

21 NCAC 46 .1816 CENTRALIZED PHARMACY SERVICES

(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, 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, rules, 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, rules, and regulations applicable to the practice of pharmacy and the distribution of drugs, devices, and medical equipment, in addition to the 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, or medical equipment are shipped and dispensed (if not North Carolina). The pharmacies, their pharmacist-managers, and their pharmacy personnel are responsible for ensuring that these 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 the drug, device, or medical equipment to the originating pharmacy for dispensing to the 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 or the prescriber or by transfer. 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) of this Rule.
- (3) The receiving pharmacy may process a request for the filling or refilling of a prescription order received by the originating pharmacy, provided:
 - (A) Both the originating pharmacy and the receiving pharmacy satisfy the requirements in Paragraph (b) of this Rule.
 - (B) The drug, device, or medical equipment is labeled with both the name and address of the receiving pharmacy and the name and address of the originating pharmacy; and
 - (C) The originating pharmacy satisfies all responsibility for compliance with the requirements of Federal and State statutes, rules, and regulations regarding recordkeeping and patient counseling, and the receiving pharmacy further maintains all required records of each prescription for at least three years.
- (4) Centralized prescription filling services do not include prescriptions that are either:
 - (A) Transferred to another pharmacy to perform all acts related to dispensing or delivery, including recordkeeping and counseling, for which the pharmacies shall comply with the requirements for the originating pharmacy to transfer the prescription under Rule .1806 of this Chapter; or
 - (B) Prescriptions for which remote order processing services are performed, but all physical acts in the dispensing process are performed by the pharmacy to which the prescription

was presented, for which the pharmacies shall comply with the requirements for remote medication order processing services in Paragraph (d) of this Rule.

(d) Remote medication order processing services.

- (1) "Remote medication order processing services" consist of a pharmacy performing some act in the practice of pharmacy, other than a physical act in the dispensing process, for another pharmacy that dispenses a drug, device, or medical equipment. Remote medication order processing services include the following:
 - (A) receiving, interpreting, or clarifying medication orders;
 - (B) entering data and transferring medication order information;
 - (C) performing drug regimen review;
 - (D) interpreting patient clinical data to ensure proper prescription drug therapy;
 - (E) performing therapeutic interventions; and
 - (F) providing patient counseling or other drug information to patients and providers concerning prescriptions or drugs, devices, or medical equipment; 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 dispensing pharmacy to counsel the patient in accordance with the requirements of Rule .2504 of this Chapter.
- (2) In this Rule, the "dispensing pharmacy" is the pharmacy that was presented the prescription and dispenses the drug, device, or medical equipment. In this Rule, a "remote medication order processing pharmacy" is a pharmacy that provides an act in the practice of pharmacy for the dispensing pharmacy pursuant to this Rule.
- (3) The remote medication order processing pharmacy may provide remote medication order processing services for the dispensing pharmacy, provided:
 - (A) The dispensing pharmacy and the remote medication order processing pharmacy satisfy the requirements in Paragraph (b) of this Rule.
 - (B) The pharmacies involved in remote medication order processing services jointly develop, maintain, and follow a manual of policies and procedures that include policies and procedures for:
 - (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 is reviewed at least annually, updated as needed, and any review and changes are documented and communicated to all pharmacy personnel.
 - (D) The remote medication order processing pharmacy trains 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 are provided 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, rules, and regulations, including this Rule, are satisfied.
 - (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.
 - (I) The remote medication order processing pharmacy, its pharmacist-manager, and its pharmacy personnel are responsible for compliance with all state and federal statutes, rules and regulations and the pharmacies' policies and procedures governing the provision of remote medication order processing services.
 - (J) The dispensing pharmacy satisfies all responsibility for compliance with the requirements of state and federal statutes, rules, and regulations regarding recordkeeping, and the records document the activities of each pharmacy personnel providing remote medication order processing services and the specific activity or activities performed by each person. These records shall be maintained for a period of at least three years.
- (4) Remote medication order processing services do not include services with respect to prescriptions in which some physical act in the dispensing process is performed by a pharmacy other than the dispensing pharmacy. If a pharmacy receiving a prescription from a patient or prescriber or by transfer wishes for another pharmacy to perform a physical act in the dispensing process, it must either transfer the prescription to that pharmacy under Rule .1806 of this Chapter, or follow the procedures for centralized prescription filling services in this Rule.
- (e) Nothing in this Rule relieves a pharmacy receiving centralized pharmacy services (i.e., an originating pharmacy or a dispensing pharmacy) of the need to provide on-site services required for permitting as provided in the Pharmacy Practice Act and this Chapter.

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