



**STATE OF NORTH CAROLINA
OFFICE OF ADMINISTRATIVE HEARINGS**

December 16, 2021

Clinton Pinyan
Board of Pharmacy
Sent via email only to: cpinyan@brookspierce.com

Re: Extension of the Period of Review for 21 NCAC 46 .1417 and .1816

Dear Mr. Pinyan:

At its meeting this morning, the Rules Review Commission extended the period of review for the above-captioned rules in accordance with G.S. 150B-21.10. They did so in response to a request from the agency to extend the period of review in order to allow the Board an opportunity to review the letter sent by CVS dated December 8, 2021.

Pursuant to G.S. 150B-21.13, when the Commission extends the period of review, it is required to approve or object to rules or call a public hearing on the same within 70 days.

If you have any questions regarding the Commission's actions, please let me know.

Sincerely,

Amber May
Commission Counsel

Cc: Jay Campbell

Donald R. van der Vaart, Director
Chief Administrative Law Judge

Fred G. Morrison, Jr.
Senior Administrative Law Judge

Linda T. Worth
Deputy Director

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21 NCAC 46 .1417 is repealed as published in 35:22 NCR 2446 as follows:

21 NCAC 46 .1417 REMOTE MEDICATION ORDER PROCESSING SERVICES

History Note: Authority G.S. 90-85.6; 90-85.21; 90-85.21A; 90-85.26; 90-85.32; 90-85.34;

Eff. February 1, 2006;

Amended Eff. December 1, 2015; March 1, 2013;

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

Repealed Eff. March 1, 2022.

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1816

DEADLINE FOR RECEIPT: Wednesday December 8, 2021

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 call our office to inquire concerning the staff recommendation.

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

Are remote medication order processing services and centralized prescription services considered to be "unique pharmacy practices" for purposes of G.S. 90-85.34?

Throughout this Rule, is "Federal and State statutes and regulations" also intended to include "rules"? If so, please consider "Federal and State statutes, rules, and regulations."

In (a), I assume that "centralized pharmacy services" as referenced on line 6 are the same as "centralized prescription filling services" as define in (c)(1). If that's correct, please change "centralized pharmacy services" to "centralized prescription filling services."

In (a), line 7, please put "remote medication order processing services" in quotations as you have for "centralized pharmacy services."

In (a), please add a comma after "shipped" and "mailed"

Just to be clear, (b) applies to both the sending and receiving pharmacies?

I note that G.S. 90-85.21A(a) requires "any pharmacy operating outside the State which ships, mails, or delivers in any manner a dispensed legend drug into this State shall annually register..." I'm reading (b)(1) to require permitting of out of State pharmacies. Please use language that is consistent with the statute where you can.

In (b)(4), please add a comma after "pharmacist-managers"

In (c)(1), please break (A) and (B) out into list form.

In (c)(2), please add a comma after "the prescriber"

In (c)(2), line 4, add a comma after "device"

In (c)(2), line 5, please change "above" to "of this Rule"

Amber May
Commission Counsel
Date submitted to agency: November 22, 2021

In (c)(3), it looks like (A), (B), and (D) are all required. If that's the case, please end (c)(3)(A) semi-colon and add an "and" at the end of (c)(3)(B). Also, since (C) has been deleted, please change "(D)" to "(C)".

In (c)(3)(B), please add a comma after "device"

In (c)(3)(D), delete or define "complete" and "accurate."

Since (c)(4) and (5) both appear to address what are not considered to be centralized prescription filling services, would it make sense to group these together in list form?

In (c)(4), what is meant by "for which the pharmacies should comply with the requirements for the originating pharmacy to transfer the prescription under Rule .1806 of this Chapter"? Should "should" be "shall"?

In (c)(5), what is meant by "for which the pharmacies should comply with the requirements in this Rule"? Should "should" be "shall"?

It appears as though (d)(1) and (2) provides definitions applicable to this Paragraph. If that's correct, please consider saying something like "For purposes of this Paragraph, the following definitions shall apply:", then break the definitions for "remote medication order processing services", "dispensing pharmacy", and "remote medication order processing pharmacy" into list form in separate Parts?

In (d)(1), please change the dashes to commas on line 12.

In (d)(1), please add a comma after "device"

In (d)(1)(D), what is "proper prescription drug therapy"?

In (d)(1)(F), please add a comma after "device"

In (d)(2), please add a comma after "device"

In (d)(3)(B), please add a comma after "maintain"

In (d)(3)(B)(x), please capitalize "state"

In (d)(3)(B)(xi), please delete or define "objectively" and "systematically"

In (d)(3)(C), should "be" be "is"?

In (d)(3)(D), should "train" be "trains"

In (d)(3)(D), please add a comma after "attention"

In (d)(3)(D), what is meant by "are able to perform at the same level of competence, attention, and proficiency as if the personnel were in the dispensing pharmacy personal were in the dispensing pharmacy." Are there specific requirements or rules that they are required to meet?

In (d)(3)(E), should “be provided” be “are provided”?

In (d)(3)(E), should “from a site” be “at a site”?

In (d)(3)(G) and (H), please delete the “(a)” and the “(b)” or change these to “i” and “ii” and put them in list form.

In (d)(3)(I), please add a comma after “pharmacist-manager”

In (d)(3)(I), should “be responsible” be “are responsible”?

In (d)(3)(I), do you want to include federal regulations, in addition to State rules?

In (d)(3)(I), are these policies and procedures those of the pharmacy?

In (d)(3)(J), should “satisfy” be “satisfies”?

In (d)(4), please add a comma after “prescriber”

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

Amber May
Commission Counsel
Date submitted to agency: November 22, 2021

21 NCAC 46 .1816 is amended **with changes** as published in 35:22 NCR 2446 as follows:

**21 NCAC 46 .1816 ~~PROCEDURES FOR CENTRALIZED PHARMACY SERVICES PROCESSING~~
~~OF PRESCRIPTION ORDERS~~**

(a) This Rule sets out the requirements under which pharmacies may engage in “centralized pharmacy services,” which consist of both centralized prescription **filling** services and remote medication order processing services, as defined in this Rule, with respect to any prescription to be dispensed by a pharmacy located within this State, or shipped mailed or delivered in any manner into this State.

(b) Regardless of whether located within or outside the State of North Carolina, the following requirements apply to any pharmacy involved with any part of the practice of pharmacy in centralized pharmacy services:

(1) The pharmacies must be permitted by the Board before providing any centralized pharmacy services.

(2) The pharmacies must either:

(A) Be owned by the same person or entity; or

(B) Before dispensing any prescription within or into this State, must have entered into a written contract that specifies the services to be provided and the responsibilities and accountabilities of each pharmacy to ensure compliance with state and federal statutes and regulations.

(3) The pharmacies must share a real-time, online database, or have technology to allow secure access to the pharmacies’ information system and to provide access to the information required to provide centralized pharmacy services in compliance with state and federal statutes and regulations.

(4) The pharmacies, their pharmacist-managers and their pharmacy personnel must comply with all provisions of the Pharmacy Practice Act, this Chapter and all other State of North Carolina and federal statutes and regulations applicable to the practice of pharmacy and the distribution of drugs, devices and medical equipment in addition to the statutes and regulations of the state(s) in which the pharmacies are located (if not located in North Carolina) and into which any drugs, devices or medical equipment are shipped and dispensed (if not North Carolina). The pharmacies, their pharmacist-managers and their pharmacy personnel are **jointly and severally** responsible for ensuring that these statutes and regulations are followed.

(5) The pharmacies must notify the Board before providing centralized pharmacy services.

(c) Centralized prescription filling services.

(1) “Centralized prescription filling services” consist of a receiving pharmacy receiving a prescription from an originating pharmacy, processing that prescription, and **either (a)** delivering the drug, device, or medical equipment to the originating pharmacy for dispensing to the **[patient.] patient** or **(b) delivering the drug, device, or medical equipment directly to the patient, if the patient requests delivery from the receiving pharmacy.**

- (2) In this Rule, the “originating pharmacy” is the pharmacy that was presented the prescription, whether by the patient, the prescriber or by transfer. ~~[transfer, and that ultimately dispenses the drug, device or medical equipment to the patient.]~~ In this Rule, the “receiving pharmacy” is the pharmacy that processes the prescription and delivers the drug, device or medical equipment as set forth in Subparagraph (c)(1) above. ~~[to the originating pharmacy for dispensing to the patient.]~~
- (a) (3) A pharmacy permitted by the Board The receiving pharmacy may process a request for the filling or refilling of a prescription order received by a pharmacy within this State, the originating pharmacy, provided:
- (1) The pharmacy that is to fill or refill the prescription either has a contract with the pharmacy which received the prescription or has the same owner as the other originating pharmacy;
- (A) Both the originating pharmacy and the receiving pharmacy satisfy the requirements in Paragraph (b) of this Rule.
- (2) (B) The prescription container: drug, device or medical equipment (A) is clearly labeled with all information required by Federal and State laws and regulations; and (B) clearly shows both the name and address of the receiving pharmacy refilling the prescription and the name and address of the originating pharmacy; pharmacy which receives the refilled prescription for dispensing to the patient.
- (3) ~~[(C)]~~ The patient is provided with written information, either on the prescription label or with the prescription container [drug, device, or medical equipment] that describes which pharmacy to contact [for patient counseling or other questions; however, if the drug, device, or medical equipment is dispensed in person to the patient or the patient's agent, an offer must be made for a pharmacist at the originating pharmacy to counsel the patient in accordance with the requirements of Rule .2504 of this Chapter;] if the patient has any questions about the prescription or medication.
- (4) Both pharmacies maintain complete and accurate records of the prescription, including:
- (A) the name of the pharmacist who fill or refills the prescription;
- (B) the name of the pharmacy filling or refilling the prescription; and
- (C) the name of the pharmacy that received the fill or refill request.
- (5) The pharmacy that fills or refills the prescription and the pharmacy that receives the prescription for dispensing to the patient share a common electronic file; and
- (6) (D) The originating pharmacy satisfies all responsibility ~~is responsible~~ for compliance with the requirements of Federal and State laws statutes and regulations regarding recordkeeping and patient counseling. ~~[recordkeeping, counseling, and the receiving pharmacy further maintains complete and accurate records of each prescription for at least three years.~~
- (4) Centralized prescription filling services do not include prescriptions that are [dispensed or delivered by the receiving pharmacy,] transferred to another pharmacy to perform all acts related to dispensing or delivery, including recordkeeping and counseling, for which the pharmacies

1 should comply with the requirements for the originating pharmacy to transfer the prescription
2 under Rule .1806 of this Chapter.

3 (5) Centralized prescription filling services do not include prescriptions for which remote order
4 processing services are performed, but [the drug, device, or medical equipment is dispensed or
5 delivered] all physical acts in the dispensing process are performed by the pharmacy to which the
6 prescription was presented, for which the pharmacies should comply with the requirements for
7 remote medication order processing services in this Rule.

8 ~~(b) Nothing in this Rule shall be construed as barring a pharmacy from also filling new prescriptions presented by a~~
9 ~~patient or a patient's agent or transmitted to it by a prescriber.~~

10 (d) Remote medication order processing services.

11 (1) "Remote medication order processing services" consist of a pharmacy performing some act in the
12 practice of pharmacy -- other than a physical act in the dispensing process -- for another pharmacy
13 that dispenses a drug, device or medical equipment. Remote medication order processing services
14 include the following:

15 (A) receiving, interpreting, or clarifying medication orders;

16 (B) entering data and transferring medication order information;

17 (C) performing drug regimen review;

18 (D) interpreting patient clinical data to ensure proper prescription drug therapy;

19 (E) performing therapeutic interventions; and

20 (F) providing patient counseling or other drug information to patients and providers
21 concerning prescriptions or drugs, devices or medical equipment; however, if the drug,
22 device or medical equipment is dispensed in person to the patient or the patient's agent,
23 an offer must be made for a pharmacist at the dispensing pharmacy to counsel the patient
24 in accordance with the requirements of Rule .2504 of this Chapter.

25 (2) In this Rule, the "dispensing pharmacy" is the pharmacy that was presented the prescription and
26 dispenses the drug, device or medical equipment. In this Rule, a "remote medication order
27 processing pharmacy" is a pharmacy that provides an act in the practice of pharmacy for the
28 dispensing pharmacy pursuant to this Rule.

29 (3) The remote medication order processing pharmacy may provide remote medication order
30 processing services for the dispensing pharmacy, provided:

31 (A) The dispensing pharmacy and the remote medication order processing pharmacy satisfy
32 the requirements in Paragraph (b) of this Rule.

33 (B) The pharmacies involved in remote medication order processing services jointly develop,
34 maintain and follow a manual of policies and procedures that include policies and
35 procedures for:

36 (i) operation of the system described in Subparagraph (b)(3) of this Rule;

- (ii) following the dispensing pharmacy's policies regarding medication order processing;
- (iii) defining and ensuring the performance of each pharmacy's responsibilities;
- (iv) maintaining contact information for how to communicate with the pharmacies at all times when remote medication order processing services are performed;
- (v) training and annual review of pharmacy personnel of the remote medication order processing pharmacy;
- (vi) communicating and resolving questions or problems arising during the remote medication order processing services.
- (vii) communicating changes in the formulary to pharmacy personnel;
- (viii) protecting the confidentiality and integrity of patient information;
- (ix) identifying the name(s), initial(s) or identification code(s) and specific activity or activity of each pharmacy personnel who perform any remote medication order processing services;
- (x) complying with all state and federal laws;
- (xi) operating a quality improvement program designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, to pursue opportunities to improve patient care, and resolve identified problems;
- (xii) updating these policies and procedures any time changes are necessary; and
- (xiii) communicating changes in these policies and procedures to pharmacy personnel.
- (C) The policy and procedures manual be reviewed at least annually, updated as needed, and any review and changes be documented and communicated to all pharmacy personnel.
- (D) The remote medication order processing pharmacy train all pharmacy personnel providing remote medication order processing services on the policies and procedures required by Part B of this Subparagraph. The pharmacist-manager of the remote medication order processing pharmacy must ensure that pharmacy personnel are able to perform at the same level of competence, attention and proficiency as if the personnel were in the dispensing pharmacy. The pharmacist-manager shall document all training.
- (E) All remote medication order processing services be provided from a site operated by a remote medication order processing pharmacy, located within the United States, and with access to the technology required in Subparagraph (b)(3) of this Rule. This may include a remote site outside of the remote medication order processing pharmacy, so long as all requirements of state and federal laws and regulations, including this Rule, are satisfied.
- ~~(F) Regardless of whether pharmacy personnel or the pharmacies are located within or outside the State of North Carolina, all remote medication order processing services be provided by a pharmacist who is licensed by this Board, or by a pharmacy technician who~~

1 ~~is registered with this Board. Pharmacy technicians may provide only those remote~~
2 ~~medication order processing services that they are permitted to perform under G.S. 90-~~
3 ~~85.3(q2).]~~

4 (F) Each remote medication order processing pharmacy must notify the Board of each
5 pharmacist who will provide remote medication order processing services before those
6 pharmacy personnel perform any such services.

7 (G) In order for the Board to ensure continual monitoring of pharmacist good standing, each
8 pharmacist who will provide remote medication order processing services must either (a)
9 hold a North Carolina license to practice pharmacy or (b) participate in the NABP Verify
10 service before and at all times when that pharmacist provides remote medication order
11 entry services. The remote medication order entry pharmacy must provide the NABP
12 Verify information for each pharmacist when it notifies the Board that the pharmacist
13 may provide remote medication order entry services.

14 (H) Pharmacy technicians may perform remote medication order processing services only if
15 they are registered or otherwise permitted to work as a pharmacy technician in their home
16 state. While pharmacy technicians either within or outside of this state may perform
17 remote medication order processing services, pharmacy technicians may provide only
18 those remote medication order processing services that both (a) they are permitted to
19 perform under the laws of the state in which they are located, and (b) pharmacy
20 technicians are permitted to perform under G.S. 90-85.3(q2), regardless of where they are
21 located.

22 ~~[(G)]~~ (I) The remote medication order processing pharmacy, its pharmacist-manager and its
23 pharmacy personnel be responsible for compliance with all state and federal statutes and
24 rules and their policies and procedures governing the provision of remote medication
25 order processing services.

26 ~~[(H)]~~ (J) The dispensing pharmacy satisfy all responsibility for compliance with the requirements
27 of state and federal statutes and regulations regarding recordkeeping, and the records
28 document the activities of each pharmacy personnel providing remote medication order
29 processing services and the specific activity or activities performed by each person.
30 These records shall be maintained for a period of at least three years.

31 (4) Remote medication order processing services do not include services with respect to prescriptions
32 in which some physical act in the dispensing process is performed by a pharmacy other than the
33 dispensing pharmacy. If a pharmacy receiving a prescription from a patient, prescriber or by
34 transfer wishes for another pharmacy to perform a physical act in the dispensing process, it must
35 either transfer the prescription to that pharmacy under Rule .1806 of this Chapter, or follow the
36 procedures for centralized prescription filling services in this Rule.

1 (e) Nothing in this Rule relieves a pharmacy receiving centralized pharmacy services (i.e., an originating pharmacy
2 or a dispensing pharmacy) of the need to provide on-site services required for permitting as provided in the
3 Pharmacy Practice Act and this Chapter.

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5 *History Note: Authority G.S. 90-85.6; 90-85.21; 90-85.21A; 90-85.26; 90-85.32; 90-85.34;*

6 *Eff. August 1, 2000;*

7 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*
8 *2017; 2017.*

9 *Amended Eff. March 1, 2022.*