

1 21 NCAC 46 .2504 is amended **with changes** as published in 38:20 NCR 1322 as follows:

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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) (a) 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 ~~information that, in the pharmacist's professional judgment, is pertinent to safe dispensing, including:~~

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

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

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

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

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

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

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

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

16 (b) To the extent necessary to undertake a reasonable effort to obtain the information required in Paragraph (a) of

17 this Rule, information shall be obtained from the patient, the patient's representative, or the patient's health care

18 providers. The information required in Paragraph (a) of this Rule shall be obtained, recorded, maintained, and

19 updated by:

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

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

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

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

29 ~~clarify where necessary, and apply the information set out in Paragraph (a) of this Rule before each prescription or~~

30 ~~order is dispensed filled or delivered, typically at the point of sale or point of distribution to screen for potential~~

31 ~~therapeutic issues drug therapy problems due to:~~

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

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

2 (1) An offer to counsel shall be made in the following circumstances:

3 (A) On any new or transfer prescription; and

4 (B) On any prescription when deemed necessary in the exercise of the professional judgment
5 of a pharmacist or a person-in-charge of a device or medical equipment facility.

6 (2) The offer to counsel shall be communicated by:

7 (A) In a pharmacy, a pharmacist, pharmacy technician, pharmacy intern, or other employee
8 supervised by the pharmacist; or

9 (B) In a device or medical equipment facility, the person-in-charge or an employee
10 supervised by that person-in-charge.

11 (3) The offer to counsel shall be communicated:

12 (A) At the time that in-person delivery occurs at the pharmacy or at a device or medical
13 equipment facility;

14 (B) With respect to other delivery, by information or materials provided accompanying the
15 delivery, with instructions on how to access patient counseling via live communication
16 without cost to the patient with one of the persons listed in Subparagraph (e)(2) of this
17 Rule.

18 ~~(c) Unless refused by the patient or representative, patient counseling~~ Counseling shall be provided as follows:

19 ~~(1) counseling shall be "face to face" by the pharmacist, or personnel of a device and medical~~
20 ~~equipment permit holder when possible;~~ Counseling shall be performed in the following circumstances:

21 (A) Unless the offer to counsel is refused;

22 (B) If a patient requests counseling at a time other than when the offer to counsel is
23 conveyed; and

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

26 (2) Counseling shall be performed by:

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

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

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

36 (3) Counseling shall be performed on those subjects needed for the safe use of the drug, device or
37 medical equipment, within the professional judgment of a pharmacist or the person-in-charge of a

1 device or medical equipment facility. The pharmacist or person-in-charge shall consider the
2 following subjects for counseling, as appropriate under the specific circumstances:

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

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

5 (C) special directions for use by the patient;

6 (D) common severe side or adverse effects or interactions and therapeutic contraindications
7 that may be encountered, including their avoidance, and the action required if they occur;

8 (E) techniques for self-monitoring drug therapy;

9 (F) proper storage;

10 (G) prescription refill information; and

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

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

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

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

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

24 ~~(2)(5)~~ The person performing counseling under this Paragraph is authorized to use recorded
25 communication and alternative forms of patient information ~~may be used to~~ as a supplement to
26 patient counseling; counseling in any circumstance in which it is within the exercise of
27 professional judgment.

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

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

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

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

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

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

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

10 or

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

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

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

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

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

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

31
32 *History Note: Authority G.S. 90-85.6; 90-85.22; 90-85.32; 42 U.S.C. 1396r-8(g);*

33 *Eff. January 4, 1993;*

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

35 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*
36 *2017, 2017;*

37 *Amended Eff. September 1, 2024.*