – A wholesale distributor shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs, including all stored prescription drugs, all incoming and outgoing prescription drugs, and all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs. A wholesale distributor is not required, however, to keep a record of the lot number or expiration date of a prescription drug disposed of or distributed by the distributor.

A record of a prescription drug shall include all of the following information:

- (1) The source of the prescription drug, including the name and principal address of the seller or transferor and the address of the location from which the drug was shipped.
- (2) The identity and quantity of the prescription drug received and distributed or disposed of through another method.
- (3) The date the wholesale distributor received the prescription drug and the date the wholesale distributor distributed or otherwise disposed of the drug.
- (4) Documentation of the proper storage of prescription drugs. Documentation may be by manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs.

A wholesale distributor shall keep a record of a prescription drug for two years after its disposition.

(b) **Inspection.** – A wholesale distributor shall make inventories and records of prescription drugs available for inspection and photocopying by representatives of the Department or authorized federal, State, or local law enforcement officials. A wholesale drug distributor shall permit the Department or an authorized federal, State, or local law enforcement official to enter and inspect the distributor's premises and delivery vehicles and to audit the distributor's records and written operating procedures at reasonable times and in a reasonable manner.

A record that is kept at the inspection site or is immediately retrievable by computer or other electronic means shall be readily available for authorized inspection during the two-year retention period. A record kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a federal, State, or local law enforcement agency.

**§ 106-145.9. Written procedures concerning prescription drugs and lists of responsible persons.**

(a) **Procedures.** – A wholesale distributor shall establish, maintain, and adhere to written procedures for the receipt, security, storage, inventory, and distribution of prescription drugs. These shall include all of the following:

- (1) A procedure for identifying, recording, and reporting a loss or theft of a prescription drug.
- (2) A procedure for correcting all errors and inaccuracies in inventories of prescription drugs.
- (3) A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.
- (4) A procedure for handling recalls and withdrawals of prescription drugs that adequately addresses recalls and withdrawals due to any of the following:
  - a. An action initiated at the request of the Food and Drug Administration or other federal, State, or local law enforcement or other governmental agency, including the Department.
  - b. Any voluntary action by the manufacturer to remove defective or potentially defective prescription drugs from the market.

- c. Any action undertaken to promote public health and safety by replacing existing prescription drugs with an improved product or new package design.
- (5) A procedure to ensure that the wholesale distributor prepares for, protects against, and handles any crisis that affects security or operation of any facility in the event of a strike, a fire, flood, or other natural disaster, or another emergency.
- (6) A procedure to ensure that any outdated prescription drugs are segregated from other prescription drugs and either returned to the manufacturer or destroyed.
- (b) Responsible Persons. – A wholesale distributor shall establish and maintain lists of officers, directors, managers, and other persons in charge of the distribution, storage, or handling of prescription drugs. The lists shall include a description of the duties of those on the list and a summary of their qualifications.

**§ 106-145.10. Application of other laws.**

A wholesale drug distributor shall comply with applicable federal, State, and local laws and regulations. A wholesale distributor that deals in controlled substances shall register with the federal Drug Enforcement Administration (DEA) and shall comply with all applicable federal, State, and local laws and regulations. A wholesale drug distributor is subject to any applicable federal, State, or local laws or regulations that relate to prescription drug salvaging or reprocessing.

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**§ 106-145.12. Enforcement and implementation of Article.**

The Commissioner shall enforce this Article by using employees of the Department. The Commissioner may enter into agreements with federal, State, or local agencies to facilitate enforcement of this Article. The Commissioner may adopt rules to implement this Article.

**CHAPTER 115C  
ELEMENTARY AND SECONDARY EDUCATION**

***SELECTED PROVISIONS***

**Article 14A.  
Charter Schools.**

***Selected Provisions***

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**§ 115C-218.75. General operating requirements.**

(a) Health and Safety Standards. – A charter school shall meet the same health and safety requirements required of a local school administrative unit. The Department of Public Instruction shall ensure that charter schools provide parents and guardians with information about meningococcal meningitis and influenza and their vaccines at the beginning of every school year. This information shall include the causes, symptoms, and how meningococcal meningitis and influenza are spread and the places where parents and guardians may obtain additional information and vaccinations for their children.

The Department of Public Instruction shall also ensure that charter schools provide parents and guardians with information about cervical cancer, cervical dysplasia, human papillomavirus, and the vaccines available to prevent these diseases. This information shall be provided at the beginning of the school year to parents of children entering grades five through 12. This information shall include the causes and symptoms of these diseases, how they are transmitted, how they may be prevented by vaccination, including the benefits and possible side effects of vaccination, and the places where parents and guardians may obtain additional information and vaccinations for their children.

The Department of Public Instruction shall also ensure that charter schools provide students in grades seven through 12 with information annually on the preventable risks for preterm birth in subsequent pregnancies, including induced abortion, smoking, alcohol consumption, the use of illicit drugs, and inadequate prenatal care.

The Department of Public Instruction shall also ensure that charter schools provide students in grades nine through 12 with information annually on the manner in which a parent may lawfully abandon a newborn baby with a responsible person, in accordance with Article 5A of Chapter 7B of the General Statutes.

The Department of Public Instruction shall also ensure that the guidelines for individual diabetes care plans adopted by the State Board of Education under G.S. 115C-12(31) are implemented in charter schools in which students with diabetes are enrolled and that charter schools otherwise comply with G.S. 115C-375.3.

The Department of Public Instruction shall ensure that charter schools comply with G.S. 115C-375.2A. The board of directors of a charter school shall provide the school with a supply of emergency epinephrine auto-injectors necessary to meet the requirements of G.S. 115C-375.2A.

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**Article 16.  
Optional Programs.**

***Selected Provisions***

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**§ 115C-238.66. Board of directors; powers and duties.**

The board of directors shall have the following powers and duties:

...

- (7) Health and safety. – The board of directors shall require that the regional school meet the same health and safety standards required of a local school administrative unit.

The Department of Public Instruction shall ensure that regional schools comply with G.S. 115C-375.2A. The board of directors of a regional school shall provide the school with a supply of emergency epinephrine auto-injectors necessary to carry out the provisions of G.S. 115C-375.2A.

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**Article 25A.**  
**Special Medical Needs of Students.**

*Selected Provisions*

**§ 115C-375.1. To provide some medical care to students.**

Notwithstanding G.S. 90-21.10B, it is within the scope of duty of teachers, including substitute teachers, teacher assistants, student teachers, or any other public school employee when authorized by the board of education or its designee, (i) to administer any drugs or medication prescribed by a doctor upon written request of the parents, (ii) to give emergency health care when reasonably apparent circumstances indicate that any delay would seriously worsen the physical condition or endanger the life of the pupil, and (iii) to perform any other first aid or lifesaving techniques in which the employee has been trained in a program approved by the State Board of Education. No employee, however, shall be required to administer drugs or medication or attend lifesaving techniques programs.

Any public school employee, authorized by the board of education or its designee to act under (i), (ii), or (iii) above, shall not be liable in civil damages for any authorized act or for any omission relating to that act unless the act or omission amounts to gross negligence, wanton conduct, or intentional wrongdoing. Any person, serving in a voluntary position at the request of or with the permission or consent of the board of education or its designee, who has been given the authority by the board of education or its designee to act under (ii) above shall not be liable in civil damages for any authorized act or for any omission relating to the act unless the act amounts to gross negligence, wanton conduct, or intentional wrongdoing.

At the commencement of each school year, but before the beginning of classes, and thereafter as circumstances require, the principal of each school shall determine which persons will participate in the medical care program.

**§ 115C-375.2. Possession and self-administration of asthma medication by students with asthma or students subject to anaphylactic reactions, or both.**

(a) Local boards of education shall adopt a policy authorizing a student with asthma or a student subject to anaphylactic reactions, or both, to possess and self-administer asthma medication on school property during the school day, at school-sponsored activities, or while in transit to or from school or school-sponsored events. As used in this section, "asthma medication" means a medicine prescribed for the treatment of asthma or anaphylactic reactions and includes a prescribed asthma inhaler or epinephrine auto-injector. The policy shall include a requirement that the student's parent or guardian provide to the school:

- (1) Written authorization from the student's parent or guardian for the student to possess and self-administer asthma medication.
- (2) A written statement from the student's health care practitioner verifying that the student has asthma or an allergy that could result in an anaphylactic reaction, or both, and that the health care practitioner prescribed medication for use on school property during the school day, at school-sponsored activities, or while in transit to or from school or school-sponsored events.
- (3) A written statement from the student's health care practitioner who prescribed the asthma medication that the student understands, has been instructed in self-administration of the asthma medication, and has demonstrated the skill level necessary to use the asthma medication and any device that is necessary to administer the asthma medication.
- (4) A written treatment plan and written emergency protocol formulated by the health care practitioner who prescribed the medicine for managing the student's asthma or anaphylaxis episodes and for medication use by the student.
- (5) A statement provided by the school and signed by the student's parent or guardian acknowledging that the local school administrative unit and its employees and agents are not liable for an injury arising from a student's possession and self-administration of asthma medication.
- (6) Other requirements necessary to comply with State and federal laws.

(b) The student must demonstrate to the school nurse, or the nurse's designee, the skill level necessary to use the asthma medication and any device that is necessary to administer the medication.

(c) The student's parent or guardian shall provide to the school backup asthma medication that shall be kept at the student's school in a location to which the student has immediate access in the event of an asthma or anaphylaxis emergency.

(d) Information provided to the school by the student's parent or guardian shall be kept on file at the student's school in a location easily accessible in the event of an asthma or anaphylaxis emergency.

(e) If a student uses asthma medication prescribed for the student in a manner other than as prescribed, a school may impose on the student disciplinary action according to the school's disciplinary policy. A school may not impose disciplinary action that limits or restricts the student's immediate access to the asthma medication.

(f) The requirement that permission granted for a student to possess and self-administer asthma medication shall be effective only for the same school and for 365 calendar days and must be renewed annually.

(g) No local board of education, nor its members, employees, designees, agents, or volunteers, shall be liable in civil damages to any party for any act authorized by this section, or for any omission relating to that act, unless that act or omission amounts to gross negligence, wanton conduct, or intentional wrongdoing.

#### **§ 115C-375.2A. School supply of epinephrine auto-injectors.**

(a) A local board of education shall provide for a supply of emergency epinephrine auto-injectors on school property for use by trained school personnel to provide emergency medical aid to persons suffering from an anaphylactic reaction during the school day and at school-sponsored events on school property. Each school shall store in a secure but unlocked and easily accessible location a minimum of two epinephrine auto-injectors. For purposes of this section, "school property" does not include transportation to or from school.

(b) For the purposes of this section and G.S. 115C-375.2, "epinephrine auto-injector" means a disposable drug delivery system with a spring-activated, concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering a potentially fatal reaction to anaphylaxis.

(c) The principal shall designate one or more school personnel, as part of the medical care program under G.S. 115C-375.1, to receive initial training and annual retraining from a school nurse or qualified representative of the local health department regarding the storage and emergency use of an epinephrine auto-injector. Notwithstanding any other provision of law to the contrary, the school nurse or other designated school personnel who has received training under this subsection shall obtain a non-patient specific prescription for epinephrine auto-injectors from a physician, physician assistant, or nurse practitioner of the local health department serving the area in which the local school administrative unit is located.

(d) The principal shall collaborate with appropriate school personnel to develop an emergency action plan for the use of epinephrine auto-injectors in an emergency. The plan shall include at least the following components:

- (1) Standards and procedures for the storage and emergency use of epinephrine auto-injectors by trained school personnel.
- (2) Training of school personnel in recognizing symptoms of anaphylaxis.
- (3) Emergency follow-up procedures, including calling emergency services and contacting a student's parent and physician.
- (4) Instruction and certification in cardiopulmonary resuscitation.

(e) A supply of emergency epinephrine auto-injectors provided in accordance with this section shall not be used as the sole medication supply for students known to have a medical condition requiring the availability or use of an epinephrine auto-injector. Those students may be authorized to possess and self-administer their medication on school property under G.S. 115C-375.2.

(f) A local board of education, its members, employees, designees, agents, or volunteers, and a physician, physician assistant, or nurse practitioner of the local health department shall not be liable in civil damages to any party for any act authorized by this section or for any omission relating to that act unless that act or omission amounts to gross negligence, wanton conduct, or intentional wrongdoing.

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**CHAPTER 130A  
PUBLIC HEALTH  
SELECTED PROVISIONS**

**§ 130A-2. Definitions.**

The following definitions shall apply throughout this Chapter unless otherwise specified:

- ...
- (1a) "Commission" means the Commission for Public Health.
- ...
- (5) "Local health department" means a district health department or a public health authority or a county health department.
- (6) "Local health director" means the administrative head of a local health department appointed pursuant to this Chapter.
- ...
- (7) "Person" means an individual, corporation, company, association, partnership, unit of local government or other legal entity.
- ...

\* \* \* \* \*

**§ 130A-30. Commission for Public Health – Members; selection; quorum; compensation.**

- (a) The Commission for Public Health shall consist of the following 13 members:
- (1) Four elected by the North Carolina Medical Society.
- (2) Four at-large members appointed by the General Assembly in accordance with G.S. 120-121, two upon the recommendation of the President Pro Tempore of the Senate and two upon the recommendation of the Speaker of the House of Representatives.
- (b) Qualifications of Members Appointed by the Governor. – One of the members appointed by the Governor shall be a licensed pharmacist, one a licensed veterinarian, one a licensed optometrist, one a licensed dentist, and one a registered nurse.
- (b1) Length of Terms. – Members appointed to the Commission shall serve for a term of four years. At the end of the respective terms of office of members of the Commission, their successors shall be appointed for terms of four years. Any appointment to fill a vacancy on the Commission created by the resignation, dismissal, death, or disability of a member shall be filled by the appointing authority for the balance of the unexpired term. As used in this section, the term "appointing authority" means the North Carolina Medical Society in the case of members elected by the Medical Society, the General Assembly in the case of members appointed by the General Assembly, and the Governor in the case of members appointed by the Governor.
- (c) Removal of Members. – Each appointing authority may remove any member appointed by that appointing authority for misfeasance, malfeasance, or nonfeasance.
- (c1) Filling of Vacancies. – Vacancies on the Commission among the membership elected by the North Carolina Medical Society shall be filled by the executive committee of the Medical Society until the next meeting of the Medical Society, when the Medical Society shall fill the vacancy for the unexpired term. Vacancies on the Commission among the membership appointed by General Assembly shall be filled by the General Assembly as provided in subdivision (a)(2) of this section for the unexpired term. Vacancies on the Commission among the membership appointed by the the Governor shall be filled by the Governor for the unexpired term.
- (d) Quorum. – A majority of the members of the Commission constitutes a quorum for the transaction of business.
- (e) Per Diem and Expenses. – The members of the Commission shall receive per diem and necessary traveling and subsistence expenses in accordance with the provisions of G.S. 138-5.

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**§ 130A-33.60. Maternal Mortality Review Committee; membership, compensation.**

- (a) The Maternal Mortality Review Committee is established in the Department. The purpose of the committee is to reduce maternal mortality in this State by conducting multidisciplinary maternal death reviews and developing recommendations for the prevention of future maternal deaths.

(b) The Secretary shall appoint a multidisciplinary committee comprised of 20 members who represent the community, several academic disciplines, and professional specializations essential to reviewing cases of mortality due to complications from pregnancy or childbirth. Committee members shall serve without compensation, but may receive travel reimbursement from funds available to the Department.

(c) The duties of the committee shall include:

- (1) Identifying maternal death cases.
- (2) Reviewing medical records and other relevant data.
- (3) Contacting family members and other affected or involved persons to collect additional relevant data.
- (4) Consulting with relevant experts to evaluate relevant data.
- (5) Making nonindividual determinations with no legal meaning regarding the preventability of maternal deaths.
- (6) Making recommendations for the prevention of maternal deaths.
- (7) Disseminating findings and recommendations to policy makers, health care providers, health care facilities, and the general public. Reports shall include only aggregated, nonindividually identifiable data.

(d) Licensed health care providers, health care facilities, and pharmacies shall provide reasonable access to the committee to all relevant medical records associated with a case under review by the committee. A health care provider, health care facility, or pharmacy providing access to medical records pursuant to this Part shall not be held liable for civil damages or be subject to any criminal or disciplinary action for good faith efforts to provide such records.

(e) Except as provided in subsection (h) of this section, information, records, reports, statements, notes, memoranda, or other data collected pursuant to this Part shall not be admissible as evidence in any action of any kind in any court or before any other tribunal, board, agency, or person, nor shall they be exhibited nor their contents disclosed in any way, in whole or in part, by any officer or representative of the Department or any other person, except as may be necessary for the purpose of furthering the committee's review of the case to which they relate. No person participating in such review shall disclose, in any manner, the information so obtained except in strict conformity with the review process.

(f) All information, records of interviews, written reports, statements, memoranda, or other data obtained by the Department, the committee, and other persons, agencies, or organizations so authorized by the Department pursuant to this Part shall be confidential.

(g) All proceedings and activities of the committee pursuant to this Part, opinions of committee members formed as a result of such proceedings and activities, and records obtained, created, or maintained pursuant to this Part, including records of interviews, written reports, and statements procured by the Department or any other person, agency, or organization acting jointly or under contract with the Department in connection with the requirements of this Part, shall be confidential and shall not be subject to statutes relating to open meetings and open records, or subject to subpoena, discovery, or introduction into evidence in any civil or criminal proceeding.

(h) Nothing in this Part shall be construed to limit or restrict the right to discover or use in any civil or criminal proceeding anything that is available from another source.

(i) Members of the committee shall not be questioned in any civil or criminal proceeding regarding the information presented or opinions formed as a result of a meeting or communication of the committee; provided, however, that nothing in this Part shall be construed to prevent a member of the committee from testifying to information obtained independently of the committee or which is public information.

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**Article 2.**  
**Local Administration.**

*Selected Provisions*

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**§ 130A-35. County board of health; appointment; terms.**

(a) A county board of health shall be the policy-making, rule-making and adjudicatory body for a county health department.

(b) The members of a county board of health shall be appointed by the county board of commissioners. The board shall be composed of 11 members. The composition of the board shall reasonably reflect the population makeup of the county and shall include: one physician licensed to practice medicine in this State, one licensed dentist, one licensed optometrist, one licensed veterinarian, one registered nurse, one licensed pharmacist, one county commissioner, one professional engineer, and three representatives of the general public. Except as otherwise provided in this section, all members shall be residents of the county. If there is not a licensed physician, a licensed dentist, a licensed veterinarian, a registered nurse, a licensed pharmacist, or a professional engineer available for appointment, an additional representative of the general public shall be appointed. If however, one of the designated professions has only one person residing in the county, the county commissioners shall have the option of appointing that person or a member of the general public. In the event a licensed optometrist who is a resident of the county is not available for appointment, then the county commissioners shall have the option of appointing either a licensed optometrist who is a resident of another county or a member of the general public.

(c) Except as provided in this subsection, members of a county board of health shall serve three-year terms. No member may serve more than three consecutive three-year terms unless the member is the only person residing in the county who represents one of the professions designated in subsection (b) of this section. The county commissioner member shall serve only as long as the member is a county commissioner. When a representative of the general public is appointed due to the unavailability of a licensed physician, a licensed dentist, a resident licensed optometrist or a nonresident licensed optometrist as authorized by subsection (b) of this section, a licensed veterinarian, a registered nurse, a licensed pharmacist, or a professional engineer, that member shall serve only until a licensed physician, a licensed dentist, a licensed resident or nonresident optometrist, a licensed veterinarian, a registered nurse, a licensed pharmacist, or a professional engineer becomes available for appointment. In order to establish a uniform staggered term structure for the board, a member may be appointed for less than a three-year term.

(d) Vacancies shall be filled for any unexpired portion of a term.

(e) A chairperson shall be elected annually by a county board of health. The local health director shall serve as secretary to the board.

(f) A majority of the members shall constitute a quorum.

(g) A member may be removed from office by the county board of commissioners for:

(1) Commission of a felony or other crime involving moral turpitude;

(2) Violation of a State law governing conflict of interest;

(3) Violation of a written policy adopted by the county board of commissioners;

(4) Habitual failure to attend meetings;

(5) Conduct that tends to bring the office into disrepute; or

(6) Failure to maintain qualifications for appointment required under subsection (b) of this section.

A board member may be removed only after the member has been given written notice of the basis for removal and has had the opportunity to respond.

(h) A member may receive a per diem in an amount established by the county board of commissioners. Reimbursement for subsistence and travel shall be in accordance with a policy set by the county board of commissioners.

(i) The board shall meet at least quarterly. The chairperson or three of the members may call a special meeting.

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### **§ 130A-37. District board of health.**

(a) A district board of health shall be the policy-making, rule-making and adjudicatory body for a district health department and shall be composed of 15 members; provided, a district board of health may be increased up to a maximum number of 18 members by agreement of the boards of county commissioners in all counties that comprise the district. The agreement shall be evidenced by concurrent resolutions adopted by the affected boards of county commissioners.

(b) The county board of commissioners of each county in the district shall appoint one county commissioner to the district board of health. The county commissioner members of the district board of health shall appoint the other members of the board, including at least one physician licensed to practice medicine in this State, one licensed dentist, one licensed optometrist, one licensed veterinarian, one registered nurse, one licensed pharmacist, and one professional engineer. The composition of the board shall reasonably reflect the population makeup of the entire district and provide equitable district-wide representation. All members shall be residents of the



district. If there is not a licensed physician, a licensed dentist, a licensed optometrist, a licensed veterinarian, a registered nurse, a licensed pharmacist, or a professional engineer available for appointment, an additional representative of the general public shall be appointed. If however, one of the designated professions has only one person residing in the district, the county commissioner members shall have the option of appointing that person or a member of the general public.

(c) Except as provided in this subsection, members of a district board of health shall serve terms of three years. Two of the original members shall serve terms of one year and two of the original members shall serve terms of two years. No member shall serve more than three consecutive three-year terms unless the member is the only person residing in the district who represents one of the professions designated in subsection (b) of this section. County commissioner members shall serve only as long as the member is a county commissioner. When a representative of the general public is appointed due to the unavailability of a licensed physician, a licensed dentist, a licensed optometrist, a licensed veterinarian, a registered nurse, a licensed pharmacist, or a professional engineer that member shall serve only until a licensed physician, a licensed dentist, a licensed optometrist, a licensed veterinarian, a registered nurse, a licensed pharmacist, or a professional engineer becomes available for appointment. The county commissioner members may appoint a member for less than a three-year term to achieve a staggered term structure.

(d) Whenever a county shall join or withdraw from an existing district health department, the district board of health shall be dissolved and a new board shall be appointed as provided in subsection (c).

(e) Vacancies shall be filled for any unexpired portion of a term.

(f) A chairperson shall be elected annually by a district board of health. The local health director shall serve as secretary to the board.

(g) A majority of the members shall constitute a quorum.

(h) A member may be removed from office by the district board of health for:

- (1) Commission of a felony or other crime involving moral turpitude;
- (2) Violation of a State law governing conflict of interest;
- (3) Violation of a written policy adopted by the county board of commissioners of each county in the district;
- (4) Habitual failure to attend meetings;
- (5) Conduct that tends to bring the office into disrepute; or
- (6) Failure to maintain qualifications for appointment required under subsection (b) of this section.

A board member may be removed only after the member has been given written notice of the basis for removal and has had the opportunity to respond.

(i) A member may receive a per diem in an amount established by the county commissioner members of the district board of health. Reimbursement for subsistence and travel shall be in accordance with a policy set by the county commissioner members of the district board of health.

(j) The board shall meet at least quarterly. The chairperson or three of the members may call a special meeting.

(k) A district board of health is authorized to provide liability insurance for the members of the board and the employees of the district health department. A district board of health is also authorized to contract for the services of an attorney to represent the board, the district health department and its employees, as appropriate. The purchase of liability insurance pursuant to this subsection waives both the district board of health's and the district health department's governmental immunity, to the extent of insurance coverage, for any act or omission occurring in the exercise of a governmental function. By entering into a liability insurance contract with the district board of health, an insurer waives any defense based upon the governmental immunity of the district board of health or the district health department.

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**Article 6.**  
**Communicable Diseases.**

**Part 2. Immunization.**

*Selected Provisions*

**§ 130A-152. Immunization required.**

(a) Every child present in this State shall be immunized against diphtheria, tetanus, whooping cough, poliomyelitis, red measles (rubeola) and rubella. In addition, except as provided in subsection (f) of this section, every child present in this State shall be immunized against any other disease upon a determination by the Commission that the immunization is in the interest of the public health. Every parent, guardian, person in loco parentis and person or agency, whether governmental or private, with legal custody of a child shall have the responsibility to ensure that the child has received the required immunization at the age required by the Commission. If a child has not received the required immunizations by the specified age, the responsible person shall obtain the required immunization for the child as soon as possible after the lack of the required immunization is determined.

...

(c) The Commission shall adopt and the Department shall enforce rules concerning the implementation of the immunization program. The rules shall provide for:

- (1) The child's age at administration of each vaccine;
- (2) The number of doses of each vaccine;
- (3) Exemptions from the immunization requirements where medical practice suggests that immunization would not be in the best health interests of a specific category of children;
- (4) The procedures and practices for administering the vaccine; and
- (5) Redistribution of vaccines provided to local health departments.

(c1) The Commission for Public Health shall, pursuant to G.S. 130A-152 and G.S. 130A-433, adopt rules establishing reasonable fees for the administration of vaccines and rules limiting the requirements that can be placed on children, their parents, guardians, or custodians as a condition for receiving vaccines provided by the State. These rules shall become effective January 1, 1994.

(d) Only vaccine preparations which meet the standards of the United States Food and Drug Administration or its successor in licensing vaccines and are approved for use by the Commission may be used.

(e) When the Commission requires immunization against a disease not listed in paragraph (a) of this section, or requires an additional dose of a vaccine, the Commission is authorized to exempt from the new requirement children who are or who have been enrolled in school (K-12) on or before the effective date of the new requirement.

(f) Notwithstanding this section or other applicable State law, the Commission for Public Health, public school units, community colleges, constituent institutions of The University of North Carolina, and any private colleges or universities receiving State funds are prohibited from requiring a student to provide proof of vaccination against the coronavirus disease of 2019 (COVID-19) or to submit to a COVID-19 vaccination or series of COVID-19 vaccinations unless the requirement for vaccination or proof of vaccination is required for participating in a program of study, or fulfilling education requirements for a program, that requires working, volunteering, or training in a facility certified by the Centers for Medicare and Medicaid Services.

**§ 130A-153. Obtaining immunization; reporting by local health departments; access to immunization information in patient records; immunization of minors.**

(a) The required immunization may be obtained from a physician licensed to practice medicine, from a local health department, or in the case of a person at least 18 years of age, from an immunizing pharmacist. Local health departments shall administer required and State-supplied immunizations at no cost to uninsured or underinsured patients with family incomes below two hundred percent (200%) of the federal poverty level. A local health department may redistribute these vaccines only in accordance with the rules of the Commission.

(b) Local health departments shall file monthly immunization reports with the Department. The report shall be filed on forms prepared by the Department and shall state, at a minimum, each patient's age and the number of doses of each type of vaccine administered.

(c) Immunization certificates and information concerning immunizations contained in medical or other records shall, upon request, be shared with the Department, local health departments, an immunizing pharmacist, and the patient's attending physician. In addition, an insurance institution, agent, or insurance support organization, as

those terms are defined in G.S. 58-39-15, may share immunization information with the Department. The Commission may, for the purpose of assisting the Department in enforcing this Part, provide by rule that other persons may have access to immunization information, in whole or in part.

(d) A physician or local health department may immunize a minor with the consent of a parent, guardian, or person standing in loco parentis to the minor. A physician or local health department may also immunize a minor who is presented for immunization by an adult who signs a statement that he or she is authorized by a parent, guardian, or person standing in loco parentis to the minor to obtain the immunization for the minor.

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**§ 130A-156. Medical exemption.**

The Commission for Public Health shall adopt by rule medical contraindications to immunizations required by G.S. 130A-152. If a physician licensed to practice medicine in this State certifies that a required immunization is or may be detrimental to a person's health due to the presence of one of the contraindications adopted by the Commission, the person is not required to receive the specified immunization as long as the contraindication persists. The State Health Director may, upon request by a physician licensed to practice medicine in this State, grant a medical exemption to a required immunization for a contraindication not on the list adopted by the Commission.

**§ 130A-157. Religious exemption.**

If the bona fide religious beliefs of an adult or the parent, guardian or person in loco parentis of a child are contrary to the immunization requirements contained in this Chapter, the adult or the child shall be exempt from the requirements. Upon submission of a written statement of the bona fide religious beliefs and opposition to the immunization requirements, the person may attend the college, university, school or facility without presenting a certificate of immunization.

**§ 130A-158. Restitution required when vaccine spoiled due to provider negligence.**

Immunization program providers shall be liable for restitution to the State for the cost of replacement vaccine when vaccine in the provider's inventory has become spoiled or unstable due to the provider's negligence and unreasonable failure to properly handle or store the vaccine.

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**CHAPTER 131E  
HEALTH CARE FACILITIES AND SERVICES**

***SELECTED PROVISIONS***

**Article 5.  
Hospital Licensure Act.**

***Selected Provisions***

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**§ 131E-76. Definitions.**

As used in this article, unless otherwise specified:

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- (3) "Hospital" means any facility (i) that has an organized medical staff and which is designed, used, and operated to provide health care, diagnostic and therapeutic services, and continuous nursing care primarily to inpatients where such care and services are rendered under the supervision and direction of physicians licensed under Chapter 90 of the General Statutes, Article 1, to two or more persons over a period in excess of 24 hours, or (ii) designated as a rural emergency hospital by the Centers for Medicare and Medicaid Services (CMS) as defined under 42 C.F.R. § 424.575 or under section 125 of Division CC of the Consolidated Appropriations Act of 2021, Public Law 116-260. The term includes facilities for the diagnosis and treatment of disorders within the scope of specific health specialties. The term does not include private mental facilities licensed under Article 2 of Chapter 122C of the General Statutes, nursing homes licensed under G.S. 131E-102, adult care homes licensed under Part 1 of Article 1 of Chapter 131D of the General Statutes, and any outpatient department including a portion of a hospital operated as an outpatient department, on or off of the hospital's main campus, that is operated under the hospital's control or ownership and is classified as Business Occupancy by the Life Safety Code of the National Fire Protection Association as referenced under 42 C.F.R. § 482.41. Provided, however, if the Business Occupancy outpatient location is to be operated within 30 feet of any hospital facility, or any portion thereof, which is classified as Health Care Occupancy or Ambulatory Health Care Occupancy under the Life Safety Code of the National Fire Protection Association, the hospital shall provide plans and specifications to the Department for review and approval as required for hospital construction or renovations in a manner described by the Department.

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**§ 131E-79.1. Counseling patients regarding prescriptions.**

(a) Any hospital or other health care facility licensed pursuant to this Chapter or Chapter 122C of the General Statutes, health maintenance organization, local health department, community health center, medical office, or facility operated by a health care provider licensed under Chapter 90 of the General Statutes, providing patient counseling by a physician, a registered nurse, or any other appropriately trained health care professional shall be deemed in compliance with the rules adopted by the North Carolina Board of Pharmacy regarding patient counseling.

(b) As used in this section, "patient counseling" means the effective communication of information to the patient or representative in order to improve therapeutic outcomes by maximizing proper use of prescription medications and devices.

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**Article 6.**  
**Health Care Facility Licensure Act.**

**Part 2. Nursing Home Patients' Bill of Rights.**

*Selected Provisions*

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**§ 131E-116. Definitions.**

As used in this Part, unless otherwise specified:

- (1) "Administrator" means an administrator of a facility.
- (1a) "Commission" means the North Carolina Medical Care Commission.
- (2) "Facility" means a nursing home and a home for the aged or disabled licensed pursuant to G.S. 131E-102, and also means a nursing home operated by a hospital which is licensed under Article 5 of G.S. Chapter 131E.
- (3) "Patient" means a person who has been admitted to a facility.
- (4) "Representative payee" means a person certified by the federal government to receive and disburse benefits for a recipient of governmental assistance.

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**§ 131E-128.1. Nursing home medication management advisory committee.**

(a) Definitions. – As used in this section, unless the context requires otherwise, the term:

- (1) "Advisory committee" means a medication management committee established under this section to advise the quality assurance committee.
- (2) "Medication-related error" means any preventable medication-related event that adversely affects a patient in a nursing home and that is related to professional practice, or health care products, procedures, and systems, including prescribing, prescription order communications, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.
- (3) "Nursing home" means a nursing home licensed under this Chapter and includes an adult care home operated as part of a nursing home.
- (4) "Potential medication-related error" means a medication-related error that has not yet adversely affected a patient in a nursing home, but that has the potential to if not anticipated or prevented or if left unnoticed.
- (5) "Quality assurance committee" means a committee established in a nursing home in accordance with federal and State regulations to identify circumstances requiring quality assessment and assurance activities and to develop and implement appropriate plans of action to correct deficiencies in quality of care.

(b) Purpose. – It is the purpose of the General Assembly to enhance compliance with this Part through the establishment of medication management advisory committees in nursing homes. The purpose of these committees is to assist nursing homes to identify medication-related errors, evaluate the causes of those errors, and take appropriate actions to ensure the safe prescribing, dispensing, and administration of medications to nursing home patients.

(c) Advisory Committee Established; Membership. – Every nursing home shall establish a medication management advisory committee to advise the quality assurance committee on quality of care issues related to pharmaceutical and medication management and use in the nursing home. The nursing home shall maintain the advisory committee as part of its administrative duties. The advisory committee shall be interdisciplinary and consist of the nursing home administrator and at least the following members appointed by the nursing home administrator:

- (1) The director of nursing.
- (2) The consultant pharmacist.
- (3) A physician designated by the nursing home administrator.
- (4) At least three other members of the nursing home staff.

(d) Meetings. – The advisory committee shall meet as needed but not less frequently than quarterly. The Director of Nursing or Staff Development Coordinator shall chair the advisory committee. The nursing home administrator shall ensure that a record is maintained of each meeting.

(e) Confidentiality. – The meetings or proceedings of the advisory committee, the records and materials it produces, and the materials it considers, including analyses and reports pertaining to medication-related error reporting under G.S. 131E-128.2 and pharmacy reports on drug defects and adverse reactions under G.S. 131E-128.4, shall be confidential and not be considered public records within the meaning of G.S. 132-1. The meetings or proceedings and records and materials also shall not be subject to discovery or introduction into evidence in any civil action against a nursing home or a provider of professional health services resulting from matters that are the subject of evaluation and review by the committee. No person who was in attendance at a meeting of the committee shall testify in any civil action as to any evidence or other matters produced or presented during the meetings or proceedings of the committee or as to any findings, recommendations, evaluations, opinions, or other actions of the committee or its members. Notwithstanding the foregoing:

(1) Information, documents, or records otherwise available, including any deficiencies found in the course of an inspection conducted under G.S. 131E-105, shall not be immune from discovery or use in a civil action merely because they were presented during meetings or proceedings of the advisory committee. A member of the advisory committee or a person who testifies before the committee may testify in a civil action but cannot be asked about that person's testimony before the committee or any opinion formed as a result of the committee meetings or proceedings.

(2) Information that is confidential and not subject to discovery or use in civil actions under this subsection may be released to a professional standards review organization that performs any accreditation or certification function. Information released to the professional standards review organization shall be limited to information reasonably necessary and relevant to the standards review organization's determination to grant or continue accreditation or certification. Information released to the standards review organization retains its confidentiality and is not subject to discovery or use in any civil action as provided under this subsection. The standards review organization shall keep the information confidential subject to this subsection.

(3) Information that is confidential and not subject to discovery or use in civil actions under this subsection may be released to the Department of Health and Human Services pursuant to its investigative authority under G.S. 131E-105. Information released to the Department shall be limited to information reasonably necessary and relevant to the Department's investigation of compliance with Part 1 of Article 6 of this Chapter. Information released to the Department retains its confidentiality and is not subject to discovery or use in any civil action as provided in this subsection. The Department shall keep the information confidential subject to this subsection.

(4) Information that is confidential and is not subject to discovery or use in civil actions under this subsection may be released to an occupational licensing board having jurisdiction over the license of an individual involved in an incident that is under review or investigation by the advisory committee. Information released to the occupational licensing board shall be limited to information reasonably necessary and relevant to an investigation being conducted by the licensing board pertaining to the individual's involvement in the incident under review by the advisory committee. Information released to an occupational licensing board retains its confidentiality and is not subject to discovery or use in any civil action as provided in this subsection. The occupational licensing board shall keep the information confidential subject to this subsection.

(f) Duties. – The advisory committee shall do the following:

(1) Assess the nursing home's pharmaceutical management system, including its prescribing, distribution, administration policies, procedures, and practices and identify areas at high risk for medication-related errors.

(2) Review the nursing home's pharmaceutical management goals and respond accordingly to ensure that these goals are being met.

(3) Review, investigate, and respond to nursing home incident reports, deficiencies cited by licensing or credentialing agencies, and resident grievances that involve actual or potential medication-related errors.

- (4) Identify goals and recommendations to implement best practices and procedures, including risk reduction technology, to improve patient safety by reducing the risk of medication-related errors.
  - (5) Develop recommendations to establish a mandatory, nonpunitive, confidential reporting system within the nursing home of actual and potential medication-related errors.
  - (6) Develop specifications for drug dispensing and administration documentation procedures to ensure compliance with federal and State law, including the North Carolina Nursing Practice Act.
  - (7) Develop specifications for self-administration of drugs by qualified patients in accordance with law, including recommendations for assessment procedures that identify patients who may be qualified to self-administer their medications.
- (g) Penalty. – The Department may take adverse action against the license of a nursing home upon a finding that the nursing home has failed to comply with this section, G.S. 131E-128.2, 131E-128.3, or 131E-128.4.

**§ 131E-128.2. Nursing home quality assurance committee; duties related to medication error prevention.**

Every nursing home administrator shall ensure that the nursing home quality assurance committee develops and implements appropriate measures to minimize the risk of actual and potential medication-related errors, including the measures listed in this section. The design and implementation of the measures shall be based upon recommendations of the medication management advisory committee and shall:

- (1) Increase awareness and education of the patient and family members about all medications that the patient is using, both prescription and over-the-counter, including dietary supplements.
- (2) Increase prescription legibility.
- (3) Minimize confusion in prescription drug labeling and packaging, including unit dose packaging.
- (4) Develop a confidential and nonpunitive process for internal reporting of actual and potential medication-related errors.
- (5) To the extent practicable, implement proven medication safety practices, including the use of automated drug ordering and dispensing systems.
- (6) Educate facility staff engaged in medication administration activities on similar-sounding drug names.
- (7) Implement a system to accurately identify recipients before any drug is administered.
- (8) Implement policies and procedures designed to improve accuracy in medication administration and in documentation by properly authorized individuals, in accordance with prescribed orders and stop order policies.
- (9) Implement policies and procedures for patient self-administration of medication.
- (10) Investigate and analyze the frequency and root causes of general categories and specific types of actual or potential medication-related errors.
- (11) Develop recommendations for plans of action to correct identified deficiencies in the facility's pharmaceutical management practices.

**§ 131E-128.3. Staff orientation on medication error prevention.**

The nursing home administrator shall ensure that the nursing home provide a minimum of one hour of education and training in the prevention of actual or potential medication-related errors. This training shall be provided upon orientation and annually thereafter to all nonphysician personnel involved in direct patient care. The content of the training shall include at least the following:

- (1) General information relevant to the administration of medications including terminology, procedures, routes of medication administration, potential side effects, and adverse reactions.
- (2) Additional instruction on categories of medication pertaining to the specific needs of the patient receiving the medication.
- (3) The facility's policy and procedures regarding its medication administration system.
- (4) How to assist patients with safe and accurate self-administration of medication, where appropriate.
- (5) Identifying and reporting actual and potential medication-related errors.

**§ 131E-128.4. Nursing home pharmacy reports; duties of consultant pharmacist.**

(a) The consultant pharmacist for a nursing home shall conduct a drug regimen review for actual and potential drug therapy problems in the nursing home and make remedial or preventive clinical recommendations into the medical record of every patient receiving medication. The consultant pharmacist shall conduct the review at least monthly in accordance with the nursing home's policies and procedures.

(b) The consultant pharmacist shall report and document any drug irregularities and clinical recommendations promptly to the attending physician or nurse-in-charge and the nursing home administrator. The reports shall include problems identified and recommendations concerning:

- (1) Drug therapy that may be affected by biological agents, laboratory tests, special dietary requirements, and foods used or administered concomitantly with other medication to the same recipient.
- (2) Monitoring for potential adverse effects.
- (3) Allergies.
- (4) Drug interactions, including interactions between prescription drugs and over-the-counter drugs, drugs and disease, and interactions between drugs and nutrients.
- (5) Contraindications and precautions.
- (6) Potential therapeutic duplication.
- (7) Overextended length of treatment of certain drugs typically prescribed for a short period of time.
- (8) Beer's listed drugs that are potentially inappropriate for use by elderly persons.
- (9) Undertreatment or medical conditions that are suboptimally treated or not treated at all that warrant additional drug therapy to ensure quality of care.
- (10) Other identified problems and recommendations.

(c) The consultant pharmacist shall report drug product defects and adverse drug reactions in accordance with the ASHSP-USP-FDA Drug Product Defect Reporting System and the USP Adverse Drug Reaction Reporting System. The term "ASHSP-USP-FDA" means American Society of Health System Pharmacists-United States Pharmacopoeia-Food and Drug Administration. Information released to the ASHSP-USP-FDA retains its confidentiality and is not subject to discovery or use in any civil action as provided under G.S. 131E-128.1.

(d) The consultant pharmacist shall ensure that all known allergies and adverse effects are documented in plain view in the patient's medical record, including the medication administration records, and communicated to the dispensing pharmacy. The specific medications and the type of allergy or adverse reaction shall be specified in the documentation.

(e) The consultant pharmacist shall ensure that drugs that are not specifically limited as to duration of use or number of doses shall be controlled by automatic stop orders. The consultant pharmacist shall further ensure that the prescribing provider is notified of the automatic stop order prior to the dispensing of the last dose so that the provider may decide whether to continue to use the drug.

(f) The consultant pharmacist shall, on a quarterly basis, submit a summary of the reports submitted under subsections (a) and (b) of this section to the medication management advisory committee established under G.S. 131E-128.1. The summary shall not include any information that would identify a patient, a family member, or an employee of the nursing home. The purpose of the summary shall be to facilitate the identification and analysis of weaknesses in the nursing home's pharmaceutical care system that have an adverse impact on patient safety.

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**CHAPTER 143B**  
**EXECUTIVE ORGANIZATION ACT OF 1973**

***SELECTED PROVISIONS***

**§ 143B-216.60. The Justus-Warren Heart Disease and Stroke Prevention Task Force.**

(a) The Justus-Warren Heart Disease and Stroke Prevention Task Force is created in the Department of Health and Human Services.

(b) The Task Force shall have 27 members. The Governor shall appoint the Chair, and the Vice-Chair shall be elected by the Task Force. The Director of the Department of Health and Human Services, the Director of the Division of Medical Assistance in the Department of Health and Human Services, and the Director of the Division of Aging in the Department of Health and Human Services, or their designees, shall be members of the Task Force. Appointments to the Task Force shall be made as follows:

- (1) By the General Assembly upon the recommendation of the President Pro Tempore of the Senate, as follows:
  - a. Three members of the Senate;
  - b. A heart attack survivor;
  - c. A local health director;
  - d. A certified health educator;
  - e. A hospital administrator; and
  - f. A representative of the North Carolina Association of Area Agencies on Aging.
- (2) By the General Assembly upon the recommendation of the Speaker of the House of Representatives, as follows:
  - a. Three members of the House of Representatives;
  - b. A stroke survivor;
  - c. A county commissioner;
  - d. A licensed dietitian/nutritionist;
  - e. A pharmacist; and
  - f. A registered nurse.
- (3) By the Governor, as follows:
  - a. A practicing family physician, pediatrician, or internist;
  - b. A president or chief executive officer of a business upon recommendation of a North Carolina wellness council which is a member of the Wellness Councils of America;
  - c. A news director of a newspaper or television or radio station;
  - d. A volunteer of the North Carolina Affiliate of the American Heart Association;
  - e. A representative from the North Carolina Cooperative Extension Service;
  - f. A representative of the Governor's Council on Physical Fitness and Health; and
  - g. Two members at large.

(c) Each appointing authority shall assure insofar as possible that its appointees to the Task Force reflect the composition of the North Carolina population with regard to ethnic, racial, age, gender, and religious composition.

(d) The General Assembly and the Governor shall make their appointments to the Task Force not later than 30 days after the adjournment of the 1995 General Assembly, Regular Session 1995. A vacancy on the Task Force shall be filled by the original appointing authority, using the criteria set out in this section for the original appointment.

(e) The Task Force shall meet not more than twice annually at the call of the Chair.

...

(g) Members of the Task Force shall receive per diem and necessary travel and subsistence expenses in accordance with G.S. 120-3.1, 138-5 and 138-6, as applicable.

(h) A majority of the Task Force shall constitute a quorum for the transaction of its business.

(i) The Task Force may use funds allocated to it to establish two positions and for other expenditures needed to assist the Task Force in carrying out its duties.

(j) The Task Force has the following duties:

- (1) To undertake a statistical and qualitative examination of the incidence of and causes of heart disease and stroke deaths and risks, including identification of subpopulations at highest risk for developing heart disease and stroke, and establish a profile of the heart disease and stroke burden in North Carolina.

- (2) To publicize the profile of the heart disease and stroke burden and its preventability in North Carolina.
- (3) To identify priority strategies which are effective in preventing and controlling risks for heart disease and stroke.
- (4) To identify, examine limitations of, and recommend to the Governor and the General Assembly changes to existing laws, regulations, programs, services, and policies to enhance heart disease and stroke prevention by and for the people of North Carolina.
- (5) To determine and recommend to the Governor and the General Assembly the funding and strategies needed to enact new or to modify existing laws, regulations, programs, services, and policies to enhance heart disease and stroke prevention by and for the people of North Carolina.
- (6) To adopt and promote a statewide comprehensive Heart Disease and Stroke Prevention Plan to the general public, State and local elected officials, various public and private organizations and associations, businesses and industries, agencies, potential funders, and other community resources.
- (7) To identify and facilitate specific commitments to help implement the Plan from the entities listed in subdivision (6) above.
- (8) To facilitate coordination of and communication among State and local agencies and organizations regarding current or future involvement in achieving the aims of the Heart Disease and Stroke Prevention Plan.
- (9) To receive and consider reports and testimony from individuals, local health departments, community-based organizations, voluntary health organizations, and other public and private organizations statewide, to learn more about their contributions to heart disease and stroke prevention, and their ideas for improving heart disease and stroke prevention in North Carolina.
- (10) Establish and maintain a Stroke Advisory Council, which shall advise the Task Force regarding the development of a statewide system of stroke care that shall include, among other items, a system for identifying and disseminating information about the location of primary stroke centers.

(k) Notwithstanding Section 11.57 of S.L. 1999-237, the Task Force shall submit a final report to the Governor and the General Assembly by June 30, 2003, and a report to each subsequent regular legislative session within one week of its convening.

**CHAPTER 150B.**  
**ADMINISTRATIVE PROCEDURE ACT.**  
**SELECTED PROVISIONS**

**Article 1.**  
**General Provisions.**

**§ 150B-1. Policy and scope.**

(a) Purpose. - This Chapter establishes a uniform system of administrative rule making and adjudicatory procedures for agencies. The procedures ensure that the functions of rule making, investigation, advocacy, and adjudication are not all performed by the same person in the administrative process.

(b) Rights. - This Chapter confers procedural rights.

...

**§ 150B-2. Definitions.**

As used in this Chapter, the following definitions apply:

- (1) Administrative law judge. – A person appointed under G.S. 7A-752, 7A-753, or 7A-757.
- (1a) Adopt. – To take final action to create, amend, or repeal a rule.
- (1b) Agency. – An agency or an officer in the executive branch of the government of this State. The term includes the Council of State, the Governor's Office, a board, a commission, a department, a division, a council, and any other unit of government in the executive branch. A local unit of government is not an agency.
- (1c) Codifier of Rules. – The person appointed by the Chief Administrative Law Judge of the Office of Administrative Hearings pursuant to G.S. 7A-760(b).
- (1d) Commission. – The Rules Review Commission.
- (2) Contested case. – An administrative proceeding pursuant to this Chapter to resolve a dispute between an agency and another person that involves the person's rights, duties, or privileges, including licensing or the levy of a monetary penalty. The term does not include rulemaking, declaratory rulings, or the award or denial of a scholarship, a grant, or a loan.  
...
- (2b) Hearing officer. – A person or group of persons designated by an agency that is subject to Article 3A of this Chapter to preside in a contested case hearing conducted under that Article.
- (3) License. – Any certificate, permit, or other evidence, by whatever name called, of a right or privilege to engage in any activity, except licenses issued under Chapter 20 and Subchapter I of Chapter 105 of the General Statutes, occupational licenses, and certifications of electronic poll books, ballot duplication systems, or voting systems under G.S. 163-165.7.
- (4) Licensing. – Any administrative action issuing, failing to issue, suspending, or revoking a license or occupational license. The term does not include controversies over whether an examination was fair or whether the applicant passed the examination.
- (4a) Occupational license. – Any certificate, permit, or other evidence, by whatever name called, of a right or privilege to engage in a profession, occupation, or field of endeavor that is issued by an occupational licensing agency.
- (4b) Occupational licensing agency. – Any board, commission, committee, or other agency of the State that is established for the primary purpose of regulating the entry of persons into, or the conduct of persons within a particular profession, occupation, or field of endeavor, and that is authorized to issue and revoke licenses. The term does not include State agencies or departments that may as only a part of their regular function issue permits or licenses.
- (5) Party. – Any person or agency named or admitted as a party or properly seeking as of right to be admitted as a party and includes the agency as appropriate.
- (5a) Person. – Any natural person, partnership, corporation, body politic, and any unincorporated association, organization, or society that may sue or be sued under a common name.
- (6) Person aggrieved. – Any person or group of persons of common interest directly or indirectly affected substantially in his his, her, or its person, property, or employment by an administrative decision.

- (7a) Policy. – Any nonbinding interpretive statement within the delegated authority of an agency that merely defines, interprets, or explains the meaning of a statute or rule. The term includes any document issued by an agency that is intended and used purely to assist a person to comply with the law, such as a guidance document.
- (8) Residence. – Domicile or principal place of business
- (8a) Rule. – Any agency regulation, standard, or statement of general applicability that implements or interprets an enactment of the General Assembly or Congress or a regulation adopted by a federal agency or that describes the procedure or practice requirements of an agency. The term includes the establishment of a fee and the amendment or repeal of a prior rule. The term does not include the following:
  - a. Statements concerning only the internal management of an agency or group of agencies within the same principal office or department enumerated in G.S. 143A-11 or 143B-6, including policies and procedures manuals, if the statement does not directly or substantially affect the procedural or substantive rights or duties of a person not employed by the agency or group of agencies.
  - b. Budgets and budget policies and procedures issued by the Director of the Budget, by the head of a department, as defined by G.S. 143A-2 or G.S. 143B-3, or by an occupational licensing board, as defined by G.S. 93B-1.
  - c. Nonbinding interpretative statements within the delegated authority of an agency that merely define, interpret, or explain the meaning of a statute or rule.
  - d. A form, the contents or substantive requirements of which are prescribed by rule or statute.
  - e. Statements of agency policy made in the context of another proceeding, including:
    - 1. Declaratory rulings under G.S. 150B-4.
    - 2. Orders establishing or fixing rates or tariffs.
  - f. Requirements, communicated to the public by the use of signs or symbols, concerning the use of public roads, bridges, ferries, buildings, or facilities.
  - g. Statements that set forth criteria or guidelines to be used by the staff of an agency in performing audits, investigations, or inspections; in settling financial disputes or negotiating financial arrangements; or in the defense, prosecution, or settlement of cases.
  - h. Scientific, architectural, or engineering standards, forms, or procedures, including design criteria and construction standards used to construct or maintain highways, bridges, or ferries.
- ...
  - (8c) Substantial evidence. – Relevant evidence a reasonable mind might accept as adequate to support a conclusion.
  - ...

**§ 150B-3. Special provisions on licensing.**

(a) When an applicant or a licensee makes a timely and sufficient application for issuance or renewal of a license or occupational license, including the payment of any required license fee, the existing license or occupational license does not expire until a decision on the application is finally made by the agency, and if the application is denied or the terms of the new license or occupational license are limited, until the last day for applying for judicial review of the agency order. This subsection does not affect agency action summarily suspending a license or occupational license under subsections (b) and (c) of this section.

(b) Before the commencement of proceedings for the suspension, revocation, annulment, withdrawal, recall, cancellation, or amendment of any license other than an occupational license, the agency shall give notice to the licensee, pursuant to the provisions of G.S. 150B-23. Before the commencement of such proceedings involving an occupational license, the agency shall give notice pursuant to the provisions of G.S. 150B-38. In either case, the licensee shall be given an opportunity to show compliance with all lawful requirements for retention of the license or occupational license.

(c) If the agency finds that the public health, safety, or welfare requires emergency action and incorporates this finding in its order, summary suspension of a license or occupational license may be ordered effective on the date specified in the order or on service of the certified copy of the order at the last known address of the licensee,

whichever is later, and effective during the proceedings. The proceedings shall be promptly commenced and determined.

Nothing in this subsection shall be construed as amending or repealing any special statutes, in effect prior to February 1, 1976, which provide for the summary suspension of a license.

- (d) This section does not apply to the following:
- (1) Revocations of occupational licenses based solely on a court order of child support delinquency or a Department of Health and Human Services determination of child support delinquency issued pursuant to G.S. 110-142, 110-142.1, or 110-142.2.
  - (2) Refusal to renew an occupational license pursuant to G.S. 87-10.1, 87-22.2, 87-44.2, or 89C-18.1, based solely on a Department of Revenue determination that the licensee owes a delinquent income tax debt.

#### **§ 150B-4. Declaratory rulings.**

(a) On request of a person aggrieved, an agency shall issue a declaratory ruling as to the validity of a rule or as to the applicability to a given state of facts of a statute administered by the agency or of a rule or order of the agency. Upon request, an agency shall also issue a declaratory ruling to resolve a conflict or inconsistency within the agency regarding an interpretation of the law or a rule adopted by the agency. The agency shall prescribe in its rules the procedure for requesting a declaratory ruling and the circumstances in which rulings shall or shall not be issued. A declaratory ruling is binding on the agency and the person requesting it unless it is altered or set aside by the court. An agency may not retroactively change a declaratory ruling, but nothing in this section prevents an agency from prospectively changing a declaratory ruling.

- (a1) An agency shall respond to a request for a declaratory ruling as follows:
- (1) Within 30 days of receipt of the request for a declaratory ruling, the agency shall make a written decision to grant or deny the request. If the agency fails to make a written decision to grant or deny the request within 30 days, the failure shall be deemed a decision to deny the request.
  - (2) If the agency denies the request, the decision is immediately subject to judicial review in accordance with Article 4 of this Chapter.
  - (3) If the agency grants the request, the agency shall issue a written ruling on the merits within 45 days of the decision to grant the request. A declaratory ruling is subject to judicial review in accordance with Article 4 of this Chapter.
  - (4) If the agency fails to issue a declaratory ruling within 45 days, the failure shall be deemed a denial on the merits, and the person aggrieved may seek judicial review pursuant to Article 4 of this Chapter. Upon review of an agency's failure to issue a declaratory ruling, the court shall not consider any basis for the denial that was not presented in writing to the person aggrieved.

### **Article 2A. Rules.**

#### **Part 1. General Provisions. *Selected Provisions***

#### **§ 150B-18. Scope and effect.**

This Article applies to an agency's exercise of its authority to adopt a rule. A rule is not valid unless it is adopted in substantial compliance with this Article. An agency shall not seek to implement or enforce against any person a policy, guideline, or other interpretive statement that meets the definition of a rule contained in G.S. 150B-2(8a) if the policy, guideline, or other interpretive statement has not been adopted as a rule in accordance with this Article.

#### **§ 150B-19. Restrictions on what can be adopted as a rule.**

An agency may not adopt a rule that does one or more of the following:

- (1) Implements or interprets a law unless that law or another law specifically authorizes the agency to do so.
- (2) Enlarges the scope of a profession, occupation, or field of endeavor for which an occupational license is required.
- (3) Imposes criminal liability or a civil penalty for an act or omission, including the violation of a rule, unless a law specifically authorizes the agency to do so or a law declares that violation of the rule is a criminal offense or is grounds for a civil penalty.

- (4) Repeats the content of a law, a rule, or a federal regulation. A brief statement that informs the public of a requirement imposed by law does not violate this subdivision and satisfies the "reasonably necessary" standard of review set in G.S. 150B-21.9(a)(3).
- (5) Establishes a fee or other charge for providing a service in fulfillment of a duty unless a law specifically authorizes the agency to do so or the fee or other charge is for one of the following:
  - a. A service to a State, federal, or local governmental unit.
  - b. A copy of part or all of a State publication or other document, the cost of mailing a document, or both.
  - c. A transcript of a public hearing.
  - d. A conference, workshop, or course.
  - e. Data processing services.
- (6) Allows the agency to waive or modify a requirement set in a rule unless a rule establishes specific guidelines the agency must follow in determining whether to waive or modify the requirement.

**§ 150B-19.1. Requirements for agencies in the rule-making process.**

(a) In developing and drafting rules for adoption in accordance with this Article, agencies shall adhere to the following principles:

- (1) An agency may adopt only rules that are expressly authorized by federal or State law and that are necessary to serve the public interest.
- (2) An agency shall seek to reduce the burden upon those persons or entities who must comply with the rule.
- (3) Rules shall be written in a clear and unambiguous manner and must be reasonably necessary to implement or interpret federal or State law.
- (4) An agency shall consider the cumulative effect of all rules adopted by the agency related to the specific purpose for which the rule is proposed. The agency shall not adopt a rule that is unnecessary or redundant.
- (5) When appropriate, rules shall be based on sound, reasonably available scientific, technical, economic, and other relevant information. Agencies shall include a reference to this information in the notice of text required by G.S. 150B-21.2(c).
- (6) Rules shall be designed to achieve the regulatory objective in a cost-effective and timely manner.

(b) Each agency subject to this Article shall conduct an annual review of its rules to identify existing rules that are unnecessary, unduly burdensome, or inconsistent with the principles set forth in subsection (a) of this section. The agency shall repeal any rule identified by this review.

(c) Each agency subject to this Article shall post on its Web site, no later than the publication date of the notice of text in the North Carolina Register, all of the following:

- (1) The text of a proposed rule.
- (2) An explanation of the proposed rule and the reason for the proposed rule.
- (3) The federal certification required by subsection (g) of this section.
- (4) Instructions on how and where to submit oral or written comments on the proposed rule, including a description of the procedure by which a person can object to a proposed rule and subject the proposed rule to legislative review.
- (5) Any fiscal note that has been prepared for the proposed rule.

If an agency proposes any change to a rule or fiscal note prior to the date it proposes to adopt a rule, the agency shall publish the proposed change on its Web site as soon as practicable after the change is drafted. If an agency's staff proposes any such change to be presented to the rule-making agency, the staff shall publish the proposed change on the agency's Web site as soon as practicable after the change is drafted.

(d) Each agency shall determine whether its policies and programs overlap with the policies and programs of another agency. In the event two or more agencies' policies and programs overlap, the agencies shall coordinate the rules adopted by each agency to avoid unnecessary, unduly burdensome, or inconsistent rules.

(e) Each agency shall quantify the costs and benefits to all parties of a proposed rule to the greatest extent possible. Prior to submission of a proposed rule for publication in accordance with G.S. 150B-21.2, the agency shall review the details of any fiscal note prepared in connection with the proposed rule and approve the fiscal note before submission.

(f) If the agency determines that a proposed rule will have a substantial economic impact as defined in G.S. 150B-21.4(b1), the agency shall consider at least two alternatives to the proposed rule. The alternatives may have been identified by the agency or by members of the public.

(g) Whenever an agency proposes a rule that is purported to implement a federal law, or required by or necessary for compliance with federal law, or on which the receipt of federal funds is conditioned, the agency shall:

- (1) Prepare a certification identifying the federal law requiring adoption of the proposed rule. The certification shall contain a statement setting forth the reasons why the proposed rule is required by federal law. If all or part of the proposed rule is not required by federal law or exceeds the requirements of federal law, then the certification shall state the reasons for that opinion.
- (2) Post the certification on the agency Web site in accordance with subsection (c) of this section.
- (3) Maintain a copy of the federal law and provide to the Office of State Budget and Management the citation to the federal law requiring or pertaining to the proposed rule.

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#### **§ 150B-20. Petitioning an agency to adopt a rule.**

(a) **Petition.** - A person may petition an agency to adopt a rule by submitting to the agency a written rule-making petition requesting the adoption. A person may submit written comments with a rule-making petition. If a rule-making petition requests the agency to create or amend a rule, the person must submit the proposed text of the requested rule change and a statement of the effect of the requested rule change. Each agency must establish by rule the procedure for submitting a rule-making petition to it and the procedure the agency follows in considering a rule-making petition. An agency receiving a rule-making petition shall, within three business days of receipt of the petition, send the proposed text of the requested rule change and the statement of the effect of the requested rule change to the Office of Administrative Hearings. The Office of Administrative Hearings shall, within three business days of receipt of the proposed text of the requested rule change and the statement of the effect of the requested rule change, distribute the information via its mailing list and publish the information on its Web site.

(b) **Time.** - An agency must grant or deny a rule-making petition submitted to it within 30 days after the date the rule-making petition is submitted, unless the agency is a board or commission. If the agency is a board or commission, it must grant or deny a rule-making petition within 120 days after the date the rule-making petition is submitted.

(c) **Action.** - If an agency denies a rule-making petition, it must send the person who submitted the petition a written statement of the reasons for denying the petition. If an agency grants a rule-making petition, it must inform the person who submitted the rule-making petition of its decision and must initiate rule-making proceedings. When an agency grants a rule-making petition, the notice of text it publishes in the North Carolina Register may state that the agency is initiating rule making as the result of a rule-making petition and state the name of the person who submitted the rule-making petition. If the rule-making petition requested the creation or amendment of a rule, the notice of text the agency publishes may set out the text of the requested rule change submitted with the rule-making petition and state whether the agency endorses the proposed text.

(d) **Review.** - Denial of a rule-making petition is a final agency decision and is subject to judicial review under Article 4 of this Chapter. Failure of an agency to grant or deny a rule-making petition within the time limits set in subsection (b) is a denial of the rule-making petition.

#### **§ 150B-21. Agency must designate rule-making coordinator; duties of coordinator.**

(a) Each agency must designate one or more rule-making coordinators to oversee the agency's rule-making functions. The coordinator shall serve as the liaison between the agency, other agencies, units of local government, and the public in the rule-making process. The coordinator shall report directly to the agency head.

(b) The rule-making coordinator shall be responsible for the following:

- (1) Preparing notices of public hearings.
- (2) Coordinating access to the agency's rules.
- (3) Screening all proposed rule actions prior to publication in the North Carolina Register to assure that an accurate fiscal note has been completed as required by G.S. 150B-21.4(b).
- (4) Consulting with the North Carolina Association of County Commissioners and the North Carolina League of Municipalities to determine which local governments would be affected by any proposed rule action.

- (5) Providing the North Carolina Association of County Commissioners and the North Carolina League of Municipalities with copies of all fiscal notes required by G.S. 150B-21.4(b), prior to publication in the North Carolina Register of the proposed text of a permanent rule change.
- (6) Coordinating the submission of proposed rules to the Governor as provided by G.S. 150B-21.26.

(c) At the earliest point in the rule-making process and in consultation with the North Carolina Association of County Commissioners, the North Carolina League of Municipalities, and with samples of county managers or city managers, as appropriate, the rule-making coordinator shall lead the agency's efforts in the development and drafting of any rules or rule changes that could:

- (1) Require any unit of local government, including a county, city, school administrative unit, or other local entity funded by or through a unit of local government to carry out additional or modified responsibilities;
- (2) Increase the cost of providing or delivering a public service funded in whole or in part by any unit of local government; or
- (3) Otherwise affect the expenditures or revenues of a unit of local government.

(d) The rule-making coordinator shall send to the Office of State Budget and Management for compilation a copy of each final fiscal note prepared pursuant to G.S. 150B-21.4(b).

(e) The rule-making coordinator shall compile a schedule of the administrative rules and amendments expected to be proposed during the next fiscal year. The coordinator shall provide a copy of the schedule to the Office of State Budget and Management in a manner proposed by that Office.

## **Part 2. Adoption of Rules.**

### **§ 150B-21.1. Procedure for adopting a temporary rule.**

(a) Adoption. - An agency may adopt a temporary rule when it finds that adherence to the notice and hearing requirements of G.S. 150B-21.2 would be contrary to the public interest and that the immediate adoption of the rule is required by one or more of the following:

- (1) A serious and unforeseen threat to the public health, safety, or welfare.
- (2) The effective date of a recent act of the General Assembly or the United States Congress.
- (3) A recent change in federal or State budgetary policy.
- (4) A recent federal regulation.
- (5) A recent court order.

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- (17) To maximize receipt of federal funds for the Medicaid program within existing State appropriations, to reduce Medicaid expenditures, and to reduce Medicaid fraud and abuse.

(a2) A recent act, change, regulation, or order as used in subdivisions (2) through (5) of subsection (a) of this section means an act, change, regulation, or order occurring or made effective no more than 210 days prior to the submission of a temporary rule to the Rules Review Commission. Upon written request of the agency, the Commission may waive the 210-day requirement upon consideration of the degree of public benefit, whether the agency had control over the circumstances that required the requested waiver, notice to and opposition by the public, the need for the waiver, and previous requests for waivers submitted by the agency.

(a3) Unless otherwise provided by law, the agency shall:

- (1) At least 30 business days prior to adopting a temporary rule, submit the rule and a notice of public hearing to the Codifier of Rules, and the Codifier of Rules shall publish the proposed temporary rule and the notice of public hearing on the Internet to be posted within five business days.
- (2) At least 30 business days prior to adopting a temporary rule, notify persons on the mailing list maintained pursuant to G.S. 150B-21.2(d) and any other interested parties of its intent to adopt a temporary rule and of the public hearing.
- (3) Accept written comments on the proposed temporary rule for at least 15 business days prior to adoption of the temporary rule.
- (4) Hold at least one public hearing on the proposed temporary rule no less than five days after the rule and notice have been published. If notice of a public hearing has been published and that public hearing has been cancelled, the agency shall publish notice at least five days prior to the date of any rescheduled hearing.



(a4) An agency must also prepare a written statement of its findings of need for a temporary rule stating why adherence to the notice and hearing requirements in G.S. 150B-21.2 would be contrary to the public interest and why the immediate adoption of the rule is required. If the temporary rule establishes a new fee or increases an existing fee, the agency shall include in the written statement that it has complied with the requirements of G.S. 12-3.1. The statement must be signed by the head of the agency adopting the temporary rule.

(b) Review. - When an agency adopts a temporary rule it must submit the rule and the agency's written statement of its findings of the need for the rule to the Rules Review Commission. Within 15 business days after receiving the proposed temporary rule, the Commission shall review the agency's written statement of findings of need for the rule and the rule to determine whether the statement meets the criteria listed in subsection (a) of this section and the rule meets the standards in G.S. 150B-21.9. The Commission shall direct a member of its staff who is an attorney licensed to practice law in North Carolina to review the statement of findings of need and the rule. The staff member shall make a recommendation to the Commission, which must be approved by the Commission or its designee. The Commission's designee shall be a panel of at least three members of the Commission. In reviewing the statement, the Commission or its designee may consider any information submitted by the agency or another person. If the Commission or its designee finds that the statement meets the criteria listed in subsection (a) of this section and the rule meets the standards in G.S. 150B-21.9, the Commission or its designee must approve the temporary rule and deliver the rule to the Codifier of Rules within two business days of approval. The Codifier of Rules must enter the rule into the North Carolina Administrative Code on the sixth business day following receipt from the Commission or its designee.

(b1) If the Commission or its designee finds that the statement does not meet the criteria listed in subsection (a) of this section or that the rule does not meet the standards in G.S. 150B-21.9, the Commission or its designee must immediately notify the head of the agency. The agency may supplement its statement of need with additional findings or submit a new statement within 30 days of the notification. If the agency fails to supplement its statement of need with additional findings or submit a new statement to the Commission within 30 days, or submits written notice within 30 days to the Commission that the agency does not intend to supplement its statement of need with additional findings or submit a new statement, the Commission or its designee shall immediately return the rule to the agency. If the agency provides additional findings or submits a new statement within 30 days of the notification, the Commission or its designee must review the additional findings or new statement within five business days after the agency submits the additional findings or new statement. If the Commission or its designee again finds that the statement does not meet the criteria listed in subsection (a) of this section or that the rule does not meet the standards in G.S. 150B-21.9, the Commission or its designee must immediately notify the head of the agency and return the rule to the agency. When the Commission returns a rule to an agency in accordance with this subsection, the agency may file an action for declaratory judgment within 30 days after notification of the return of the rule by the Commission in Wake County Superior Court pursuant to Article 26 of Chapter 1 of the General Statutes.

(b2) If an agency decides not to provide additional findings or submit a new statement when notified by the Commission or its designee that the agency's findings of need for a rule do not meet the required criteria or that the rule does not meet the required standards, the agency must notify the Commission or its designee of its decision. The Commission or its designee shall then return the rule to the agency. When the Commission returns a rule to an agency in accordance with this subsection, the agency may file an action for declaratory judgment in Wake County Superior Court pursuant to Article 26 of Chapter 1 of the General Statutes within 30 days of the date the rule is returned to the agency.

(b3) Notwithstanding any other provision of this subsection, if the agency has not complied with the provisions of G.S. 12-3.1, the Codifier of Rules shall not enter the rule into the Code.

(b4) When the Commission returns to an agency a proposed permanent rule intended to replace a temporary rule, the holder of a permit from the agency may submit revised plans for a revised permit removing the impacts of the returned rule if all of the following conditions apply:

- (1) The permit was conditioned upon adherence to the requirements of a temporary rule that the returned proposed permanent rule was intended to replace.
- (2) The revised plans comply with all other applicable regulations.

The agency shall review the revised plans and approve or deny the revised permit within 45 days of the receipt of the revised plans. The agency may not impose an additional permit fee for review of a revised plan resulting from the expiration of a temporary rule

(c) Standing. - A person aggrieved by a temporary rule adopted by an agency may file an action for declaratory judgment in Wake County Superior Court pursuant to Article 26 of Chapter 1 of the General Statutes. In the action, the court shall determine whether the agency's written statement of findings of need for the rule meets the

criteria listed in subsection (a) of this section and whether the rule meets the standards in G.S. 150B-21.9. The court shall not grant an ex parte temporary restraining order.

(c1) Filing a petition for rule making or a request for a declaratory ruling with the agency that adopted the rule is not a prerequisite to filing an action under this subsection. A person who files an action for declaratory judgment under this subsection must serve a copy of the complaint on the agency that adopted the rule being contested, the Codifier of Rules, and the Commission.

(d) Effective Date and Expiration. - A temporary rule becomes effective on the date specified in G.S. 150B-21.3. A temporary rule expires on the earliest of the following dates:

- (1) The date specified in the rule.
- (2) The effective date of the permanent rule adopted to replace the temporary rule, if the Commission approves the permanent rule.
- (3) The date the Commission returns to an agency a permanent rule the agency adopted to replace the temporary rule.
- (4) The effective date of an act of the General Assembly that specifically disapproves a permanent rule adopted to replace the temporary rule.
- (5) 270 days from the date the temporary rule was published in the North Carolina Register, unless the permanent rule adopted to replace the temporary rule has been submitted to the Commission.
- (6) Notwithstanding subdivision (5) of this subsection, 12 months after the effective date of the temporary rule.

(e) Publication. - When the Codifier of Rules enters a temporary rule in the North Carolina Administrative Code, the Codifier must publish the rule in the North Carolina Register.

#### **§ 150B-21.1A. Adoption of an emergency rule.**

(a) Adoption. - An agency may adopt an emergency rule without prior notice or hearing or upon any abbreviated notice or hearing the agency finds practical when it finds that adherence to the notice and hearing requirements of this Part would be contrary to the public interest and that the immediate adoption of the rule is required by a serious and unforeseen threat to the public health or safety. When an agency adopts an emergency rule, it must simultaneously commence the process for adopting a temporary rule by submitting the rule to the Codifier of Rules for publication on the Internet in accordance with G.S. 150B-21.1(a3). . . .

(b) Review. - An agency must prepare a written statement of its findings of need for an emergency rule. The statement must be signed by the head of the agency adopting the rule. When an agency adopts an emergency rule, it must submit the rule and the agency's written statement of its findings of the need for the rule to the Codifier of Rules. Within two business days after an agency submits an emergency rule, the Codifier of Rules must review the agency's written statement of findings of need for the rule to determine whether the statement of need meets the criteria in subsection (a) of this section. In reviewing the statement, the Codifier of Rules may consider any information submitted by the agency or another person. If the Codifier of Rules finds that the statement meets the criteria, the Codifier of Rules must notify the head of the agency and enter the rule in the North Carolina Administrative Code on the sixth business day following approval by the Codifier of Rules.

If the Codifier of Rules finds that the statement does not meet the criteria in subsection (a) of this section, the Codifier of Rules must immediately notify the head of the agency. The agency may supplement its statement of need with additional findings or submit a new statement. If the agency provides additional findings or submits a new statement, the Codifier of Rules must review the additional findings or new statement within one business day after the agency submits the additional findings or new statement. If the Codifier of Rules again finds that the statement does not meet the criteria in subsection (a) of this section, the Codifier of Rules must immediately notify the head of the agency.

If an agency decides not to provide additional findings or submit a new statement when notified by the Codifier of Rules that the agency's findings of need for a rule do not meet the required criteria, the agency must notify the Codifier of Rules of its decision. The Codifier of Rules must then enter the rule in the North Carolina Administrative Code on the sixth business day after receiving notice of the agency's decision. Notwithstanding any other provision of this subsection, if the agency has not complied with the provisions of G.S. 12-3.1, the Codifier of Rules shall not enter the rule into the Code.

(c) Standing. - A person aggrieved by an emergency rule adopted by an agency may file an action for declaratory judgment in Wake County Superior Court pursuant to Article 26 of Chapter 1 of the General Statutes. In the action, the court shall determine whether the agency's written statement of findings of need for the rule meets the

criteria listed in subsection (a) of this section and whether the rule meets the standards in G.S. 150B-21.9. The court shall not grant an ex parte temporary restraining order.

Filing a petition for rule making or a request for a declaratory ruling with the agency that adopted the rule is not a prerequisite to filing an action under this subsection. A person who files an action for declaratory judgment under this subsection must serve a copy of the complaint on the agency that adopted the rule being contested, the Codifier of Rules, and the Commission.

(d) **Effective Date and Expiration.** - An emergency rule becomes effective on the date specified in G.S. 150B-21.3. An emergency rule expires on the earliest of the following dates:

- (1) The date specified in the rule.
- (2) The effective date of the temporary rule adopted to replace the emergency rule, if the Commission approves the temporary rule.
- (3) The date the Commission returns to an agency a temporary rule the agency adopted to replace the emergency rule.
- (4) Sixty days from the date the emergency rule was published in the North Carolina Register, unless the temporary rule adopted to replace the emergency rule has been submitted to the Commission.

(e) **Publication.** - When the Codifier of Rules enters an emergency rule in the North Carolina Administrative Code, the Codifier of Rules must publish the rule in the North Carolina Register.

### **§ 150B-21.2. Procedure for adopting a permanent rule.**

(a) **Steps.** - Before an agency adopts a permanent rule, the agency must comply with the requirements of G.S. 150B-19.1, and it must take the following actions:

- (1) Publish a notice of text in the North Carolina Register.
- (2) When required by G.S. 150B-21.4, prepare or obtain a fiscal note for the proposed rule.
- (4) When required by subsection (e) of this section, hold a public hearing on the proposed rule after publication of the proposed text of the rule.
- (5) Accept oral or written comments on the proposed rule as required by subsection (f) of this section.

(c) **Notice of Text.** - A notice of the proposed text of a rule must include all of the following:

- (1) The text of the proposed rule, unless the rule is a readoption without substantive changes to the existing rule proposed in accordance with G.S. 150B-21.3A.
- (2) A short explanation of the reason for the proposed rule.
- (2a) A link to the agency's website containing the information required by G.S. 150B-19.1(c).
- (3) A citation to the law that gives the agency the authority to adopt the rule.
- (4) The proposed effective date of the rule.
- (5) The date, time, and place of any public hearing scheduled on the rule.
- (6) Instructions on how a person may demand a public hearing on a proposed rule if the notice does not schedule a public hearing on the proposed rule and subsection (e) of this section requires the agency to hold a public hearing on the proposed rule when requested to do so.
- (7) The (i) period of time during which and (ii) person within the agency to whom written comments may be submitted on the proposed rule.
- (8) If a fiscal note has been prepared for the rule, a statement that a copy of the fiscal note can be obtained from the agency.

(d) **Mailing List.** - An agency must maintain a mailing list of persons that have requested notice of rulemaking. When an agency publishes in the North Carolina Register a notice of text of a proposed rule, it must mail a copy of the notice of text to each person on the mailing list that has requested notice on the subject matter described in the notice or the rule affected. An agency may charge an annual fee to each person on the agency's mailing list to cover copying and mailing costs.

(e) **Hearing.** - An agency must hold a public hearing on a rule it proposes to adopt if the agency publishes the text of the proposed rule in the North Carolina Register and the agency receives a written request for a public hearing on the proposed rule within 15 but not later than 60 days after the notice of text is published. The agency must accept comments at the public hearing on both the proposed rule and any fiscal note that has been prepared in connection with the proposed rule.

An agency may hold a public hearing on a proposed rule and fiscal note in other circumstances. When an agency is required to hold a public hearing on a proposed rule or decides to hold a public hearing on a proposed rule when it

is not required to do so, the agency must publish in the North Carolina Register a notice of the date, time, and place of the public hearing. The hearing date of a public hearing held after the agency publishes notice of the hearing in the North Carolina Register must be at least 15 days after the date the notice is published. If notice of a public hearing has been published in the North Carolina Register and that public hearing has been cancelled, the agency must publish notice in the North Carolina Register at least 15 days prior to the date of any rescheduled hearing.

(f) Comments. - An agency must accept comments on the text of a proposed rule that is published in the North Carolina Register and any fiscal note that has been prepared in connection with the proposed rule for at least 60 days after the text is published or until the date of any public hearing held on the proposed rule, whichever is longer. An agency must consider fully all written and oral comments received.

(g) Adoption. - An agency shall not adopt a rule until the time for commenting on the proposed text of the rule has elapsed and shall not adopt a rule if more than 12 months have elapsed since the end of the time for commenting on the proposed text of the rule. Prior to adoption, an agency must review any fiscal note that has been prepared for the proposed rule and consider any public comments received in connection with the proposed rule or the fiscal note. An agency shall not adopt a rule that differs substantially from the text of a proposed rule published in the North Carolina Register unless the agency publishes the text of the proposed different rule in the North Carolina Register and accepts comments on the proposed different rule for the time set in subsection (f) of this section.

An adopted rule differs substantially from a proposed rule if it does one or more of the following:

- (1) Affects the interests of persons that, based on the proposed text of the rule published in the North Carolina Register, could not reasonably have determined that the rule would affect their interests.
- (2) Addresses a subject matter or an issue that is not addressed in the proposed text of the rule.
- (3) Produces an effect that could not reasonably have been expected based on the proposed text of the rule.

When an agency adopts a rule, it shall not take subsequent action on the rule without following the procedures in this Part. An agency must submit an adopted rule to the Rules Review Commission within 30 days of the agency's adoption of the rule.

(h) Explanation. - An agency must issue a concise written statement explaining why the agency adopted a rule if, within 15 days after the agency adopts the rule, a person asks the agency to do so. The explanation must state the principal reasons for and against adopting the rule and must discuss why the agency rejected any arguments made or considerations urged against the adoption of the rule. The agency must issue the explanation within 15 days after receipt of the request for an explanation.

(i) Record. - An agency must keep a record of a rulemaking proceeding. The record must include all written comments received, a transcript or recording of any public hearing held on the rule, any fiscal note that has been prepared for the rule, and any written explanation made by the agency for adopting the rule.

### **§ 150B-21.3. Effective date of rules.**

(a) Temporary and Emergency Rules. - A temporary rule or an emergency rule becomes effective on the date the Codifier of Rules enters the rule in the North Carolina Administrative Code.

(b) Permanent Rule. - A permanent rule approved by the Commission becomes effective on the first day of the month following the month the rule is approved by the Commission, unless the Commission received written objections to the rule in accordance with subsection (b2) of this section, or unless the agency that adopted the rule specifies a later effective date.

(b1) Delayed Effective Dates. - Except as provided in G.S. 14-4.1, if the Commission received written objections to the rule in accordance with subsection (b2) of this section, the rule becomes effective on the earlier of the thirty-first legislative day or the day of adjournment of the next regular session of the General Assembly that begins at least 25 days after the date the Commission approved the rule, unless a different effective date applies under this section. If a bill that specifically disapproves the rule is introduced in either house of the General Assembly before the thirty-first legislative day of that session, the rule becomes effective on the earlier of either the day an unfavorable final action is taken on the bill or the day that session of the General Assembly adjourns without ratifying a bill that specifically disapproves the rule. If the agency adopting the rule specifies a later effective date than the date that would otherwise apply under this subsection, the later date applies. A permanent rule that is not approved by the Commission or that is specifically disapproved by a bill enacted into law before it becomes effective does not become effective.

A bill specifically disapproves a rule if it contains a provision that refers to the rule by appropriate North Carolina Administrative Code citation and states that the rule is disapproved. Notwithstanding any rule of either house of the General Assembly, any member of the General Assembly may introduce a bill during the first 30 legislative days of

any regular session to disapprove a rule that has been approved by the Commission and that either has not become effective or has become effective by executive order under subsection (c) of this section.

(b2) **Objection.** - Any person who objects to the adoption of a permanent rule may submit written comments to the agency. If the objection is not resolved prior to adoption of the rule, a person may submit written objections to the Commission. If the Commission receives written objections from 10 or more persons, no later than 5:00 P.M. of the day following the day the Commission approves the rule, clearly requesting review by the legislature in accordance with instructions posted on the agency's Web site pursuant to G.S. 150B-19.1(c)(4), and the Commission approves the rule, the rule will become effective as provided in subsection (b1) of this section. The Commission shall notify the agency that the rule is subject to legislative disapproval on the day following the day it receives 10 or more written objections. If the Commission receives objections from 10 or more persons clearly requesting review by the legislature, and the rule objected to is one of a group of related rules adopted by the agency at the same time, the agency that adopted the rule may cause any of the other rules in the group to become effective as provided in subsection (b1) of this section by submitting a written statement to that effect to the Codifier of Rules before the other rules become effective.

(c) **Executive Order Exception.** - The Governor may, by executive order, make effective a permanent rule that has been approved by the Commission but the effective date of which has been delayed in accordance with subsection (b1) of this section upon finding that it is necessary that the rule become effective in order to protect public health, safety, or welfare. A rule made effective by executive order becomes effective on the date the order is issued or at a later date specified in the order. When the Codifier of Rules enters in the North Carolina Administrative Code a rule made effective by executive order, the entry must reflect this action.

A rule that is made effective by executive order remains in effect unless it is specifically disapproved by the General Assembly in a bill enacted into law on or before the day of adjournment of the regular session of the General Assembly that begins at least 25 days after the date the executive order is issued. A rule that is made effective by executive order and that is specifically disapproved by a bill enacted into law is repealed as of the date specified in the bill. If a rule that is made effective by executive order is not specifically disapproved by a bill enacted into law within the time set by this subsection, the Codifier of Rules must note this in the North Carolina Administrative Code.

(c1) **Fees.** - Notwithstanding any other provision of this section, a rule that establishes a new fee or increases an existing fee shall not become effective until the agency has complied with the requirements of G.S. 12-3.1.

(d) **Legislative Day and Day of Adjournment.** - As used in this section:

- (1) A "legislative day" is a day on which either house of the General Assembly convenes in regular session.
- (2) The "day of adjournment" of a regular session held in an odd-numbered year is the day the General Assembly adjourns by joint resolution or by operation of law for more than 30 days.
- (3) The "day of adjournment" of a regular session held in an even-numbered year is the day the General Assembly adjourns sine die.

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(f) **Technical Change.** - A permanent rule for which no notice or hearing is required under G.S. 150B-21.5(a)(1) through (a)(5) or G.S. 150B-21.5(b) becomes effective on the first day of the month following the month the rule is approved by the Rules Review Commission or the Codifier of Rules, as applicable.

### **§ 150B-21.3A. Periodic review and expiration of existing rules.**

(a) **Definitions.** - For purposes of this section, the following definitions apply:

- (1) **Commission.** - Means the Rules Review Commission.
- (2) **Committee.** - Means the Joint Legislative Administrative Procedure Oversight Committee.
- (2a) **Necessary rule.** - Means any rule other than an unnecessary rule.
- (5) **Public comment.** - Means written comments objecting to the rule, in whole or in part, or objecting to an agency's determination of the rule as necessary or unnecessary, received by an agency from any member of the public, including an association or other organization representing the regulated community or other members of the public.
- (6) **Unnecessary rule.** - Means a rule that the agency determines to be obsolete, redundant, or otherwise not needed.

(b) **Automatic Expiration.** - Except as provided in subsection (e) of this section, any rule for which the agency that adopted the rule has not conducted a review in accordance with this section shall expire on the date set in the schedule established by the Commission pursuant to subsection (d) of this section.

(c) **Review Process.** - Each agency subject to this Article shall conduct a review of the agency's existing rules at least once every 10 years in accordance with the following process:

- (1) Step 1: The agency shall conduct an analysis of each existing rule and make an initial determination as to whether the rule is necessary or unnecessary. The agency shall then post the results of the initial determination on its Web site and invite the public to comment on the rules and the agency's initial determination. The agency shall also submit the results of the initial determination to the Office of Administrative Hearings for posting on its Web site. The agency shall accept public comment for no less than 60 days following the posting. The agency shall review the public comments and prepare a brief response addressing the merits of each comment. After completing this process, the agency shall submit a report to the Commission. The report shall include the following items:
    - a. The agency's initial determination.
    - b. All public comments received in response to the agency's initial determination.
    - c. The agency's response to the public comments.
  - (2) Step 2: The Commission shall review the reports received from the agencies pursuant to subdivision (1) of this subsection. If a public comment relates to a rule that the agency determined to be unnecessary, the Commission shall determine whether the public comment has merit and, if so, designate the rule as necessary. For purposes of this subsection, a public comment has merit if it addresses the specific substance of the rule. The Commission shall prepare a final determination report and submit the report to the Committee for consultation in accordance with subdivision (3) of this subsection. The report shall include the following items:
    - a. The agency's initial determination.
    - b. All public comments received in response to the agency's initial determination.
    - c. The agency's response to the public comments.
    - d. A summary of the Commission's determinations regarding public comments.
    - f. A determination that all rules that the agency determined to be unnecessary and for which no public comment was received or for which the Commission determined that the public comment was without merit shall expire on the first day of the month following the date the report becomes effective in accordance with this section.
    - g. A determination that all rules that the agency determined to be necessary or that the Commission designated as necessary shall be readopted as though the rules were new rules in accordance with this Article.
  - (3) Step 3: The final determination report shall not become effective until the agency has consulted with the Committee. The determinations contained in the report pursuant to sub-subdivisions f. and g. of subdivision (2) of this subsection shall become effective on the date the report is reviewed by the Committee. If the Committee does not hold a meeting to hear the consultation required by this subdivision within 60 days of receipt of the final determination report, the consultation requirement is deemed satisfied, and the determinations contained in the report become effective on the 61st day following the date the Committee received the report. If the Committee disagrees with a determination regarding a specific rule contained in the report, the Committee may recommend that the General Assembly direct the agency to conduct a review of the specific rule in accordance with this section in the next year following the consultation.
- (d) Timetable. - The Commission shall establish a schedule for the review and readoption of existing rules in accordance with this section on a decennial basis as follows:
- (1) With regard to the review process, the Commission shall assign each Title of the Administrative Code a date by which the review required by this section must be completed. In establishing the schedule, the Commission shall consider the scope and complexity of rules subject to this section and the resources required to conduct the review required by this section. The Commission shall have broad authority to modify the schedule and extend the time for review in appropriate circumstances. Except as provided in subsections (e) and (f) of this section, if the agency fails to conduct the review by the date set by the Commission, the rules contained in that Title which have not been reviewed will expire. The Commission shall report to the Committee any agency that fails to conduct the review. The Commission may exempt rules that have been adopted or amended within the previous 10 years from the review required by this section. However, any rule exempted on this basis must be reviewed in accordance with this section no more than 10 years following the last time the rule was amended.

- (2) With regard to the readoption of rules as required by sub-subdivision (c)(2)g. of this section, once the final determination report becomes effective, the Commission shall establish a date by which the agency must readopt the rules. The Commission shall consult with the agency and shall consider the agency's rule-making priorities in establishing the readoption date. The agency may amend a rule as part of the readoption process. If a rule is readopted without substantive change or if the rule is amended to impose a less stringent burden on regulated persons, the agency is not required to prepare a fiscal note as provided by G.S. 150B-21.4.
- (e) Exclusions. – The Commission shall report annually to the Committee on any rules that do no expire pursuant to this subsection. The following rules shall not expire as provided in this section:
  - (1) Rules adopted to conform to or implement federal law.
- (f) Other Reviews. - Notwithstanding any provision of this section, an agency may subject a rule that it determines to be unnecessary to review under this section at any time by notifying the Commission that it wishes to be placed on the schedule for the current year. The Commission may also subject a rule to review under this section at any time by notifying the agency that the rule has been placed on the schedule for the current year.

**§ 150B-21.4. Fiscal and regulatory impact analysis on rules.**

(a) State Funds. - Before an agency publishes in the North Carolina Register the proposed text of a permanent rule change that would require the expenditure or distribution of funds subject to the State Budget Act, Chapter 143C of the General Statutes, it must submit the text of the proposed rule change, an analysis of the proposed rule change, and a fiscal note on the proposed rule change to the Office of State Budget and Management and obtain certification from the Office of State Budget and Management that the funds that would be required by the proposed rule change are available. The fiscal note must state the amount of funds that would be expended or distributed as a result of the proposed rule change and explain how the amount was computed. The Office of State Budget and Management must certify a proposed rule change if funds are available to cover the expenditure or distribution required by the proposed rule change.

(b) Local Funds. - Before an agency publishes in the North Carolina Register the proposed text of a permanent rule change that would affect a unit of local government, it must submit the text of the proposed rule change and a fiscal note on the proposed rule change to the Office of State Budget and Management as provided by G.S. 150B-21.26, the Fiscal Research Division of the General Assembly, the North Carolina Association of County Commissioners, and the North Carolina League of Municipalities. The fiscal note must state the amount by which the proposed rule change would increase or decrease the direct or indirect expenditures or revenues of a unit of local government and must explain how the amount was computed.

(b1) Substantial Economic Impact. - Before an agency publishes in the North Carolina Register the proposed text of a permanent rule change that would have a substantial economic impact and that is not identical to a federal regulation that the agency is required to adopt, the agency shall prepare a fiscal note for the proposed rule change and have the note approved by the Office of State Budget and Management. The agency must also obtain from the Office a certification that the agency adhered to the regulatory principles set forth in G.S. 150B-19.1(a)(2), (5), and (6). The agency may request the Office of State Budget and Management to prepare the fiscal note only after, working with the Office, it has exhausted all resources, internal and external, to otherwise prepare the required fiscal note. If an agency requests the Office of State Budget and Management to prepare a fiscal note for a proposed rule change, that Office must prepare the note within 90 days after receiving a written request for the note. If the Office of State Budget and Management fails to prepare a fiscal note within this time period, the agency proposing the rule change shall prepare a fiscal note. A fiscal note prepared in this circumstance does not require approval of the Office of State Budget and Management.

If an agency prepares the required fiscal note, the agency must submit the note to the Office of State Budget and Management for review. The Office of State Budget and Management shall review the fiscal note within 14 days after it is submitted and either approve the note or inform the agency in writing of the reasons why it does not approve the fiscal note. After addressing these reasons, the agency may submit the revised fiscal note to that Office for its review. If an agency is not sure whether a proposed rule change would have a substantial economic impact, the agency shall ask the Office of State Budget and Management to determine whether the proposed rule change has a substantial economic impact. Failure to prepare or obtain approval of the fiscal note as required by this subsection shall be a basis for objection to the rule under G.S. 150B-21.9(a)(4).

As used in this subsection, the term "substantial economic impact" means an aggregate financial impact on all persons affected of at least one million dollars (\$1,000,000) in a 12-month period. In analyzing substantial economic impact, an agency shall do the following:

- (1) Determine and identify the appropriate time frame of the analysis.
  - (2) Assess the baseline conditions against which the proposed rule is to be measured.
  - (3) Describe the persons who would be subject to the proposed rule and the type of expenditures these persons would be required to make.
  - (4) Estimate any additional costs that would be created by implementation of the proposed rule by measuring the incremental difference between the baseline and the future condition expected after implementation of the rule. The analysis should include direct costs as well as opportunity costs. Cost estimates must be monetized to the greatest extent possible. Where costs are not monetized, they must be listed and described.
  - (5) For costs that occur in the future, the agency shall determine the net present value of the costs by using a discount factor of seven percent (7%).
- (b2) Content. - A fiscal note required by subsection (b1) of this section must contain the following:
- (1) A description of the persons who would be affected by the proposed rule change.
  - (2) A description of the types of expenditures that persons affected by the proposed rule change would have to make to comply with the rule and an estimate of these expenditures.
  - (3) A description of the purpose and benefits of the proposed rule change.
  - (4) An explanation of how the estimate of expenditures was computed.
  - (5) A description of at least two alternatives to the proposed rule that were considered by the agency and the reason the alternatives were rejected. The alternatives may have been identified by the agency or by members of the public.
- (c) Errors. - An erroneous fiscal note prepared in good faith does not affect the validity of a rule.
- (d) If an agency proposes the repeal of an existing rule, the agency is not required to prepare a fiscal note on the proposed rule change as provided by this section.

**§ 150B-21.5. Circumstances when notice and rule-making hearing not required; circumstances when submission to the Commission is not required.**

(a) Amendment. - An agency is not required to publish a notice of text in the North Carolina Register, hold a public hearing, or submit the amended rule to the Commission for review when it proposes to amend a rule to do one of the following:

- (1) Reletter or renumber the rule or subparts of the rule.
- (2) Substitute one name for another when an organization or position is renamed.
- (3) Correct a citation in the rule to another rule or law when the citation has become inaccurate since the rule was adopted because of the repeal or renumbering of the cited rule or law.
- (4) Change information that is readily available to the public, such as an address, email address, a telephone number, or a Web site.
- (5) Correct a typographical error.

(a1) Response to Commission – An agency is not required to publish a notice of text in the North Carolina Register or hold a public hearing when it proposes to change the rule in response to a request or an objection by the Commission, unless the Commission determines that the change is substantial.

(b) Repeal. - An agency is not required to publish a notice of text in the North Carolina Register or hold a public hearing when it proposes to repeal a rule as a result of any of the following:

- (1) The law under which the rule was adopted is repealed.
- (2) The law under which the rule was adopted or the rule itself is declared unconstitutional.
- (3) The rule is declared to be in excess of the agency's statutory authority.

...

(e) An agency that adopts or amends a rule pursuant to subsection (a) . . . of this section shall notify the Codifier of Rules of its actions. When notified of an agency action taken pursuant to subsection (a) . . . of this section, the Codifier of Rules shall make the appropriate change to the North Carolina Administrative Code.

**§ 150B-21.6. Incorporating material in a rule by reference.**

An agency may incorporate the following material by reference in a rule without repeating the text of the referenced material:

- (1) Another rule or part of a rule adopted by the agency.



- (2) All or part of a code, standard, or regulation adopted by another agency, the federal government, or a generally recognized organization or association.

In incorporating material by reference, the agency must designate in the rule whether or not the incorporation includes subsequent amendments and editions of the referenced material. The agency can change this designation only by a subsequent rule-making proceeding. The agency must have copies of the incorporated material available for inspection and must specify in the rule both where copies of the material can be obtained and the cost on the date the rule is adopted of a copy of the material.

...

**§ 150B-21.7. Effect of transfer of duties or termination of agency on rules.**

(a) When a law that authorizes an agency to adopt a rule is repealed and another law gives the same or another agency substantially the same authority to adopt a rule, the rule remains in effect until the agency with authority over the rule amends or repeals the rule. When a law that authorizes an agency to adopt a rule is repealed and another law does not give the same or another agency substantially the same authority to adopt a rule, a rule adopted under the repealed law is repealed as of the date the law is repealed. The agency that adopted the rule shall notify the Codifier of Rules that the rule is repealed pursuant to this subsection.

...

(c) When notified of a rule repealed under this section, the Codifier of Rules must enter the repeal of the rule in the North Carolina Administrative Code.

**Part 3. Review by Commission.**

**§ 150B-21.8. Review of rule by Commission.**

- (a) Emergency Rule. - The Commission does not review an emergency rule.
- (b) Temporary and Permanent Rules. - An agency must submit temporary and permanent rules adopted by it to the Commission before the rule can be included in the North Carolina Administrative Code. The Commission reviews a temporary or permanent rule in accordance with the standards in G.S. 150B-21.9 and follows the procedure in this Part in its review of a rule.
- (c) Scope. - When the Commission reviews an amendment to a temporary or permanent rule, it may review the entire rule that is being amended. The procedure in G.S. 150B-21.1 applies when the Commission objects to part of a temporary rule that is within its scope of review but is not changed by a rule amendment. The procedure in G.S. 150B-21.12 applies when the Commission objects to a part of a permanent rule that is within its scope of review but is not changed by a rule amendment.
- (d) Judicial Review. - When the Commission returns a permanent rule to an agency in accordance with G.S. 150B-21.12(d), the agency may file an action for declaratory judgment in Wake County Superior Court within 30 days of the date the rule is returned to the agency, pursuant to Article 26 of Chapter 1 of the General Statutes.

**§ 150B-21.9. Standards and timetable for review by Commission.**

- (a) Standards. - The Commission must determine whether a rule meets all of the following criteria:
  - (1) It is within the authority delegated to the agency by the General Assembly.
  - (2) It is clear and unambiguous.
  - (3) It is reasonably necessary to implement or interpret an enactment of the General Assembly, or of Congress, or a regulation of a federal agency. The Commission shall consider the cumulative effect of all rules adopted by the agency related to the specific purpose for which the rule is proposed.
  - (4) It was adopted in accordance with Part 2 of this Article.

The Commission shall not consider questions relating to the quality or efficacy of the rule but shall restrict its review to determination of the standards set forth in this subsection.

The Commission may ask the Office of State Budget and Management to determine if a rule has a substantial economic impact and is therefore required to have a fiscal note. The Commission must ask the Office of State Budget and Management to make this determination if a fiscal note was not prepared for a rule and the Commission receives a written request for a determination of whether the rule has a substantial economic impact.

In the event that a proposed temporary or permanent rule fails to comply with any of the standards set forth in this section, the Commission shall object to the temporary or permanent rule.

- (b) Timetable. - The Commission must review a permanent rule submitted to it on or before the twentieth of a month by the last day of the next month. The Commission must review a rule submitted to it after the twentieth

of a month by the last day of the second subsequent month. The Commission must review a temporary rule in accordance with the timetable and procedure set forth in G.S. 150B-21.1.

**§ 150B-21.10. Commission action on permanent rule.**

At the first meeting at which a permanent rule is before the Commission for review, the Commission must take one of the following actions:

- (1) Approve the rule, if the Commission determines that the rule meets the standards for review.
- (2) Object to the rule, if the Commission determines that the rule does not meet the standards for review.
- (3) Extend the period for reviewing the rule, if the Commission determines it needs additional information on the rule to be able to decide whether the rule meets the standards for review.

In reviewing a new rule or an amendment to an existing rule, the Commission may request an agency to make technical changes to the rule and may condition its approval of the rule on the agency's making the requested technical changes.

**§ 150B-21.11. Procedure when Commission approves permanent rule.**

When the Commission approves a permanent rule, it must notify the agency that adopted the rule of the Commission's approval, and deliver the approved rule to the Codifier of Rules.

If the approved rule will increase or decrease expenditures or revenues of a unit of local government, the Commission must also notify the Governor of the Commission's approval of the rule and deliver a copy of the approved rule to the Governor by the end of the month in which the Commission approved the rule.

**§ 150B-21.12. Procedure when Commission objects to a permanent rule.**

(a) Action. - When the Commission objects to a permanent rule, it must send the agency that adopted the rule a written statement of the objection and the reason for the objection. The agency that adopted the rule must take one of the following actions:

- (1) Change the rule to satisfy the Commission's objection and submit the revised rule to the Commission.
- (2) Submit a written response to the Commission indicating that the agency has decided not to change the rule.

(b) Time Limit. - An agency that is not a board or commission must take one of the actions listed in subsection (a) of this section within 30 days after receiving the Commission's statement of objection. A board or commission must take one of these actions within 30 days after receiving the Commission's statement of objection or within 10 days after the board or commission's next regularly scheduled meeting, whichever comes later.

(c) Changes. - When an agency changes a rule in response to an objection by the Commission, the Commission must determine whether the change satisfies the Commission's objection. If it does, the Commission must approve the rule. If it does not, the Commission must send the agency a written statement of the Commission's continued objection and the reason for the continued objection. The Commission must also determine whether the change is substantial. In making this determination, the Commission shall use the standards set forth in G.S. 150B-21.2(g). If the change is substantial, the revised rule shall be published and reviewed in accordance with the procedure set forth in G.S. 150B-21.2.

(d) Return of Rule. - A rule to which the Commission has objected remains under review by the Commission until the agency that adopted the rule decides satisfies the Commission's objection or submits a written response to the Commission indicating that the agency has decided not to change the rule. If the agency does not submit a revised rule to satisfy the Commission's objection within the time limit established in subsection (b) of this section, or submits a written response indicating that the agency has decided not to change the rule within the time limit established by subsection (b) of this section, the Commission shall return the rule to the agency and notify the Codifier of Rules of its action. If the rule that is returned would have increased or decreased expenditures or revenues of a unit of local government, the Commission must also notify the Governor of its action and must send a copy of the record of the Commission's review of the rule to the Governor. The record of review consists of the rule, the Commission's letter of objection to the rule, the agency's written response to the Commission's letter, and any other relevant documents before the Commission when it decided to object to the rule.

**§ 150B-21.13. Procedure when Commission extends period for review of permanent rule.**

When the Commission extends the period for review of a permanent rule, it must notify the agency that adopted the rule of the extension and the reason for the extension. After the Commission extends the period for review of a

rule, it may call a public hearing on the rule. Within 70 days after extending the period for review of a rule, the Commission must decide whether to approve the rule, object to the rule, or call a public hearing on the rule.

**§ 150B-21.14. Public hearing on a rule.**

The Commission may call a public hearing on a rule when it extends the period for review of the rule. At the request of an agency, the Commission may call a public hearing on a rule that is not before it for review. Calling a public hearing on a rule not already before the Commission for review places the rule before the Commission for review. When the Commission decides to call a public hearing on a rule, it must publish notice of the public hearing in the North Carolina Register.

After a public hearing on a rule, the Commission must approve the rule or object to the rule in accordance with the standards and procedures in this Part. The Commission must make its decision of whether to approve or object to the rule within 70 days after the public hearing.

\* \* \* \* \*

**Part 5. Rules Affecting Local Governments.**

**§ 150B-21.26. Office of State Budget and Management to conduct preliminary review of certain administrative rules.**

(a) Preliminary Review. - At least 60 days before an agency publishes in the North Carolina Register the proposed text of a permanent rule change that would affect the expenditures or revenues of a unit of local government, the agency must submit all of the following to the Office of State Budget and Management for preliminary review:

- (1) The text of the proposed rule change.
- (2) A short explanation of the reason for the proposed change.
- (3) A fiscal note stating the amount by which the proposed rule change would increase or decrease expenditures or revenues of a unit of local government and explaining how the amount was computed.

(b) Scope. - The preliminary review of a proposed permanent rule change that would affect the expenditures or revenues of a unit of local government shall include consideration of the following:

- (1) The agency's explanation of the reason for the proposed change.
- (2) Any unanticipated effects of the proposed change on local government budgets.
- (3) The potential costs of the proposed change weighed against the potential risks to the public of not taking the proposed change.

**§ 150B-21.27. Minimizing the effects of rules on local budgets.**

In adopting permanent rules that would increase or decrease the expenditures or revenues of a unit of local government, the agency shall consider the timing for implementation of the proposed rule as part of the preparation of the fiscal note required by G.S. 150B-21.4(b). If the computation of costs in a fiscal note indicates that the proposed rule change will disrupt the budget process as set out in the Local Government Budget and Fiscal Control Act, Article 3 of Chapter 159 of the General Statutes, the agency shall specify the effective date of the change as July 1 following the date the change would otherwise become effective under G.S. 150B-21.3.

**§ 150B-21.28. Role of the Office of State Budget and Management.**

The Office of State Budget and Management shall:

- (1) Compile an annual summary of the projected fiscal impact on units of local government of State administrative rules adopted during the preceding fiscal year.
- (2) Compile from information provided by each agency schedules of anticipated rule actions for the upcoming fiscal year.
- (3) Provide the Governor, the General Assembly, the North Carolina Association of County Commissioners, and the North Carolina League of Municipalities with a copy of the annual summary and schedules by no later than March 1 of each year.

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**Article 3A.**  
**Other Administrative Hearings.**

**§ 150B-38. Scope; hearing required; notice; venue.**

- (a) The provisions of this Article shall apply to:
- (1) Occupational licensing agencies.
  - ...
- (b) Prior to any agency action in a contested case, the agency shall give the parties in the case an opportunity for a hearing without undue delay and notice not less than 15 days before the hearing. Notice to the parties shall include all of the following:
- (1) A statement of the date, hour, place, and nature of the hearing.
  - (2) A reference to the particular sections of the statutes and rules involved.
  - (3) A short and plain statement of the facts alleged.
- (c) Notice shall be given by one of the methods for service of process under G.S. 1A-1, Rule 4(j) or Rule 4(j3). If given by registered or certified mail, by signature confirmation as provided by the United States Postal Service, or by designated delivery service authorized pursuant to 26 U.S.C. § 7502(f)(2) with delivery receipt, notice shall be deemed to have been given on the delivery date appearing on the return receipt, copy of proof of delivery provided by the United States Postal Service, or delivery receipt. If notice cannot be given by one of the methods for service of process under G.S. 1A-1, Rule 4(j) or Rule 4(j3), then notice shall be given in the manner provided in G.S. 1A-1, Rule 4(j1).
- (d) A party that has been served with a notice of hearing may file a written response with the agency. If a written response is filed, a copy of the response shall be mailed to all other parties not less than 10 days before the date set for the hearing.
- (e) All hearings conducted under this Article shall be open to the public. A hearing conducted by the agency shall be held in the county where the agency maintains its principal office. A hearing conducted for the agency by an administrative law judge requested under G.S. 150B-40 shall be held in a county in this State where any person whose property or rights are the subject matter of the hearing resides. If a different venue would promote the ends of justice or better serve the convenience of witnesses, the agency or the administrative law judge may designate another county. A person whose property or rights are the subject matter of the hearing waives his objection to venue by proceeding in the hearing.
- (f) Any person may petition to become a party by filing with the agency or hearing officer a motion to intervene in the manner provided by G.S. 1A-1, Rule 24. In addition, any person interested in a contested case under this Article may intervene and participate to the extent deemed appropriate by the agency hearing officer.
- (g) When contested cases involving a common question of law or fact or multiple proceedings involving the same or related parties are pending before an agency, the agency may order a joint hearing of any matters at issue in the cases, order the cases consolidated, or make other orders to reduce costs or delay in the proceedings.
- (h) Every agency shall adopt rules governing the conduct of hearings that are consistent with the provisions of this Article.
- ...

**§ 150B-39. Depositions; discovery; subpoenas.**

- (a) A deposition may be used in lieu of other evidence when taken in compliance with the Rules of Civil Procedure, G.S. 1A-1. Parties in a contested case may engage in discovery pursuant to the provisions of the Rules of Civil Procedure, G.S. 1A-1.
- (b) Upon a request for an identifiable agency record involving a material fact in a contested case, the agency shall promptly provide the record to a party, unless the record relates solely to the agency's internal procedures or is exempt from disclosure by law.
- (c) In preparation for, or in the conduct of, a contested case subpoenas may be issued and served in accordance with G.S. 1A-1, Rule 45. Upon a motion, the agency may quash a subpoena if, upon a hearing, the agency finds that the evidence, the production of which is required, does not relate to a matter in issue, the subpoena does not describe with sufficient particularity the evidence the production of which is required, or for any other reason sufficient in law the subpoena may be quashed. Witness fees shall be paid by the party requesting the subpoena to subpoenaed witnesses in accordance with G.S. 7A-314. However, State officials or employees who are subpoenaed shall not be entitled to any witness fees, but they shall receive their normal salary and they shall not be required to take any annual leave for the witness days. Travel expenses of State officials or employees who are subpoenaed shall be reimbursed as provided in G.S. 138-6.

**§ 150B-40. Conduct of hearing; presiding officer; ex parte communication.**

(a) Hearings shall be conducted in a fair and impartial manner. At the hearing, the agency and the parties shall be given an opportunity to present evidence on issues of fact, examine and cross-examine witnesses, including the author of a document prepared by, on behalf of or for the use of the agency and offered into evidence, submit rebuttal evidence, and present arguments on issues of law or policy.

If a party fails to appear in a contested case after he has been given proper notice, the agency may continue the hearing or proceed with the hearing and make its decision in the absence of the party.

(b) Except as provided under subsection (e) of this section, hearings under this Article shall be conducted by a majority of the agency. An agency shall designate one or more of its members to preside at the hearing. If a party files in good faith a timely and sufficient affidavit of the personal bias or other reason for disqualification of any member of the agency, the agency shall determine the matter as a part of the record in the case, and its determination shall be subject to judicial review at the conclusion of the proceeding. If a presiding officer is disqualified or it is impracticable for him to continue the hearing, another presiding officer shall be assigned to continue with the case, except that if assignment of a new presiding officer will cause substantial prejudice to any party, a new hearing shall be held or the case dismissed without prejudice.

(c) The presiding officer may:

- (1) Administer oaths and affirmations;
- (2) Sign and issue subpoenas in the name of the agency, requiring attendance and giving of testimony by witnesses and the production of books, papers, and other documentary evidence;
- (3) Provide for the taking of testimony by deposition;
- (4) Regulate the course of the hearings, set the time and place for continued hearings, and fix the time for filing of briefs and other documents;
- (5) Direct the parties to appear and confer to consider simplification of the issues by consent of the parties; and
- (6) Apply to any judge of the superior court resident in the district or presiding at a term of court in the county where a hearing is pending for an order to show cause why any person should not be held in contempt of the agency and its processes, and the court shall have the power to impose punishment as for contempt for acts which would constitute direct or indirect contempt if the acts occurred in an action pending in superior court.

(d) Unless required for disposition of an ex parte matter authorized by law, a member of an agency assigned to make a decision or to make findings of fact and conclusions of law in a contested case under this Article shall not communicate, directly or indirectly, in connection with any issue of fact or question of law, with any person or party or his representative, except on notice and opportunity for all parties to participate. This prohibition begins at the time of the notice of hearing. An agency member may communicate with other members of the agency and may have the aid and advice of the agency staff other than the staff which has been or is engaged in investigating or prosecuting functions in connection with the case under consideration or a factually-related case. This section does not apply to an agency employee or party representative with professional training in accounting, actuarial science, economics or financial analysis insofar as the case involves financial practices or conditions.

(e) When a majority of an agency is unable or elects not to hear a contested case, the agency shall apply to the Director of the Office of Administrative Hearings for the designation of an administrative law judge to preside at the hearing of a contested case under this Article. Upon receipt of the application, the Director shall, without undue delay, assign an administrative law judge to hear the case.

The provisions of this Article, rather than the provisions of Article 3, shall govern a contested case in which the agency requests an administrative law judge from the Office of Administrative Hearings.

The administrative law judge assigned to hear a contested case under this Article shall sit in place of the agency and shall have the authority of the presiding officer in a contested case under this Article. The administrative law judge shall make a proposal for decision, which shall contain proposed findings of fact and proposed conclusions of law.

An administrative law judge shall stay any contested case under this Article on motion of an agency which is a party to the contested case, if the agency shows by supporting affidavits that it is engaged in other litigation or administrative proceedings, by whatever name called, with or before a federal agency, and this other litigation or administrative proceedings will determine the position, in whole or in part, of the agency in the contested case. At the conclusion of the other litigation or administrative proceedings, the contested case shall proceed and be determined as expeditiously as possible.

The agency may make its final decision only after the administrative law judge's proposal for decision is served on the parties, and an opportunity is given to each party to file exceptions and proposed findings of fact and to present oral and written arguments to the agency.

**§ 150B-41. Evidence; stipulations; official notice.**

(a) In all contested cases, irrelevant, immaterial, and unduly repetitious evidence shall be excluded. Except as otherwise provided, the rules of evidence as applied in the trial division of the General Court of Justice shall be followed; but, when evidence is not reasonably available under such rules to show relevant facts, they may be shown by the most reliable and substantial evidence available. It shall not be necessary for a party or his attorney to object to evidence at the hearing in order to preserve the right to object to its consideration by the agency in reaching its decision, or by the court of judicial review.

(b) Evidence in a contested case, including records and documents shall be offered and made a part of the record. Other factual information or evidence shall not be considered in determination of the case, except as permitted under subsection (d) of this section. Documentary evidence may be received in the form of a copy or excerpt or may be incorporated by reference, if the materials so incorporated are available for examination by the parties. Upon timely request, a party shall be given an opportunity to compare the copy with the original if available.

(c) The parties in a contested case under this Article by a stipulation in writing filed with the agency may agree upon any fact involved in the controversy, which stipulation shall be used as evidence at the hearing and be binding on the parties thereto. Parties should agree upon facts when practicable. Except as otherwise provided by law, disposition may be made of a contested case by stipulation, agreed settlement, consent order, waiver, default, or other method agreed upon by the parties.

(d) Official notice may be taken of all facts of which judicial notice may be taken and of other facts within the specialized knowledge of the agency. The noticed fact and its source shall be stated and made known to affected parties at the earliest practicable time, and any party shall on timely request be afforded an opportunity to dispute the noticed fact through submission of evidence and argument. An agency may use its experience, technical competence, and specialized knowledge in the evaluation of evidence presented to it.

**§ 150B-42. Final agency decision; official record.**

(a) After compliance with the provisions of G.S. 150B-40(e), if applicable, and review of the official record, as defined in subsection (b) of this section, an agency shall make a written final decision or order in a contested case. The decision or order shall include findings of fact and conclusions of law. Findings of fact shall be based exclusively on the evidence and on matters officially noticed. Findings of fact, if set forth in statutory language, shall be accompanied by a concise and explicit statement of the underlying facts supporting them. A decision or order shall not be made except upon consideration of the record as a whole or such portion thereof as may be cited by any party to the proceeding and shall be supported by substantial evidence admissible under G.S. 150B-41. A copy of the decision or order shall be served upon each party by one of the methods for service of process under G.S. 1A-1, Rule 5(b). If service is by registered, certified, or first-class mail, by signature confirmation as provided by the United States Postal Service, or by designated delivery service authorized pursuant to 26 U.S.C. § 7502(f)(2) with delivery receipt, the copy shall be addressed to the party at the latest address given by the party to the agency. Service by one of the additional methods provided in G.S. 1A-1, Rule 5(b), is effective as provided therein and shall be accompanied by a certificate of service as provided in G.S. 1A-1, Rule 5(b1). G.S. 1A-1, Rule 6(e), applies if service is by first-class mail. A copy shall be furnished to the party's attorney of record.

(b) An agency shall prepare an official record of a hearing that shall include:

- (1) Notices, pleadings, motions, and intermediate rulings;
- (2) Questions and offers of proof, objections, and rulings thereon;
- (3) Evidence presented;
- (4) Matters officially noticed, except matters so obvious that a statement of them would serve no useful purpose;
- (5) Proposed findings and exceptions; and
- (6) Any decision, opinion, order, or report by the officer presiding at the hearing and by the agency.

(c) Proceedings at which oral evidence is presented shall be recorded, but need not be transcribed unless requested by a party. Each party shall bear the cost of the transcript or part thereof or copy of said transcript or part thereof which said party requests.

**Article 4.**  
**Judicial Review.**

**§ 150B-43. Right to judicial review.**

Any party or person aggrieved by the final decision in a contested case, and who has exhausted all administrative remedies made available to the party or person aggrieved by statute or agency rule, is entitled to judicial review of the decision under this Article, unless adequate procedure for judicial review is provided by another statute, in which case the review shall be under such other statute. Nothing in this Chapter shall prevent any party or person aggrieved from invoking any judicial remedy available to the party or person aggrieved under the law to test the validity of any administrative action not made reviewable under this Article. A party or person aggrieved shall not be required to petition an agency for rule making or to seek or obtain a declaratory ruling before obtaining judicial review of a final decision or order made pursuant to G.S. 150B-34.

**§ 150B-44. Right to judicial intervention when final decision unreasonably delayed.**

... [F]ailure of an agency subject to Article 3A of this Chapter to make a final decision within 120 days of the close of the contested case hearing is justification for a person whose rights, duties, or privileges are adversely affected by the delay to seek a court order compelling action by the agency or by the administrative law judge.

**§ 150B-45. Procedure for seeking review; waiver.**

(a) **Deadline.** – To obtain judicial review of a final decision under this Article, the person seeking review must file a petition in superior court within 30 days after the person is served with a written copy of the decision. A person that fails to file a petition within the required time waives the right to judicial review under this Article. For good cause shown, however, the superior court may accept an untimely petition.

(b) **Waiver.** –The petition must be filed as follows:

...

(2) **Other final decisions.** – A petition for review of any other final decision under this Article must be filed in the superior court of the county where the person aggrieved by the administrative decision resides, or in the case of a person Page 6 Session Law 2022-64 House Bill 1018 residing outside the State, in the county where the contested case that resulted in the final decision was filed.

(3) **Change of venue.** – If a petition is filed in an improper county, the superior court of that county may order a change of venue consistent with G.S. 1-83 but shall not dismiss the petition on the ground of improper venue.

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**§ 150B-46. Contents of petition; copies served on all parties; intervention.**

The petition shall explicitly state what exceptions are taken to the decision or procedure and what relief the petitioner seeks. Within 10 days after the petition is filed with the court, the party seeking the review shall serve copies of the petition by personal service or by certified mail upon all who were parties of record to the administrative proceedings. Names and addresses of such parties shall be furnished to the petitioner by the agency upon request. Any party to the administrative proceeding is a party to the review proceedings unless the party withdraws by notifying the court of the withdrawal and serving the other parties with notice of the withdrawal. Other parties to the proceeding may file a response to the petition within 30 days of service. Parties, including agencies, may state exceptions to the decision or procedure and what relief is sought in the response.

Any person aggrieved may petition to become a party by filing a motion to intervene as provided in G.S. 1A-1, Rule 24.

**§ 150B-47. Records filed with clerk of superior court; contents of records; costs.**

Within 30 days after receipt of the copy of the petition for review, or within such additional time as the court may allow, the Office of Administrative Hearings shall transmit to the reviewing court the original or a certified copy of the official record in the contested case under review. With the permission of the court, the record may be shortened by stipulation of all parties to the review proceedings. Any party unreasonably refusing to stipulate to limit the record may be taxed by the court for such additional costs as may be occasioned by the refusal. The court may require or permit subsequent corrections or additions to the record when deemed desirable.

**§ 150B-48. Stay of decision.**

At any time before or during the review proceeding, the person aggrieved may apply to the reviewing court for an order staying the operation of the administrative decision pending the outcome of the review. The court may grant or deny the stay in its discretion upon such terms as it deems proper and subject to the provisions of G.S. 1A-1, Rule 65.

**§ 150B-49. New evidence.**

A party or person aggrieved who files a petition in the superior court may apply to the court to present additional evidence. If the court is satisfied that the evidence is material to the issues, is not merely cumulative, and could not reasonably have been presented at the administrative hearing, the court may remand the case so that additional evidence can be taken. If an administrative law judge did not make a final decision in the case, the court shall remand the case to the agency that conducted the administrative hearing under Article 3A of this Chapter. After hearing the evidence, the agency may affirm or modify its previous findings of fact and final decision. If an administrative law judge made a final decision in the case, the court shall remand the case to the administrative law judge. After hearing the evidence, the administrative law judge may affirm or modify his previous findings of fact and final decision. The additional evidence and any affirmation or modification of a final decision shall be made part of the official record.

**§ 150B-50. Review by superior court without jury.**

The review by a superior court of administrative decisions under this Chapter shall be conducted by the court without a jury.

**§ 150B-51. Scope and standard of review.**

(b) The court reviewing a final decision may affirm the decision or remand the case for further proceedings. It may also reverse or modify the decision if the substantial rights of the petitioners may have been prejudiced because the findings, inferences, conclusions, or decisions are:

- (1) In violation of constitutional provisions;
- (2) In excess of the statutory authority or jurisdiction of the agency or administrative law judge;
- (3) Made upon unlawful procedure;
- (4) Affected by other error of law;
- (5) Unsupported by substantial evidence admissible under G.S. 150B-29(a), 150B-30, or 150B-31 in view of the entire record as submitted; or
- (6) Arbitrary, capricious, or an abuse of discretion.

(c) In reviewing a final decision in a contested case, the court shall determine whether the petitioner is entitled to the relief sought in the petition based upon its review of the final decision and the official record. With regard to asserted errors pursuant to subdivisions (1) through (4) of subsection (b) of this section, the court shall conduct its review of the final decision using the de novo standard of review. With regard to asserted errors pursuant to subdivisions (5) and (6) of subsection (b) of this section, the court shall conduct its review of the final decision using the whole record standard of review.

(d) In reviewing a final decision allowing judgment on the pleadings or summary judgment, the court may enter any order allowed by G.S. 1A-1, Rule 12(c) or Rule 56. If the order of the court does not fully adjudicate the case, the court shall remand the case to the administrative law judge for such further proceedings as are just.

**§ 150B-52. Appeal; stay of court's decision.**

A party to a review proceeding in a superior court may appeal to the appellate division from the final judgment of the superior court as provided in G.S. 7A-27. The scope of review to be applied by the appellate court under this section is the same as it is for other civil cases. In cases reviewed under G.S. 150B-51(c), the court's findings of fact shall be upheld if supported by substantial evidence. Pending the outcome of an appeal, an appealing party may apply to the court that issued the judgment under appeal for a stay of that judgment or a stay of the administrative decision that is the subject of the appeal, as appropriate.



**CHAPTER 153A  
COUNTIES**

***SELECTED PROVISIONS***

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**§ 153A-77. Authority of boards of commissioners over commissions, boards, agencies, etc.**

(a) In the exercise of its jurisdiction over commissions, boards and agencies, the board of county commissioners may assume direct control of any activities theretofore conducted by or through any commission, board or agency by the adoption of a resolution assuming and conferring upon the board of county commissioners all powers, responsibilities and duties of any such commission, board or agency. This section shall apply to the board of health, the social services board, area mental health, developmental disabilities, and substance use area board or any other commission, board or agency appointed by the board of county commissioners or acting under and pursuant to authority of the board of county commissioners of said county except as provided in G.S. 153A-76. A board of county commissioners exercising the power and authority under this subsection may, notwithstanding G.S. 130A-25, enforce public health rules adopted by the board through the imposition of civil penalties. If a public health rule adopted by a board of county commissioners imposes a civil penalty, the provisions of G.S. 130A-25 making its violation a misdemeanor shall not be applicable to that public health rule unless the rule states that a violation of the rule is a misdemeanor. The board of county commissioners may exercise the power and authority herein conferred only after a public hearing held by said board pursuant to 30 days' notice of said public hearing given in a newspaper having general circulation in said county.

The board of county commissioners may also appoint advisory boards, committees, councils and agencies composed of qualified and interested county residents to study, interpret and develop community support and cooperation in activities conducted by or under the authority of the board of county commissioners of said county.

A board of county commissioners that has assumed direct control of a local health board after January 1, 2012, and that does not delegate the powers and duties of that board to a consolidated health service board shall appoint an advisory committee consistent with the membership described in G.S. 130A-35.

(b) In the exercise of its jurisdiction over commissions, boards, and agencies, the board of county commissioners of a county having a county manager pursuant to G.S. 153A-81 may:

- (1) Consolidate certain provisions of human services in the county under the direct control of a human services director appointed and supervised by the county manager in accordance with subsection (e) of this section;
- (2) Create a consolidated human services board having the powers conferred by subsection (c) of this section;
- (3) Create a consolidated county human services agency having the authority to carry out the functions of any combination of commissions, boards, or agencies appointed by the board of county commissioners or acting under and pursuant to authority of the board of county commissioners, including the local health department, the county department of social services, or the area mental health, developmental disabilities, and substance use services authority; and
- (4) Assign other county human services functions to be performed by the consolidated human services agency under the direction of the human services director, with policy-making authority granted to the consolidated human services board as determined by the board of county commissioners.

(c) A consolidated human services board appointed by the board of county commissioners shall serve as the policy-making, rule-making, and administrative board of the consolidated human services agency. The consolidated human services board shall be composed of no more than 25 members. The composition of the board shall reasonably reflect the population makeup of the county and shall include:

- (1) Eight persons who are consumers of human services, public advocates, or family members of clients of the consolidated human services agency, including: one person with mental illness, one person with a developmental disability, one person in recovery from substance abuse, one family member of a person with mental illness, one family member of a person with a developmental disability, one family member of a person with a substance abuse problem, and two consumers of other human services.

- (1a) Notwithstanding subdivision (1) of this subsection, a consolidated human services board not exercising powers and duties of an area mental health, developmental disabilities, and substance use services board shall include four persons who are consumers of human services.
- (2) Eight persons who are professionals, each with qualifications in one of these categories: one psychologist, one pharmacist, one engineer, one dentist, one optometrist, one veterinarian, one social worker, and one registered nurse.
- (3) Two physicians licensed to practice medicine in this State, one of whom shall be a psychiatrist.
- (4) One member of the board of county commissioners.
- (5) Other persons, including members of the general public representing various occupations.

The board of county commissioners may elect to appoint a member of the consolidated human services board to fill concurrently more than one category of membership if the member has the qualifications or attributes of more than one category of membership.

All members of the consolidated human services board shall be residents of the county. The members of the board shall serve four-year terms. No member may serve more than two consecutive four-year terms. The county commissioner member shall serve only as long as the member is a county commissioner.

The initial board shall be appointed by the board of county commissioners upon the recommendation of a nominating committee comprised of members of the preconsolidation board of health, social services board, and area mental health, developmental disabilities, and substance use services board. In order to establish a uniform staggered term structure for the board, a member may be appointed for less than a four-year term. After the subsequent establishment of the board, its board shall be appointed by the board of county commissioners from nominees presented by the human services board. Vacancies shall be filled for any unexpired portion of a term.

A chairperson shall be elected annually by the members of the consolidated human services board. A majority of the members shall constitute a quorum. A member may be removed from office by the county board of commissioners for (i) commission of a felony or other crime involving moral turpitude; (ii) violation of a State law governing conflict of interest; (iii) violation of a written policy adopted by the county board of commissioners; (iv) habitual failure to attend meetings; (v) conduct that tends to bring the office into disrepute; or (vi) failure to maintain qualifications for appointment required under this subsection. A board member may be removed only after the member has been given written notice of the basis for removal and has had the opportunity to respond.

A member may receive a per diem in an amount established by the county board of commissioners. Reimbursement for subsistence and travel shall be in accordance with a policy set by the county board of commissioners. The board shall meet at least quarterly. The chairperson or three of the members may call a special meeting.

- (d) The consolidated human services board shall have authority to:
  - (1) Set fees for departmental services based upon recommendations of the human services director. Fees set under this subdivision are subject to the same restrictions on amount and scope that would apply if the fees were set by a county board of health, a county board of social services, or a mental health, developmental disabilities, and substance use area authority.
  - (2) Assure compliance with laws related to State and federal programs.
  - (3) Recommend creation of local human services programs.
  - (4) Adopt local health regulations and participate in enforcement appeals of local regulations.
  - (5) Perform regulatory health functions required by State law.
  - (6) Act as coordinator or agent of the State to the extent required by State or federal law.
  - (7) Plan and recommend a consolidated human services budget.
  - (8) Conduct audits and reviews of human services programs, including quality assurance activities, as required by State and federal law or as may otherwise be necessary periodically.
  - (9) Advise local officials through the county manager.
  - (10) Perform public relations and advocacy functions.
  - (11) Protect the public health to the extent required by law.
  - (12) Perform comprehensive mental health services planning if the county is exercising the powers and duties of an area mental health, developmental disabilities, and substance use services board under the consolidated human services board.
  - (13) Develop dispute resolution procedures for human services contractors and clients and public advocates, subject to applicable State and federal dispute resolution procedures for human services programs, when applicable.

Except as otherwise provided, the consolidated human services board shall have the powers and duties conferred by law upon a board of health, a social services board, and an area mental health, developmental disabilities, and substance use services board.

Local employees who serve as staff of a consolidated county human services agency are subject to county personnel policies and ordinances only and are not subject to the provisions of the North Carolina Human Resources Act, unless the county board of commissioners elects to subject the local employees to the provisions of that Act. All consolidated county human services agencies shall comply with all applicable federal laws, rules, and regulations requiring the establishment of merit personnel systems.

(e) The human services director of a consolidated county human services agency shall be appointed and dismissed by the county manager with the advice and consent of the consolidated human services board. The human services director shall report directly to the county manager. The human services director shall:

- (1) Appoint staff of the consolidated human services agency with the county manager's approval.
- (2) Administer State human services programs.
- (3) Administer human services programs of the local board of county commissioners.
- (4) Act as secretary and staff to the consolidated human services board under the direction of the county manager.
- (5) Plan the budget of the consolidated human services agency.
- (6) Advise the board of county commissioners through the county manager.
- (7) Perform regulatory functions of investigation and enforcement of State and local health regulations, as required by State law.
- (8) Act as an agent of and liaison to the State, to the extent required by law.
- (9) Appoint, with the county manager's approval, an individual that meets the requirements of G.S. 130A-40(a).

Except as otherwise provided by law, the human services director or the director's designee shall have the same powers and duties as a social services director, a local health director, or a director of an area mental health, developmental disabilities, and substance use services authority.

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