

## Burgos, Alexander N

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**From:** Peaslee, William W  
**Sent:** Tuesday, July 30, 2024 2:11 PM  
**To:** Clint Pinyan  
**Cc:** Burgos, Alexander N  
**Subject:** RE: [External] Permit Definition

I provided the statute citation to the Commissioner and he has some questions to which he will want answers. You may want to come to the meeting.

**William W. Peaslee**  
**Rules Review Commission Counsel / Legislative Liaison**  
Office of Administrative Hearings  
1711 New Hope Church Road  
Raleigh NC, 27609  
(984) 236-1939  
[Bill.Peaslee@oah.nc.gov](mailto:Bill.Peaslee@oah.nc.gov)

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**From:** Clint Pinyan <CPINYAN@brookspierce.com>  
**Sent:** Tuesday, July 30, 2024 2:00 PM  
**To:** Peaslee, William W <bill.peaslee@oah.nc.gov>  
**Subject:** [External] Permit Definition

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NCGS 90-85.3(m).

Thanks for the call.

[Clint Pinyan](#)



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P.O. Box 26000 (27420)

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## Burgos, Alexander N

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**Subject:** FW: [External] RE: 21 NCAC 46 .2504 - August 2024 RRC  
**Attachments:** 21 ncac 46 .2504 4887-4228-5994 v.1.doc; 08.2024 - Response to Board of Pharmacy Request for Changes 4857-7343-9954 v.1.docx

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**From:** Clint Pinyan <CPINYAN@brookspierce.com>  
**Sent:** Friday, July 19, 2024 1:17 PM  
**To:** Liebman, Brian R <brian.liebman@oah.nc.gov>  
**Cc:** Burgos, Alexander N <alexander.burgos@oah.nc.gov>  
**Subject:** RE: [External] RE: 21 NCAC 46 .2504 - August 2024 RRC

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See if these answer your questions. Thanks for the help.

[Clint Pinyan](#)



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P.O. Box 26000 (27420)

1 21 NCAC 46 .2504 is amended **with changes** as published in 38:20 NCR 1322 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) (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;~~
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- 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.*

## Burgos, Alexander N

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**Subject:** FW: [External] RE: 21 NCAC 46 .2504 - August 2024 RRC  
**Attachments:** 21 ncac 46 .2504 4887-4228-5994 v.1.doc; 08.2024 - Response to Board of Pharmacy Request for Changes 4857-7343-9954 v.1.docx

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Greensboro, NC 27401  
P.O. Box 26000 (27420)

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).*

*It could, but that would be dependent on the drug, the patient and the circumstance. One that occurs to me is whether a patient has access to an adequate refrigerator for refrigerated drugs. Since those are odd one-off kind of cases, I've changed it to a use of professional judgment. See how that grabs you.*

*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.*

*That's a fact. See if I made it clearer.*

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

*The person-in-charge is, as the name suggests, the person who is in charge of a device or medical equipment permit. In 21 NCAC 46 .1608(b), the person-in-charge is the person to whom the permit is issued. Those folks' names are on the permits, so there is no confusion among the regulated people who that person is. It's the equivalent of a pharmacist manager for a non-pharmacy DME facility.*

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

*Absolutely. A pharmacy technician can gather information. But they don't have the education needed to interpret or apply that information to do drug screening.*

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

Brian Liebman  
Commission Counsel

Date submitted to agency: July 19, 2024

*I guess it's one that you wouldn't want to have happen to you. It's unnecessary, though, since this is about "potential" issues, which would include any interactions. (See what you get when you leave even 10 percent of the old rule in there.)*

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

*Considered. And done.*

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

*Yes. That's kinda key.*

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

*Absolutely. Again, that's a non-delegable act in the practice of pharmacy.*

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

*That's why we left that up to the person-in-charge's professional judgment. It's just going to depend. I'm probably proficient at explaining how to use crutches with zero training. Definitely not proficient in explaining how to use a CPAP. The person-in-charge gets to decide.*

*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?*

*Other than restructuring, this provision is the raison d'être for the amendment. Here's what we're saying: As an initial matter, you can use technology to counsel a patient. However, if "in the exercise of your professional judgment," you really need to make sure the patient understands, then you can't. So, for example, if I'm prescribed baby aspirin, there's not a whole lot of crucial information that I'm not going to get from a recording. But, if I'm taking insulin for the first time, you're going to need to tell me how to do it. Also, a pharmacist might let some common sense things go unsaid for a brilliant young RRC lawyer, but would need to lay eyes on grandpa and explain things to make sure he understands what's up. It's defined by their professional judgment.*

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

*Correct. Done.*

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

*Done. It was way too confusing.*

Brian Liebman  
Commission Counsel

Date submitted to agency: July 19, 2024

*In (g), line 15, please add a comma following “device”.*

*Done.*

*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.*

*See e-mail exchange.*

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

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



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**

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- 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 Subparagraph (e)(2) of this  
16                     Rule.

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

- 18           (1) ~~counseling shall be "face to face" by the pharmacist, or personnel of a device and medical~~  
19 ~~equipment permit holder when possible; Counseling shall be performed in the following circumstances:~~  
20               (A) Unless the offer to counsel is refused;  
21               (B) If a patient requests counseling at a time other than when the offer to counsel is  
22                     conveyed; and  
23               (C) If a pharmacist or person-in-charge deems **counseling** necessary in the exercise of the  
24                     professional judgment.  
25          (2) Counseling shall be performed by:  
26               (A) With respect to a pharmacy, a pharmacist or a pharmacy intern under the supervision of a  
27                     pharmacist; or  
28               (B) With respect to a device or medical equipment facility, either the person-in-charge; or an  
29                     employee of the device or medical equipment facility whom the person-in-charge has  
30                     determined is proficient in explaining the safe and proper use of devices or medical  
31                     equipment, in the person-in-charge's professional judgment.  
32               (C) With respect to instances in which non-pharmacists and non-persons-in-charge are  
33                     authorized to dispense drugs, devices or medical equipment, by those persons authorized  
34                     to perform the dispensing.  
35          (3) Counseling shall be performed on those subjects needed for the safe use of the drug, device or  
36                     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.*

## Burgos, Alexander N

---

**Subject:** FW: [External] RE: 21 NCAC 46 .2504 - August 2024 RRC

---

**From:** Clint Pinyan <CPINYAN@brookspierce.com>  
**Sent:** Friday, July 19, 2024 1:08 PM  
**To:** Liebman, Brian R <brian.liebman@oah.nc.gov>  
**Cc:** Burgos, Alexander N <alexander.burgos@oah.nc.gov>  
**Subject:** RE: [External] RE: 21 NCAC 46 .2504 - August 2024 RRC

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Thanks. I'd rather leave it, for that reason, even though we both know the deal.

[Clint Pinyan](#)



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---

**From:** Liebman, Brian R <[brian.liebman@oah.nc.gov](mailto:brian.liebman@oah.nc.gov)>  
**Sent:** Friday, July 19, 2024 12:35 PM  
**To:** Clint Pinyan <[CPINYAN@brookspierce.com](mailto:CPINYAN@brookspierce.com)>  
**Cc:** Burgos, Alexander N <[alexander.burgos@oah.nc.gov](mailto:alexander.burgos@oah.nc.gov)>  
**Subject:** RE: [External] RE: 21 NCAC 46 .2504 - August 2024 RRC

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Yeah, I understand that when it comes to interactions with the feds, sometimes you need something obvious, like a cite in the History Note, to show them that the rule is linked to the federal statute. I'm just asking if that's the case here, and if so, I'm not gonna go to war with you over it.

Brian

Brian Liebman  
Counsel to the North Carolina Rules Review Commission  
Office of Administrative Hearings  
(984)236-1948  
[brian.liebman@oah.nc.gov](mailto:brian.liebman@oah.nc.gov)

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---

**From:** Clint Pinyan <[CPINYAN@brookspierce.com](mailto:CPINYAN@brookspierce.com)>  
**Sent:** Friday, July 19, 2024 12:32 PM  
**To:** Liebman, Brian R <[brian.liebman@oah.nc.gov](mailto:brian.liebman@oah.nc.gov)>  
**Cc:** Burgos, Alexander N <[alexander.burgos@oah.nc.gov](mailto:alexander.burgos@oah.nc.gov)>  
**Subject:** [External] RE: 21 NCAC 46 .2504 - August 2024 RRC

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Received. I'll take a look.

On the authority question, you can tell me whether the federal statute needs to be listed: Federal law requires that each state have a patient counseling rule in order to receive federal Medicaid funding. So, does that statute authorize us to adopt that rule, if state law otherwise did not? No. But it effectively requires us to have that rule, or else everybody over at Medicaid would freak out and the governor would chew our butts.

We might have even added that in at some point after the periodic rule review came around, in case there were any question that the rule is necessary.

[Clint Pinyan](#)



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---

**From:** Liebman, Brian R <[brian.liebman@oah.nc.gov](mailto:brian.liebman@oah.nc.gov)>  
**Sent:** Friday, July 19, 2024 12:25 PM  
**To:** Clint Pinyan <[CPINYAN@brookspierce.com](mailto:CPINYAN@brookspierce.com)>

Cc: Burgos, Alexander N <[alexander.burgos@oah.nc.gov](mailto:alexander.burgos@oah.nc.gov)>

Subject: 21 NCAC 46 .2504 - August 2024 RRC

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Good afternoon,

I'm the attorney who reviewed the Rules submitted by the Board for the August 2024 RRC meeting. The RRC will formally review these Rules at its meeting on Wednesday, August 28, 2024, at 10:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get closer to the meeting. If there are any other representatives from your agency who will want to attend virtually, let me know prior to the meeting, and we will get evites out to them as well.

Please submit the revised Rules and forms to me via email, no later than 5 p.m. on Friday, August 2, 2024.

In the meantime, please do not hesitate to reach out via email with any questions or concerns.

Thanks,

Brian

Brian Liebman  
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[brian.liebman@oah.nc.gov](mailto:brian.liebman@oah.nc.gov)

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## **Burgos, Alexander N**

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**Subject:** FW: [External] RE: 21 NCAC 46 .2201 and .2516  
**Attachments:** 21 ncac 46 2516 with technical changes 4889-0449-4797 v.1.docx; 21 ncac 46 .2201 with technical changes 4859-3335-4189 v.1.doc

---

**From:** Peaslee, William W <bill.peaslee@oah.nc.gov>  
**Sent:** Monday, July 1, 2024 5:08 PM  
**To:** Rules, Oah <oah.rules@oah.nc.gov>  
**Cc:** Clint Pinyan <CPINYAN@brookspierce.com>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>  
**Subject:** FW: [External] RE: 21 NCAC 46 .2201 and .2516

Good afternoon,

It is my intention to recommend approval of the attached final rules at the July RRC meeting.

If you have any questions or concerns please feel free to contact me.

**William W. Peaslee**  
**Rules Review Commission Counsel / Legislative Liaison**  
Office of Administrative Hearings  
1711 New Hope Church Road  
Raleigh NC, 27609  
(984) 236-1939  
[Bill.Peaslee@oah.nc.gov](mailto:Bill.Peaslee@oah.nc.gov)

---

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1 21 NCAC 46 .2201 is adopted **with changes** as published in 38:15 NCR 971-972:

2  
3 **21 NCAC 46 .2201 HOURS: RECORDS: PROVIDERS: CORRESPONDENCE: RECIPROCITY**

4 (a) As a condition of license renewal, a pharmacist shall accumulate 15 hours of continuing education annually.

5 (b) Five of these continuing education hours shall be obtained through contact programs. Contact programs are  
6 those in which there is an opportunity for live two-way communication between the presenter and attendee. An  
7 online continuing education course may satisfy this contact-hour requirement provided that the continuing education  
8 course includes live two-way communication between the presenter and attendee.

9 (c) A pharmacist who accumulates more than the required 15 hours of continuing education in a single year may  
10 carry forward up to five surplus hours to be applied to the following year's continuing education requirements.

11 (d) A pharmacist shall preserve all continuing education records for three years. If a continuing education provider  
12 approved in Paragraph (f) ~~(e)~~ of this Rule maintains an electronic database of all pharmacists granted continuing  
13 education credits accredited by the provider, then the storage of that information in the provider's database shall be  
14 deemed to satisfy the pharmacist's recordkeeping requirement.

15 ~~(d)~~(e) Upon license renewal, the pharmacist shall report continuing education hours through the Board's online  
16 license renewal portal. The Board **may shall** require a pharmacist to submit records, reports of accredited hours and  
17 certificates of credit **on a random basis pursuant to a as part of any** continuing education audit.

18 ~~(e)~~(f) All continuing education shall be obtained through continuing education courses accredited by the  
19 Accreditation Council for Pharmacy Education or the North Carolina Association of Pharmacists. Pharmacists may  
20 also acquire five hours continuing education credit for precepting, for at least 160 hours, a student enrolled in the  
21 University of North Carolina Eshelman School of Pharmacy, the Campbell University College of Pharmacy and  
22 Health Sciences, the Wingate University School of Pharmacy, or the High Point University Fred Wilson School of  
23 Pharmacy as part of these schools' academic program.

24 ~~(f)~~(g) A pharmacist shall be exempt from the requirements of this Rule if:

25 (1) The pharmacist is eligible for a waiver of continuing education requirements under 21 NCAC 46  
26 .1613; or

27 (2) For the entire year preceding license renewal, the pharmacist resided in another state, did not  
28 practice pharmacy in North Carolina, and satisfied the state of residence's continuing education  
29 requirements for pharmacist licensure. **For the purposes of this Rule, a pharmacist's residence is**  
30 **determined by where the individual is a resident for state income tax purposes under G.S. 105-**  
31 **153.3(15).**

32 ~~(g)~~(h) Continuing education shall not serve as a barrier to reciprocity; however, all licensees by reciprocity **shall**  
33 **must** observe the continuing education standards specified in Paragraphs (a), (b), (c), (d), (e), (f), ~~(e)~~ and (g)-~~(f)~~ of  
34 this Rule within the first renewal period after licensure in this state.

35  
36 *History Note: Authority G.S. 90-85.6; 90-85.17; 90-85.18;*

37 *Eff. January 1, 1985;*

1                    *Amended Eff. January 1, 2008; April 1, 2005; August 1, 2004; August 1, 1998; September 1,*  
2                    *1993; May 1, 1989;*  
3                    *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*  
4                    *2017;*  
5                    *Amended Eff. January 1, 2018; June 1, 2024. ~~2018.~~*

21 NCAC 46 .2516 is adopted with changes as published in 38:15 NCR 972-973:

**21 NCAC 46 .2516 EMERGENCY CLOSURE**

(a) The pharmacist-manager of a pharmacy has the responsibility and authority to cease some or all of the pharmacy operations when doing so is necessary to fill the pharmacist-manager’s responsibility (a) for the safe, lawful and secure receipt of prescription orders and delivery of prescription drugs under Rule .1804(a) of this Chapter, or (b) to ensure that adequate qualified personnel are in place to properly render pharmaceutical service in compliance with state and federal law under Rule .1601(a)(1) of this Chapter.

(b) In the event that a pharmacist-manager [reasonably] anticipates that a permit is will be closed for more than two hours, either to receive prescription orders or to dispense prescription drugs, [drugs] during the regular hours that it has posted that it is open under Rule .1601(a)(2) of this Chapter, the pharmacist-manager shall take the following actions before closing:

(1) Post a notice in a location conspicuous to the public of (a) which services the pharmacy has ceased providing, and (b) the date and time that the pharmacist-manager anticipates that the pharmacy will resume providing those services. The pharmacist-manager shall change the posted notice in the event that the pharmacist-manager determines that it is no longer accurate.

(2) Send an e-mail to [emergencyclosure@ncbop.org](mailto:emergencyclosure@ncbop.org) with the information provided in Paragraph (b)(1) of this Rule, including any changes to the required notice.

(3) Arrange for the Offer to transfer of any prescriptions at the patient’s request during any time when the pharmacy is not dispensing prescription drugs, and post a notice in a location conspicuous to the public of ~~the pharmacy to which prescriptions will be transferred and~~ the process for having those prescriptions transferred. This includes prescriptions that have been filled but not delivered before the pharmacy is closed. However, the pharmacy is not required to transfer prescriptions at any time at which there is no pharmacist or certified technician who is able to transfer prescriptions. [prescriptions, i.e., who] For the purposes of this rule, a pharmacist or certified technician is able to transfer prescriptions if that person either:

(A) is present at the pharmacy, or

(B) has remote access to the pharmacy’s systems, either because that person is employed by the pharmacy, or employed by a pharmacy with a remote medication order processing services arrangement with the closed pharmacy under Rule .1816 of this Section.

(c) In the event that the pharmacist-manager is unable to exercise the authority in this Rule, [unavailable,] a pharmacist who is on duty at the pharmacy has the responsibility and authority set out in Paragraph (a) of this Rule if the pharmacist follows the procedures set out in Paragraph (b) of this Rule.

(d) This Rule does not apply in the following circumstances:

(1) to permanent Permanent closures or to temporary closures lasting more than 14 consecutive days, which are instead governed by the provisions of Rule .2502(h) and (i) of this Section; Section.

1 ~~(2) This Rule further does not apply to pharmacies~~ Pharmacies located outside the State of North Carolina,  
2 which should follow any closure rules of their home ~~states; or states.~~

3 (3) During the duration of time when the Governor ~~[of the State of North Carolina]~~ or any county or  
4 municipality has declared a state of emergency in the pharmacy's location pursuant to Chapter 166A of the North  
5 Carolina General Statutes. ~~[any geographic area in the State of North Carolina.]~~

6 (e) In the event that the either (a) the pharmacist-manager suffers an emergency that renders the pharmacist-manager  
7 unable to exercise the responsibilities in Paragraph (b) of this Rule, or (b) the pharmacist-manager is unavailable and  
8 the only pharmacist(s) on duty suffers an emergency that renders the pharmacist unable to exercise the responsibilities  
9 in Paragraph (b) of this Rule, the exercise of the responsibilities in Paragraph (b) of this Rule shall be excused until  
10 such time as an employee authorized by the pharmacist-manager or permit holder can exercise those responsibilities.

11  
12 *History Note: Authority G.S. 90-85.6, 90-85.15A, 90-85.21, 90-85.25, 90-85.32,*

13 *Eff. August 1, 2024.*

14

## Burgos, Alexander N

---

**Subject:** FW: [External] RE: 21 NCAC 46 .2201 and .2516

---

**From:** Clint Pinyan <CPINYAN@brookspierce.com>

**Sent:** Monday, July 1, 2024 5:08 PM

**To:** Peaslee, William W <bill.peaslee@oah.nc.gov>; Rules, Oah <oah.rules@oah.nc.gov>

**Cc:** Burgos, Alexander N <alexander.burgos@oah.nc.gov>

**Subject:** RE: [External] RE: 21 NCAC 46 .2201 and .2516

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Thanks much for making them better.

[Clint Pinyan](#)



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## Burgos, Alexander N

---

**Subject:** FW: [External] RE: 21 NCAC 46 .2201 and .2516  
**Attachments:** 21 ncac 46 .2201 with technical changes 4859-3335-4189 v.1.doc

---

**From:** Clint Pinyan <CPINYAN@brookspierce.com>  
**Sent:** Monday, July 1, 2024 4:36 PM  
**To:** Peaslee, William W <bill.peaslee@oah.nc.gov>  
**Cc:** Burgos, Alexander N <alexander.burgos@oah.nc.gov>  
**Subject:** RE: [External] RE: 21 NCAC 46 .2201 and .2516

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Here you go. I just changed it to “shall” and changed “pursuant to an audit” to “as part of any audit,” since (a) it “pursuant to” didn’t really make sense from the get go, and (b) it doesn’t make sense with shall. So, it now reads that, if we do an audit, we shall require records.

I frankly don’t think we do them with any regularity, since it’s all out there in the cloud. But I expect we could, particularly if there is some malfunction in the cloud. I think it’s like the State Bar, where the sponsors are really the ones doing the reporting, and the pharmacists just say “yeah, that looks right.”

[Clint Pinyan](#)



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1 21 NCAC 46 .2201 is adopted **with changes** as published in 38:15 NCR 971-972:

2  
3 **21 NCAC 46 .2201 HOURS: RECORDS: PROVIDERS: CORRESPONDENCE: RECIPROCITY**

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5 (b) Five of these continuing education hours shall be obtained through contact programs. Contact programs are  
6 those in which there is an opportunity for live two-way communication between the presenter and attendee. An  
7 online continuing education course may satisfy this contact-hour requirement provided that the continuing education  
8 course includes live two-way communication between the presenter and attendee.

9 (c) A pharmacist who accumulates more than the required 15 hours of continuing education in a single year may  
10 carry forward up to five surplus hours to be applied to the following year's continuing education requirements.

11 (d) A pharmacist shall preserve all continuing education records for three years. If a continuing education provider  
12 approved in Paragraph (f) ~~(e)~~ of this Rule maintains an electronic database of all pharmacists granted continuing  
13 education credits accredited by the provider, then the storage of that information in the provider's database shall be  
14 deemed to satisfy the pharmacist's recordkeeping requirement.

15 ~~(d)~~(e) Upon license renewal, the pharmacist shall report continuing education hours through the Board's online  
16 license renewal portal. The Board **may shall** require a pharmacist to submit records, reports of accredited hours and  
17 certificates of credit **on a random basis pursuant to a as part of any** continuing education audit.

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19 Accreditation Council for Pharmacy Education or the North Carolina Association of Pharmacists. Pharmacists may  
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21 University of North Carolina Eshelman School of Pharmacy, the Campbell University College of Pharmacy and  
22 Health Sciences, the Wingate University School of Pharmacy, or the High Point University Fred Wilson School of  
23 Pharmacy as part of these schools' academic program.

24 ~~(f)~~(g) A pharmacist shall be exempt from the requirements of this Rule if:

25 (1) The pharmacist is eligible for a waiver of continuing education requirements under 21 NCAC 46  
26 .1613; or

27 (2) For the entire year preceding license renewal, the pharmacist resided in another state, did not  
28 practice pharmacy in North Carolina, and satisfied the state of residence's continuing education  
29 requirements for pharmacist licensure. **For the purposes of this Rule, a pharmacist's residence is**  
30 **determined by where the individual is a resident for state income tax purposes under G.S. 105-**  
31 **153.3(15).**

32 ~~(g)~~(h) Continuing education shall not serve as a barrier to reciprocity; however, all licensees by reciprocity **shall**  
33 **must** observe the continuing education standards specified in Paragraphs (a), (b), (c), (d), ~~(e)~~, ~~(f)~~, ~~(e)~~ and ~~(g)~~-~~(f)~~ of  
34 this Rule within the first renewal period after licensure in this state.

35  
36 *History Note: Authority G.S. 90-85.6; 90-85.17; 90-85.18;*

37 *Eff. January 1, 1985;*



1                    *Amended Eff. January 1, 2008; April 1, 2005; August 1, 2004; August 1, 1998; September 1,*  
2                    *1993; May 1, 1989;*  
3                    *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*  
4                    *2017;*  
5                    *Amended Eff. January 1, 2018; June 1, 2024. ~~2018.~~*

## **Burgos, Alexander N**

---

**Subject:** FW: [External] RE: 21 NCAC 46 .2201 and .2516

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**From:** Peaslee, William W <bill.peaslee@oah.nc.gov>  
**Sent:** Monday, July 1, 2024 4:22 PM  
**To:** Clint Pinyan <CPINYAN@brookspierce.com>  
**Cc:** Burgos, Alexander N <alexander.burgos@oah.nc.gov>  
**Subject:** RE: [External] RE: 21 NCAC 46 .2201 and .2516

Thank you for the quick response.

The only issue I have left is in 21 NCAC 46 .2201, Lines 16-17. The use of the word “may” implies discretion by the Board. What factors does the Board use in deciding which pharmacists-subject-to-an-audit will be required to submit records, reports and certificates? Or change “may” to “shall.”

**William W. Peaslee**  
**Rules Review Commission Counsel / Legislative Liaison**  
Office of Administrative Hearings  
1711 New Hope Church Road  
Raleigh NC, 27609  
(984) 236-1939  
[Bill.Peaslee@oah.nc.gov](mailto:Bill.Peaslee@oah.nc.gov)

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Email correspondence to and from this address may be subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized state official.

## Burgos, Alexander N

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**Subject:** FW: [External] RE: 21 NCAC 46 .2201 and .2516  
**Attachments:** 21 ncac 46 2516 with technical changes 4889-0449-4797 v.1.docx; Response to Request for Changes 4873-2186-5677 v.1.docx; 21 ncac 46 .2201 with technical changes 4859-3335-4189 v.1.doc

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**From:** Clint Pinyan <CPINYAN@brookspierce.com>  
**Sent:** Monday, July 1, 2024 3:45 PM  
**To:** Peaslee, William W <bill.peaslee@oah.nc.gov>  
**Cc:** Burgos, Alexander N <alexander.burgos@oah.nc.gov>  
**Subject:** [External] RE: 21 NCAC 46 .2201 and .2516

**CAUTION:** External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Take a gander at these and see how they float your boat. If I didn't capture anything, let me know and I'll try again.

Thanks for your help.

[Clint Pinyan](#)



t: 336.271.3157

f: 336.232.9157

2000 Renaissance Plaza  
230 North Elm Street  
Greensboro, NC 27401  
P.O. Box 26000 (27420)

## **Burgos, Alexander N**

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**From:** Peaslee, William W  
**Sent:** Friday, June 28, 2024 4:24 PM  
**To:** Clint Pinyan  
**Cc:** Burgos, Alexander N  
**Subject:** 21 NCAC 46 .2201 and .2516  
**Attachments:** 07.2024 Board of Pharmacy Request for Changes.docx

Good afternoon Clint,

Attached please find the Request for Changes on the above captioned rules which will be considered at the July 2024 RRC meeting.

As always if you have any questions or concerns please feel free to contact me.

Have a good weekend.

Bill

**William W. Peaslee**  
**Rules Review Commission Counsel / Legislative Liaison**  
Office of Administrative Hearings  
1711 New Hope Church Road  
Raleigh NC, 27609  
(984) 236-1939  
[Bill.Peaslee@oah.nc.gov](mailto:Bill.Peaslee@oah.nc.gov)

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Email correspondence to and from this address may be subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized state official.

1 21 NCAC 46 .2201 is adopted **with changes** as published in 38:15 NCR 971-972:

2  
3 **21 NCAC 46 .2201 HOURS: RECORDS: PROVIDERS: CORRESPONDENCE: RECIPROCITY**

4 (a) As a condition of license renewal, a pharmacist shall accumulate 15 hours of continuing education annually.

5 (b) Five of these continuing education hours shall be obtained through contact programs. Contact programs are  
6 those in which there is an opportunity for live two-way communication between the presenter and attendee. An  
7 online continuing education course may satisfy this contact-hour requirement provided that the continuing education  
8 course includes live two-way communication between the presenter and attendee.

9 (c) A pharmacist who accumulates more than the required 15 hours of continuing education in a single year may  
10 carry forward up to five surplus hours to be applied to the following year's continuing education requirements.

11 (d) A pharmacist shall preserve all continuing education records for three years. If a continuing education provider  
12 approved in Paragraph (f) ~~(e)~~ of this Rule maintains an electronic database of all pharmacists granted continuing  
13 education credits accredited by the provider, then the storage of that information in the provider's database shall be  
14 deemed to satisfy the pharmacist's recordkeeping requirement.

15 ~~(d)~~(e) Upon license renewal, the pharmacist shall report continuing education hours through the Board's online  
16 license renewal portal. The Board may require a pharmacist to submit records, reports of accredited hours and  
17 certificates of credit **on a random basis** pursuant to a continuing education audit.

18 ~~(e)~~(f) All continuing education shall be obtained through continuing education courses accredited by the  
19 Accreditation Council for Pharmacy Education or the North Carolina Association of Pharmacists. Pharmacists may  
20 also acquire five hours continuing education credit for precepting, for at least 160 hours, a student enrolled in the  
21 University of North Carolina Eshelman School of Pharmacy, the Campbell University College of Pharmacy and  
22 Health Sciences, the Wingate University School of Pharmacy, or the High Point University Fred Wilson School of  
23 Pharmacy as part of these schools' academic program.

24 ~~(f)~~(g) A pharmacist shall be exempt from the requirements of this Rule if:

25 (1) The pharmacist is eligible for a waiver of continuing education requirements under 21 NCAC 46  
26 .1613; or

27 (2) For the entire year preceding license renewal, the pharmacist resided in another state, did not  
28 practice pharmacy in North Carolina, and satisfied the state of residence's continuing education  
29 requirements for pharmacist licensure. **For the purposes of this Rule, a pharmacist's residence is**  
30 **determined by where the individual is a resident for state income tax purposes under G.S. 105-**  
31 **153.3(15).**

32 ~~(g)~~(h) Continuing education shall not serve as a barrier to reciprocity; however, all licensees by reciprocity **shall**  
33 **must** observe the continuing education standards specified in Paragraphs (a), (b), (c), (d), (e), (f), ~~(e)~~ and (g) ~~(f)~~ of  
34 this Rule within the first renewal period after licensure in this state.

35  
36 *History Note: Authority G.S. 90-85.6; 90-85.17; 90-85.18;*

37 *Eff. January 1, 1985;*

1                    *Amended Eff. January 1, 2008; April 1, 2005; August 1, 2004; August 1, 1998; September 1,*  
2                    *1993; May 1, 1989;*  
3                    *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*  
4                    *2017;*  
5                    *Amended Eff. January 1, 2018; June 1, 2024. ~~2018.~~*

21 NCAC 46 .2516 is adopted with changes as published in 38:15 NCR 972-973:

**21 NCAC 46 .2516 EMERGENCY CLOSURE**

(a) The pharmacist-manager of a pharmacy has the responsibility and authority to cease some or all of the pharmacy operations when doing so is necessary to fill the pharmacist-manager’s responsibility (a) for the safe, lawful and secure receipt of prescription orders and delivery of prescription drugs under Rule .1804(a) of this Chapter, or (b) to ensure that adequate qualified personnel are in place to properly render pharmaceutical service in compliance with state and federal law under Rule .1601(a)(1) of this Chapter.

(b) In the event that a pharmacist-manager [reasonably] anticipates that a permit is-will be closed for more than two hours, either to receive prescription orders or to dispense prescription drugs, [drugs] during the regular hours that it has posted that it is open under Rule .1601(a)(2) of this Chapter, the pharmacist-manager shall take the following actions before closing:

(1) Post a notice in a location conspicuous to the public of (a) which services the pharmacy has ceased providing, and (b) the date and time that the pharmacist-manager anticipates that the pharmacy will resume providing those services. The pharmacist-manager shall change the posted notice in the event that the pharmacist-manager determines that it is no longer accurate.

(2) Send an e-mail to [emergencyclosure@ncbop.org](mailto:emergencyclosure@ncbop.org) with the information provided in Paragraph (b)(1) of this Rule, including any changes to the required notice.

(3) Arrange for the Offer to transfer of any prescriptions at the patient’s request during any time when the pharmacy is not dispensing prescription drugs, and post a notice in a location conspicuous to the public of ~~the pharmacy to which prescriptions will be transferred and~~ the process for having those prescriptions transferred. This includes prescriptions that have been filled but not delivered before the pharmacy is closed. However, the pharmacy is not required to transfer prescriptions at any time at which there is no pharmacist or certified technician who is able to transfer prescriptions. [prescriptions, i.e., who] For the purposes of this rule, a pharmacist or certified technician is able to transfer prescriptions if that person either:

(A) is present at the pharmacy, or

(B) has remote access to the pharmacy’s systems, either because that person is employed by the pharmacy, or employed by a pharmacy with a remote medication order processing services arrangement with the closed pharmacy under Rule .1816 of this Section.

(c) In the event that the pharmacist-manager is unable to exercise the authority in this Rule, [unavailable,] a pharmacist who is on duty at the pharmacy has the responsibility and authority set out in Paragraph (a) of this Rule if the pharmacist follows the procedures set out in Paragraph (b) of this Rule.

(d) This Rule does not apply in the following circumstances:

(1) to permanent Permanent closures or to temporary closures lasting more than 14 consecutive days, which are instead governed by the provisions of Rule .2502(h) and (i) of this Section; Section.

1 ~~(2) This Rule further does not apply to pharmacies~~ Pharmacies located outside the State of North Carolina,  
2 which should follow any closure rules of their home ~~states; or states.~~

3 (3) During the duration of time when the Governor ~~[of the State of North Carolina]~~ or any county or  
4 municipality has declared a state of emergency in the pharmacy's location pursuant to Chapter 166A of the North  
5 Carolina General Statutes. ~~[any geographic area in the State of North Carolina.]~~

6 (e) In the event that the either (a) the pharmacist-manager suffers an emergency that renders the pharmacist-manager  
7 unable to exercise the responsibilities in Paragraph (b) of this Rule, or (b) the pharmacist-manager is unavailable and  
8 the only pharmacist(s) on duty suffers an emergency that renders the pharmacist unable to exercise the responsibilities  
9 in Paragraph (b) of this Rule, the exercise of the responsibilities in Paragraph (b) of this Rule shall be excused until  
10 such time as an employee authorized by the pharmacist-manager or permit holder can exercise those responsibilities.

11  
12 *History Note: Authority G.S. 90-85.6, 90-85.15A, 90-85.21, 90-85.25, 90-85.32,*

13 *Eff. August 1, 2024.*

14



## Request for Changes Pursuant to N.C. Gen. Stat. § 150B-21.10

Staff reviewed these Rules to ensure that each Rule is within the agency's statutory authority, reasonably necessary, clear and unambiguous, and adopted in accordance with Part 2 of the North Carolina Administrative Procedure Act. Following review, staff has issued this document that may request changes pursuant to G.S. 150B-21.10 from your agency or ask clarifying questions.

Questions contained herein suggest that the rule as written is unclear or there is some ambiguity. If this document includes questions and you do not understand the question, please contact the reviewing attorney to discuss. Failure to respond may result in a staff opinion recommending objection.

Staff may suggest the agency "consider" an idea or language in this document. This is in no way a formal request that the agency adopt the idea or language but rather is offered merely for the agency's consideration which the agency may find preferable and clarifying.

To properly submit rewritten rules, please refer to the following Rules in the NC Administrative Code:

- Rule 26 NCAC 02C .0108 – The Rule addresses general formatting.
- Rule 26 NCAC 02C .0404 – The Rule addresses changing the introductory statement.
- Rule 26 NCAC 02C .0405 – The Rule addresses properly formatting changes made after publication in the NC Register.

### Note the following general instructions:

1. You must submit the revised rule via email to [oah.rules@oah.nc.gov](mailto:oah.rules@oah.nc.gov) and copy RRC Counsel. The electronic copy must be saved as the official rule name (XX NCAC XXXX).
2. For rules longer than one page, insert a page number.
3. Use line numbers; if the rule spans more than one page, have the line numbers reset at one for each page.
4. Do not use track changes. Make all changes using manual strikethroughs, underlines and highlighting.
5. You cannot change just one part of a word. For example:
  - Wrong: "~~a~~Association"
  - Right: "~~association~~ Association"
6. Treat punctuation as part of a word. For example:
  - Wrong: "day~~,~~ and"
  - Right: "~~day,~~ day, and"
7. Formatting instructions and examples may be found at:  
[www.ncoah.com/rules/examples.html](http://www.ncoah.com/rules/examples.html)

If you have any questions regarding proper formatting of edits after reviewing the rules and examples, please contact the reviewing attorney.

William W. Peaslee  
Commission Counsel

Date submitted to agency: June 28, 2024

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

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2201

**DEADLINE FOR RECEIPT: July 15, 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:

*Lines 16-17: Describe the “random basis” under which the Board will exercise this discretion. This can be read two ways. Either each pharmacy may be randomly selected to submit records, or the Board may randomly require a particular pharmacy to submit records to the exclusion of other pharmacies. In the former, every pharmacy has an equal likelihood of being required to submit records. In the later, individual pharmacies may be signaled out for this treatment. If the latter, the factors upon which the Board will exercise its discretion must be in the rule. As written, it is unclear.*

*I can do you one better: Because of automation, we’re not really doing random CE audits anymore. So, we can take that part out.*

*Lines 19-23: How is this documented or applied for? What does the Board require as proof?*

*The schools select their own preceptors and control the application process, as well as how their programs work. So, this is like the State Bar excepting judges from CLE – they are assumed to be keeping up with developments by virtue of their service, but the State Bar doesn’t pick the judges. The individuals report that they are preceptors, just like they do for regular CEs.*

*Line 27: Define “resided.”*

*Done. (We used to have an applicable definition of “residing” in the definition section, but we changed it in a general overhaul to make it just apply to patients. So, that’s not helpful.) We’ll go with state income tax purposes, rather than some more obscure definition, so that people will clearly know how this is interpreted.*

*Line 30: Change “must” to “shall.”*

William W. Peaslee  
Commission Counsel

Date submitted to agency: June 28, 2024

*Done.*

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

William W. Peaslee  
Commission Counsel  
Date submitted to agency: June 28, 2024

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

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2516

**DEADLINE FOR RECEIPT: July 15, 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:

*Line 9: Define a "reasonable" anticipation?*

*This was language proposed by the regulated persons. I'm going to just drop out reasonable, and we'll base it on their actual anticipation.*

*Line 9: Is the trigger the reasonable anticipation or the actual closure for more than two hours? As written, if the pharmacist-manager does not anticipate the closure, he/she is absolved of the responsibility.*

*It is anticipation, not actual. If you close down to go to a doctor's visit, and they have to admit you to the hospital, we're not going to come down on you.*

*Line 10: I think you need a comma after "drugs."*

*Done.*

*Line 24-27: These lines are unclear.*

*Yeah, it was a long sentence. See if breaking it down helps.*

*Line 28: Define "unavailable."*

*As you can imagine, the idea of the rule is that it's the pharmacist-manager's call to shut down, unless the pharmacist-manager is the one being hauled out by ambulance or the pharmacist-manager is unreachable on the Appalachian Trail or whatever. See if this helps. If you think it's better we could leave it as "unavailable" but make it "unavailable to exercise the authority in this Rule"*

William W. Peaslee  
Commission Counsel

Date submitted to agency: June 28, 2024

*Lies 36-37: As written, the rule would be inapplicable to a pharmacy in Boone when a state of emergency is declared in Manteo only. Was this the intention? Consider, "During a state of emergency declared pursuant to Chapter 166A of the North Carolina General Statutes for the area in which the pharmacy is located."*

*Good catch.*

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

William W. Peaslee  
Commission Counsel  
Date submitted to agency: June 28, 2024