21 NCAC 46 .2504 PATIENT COUNSELING

(a) In order to ensure that a prescription is safe for a patient and to counsel a patient effectively, a reasonable effort shall be made to obtain, record, maintain, and update patient information that, in the pharmacist's professional judgment, is pertinent to safe dispensing, including:

(1) contact information for reaching the patient or patient's representative;
(2) age and sex; and
(3) medical history relevant to safe use of the drug, device, or medical equipment, which may include:
    (A) disease states;
    (B) allergies and drug reactions;
    (C) current list of non-prescription and prescription medications, devices, and medical equipment; and
    (D) past experience with the patient's drug, device or medical equipment.

A "reasonable effort" shall mean an effort that is consistent with a pharmacist's professional judgment under the specific circumstances.

(b) To the extent necessary to undertake a reasonable effort to obtain the information required in Paragraph (a) of this Rule, information shall be obtained from the patient, the patient's representative, or the patient's health care providers. The information required in Paragraph (a) of this Rule shall be obtained, recorded, maintained, and updated by:

(1) In a pharmacy, either
    (A) a pharmacist, or
    (B) a pharmacy technician or pharmacy intern supervised by the pharmacist; or
(2) In a device or medical equipment facility, the person-in-charge to whom the permit is issued under Rule .1608(b) of this Chapter, or a person who is trained in obtaining, recording, maintaining, and updating the information required in Paragraph (a) of this Rule.

(c) A pharmacist, pharmacy intern under the supervision of a pharmacist, or person-in-charge of the device or medical equipment facility shall review, interpret, clarify where necessary, and apply the information set out in Paragraph (a) of this Rule before each prescription or order is dispensed to screen for potential therapeutic issues due to:

(1) therapeutic duplication;
(2) drug-disease contraindication;
(3) drug-drug interactions, including 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 or misuse.

(d) An offer to counsel shall be made as follows:

(1) An offer to counsel shall be made in the following circumstances:
    (A) On any new or transfer prescription; and
    (B) On any prescription when deemed necessary in the exercise of the professional judgment of a pharmacist or a person-in-charge of a device or medical equipment facility.
(2) The offer to counsel shall be communicated by:
    (A) In a pharmacy, a pharmacist, pharmacy technician, pharmacy intern, or other employee supervised by the pharmacist; or
    (B) In a device or medical equipment facility, the person-in-charge or an employee supervised by that person-in-charge.
(3) The offer to counsel shall be communicated:
    (A) At the time that in-person delivery occurs at the pharmacy or at a device or medical equipment facility;
    (B) With respect to other delivery, by information or materials provided accompanying the delivery, with instructions on how to access patient counseling via live communication without cost to the patient with one of the persons listed in Subparagraph (e)(2) of this Rule.

(e) Counseling shall be provided as follows:

(1) Counseling shall be performed in the following circumstances:
    (A) Unless the offer to counsel is refused;
    (B) If a patient requests counseling at a time other than when the offer to counsel is conveyed; and

(C) If a pharmacist or person-in-charge deems counseling necessary in the exercise of the professional judgment.

(2) Counseling shall be performed by:

(A) With respect to a pharmacy, a pharmacist or a pharmacy intern under the supervision of a pharmacist; or

(B) With respect to a device or medical equipment facility, either the person-in-charge; or an employee of the device or medical equipment facility whom the person-in-charge has determined is proficient in explaining the safe and proper use of devices or medical equipment, in the person-in-charge's professional judgment.

(C) With respect to instances in which non-pharmacists and non-persons-in-charge are authorized to dispense drugs, devices or medical equipment, by those persons authorized to perform the dispensing.

(3) Counseling shall be performed on those subjects needed for the safe use of the drug, device or medical equipment, within the professional judgment of a pharmacist or the person-in-charge of a device or medical equipment facility. The pharmacist or person-in-charge shall consider the following subjects for counseling, as appropriate under the specific circumstances:

(A) name, description, and purpose of the medication;

(B) route, dosage, administration, and continuity of therapy;

(C) special directions for use by the patient;

(D) 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;

(E) techniques for self-monitoring drug therapy;

(F) proper storage;

(G) prescription refill information; and

(H) action to be taken in the event of a missed dose.

(4) As an initial matter, upon request by the patient or patient's representative, counseling may be conducted by recorded communication accompanied by instructions on how to access additional follow-up patient counseling via live communication from one of the persons in Subparagraph (2) of this Paragraph unless:

(A) A pharmacist or person-in-charge may need to receive additional information regarding a patient in order to provide counseling consistent with this Rule in the exercise of professional judgment;

(B) The recorded communication does not address all subjects of counseling that should be covered under the standard of Subparagraph (3) of this Paragraph; or

(C) The circumstances require the pharmacist or person-in-charge of the device or medical facility to ensure that the patient understands the subjects of counseling in the exercise of professional judgment.

(5) The person performing counseling under this Paragraph is authorized to use recorded communication and alternative forms of patient information as a supplement to counseling in any circumstance in which it is within the exercise of professional judgment.

(f) With respect to inmates:

(1) With respect to Paragraphs (a) and (b) of this Rule, a pharmacist or person-in-charge of a device or medical equipment facility, is not required to gather information beyond what may be gathered from records available to the pharmacy, including, for example, from the pharmacy's own records, from the penal institution, from the controlled substance reporting system, or from the health care provider.

(2) The requirements of Paragraph (c) of this Rule remain in effect as to the information available under Subparagraph (1) of this Paragraph.

(3) Offers to counsel under Paragraph (d) and patient counseling under Paragraph (e) may be made:

(A) Through printed or electronic material, where such material can be provided to the patient; or

(B) By a correctional or law enforcement officer, where such material cannot be provided or in addition to such material.

(g) With respect to inpatients of health care facilities, as defined in Rule .1317 of this Chapter, who are administered a drug, device, or medical equipment by an authorized health care professional in the health care facility:

(1) The requirements of Paragraphs (a), (b) and (c) of this Rule remain in effect, though the information required in Paragraph (a) of this Rule may be gathered by any authorized health care professional, in addition to or instead of the persons set forth in Paragraph (b) of this Rule.

(2) Paragraphs (d) and (e) of this Rule do not apply.

(h) In addition to the counseling set forth in this Rule and regardless of patient request, persons-in-charge of device and medical equipment permit holders shall give written notice of warranty, if any, regarding service after the sale.

(i) Records of compliance with this Rule shall be maintained for three years in accordance with Section .2300 of this Chapter.

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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