



NOTICE OF TEXT

[Authority G.S. 150B-21.2(c)]

OAH USE ONLY

VOLUME: 38

ISSUE: 20

CHECK APPROPRIATE BOX:

- Notice with a scheduled hearing
- Notice without a scheduled hearing
- Republication of text. Complete the following cite for the volume and issue of previous publication, as well as blocks 1 - 4 and 7 - 14. If a hearing is scheduled, complete block 5.
Previous publication of text was published in Volume: Issue:

1. Rule-Making Agency: [Board of Pharmacy](#)

2. Link to agency website pursuant to G.S. 150B-19.1(c): www.ncbop.org/rulemakings.htm

3. Proposed Action -- Check the appropriate box(es) and list rule citation(s) beside proposed action:

ADOPTION:

AMENDMENT: [21 NCAC 46 .2504](#)

REPEAL:

READOPTION with substantive changes:

READOPTION without substantive changes:

REPEAL through READOPTION:

4. Proposed effective date: [08/01/2024](#)

5. Is a public hearing planned? [Yes](#)

If yes:

Date	Time	Location
05/21/2024	9:30 a.m.	North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, North Carolina 27517

6. If no public hearing is scheduled, provide instructions on how to demand a public hearing:

7. Explain Reason For Proposed Rule(s):

The principal purpose of the amendment is to clarify the rule. The existing rule addresses patient history information requirements, drug utilization reviews, offers to counsel and counseling in a non-chronological and circuitous fashion. The amended rule would address these topics in a sequential work-flow order. It further would clarify how the rule operates, and may differ, in different practice settings. Substantively, the amendment would provide for initial general counseling to take place through recorded technological means, in cases where that is appropriate.

8. Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or email. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 984-236-1850.

Rule(s) is automatically subject to legislative review. Cite statutory reference:

9. The person to whom written comments may be submitted on the proposed rule(s):

Name: Jay Campbell
Address: 6015 Farrington Rd Ste 201
Chapel Hill, NC 27517
Phone (optional):
Fax (optional):
EMail (optional) ncboprulmaking@ncbop.org

10. Comment Period Ends: 06/14/2024

11. Fiscal impact. Does any rule or combination of rules in this notice create an economic impact? Check all that apply.

No fiscal note required

12. Rule-making Coordinator:

Name: Clinton R. Pinyan
336-271-3157
cpinyan@brookspierce.com

Agency contact, if any:

Name: Jay Campbell
Phone:
Email: ncboprulmaking@ncbop.org

13. The Agency formally proposed the text of this rule(s) on

Date: 03/12/2024

1 21 NCAC 46 .2504 is proposed for amendment as follows:

2
3 **21 NCAC 46 .2504 PATIENT COUNSELING**

4 (a) ~~"Patient Counseling" shall mean the effective communication of information, as defined in this Rule, to the~~
5 ~~patient or representative in order to improve therapeutic outcomes by maximizing proper use of prescription~~
6 ~~medications, devices, and medical equipment. All provisions of this Rule shall apply to device and medical~~
7 ~~equipment permit holders, except Subparagraph (a)(8) of this Rule and except where otherwise noted. Specific areas~~
8 ~~of patient counseling include, but are not limited to, those matters listed in this Rule that in the exercise of the~~
9 ~~pharmacist's or device and medical equipment permit holder's professional judgment are considered significant:~~

- 10 (1) ~~name, description, and purpose of the medication;~~
11 (2) ~~route, dosage, administration, and continuity of therapy;~~
12 (3) ~~special directions for use by the patient;~~
13 (4) ~~common severe side or adverse effects or interactions and therapeutic contraindications that may~~
14 ~~be encountered, including their avoidance, and the action required if they occur;~~
15 (5) ~~techniques for self-monitoring drug therapy;~~
16 (6) ~~proper storage;~~
17 (7) ~~prescription refill information; and~~
18 (8) ~~action to be taken in the event of a missed dose.~~

19 (b) ~~An offer to counsel shall be made on new or transfer prescriptions at the time the prescription is dispensed or~~
20 ~~delivered to the patient or representative. Ancillary personnel may make the offer to counsel, but the pharmacist~~
21 ~~must personally conduct counseling if the offer is accepted. Counseling by device and medical equipment permit~~
22 ~~holders must be conducted by personnel proficient in explaining and demonstrating the safe and proper use of~~
23 ~~devices and equipment. The person in charge shall be responsible for ensuring that all personnel conducting~~
24 ~~counseling are proficient in explaining and demonstrating the safe and proper use of devices and equipment and for~~
25 ~~documenting the demonstration of such proficiency. The offer shall be made orally and in person when delivery~~
26 ~~occurs at the pharmacy. When delivery occurs outside of the pharmacy, whether by mail, vehicular delivery or other~~
27 ~~means, the offer shall be made either orally and in person, or by telephone from the pharmacist to the patient. If~~
28 ~~delivery occurs outside of the pharmacy, the pharmacist shall provide the patient with access to a telephone service~~
29 ~~that is toll free for long distance calls. A pharmacy whose primary patient population is accessible through a local~~
30 ~~measured or toll free exchange need not be required to offer toll free service. Counseling may be conducted by the~~
31 ~~provision of printed information in a foreign language if requested by the patient or representative. Professional~~
32 ~~judgment shall be exercised in determining whether or not to offer counseling for prescription refills. An offer to~~
33 ~~counsel shall be communicated in a positive manner to encourage acceptance.~~

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

- 1 (1) contact information for reaching the patient or patient's representative; name, address, telephone
- 2 number;
- 3 (2) date of birth (age), gender, age and sex; and
- 4 (3) medical history; history relevant to safe use of the drug, device, or medical equipment, which may
- 5 include:
 - 6 (A) disease states; state(s);
 - 7 (B) allergies/drug allergies and drug reactions;
 - 8 (C) current list of ~~on~~-non-prescription and prescription medications, devices, and medical
 - 9 equipment; and equipment.
 - 10 (D) past experience with the patient's drug, device or medical equipment.
- 11 (4) ~~comments relevant to the individual's drug therapy.~~

12 A "reasonable effort" shall mean an a good faith effort that is consistent with a pharmacist's professional judgment

13 under the specific circumstances, to obtain from the patient or representative the foregoing patient information.

14 Ancillary personnel may collect, record, and obtain patient profile information, but the pharmacist or person in

15 charge of the facility holding the device and medical equipment permit must review and interpret patient profile

16 information and clarify confusing or conflicting information. Professional judgment shall be exercised as to whether

17 and when individual patient history information should be sought from other health care providers.

18 (b) To the extent necessary to undertake a reasonable effort to obtain the information required in paragraph (a),

19 information shall be obtained from the patient, the patient's representative, or the patient's health care providers.

20 The information required in paragraph (a) shall be obtained, recorded, maintained, and updated by:

- 21 (1) In a pharmacy, a pharmacist, or a pharmacy technician or pharmacy intern supervised by the
- 22 pharmacist; or
- 23 (2) In a device or medical equipment facility, the person-in-charge or a person who is trained in
- 24 obtaining, recording, maintaining, and updating the information required in paragraph (a).

25 ~~(c)-(d) Once patient information is obtained, this information shall be reviewed and updated by the pharmacist or~~

26 ~~person in-charge~~ A pharmacist, pharmacy intern under the supervision of a pharmacist, or person-in-charge of the

27 device or medical equipment facility holding the device and medical equipment permit shall review, interpret,

28 clarify where necessary, and apply the information set out in paragraph (a) before each prescription or order is

29 dispensed filled or delivered, typically at the point of sale or point of distribution to screen for potential therapeutic

30 issues drug therapy problems due to:

- 31 (1) therapeutic duplication;
- 32 (2) drug-disease contraindication;
- 33 (3) drug-drug interactions, including serious interactions with prescription or over-the-counter drugs;
- 34 (4) incorrect drug dosage or duration of drug treatment;
- 35 (5) drug-allergy interactions; and
- 36 (6) clinical abuse/misuse.

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

- 1 (1) An offer to counsel shall be made in the following circumstances:
- 2 (A) On any new or transfer prescription; and
- 3 (B) On any prescription when deemed necessary in the exercise of the professional judgment
- 4 of a pharmacist or a person-in-charge of a device or medical equipment facility.
- 5 (2) The offer to counsel shall be communicated by:
- 6 (A) In a pharmacy, a pharmacist, pharmacy technician, pharmacy intern, or other employee
- 7 supervised by the pharmacist; or
- 8 (B) In a device or medical equipment facility, the person-in-charge or an employee
- 9 supervised by that person-in-charge.
- 10 (3) The offer to counsel shall be communicated:
- 11 (A) At the time that in-person delivery occurs at the pharmacy or at a device or medical
- 12 equipment facility;
- 13 (B) With respect to other delivery, by information or materials provided accompanying the
- 14 delivery, with instructions on how to access patient counseling via live communication
- 15 without cost to the patient with one of the persons listed in paragraph (e)(2).
- 16 (e) ~~Unless refused by the patient or representative, patient counseling~~ Counseling shall be provided as follows:
- 17 (1) Counseling shall be performed in the following circumstances:
- 18 (A) Unless the offer to counsel is refused;
- 19 (B) If a patient requests counseling at a time other than when the offer to counsel is
- 20 conveyed; and
- 21 (C) If a pharmacist or person-in-charge deems necessary in the exercise of the professional
- 22 judgment, counseling shall be "face to face" by the pharmacist, or personnel of a device
- 23 and medical equipment permit holder when possible;
- 24 (2) Counseling shall be performed by:
- 25 (A) With respect to a pharmacy, a pharmacist or a pharmacy intern under the supervision of a
- 26 pharmacist; or
- 27 (B) With respect to a device or medical equipment facility, either the person-in-charge; or an
- 28 employee of the device or medical equipment facility whom the person-in-charge has
- 29 determined is proficient in explaining the safe and proper use of devices or medical
- 30 equipment, in the person-in-charge's professional judgment.
- 31 (C) With respect to instances in which non-pharmacists and non-persons-in-charge are
- 32 authorized to dispense drugs, devices or medical equipment, by those persons authorized
- 33 to perform the dispensing.
- 34 (3) Counseling shall be performed on those subjects needed for the safe use of the drug, device or
- 35 medical equipment, within the professional judgment of a pharmacist or the person-in-charge of a
- 36 device or medical equipment facility. The pharmacist or person-in-charge shall consider the
- 37 following subjects for counseling, as appropriate under the specific circumstances:

- 1 (A) name, description, and purpose of the medication;
- 2 (B) route, dosage, administration, and continuity of therapy;
- 3 (C) special directions for use by the patient;
- 4 (D) common severe side or adverse effects or interactions and therapeutic contraindications
- 5 that may be encountered, including their avoidance, and the action required if they occur;
- 6 (E) techniques for self-monitoring drug therapy;
- 7 (F) proper storage;
- 8 (G) prescription refill information; and
- 9 (H) action to be taken in the event of a missed dose.

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

- 14 (A) A pharmacist or person-in-charge may need to receive additional information regarding a
15 patient in order to provide counseling consistent with this Rule in the exercise of
16 professional judgment;
- 17 (B) The recorded communication does not address all subjects of counseling that should be
18 covered under the standard of subparagraph (3); or
- 19 (C) The circumstances require the pharmacist or person-in-charge of the device or medical
20 facility to ensure that the patient understands the subjects of counseling in the exercise of
21 professional judgment.

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

26 ~~(3) patient counseling, as described in this Rule, shall be required for outpatient and discharge patients~~
27 ~~of hospitals, health maintenance organizations, health departments, and other institutions;~~
28 ~~however, compliance with this Rule in locations in which non-pharmacists are authorized by law~~
29 ~~or regulations to dispense may be accomplished by such authorized non-pharmacists; and~~

30 ~~(4) patient counseling, as described in this Rule, shall not be required for inpatients of hospitals or~~
31 ~~other institutions where a nurse or other licensed health care professional administers the~~
32 ~~medication(s).~~

33 ~~(f) Pharmacists that distribute prescription medication by mail, and where the practitioner-pharmacist-patient~~
34 ~~relationship does not exist, shall provide counseling services for recipients of such medication in accordance with~~
35 ~~this Rule. With respect to inmates:~~

36 (1) With respect to paragraphs (a) and (b), a pharmacist or person-in-charge of a device or medical
37 equipment facility, is not required gather information beyond what may be gathered from records

1 either available to the pharmacy (including, for example, the pharmacy's own records, records
2 from the penal institution, and the controlled substance reporting system) or from the health care
3 provider.

4 (2) The requirements of paragraph (c) remain in effect as to the information available under paragraph
5 (f)(1).

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

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

8 or

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

11 ~~(g) Records resulting from compliance with this Rule, including documentation of refusals to receive counseling,~~
12 ~~shall be maintained for three years in accordance with Section .2300 of this Chapter. With respect to inpatients of~~
13 ~~health care facilities, as defined in Rule 1317 of this Section, who are administered a drug, device or medical~~
14 ~~equipment by an authorized health care professional in the health care facility:~~

15 (1) The requirements of paragraphs (a), (b) and (c) remain in effect, though the information required
16 in paragraph (a) may be gathered by any authorized health care professional, in addition to or
17 instead of the persons set forth in (b).

18 (2) Paragraphs (d) and (e) do not apply.

19 ~~(h) Personnel of~~ In addition to the counseling set forth in this rule and regardless of patient request, persons-in-
20 charge of device and medical equipment permit holders shall give written notice of warranty, if any, regarding
21 service after the sale. The permit holder shall maintain documentation demonstrating that the written notice of
22 warranty was given to the patient.

23 ~~(i) Records of compliance with this Rule shall be maintained for three years in accordance with Section .2300 of~~
24 ~~this Chapter. Offers to counsel and patient counseling for inmates need not be "face to face", but rather, may be~~
25 ~~conducted through a correctional or law enforcement officer or through printed material. A pharmacist or a device~~
26 ~~and medical equipment permit holder dispensing drugs or devices or delivering medical equipment to inmates need~~
27 ~~not comply with Paragraph (c) of this Rule. However, once such patient information is obtained, the requirements of~~
28 ~~Paragraph (d) of this Rule shall be followed.~~

29
30 *History Note: Authority G.S. 90-85.6; 90-85.22; 90-85.32; 42 U.S.C. 1396r-8(g);*

31 *Eff. January 4, 1993;*

32 *Amended Eff. June 1, 2004; July 1, 1996; September 1, 1995;*

33 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*
34 *2017-2017;*

35 *Amended Eff. August 1, 2024.*