

## SECTION .1800 - PRESCRIPTIONS

### 21 NCAC 46 .1801 RIGHT TO REFUSE A PRESCRIPTION

(a) A pharmacist or device and medical equipment dispenser may refuse to fill or refill a prescription order, if, in his professional judgment, it would be harmful to the recipient, is not in the recipient's best interest or if there is a question as to its validity.

(b) A pharmacist shall not fill or refill a prescription order if the pharmacist actually knows or reasonably should know that the order was issued without a physical examination of the patient and in the absence of a prior prescriber-patient relationship, unless:

- (1) the prescription order was issued for the patient by a psychiatrist;
- (2) the prescription order was issued for the patient after discussion of the patient status with a treating psychologist, therapist, or physician;
- (3) the prescription order was ordered by a physician for flu vaccinations for groups of patients or members of the public;
- (4) the prescription order was for prophylactic purposes, such as the ordering of antibiotics by a pediatrician for members of a child's family when the child has a positive strep test;
- (5) the prescription order was an emergency order for medication related to pregnancy prevention; or
- (6) the prescription order was an order for medications to be taken by groups traveling to foreign countries.

*History Note:* Authority G.S. 90-85.6; 90-85.32;  
Eff. April 1, 1983;  
Amended Eff. February 1, 2007; March 1, 2004; April 1, 2003; September 1, 1995.

### 21 NCAC 46 .1802 PRESCRIPTION REFILLS

(a) Authorization for prescription refills is presumed to be within the prescribed dosage or normal therapeutic use. Refilling prescriptions more frequently than the prescribed dosage would require, or refilling prescriptions in significant excess of normal therapeutic use, may be considered as negligence under G.S. 90-85.38(a)(9).

(b) If deemed appropriate in the pharmacist's professional judgment, a patient may receive upon request drug quantities in excess of the face amount of a prescription for a non-controlled substance, up to the total amount authorized. The pharmacist shall not dispense in excess of the face amount of a prescription for a controlled substance or psychotherapeutic drug without authorization from the prescriber.

*History Note:* Authority G.S. 90-85.6; 90-85.32;  
Eff. April 1, 1983;  
Amended Eff. September 1, 1993; May 1, 1989.

### 21 NCAC 46 .1803 PRESCRIPTION RECORDS

All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.

*History Note:* Authority G.S. 90-85.6; 90-85.32; 90-85.36;  
Eff. April 1, 1983.

### 21 NCAC 46 .1804 PRESCRIPTION: RECEIVING AND DISPENSING

(a) In order to assure that the practitioner-pharmacist-patient relationship exists and to promote the safe and secure distribution of drugs and devices from a pharmacy, prescription orders may be received for filling and refilling only by a pharmacist or a bona fide employee of the pharmacy. The pharmacist-manager of the pharmacy shall be ultimately responsible for the safe, lawful and secure receipt of prescription orders and delivery of prescription drugs. Notwithstanding the provisions of this Rule, prescription drugs also may be delivered by mail in accordance with the provisions of 21 NCAC 46 .1601(b).

(b) In filling or refilling prescription orders, the pharmacist shall not be required to deal with parties, including managed care companies and insurance providers, outside the practitioner-pharmacist-patient relationship.

(c) In order to promote the safe and secure distribution of devices and medical equipment from a facility holding a device and medical equipment permit, prescription orders for devices and medical equipment may be received for filling and refilling only by the person in charge of the facility holding the device and medical equipment permit or a bona fide employee of the facility. The person in charge shall be ultimately responsible for the safe, lawful and secure receipt of prescription orders and delivery of devices and medical equipment. Unless the location also holds a pharmacy permit, a facility holding a device and medical equipment permit shall not acquire, receive, store, or deliver prescription drugs.

*History Note:* Authority G.S. 90-85.6; 90-85.32;  
Eff. December 1, 1983;  
Amended Eff. April 1, 2004; August 1, 2000; September 1, 1995; May 1, 1989; August 1, 1988.

#### **21 NCAC 46 .1805 DISPENSING DRUGS WITHOUT A PRESCRIPTION**

The dispensing of or any delivery of a prescription drug, including the surrender of control or possession in any manner which results in a delivery of a prescription drug, without a valid prescription order is unlawful. Refilling a prescription for a prescription drug without authorization is unlawful.

*History Note:* Authority G.S. 90-85.3(s); 90-85.6; 90-85.32;  
Eff. March 1, 1984;  
Amended Eff. May 1, 1989.

#### **21 NCAC 46 .1806 TRANSFER OF PRESCRIPTION INFORMATION**

(a) The transfer of original prescription information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

- (1) the transfer is communicated directly from either a pharmacist or certified technician to either a pharmacist or certified technician and not by only one pharmacist or certified technician gaining access to an information file containing data for several locations, unless all locations accessed are under common ownership or accessed pursuant to contractual agreement of the pharmacies;
- (2) the transferring pharmacist or certified technician invalidates the prescription and any remaining refills at the transferring pharmacy by marking the word "void" on the face of the prescription or its equivalent;
- (3) the transferring pharmacist or certified technician records the name and address of the pharmacy to which it was transferred and the name of the pharmacist or certified technician receiving the prescription information on the reverse of the invalidated prescription;
- (4) the transferring pharmacist or certified technician records the date of the transfer and the name of the pharmacist or certified technician transferring the information.

(b) The pharmacist or certified technician receiving the transferred prescription information shall reduce to writing the following:

- (1) The word "transfer" on the face of the transferred prescription;
- (2) All information required to be on a prescription, including:
  - (A) Date of issuance of original prescription;
  - (B) Number of refills authorized on original prescription;
  - (C) Date and time of transfer;
  - (D) Number of valid refills remaining and date of last refill;
  - (E) Pharmacy's name, address and original prescription number from which the prescription information was transferred;
  - (F) Name of transferring pharmacist or certified technician; and
  - (G) Manufacturer or brand of drug dispensed.

(c) The transferred prescription, as well as the original, must be maintained for a period of three years from the date of last refill.

(d) Dispensing is permitted only within the original authorization for refills and no dispensing on such transfer shall occur beyond that authorized on the original prescription. Any dispensing beyond that originally authorized or one year, whichever is less, may occur only on a new prescription.

(e) The requirements of Paragraphs (a) and (b) of this Rule may be facilitated by use of a computer or data system without reference to an original prescription document. The system must be able to identify transferred prescriptions and prevent subsequent prescription refills at that pharmacy.

(f) This Rule applies to the transfer of prescriptions issued by prescribers in other states, provided that the pharmacist or certified technician receiving the prescription actually knows or reasonably should know that a physician-patient relationship exists and dispensing the drug is in the patient's best interests.

(g) All records pertinent to this Rule shall be readily retrievable.

(h) A system must be in place that will allow only authorized access by a pharmacist or certified technician to all records pertinent to this Rule and will indicate on the prescription record when and by whom such access was made.

(i) The transfer of original prescription information for the purpose of refill dispensing is permissible between device and medical equipment permit holders so long as the transferring permit holder provides all records and documentation necessary

for dispensing and does not interfere with the service and claims processing procedures of the receiving permit holder.

*History Note:* Authority G.S. 90-85.6(a); 90-85.32;  
Eff. December 31, 1985;  
Amended Eff. June 1, 2004; September 1, 1995; July 1, 1992; May 1, 1989.

#### **21 NCAC 46 .1807 FACSIMILE TRANSMISSION OF PRESCRIPTION ORDERS**

*History Note:* Authority G.S. 90-85.6(a); 90-85.32;  
Eff. October 1, 1990;  
Amended Eff. September 1, 1995;  
Repealed Eff. March 1, 2004.

#### **21 NCAC 46 .1808 REPACKAGED PHARMACEUTICALS**

A drug product which is manufactured and sold by a manufacturer as a generic drug product shall be considered a generic drug product, though subsequently repackaged and given a brand name.

*History Note:* Authority G.S. 90-85.6(a); 90-85.32;  
Eff. December 1, 1991.

#### **21 NCAC 46 .1809 EMERGENCY PRESCRIPTION REFILLS**

In the event a pharmacist or device and medical equipment permit holder receives a request for a prescription refill and the pharmacist or permit holder is unable to obtain refill authorization from the prescriber, the pharmacist or permit holder may dispense a one-time emergency refill of up to a 30 day supply of the prescribed medication, provided that:

- (1) The prescription is not for a Schedule II controlled substance;
- (2) The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition;
- (3) In the pharmacist's or permit holder's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences;
- (4) The dispensing pharmacist or permit holder creates a written order containing all of the prescription information required by Section .2300 of these Rules and signs that order;
- (5) The dispensing pharmacist or permit holder notifies the prescriber or the prescriber's office of the emergency dispensing within 72 hours after such dispensing.

*History Note:* Authority G.S. 90-85.6; 90-85.25; 90-85.32;  
Eff. September 1, 1993;  
Amended Eff. April 1, 1999; September 1, 1995.

## **21 NCAC 46 .1810        COMPOUNDING**

In accordance with G.S. 90-85.3(c) and (r), and 90-85.6(a), the Board has primary jurisdiction over compounding occurring in locations holding a pharmacy permit, and such compounding shall comply with the following:

- (1) based on the existence of a practitioner-pharmacist-patient relationship and the presentation of a valid prescription, or in anticipation of prescription orders based on established prescribing patterns, a pharmacist may compound a drug product for an individual patient. A pharmacist also may compound a drug product prior to receiving a valid prescription based on a history of receiving valid prescriptions generated within an established practitioner-pharmacist-patient relationship. Compounded drug products shall not be offered to other entities for resale; however, practitioners may obtain compounded drug products to administer to patients within the scope of their professional practice;
- (2) the pharmacist is responsible for all aspects of compounding; however, unlicensed personnel working under the supervision of the pharmacist may assist in compounding;
- (3) drug substances used for compounding shall be USP or NF grade, or if unavailable, AR, CP, ACS, or FCC grade substances may be used. If none of the foregoing grades are available, then the pharmacist must establish the purity and safety of the ingredient prior to its use. Manufactured drug products used for ingredients must be labeled with a batch control number and a future expiration date;
- (4) equipment and utensils used for compounding shall not be reactive, additive or absorptive so that the safety, identity, strength, quality, and purity of the compounded drug product will not be adversely affected. All compounding equipment and utensils shall be cleaned and sanitized prior to use. A compounding pharmacy shall have written procedures and formulas for the compounding of drug products;
- (5) any excess compounded drug product retained by the pharmacy shall be labeled with a complete list of ingredients or reference to such information, the preparation date, and an expiration date based upon the pharmacist's professional judgment. The excess compounded drug product shall be stored under conditions to preserve its strength, quality and purity;
- (6) with the exception of the simple reconstitution of drug products, the pharmacy shall maintain a log showing the name or initials of the person who compounded a drug product and the name or initials of the pharmacist who checked the compounded drug product;
- (7) with the exception of the simple reconstitution of drug products, the pharmacy shall maintain a recordkeeping system from which the date of purchase, supplier, manufacturer, and lot number or other identifier of each ingredient can be determined for each compounded drug product dispensed; provided however, that health care facility pharmacies may comply with this requirement by maintaining records of lot numbers only. All pharmacy records resulting from compounding, including the compounding log, shall be readily retrievable and maintained in the pharmacy for a period of three years;
- (8) in addition to the requirements of this Section, the compounding of radiopharmaceutical drug products shall comply with Section .2700 of this Chapter;
- (9) in addition to the requirements of this Section, the compounding of sterile parenteral drug products shall comply with Section .2800 of this Chapter.

*History Note:*     *Authority G.S. 90-85.6; 90-85.32;*  
                          *Eff. September 1, 1995;*  
                          *Amended Eff. August 1, 1998.*

## **21 NCAC 46 .1811        EXCESSIVE DISPENSING OF PRESCRIPTION DRUGS**

Pharmacists shall not dispense and permit holders shall not allow a pharmacist to dispense prescription drugs at such a rate per hour or per day as to pose a danger to the public health or safety.

*History Note:*     *Authority G.S. 90-85.6; 90-85.32;*

*Eff. July 1, 1996.*

**21 NCAC 46 .1812 CHANGES IN PRESCRIPTION ORDERS**

A permit holder or registrant requesting a change from the prescription drug originally prescribed to a different prescription drug shall disclose to the prescriber at the time of the request any business relationship between the permit holder or registrant and the manufacturer of the requested prescription drug.

*History Note: Authority G.S. 90-85.6; 90-85.32;  
Eff. April 1, 1997.*

**21 NCAC 46 .1813 TRANSMISSION OF PRESCRIPTION ORDERS**

(a) Prescription orders may be transmitted by using a facsimile machine ("FAX") or by other electronic transmission from a prescriber to a pharmacy. "Electronic transmission" means transmission of the digital representation of information by way of electronic equipment.

(b) All prescription drug orders transmitted by FAX or by electronic transmission shall:

- (1) be transmitted directly to a pharmacist or certified technician in a pharmacy of the patient's choice with no intervening person altering the content of the prescription drug order;
- (2) identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the transmission;
- (3) be transmitted by an authorized practitioner or his designated agent and contain either a written signature or an electronic signature unique to the practitioner;
- (4) be deemed the original prescription drug order, provided it meets all requirements of federal and state laws and regulations; and
- (5) if a refill order, contain all information required for original prescription orders except for the prescriber's signature.

(c) The prescribing practitioner may authorize his agent to transmit by FAX or by electronic transmission a prescription drug order to a pharmacist or certified technician in a pharmacy provided that the identity of the transmitting agent is included in the order.

(d) The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of a prescription drug order transmitted by FAX or by electronic transmission consistent with federal and state laws and regulations.

(e) All equipment for receipt of prescription drug orders by FAX or by electronic transmission shall be maintained so as to ensure against unauthorized access.

(f) Prescriptions may be transferred by FAX or by electronic transmission if all the requirements of Rule .1806 of this Section are met.

(g) No agreement between a prescriber and a pharmacy or device and medical equipment permit holder shall require that prescription orders be transmitted by FAX or by electronic transmission from the prescriber to only that pharmacy or device and medical equipment permit holder.

*History Note: Authority G.S. 90-85.6; 90-85.32;  
Eff. August 1, 1998;  
Amended Eff. March 1, 2004.*

**21 NCAC 46 .1814 AUTOMATED DISPENSING OR DRUG SUPPLY DEVICES**

(a) Automated dispensing or drug supply devices may be used in health care facility pharmacies and where a pharmacy permit exists, for maintaining patient care unit medication inventories or for a patient profile dispensing system, provided the utilization of such devices is under the supervision of a pharmacist. The pharmacist-manager shall develop and implement procedures to assure safe and effective use of medications, and, at a minimum, shall assure that:

- (1) only authorized personnel, as indicated by written policies and procedures, may obtain access to the drug inventories;

- (2) all drugs therein are reviewed no less than monthly;
  - (3) a system of accountability must exist for all drugs contained therein; the purity, potency, and integrity of the drugs shall be preserved;
  - (4) the device provides records required by this Section and other applicable laws and rules;
  - (5) requirements for controlled substances security are met; and
  - (6) prior to the drug being released for access by the nurse, the pharmacist enters the medication order into a computerized pharmacy profile that is interfaced to the automated dispensing unit, so that drug allergy screening, therapeutic duplication, and appropriate dose verification is done prior to the drug being administered.
- (b) Notwithstanding the provisions of Rule 21 NCAC 46 .2501, a pharmacist is required to supervise only the following activities pursuant to this Rule:
- (1) The packaging and labeling of drugs to be placed in the dispensing devices. Such packaging and labeling shall conform to all requirements pertaining to containers and label contents;
  - (2) The placing of previously packaged and labeled drug units into the dispensing device; and
  - (3) The restocking of automated dispensing devices.
- (c) Only persons authorized by the pharmacist-manager may remove drugs from the dispensing devices and only in the quantity of doses needed to satisfy immediate patient needs. Should a violation of the foregoing occur, the pharmacist-manager shall conduct an investigation and report any violations to the entity having jurisdiction over these issues.
- (d) Bar code scanning of drug packaging and storage units may be utilized as a quality control mechanism if this technology is available in the automated dispensing system.

*History Note:* Authority G.S. 90-85.6; 90-85.32; 90-85.33;  
 Eff. April 1, 1999;  
 Amended Eff. August 1, 2002.

**21 NCAC 46 1815 EMERGENCY PRESCRIPTION REFILL DUE TO INTERRUPTION OF MEDICAL SERVICES**

In the event a pharmacist or device and medical equipment permit holder receives a request for a prescription refill and the pharmacist or permit holder is unable to readily obtain refill authorization from the prescriber because of the prescriber's inability to provide medical services to the patient, the pharmacist or permit holder may dispense a one-time emergency supply of up to 90 days of the prescribed medication, provided that:

- (1) The prescription is not for a Schedule II controlled substance;
- (2) The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition;
- (3) In the pharmacist's or permit holder's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences;
- (4) The dispensing pharmacist or permit holder creates a written order entered in the pharmacy's automated data processing system containing all of the prescription information required by Section .2300 of these Rules and signs that order;
- (5) The dispensing pharmacist or permit holder notifies, or makes a good faith attempt to notify, the prescriber or the prescriber's office of the emergency dispensing within 72 hours after such dispensing.

*History Note:* Authority G.S. 90-85.6; 90-85.25; 90-85.32;  
 Temporary Adoption Eff. October 29, 1998;  
 Eff. August 1, 2000.

**21 NCAC 46 .1816 PROCEDURES FOR CENTRALIZED PROCESSING OF PRESCRIPTION ORDERS**

(a) A pharmacy permitted by the Board may process a request for the filling or refilling of a prescription order received by a pharmacy within this State, provided:

- (1) The pharmacy that is to fill or refill the prescription either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy.
  - (2) The prescription container:
    - (A) is clearly labeled with all information required by Federal and State laws and regulations; and
    - (B) clearly shows the name and address of the pharmacy refilling the prescription and the name and address of the pharmacy which receives the refilled prescription for dispensing to the patient.
  - (3) The patient is provided with written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.
  - (4) Both pharmacies maintain complete and accurate records of the prescription, including:
    - (A) the name of the pharmacist who fill or refills the prescription;
    - (B) the name of the pharmacy filling or refilling the prescription; and
    - (C) the name of the pharmacy that received the fill or refill request.
  - (5) The pharmacy that fills or refills the prescription and the pharmacy that receives the prescription for dispensing to the patient share a common electronic file.
  - (6) The originating pharmacy is responsible for compliance with the requirements of Federal and State laws and regulations regarding recordkeeping and patient counseling.
- (b) Nothing in this Rule shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or a patient's agent or transmitted to it by a prescriber.

*History Note:* Authority G.S. 90-85.6; 90-85.32;  
Eff. August 1, 2000.

#### **21 NCAC 46 .1817 PROOF OF IDENTIFICATION**

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

- (1) A valid motor vehicle operator's license;
- (2) A valid identification card;
- (3) A valid United States passport; or
- (4) Other valid, tamper-resistant, photographic identification.

(b) A pharmacist or person acting at the direction of a pharmacist may exercise discretion and refuse to fill any prescription or dispense any drug if unsatisfied as to the legitimacy or appropriateness of any prescription presented, the validity of any photographic identification or the identity of any patient presenting a prescription or any person acting on behalf of the patient. Refusal to fill pursuant to this Paragraph shall be noted on the prescription by the pharmacist or person acting at the direction of a pharmacist.

*History Notes:* Authority G.S. 90-85.6; 90-85.32;  
Eff. August 1, 2002.

#### **21 NCAC 46 .1818 PRESCRIPTION LABELS**

Prescription labels shall list at a minimum the generic name of the drug, even if the generic drug is unavailable to dispense or even if the substitution of a generic drug is not authorized.

*History Note:* Authority G.S. 90-85.6; 90-85.32;  
Eff. January 1, 2006.