

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);
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