REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2504

DEADLINE FOR RECEIPT: Friday, August 2, 2024.

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

In (a), line 35, please define "significant" patient information, to the extent that it includes anything other than what is listed in items (1)-(4).

In (b)(1), p.2, line 20, to be clear, both a pharmacy technician and a pharmacy intern must be supervised by the pharmacist? That's how it reads to me.

In (b)(2), line 22, is "person-in-charge" defined elsewhere?

In (c), line 26, I assume that the omission of pharmacy technicians here was intentional?

In (c)(3), line 33, what is a "serious" interaction?

In (c)(6), line 36, please consider making that "abuse or misuse".

In (e)(1)(C), p.3, line 23, I think you need to add "counseling" in between "deems" and "necessary".

In (e)(2)(A), again, I assume the omission of pharmacy technicians here was intentional?

In (e)(2)(B), line 30, how would someone be deemed "proficient"? What standards would guide that determination?

In (e)(4)(C), p.4, when would it not be true that the pharmacist or person-in-charge needs to ensure that the patient understands the subjects of counseling?

In (f)(1), p.5, line 2, I believe it should say "…is not required to gather information…"

Also in (f)(1), lines 3-4, please omit the parentheses and incorporate the parenthetical material into the text.

Brian Liebman
Commission Counsel
Date submitted to agency: July 19, 2024

In (g), line 15, please add a comma following "device".

In your History Note, do you need the reference to 42 USC 1396r-8(g) in the "Authority" line? I know there can be a complicated path where federal law does confer some authority to a state agency for rulemaking purposes, but generally I am skeptical of federal cites in state level rules.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

21 NCAC 46 .2504 is amended as published in 38:20 NCR 1322 as follows:

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)~~ (a) In order to ensure that a prescription is safe for a patient and to counsel a patient ~~patients~~ effectively, a reasonable effort shall be made to obtain, record, maintain, and update ~~and maintain~~ significant patient information, including:

(1) contact information for reaching the patient or patient's representative; ~~name, address, telephone number;~~

(2) ~~date of birth (age), gender;~~ age and sex; and

(3) medical ~~history:~~ history relevant to safe use of the drug, device, or medical equipment, which may include:

(A) disease states; ~~state(s);~~

(B) ~~allergies/drug~~ allergies and drug reactions;

(C) current list of ~~on~~ non-prescription and prescription medications, devices, and medical equipment; and ~~equipment.~~

(D) past experience with the patient's drug, device or medical equipment.

~~(4) comments relevant to the individual's drug therapy.~~

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

(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, a pharmacist, or a pharmacy technician or pharmacy intern supervised by the pharmacist; or

(2) In a device or medical equipment facility, the person-in-charge or a person who is trained in obtaining, recording, maintaining, and updating the information required in Paragraph (a) of this Rule.

~~(d)~~ (c) ~~Once patient information is obtained, this information shall be reviewed and updated by the pharmacist or person in charge~~ A pharmacist, pharmacy intern under the supervision of a pharmacist, or person-in-charge of the device or medical equipment facility ~~holding the device and medical equipment permit~~ 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 ~~filled or delivered, typically at the point of sale or point of distribution~~ to screen for potential therapeutic issues ~~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.

(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) ~~Unless refused by the patient or representative, patient counseling~~ 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;~~ 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 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.

~~(2)~~ (5) The person performing counseling under this Paragraph is authorized to use recorded communication and alternative forms of patient information ~~may be used to~~ as a supplement to ~~patient counseling;~~ counseling in any circumstance in which it is within the exercise of professional judgment.

~~(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.~~ 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 gather information beyond what may be gathered from records either available to the pharmacy (including, for example, the pharmacy's own records, records from the penal institution, and 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) ~~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.~~ 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) ~~Personnel of~~ 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. ~~The permit holder shall maintain documentation demonstrating that the written notice of warranty was given to the patient.~~

(i) Records of compliance with this Rule shall be maintained for three years in accordance with Section .2300 of this Chapter. ~~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);*
Eff. January 4, 1993;
Amended Eff. June 1, 2004; July 1, 1996; September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, ~~2017.~~ 2017;
Amended Eff. September 1, 2024.