

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.

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

Line 27: Define “resided.”

Line 30: Change “must” to “shall.”

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

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

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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.

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

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34 *History Note: Authority G.S. 90-85.6; 90-85.17; 90-85.18;*
35 *Eff. January 1, 1985;*
36 *Amended Eff. January 1, 2008; April 1, 2005; August 1, 2004; August 1, 1998; September 1,*
37 *1993; May 1, 1989;*

1 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*
2 *2017;*
3 *Amended Eff. January 1, 2018; August 1, 2024, ~~2018~~.*

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?

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.

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

Line 24-27: These lines are unclear.

Line 28: Define "unavailable."

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."

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

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 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 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, i.e., who is present at the pharmacy or 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 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.~~
- (2) ~~This Rule further does not apply to pharmacies~~ Pharmacies located outside the State of North Carolina, which should follow any closure rules of their home ~~states; or states.~~
- (3) ~~During the duration of time when the Governor of the State of North Carolina or any county or municipality has declared a state of emergency in any geographic area in the State of North Carolina.~~

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

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

8 Eff. August 1, 2024.

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