REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1616

DEADLINE FOR RECEIPT: August 4, 2023

***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 email the reviewing attorney to inquire concerning the staff recommendation.

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

Generally, to the Rule: The Board uses the term "limited service permit" throughout the rule. Where is this term defined?

Generally, to the Rule: Change all "must" to "shall".

Page 1, Paragraph (b): This paragraph implies that the option assistant pharmacist manager must be selected at the time of application only. See "on the limited service permit application." Can this option be elected after permitting?

Page 1, Line 24-25, Paragraph (b): The Board uses the phrase "is not present at the limited service permit." Is the "permit" a location or authorizing documentation? Choose one.

Pages 1-2, Paragraph (c): See note from Page 1, Line 24-25, Paragraph (b).

Page 1, Line 34, Paragraph (c)(1): By "inspect the permit" is the Board requiring an inspection of the pharmacy which holds the permit or an inspection of the documentation granting the permit?

Page 1, Line 34, Paragraph (c)(1): By "review the operations of the permit with the persons involved in accessing them" the Board implies that "permit" means the pharmacy and not the location or the documentation, but it is unclear. Further, who are the "persons involved in accessing them"? Aren't the accessors the pharmacist-managers?

Page 2, Lines 3-4, Paragraph (c)(2): See the note for Page 1, Line 34, Paragraph (c)(1).

Page 2, Line 14, Paragraph (c)(4): Who has the authority to name the temporary pharmacist?

William W. Peaslee
Commission Counsel
Date submitted to agency: July 21, 2023

Page 2, Line 22-23, Paragraph (d): This needs to be re-written. Either I have not had enough coffee or it makes no sense.

Page 2, Lines 24-25, Paragraph (d): These lines set an ambiguous standard which is open to arbitrary or capricious enforcement.

Page 2, Lines 26-28, Paragraph (e): Explain why this paragraph is necessary.

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

William W. Peaslee
Commission Counsel
Date submitted to agency: July 21, 2023

21 NCAC 46 .1616 is amended as published in 37:20 NCR 2030-34 as follows:

21 NCAC 46 .1616 LIMITED SERVICE PERMITS

(a) The following pharmacy practice locations are eligible to apply for "limited service permits" whose operations are modified by the provisions set forth in this Rule:

(1) auxiliary medication inventories permitted and operating in health care facilities pursuant to Rule .1414(d) of this Chapter;

(2) automated dispensing or drug supply devices permitted and operating in health care facilities pursuant to Rule .1419 of this Chapter;

(3) direct to patient systems that are not located at the home pharmacy's facility pursuant to Rule .1821 of this Chapter;

~~(3)~~(4) facilities where drugs are dispensed only by nurse practitioners or physician assistants pursuant to Section .1700 of this Chapter;

~~(4)~~(5) county health departments or other governmental entities providing local health services under G.S. 130A-34 where drugs are dispensed only by registered nurses and only pursuant to G.S. 90-85.34A and Section .2400 of this Chapter;

~~(5)~~(6) county health departments or other governmental entities providing local health services under G.S. 130A-34 that engage in dispensing beyond that set out in G.S. 90-85.34A and Section .2400 of this Chapter;

~~(6)~~(7) free clinics, as defined in G.S. 90-85.44(a)(6); or

~~(7)~~(8) critical access hospitals, as defined in G.S. 131E-76.

(b) A pharmacist-manager for a limited service permit may designate one assistant pharmacist-manager but is not required to do so. The assistant pharmacist-manager shall be responsible for exercising all of the responsibilities of a pharmacist-manager when the assistant pharmacist-manager is present and the pharmacist-manager is not present at the limited service permit. If the pharmacist-manager chooses to designate an assistant pharmacist-manager, the pharmacist-manager shall notify the Board on the limited service permit application and, in writing, within 15 days of any change in the designation. Notwithstanding the pharmacist-manager's designation of an assistant pharmacist-manager, the pharmacist-manager shall be responsible for ensuring the pharmacy's compliance with all statutes, rules, and standards at all times.

(c) For limited service permits, the pharmacist-manager attendance requirements set out in Rule .2502(b) of this Chapter are modified only as set forth herein:

(1) For limited service permits described in Subparagraphs ~~(a)(1) and~~ (a)(1), (2) and (3) of this Rule, either the pharmacist-manager or the assistant pharmacist-manager must perform an in-person, on-site visit at least once per calendar quarter to inspect the permit, review the operations of the permit with the persons involved in accessing them, and ensure that the permits are operated in compliance with all applicable State and federal laws.

(2) For limited service permits described in Subparagraphs (a)(4) and (5)~~(a)(3) and (4)~~ of this Rule, either the pharmacist-manager or the assistant pharmacist-manager must perform an in-person, on-site visit at least once per week to inspect the permit, review the operations of the permit with the persons involved in dispensing, and ensure that the permits are operated in compliance with all applicable State and federal laws.

(3) For limited service permits described in Subparagraphs ~~(a)(5), (6), and~~ (a)(6), (7) and (8) of this Rule, either the pharmacist-manager or the assistant pharmacist-manager employed or otherwise engaged to supply pharmaceutical services may have a flexible schedule of attendance but shall be present for at least one-half of the hours the pharmacy is open or 20 hours a week, whichever is less. For the limited service permits described in Subparagraphs (a)(5) and (6) of this Rule, a licensed pharmacist must be present when the pharmacy is open as described in Rule .2502(e) of this Chapter. For the limited service permits described in Subparagraph (a)(7) of this Rule, the limited service permit may operate in the absence of a pharmacist only as set out in Rule .1413 of this Chapter.

(4) The limited service permit may name a temporary pharmacist-manager or assistant pharmacist-manager for a period not to exceed 90 days from the departure date of the previous pharmacist-manager or assistant pharmacist-manager. The temporary pharmacist-manager or assistant pharmacist-manager must accept the responsibilities of that position and must be present as set forth in this Rule. A limited service permit may not operate for a period of more than 30 days without a pharmacist employed or otherwise engaged as a permanent or temporary pharmacist-manager who has signed the permit for that pharmacy.

(d) A person may serve as the pharmacist-manager or the assistant pharmacist-manager for multiple limited service permits, and may serve as the pharmacist-manager or assistant pharmacist-manager for limited service permits in addition to serving as the pharmacist-manager for a maximum of one permit other than a limited service permit. A person may serve multiple limited permits only if that person is able to fulfill all of that person's duties under State and federal law.

(e) Other than as set forth in this Rule, limited service permits and their personnel must follow all requirements of State and federal law. This Rule does not replace or modify the requirements that the pharmacist-manager provide oversight and supervision as provided elsewhere in this Chapter.

History Note: *Authority G.S. 90-18.1(c); 90-18.2; 90-85.6; 90-85.21; 90-85.32; 90-85.33; 90-85.34;*
Eff. November 1, 2021; ~~2021.~~
Amended Eff. September 1, 2023.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1821

DEADLINE FOR RECEIPT: August 4, 2023

***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 email the reviewing attorney to inquire concerning the staff recommendation.

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

Generally, to the Rule: Change "must" to "shall".

Page 1, Line 16, Paragraph (b)(1)(D): Neither "licensee" nor "permittee" is defined. Either add a definition or a reference such as "pursuant to (add in license statute or rule."

Page 1, Line 2, Paragraph (b)(3): What does the Board mean by "completed"?

Page 1, Line 24, Paragraph (b)(4): Should there be a comma after "labeling"?

Page 1, Line 29, Paragraph (c)(1): "Permitted" pursuant to what? Cite rule or statute by which the pharmacy is permitted.

Page 1, Line 30-31, Paragraph (c)(1): What is a "limited service permit"? Cite rule or statute by which the limited service permit is issued.

Page 1, Line 32, Paragraph (c)(2): It is unclear whether the Board wants notification for each use, or only upon the first use. Further, the Board does not appear to have adopted an agency contact rule, so it is unclear where and how the notifications are to be sent. See the RRC style guide Chapter 4.

Page 1, Line 33, Paragraph (c)(2): By "location" does the Board mean address? If a pharmacy replied "down east" would that be sufficient?

Page 1, Line 336-37, Paragraph (c)(2): It is unclear what the even is that triggers the required notification. Is it within 10 days from when the determination has been made to discontinue use? When is "discontinuing use"?

William W. Peaslee
Commission Counsel
Date submitted to agency: July 21, 2023

Page 2, Line 1, Paragraph (c)(3): Consider a re-write. This appears to be unnecessarily wordy. It appears that the Board is simply requiring exclusive use of any DTP employed by the home pharmacy.

Page 2, Line 3, Paragraph (c)(4): "in order to facilitate supervision of the DTP system" is unnecessary verbiage.

Page 2, Lines 5-6, Paragraph (c)(5): The home pharmacy must own and control the DTP system but not have exclusive use? What does this subparagraph do that isn't covered by Paragraph (3)? Further, the subparagraph is permissive in nature. Consider re-writing. Consider "Any DTP located within a prescriber's office shall be under the exclusive use and control of the home pharmacy."

Page 2, Lines 5-6, Paragraph (c)(5): Is there any circumstance under which the home pharmacy is not responsible for compliance with the law regarding the DTP system or is it only under this circumstance?

Page 2, Line 9, Paragraph (c)(6): What does the Board mean by "secured"? For example, if the locker needs to be bolted to the floor, the Board needs to state that lockers shall be bolted to the floor.

Page 2, Lines 9-13, Paragraph (c)(6): This subparagraph is unnecessarily wordy. Consider a re-write. Define "continuous supervision". The rules tells the pharmacist what they do not have to do but fails to tell the pharmacist that which is required.

Page 2, Line 13, Paragraph (c)(6): What does the Board mean by "electronically supervises"? Pursuant to Subparagraph (c)(8)?

Page 2, Lines 18, Paragraph (c)(8): Is the video surveillance continuous? 24-7?

Page 2, Line 19, Paragraph (c)(8): Are recordings required? The rule is ambiguous on this point. The rules simply states that any recording be maintained for 90 days but it does not require recordings.

Pages 2, Lines 20-36 and Page 1-7, Paragraph (c),(9): Do the polices and procedures need to be approved by anyone other than the home pharmacy? If so, by who and by what procedure? Does the Board require these to be kept on file or submitted to the Board? If so, by what time, manner, and place?

Pages 2, Lines 20-36 and Page 1-7, Paragraph (c),(9): How will this be enforced?

Page 3, Line 7, Paragraph (c),(9): "If needed" is ambiguous. Define or delete.

Page 3, Line 14, Paragraph (c),(11): Consider re-wording to avoid the permissive. Use "shall".

Page 3, Line 14, Paragraph (c),(11): As written, the patient could not remove drugs, devices, or medical equipment from the DTP. This seems to defeat its purpose.

Page 3, Line 19, Paragraph (c),(12): Consider re-wording to avoid the permissive. Use "shall".

Page 3, Line 20-21, Paragraph (c),(13): This appears to be redundant as a pharmacist must be licensed to be a pharmacist. See G.S. 90-85.3(p)

Page 3, Line 23, Paragraph (c),(14): Where is "drug utilization review" defined?

Page 3, Line 28, Paragraph (c),(16): To what "required records" is the Board referring? Either list them or cite a statute or rule.

Page 3, Line 30, Paragraph (c),(16): To what "automated data processing system" is the Board referring? Is it required? 21 NCAC 46 .2304 does not appear to require an automated data processing system. Is it the Board's intention to require one when kiosks are employed?

Page 3, Line 32, Paragraph (c),(16): Consider whether "reflect" is the best word.

Page 3, Lines 35-36, Page 4, Lines 1-2, Paragraph (c),(17): The first and second lines of Subparagraph 17 are in conflict. How does a DPT system "identify" a person?

Page 4, Line 3, Paragraph (c),(18): How does a "system" "offer" to counsel a patient?

Page 4, Line 19, Paragraph (c),(19): What is the "quality assurance program"? 21 NCAC 46 .3406 does not appear to have been adopted. Does the Board mean "…pursuant to 21 NCAC 46 .3402" which applies only to automated medication systems?

Page 4, Line 34, Paragraph (d),(3): Change "may" to "shall".

Page 4, Line 36, Paragraph (d),(3): Does the Board mean the rules of Chapter 46 of the North Carolina Administrative Code?

Page 5, Line 3, Paragraph (d),(5): Change "may" to "shall". Where is "compounded medications" defined?

Page 4, Line 6, Paragraph (e): Change "may" to "shall".

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

21 NCAC 46 .1821 is adopted as proposed in 37:20 NCR 2030-34 as follows:

21 NCAC 46 .1821 DIRECT-TO-PATIENT DELIVERY SYSTEMS

(a) This Rule sets out the requirements under which pharmacies may utilize "direct-to-patient" or ("DTP") delivery systems for dispensing in the State of North Carolina.

(b) Definitions.

(1) "Direct to patient system" or "DTP system" means any delivery system through which a pharmacy dispenses drugs, devices or medical equipment to a patient through any means other than:

(A) in-person dispensing to a patient by pharmacy personnel inside a pharmacy,

(B) in-person dispensing by delivery to a patient's residence or to a health care provider treating that patient,

(C) shipping through common carrier to a patient or to a health care provider treating that patient, or

(D) the use of an automated dispensing device by a health care facility pharmacy that is governed by Rule .1419 of this Chapter.

Except as provided in this Rule or one of the exceptions set out above, no licensee or permittee shall participate in any arrangement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any other place. The only DTP systems allowed are "lockers" and "kiosks" as defined herein.

(2) The "home pharmacy" means the pharmacy responsible for dispensing drugs, devices or medical equipment through a DTP system.

(3) A "locker" means a secure container in which pharmacy personnel place completed and labeled patient-specific drugs, devices, or medical equipment to be picked up by the patient.

(4) A "kiosk" means an automated system that is capable of filling, labeling and dispensing drugs, devices, or medical equipment to be dispensed to a patient.

(c) Any DTP system located within the State of North Carolina (whether a locker or a kiosk) must meet the following requirements:

(1) Before any drugs, devices, or medical equipment may be dispensed from a DTP system, the home pharmacy must be permitted by the Board. In addition, before any drugs, devices, or medical equipment may be dispensed from the DTP system, the DTP system must hold a limited service permit if it is not located at the home pharmacy's permitted facility.

(2) The home pharmacy must notify the Board, in writing, prior to using any DTP system, including the location of the DTP system and the licensed pharmacist(s) responsible for the DTP system. The home pharmacy must notify the Board prior to moving the DTP system and must secure a new limited service permit, if one is required by Subparagraph (c)(1) of this Rule, before operating the DTP system in the new location. The home pharmacy must notify the Board within 10 days after discontinuing the use of any DTP system.

(3) The home pharmacy must own or otherwise have the legal right to sole use of the DTP system.

(4) Any DTP system must be 60 miles or fewer from the home pharmacy (via the shortest surface street route) in order to facilitate supervision of the DTP system.

(5) A DTP system may be placed in the office of a prescriber only if the DTP system is under the ownership and control of the home pharmacy, which is responsible for compliance with all laws regarding the DTP system. The prescriber must offer patients a choice of pharmacy, and neither the home pharmacy nor the prescriber may compensate the other for the placement of the DTP system or for any prescriptions filled by the DTP system.

(6) The DTP system must be secured to prohibit access by unauthorized personnel and to maintain confidentiality of patient information. The DTP system must be under the continuous supervision of a pharmacist employed by the home pharmacy. To qualify as continuous supervision, the pharmacist is not required to be physically present at the site of the DTP system if the pharmacist electronically supervises the DTP system.

(7) The DTP system must display the home pharmacy's name, address, phone number, North Carolina permit number, and the name of the home pharmacy's pharmacist-manager, as well as (where applicable) the limited service permit number for the DTP system and the name of the limited service permit's pharmacist-manager and assistant pharmacist-manager, if any.

(8) The home pharmacy must ensure that there is video surveillance of the DTP system and any persons using or accessing the DTP system. It must maintain any recordings for a minimum of 90 days.

(9) The home pharmacy shall develop, maintain, and follow a manual of policies and procedures that includes policies and procedures for:

(A) Maintaining the security of the DTP system and the drugs, devices, and medical equipment within the DTP system.

(B) Determining and applying criteria regarding which drugs, devices, and medical equipment are appropriate for placement in the DTP system and which patients are eligible to use the DTP system.

(C) Maintaining any drugs, devices, and medical equipment at temperatures, humidities and other environmental conditions to ensure that they do not become adulterated under G.S. 106-133 and to ensure that they are transported and stored in accordance with manufacturer's specifications, if any, for those items.

(D) Removing outdated drugs, devices, and medical equipment from the DTP system as set forth in Subparagraph (c)(11) of this Rule on a regular basis so that patients do not receive drugs, devices, and medical equipment with a beyond use date during the period when the patient is to use the item.

(E) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the DTP system.

(F) Orienting participating patients on use of the DTP system; notifying patients when expected drugs, devices, or medical equipment are not available in the DTP system or when the DTP system is not functioning and notifying them of alternate methods for having those prescriptions filled; and ensuring that patient use of the DTP system does not interfere with the delivery of drugs, devices, and medical equipment to patients.

(G) Inspecting the DTP system during each required inspection.

This written manual of policies and procedures shall be reviewed and updated, if needed, annually.

(10) The home pharmacy shall comply with any federal and state controlled substance laws and rules, including but not limited to registrations that may be required for any DTP systems, before any controlled substances are dispensed from any DTP systems. The home pharmacy must comply with G.S. 90-106.1 in dispensing any drugs covered by that statute from a DTP system, and must visually confirm that the person seeking the dispensation is the same as the person on the photographic identification provided.

(11) Drugs, devices, and medical equipment may be stocked in, or removed from, a DTP system in the State of North Carolina only by pharmacy personnel who are licensed with this Board as pharmacists or registered with this Board as technicians or pharmacy interns. The home pharmacy must maintain records of any access to the DTP system by pharmacy personnel stocking or otherwise accessing the DTP system.

(12) The home pharmacy may use DTP system only with prior approval of the patient.

(13) The dispensing pharmacist on any drugs, devices, or medical equipment dispensed from a DTP system in the State of North Carolina must be licensed with this Board.

(14) Before a prescription is dispensed from the DTP system, the dispensing pharmacist at the home pharmacy must verify each prescription and must conduct a drug utilization review and otherwise assure that the drug, device, or medical equipment may safely be dispensed to the patient.

(15) The labels of any drugs, devices, and medical equipment dispensed from a DTP system must be labeled for the individual patient and contain all information required by law, including but not limited to having the dispensing pharmacist identified on the label.

(16) The home pharmacy must create and maintain all required records for any drugs, devices, and medical equipment dispensed in a DTP system. Any kiosk must be connected to the home pharmacy's automated data processing system, and any drugs, devices, or medical equipment dispensed from any locker must be recorded in the home pharmacy's recordkeeping system. The records must reflect that the drugs, devices, and medical equipment were dispensed by the DTP system, and the recordkeeping system must be capable of producing a record of all drugs, devices, and medical equipment dispensed from the DTP system.

(17) The DTP system must have a means to identify each patient and release only that patient's prescription drugs, devices, or medical equipment to the patient. In the event that the DTP system

releases a patient's drugs to the agent for a patient, the DTP system must have a means to ensure that the agent is authorized to receive drugs, devices, or medical equipment for that patient.

(18) The DTP system must offer to counsel a patient as required by Rule .2504 of this Chapter and must provide the ability for the patient to have an immediate real-time consultation with a pharmacist licensed by this Board and employed by the home pharmacy who has access to all of the home pharmacy's information related to the patient. The communication link shall protect the confidentiality of the patient's information. The home pharmacy must check the communication link at least daily and the DTP system must be closed if the link malfunctions or if a licensed pharmacist is not available from the home pharmacy for counseling, unless a licensed pharmacist is physically present at the DTP system. A pharmacist who is responsible for counseling may not provide that service for more than three sites simultaneously. In the event that the DTP system is placed in the same physical space as the dispensing area of the home pharmacy, this provision may be satisfied during the time that the pharmacy is open by informing the patient how to receive counseling from a pharmacist in the home pharmacy. If the dispensing pharmacist has determined that the patient should receive counseling before the prescription is dispensed, the DTP system must provide the ability for the pharmacist to force counseling before the DTP system dispenses the drug, device, or medical equipment.

(19) The home pharmacy shall record and review any incident involving a complaint, delivery error, or omission regarding a DTP as part of the home pharmacy's quality assurance program.

(20) Drugs, devices, or medical equipment that are not picked up by a patient may be returned to stock under the same conditions as if the item had been maintained in the pharmacy, as long as the requirements of this Rule for operating the DTP system have been followed.

(d) With respect to drugs, devices, or medical equipment dispensed through a kiosk, the following additional requirements shall be met:

(1) The dispensing pharmacist shall electronically compare via video link the stock bottle, drug dispensed, the strength, and the beyond-use date. The dispensing pharmacist must verify the entire label for accuracy on the video link.

(2) The kiosk shall utilize a barcode system that prints the barcode of the stock bottle or other packaging on the label of the dispensed drug, device, or medical equipment. If the stock bottle or other packaging does not have a barcode, the home pharmacy shall create one. Pharmacy personnel shall scan both the stock bottle or other packaging and the label of the dispensed drug, device, or medical equipment to verify that the item dispensed is the same as the one in the stock bottle or other packaging for each prescription dispensed.

(3) Drugs, devices, or medical equipment dispensed by the kiosk may be packaged only by a licensed manufacturer or repackager, or prepackaged by the home pharmacy in compliance with the Pharmacy Practice Act and its rules.

(4) The home pharmacy shall keep a perpetual inventory of controlled substances that are received and dispensed from each kiosk.

(5) The home pharmacy may not dispense compounded medications through a kiosk.

(6) The kiosk shall not accept returns of drugs, devices and medical equipment from patients.

(e) This Rule does not alter the method by which patients or providers may transmit prescriptions to the home pharmacy. Prescriptions may not be collected by the home pharmacy through the DTP system.

History Note: *Authority G.S. 90-85.6; 90-85.15A; 90-85.21; 90-85.32;*
Eff. September 1, 2023.