

## 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 shall be made and kept by pharmacies for three years and shall include:

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

(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. March 1, 2013; May 1, 1989.

### 21 NCAC 46 .2303 RECORDS OF PRESCRIPTION FILLING AND REFILLING

In a pharmacy with a manual system of recordkeeping of prescription filling and refilling, the dispensing pharmacist shall indicate by date and initial the filling or refilling of a prescription on the document. In a pharmacy with an automated data processing system as provided in Rule .2304 of this Section, a designation of the dispensing pharmacist filling or refilling each prescription is required as provided in Rule .2304 of this Section. 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. March 1, 2013; May 1, 1989.

### 21 NCAC 46 .2304 AUTOMATED DATA PROCESSING SYSTEMS

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

- (1) The system has the capability of producing sight-readable documents of all original and refilled prescription information. The term "sight-readable" means that a regulatory agent is able to examine the record and read the information. In administrative proceedings before the Board, records must be provided in a readable paper printout form.
- (2) Information includes 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 provides documentation of the fact that prescription information entered into the computer is correct.
- (4) Documentation in Item (3) of this Rule is provided in the pharmacy within 72 hours of date of dispensing.
- (5) An auxiliary recordkeeping system is 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 Item precludes 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) The pharmacy makes 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 the supplier is terminated for any reason. A pharmacy shall assure continuity in the maintenance of records.
- (7) A current version of drug interactions software is used and policies and procedures are established to address overriding the software's alerts of any drug interactions.

*History Note:* Authority G.S. 90-85.6(a); 90-85.26; 90-85.32; 90-107;  
Eff. December 31, 1985;  
Amended Eff. March 1, 2013; 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.