

SECTION .2300 - PRESCRIPTION INFORMATION AND RECORDS

21 NCAC 46 .2301 PRESCRIPTION: DRUG ORDER REQUIREMENTS

(a) Prescription orders shall include, but not be limited to:

- (1) date of issuance;
- (2) name and address of patient;
- (3) name, address and telephone number of prescriber except that indication of the name of the prescriber is sufficient if a data file specified in (b) of this Rule is current and in effect;
- (4) Drug Enforcement Agency (DEA) number of prescriber in the case of controlled substances;
- (5) name, strength, dosage form and quantity of drug prescribed;
- (6) refills if authorized or, in institutions, the stop date;
- (7) route of administration of drug prescribed; and
- (8) directions for use.

(b) Information in Subparagraphs (a)(2), (a)(3), (a)(4), (a)(6) and (a)(7) may be stored in a readily retrievable data file specifically compiled for use in the pharmacy, which is not a commercial publication, in lieu of the requirements of the named Subparagraphs.

*History Note: Authority G.S. 90-85.6(a); 90-85.32; 90-106(h);
Eff. December 31, 1985;
Amended Eff. May 1, 1989.*

21 NCAC 46 .2302 RECORDS OF DISPENSING

(a) Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for three years and shall include, but are not limited to:

- (1) quantity dispensed, if quantity of refill is different than quantity of original;
- (2) date of dispensing;
- (3) serial number (or equivalent in an institution);
- (4) the identification of the pharmacist responsible for dispensing;
- (5) records of refills to date;
- (6) documentation of satisfaction of state requirements for drug selection.

(b) Records in institutional pharmacies may be made and kept as part of the patient's medical record.

*History Note: Authority G.S. 90-85.6(a); 90-85.26; 90-85.30; 90-85.35; 90-106(h);
Eff. December 31, 1985;
Amended Eff. May 1, 1989.*

21 NCAC 46 .2303 RECORDS OF PRESCRIPTION FILLING AND REFILLING

In a pharmacy with a manual system, the dispensing pharmacist shall indicate by date and initial the filling or refilling of a prescription on the document. In a pharmacy with a computer or data system, a designation of the dispensing pharmacist accompanied by the daily signature of the pharmacist filling or refilling each prescription is required as noted in Rule .2304(3)(a) or (3)(b). Information must be kept for three years. This does not preclude the use of unlicensed personnel entering information in a data system provided that supervision is maintained pursuant to Board rules.

*History Note: Authority G.S. 90-85.6(a); 90-85.26; 90-85.32;
Eff. December 31, 1985;
Amended Eff. May 1, 1989.*

21 NCAC 46 .2304 AUTOMATED DATA PROCESSING SYSTEMS

An automated data processing system may be employed as a record-keeping system if the following conditions are met:

- (1) The system shall have the capability of producing sight-readable documents of all original and refilled prescription information. The term "sight-readable" means that a regulatory agent shall be able to examine the record and read the information. In the case

- of administrative proceedings before the Board, records must be provided in a readable paper printout form.
- (2) Such information shall include, but not be limited to the prescription requirements and records of dispensing as indicated in Rules .2301 and .2302 of this Section.
 - (3) The individual pharmacist responsible for completeness and accuracy of the entries to the system must provide documentation of the fact that prescription information entered into the computer is correct. In documenting this information, the pharmacist shall have the option of either:
 - (a) providing a printout of each day's prescription information. That printout shall be dated and the individual pharmacist shall verify that the information indicated is correct and sign the printout in the same manner as a check or legal document (e.g. J.H. Smith, or John H. Smith). Such printout must be maintained three years from the date of last dispensing; or
 - (b) maintaining a log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day attesting to the fact that the prescription information entered into the computer that day has been reviewed and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of three years after the date of last dispensing.
 - (4) Documentation in Paragraph (3) of this Rule must be provided in the pharmacy within 72 hours of date of dispensing.
 - (5) An auxiliary recordkeeping system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason. When the automated data processing system is restored to operation, the information regarding prescriptions filled, refilled or transferred during the inoperative period shall be entered into the automated data processing system within the time equal to the number of inoperative days times three; for example, if the system were inoperative for five days then all interim data shall be entered within 15 days of the last inoperative day. However, nothing in this Paragraph shall preclude the pharmacist from using professional judgment for the benefit of a patient's health and safety. The auxiliary record keeping system shall be backed up at least weekly.
 - (6) A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with such supplier is terminated for any reason. A pharmacy shall assure continuity in the maintenance of records.
 - (7) A current version of drug interactions software shall be used and policies and procedures shall be established to address overriding the interactions prompt.

History Note: Authority G.S. 90-85.6(a); 90-85.26; 90-85.32; 90-107;
Eff. December 31, 1985;
Amended Eff. April 1, 1999; May 1, 1989.

21 NCAC 46 .2305 SECURITY

To maintain the confidentiality of patients' prescription orders, there must exist adequate safeguards or security of the records.

History Note: Authority G.S. 90-85.6(a); 90-85.36;
Eff. December 31, 1985;
Amended Eff. May 1, 1989.