

TITLE 21 - OCCUPATIONAL LICENSING BOARDS AND COMMISSIONS

CHAPTER 46 – BOARD OF PHARMACY

Notice is hereby given in accordance with G.S. 150B-21.2 that the Board of Pharmacy intends to amend the rule cited as 21 NCAC 46 .1816 and repeal the rule cited as 21 NCAC 46 .1417.

Pursuant to G.S. 150B-21.17, the Codifier has determined it impractical to publish the text of rules proposed for repeal unless the agency requests otherwise. The text of the rule(s) are available on the OAH website at <http://reports.oah.state.nc.us/ncac.asp>.

Link to agency website pursuant to G.S. 150B-19.1(c): www.ncbop.org/rulemakings.htm

Proposed Effective Date: *September 1, 2021*

Public Hearing:

Date: *July 20, 2021*

Time: *10:00 a.m.*

Location: *The public hearing will be held remotely. The public can participate on Teams at <https://tinyurl.com/3wn9x3xc> or may call 336-604-5350, conference ID 560 519 380#.*

Reason for Proposed Action: *The rule changes would consolidate two existing rules (21 NCAC 46 .1417 and 21 NCAC .1816) into one rule that governs situations where two pharmacies provide services with respect to a prescription. The principal substantive changes are: (1) to expand remote medication order processing services from its existing use with health care facility pharmacies so that remote medication order processing services can be used by any pharmacy permitted by the state; (2) to expand the pharmacy personnel who may provide remote medication order processing services so that they may be provided by registered technicians in addition to licensed pharmacists; and (3) to provide that pharmacies involved in centralized pharmacy services may decide which of those pharmacies provide the required patient counseling for mail-order or other delivered prescriptions.*

Comments may be submitted to: *Jay Campbell, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517; fax (919) 246-1056; email ncboprulemaking@ncbop.org*

Comment period ends: *July 20, 2021 at 10:00 a.m.*

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission after the adoption of the Rule. If the Rules Review Commission receives written and signed objections after the adoption of the Rule in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-431-3000.

Fiscal impact. Does any rule or combination of rules in this notice create an economic impact? Check all that apply.

- State funds affected
- Local funds affected
- Substantial economic impact (\geq \$1,000,000)
- Approved by OSBM
- No fiscal note required

SECTION .1400 - HOSPITALS: OTHER HEALTH FACILITIES

21 NCAC 46 .1417 REMOTE MEDICATION ORDER PROCESSING SERVICES

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

SECTION .1800 - PRESCRIPTIONS

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 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 delivering the drug, device, or medical equipment to the originating pharmacy for dispensing to the patient.
 - (2) In this Rule, the "originating pharmacy" is the pharmacy that was presented the prescription, whether by the patient, the prescriber, or by 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 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, 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, for which the pharmacies should comply with the requirements for the originating pharmacy to transfer the prescription under Rule .1806 of this Chapter.
 - (5) Centralized prescription filling services do not include prescriptions for which remote order processing services are performed, but the drug, device, or medical equipment is dispensed or delivered by the pharmacy to which the prescription was presented, for which the pharmacies should comply with the requirements for remote medication order processing services in this Rule.
- ~~(b) Nothing in this Rule shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or a patient's agent or transmitted to it by a prescriber.~~
- (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 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 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).
 - (G) The remote medication order processing pharmacy, its pharmacist-manager, and its pharmacy personnel be responsible for compliance with all state and federal statutes and rules and their policies and procedures governing the provision of remote medication order processing services.
 - (H) The dispensing pharmacy satisfy all responsibility for compliance with the requirements of state and federal statutes 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, 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.

Authority G.S. 90-85.6; 90-85.15A; 90-85.21; 90-85.21A; 90-85.26; 90-85.32; 90-85.33; 90-85.34.