SECTION .2500 - MISCELLANEOUS PROVISIONS

21 NCAC 46 .2501 SUPERVISION

In order to properly exercise the supervision of unlicensed personnel required by these rules, the responsible pharmacist must physically review the prescription order and the dispensed product before the product is delivered to the patient or person acting on the patient's behalf.

History Note: *Authority G.S. 90-85.6; 90-85.40(a);*
Eff. May 1, 1989.

21 NCAC 46.2502 RESPONSIBILITIES OF PHARMACIST-MANAGER

(a) The pharmacist-manager shall assure that prescription legend drugs and controlled substances are safe and secure within the pharmacy.

(b) The pharmacist-manager employed or otherwise engaged to supply pharmaceutical services may have a flexible schedule of attendance but shall be present for at least one-half the hours the pharmacy is open or 32 hours a week, whichever is less. A pharmacist employee not meeting this requirement may serve as pharmacist-manager of the permit holder temporarily for a period not to exceed 90 days from the departure date of the previous pharmacist-manager, if the pharmacist employee is present at least 20 hours per week in the pharmacy.

(c) Whenever a change of ownership or change of pharmacist-manager occurs, the successor pharmacist-manager shall complete an inventory of all controlled substances in the pharmacy within 10 days. A written record of such inventory, signed and dated by the successor pharmacist-manager, shall be maintained in the pharmacy with other controlled substances records for a period of three years.

(d) The pharmacist-manager shall develop and implement a system of inventory record-keeping and control which will enable that pharmacist-manager to detect any shortage or discrepancy in the inventories of controlled substances at that pharmacy at the earliest practicable time.

(e) The pharmacist-manager shall maintain authority and control over any and all keys to the pharmacy and shall be responsible for the security of the pharmacy. A pharmacy shall be secured to prohibit unauthorized entry if no pharmacist will be present in the pharmacy for a period of 90 minutes or more.

(f) These duties are in addition to the specific duties of pharmacist-managers at institutional pharmacies and pharmacies in health departments as set forth in the Rules in this Chapter.

(g) A person shall not serve as pharmacist-manager at more than one pharmacy at any one time except for limited service pharmacies.

(h) When a pharmacy is to be closed permanently, the pharmacist-manager shall inform the Board and the United States Drug Enforcement Administration of the closing, arrange for the proper disposition of the pharmaceuticals and return the pharmacy permit to the Board's offices within 10 days of the closing date. If possible, notice of the closing shall be given to the public by posted notice at the pharmacy at least 30 days prior to the closing date and 15 days after the closing date. Such notice shall notify the public that prescription files may be transferred to a pharmacy of the patient's or customer’s choice during the 30 day period prior to the closing date. During the 30 day period prior to the closing date, the pharmacist-manager, and the pharmacy's owner (if the owner is other than the pharmacist-manager), shall transfer prescription files to another pharmacy chosen by the patient or customer, upon request. Absent specific instructions from the patient or customer, the pharmacist-manager, and the pharmacy's owner (if the owner is other than the pharmacist-manager), shall transfer prescription files to another pharmacy for maintenance of patient therapy and shall inform the public of such transfer by posted notice at the pharmacy for 15 days after the closing date, if possible. Controlled substance records shall be retained for the period of time required by law.

(i) If possible, the pharmacist-manager shall ensure that notice of the temporary closing of any pharmacy for more than 14 consecutive days is given to the public by posted notice at the pharmacy at least 30 days prior to the closing date, and 15 days after the closing date. Such notice shall notify the public that prescription files may be transferred to a pharmacy of the patient's or customer's choice during the 30 day period prior to the closing date. During the 30 day period prior to the closing date, the pharmacist-manager, and the pharmacy's owner (if the owner is other than the pharmacist-manager), shall transfer prescription files to another pharmacy chosen by the patient or customer, upon request.

(j) The pharmacist-manager shall prepare a plan to safeguard prescription records and pharmaceuticals and minimize the interruption of pharmacy services in the event of a natural disaster such as hurricane or flood.
(k) The pharmacist-manager shall separate from the dispensing stock all drug products more than six months out of date.
(l) The pharmacist-manager shall report to the Board of Pharmacy information that reasonably suggests that there is a probability that a prescription drug or device dispensed from a location holding a permit has caused or contributed to the death of a patient or customer. This report shall be filed in writing on a form provided by the Board within 14 days of the owner representative or pharmacist-manager's becoming aware of the event. The pharmacist-manager shall retain all documents, labels, vials, supplies, substances and internal investigative reports relating to the event. All such items shall be made available to the Board upon request.
(m) The Board shall not disclose the identity of a pharmacist-manager who makes a report under Paragraph (l) of this Rule, except as required by law. No report made under Paragraph (l) of this Rule shall be released except as required by law.
(n) In any Board proceeding, the Board shall consider compliance with Paragraph (l) of this Rule as a mitigating factor and noncompliance with Paragraph (l) of this Rule as an aggravating factor.
(o) The pharmacist-manager shall ensure that all starter doses of medication supplied to doctors' offices from the pharmacy are accompanied by written materials advising the patient that such doses of medication may be supplied by any pharmacy. Starter doses shall be limited to a 24 hour dose supply per patient.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.25; 90-85.26; 90-85.32;*
Eff. May 1, 1989;
Amended Eff. April 1, 2006; February 1, 2005; August 1,2002; December 1, 2001; April 1, 2001; April 1, 1999; July 1, 1996; March 1, 1992; October 1, 1990.

21 NCAC 46 .2503 RESEARCH PARTICIPATION
Pharmacists are encouraged to participate in research efforts, including protocol dosing, precision and time of drug administration, obtaining informed consent and other activities connected with investigational drug studies.

History Note: *Authority G.S. 90-85.3(r); 90-85.6;*
Eff. May 1, 1989.

21 NCAC 46 .2504 PATIENT COUNSELING
(a) "Patient Counseling" shall mean the effective communication of information, as defined in this Rule, to the patient or representative in order to improve therapeutic outcomes by maximizing proper use of prescription medications, devices, and medical equipment. All provisions of this Rule shall apply to device and medical equipment permit holders, except Subparagraph (a)(8) of this Rule and except where otherwise noted. Specific areas of patient counseling include, but are not limited to, those matters listed in this Rule that in the exercise of the pharmacist's or device and medical equipment permit holder's professional judgment are considered significant:

(1) name, description, and purpose of the medication;
(2) route, dosage, administration, and continuity of therapy;
(3) special directions for use by the patient;
(4) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(5) techniques for self-monitoring drug therapy;
(6) proper storage;
(7) prescription refill information; and
(8) action to be taken in the event of a missed dose.

(b) An offer to counsel shall be made on new or transfer prescriptions at the time the prescription is dispensed or delivered to the patient or representative. Ancillary personnel may make the offer to counsel, but the pharmacist must personally conduct counseling if the offer is accepted. Counseling by device and medical equipment permit holders must be conducted by personnel proficient in explaining and demonstrating the safe and proper use of devices and equipment. The person in charge shall be responsible

for ensuring that all personnel conducting counseling are proficient in explaining and demonstrating the safe and proper use of devices and equipment and for documenting the demonstration of such proficiency. The offer shall be made orally and in person when delivery occurs at the pharmacy. When delivery occurs outside of the pharmacy, whether by mail, vehicular delivery or other means, the offer shall be made either orally and in person, or by telephone from the pharmacist to the patient. If delivery occurs outside of the pharmacy, the pharmacist shall provide the patient with access to a telephone service that is toll-free for long-distance calls. A pharmacy whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. Counseling may be conducted by the provision of printed information in a foreign language if requested by the patient or representative. Professional judgment shall be exercised in determining whether or not to offer counseling for prescription refills. An offer to counsel shall be communicated in a positive manner to encourage acceptance.

(c) In order to counsel patients effectively, a reasonable effort shall be made to obtain, record, and maintain significant patient information, including:

(1) name, address, telephone number;
(2) date of birth (age), gender;
(3) medical history:
    (A) disease state(s);
    (B) allergies/drug reactions;
    (C) current list on non-prescription and prescription medications, devices, and medical equipment.
(4) comments relevant to the individual's drug therapy.

A "reasonable effort" shall mean a good faith effort to obtain from the patient or representative the foregoing patient information. Ancillary personnel may collect, record, and obtain patient profile information, but the pharmacist or person in charge of the facility holding the device and medical equipment permit must review and interpret patient profile information and clarify confusing or conflicting information. Professional judgment shall be exercised as to whether and when individual patient history information should be sought from other health care providers.

(d) Once patient information is obtained, this information shall be reviewed and updated by the pharmacist or person in charge of the facility holding the device and medical equipment permit before each prescription is filled or delivered, typically at the point-of-sale or point of distribution to screen for potential drug therapy problems due to:

(1) therapeutic duplication;
(2) drug-disease contraindication;
(3) drug-drug interactions, including serious interactions with prescription or over-the-counter drugs;
(4) incorrect drug dosage or duration of drug treatment;
(5) drug-allergy interactions; and
(6) clinical abuse/misuse.

(e) Unless refused by the patient or representative, patient counseling shall be provided as follows:

(1) counseling shall be "face to face" by the pharmacist, or personnel of a device and medical equipment permit holder when possible;
(2) alternative forms of patient information may be used to supplement patient counseling;
(3) patient counseling, as described in this Rule, shall be required for outpatient and discharge patients of hospitals, health maintenance organizations, health departments, and other institutions; however, compliance with this Rule in locations in which non-pharmacists are authorized by law or regulations to dispense may be accomplished by such authorized non-pharmacists; and
(4) patient counseling, as described in this Rule, shall not be required for inpatients of hospitals or other institutions where a nurse or other licensed health care professional administers the medication(s).

(f) Pharmacists that distribute prescription medication by mail, and where the practitioner-pharmacist-patient relationship does not exist, shall provide counseling services for recipients of such medication in accordance with this Rule.

(g) Records resulting from compliance with this Rule, including documentation of refusals to receive counseling, shall be maintained for three years in accordance with Section .2300 of this Chapter.

(h) Personnel of device and medical equipment permit holders shall give written notice of warranty, if any, regarding service after the sale. The permit holder shall maintain documentation demonstrating that the written notice of warranty was given to the patient.
(i) Offers to counsel and patient counseling for inmates need not be "face to face", but rather, may be conducted through a correctional or law enforcement officer or through printed material. A pharmacist or a device and medical equipment permit holder dispensing drugs or devices or delivering medical equipment to inmates need not comply with Paragraph (c) of this Rule. However, once such patient information is obtained, the requirements of Paragraph (d) of this Rule shall be followed.

History Note: *Authority G.S. 90-85.6; 90-85.22; 90-85.32; 42 U.S.C. 1396r-8(g);*
Eff. January 4, 1993;
Amended Eff. June 1, 2004; July 1, 1996; September 1, 1995.

21 NCAC 46 .2505 VETERINARY PRESCRIPTION DRUGS
A drug that under federal law is required, prior to being dispensed, to be labeled with the statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" may be dispensed only by a licensed veterinarian or by a pharmacist from a pharmacy pursuant to prescription or order of a licensed veterinarian.

History Note: *Authority G.S. 90-85.3; 90-85.6;*
Eff. September 1, 1995.

21 NCAC 46 .2506 EXCEPTIONS TO HEALTH CARE PRACTITIONERS IDENTIFICATION REQUIREMENTS
(a) A pharmacist is not required to wear a readily visible badge or other form of identification in the following direct patient care situations:
(1) procedures requiring full sterile dress; or
(2) procedures requiring other protective clothing or covering.
(b) Identification of a pharmacist may be limited to first name only with reference to licensure or other professional designation when the full name identification may:
(1) place the personal safety of the pharmacist in jeopardy; or

(2) interfere with the therapeutic relationship between the pharmacist and client(s).

History Note: *Authority G.S. 90-640;*
Eff. August 1, 2002.

21 NCAC 46 .2507 ADMINISTRATION OF VACCINES BY PHARMACISTS
(a) An Immunizing Pharmacist shall administer only those vaccines or immunizations permitted by G.S. 90-85.15B and shall do so subject to all requirements of that statute and this Rule.
(b) The following words and terms, when used in this Rule, have the following meanings:
(1) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or other means by:
(A) an Immunizing Pharmacist or a Pharmacy Intern who is under the direct, in-person supervision of an Immunizing Pharmacist; or
(B) the patient at the direction of either an Immunizing Pharmacist or a health care provider authorized by North Carolina law to prescribe the vaccine.
(2) "Immunizing Pharmacist" shall have the meaning provided in G.S. 90-85.3(i1).
(3) "Pharmacy Intern" shall have the meaning provided in 21 NCAC 46 .1317(28).
(4) "Physician" means an M.D. or D.O. currently licensed with the North Carolina Medical Board who is responsible for the supervision of the Immunizing Pharmacist pursuant to the Written Protocol between the Immunizing Pharmacist and the Physician.
(5) RESERVED
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(10) RESERVED
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(12) "Written Protocol" is a document prepared, signed, and dated by the Physician and Immunizing Pharmacist that shall contain the following:
(A) the name of the Physician responsible for authorizing the Written Protocol;
(B) the name of the Immunizing Pharmacist authorized to administer vaccines;
(C) the immunizations or vaccinations that may be administered by the Immunizing Pharmacist;
(D) the screening questionnaires and safety procedures that shall at least include the then-current minimum standard screening questionnaire and safety procedures adopted by the Medical Board, the Board of Nursing, and the Board of Pharmacy pursuant to S.L. 2013-246, s. 6, and available at the Board of Pharmacy's office and on its website (www.ncbop.org).
(E) the procedures to follow, including any drugs required by the Immunizing Pharmacist for treatment of the patient, in the event of an emergency or adverse event following vaccine administration;
(F) the reporting requirements by the Immunizing Pharmacist to the Physician, including content and time frame; and
(G) the locations at which the Immunizing Pharmacist may administer immunizations or vaccinations.

The Physician and the Immunizing Pharmacist shall review the Written Protocol at least annually and revise it if necessary.

(c) An Immunizing Pharmacist who, because of physical disability, is unable to obtain a current provider level CPR certification pursuant to G.S. 90-85.3(i1)(1), may administer vaccines in the presence of a pharmacy technician or pharmacist who holds a current provider level CPR certification.

(d) With each dose of vaccine, either the Immunizing Pharmacist or a Pharmacy Intern shall give the most current vaccine information regarding the purpose, risks, benefits, and contraindications of the vaccine to the patient or legal representative. The Immunizing Pharmacist or Pharmacy Intern must ensure that the patient or legal representative has the opportunity to read, or to have read to him or her, the information provided and to have any questions answered prior to administration of the vaccine.

(e) In agreeing to serve as a supervising Physician, the Physician shall agree to meet the following requirements:

(1) be responsible for the formulation or approval of the Written Protocol and review the Written Protocol and the services provided to patients under the Written Protocol, as set out in Subparagraph (b)(12) of this Rule;
(2) be accessible to the Immunizing Pharmacist or be available through direct telecommunication for consultation, assistance, direction, and provide back-up coverage; and
(3) receive periodic status reports from the Immunizing Pharmacist, including any problems or complications encountered.

(f) The following requirements pertain to drugs administered by an Immunizing Pharmacist:

(1) Drugs administered by an Immunizing Pharmacist under the provisions of this Rule shall be in the legal possession of:
(A) a pharmacy, which shall be the pharmacy responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination; or
(B) the Physician, who shall be responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination;
(2) Drugs shall be transported and stored at the proper temperatures indicated for each drug;
(3) Immunizing Pharmacists, while engaged in the administration of vaccines under the Written Protocol, shall have in their custody and control the vaccines identified in the Written Protocol and any other drugs listed in the Written Protocol to treat adverse events; and

(4) After administering vaccines at a location other than a pharmacy, the Immunizing Pharmacist shall return all unused prescription medications to the pharmacy or Physician responsible for the drugs.

(g) Record Keeping and Reporting.

(1) An Immunizing Pharmacist shall maintain the following information, readily retrievable, in the pharmacy records in accordance with the applicable rules and statute regarding each administration:
   (A) the name, address, and date of birth of the patient;
   (B) the date of the administration;
   (C) the administration site of injection (e.g., right arm, left leg, right upper arm);
   (D) route of administration of the vaccine;
   (E) the name, manufacturer, lot number, and expiration date of the vaccine;
   (F) dose administered;
   (G) the name and address of the patient's primary health care provider, as identified by the patient; and
   (H) the name or identifiable initials of the Immunizing Pharmacist.

(2) An Immunizing Pharmacist shall document the annual review with the Physician of the Written Protocol as required in this Rule.

(3) An Immunizing Pharmacist shall report adverse events associated with administration of a vaccine to either the prescriber, when administering a vaccine pursuant to G.S. 90-85.15B(a), or the patient's primary care provider, if the patient identifies one, when administering a vaccine pursuant to G.S. 90-85.15B(b).

(h) The Immunizing Pharmacist shall maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies.

History Note: *Authority G.S. 90-85.3; 90-85.6; 90-85.15B;*
Eff. April 1, 2003;
Emergency Amendment Eff. May 11, 2004;
Temporary Amendment approved by RRC October 21, 2004;
Amended Eff. February 1, 2008; November 1, 2005; November 1, 2004;
Emergency Amendment Eff. October 9, 2009;
Temporary Amendment Eff. December 29, 2009;
Amended Eff. September 1, 2014; March 1, 2012.

21 NCAC 46 .2508 ELECTRONIC RECORDS

Unless otherwise specified in the rules in this Section or other applicable law, any documentation required by the rules in this Section may be electronically created and maintained, provided that the system that creates and maintains the electronic record:

(1) is capable of printing the documentation so that the pharmacist-manager can provide it to the Board within 48 hours of a request;

(2) contains security features to prevent unauthorized access to the records; and

(3) contains daily back-up functionality to protect against record loss.

History Note: *Authority G.S. 90-85.6; 90-85.26; 90-85.30; 90-85.32; 90-85.33; 90-85.35; 90-85.36;90-85.47; 90-106; 90-107;*
Eff. March 1, 2013.

21 NCAC 46 .2509 AVAILABILITY OF PHARMACY RECORDS

A pharmacist may disclose pharmacy records to investigators of occupational licensing boards whose licensees have prescribing authority during the course of an investigation of such licensee as permitted by state or federal law.

History Note: *Authority G.S. 90-85.6; 90-85.36;*
Eff. March 1, 2004.

21 NCAC 46 .2510 WAIVER OF ENFORCEMENT

The Board may waive the enforcement of specific rules under the following circumstances:

(1) The departure from ordinary practice is designed to have a positive impact on the delivery of pharmaceutical care or designed to reduce healthcare expenditures;
(2) Patient health and safety are not compromised by the waiver;
(3) A policy and procedure manual detailing the type and method of operation, hours of operation, and method of documentation of continuing pharmacist control accompanies the application; and
(4) The waiver is subject to continuing compliance with the conditions approved by the Board.

History Note: *Authority G.S. 90-85.6; 90-85.34; 150B-19(6);*
Eff. July 1, 2004.

21 NCAC 46 .2511 CHARGE FOR STATUS AFFIDAVIT

The Board shall charge persons requesting a verified duplicate copy of any license, permit, or registration a fee of twenty-five dollars ($25.00). The Board shall furnish such affidavits free of charge to governmental entities.

History Note: *Authority G.S. 90-85.24(a)(16);*
Eff. March 1, 2006.

21 NCAC 46 .2512 PHARMACIST WORK CONDITIONS

A permit holder shall not require a pharmacist to work longer than 12 continuous hours per work day. A pharmacist working longer than six continuous hours per work day shall be allowed during that time period to take a 30 minute meal break and one additional 15 minute break.

History Note: *Authority G.S. 90-85.2; 90-85.6(a); 90-85.21(a); 85-32(a);*
Eff. April 1, 2007.

21 NCAC 46 .2513 DRUG, SUPPLIES AND MEDICAL DEVICE REPOSITORY PROGRAM

(a) This Rule establishes the Drug, Supplies and Medical Device Repository Program as specified in G.S. 90-85.44.

(b) Definitions. Any term defined in G.S. 90-85.44(a) shall have the same definition under this Rule.

(c) Requirements For a Pharmacy to Participate in Accepting and Dispensing Donated Drugs, Supplies and Medical Devices.

(1) Any pharmacy or free clinic holding a valid, current North Carolina pharmacy permit may accept and dispense donated drugs, supplies and medical devices in accordance with the requirements of this Rule and G.S. 90-85.44.
(2) A dispensing physician registered with the Board in compliance with G.S. 90-85.21(b) and providing services to patients of a free clinic that does not hold a pharmacy permit may accept and dispense donated drugs, supplies and medical devices in accordance with the requirements of this Rule and G.S. 90-85.44.
(3) A participating pharmacy or dispensing physician shall notify the Board in writing of such participation at the time participation begins and annually on its permit or registration renewal application.
(4) A participating pharmacy or dispensing physician that ceases participation in the program shall notify the Board in writing within 30 days of doing so and shall submit a written report detailing the final disposition of all donated drugs, supplies and medical devices held by the participating pharmacy or dispensing physician.

(d) Drugs, Supplies and Medical Devices Eligible for Donation.

(1) A participating pharmacy or dispensing physician may accept donation of a drug, supply or medical device meeting the criteria specified in G.S. 90-85.44(c).
(2) The following categories of drugs, supplies and medical devices shall not be accepted by a participating pharmacy or dispensing physician:
    (A) A controlled substance, unless acceptance of a donated controlled substance is authorized by federal law.

(B) Any prescription drug or medical device subject to a restricted distribution system mandated by the United States Food and Drug Administration.

(C) Biologicals, unless donated by the manufacturer or a prescription drug wholesaler. A pharmacy may donate a biological if the biological has been stored according to the manufacturer's labeling and has not previously been dispensed to a patient or other person.

(D) Compounded drugs or parenteral admixtures.

(E) Any drug requiring refrigerated storage, unless donated by either (a) the manufacturer, (b) a prescription drug wholesaler or (c) a pharmacy that has stored the drug according to the manufacturer's labeling and has not previously dispensed the drug to a patient or other person.

(e) Required Records.

(1) A participating pharmacy or dispensing physician that dispenses donated drugs, supplies or medical devices to an eligible patient shall maintain a written or electronic inventory of each donated drug, supply and medical device that shall include the following:

(A) The name, strength, dosage form, number of units, manufacturer's lot number and expiration date.

(B) The name, address and phone number of the eligible donor providing each drug, supply or medical device.

(2) A participating pharmacy or dispensing physician shall keep all donated drugs, supplies and medical devices physically separated from other inventory. The physically separate storage area for donated drugs, supplies and medical devices shall be identified.

(3) In addition to all records required for dispensing a prescription drug, supply or medical device under the North Carolina Pharmacy Practice Act and rules, a participating pharmacy or dispensing physician that dispenses donated drugs, supplies or medical devices to an eligible patient shall note – either on the face of a written prescription or in the electronic record of a prescription – that a donated prescription drug, supply or medical device was dispensed to the patient.

(4) A participating pharmacy or dispensing physician that dispenses donated drugs, supplies or medical devices to an eligible patient shall maintain patient-specific written or electronic documentation of any dispensing of a donated non-prescription drug, supply or medical device.

(f) Eligible Patient.

(1) A participating pharmacy or dispensing physician shall establish and maintain a written patient eligibility policy that shall conform to the priorities specified in G.S. 90-85.44(f).

(2) Donated drugs, supplies or medical devices shall be dispensed to patients who are residents of North Carolina and meet the participating pharmacy's or dispensing physician's eligibility criteria.

(g) Handling Fee.

(1) A participating pharmacy or dispensing physician may charge a prescription drug handling fee to an eligible patient that shall not exceed the co-payment established by North Carolina Medicaid and required of a North Carolina Medicaid beneficiary who receives the same prescription drug in the same quantity.

(2) A participating pharmacy or dispensing physician may charge a medical device or supply handling fee to an eligible patient that shall not exceed the co-payment established by North Carolina Medicaid and required of a North Carolina Medicaid beneficiary to whom a brand-name prescription drug is dispensed.

(3) Nothing in this Rule shall require a participating pharmacy or dispensing physician to charge an eligible patient a handling fee, nor shall a participating pharmacy or dispensing physician charge a handling fee where doing so is otherwise prohibited by law.

(h) Confidentiality of Records.

(1) A participating pharmacy or dispensing physician that dispenses donated drugs, medical devices or supplies to an eligible patient shall remove or alter any labeling or other material from a donated drug, supply or medical device that could identify the patient to whom the donated product was originally dispensed so that the identity of that patient cannot be determined.

(2) Records required by this Rule shall be governed by the confidentiality provisions of G.S. 90-85.36 and the Health Insurance Portability and Accountability Act of 1996.

(3) Records required by this Rule shall be maintained by the participating pharmacy or dispensing physician for a period of three years.

History Note: *Authority G.S. 90-85.6; 90-85.26; 90-85.32; 90-85.44;*
Eff. June 1, 2010.