

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] 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] statutes, rules, 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] statutes, rules, and regulations.

(4) The pharmacies, their [pharmacist-managers] 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] statutes, rules, and regulations applicable to the practice of pharmacy and the distribution of drugs, [devices] devices, and medical [equipment] equipment, in addition to the [statutes] statutes, rules, and regulations of the state(s) in which the pharmacies are located (if not located in North Carolina) and into which any drugs, [devices] devices, or medical equipment are shipped and dispensed (if not North Carolina). The pharmacies, their [pharmacist-managers] pharmacist-managers, and their pharmacy personnel are [jointly and severally] responsible for ensuring that these [statutes] statutes, rules, 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]~~ 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,]~~ patient or 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]~~ device, or medical equipment as set forth in Subparagraph (c)(1) of this Rule. ~~[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] 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; and 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)]~~ (C) The originating pharmacy satisfies all responsibility is responsible for compliance with the requirements of Federal and State laws ~~[statutes]~~ statutes, rules, and regulations regarding recordkeeping and patient counseling. ~~[recordkeeping,]~~ counseling, and the

1 receiving pharmacy further maintains ~~[complete and accurate]~~ all required records of  
2 each prescription for at least three years.

3 (4) Centralized prescription filling services do not include prescriptions that are either: ~~[dispensed or~~  
4 ~~delivered by the receiving pharmacy,]~~

5 (A) Transferred to another pharmacy to perform all acts related to dispensing or delivery,  
6 including recordkeeping and counseling, for which the pharmacies ~~should~~ shall comply  
7 with the requirements for the originating pharmacy to transfer the prescription under Rule  
8 .1806 of this ~~Chapter, Chapter,~~ or

9 (B) ~~[(5) Centralized prescription filling services do not include prescriptions]~~  
10 Prescriptions for which remote order processing services are performed, but ~~[the drug,~~  
11 ~~device, or medical equipment is dispensed or delivered]~~ all physical acts in the dispensing  
12 process are performed by the pharmacy to which the prescription was presented, for  
13 which the pharmacies ~~[should]~~ shall comply with the requirements for remote medication  
14 order processing services in Paragraph (d) of this Rule.

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

17 (d) Remote medication order processing services.

18 (1) "Remote medication order processing services" consist of a pharmacy performing some act in the  
19 practice of ~~[pharmacy—]~~ pharmacy, other than a physical act in the dispensing process, ~~[process—~~  
20 ~~]~~ for another pharmacy that dispenses a drug, ~~[device]~~ device, or medical equipment. Remote  
21 medication order processing services include the following:

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

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

24 (C) performing drug regimen review;

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

26 (E) performing therapeutic interventions; and

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

32 (2) In this Rule, the "dispensing pharmacy" is the pharmacy that was presented the prescription and  
33 dispenses the drug, ~~[device]~~ device, or medical equipment. In this Rule, a "remote medication  
34 order processing pharmacy" is a pharmacy that provides an act in the practice of pharmacy for the  
35 dispensing pharmacy pursuant to this Rule.

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

- 1           (A)    The dispensing pharmacy and the remote medication order processing pharmacy satisfy  
2               the requirements in Paragraph (b) of this Rule.
- 3           (B)    The pharmacies involved in remote medication order processing services jointly develop,  
4               ~~[maintain]~~ maintain, and follow a manual of policies and procedures that include policies  
5               and procedures for:
- 6               (i)     operation of the system described in Subparagraph (b)(3) of this Rule;  
7               (ii)    following the dispensing pharmacy's policies regarding medication order  
8               processing;  
9               (iii)   defining and ensuring the performance of each pharmacy's responsibilities;  
10              (iv)   maintaining contact information for how to communicate with the pharmacies at  
11              all times when remote medication order processing services are performed;  
12              (v)     training and annual review of pharmacy personnel of the remote medication  
13              order processing pharmacy;  
14              (vi)    communicating and resolving questions or problems arising during the remote  
15              medication order processing services;  
16              (vii)   communicating changes in the formulary to pharmacy personnel;  
17              (viii)  protecting the confidentiality and integrity of patient information;  
18              (ix)    identifying the name(s), initial(s) or identification code(s) and specific activity  
19              or activity of each pharmacy personnel who perform any remote medication  
20              order processing services;  
21              (x)     complying with all state and federal laws;  
22              (xi)    operating a quality improvement program designed to objectively and  
23              systematically monitor and evaluate the quality and appropriateness of patient  
24              care, to pursue opportunities to improve patient care, and resolve identified  
25              problems;  
26              (xii)   updating these policies and procedures any time changes are necessary; and  
27              (xiii)   communicating changes in these policies and procedures to pharmacy personnel.
- 28           (C)    The policy and procedures manual ~~[be]~~ is reviewed at least annually, updated as needed,  
29               and any review and changes ~~[be]~~ are documented and communicated to all pharmacy  
30               personnel.
- 31           (D)    The remote medication order processing pharmacy ~~[train]~~ trains all pharmacy personnel  
32               providing remote medication order processing services on the policies and procedures  
33               required by Part B of this Subparagraph. The pharmacist-manager of the remote  
34               medication order processing pharmacy must ensure that pharmacy personnel are able to  
35               perform at the same level of competence, ~~[attention]~~ attention, and proficiency as if the  
36               personnel were in the dispensing pharmacy. The pharmacist-manager shall document all  
37               training.

(E) All remote medication order processing services ~~[be]~~ are provided ~~[from]~~ at 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 ~~[statutes]~~ statutes, rules, 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 is registered with this Board. Pharmacy technicians may provide only those remote medication order processing services that they are permitted to perform under G.S. 90-85.3(q2).]

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

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

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

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

~~[(H)]~~ (J) The dispensing pharmacy ~~[satisfy]~~ satisfies all responsibility for compliance with the requirements of state and federal ~~[statutes]~~ statutes, rules, and regulations regarding

1 recordkeeping, and the records document the activities of each pharmacy personnel  
2 providing remote medication order processing services and the specific activity or  
3 activities performed by each person. These records shall be maintained for a period of at  
4 least three years.

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

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

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

16 *Eff. August 1, 2000;*

17 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*  
18 *2017; 2017.*

19 *Amended Eff. March 1, 2022.*