Burgos, Alexander N

Subject: FW: [External] RE: Board of Pharmacy-August 2026 RRC Meeting-Request for Technical Changes

Attachments: 21 NCAC 46 .1821 full version 4929-1433-4387 v.2.docx; 21 NCAC 46 .1420 4920-3144-5875 v.2.docx; 21 NCAC 46 .1616 full version 4936-7002-3104 v.1.docx; 21 NCAC 46 .1822 4933-8468-6259 v.1.docx; 21 NCAC 46 .2516 4930-7280-0691 v.1.docx

From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Monday, July 27, 2026 11:31 AM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Rules, Oah <oah.rules@oah.nc.gov>
Subject: RE: [External] RE: Board of Pharmacy-August 2026 RRC Meeting-Request for Technical Changes

Rules are attached. At least I hope they are. I left my glasses at home, so all I know if that there are definitely five blobs attached to this e-mail.

By the time we get to readoption, I will have scrubbed down the rest of our rules to RRC 2026 standards (or 2027 or 2028 or 2029 or whenever we're up).

I'll probably be there in person at both July and August.

Clint Pinyan

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21 NCAC 46 .1420 is adopted with changes as published in 40:20 ~~40:22~~ NCR 1611 as follows:

21 NCAC 46 .1420 STANDARDIZED ORDERS

(a) This Rule applies if a Health Care Facility has developed a set of standardized orders for its patients. As used in this Rule, standardized orders are pre-established written protocols that allow authorized practitioners at the Health Care Facility to administer medications to a patient who meets defined criteria.

(b) A pharmacist-manager of a Health Care Facility Pharmacy may establish which of those standardized orders are safe and effective for all patients presenting a set of predetermined criteria established by the pharmacist-manager. Those orders must be safe and effective for all patients presenting those criteria, regardless of any drugs, supplements, ~~supplements~~ or other substances that might have been consumed by any patient. Any standardized orders so designated by the pharmacist-manager may be dispensed by the pharmacy to a Health Care Facility patient without any patient-specific drug regimen review being performed by the pharmacist.

(c) The pharmacist-manager must maintain policies and procedures sufficient to identify the standardized orders and the criteria for issuing those standardized orders, as well as the process by which those orders are to be dispensed. The pharmacist-manager must also keep records of all dispensing pursuant to this Rule, ~~rule,~~ including the authorized practitioner's determination that the standardized order was appropriate and documentation that any criteria have been met.

(d) This Rule, ~~rule,~~ does not apply to outpatient pharmacies or to drugs dispensed pursuant to 21 NCAC 46 .1415.

History Note: *Authority G.S. 90-18.1; 90-18.2; 90-85.6; 90-85.21; ~~90-85.21;~~ 90-85.26; 90-85.33; 90-85.34; Eff. September 1, 2026.*

21 NCAC 46 .1616 is amended with changes as published in 40:20 NCR 1613 as follows:

21 NCAC 46 .1616 LIMITED SERVICE PERMITS

(a) The following pharmacy practice locations are eligible to apply for "limited service permits," which are pharmacy locations whose operations are modified by the provisions set forth in Paragraphs (b), (c), and (d) of 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;

(4) alternate delivery sites pursuant to Rule .1822 of this Chapter;

~~(4)~~(5) facilities where drugs are dispensed only by nurse practitioners or physician assistants pursuant to Section .1700 of this Chapter;

~~(5)~~(6) 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;

~~(6)~~(7) 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;

~~(7)~~(8) free clinics, as defined in G.S. 90-85.44(a)(6); or

~~(8)~~(9) 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 location holding 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, if an assistant pharmacist-manager is desired at that time.~~ If a designation is made or changed after the limited service permit ~~application~~ is issued, ~~filed~~, the pharmacist-manager shall notify the Board, in writing, within 15 days of ~~any~~ a 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 follows: ~~set forth herein:~~

(1) For limited service permits described in Subparagraphs (a)(1), (2), (3), and (4) ~~(2) and (3)~~ of this Rule, either the pharmacist-manager or the assistant pharmacist-manager shall perform an in-person, on-site visit ~~at least~~ once per calendar quarter to inspect the location holding the permit, review the

operations of the location holding the permit with the persons involved in accessing them as permitted by the rules referenced in Subparagraphs (a)(1), (2), (3), and (4) ~~and (3)~~ of this Rule, and ensure that the location holding the permit is operated in compliance with all applicable State and federal laws.

(2) For limited service permits described in Subparagraphs (a)(5) and (6) ~~(a)(4) and (5)~~ of this Rule, either the pharmacist-manager or the assistant pharmacist-manager shall perform an in-person, on-site visit ~~at least~~ once per week to inspect the location holding the permit, review the operations of the location holding the permit with the persons involved in dispensing, and ensure that the location holding the permit is operated in compliance with all applicable State and federal laws.

(3) For limited service permits described in Subparagraphs (a)(7), (8), and (9) ~~(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)(7) and (8) ~~(a)(5) and (6)~~ of this Rule, a licensed pharmacist shall 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)(9) ~~(a)(7)~~ of this Rule, the location holding 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 holder 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 shall accept the responsibilities of that position and shall be present as set forth in this Rule. A location holding 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~~ pharmacist-manager 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 do so while also serving as the pharmacist-manager for a maximum of one permit other than a limited service permit. A person serving multiple limited service permit locations shall ~~must~~ fulfill all of that person's duties under State and federal law as to each location.

(e) Except as expressly set forth in this Rule, the pharmacist-manager shall ~~must~~ 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;
Amended Eff. September 1, ~~2023.~~ 2023; September 1, 2026.

21 NCAC 46 .1821 is amended with changes as published in 40:20 NCR 1613 as follows:

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

(a) This Rule sets out the requirements ~~under which~~ for pharmacies to employ ~~may utilize~~ "direct-to-patient" or ("DTP") delivery systems for delivery ~~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 delivers ~~dispenses~~ drugs, devices, ~~devices~~ or medical equipment to a patient through any means other than:

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

(B) in-person ~~dispensing by~~ delivery to a patient's ~~residence or~~ residence, to a health care provider treating that patient, or at an alternate delivery site governed by Rule .1822 of this Section,

(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 in Parts (A)-(D) of this Subparagraph, no person holding any license or permit from the Board shall participate in an ~~any~~ arrangement ~~whereby prescriptions may~~ for prescription orders or prescription drugs, devices, or medical equipment to 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~~ delivering prescription drugs, devices, ~~devices~~ or medical equipment through a DTP system.

(3) A "locker" means a secure container in which pharmacy personnel place 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~~ delivering drugs, devices, or medical equipment ~~to be dispensed~~ to a patient.

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

(1) Before ~~any~~ prescription drugs, devices, or medical equipment may be ~~dispensed~~ delivered from a DTP system, the home pharmacy shall have been issued a pharmacy permit by the Board pursuant to G.S. 90-85.21 or 90-85.21A. In addition, before ~~any~~ prescription drugs, devices, or medical equipment may be ~~dispensed~~ delivered from the DTP system, the DTP system shall hold a limited service permit under Rule .1616 of this Section if it is not located at the home pharmacy's permitted facility.

(2) The home pharmacy shall notify the Board, in writing, through the home pharmacy's online permit portal, prior to beginning to use ~~any~~ a DTP system, including the address and geographical coordinates of the DTP system and the licensed pharmacist(s) responsible for the DTP system. The home pharmacy shall notify the Board prior to moving the DTP system and shall 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 shall notify the Board within 10 days after discontinuing patient use of ~~any~~ a DTP system.

(3) A DTP system shall be used exclusively by the home pharmacy.

(4) ~~Any~~ A DTP system shall be 60 miles or fewer from the home pharmacy (via the shortest surface street route).

(5) A DTP system may be placed in the office of a prescriber only if the DTP system is under the control of the home pharmacy, which is responsible for compliance with all laws, rules, and regulations ~~laws~~ regarding the DTP system. The home pharmacy shall maintain the DTP system in the prescriber's office only if the prescriber offers patients a choice of pharmacy. The home pharmacy shall not give compensation to or receive compensation from the prescriber for the placement of the DTP system or for any prescription orders ~~prescriptions~~ filled by the DTP system.

(6) The home pharmacy shall prohibit access to the DTP system and its contents by unauthorized personnel and maintain confidentiality of patient information. The DTP system shall be under the continuous supervision of a pharmacist employed by the home pharmacy, which may be satisfied by real-time remote supervision of the pharmacy through video and audio connections.

(7) The DTP system shall 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 shall ensure that there is continuous, recorded video surveillance of the DTP system and any persons using or accessing the DTP system. It shall 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~~ maintaining the security of the DTP system and the drugs, devices, and medical equipment within the DTP system.

(B) ~~Determining~~ 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~~ 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~~ 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~~ describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the DTP system.

(F) ~~Orienting~~ orienting participating patients on use of the DTP system; notifying patients when expected prescription 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 prescription drugs, devices, or medical equipment delivered; ~~prescriptions filled~~; and ensuring that patient use of the DTP system does not interfere with the delivery of prescription drugs, devices, and medical equipment to patients.

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

This written manual of policies and procedures shall be reviewed and updated 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~~ a DTP system, ~~systems,~~ before ~~any~~ delivering controlled substances ~~are dispensed~~ from ~~any~~ the DTP system. ~~systems~~. The home pharmacy shall comply with G.S. 90-106.1 in ~~dispensing any~~ delivering prescription drugs covered by that statute from a DTP system, and shall visually confirm that the person seeking the ~~dispensation~~ delivery is the same as the person on the photographic identification provided.

(11) Only pharmacy personnel who are licensed with this Board as pharmacists or registered with this Board as technicians or pharmacy interns shall ~~may~~ stock drugs, devices, and medical equipment in, or remove drugs, devices, and medical equipment from, the inventory of a DTP system. The home pharmacy shall maintain records of ~~any~~ access to the DTP system by pharmacy personnel stocking or otherwise accessing the DTP system.

(12) Before a home pharmacy ~~dispenses~~ delivers prescription drugs, devices, ~~devices~~ and medical equipment to a patient through a DTP system, the home pharmacy shall secure the affirmative consent of the patient to use the DTP system.

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

(14) Before delivering a prescription drug, device or medical equipment ~~is dispensed~~ from the DTP system, the dispensing pharmacist at the home pharmacy shall verify ~~each~~ the prescription order and shall 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~~ Prescription drugs, devices, and medical equipment ~~dispensed~~ delivered from a DTP system shall 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 shall create and maintain records of dispensing for ~~any~~ prescription drugs, devices, and medical equipment delivered by ~~dispensed in~~ a DTP system in compliance with State and federal law. ~~Any~~ A kiosk shall be connected to the home pharmacy's automated data processing system, and ~~any~~ prescription drugs, devices, or medical equipment delivered ~~dispensed~~ from ~~any~~ a locker shall be recorded in the home pharmacy's recordkeeping system. The recordkeeping system shall be capable of producing a record of ~~all~~ prescription drugs, devices, and medical equipment dispensed from the DTP system.

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

(18) The DTP system shall convey the home pharmacy's offer to counsel a patient as required by Rule .2504 of this Chapter and shall 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 shall check the communication link at least daily and the DTP system shall 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~~ If the DTP system is placed in the same physical space as the dispensing area of the home pharmacy, this provision may be satisfied when ~~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 drug, device, or medical equipment is delivered, ~~dispensed,~~ the DTP system shall provide the ability for the pharmacist to force counseling before the DTP system delivers ~~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 system 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 prescription 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, prescription drug dispensed, the strength, and the beyond-use date. The dispensing pharmacist shall verify the entire label for accuracy on the video link.

(2) The kiosk shall use ~~utilize~~ a barcode system that prints the barcode of the stock bottle or other packaging on the label of the dispensed prescription 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 prescription 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 drug, device, or medical equipment dispensed.

(3) ~~Drugs,~~ Prescription drugs, devices, or medical equipment dispensed by the kiosk shall be packaged only by a licensed manufacturer or repackager, or prepackaged by the home pharmacy in compliance with the Pharmacy Practice Act, Article 4A of Chapter 90 of the General Statutes, ~~Act~~ and this Chapter.

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

(5) The home pharmacy shall 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 shall transmit prescription orders ~~prescriptions~~ to the home pharmacy. ~~Prescriptions~~ Prescription orders 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.~~ 2023;
Amended Eff. September 1, 2026.

1

21 NCAC 46 .1822 is adopted with changes as published in 40:20 NCR 1613 as follows:

21 NCAC 46 .1822 ALTERNATE DELIVERY SITES

(a) This Rule sets out the requirements under which pharmacies may utilize alternate delivery sites for delivery of drugs, devices, or medical equipment or for receipt of prescriptions in the State of North Carolina.

(b) Before any drugs, devices, or medical equipment may be delivered at an alternate delivery site, the pharmacy shall have been issued a pharmacy permit by the Board pursuant to G.S. 90-85.21 or G.S. 90-85.21A, and the alternate delivery site shall have been issued a limited service permit under Rule .1616 of this Chapter. The limited service permit shall be granted only if, and so long as, compliance with all requirements ~~for~~ of this Rule can be ~~reasonably~~ assured.

(c) Location.

(1) An alternate delivery site shall be within the State of North Carolina and 60 miles or fewer from the pharmacy (via the shortest surface street route).

(2) An alternate delivery site may not be located in the same building or on the same property as the pharmacy or any pharmacy under common ownership.

(3) An alternate delivery site may be placed in the office of a prescriber only if the alternate delivery site is under the control of the pharmacy, which is responsible for compliance with all laws, rules, and regulations ~~laws~~ regarding the alternate delivery site, and only if the alternate delivery site is staffed with pharmacy personnel, as set forth herein. The pharmacy shall maintain the alternate delivery site in the prescriber's office only if the prescriber offers patients a choice of pharmacy. The pharmacy shall not give compensation to or receive compensation from the prescriber for the placement of the alternate delivery site or for any prescriptions delivered at the alternate delivery site.

(4) An alternate delivery site may not be located on residential property.

(5) The pharmacy shall notify the Board within 10 days after discontinuing patient use of any alternate delivery site.

(d) Staffing and Management.

(1) When the alternate delivery site is open, it must be continuously staffed by a pharmacist or certified pharmacy technician who is an employee of the pharmacy.

(2) The alternate delivery site shall be used exclusively by the one pharmacy whose pharmacist-manager is responsible for the alternate delivery site’s operation.

(3) The dispensing pharmacist for any drugs, devices, or medical equipment delivered to an alternate delivery site shall be employed by the pharmacy and licensed with this Board.

(4) At all times that the alternate delivery site is open, a pharmacist employed by the pharmacy must be available for counseling, as set forth in this Rule, and for consultation with the staff of the alternate delivery site.

(5) All staff at the alternate delivery site shall wear identification badges as set forth in G.S. 90-640.

(e) Services Limited to Prescription Pickup and Drop Off for the Pharmacy.

(1) At the alternate delivery site, a pharmacist or a certified technician employed by the pharmacy may personally deliver any drug, device, or medical equipment to the patient or the patient's agent, after that drug, device, ~~device~~ or medical equipment has been previously dispensed by the pharmacy. All physical steps in the dispensing process (other than delivery to the patient) must occur at the pharmacy, ~~including~~ including, but not limited to, ~~to~~ filling and patient-specific labeling. No drugs, devices, ~~devices~~ or medical equipment may be maintained at the alternate delivery site, other than completed patient-specific labeled and previously dispensed drugs, devices, or medical equipment that have been transported from the pharmacy to the alternate delivery site to be delivered.

(2) At the alternate delivery site, a pharmacist or certified pharmacy technician who is an employee of the pharmacy may personally accept a written prescription from the patient or the patient's agent, so long as the prescription is then transmitted to the pharmacy so that all physical steps in the dispensing process may take place in the pharmacy. Patients or their agents may not leave prescriptions at the alternate delivery site, other than by personally delivering them to the pharmacist or certified pharmacy technician.

(f) Requirements for Use of Alternate Delivery Site.

(1) Before a pharmacy delivers drugs, devices, or medical equipment to a patient at an alternate delivery site, the pharmacy shall secure the affirmative consent of the patient to use the alternate delivery site. The pharmacy shall not require patients to pick up their prescriptions from an alternate delivery site, rather than at the pharmacy or through delivery mechanisms otherwise available at the pharmacy.

(2) To ensure appropriate coordination of patient care, the pharmacy shall notify the alternate delivery site of the anticipated arrival time of the transportation of the drug, device, or medical equipment to the alternate delivery site, the name of the patient for whom the drug, device or medical equipment was dispensed, and any special storage requirements.

(3) The hours of the alternate delivery site shall be reported to the Board, and the alternate delivery site shall be open during the hours that have been reported to the Board. Emergency closure of the alternate delivery site shall require the pharmacist-manager of the pharmacy to follow the procedures in Rule .2516 of this Chapter.

(4) The pharmacist or certified pharmacy technician at the alternate delivery site shall convey the pharmacy's offer to counsel a patient as required by Rule .2504 of this Chapter and shall provide the ability for the patient to have an immediate real-time consultation with a pharmacist licensed by this Board and employed by the pharmacy who has access to all of the pharmacy's information related to the patient. The communication link shall protect the confidentiality of the patient's information. A pharmacist who is responsible for counseling may not provide that service for more than three limited service permits simultaneously. A certified pharmacy technician staffing an alternate delivery site may not perform counseling of any sort.

(5) The alternate delivery site shall have real-time access to the pharmacy's information system and shall comply with all recordkeeping requirements for drugs, devices, and medical equipment delivered at the site.

(6) The pharmacist or certified pharmacy technician delivering drugs, devices, or medical equipment has the authority conferred by Rule .1817 of this Section with respect to proof of identification.

(7) Controlled substances may be delivered to an alternate delivery site only if permitted by state and federal controlled substances laws. If permitted, both the pharmacy and alternate delivery site shall comply with any federal and state controlled substance laws and rules, including but not limited to receiving any registrations that may be required for any alternate delivery site, before any controlled substances are delivered to any alternate delivery site. The pharmacist or certified pharmacy technician delivering drugs at the alternate delivery site must comply with G.S. 90-106.1 in delivering any drugs covered by that statute from an alternate delivery site and shall visually confirm that the person seeking the delivery is the same as the person on the photographic identification provided.

(8) The pharmacy shall retrieve any drugs, devices, or medical equipment not delivered to the patient within [~~one week~~] twenty-one days of being delivered to the alternate delivery site.

(9) 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 alternate delivery site have been followed and the drugs, devices, ~~devices~~ or medical equipment can be returned to stock consistent with the public health, safety, ~~safety~~ and welfare.

(g) Safety and Security.

(1) The pharmacist-manager shall not deliver drugs, devices, or medical equipment to or at the alternate delivery site unless the pharmacist-manager is satisfied that drugs, devices, ~~devices~~ or medical equipment may be as safely and effectively stored and delivered at the alternate delivery site as in the pharmacy itself.

(2) Drugs, devices, or medical equipment delivered to the alternate delivery site shall be stored in a lockable room or lockable cabinet or other irremovable device. The lockable storage must remain locked at all times except when a drug, device, or medical equipment is being actively removed from storage. If prescriptions require special storage, such as refrigeration, those storage devices must be similarly secured. Access shall be restricted to the pharmacist or certified pharmacy technician who is personally delivering the prescriptions.

(3) The pharmacy shall ensure the transportation and storage of 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.

(4) The pharmacy shall ensure that there is continuous, recorded video surveillance of the storage and delivery of drugs, devices, and medical equipment at the alternate delivery site. It shall maintain any recordings for a minimum of 90 days.

(h) Policies and Procedures: The pharmacy must develop and implement written policies and procedures to ensure that the requirements of the Pharmacy Practice Act, Article 4A of Chapter 90 of the General Statutes, ~~Act~~ and its rules and regulations are complied with at the alternate delivery site. These shall include:

(1) Tracking and maintaining the security of delivery of drugs, devices, and medical equipment between the pharmacy and the alternate delivery site.

(2) Maintaining the security of the alternate delivery site and the drugs, devices, and medical equipment at the alternate delivery site.

(3) Transporting and maintaining any drugs, devices, and medical equipment in the appropriate environmental conditions.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the transportation, storage, and delivery procedures for the alternate delivery site.

(5) Offering to counsel and providing counseling at the alternate delivery site, including keeping records of offers to counsel.

(6) Orienting participating patients on use of the alternate delivery site; notifying patients when their dispensed prescription will be available at the alternate delivery site; and ensuring that use of the alternate delivery site does not interfere with the delivery of drugs, devices, and medical equipment to patients.

(7) Keeping records of the delivery of drugs, devices, and medical equipment to patients at the alternative delivery site.

(8) Returning to the pharmacy any drugs, devices, or medical equipment that are not delivered to the patient.

(9) Assuring confidentiality of patient information.

(10) Inspecting the alternate delivery site during each required inspection.

This written manual of policies and procedures shall be maintained both in the pharmacy and at the alternate delivery site. The manual shall be reviewed and updated annually.

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

(j) This Rule does not prohibit the use of other delivery methods set forth in Rule .1821(b)(1) of this Section, which are exclusive.

History Note: *Authority G.S. 90-85.6; 90-85.15A; 90-85-21; 90-85.21A; 90-85.26;*
Eff. September 1, 2026.

21 NCAC 46 .2516 is amended with changes as published in 40:20 NCR 1613 as follows:

21 NCAC 46 .2516 EMERGENCY CLOSURE

(a) The pharmacist-manager of a pharmacy has the responsibility and authority to cease some or all of the pharmacy operations when doing so is necessary to fill the pharmacist-manager's responsibility (a) for the safe, lawful, ~~lawful~~ and secure receipt of prescription orders and delivery of prescription drugs under Rule .1804(a) of this Chapter, or (b) to ensure that adequate qualified personnel are in place to properly render pharmaceutical service in compliance with state and federal law under Rule .1601(a)(1) of this Chapter.

(b) In the event that a pharmacist-manager anticipates that a pharmacy will be closed for more than two hours, either to receive prescription orders or to dispense prescription drugs, during the regular hours that it has posted that it is open under Rule .1601(a)(2) of this Chapter, the pharmacist-manager shall take the following actions before closing:

(1) Post a notice in a location conspicuous to the public of (a) which services the pharmacy has ceased providing, and (b) the date and time that the pharmacist-manager anticipates that the pharmacy will resume providing those services. The pharmacist-manager shall change the posted notice in the event that the pharmacist-manager determines that it is no longer accurate.

(2) Send an e-mail to emergencyclosure@ncbop.org with the information provided in Paragraph (b)(1) of this Rule, including any changes to the required notice.

(3) If the pharmacy will not be dispensing prescription drugs during the closure, take each of the following actions and post a notice in a location conspicuous to the public of the actions taken:

(A) If the pharmacy maintains an alternate delivery site within 10 miles of the pharmacy (via the shortest surface street route), the pharmacy shall deliver any prescription drugs that have been filled but not delivered to the alternate delivery site and shall notify patients that prescriptions will be available at that alternate delivery site during the emergency closure. Immediately upon the end of the emergency closure, the pharmacy shall retrieve any drugs delivered to the alternate delivery site pursuant to this Subparagraph.

(B) Offer to transfer any prescriptions at the patient's request ~~during any time when the pharmacy is not dispensing prescription drugs~~ and notify ~~post a notice in a location conspicuous to~~ the public ~~notify~~ of the process for having those prescriptions transferred. This includes prescriptions that have been filled but not delivered before the pharmacy is closed. However, the pharmacy is not required to transfer prescriptions at any time at which there is no pharmacist or certified technician who is able to transfer prescriptions. For the purposes of this Rule, ~~rule,~~ a pharmacist or certified technician is able to transfer prescriptions if that person either: (i) is present at the pharmacy, or (ii) has remote access to the pharmacy's systems, either because that person is employed by the pharmacy, or employed by a pharmacy with a remote medication order processing services arrangement with the closed pharmacy under Rule .1816 of this Section.

~~(A) is present at the pharmacy, or~~

~~(B) has remote access to the pharmacy's systems, either because that person is employed by the pharmacy, or employed by a pharmacy with a remote medication order processing services arrangement with the closed pharmacy under Rule .1816 of this Section.~~

(c) In the event that the pharmacist-manager is unable to exercise the authority in this Rule, a pharmacist who is on duty at the pharmacy has the responsibility and authority set out in Paragraph (a) of this Rule if the pharmacist follows the procedures set out in Paragraph (b) of this Rule.

(d) This Rule does not apply in the following circumstances:

(1) Permanent closures or temporary closures lasting more than 14 consecutive days, which are instead governed by the provisions of Rule .2502(h) and (i) of this Section;

(2) Pharmacies located outside the State of North Carolina, which should follow any closure rules of their home states; or

(3) During the duration of time when the Governor or any county or municipality has declared a state of emergency in the pharmacy's location pursuant to Chapter 166A of the North Carolina General Statutes.

(e) In the event that the either (a) the pharmacist-manager suffers an emergency that renders the pharmacist-manager unable to exercise the responsibilities in Paragraph (b) of this Rule, or (b) the pharmacist-manager is unavailable and the only pharmacist(s) on duty suffers an emergency that renders the pharmacist unable to exercise the responsibilities in Paragraph (b) of this Rule, the exercise of the responsibilities in Paragraph (b) of this Rule shall be excused until such time as an employee authorized by the pharmacist-manager or permit holder can exercise those responsibilities.

History Note: *Authority G.S. 90-85.6; 90-85.15A; 90-85.21; 90-85.25; 90-85.32;*
Eff. August 1, ~~2024.~~ 2024;
Amended Eff. September 1, 2026.

Burgos, Alexander N

Subject: FW: [External] RE: Board of Pharmacy-August 2026 RRC Meeting-Request for Technical Changes

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From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Monday, July 27, 2026 10:47 AM
To: Clint Pinyan <CPINYAN@brookspierce.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Rules, Oah <oah.rules@oah.nc.gov>
Subject: Re: [External] RE: Board of Pharmacy-August 2026 RRC Meeting-Request for Technical Changes

Good morning,

I'm satisfied with the changes made and let's use the fuller versions of 21 NCAC .1821 and .1616. Please send the final revised rules to oah.rules@oah.nc.gov and cc Mr. Burgos and I (or just reply all).

These rules are final for review and can be placed on August's agenda. Please let us know if anyone from your agency will be present for the meeting, in-person or on WebEx.

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

Burgos, Alexander N

Subject: FW: [External] RE: Board of Pharmacy-August 2026 RRC Meeting-Request for Technical Changes

Attachments: 21 NCAC 46 .1821 4925-6790-3424 v.1.docx; 21 NCAC 46 .1821 full version 4929-1433-4387 v.2.docx; 21 NCAC 46 .1420 4920-3144-5875 v.2.docx; 21 NCAC 46 .1616 full version 4936-7002-3104 v.1.docx; 21 NCAC 46 .1616 4938-6755-5507 v.1.docx; 21 NCAC 46 .1822 4933-8468-6259 v.1.docx; 21 NCAC 46 .2516 4930-7280-0691 v.1.docx; 08_2026-Board of Pharmacy- Response to Request for Technical Changes 4902-3934-0992 v.1.docx

From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Friday, July 24, 2026 4:08 PM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: [External] RE: Board of Pharmacy-August 2026 RRC Meeting-Request for Technical Changes

Here goes. I hope I've answered your questions, but if I didn't, please let me know. As I previously mentioned, there are two rules for which I had recently done some stylebook-type editing in preparation for readoption. So I've attached optional more fulsome versions of changes for those two rules. Feel free to take some, all or none of those additional changes. If you want "some," then let me know and I'll edit.

Thanks for your help with these. If you're good with some version of these, let me know and I'll send to oah.rules.

Clint Pinyan

BROOKS PIERCE

t: 336.271.3157
f: 336.232.9157

230 North Elm Street, Suite 2000
Greensboro, NC 27401
P.O. Box 26000 (27420)

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

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1420

DEADLINE FOR RECEIPT: Thursday, August 6, 2026.

***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:

Line 1, this Rule was published in "40:20". Please change from Issue "40:22".

Done.

Line 7, add "a" before "Health".

Done.

Line 10, consider adding a comma after "supplements".

Considered and done.

Lines 13 and 18, capitalize "rule".

Done.

Line 20, which specific General Statute(s) is your agency relying on that authorizes a "pharmacist-manager" of a Health Care Facility Pharmacy to define "criteria" and to establish "standardized orders"?

It's the ones that are cited as authority, but the generally applicable one is 90-85.6 dealing with reasonably necessary rules and the most specific notable one is probably for unique pharmacy practice (90-85.34). This a special rule of application for health care facilities (i.e., hospitals, long-term care) due to their unique practice. Let me explain the concept a little bit because the pharmacist-manager is not establishing the standardized orders: Hospitals already have many standardized orders. I'll make something up here, as a non-medical knower: If you come in unconscious, a hospital has a standardized order in their system to prescribe you a certain kind of IV. A doctor doesn't have to write out an order like that one that never changes. It's just

Travis Wiggs
Commission Counsel
Date submitted to agency: July 23, 2026

preloaded into the system, and the doctor picks it from a template. This rule would give the pharmacist-manager the ability to go through the template for these standardized orders and say "Yeah, this certain IV in this template is going to be appropriate for any patient who meets the criteria (in this example, being unconscious). Doesn't matter if they're taking Oxycodone, or blood thinnners, or whatever." If the pharmacist-manager determines that the drug is safe under those circumstances for all patients, then – each time a patient is prescribed that drug -- a pharmacist would not have to take the step of looking at what other drugs the patient is taking (since it doesn't matter). The assumption is that the pharmacist-manager will designate some of the hospital's standardized orders as not needing further drug regimen review, while some would need it. In the absence of this rule, a pharmacist would have to perform a full drug regimen review every time, even when there is only one criteria (here, unconsciousness) that matters.

Line 20, please correct the typo in "90-85-21".

Done.

Please use correct formatting for this Rule and all others.

I have double checked these rules for formatting issues. If I missed something, please let me know what it is and I'll fix it. Thanks.

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

Travis Wiggs
Commission Counsel
Date submitted to agency: July 23, 2026

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

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1616

DEADLINE FOR RECEIPT: Thursday, August 6, 2026.

***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:

Line 27, how and where can the "limited service permit application" be accessed? Are all the contents of the "limited service permit application" listed in rule or statute? All the required information on the application must be included in rule or statute.

Ah. Let me see if I can make another change that will take care of this problem. The point was not to set out a requirement for an application. It was instead really meant to say that you can name an assistant pharmacist-manager when you get the permit, or after you get the permit. It was a sloppy intended reference to time. In fact, the whole sentence starting on line 26 is unnecessary, since the first sentence of that paragraph at line 23 already says that a pharmacist-manager can designate an assistant. The only necessary sentence is the one at 28, which talks about updating the designation. Take a look and see if this works. It's certainly more precise now.

I've also attached a fuller version with a small handful of additional stylebook changes (shall/must, "at least," any/a, a couple of wordy phrases). Also, "permanent pharmacist-manager" isn't a real term. There's "pharmacist-manager," which is assumed to extend indefinitely into the future, and "temporary pharmacist-manager," which is not.)

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

Travis Wiggs
Commission Counsel
Date submitted to agency: July 23, 2026

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

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1821

DEADLINE FOR RECEIPT: Thursday, August 6, 2026.

***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:

Lines 8 and 21, add a comma after "devices".

Done

Page 2, line 8, consider adding "rules and regulations" beside "laws" for clarity.

Done

Page 3, line 23, add a comma after "devices".

Done

Page 4, line 22, add "System" after "DTP".

Oops. Done.

Page 5, line 3, cite the General Statute for the "Pharmacy Practice Act".

Done.

This is one for which I have submitted an alternative, more complete set of changes. You'll quickly recognize that many of these changes were to comply with the style guide (i.e., capitalization of lists, "any"/"all"/"every"/"each" (which I clearly loved when I was writing the original rule), "minimum of"). The rest are for consistency and clarity. "Deliver" and "dispense" were used interchangeably to refer to the same activity, which I've now changed to "deliver." "Prescription" was sometimes used in the slang common use to refer to either a written prescription ("The doctor gave me a prescription") or to the drugs, devices or medical equipment dispensed ("I picked up my prescription."). While the use was

Travis Wiggs
Commission Counsel
Date submitted to agency: July 23, 2026

clear from the context, I have cleaned that up with “prescription order” and “prescription drugs . . . “ which are the statutory terms. For the same statutory reason, “prescription” was added before “drugs” where appropriate. I think that explains them all.

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

Travis Wiggs
Commission Counsel
Date submitted to agency: July 23, 2026

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

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1822

DEADLINE FOR RECEIPT: Thursday, August 6, 2026.

***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:

Line 8, delete extra space(s) between "Chapter. The…"

Done

Lines 9-10, delete either "for" or "of" before "this Rule". Also, "reasonably assured" is unclear and ambiguous. Please delete "reasonably" or replace the phrase.

You are quite correct. The permit is, in fact, contingent upon compliance, so I've changed that.

Line 17, consider adding "rules and regulations" beside "laws" for clarity.

Considered and done

Page 2, lines 3 and 5, add a comma after "device" and after "devices".

Done

Line 5, add a comma after "including" and after "limited".

Done

Page 3, line 16, "twenty-one days" was not included in the Register. Why was this language added after publication? Why does this not constitute a substantial change under G.S. 150B-21.2(g)?

This change does not meet the criteria for a substantial change. The explanation for the change was included in the submission form, but I will elaborate here. The rule originally contained a requirement that the pharmacy retrieve any unclaimed drugs within seven days. This provision was to ensure that drugs will not sit around

Travis Wiggs
Commission Counsel
Date submitted to agency: July 23, 2026

indefinitely at the alternative delivery site if the patient does not pick them up. The specific period (7 days) was far less important than the concept of only storing those drugs that are still waiting to be delivered, and not having drugs stack up at the alternative delivery site. The Board received numerous public comments requesting that this period be extended because many insurers call for a longer waiting period before drugs are returned to stock. The Board responded by making a change consistent with these public comments. The change does not affect the interests of any different persons nor does it address a new subject matter (since the only people interested in the change would be the pharmacies and patients, all of whom were on notice that the rule was proposed and that it would contain a return-to-stock provision). And, to the extent that there is any difference in effect, the change benefits the pharmacies who requested this change (since the rule is now harmonized with their normal return to stock policies and will require them to retrieve drugs less frequently) and the patients (who can now expect their medications to be at their chosen alternative delivery site for a longer period, and therefore are less likely to arrive to find their medications returned to the pharmacy). Nobody is adversely affected by the new date.

Lines 20 and 24, add a comma after "devices".

Done. I also noticed an additional oxford comma needed in "public health, safety, and welfare."

Page 4, line 5, consider adding "rules and" before "regulations" for clarity. Also, cite the General Statute for the "Pharmacy Practice Act".

Done.

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

Travis Wiggs
Commission Counsel
Date submitted to agency: July 23, 2026

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

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2516

DEADLINE FOR RECEIPT: Thursday, August 6, 2026.

***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:

Line 5, add a comma after "lawful".

Done

Line 32, capitalize "rule".

Done

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

Travis Wiggs
Commission Counsel
Date submitted to agency: July 23, 2026

21 NCAC 46 .1420 is adopted with changes as published in 40:20 ~~40:22~~ NCR 1611 as follows:

21 NCAC 46 .1420 STANDARDIZED ORDERS

(a) This Rule applies if a Health Care Facility has developed a set of standardized orders for its patients. As used in this Rule, standardized orders are pre-established written protocols that allow authorized practitioners at the Health Care Facility to administer medications to a patient who meets defined criteria.

(b) A pharmacist-manager of a Health Care Facility Pharmacy may establish which of those standardized orders are safe and effective for all patients presenting a set of predetermined criteria established by the pharmacist-manager. Those orders must be safe and effective for all patients presenting those criteria, regardless of any drugs, supplements, ~~supplements~~ or other substances that might have been consumed by any patient. Any standardized orders so designated by the pharmacist-manager may be dispensed by the pharmacy to a Health Care Facility patient without any patient-specific drug regimen review being performed by the pharmacist.

(c) The pharmacist-manager must maintain policies and procedures sufficient to identify the standardized orders and the criteria for issuing those standardized orders, as well as the process by which those orders are to be dispensed. The pharmacist-manager must also keep records of all dispensing pursuant to this Rule, ~~rule,~~ including the authorized practitioner's determination that the standardized order was appropriate and documentation that any criteria have been met.

(d) This Rule, ~~rule,~~ does not apply to outpatient pharmacies or to drugs dispensed pursuant to 21 NCAC 46 .1415.

History Note: *Authority G.S. 90-18.1; 90-18.2; 90-85.6; 90-85.21; ~~90-85.21;~~ 90-85.26; 90-85.33; 90-85.34; Eff. September 1, 2026.*

21 NCAC 46 .1616 is amended with changes as published in 40:20 NCR 1613 as follows:

21 NCAC 46 .1616 LIMITED SERVICE PERMITS

(a) The following pharmacy practice locations are eligible to apply for "limited service permits," which are pharmacy locations whose operations are modified by the provisions set forth in Paragraphs (b), (c), and (d) of 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;

(4) alternate delivery sites pursuant to Rule .1822 of this Chapter;

~~(4)~~(5) facilities where drugs are dispensed only by nurse practitioners or physician assistants pursuant to Section .1700 of this Chapter;

~~(5)~~(6) 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;

~~(6)~~(7) 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;

~~(7)~~(8) free clinics, as defined in G.S. 90-85.44(a)(6); or

~~(8)~~(9) 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 location holding 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, if an assistant pharmacist-manager is desired at that time.~~ If a designation is made or changed after the limited service permit ~~application~~ is issued, ~~filed~~, the pharmacist-manager shall notify the Board, 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), (2), (3), and (4) ~~(2) and (3)~~ of this Rule, either the pharmacist-manager or the assistant pharmacist-manager shall perform an in-person, on-site visit at least once per calendar quarter to inspect the location holding the permit, review the

operations of the location holding the permit with the persons involved in accessing them as permitted by the rules referenced in Subparagraphs (a)(1), (2), (3), and (4) ~~and (3)~~ of this Rule, and ensure that the location holding the permit is operated in compliance with all applicable State and federal laws.

(2) For limited service permits described in Subparagraphs (a)(5) and (6) ~~(a)(4) and (5)~~ of this Rule, either the pharmacist-manager or the assistant pharmacist-manager shall perform an in-person, on-site visit at least once per week to inspect the location holding the permit, review the operations of the location holding the permit with the persons involved in dispensing, and ensure that the location holding the permit is operated in compliance with all applicable State and federal laws.

(3) For limited service permits described in Subparagraphs (a)(7), (8), and (9) ~~(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)(7) and (8) ~~(a)(5) and (6)~~ of this Rule, a licensed pharmacist shall 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)(9) ~~(a)(7)~~ of this Rule, the location holding 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 holder 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 shall accept the responsibilities of that position and shall be present as set forth in this Rule. A location holding 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 do so while also serving as the pharmacist-manager for a maximum of one permit other than a limited service permit. A person serving multiple limited service permit locations must fulfill all of that person's duties under State and federal law as to each location.

(e) Except as expressly set forth in this Rule, the pharmacist-manager must 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;
Amended Eff. September 1, ~~2023.~~ 2023; September 1, 2026.

21 NCAC 46 .1616 is amended with changes as published in 40:20 NCR 1613 as follows:

21 NCAC 46 .1616 LIMITED SERVICE PERMITS

(a) The following pharmacy practice locations are eligible to apply for "limited service permits," which are pharmacy locations whose operations are modified by the provisions set forth in Paragraphs (b), (c), and (d) of 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;

(4) alternate delivery sites pursuant to Rule .1822 of this Chapter;

~~(4)~~(5) facilities where drugs are dispensed only by nurse practitioners or physician assistants pursuant to Section .1700 of this Chapter;

~~(5)~~(6) 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;

~~(6)~~(7) 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;

~~(7)~~(8) free clinics, as defined in G.S. 90-85.44(a)(6); or

~~(8)~~(9) 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 location holding 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, if an assistant pharmacist-manager is desired at that time.~~ If a designation is made or changed after the limited service permit ~~application~~ is issued, ~~filed~~, the pharmacist-manager shall notify the Board, in writing, within 15 days of ~~any~~ a 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 follows: ~~set forth herein:~~

(1) For limited service permits described in Subparagraphs (a)(1), (2), (3), and (4) ~~(2) and (3)~~ of this Rule, either the pharmacist-manager or the assistant pharmacist-manager shall perform an in-person, on-site visit ~~at least~~ once per calendar quarter to inspect the location holding the permit, review the

operations of the location holding the permit with the persons involved in accessing them as permitted by the rules referenced in Subparagraphs (a)(1), (2), (3), and (4) ~~and (3)~~ of this Rule, and ensure that the location holding the permit is operated in compliance with all applicable State and federal laws.

(2) For limited service permits described in Subparagraphs (a)(5) and (6) ~~(a)(4) and (5)~~ of this Rule, either the pharmacist-manager or the assistant pharmacist-manager shall perform an in-person, on-site visit ~~at least~~ once per week to inspect the location holding the permit, review the operations of the location holding the permit with the persons involved in dispensing, and ensure that the location holding the permit is operated in compliance with all applicable State and federal laws.

(3) For limited service permits described in Subparagraphs (a)(7), (8), and (9) ~~(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)(7) and (8) ~~(a)(5) and (6)~~ of this Rule, a licensed pharmacist shall 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)(9) ~~(a)(7)~~ of this Rule, the location holding 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 holder 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 shall accept the responsibilities of that position and shall be present as set forth in this Rule. A location holding 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~~ pharmacist-manager 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 do so while also serving as the pharmacist-manager for a maximum of one permit other than a limited service permit. A person serving multiple limited service permit locations shall ~~must~~ fulfill all of that person's duties under State and federal law as to each location.

(e) Except as expressly set forth in this Rule, the pharmacist-manager shall ~~must~~ 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;
Amended Eff. September 1, ~~2023.~~ 2023; September 1, 2026.

21 NCAC 46 .1821 is amended with changes as published in 40:20 NCR 1613 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, ~~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~~ residence, to a health care provider treating that patient, or at an alternate delivery site governed by Rule .1822 of this Section,

(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 in Parts (A)-(D) of this Subparagraph, no person holding any license or permit from the Board 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, ~~devices~~ or medical equipment through a DTP system.

(3) A "locker" means a secure container in which pharmacy personnel place 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) shall meet the following requirements:

(1) Before any drugs, devices, or medical equipment may be dispensed from a DTP system, the home pharmacy shall have been issued a pharmacy permit by the Board pursuant to G.S. 90-85.21 or 90-85.21A. In addition, before any drugs, devices, or medical equipment may be dispensed from the DTP system, the DTP system shall hold a limited service permit under Rule .1616 of this Section if it is not located at the home pharmacy's permitted facility.

(2) The home pharmacy shall notify the Board, in writing, through the home pharmacy's online permit portal, prior to beginning to use any DTP system, including the address and geographical coordinates of the DTP system and the licensed pharmacist(s) responsible for the DTP system. The home pharmacy shall notify the Board prior to moving the DTP system and shall secure a new

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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 shall notify the Board within 10 days after discontinuing patient use of any DTP system.

(3) A DTP system shall be used exclusively by the home pharmacy.

(4) Any DTP system shall be 60 miles or fewer from the home pharmacy (via the shortest surface street route).

(5) A DTP system may be placed in the office of a prescriber only if the DTP system is under the control of the home pharmacy, which is responsible for compliance with all laws, rules, and regulations ~~laws~~ regarding the DTP system. The home pharmacy shall maintain the DTP system in the prescriber's office only if the prescriber offers patients a choice of pharmacy. The home pharmacy shall not give compensation to or receive compensation from the prescriber for the placement of the DTP system or for any prescriptions filled by the DTP system.

(6) The home pharmacy shall prohibit access to the DTP system and its contents by unauthorized personnel and maintain confidentiality of patient information. The DTP system shall be under the continuous supervision of a pharmacist employed by the home pharmacy, which may be satisfied by real-time remote supervision of the pharmacy through video and audio connections.

(7) The DTP system shall 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 shall ensure that there is continuous, recorded video surveillance of the DTP system and any persons using or accessing the DTP system. It shall 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

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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 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 shall comply with G.S. 90-106.1 in dispensing any drugs covered by that statute from a DTP system, and shall visually confirm that the person seeking the dispensation is the same as the person on the photographic identification provided.

(11) Only pharmacy personnel who are licensed with this Board as pharmacists or registered with this Board as technicians or pharmacy interns may stock drugs, devices, and medical equipment in, or remove drugs, devices, and medical equipment from, the inventory of a DTP system. The home pharmacy shall maintain records of any access to the DTP system by pharmacy personnel stocking or otherwise accessing the DTP system.

(12) Before a home pharmacy dispenses drugs, devices, ~~devices~~ and medical equipment to a patient through a DTP system, the home pharmacy shall secure the affirmative consent of the patient to use the DTP system.

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

(14) Before a prescription is dispensed from the DTP system, the dispensing pharmacist at the home pharmacy shall verify each prescription and shall 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 shall 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 shall create and maintain records of dispensing for any drugs, devices, and medical equipment dispensed in a DTP system in compliance with State and federal law. Any kiosk shall be connected to the home pharmacy's automated data processing system, and any drugs, devices, or medical equipment dispensed from any locker shall be recorded in the home pharmacy's

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recordkeeping system. The recordkeeping system shall be capable of producing a record of all drugs, devices, and medical equipment dispensed from the DTP system.

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

(18) The DTP system shall convey the home pharmacy's offer to counsel a patient as required by Rule .2504 of this Chapter and shall 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 shall check the communication link at least daily and the DTP system shall 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 shall 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 system 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 shall 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.

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(3) Drugs, devices, or medical equipment dispensed by the kiosk shall be packaged only by a licensed manufacturer or repackager, or prepackaged by the home pharmacy in compliance with the Pharmacy Practice Act, Article 4A of Chapter 90 of the General Statutes, ~~Act~~ and this Chapter.

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

(5) The home pharmacy shall 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 shall 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.~~ 2023;
Amended Eff. September 1, 2026.

21 NCAC 46 .1821 is amended with changes as published in 40:20 NCR 1613 as follows:

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

(a) This Rule sets out the requirements ~~under which~~ for pharmacies to employ ~~may utilize~~ "direct-to-patient" or ("DTP") delivery systems for delivery ~~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 delivers ~~dispenses~~ drugs, devices, ~~devices~~ or medical equipment to a patient through any means other than:

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

(B) in-person ~~dispensing by~~ delivery to a patient's ~~residence or~~ residence, to a health care provider treating that patient, or at an alternate delivery site governed by Rule .1822 of this Section,

(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 in Parts (A)-(D) of this Subparagraph, no person holding any license or permit from the Board shall participate in an ~~any~~ arrangement ~~whereby prescriptions may~~ for prescription orders or prescription drugs, devices, or medical equipment to 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~~ delivering prescription drugs, devices, ~~devices~~ or medical equipment through a DTP system.

(3) A "locker" means a secure container in which pharmacy personnel place 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~~ delivering drugs, devices, or medical equipment ~~to be dispensed~~ to a patient.

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

(1) Before ~~any~~ prescription drugs, devices, or medical equipment may be ~~dispensed~~ delivered from a DTP system, the home pharmacy shall have been issued a pharmacy permit by the Board pursuant to G.S. 90-85.21 or 90-85.21A. In addition, before ~~any~~ prescription drugs, devices, or medical equipment may be ~~dispensed~~ delivered from the DTP system, the DTP system shall hold a limited service permit under Rule .1616 of this Section if it is not located at the home pharmacy's permitted facility.

(2) The home pharmacy shall notify the Board, in writing, through the home pharmacy's online permit portal, prior to beginning to use ~~any~~ a DTP system, including the address and geographical coordinates of the DTP system and the licensed pharmacist(s) responsible for the DTP system. The home pharmacy shall notify the Board prior to moving the DTP system and shall 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 shall notify the Board within 10 days after discontinuing patient use of ~~any~~ a DTP system.

(3) A DTP system shall be used exclusively by the home pharmacy.

(4) ~~Any~~ A DTP system shall be 60 miles or fewer from the home pharmacy (via the shortest surface street route).

(5) A DTP system may be placed in the office of a prescriber only if the DTP system is under the control of the home pharmacy, which is responsible for compliance with all laws, rules, and regulations ~~laws~~ regarding the DTP system. The home pharmacy shall maintain the DTP system in the prescriber's office only if the prescriber offers patients a choice of pharmacy. The home pharmacy shall not give compensation to or receive compensation from the prescriber for the placement of the DTP system or for any prescription orders ~~prescriptions~~ filled by the DTP system.

(6) The home pharmacy shall prohibit access to the DTP system and its contents by unauthorized personnel and maintain confidentiality of patient information. The DTP system shall be under the continuous supervision of a pharmacist employed by the home pharmacy, which may be satisfied by real-time remote supervision of the pharmacy through video and audio connections.

(7) The DTP system shall 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 shall ensure that there is continuous, recorded video surveillance of the DTP system and any persons using or accessing the DTP system. It shall 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~~ maintaining the security of the DTP system and the drugs, devices, and medical equipment within the DTP system.

(B) ~~Determining~~ 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~~ 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~~ 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~~ describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the DTP system.

(F) ~~Orienting~~ orienting participating patients on use of the DTP system; notifying patients when expected prescription 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 prescription drugs, devices, or medical equipment delivered; ~~prescriptions filled~~; and ensuring that patient use of the DTP system does not interfere with the delivery of prescription drugs, devices, and medical equipment to patients.

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

This written manual of policies and procedures shall be reviewed and updated 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~~ a DTP system, ~~systems,~~ before ~~any~~ delivering controlled substances ~~are dispensed~~ from ~~any~~ the DTP system. ~~systems~~. The home pharmacy shall comply with G.S. 90-106.1 in ~~dispensing any~~ delivering prescription drugs covered by that statute from a DTP system, and shall visually confirm that the person seeking the ~~dispensation~~ delivery is the same as the person on the photographic identification provided.

(11) Only pharmacy personnel who are licensed with this Board as pharmacists or registered with this Board as technicians or pharmacy interns shall ~~may~~ stock drugs, devices, and medical equipment in, or remove drugs, devices, and medical equipment from, the inventory of a DTP system. The home pharmacy shall maintain records of ~~any~~ access to the DTP system by pharmacy personnel stocking or otherwise accessing the DTP system.

(12) Before a home pharmacy ~~dispenses~~ delivers prescription drugs, devices, ~~devices~~ and medical equipment to a patient through a DTP system, the home pharmacy shall secure the affirmative consent of the patient to use the DTP system.

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

(14) Before delivering a prescription drug, device or medical equipment ~~is dispensed~~ from the DTP system, the dispensing pharmacist at the home pharmacy shall verify ~~each~~ the prescription order and shall 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~~ Prescription drugs, devices, and medical equipment ~~dispensed~~ delivered from a DTP system shall 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 shall create and maintain records of dispensing for ~~any~~ prescription drugs, devices, and medical equipment delivered by ~~dispensed in~~ a DTP system in compliance with State and federal law. ~~Any~~ A kiosk shall be connected to the home pharmacy's automated data processing system, and ~~any~~ prescription drugs, devices, or medical equipment delivered ~~dispensed~~ from ~~any~~ a locker shall be recorded in the home pharmacy's recordkeeping system. The recordkeeping system shall be capable of producing a record of ~~all~~ prescription drugs, devices, and medical equipment dispensed from the DTP system.

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

(18) The DTP system shall convey the home pharmacy's offer to counsel a patient as required by Rule .2504 of this Chapter and shall 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 shall check the communication link at least daily and the DTP system shall 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~~ If the DTP system is placed in the same physical space as the dispensing area of the home pharmacy, this provision may be satisfied when ~~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 drug, device, or medical equipment is delivered, ~~dispensed,~~ the DTP system shall provide the ability for the pharmacist to force counseling before the DTP system delivers ~~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 system 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 prescription 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, prescription drug dispensed, the strength, and the beyond-use date. The dispensing pharmacist shall verify the entire label for accuracy on the video link.

(2) The kiosk shall use ~~utilize~~ a barcode system that prints the barcode of the stock bottle or other packaging on the label of the dispensed prescription 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 prescription 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 drug, device, or medical equipment dispensed.

(3) ~~Drugs,~~ Prescription drugs, devices, or medical equipment dispensed by the kiosk shall be packaged only by a licensed manufacturer or repackager, or prepackaged by the home pharmacy in compliance with the Pharmacy Practice Act, Article 4A of Chapter 90 of the General Statutes, ~~Act~~ and this Chapter.

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

(5) The home pharmacy shall 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 shall transmit prescription orders ~~prescriptions~~ to the home pharmacy. ~~Prescriptions~~ Prescription orders 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.~~ 2023;
Amended Eff. September 1, 2026.

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21 NCAC 46 .1822 is adopted with changes as published in 40:20 NCR 1613 as follows:

21 NCAC 46 .1822 ALTERNATE DELIVERY SITES

(a) This Rule sets out the requirements under which pharmacies may utilize alternate delivery sites for delivery of drugs, devices, or medical equipment or for receipt of prescriptions in the State of North Carolina.

(b) Before any drugs, devices, or medical equipment may be delivered at an alternate delivery site, the pharmacy shall have been issued a pharmacy permit by the Board pursuant to G.S. 90-85.21 or G.S. 90-85.21A, and the alternate delivery site shall have been issued a limited service permit under Rule .1616 of this Chapter. The limited service permit shall be granted only if, and so long as, compliance with all requirements ~~for~~ of this Rule can be ~~reasonably~~ assured.

(c) Location.

(1) An alternate delivery site shall be within the State of North Carolina and 60 miles or fewer from the pharmacy (via the shortest surface street route).

(2) An alternate delivery site may not be located in the same building or on the same property as the pharmacy or any pharmacy under common ownership.

(3) An alternate delivery site may be placed in the office of a prescriber only if the alternate delivery site is under the control of the pharmacy, which is responsible for compliance with all laws, rules, and regulations ~~laws~~ regarding the alternate delivery site, and only if the alternate delivery site is staffed with pharmacy personnel, as set forth herein. The pharmacy shall maintain the alternate delivery site in the prescriber's office only if the prescriber offers patients a choice of pharmacy. The pharmacy shall not give compensation to or receive compensation from the prescriber for the placement of the alternate delivery site or for any prescriptions delivered at the alternate delivery site.

(4) An alternate delivery site may not be located on residential property.

(5) The pharmacy shall notify the Board within 10 days after discontinuing patient use of any alternate delivery site.

(d) Staffing and Management.

(1) When the alternate delivery site is open, it must be continuously staffed by a pharmacist or certified pharmacy technician who is an employee of the pharmacy.

(2) The alternate delivery site shall be used exclusively by the one pharmacy whose pharmacist-manager is responsible for the alternate delivery site’s operation.

(3) The dispensing pharmacist for any drugs, devices, or medical equipment delivered to an alternate delivery site shall be employed by the pharmacy and licensed with this Board.

(4) At all times that the alternate delivery site is open, a pharmacist employed by the pharmacy must be available for counseling, as set forth in this Rule, and for consultation with the staff of the alternate delivery site.

(5) All staff at the alternate delivery site shall wear identification badges as set forth in G.S. 90-640.

(e) Services Limited to Prescription Pickup and Drop Off for the Pharmacy.

(1) At the alternate delivery site, a pharmacist or a certified technician employed by the pharmacy may personally deliver any drug, device, or medical equipment to the patient or the patient's agent, after that drug, device, ~~device~~ or medical equipment has been previously dispensed by the pharmacy. All physical steps in the dispensing process (other than delivery to the patient) must occur at the pharmacy, ~~including~~ including, but not limited to, ~~to~~ filling and patient-specific labeling. No drugs, devices, ~~devices~~ or medical equipment may be maintained at the alternate delivery site, other than completed patient-specific labeled and previously dispensed drugs, devices, or medical equipment that have been transported from the pharmacy to the alternate delivery site to be delivered.

(2) At the alternate delivery site, a pharmacist or certified pharmacy technician who is an employee of the pharmacy may personally accept a written prescription from the patient or the patient's agent, so long as the prescription is then transmitted to the pharmacy so that all physical steps in the dispensing process may take place in the pharmacy. Patients or their agents may not leave prescriptions at the alternate delivery site, other than by personally delivering them to the pharmacist or certified pharmacy technician.

(f) Requirements for Use of Alternate Delivery Site.

(1) Before a pharmacy delivers drugs, devices, or medical equipment to a patient at an alternate delivery site, the pharmacy shall secure the affirmative consent of the patient to use the alternate delivery site. The pharmacy shall not require patients to pick up their prescriptions from an alternate delivery site, rather than at the pharmacy or through delivery mechanisms otherwise available at the pharmacy.

(2) To ensure appropriate coordination of patient care, the pharmacy shall notify the alternate delivery site of the anticipated arrival time of the transportation of the drug, device, or medical equipment to the alternate delivery site, the name of the patient for whom the drug, device or medical equipment was dispensed, and any special storage requirements.

(3) The hours of the alternate delivery site shall be reported to the Board, and the alternate delivery site shall be open during the hours that have been reported to the Board. Emergency closure of the alternate delivery site shall require the pharmacist-manager of the pharmacy to follow the procedures in Rule .2516 of this Chapter.

(4) The pharmacist or certified pharmacy technician at the alternate delivery site shall convey the pharmacy's offer to counsel a patient as required by Rule .2504 of this Chapter and shall provide the ability for the patient to have an immediate real-time consultation with a pharmacist licensed by this Board and employed by the pharmacy who has access to all of the pharmacy's information related to the patient. The communication link shall protect the confidentiality of the patient's information. A pharmacist who is responsible for counseling may not provide that service for more than three limited service permits simultaneously. A certified pharmacy technician staffing an alternate delivery site may not perform counseling of any sort.

(5) The alternate delivery site shall have real-time access to the pharmacy's information system and shall comply with all recordkeeping requirements for drugs, devices, and medical equipment delivered at the site.

(6) The pharmacist or certified pharmacy technician delivering drugs, devices, or medical equipment has the authority conferred by Rule .1817 of this Section with respect to proof of identification.

(7) Controlled substances may be delivered to an alternate delivery site only if permitted by state and federal controlled substances laws. If permitted, both the pharmacy and alternate delivery site shall comply with any federal and state controlled substance laws and rules, including but not limited to receiving any registrations that may be required for any alternate delivery site, before any controlled substances are delivered to any alternate delivery site. The pharmacist or certified pharmacy technician delivering drugs at the alternate delivery site must comply with G.S. 90-106.1 in delivering any drugs covered by that statute from an alternate delivery site and shall visually confirm that the person seeking the delivery is the same as the person on the photographic identification provided.

(8) The pharmacy shall retrieve any drugs, devices, or medical equipment not delivered to the patient within [~~one week~~] twenty-one days of being delivered to the alternate delivery site.

(9) 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 alternate delivery site have been followed and the drugs, devices, ~~devices~~ or medical equipment can be returned to stock consistent with the public health, safety, ~~safety~~ and welfare.

(g) Safety and Security.

(1) The pharmacist-manager shall not deliver drugs, devices, or medical equipment to or at the alternate delivery site unless the pharmacist-manager is satisfied that drugs, devices, ~~devices~~ or medical equipment may be as safely and effectively stored and delivered at the alternate delivery site as in the pharmacy itself.

(2) Drugs, devices, or medical equipment delivered to the alternate delivery site shall be stored in a lockable room or lockable cabinet or other irremovable device. The lockable storage must remain locked at all times except when a drug, device, or medical equipment is being actively removed from storage. If prescriptions require special storage, such as refrigeration, those storage devices must be similarly secured. Access shall be restricted to the pharmacist or certified pharmacy technician who is personally delivering the prescriptions.

(3) The pharmacy shall ensure the transportation and storage of 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.

(4) The pharmacy shall ensure that there is continuous, recorded video surveillance of the storage and delivery of drugs, devices, and medical equipment at the alternate delivery site. It shall maintain any recordings for a minimum of 90 days.

(h) Policies and Procedures: The pharmacy must develop and implement written policies and procedures to ensure that the requirements of the Pharmacy Practice Act, Article 4A of Chapter 90 of the General Statutes, ~~Act~~ and its rules and regulations are complied with at the alternate delivery site. These shall include:

(1) Tracking and maintaining the security of delivery of drugs, devices, and medical equipment between the pharmacy and the alternate delivery site.

(2) Maintaining the security of the alternate delivery site and the drugs, devices, and medical equipment at the alternate delivery site.

(3) Transporting and maintaining any drugs, devices, and medical equipment in the appropriate environmental conditions.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the transportation, storage, and delivery procedures for the alternate delivery site.

(5) Offering to counsel and providing counseling at the alternate delivery site, including keeping records of offers to counsel.

(6) Orienting participating patients on use of the alternate delivery site; notifying patients when their dispensed prescription will be available at the alternate delivery site; and ensuring that use of the alternate delivery site does not interfere with the delivery of drugs, devices, and medical equipment to patients.

(7) Keeping records of the delivery of drugs, devices, and medical equipment to patients at the alternative delivery site.

(8) Returning to the pharmacy any drugs, devices, or medical equipment that are not delivered to the patient.

(9) Assuring confidentiality of patient information.

(10) Inspecting the alternate delivery site during each required inspection.

This written manual of policies and procedures shall be maintained both in the pharmacy and at the alternate delivery site. The manual shall be reviewed and updated annually.

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

(j) This Rule does not prohibit the use of other delivery methods set forth in Rule .1821(b)(1) of this Section, which are exclusive.

History Note: *Authority G.S. 90-85.6; 90-85.15A; 90-85-21; 90-85.21A; 90-85.26;*
Eff. September 1, 2026.

21 NCAC 46 .2516 is amended with changes as published in 40:20 NCR 1613 as follows:

21 NCAC 46 .2516 EMERGENCY CLOSURE

(a) The pharmacist-manager of a pharmacy has the responsibility and authority to cease some or all of the pharmacy operations when doing so is necessary to fill the pharmacist-manager's responsibility (a) for the safe, lawful, ~~lawful~~ and secure receipt of prescription orders and delivery of prescription drugs under Rule .1804(a) of this Chapter, or (b) to ensure that adequate qualified personnel are in place to properly render pharmaceutical service in compliance with state and federal law under Rule .1601(a)(1) of this Chapter.

(b) In the event that a pharmacist-manager anticipates that a pharmacy will be closed for more than two hours, either to receive prescription orders or to dispense prescription drugs, during the regular hours that it has posted that it is open under Rule .1601(a)(2) of this Chapter, the pharmacist-manager shall take the following actions before closing:

(1) Post a notice in a location conspicuous to the public of (a) which services the pharmacy has ceased providing, and (b) the date and time that the pharmacist-manager anticipates that the pharmacy will resume providing those services. The pharmacist-manager shall change the posted notice in the event that the pharmacist-manager determines that it is no longer accurate.

(2) Send an e-mail to emergencyclosure@ncbop.org with the information provided in Paragraph (b)(1) of this Rule, including any changes to the required notice.

(3) If the pharmacy will not be dispensing prescription drugs during the closure, take each of the following actions and post a notice in a location conspicuous to the public of the actions taken:

(A) If the pharmacy maintains an alternate delivery site within 10 miles of the pharmacy (via the shortest surface street route), the pharmacy shall deliver any prescription drugs that have been filled but not delivered to the alternate delivery site and shall notify patients that prescriptions will be available at that alternate delivery site during the emergency closure. Immediately upon the end of the emergency closure, the pharmacy shall retrieve any drugs delivered to the alternate delivery site pursuant to this Subparagraph.

(B) Offer to transfer any prescriptions at the patient's request ~~during any time when the pharmacy is not dispensing prescription drugs~~ and notify ~~post a notice in a location conspicuous to~~ the public ~~notify~~ of the process for having those prescriptions transferred. This includes prescriptions that have been filled but not delivered before the pharmacy is closed. However, the pharmacy is not required to transfer prescriptions at any time at which there is no pharmacist or certified technician who is able to transfer prescriptions. For the purposes of this Rule, ~~rule,~~ a pharmacist or certified technician is able to transfer prescriptions if that person either: (i) is present at the pharmacy, or (ii) has remote access to the pharmacy's systems, either because that person is employed by the pharmacy, or employed by a pharmacy with a remote medication order processing services arrangement with the closed pharmacy under Rule .1816 of this Section.

~~(A) is present at the pharmacy, or~~

~~(B) has remote access to the pharmacy's systems, either because that person is employed by the pharmacy, or employed by a pharmacy with a remote medication order processing services arrangement with the closed pharmacy under Rule .1816 of this Section.~~

(c) In the event that the pharmacist-manager is unable to exercise the authority in this Rule, a pharmacist who is on duty at the pharmacy has the responsibility and authority set out in Paragraph (a) of this Rule if the pharmacist follows the procedures set out in Paragraph (b) of this Rule.

(d) This Rule does not apply in the following circumstances:

(1) Permanent closures or temporary closures lasting more than 14 consecutive days, which are instead governed by the provisions of Rule .2502(h) and (i) of this Section;

(2) Pharmacies located outside the State of North Carolina, which should follow any closure rules of their home states; or

(3) During the duration of time when the Governor or any county or municipality has declared a state of emergency in the pharmacy's location pursuant to Chapter 166A of the North Carolina General Statutes.

(e) In the event that the either (a) the pharmacist-manager suffers an emergency that renders the pharmacist-manager unable to exercise the responsibilities in Paragraph (b) of this Rule, or (b) the pharmacist-manager is unavailable and the only pharmacist(s) on duty suffers an emergency that renders the pharmacist unable to exercise the responsibilities in Paragraph (b) of this Rule, the exercise of the responsibilities in Paragraph (b) of this Rule shall be excused until such time as an employee authorized by the pharmacist-manager or permit holder can exercise those responsibilities.

History Note: *Authority G.S. 90-85.6; 90-85.15A; 90-85.21; 90-85.25; 90-85.32;*
Eff. August 1, ~~2024.~~ 2024;
Amended Eff. September 1, 2026.

Burgos, Alexander N

From: Wiggs, Travis C
Sent: Thursday, July 23, 2026 3:20 PM
To: Clint Pinyan
Cc: Burgos, Alexander N
Subject: Board of Pharmacy-August 2026 RRC Meeting-Request for Technical Changes
Attachments: 08_2026-Board of Pharmacy-Request for Technical Changes.docx

Good afternoon,

I'm the attorney who reviewed the rule submitted by the Board of Pharmacy for the August 2026 RRC meeting. The RRC will formally review this rule at its meeting on Thursday, August 27, 2026, at 10:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get close to the meeting. If there are any other representatives from your agency who want to attend virtually, please let me know prior to the meeting, and we will get evites out to them as well.

Attached is the Request for Changes Pursuant to G.S. 150B-21.10. Please submit the revised rules to me via email, no later than 5 p.m. on August 6, 2026. Let me know if you have any questions.

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

Burgos, Alexander N

Subject: FW: [External] Board of Pharmacy-August 2026

From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Wednesday, July 22, 2026 11:52 AM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Rules, Oah <oah.rules@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] Board of Pharmacy-August 2026

Dadgummit. I am usually more competent than this. There was a public hearing on the appointed date and time. It was the highlight of my day.

Clint Pinyan

BROOKS PIERCE

t: 336.271.3157
f: 336.232.9157

230 North Elm Street, Suite 2000
Greensboro, NC 27401
P.O. Box 26000 (27420)

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Wednesday, July 22, 2026 11:36 AM
To: Clint Pinyan <CPINYAN@brookspierce.com>; Rules, Oah <oah.rules@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: Re: [External] Board of Pharmacy-August 2026

The revised forms don't list a hearing date. The register says a public hearing was conducted on 5/19/26. Was there a hearing?

Please don't resubmit the forms again.

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

Burgos, Alexander N

From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Wednesday, July 22, 2026 10:52 AM
To: Rules, Oah
Cc: Wiggs, Travis C; Burgos, Alexander N
Subject: [External] Board of Pharmacy-August 2026
Attachments: NCBOP Submission of Permanent Rule for .1616 4919-1806-6365 v.1.docx; NCBOP Submission of Permanent Rule for .1420 4927-7750-5725 v.1.docx; NCBOP Submission of Permanent Rule for .1806 4935-4792-1030 v.3.docx; NCBOP Submission of Permanent Rule for .1822 4917-0841-6701 v.1.docx; NCBOP Submission of Permanent Rule for .2516 4904-2312-4925 v.1.docx; NCBOP Submission of Permanent Rule for .1821 4898-5040-5821 v.1.docx

I have attached revised submission forms for the following rules:

21 NCAC 46 .1420 (adoption)
21 NCAC 46 .1616 (amendment)
21 NCAC 46 .1806 (amendment)
21 NCAC 46 .1821 (amendment)
21 NCAC 46 .1822 (adoption)
21 NCAC 46 .2516 (amendment)

These reflect the correct adoption date of July 14, 2026. I had failed to update that date from our last previous submission.

Please let me know if you have any questions.

Clint Pinyan

BROOKS PIERCE

t: 336.271.3157
f: 336.232.9157

230 North Elm Street, Suite 2000
Greensboro, NC 27401
P.O. Box 26000 (27420)

Confidentiality Notice:

SUBMISSION FOR PERMANENT RULE

1. Rule-Making Agency: North Carolina Board of Pharmacy

2. Rule citation & name (name not required for repeal): 21 NCAC 46 .1420 STANDARDIZED ORDERS

3. Action:
☒ **ADOPTION** ☐ **AMENDMENT** ☐ **REPEAL** ☐ **READOPTION** ☐ **REPEAL through READOPTION**

4. Rule exempt from RRC review?
☐ **Yes. Cite authority:**
☒ **No**

5. Rule automatically subject to legislative review?
☐ **Yes. Cite authority:**
☒ **No**

6. Notice for Proposed Rule:

☒ **Notice Required**
Notice of Text published on: April 15, 2026
Link to Agency notice: https://www.ncbop.org/rulemakings.htm
Hearing on:
☒ **The requirements listed in G.S. 150B-19.1(c)(1)-(5) were posted on the agency's Web site no later than the publication date of the notice of text in the N.C. Register.**
Adoption by Agency on: July 14, 2026
☐ **Notice not required under G.S.:**
Adoption by Agency on:

7. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ **Yes**
Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ **No**

8. Fiscal impact. Check all that apply.

☐ **This Rule was part of a combined analysis.**
☐ **State funds affected**
☐ **Local funds affected**
☐ **Substantial economic impact (≥$1,000,000)**
☐ **Approved by OSBM**
☒ **No fiscal note required**

9. REASON FOR ACTION

9A. What prompted this action? Check all that apply:

☒ **Agency**
☐ **Court order / cite:**
☐ **Federal statute / cite:**
☐ **Federal regulation / cite:**
☐ **Legislation enacted by the General Assembly**
Cite Session Law: SL 2025-37
☐ **Petition for rule-making**
☐ **Other:**

9B. Explain: SEE ATTACHED.

10. Rulemaking Coordinator: Clinton R. Pinyan

Phone: (336) 373-8850
E-Mail: cpinyan@brookspierce.com

Additional agency contact, if any: Jay Campbell

Phone: (919) 246-1050
E-Mail: jcampbell@ncbop;org

11. Signature of Agency Head* or Rule-making Coordinator:

By signing, I have verified that the information contained on this form is true and accurate to the best of my knowledge.

***If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**

Typed Name: Clinton R. Pinyan
Title: General Counsel and Rulemaking Coordinator

RRC AND OAH USE ONLY

Action taken:
☐ RRC extended period of review:
☐ RRC determined substantial changes:
☐ Withdrawn by agency
☐ Subject to Legislative Review
☐ Other:

9B. Explanation of Reason for Action

The Board adopted this rule to accommodate standardized orders in health care pharmacy settings (such as hospitals and long-term care facilities). Standardized orders are ones that allow a health care facility pharmacist-manager to establish criteria for ordering medications that are determined to be safe for all patients meeting those criteria, regardless of any drugs, supplements, or other substances that might have been consumer by those patients. Because of the absence of any relevant distinction among those patients, the medications would be able to be dispensed without patient-specific drug regimen review being performed. This rule was the product of study by a working group that included members from a wide variety of health care pharmacy settings.

SUBMISSION FOR PERMANENT RULE

1. Rule-Making Agency: North Carolina Board of Pharmacy

2. Rule citation & name (name not required for repeal): 21 NCAC 46 .1616 LIMITED SERVICE PERMITS

3. Action:
☐ **ADOPTION** ☒ **AMENDMENT** ☐ **REPEAL** ☐ **READOPTION** ☐ **REPEAL through READOPTION**

4. Rule exempt from RRC review?
☐ **Yes. Cite authority:**
☒ **No**

5. Rule automatically subject to legislative review?
☐ **Yes. Cite authority:**
☒ **No**

6. Notice for Proposed Rule:

☒ **Notice Required**
Notice of Text published on: April 15, 2026
Link to Agency notice: https://www.ncbop.org/rulemakings.htm
Hearing on:
☒ **The requirements listed in G.S. 150B-19.1(c)(1)-(5) were posted on the agency's Web site no later than the publication date of the notice of text in the N.C. Register.**
Adoption by Agency on: July 14, 2026
☐ **Notice not required under G.S.:**
Adoption by Agency on:

7. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ **Yes**
Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ **No**

8. Fiscal impact. Check all that apply.

☐ **This Rule was part of a combined analysis.**
☐ **State funds affected**
☐ **Local funds affected**
☐ **Substantial economic impact (≥$1,000,000)**
☐ **Approved by OSBM**
☒ **No fiscal note required**

9. REASON FOR ACTION

9A. What prompted this action? Check all that apply:

☒ **Agency**
☐ **Court order / cite:**
☐ **Federal statute / cite:**
☐ **Federal regulation / cite:**
☐ **Legislation enacted by the General Assembly**
Cite Session Law: SL 2025-37
☐ **Petition for rule-making**
☐ **Other:**

9B. Explain: SEE ATTACHED.

10. Rulemaking Coordinator: Clinton R. Pinyan

Phone: (336) 373-8850
E-Mail: cpinyan@brookspierce.com

Additional agency contact, if any: Jay Campbell

Phone: (919) 246-1050
E-Mail: jcampbell@ncbop;org

11. Signature of Agency Head* or Rule-making Coordinator:

By signing, I have verified that the information contained on this form is true and accurate to the best of my knowledge.

***If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**

Typed Name: Clinton R. Pinyan
Title: General Counsel and Rulemaking Coordinator

RRC AND OAH USE ONLY

Action taken:
☐ RRC extended period of review:
☐ RRC determined substantial changes:
☐ Withdrawn by agency
☐ Subject to Legislative Review
☐ Other:

d

9B. Explanation of Reason for Action

The Board adopted 21 NCAC 46 .1822 to permit a pharmacy to deliver prescriptions that have been fully filled and labeled for specific patients by having certain pharmacy personnel deliver them at a fixed alternate delivery site. This rule change was originally proposed by a pharmacist as a method of facilitating service to remote locations that cannot support a pharmacy. This method has recently been used successfully in Virginia with no adverse impact to the public health, safety, and welfare. The requirements of the rule largely track the requirements for direct-to-patient locker and kiosk systems (21 NCAC 46 .1821), which the Board adopted in 2023. As a result of notice and comment, the Board increased the time that the pharmacy has to retrieve undelivered drugs from the alternate delivery site, to more closely align to common insurance requirements for returning drugs to stock.

There are conforming changes to (a) the limited service permit rule (21 NCAC 46 .1616) to provide for permitting and inspection of the alternate delivery site; (b) the direct-to-patient delivery system rule (21 NCAC 46 .1821) to acknowledge the new rule; and (c) the pharmacy emergency closure rule (21 NCAC 46 .2516) to provide for delivery of filled prescriptions to a pharmacy's nearby alternate delivery site if the pharmacy is subject to emergency closure, so that patients can have the choice to retrieve drugs during that closure.

SUBMISSION FOR PERMANENT RULE

1. Rule-Making Agency: North Carolina Board of Pharmacy

2. Rule citation & name (name not required for repeal): 21 NCAC 46 .1806 TRANSFER OF PRESCRIPTION INFORMATION

3. Action:
☐ **ADOPTION** ☒ **AMENDMENT** ☐ **REPEAL** ☐ **READOPTION** ☐ **REPEAL through READOPTION**

4. Rule exempt from RRC review?
☐ **Yes. Cite authority:**
☒ **No**

5. Rule automatically subject to legislative review?
☐ **Yes. Cite authority:**
☒ **No**

6. Notice for Proposed Rule:

☒ **Notice Required**
Notice of Text published on: April 15, 2026
Link to Agency notice: https://www.ncbop.org/rulemakings.htm
Hearing on:
☒ **The requirements listed in G.S. 150B-19.1(c)(1)-(5) were posted on the agency's Web site no later than the publication date of the notice of text in the N.C. Register.**
Adoption by Agency on: July 14, 2026
☐ **Notice not required under G.S.:**
Adoption by Agency on:

7. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ **Yes**
Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ **No**

8. Fiscal impact. Check all that apply.

☐ **This Rule was part of a combined analysis.**
☐ **State funds affected**
☐ **Local funds affected**
☐ **Substantial economic impact (≥$1,000,000)**
☐ **Approved by OSBM**
☒ **No fiscal note required**

9. REASON FOR ACTION

9A. What prompted this action? Check all that apply:

☒ **Agency**
☐ **Court order / cite:**
☐ **Federal statute / cite:**
☐ **Federal regulation / cite:**
☐ **Legislation enacted by the General Assembly**
Cite Session Law: SL 2025-37
☐ **Petition for rule-making**
☐ **Other:**

9B. Explain: The Board revised the requirements for transferring prescriptions from one pharmacy to another. The rule was last revised when paper prescriptions predominated, and the requirements were written in that framework. The Board has proposed to update those requirements. The proposed amendment further streamlines the requirements, removing ones that are no longer necessary to protect the public health, safety, and welfare.

10. Rulemaking Coordinator: Clinton R. Pinyan

Phone: (336) 373-8850
E-Mail: cpinyan@brookspierce.com

Additional agency contact, if any: Jay Campbell

Phone: (919) 246-1050
E-Mail: jcampbell@ncbop;org

11. Signature of Agency Head* or Rule-making Coordinator:

By signing, I have verified that the information contained on this form is true and accurate to the best of my knowledge.

***If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**

Typed Name: Clinton R. Pinyan
Title: General Counsel and Rulemaking Coordinator

RRC AND OAH USE ONLY

Action taken:
☐ RRC extended period of review:
☐ RRC determined substantial changes:
☐ Withdrawn by agency
☐ Subject to Legislative Review
☐ Other:

SUBMISSION FOR PERMANENT RULE

1. Rule-Making Agency: North Carolina Board of Pharmacy

2. Rule citation & name (name not required for repeal): 21 NCAC 46 .1821 DIRECT-TO-PATIENT DELIVERY SYSTEMS

3. Action:
☐ **ADOPTION** ☒ **AMENDMENT** ☐ **REPEAL** ☐ **READOPTION** ☐ **REPEAL through READOPTION**

4. Rule exempt from RRC review?
☐ **Yes. Cite authority:**
☒ **No**

5. Rule automatically subject to legislative review?
☐ **Yes. Cite authority:**
☒ **No**

6. Notice for Proposed Rule:

☒ **Notice Required**
Notice of Text published on: April 15, 2026
Link to Agency notice: https://www.ncbop.org/rulemakings.htm
Hearing on:
☒ **The requirements listed in G.S. 150B-19.1(c)(1)-(5) were posted on the agency's Web site no later than the publication date of the notice of text in the N.C. Register.**
Adoption by Agency on: July 14, 2026
☐ **Notice not required under G.S.:**
Adoption by Agency on:

7. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ **Yes**
Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ **No**

8. Fiscal impact. Check all that apply.

☐ **This Rule was part of a combined analysis.**
☐ **State funds affected**
☐ **Local funds affected**
☐ **Substantial economic impact (≥$1,000,000)**
☐ **Approved by OSBM**
☒ **No fiscal note required**

9. REASON FOR ACTION

9A. What prompted this action? Check all that apply:

☒ **Agency**
☐ **Court order / cite:**
☐ **Federal statute / cite:**
☐ **Federal regulation / cite:**
☐ **Legislation enacted by the General Assembly**
Cite Session Law: SL 2025-37
☐ **Petition for rule-making**
☐ **Other:**

9B. Explain: SEE ATTACHED.

10. Rulemaking Coordinator: Clinton R. Pinyan

Phone: (336) 373-8850
E-Mail: cpinyan@brookspierce.com

Additional agency contact, if any: Jay Campbell

Phone: (919) 246-1050
E-Mail: jcampbell@ncbop;org

11. Signature of Agency Head* or Rule-making Coordinator:

By signing, I have verified that the information contained on this form is true and accurate to the best of my knowledge.

***If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**

Typed Name: Clinton R. Pinyan
Title: General Counsel and Rulemaking Coordinator

RRC AND OAH USE ONLY

Action taken:
☐ RRC extended period of review:
☐ RRC determined substantial changes:
☐ Withdrawn by agency
☐ Subject to Legislative Review
☐ Other:

9B. Explanation of Reason for Action

The Board adopted 21 NCAC 46 .1822 to permit a pharmacy to deliver prescriptions that have been fully filled and labeled for specific patients by having certain pharmacy personnel deliver them at a fixed alternate delivery site. This rule change was originally proposed by a pharmacist as a method of facilitating service to remote locations that cannot support a pharmacy. This method has recently been used successfully in Virginia with no adverse impact to the public health, safety, and welfare. The requirements of the rule largely track the requirements for direct-to-patient locker and kiosk systems (21 NCAC 46 .1821), which the Board adopted in 2023. As a result of notice and comment, the Board increased the time that the pharmacy has to retrieve undelivered drugs from the alternate delivery site, to more closely align to common insurance requirements for returning drugs to stock.

There are conforming changes to (a) the limited service permit rule (21 NCAC 46 .1616) to provide for permitting and inspection of the alternate delivery site; (b) the direct-to-patient delivery system rule (21 NCAC 46 .1821) to acknowledge the new rule; and (c) the pharmacy emergency closure rule (21 NCAC 46 .2516) to provide for delivery of filled prescriptions to a pharmacy's nearby alternate delivery site if the pharmacy is subject to emergency closure, so that patients can have the choice to retrieve drugs during that closure.

SUBMISSION FOR PERMANENT RULE

1. Rule-Making Agency: North Carolina Board of Pharmacy

2. Rule citation & name (name not required for repeal): 21 NCAC 46 .1822 ALERTNATE DELIVERY SITES

3. Action:
☒ **ADOPTION** ☐ **AMENDMENT** ☐ **REPEAL** ☐ **READOPTION** ☐ **REPEAL through READOPTION**

4. Rule exempt from RRC review?
☐ **Yes. Cite authority:**
☒ **No**

5. Rule automatically subject to legislative review?
☐ **Yes. Cite authority:**
☒ **No**

6. Notice for Proposed Rule:

☒ **Notice Required**
Notice of Text published on: April 15, 2026
Link to Agency notice: https://www.ncbop.org/rulemakings.htm
Hearing on:
☒ **The requirements listed in G.S. 150B-19.1(c)(1)-(5) were posted on the agency's Web site no later than the publication date of the notice of text in the N.C. Register.**
Adoption by Agency on: July 14, 2026
☐ **Notice not required under G.S.:**
Adoption by Agency on:

7. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ **Yes**
Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ **No**

8. Fiscal impact. Check all that apply.

☐ **This Rule was part of a combined analysis.**
☐ **State funds affected**
☐ **Local funds affected**
☐ **Substantial economic impact (≥$1,000,000)**
☐ **Approved by OSBM**
☒ **No fiscal note required**

9. REASON FOR ACTION

9A. What prompted this action? Check all that apply:

☒ **Agency**
☐ **Court order / cite:**
☐ **Federal statute / cite:**
☐ **Federal regulation / cite:**
☐ **Legislation enacted by the General Assembly**
Cite Session Law: SL 2025-37
☐ **Petition for rule-making**
☐ **Other:**

9B. Explain: SEE ATTACHED.

10. Rulemaking Coordinator: Clinton R. Pinyan

Phone: (336) 373-8850
E-Mail: cpinyan@brookspierce.com

Additional agency contact, if any: Jay Campbell

Phone: (919) 246-1050
E-Mail: jcampbell@ncbop;org

11. Signature of Agency Head* or Rule-making Coordinator:

By signing, I have verified that the information contained on this form is true and accurate to the best of my knowledge.

***If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**

Typed Name: Clinton R. Pinyan
Title: General Counsel and Rulemaking Coordinator

RRC AND OAH USE ONLY

Action taken:
☐ RRC extended period of review:
☐ RRC determined substantial changes:
☐ Withdrawn by agency
☐ Subject to Legislative Review
☐ Other:

9B. Explanation of Reason for Action

The Board adopted 21 NCAC 46 .1822 to permit a pharmacy to deliver prescriptions that have been fully filled and labeled for specific patients by having certain pharmacy personnel deliver them at a fixed alternate delivery site. This rule change was originally proposed by a pharmacist as a method of facilitating service to remote locations that cannot support a pharmacy. This method has recently been used successfully in Virginia with no adverse impact to the public health, safety, and welfare. The requirements of the rule largely track the requirements for direct-to-patient locker and kiosk systems (21 NCAC 46 .1821), which the Board adopted in 2023. As a result of notice and comment, the Board increased the time that the pharmacy has to retrieve undelivered drugs from the alternate delivery site, to relieve the burden on the regulated persons and more closely align to common insurance requirements for returning drugs to stock.

There are conforming changes to (a) the limited service permit rule (21 NCAC 46 .1616) to provide for permitting and inspection of the alternate delivery site; (b) the direct-to-patient delivery system rule (21 NCAC 46 .1821) to acknowledge the new rule; and (c) the pharmacy emergency closure rule (21 NCAC 46 .2516) to provide for delivery of filled prescriptions to a pharmacy's nearby alternate delivery site if the pharmacy is subject to emergency closure, so that patients can have the choice to retrieve drugs during that closure.

SUBMISSION FOR PERMANENT RULE

1. Rule-Making Agency: North Carolina Board of Pharmacy

2. Rule citation & name (name not required for repeal): 21 NCAC 46 .2516 EMERGENCY CLOSURE

3. Action:
☐ **ADOPTION** ☒ **AMENDMENT** ☐ **REPEAL** ☐ **READOPTION** ☐ **REPEAL through READOPTION**

4. Rule exempt from RRC review?
☐ **Yes. Cite authority:**
☒ **No**

5. Rule automatically subject to legislative review?
☐ **Yes. Cite authority:**
☒ **No**

6. Notice for Proposed Rule:

☒ **Notice Required**
Notice of Text published on: April 15, 2026
Link to Agency notice: https://www.ncbop.org/rulemakings.htm
Hearing on:
☒ **The requirements listed in G.S. 150B-19.1(c)(1)-(5) were posted on the agency's Web site no later than the publication date of the notice of text in the N.C. Register.**
Adoption by Agency on: July 14, 2026
☐ **Notice not required under G.S.:**
Adoption by Agency on:

7. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ **Yes**
Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ **No**

8. Fiscal impact. Check all that apply.

☐ **This Rule was part of a combined analysis.**
☐ **State funds affected**
☐ **Local funds affected**
☐ **Substantial economic impact (≥$1,000,000)**
☐ **Approved by OSBM**
☒ **No fiscal note required**

9. REASON FOR ACTION

9A. What prompted this action? Check all that apply:

☒ **Agency**
☐ **Court order / cite:**
☐ **Federal statute / cite:**
☐ **Federal regulation / cite:**
☐ **Legislation enacted by the General Assembly**
Cite Session Law: SL 2025-37
☐ **Petition for rule-making**
☐ **Other:**

9B. Explain: SEE ATTACHED.

10. Rulemaking Coordinator: Clinton R. Pinyan

Phone: (336) 373-8850
E-Mail: cpinyan@brookspierce.com

Additional agency contact, if any: Jay Campbell

Phone: (919) 246-1050
E-Mail: jcampbell@ncbop;org

11. Signature of Agency Head* or Rule-making Coordinator:

By signing, I have verified that the information contained on this form is true and accurate to the best of my knowledge.

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Burgos, Alexander N

From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Wednesday, July 22, 2026 10:39 AM
To: Wiggs, Travis C
Cc: Burgos, Alexander N
Subject: [External] RE: Board of Pharmacy-August 2026

Good catch. No. I just failed to change that on the form when I was revising from the last form. I'll resubmit them.

Clint Pinyan

BROOKS PIERCE

t: 336.271.3157
f: 336.232.9157

230 North Elm Street, Suite 2000
Greensboro, NC 27401
P.O. Box 26000 (27420)

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Wednesday, July 22, 2026 10:28 AM
To: Clint Pinyan <CPINYAN@brookspierce.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: Board of Pharmacy-August 2026

Good morning,

I've been assigned to review the rules submitted by the BOP for review in August. Form 0400 accompanying each rule lists an adoption date of May 19, 2026. Is this date correct?

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov
