

## REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1417

**DEADLINE FOR RECEIPT: Friday, November 13, 2015**

**NOTE WELL:** *This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

*In Paragraph (c), Page 1, line 24, replace "must" with "shall"*

*In Paragraph (d), line 27, what is "each pharmacy's" intended to mean? Are these pharmacies with remote medication order processing services serving more than one pharmacy?*

*Also in (d), on line 29, generally the term "at least" is not preferred in rule, as the rule sets the minimum standard. I take it you need to retain the term here?*

*In Subparagraph (e)(1), line 35, please replace "must" with "shall"*

*On line 36, what is a "remote pharmacy"? I take it this is not the "remote site" defined in Subparagraph (b)(3)? If it is, please use the same term here.*

*On line 37, who determines what information is "necessary" to process the order? The pharmacist?*

*In Subparagraph (e)(2), Page 2, line 5, are the "policies and procedures" referred to promulgated by the pharmacies?*

*In Paragraph (f), line 6, please replace "must" with "shall"*

*In Paragraph (g), line 10, what is a "remote location"? Is it the same as "remote site" or "remote pharmacy"? If so, please use the same term here.*

*In Paragraph (h), lines 12 and 13, replace "must" with "shall"*

Amanda J. Reeder  
Commission Counsel  
Date submitted to agency: October 29, 2015

*In Paragraph (h), line 15, the Rule states that pharmacist employed by an out-of-state remote medication processing pharmacy are required to be licensed by the Board. However, G.S. 90-85.21A(a) requires only that out-of-state pharmacists agree to be subject to the authority of the Board through certification:*

(a) Any pharmacy operating outside the State which ships, mails, or delivers in any manner a dispensed legend drug into this State shall annually register with the Board on a form provided by the Board. In order to satisfy the registration requirements of this subsection, a pharmacy shall certify that the pharmacy employs a pharmacist who is responsible for dispensing, shipping, mailing, or delivering dispensed legend drugs into this State or in a state approved by the Board and has met requirements for licensure equivalent to the requirements for licensure in this State. In order for the pharmacy's certification of the pharmacists to be valid, a pharmacist shall agree in writing, on a form approved by the Board, to be subject to the jurisdiction of the Board, the provisions of this Article, and the rules adopted by the Board. If the Board revokes this certification, the pharmacy shall no longer have authority to dispense, ship, mail, or deliver in any manner a dispensed legend drug into this State.

*Therefore, it appears that the word "licensed" should be changed to "certified" on line 15 as it relates to out-of-state pharmacists. Or is the Board issuing licenses to these individuals? Or, is the intention of the Rule to address in-state pharmacists employed by out-of-state pharmacies? Either way, I believe the language can be clarified.*

*In Part (i)(3)(D), line 28, define "continuous"*

*In Paragraph (j), line 1, "Rule" should be capitalized.*

*How does Paragraph (j) work now that Paragraph (a) has been amended to allow the health care facility pharmacies to contract for the medication order processing without limitation?*

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

Amanda J. Reeder  
Commission Counsel  
Date submitted to agency: October 29, 2015

21 NCAC 46 .1417 is amended as published in 30:02 NCR 179 as follows:

**21 NCAC 46 .1417 REMOTE MEDICATION ORDER PROCESSING SERVICES**

(a) Purpose. The purpose of this Rule is to set out requirements under which health care facility pharmacies ~~that are not open 24 hours a day, seven days a week,~~ may contract for the provision of remote medication order processing services. ~~services when no pharmacist is present.~~

(b) Definitions of terms in this Rule:

(1) "Remote medication order processing services" consists of the following:

- (A) receiving, interpreting, or clarifying medication orders;
- (B) entering data and transferring medication order information;
- (C) performing drug regimen review;
- (D) interpreting clinical data;
- (E) performing therapeutic interventions; and
- (F) providing drug information concerning medication orders or drugs.

(2) "Remote medication order processing pharmacy" is a pharmacy permitted by the Board that provides remote medication order processing services.

(3) "Remote site" is a site located within the United States that is electronically linked to a health care facility licensed by the State of North Carolina for the purpose of providing remote medication order processing services.

(c) Outsourcing. A health care facility pharmacy may outsource medication order processing services to a remote medication order processing pharmacy provided the pharmacies have the same owner or the pharmacy has entered into a written contract or agreement with a remote medication order processing pharmacy that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations. The pharmacy providing the remote processing of medication orders must notify the Board of Pharmacy prior to providing such services.

(d) Training. A pharmacy providing remote medication order processing must ensure that all pharmacists providing such services have been trained on each pharmacy's policies and procedures relating to medication order processing. The training of each pharmacist shall be documented by the pharmacist-manager to ensure competency and to ensure that performance is at least at the same level of performance as pharmacists in the outsourcing pharmacy. The training shall include policies on drug and food allergy documentation, abbreviations, administration times, automatic stop orders, substitution, and formulary compliance. The pharmacies shall jointly develop a procedure to communicate changes in the formulary and changes in policies and procedures related to medication order processing.

(e) Access.

(1) The pharmacies must share common electronic files or have technology to allow secure access to the pharmacy's information system and to provide the remote pharmacy with access to the information necessary or required to process a medication order.

- (2) Pharmacists employed by or otherwise acting as an agent for a remote medication order processing pharmacy may provide those services from a remote site. Both the pharmacist providing those services from a remote site and the remote medication order processing pharmacy on whose behalf the pharmacist is providing such services are responsible for compliance with all statutes, rules, policies, and procedures governing the provision of remote medication order processing services.
- (f) Communication. The pharmacies must jointly define the procedures for resolving problems detected during the medication order review and communicating these problems to the prescriber and the nursing staff providing direct care.
- (g) Recordkeeping. A pharmacy using remote order entry processing services shall maintain records of all orders entered into their information system including orders entered from a remote location. The system shall have the ability to audit the activities of the individuals remotely processing medication orders.
- (h) Licensure. All remote medication order processing pharmacies must be permitted by the Board. An out-of-state remote medication order processing pharmacy must be registered with the Board as an out-of-state pharmacy. All pharmacists located in this State or employed by an out-of-state remote medication order processing pharmacy providing services in this State shall be licensed by the Board.
- (i) Policy and Procedure Manual. All remote medication order processing pharmacies shall maintain a policy and procedure manual. Each remote medication order processing pharmacy, remote site, and health care facility pharmacy shall maintain those portions of the policy and procedure manual that relate to that pharmacy's or site's operations. The manual shall:
- (1) outline the responsibilities of each of the pharmacies;
  - (2) include a list of the name, address, telephone numbers, and all permit numbers of the pharmacies involved in remote order processing; and
  - (3) include policies and procedures for:
    - (A) protecting the confidentiality and integrity of patient information;
    - (B) maintaining records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist who performed any processing;
    - (C) complying with federal and state laws and regulations;
    - (D) operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;
    - (E) annually reviewing the written policies and procedures and documenting such review; and
    - (F) annually reviewing the competencies of pharmacists providing the remote order review service.

(j) Nothing in this rule shall be construed to relieve a health care facility pharmacy of the need to provide on-site pharmacy services required for licensure as specified in the Pharmacy Practice Act and rules promulgated thereunder.

*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.*