

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

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

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

10 (3) For limited service permits described in Subparagraphs ~~(a)(7), (8), and (9)~~ ~~(a)(6), (7) and (8)~~ of this
11 Rule, either the pharmacist-manager or the assistant pharmacist-manager employed or otherwise
12 engaged to supply pharmaceutical services may have a flexible schedule of attendance but shall be
13 present for **at least** one-half of the hours the pharmacy is open or 20 hours a week, whichever is less.
14 For the limited service permits described in Subparagraphs ~~(a)(7) and (8)~~ ~~(a)(5) and (6)~~ of this Rule,
15 a licensed pharmacist shall be present when the pharmacy is open as described in Rule .2502(e) of
16 this Chapter. For the limited service permits described in Subparagraph ~~(a)(9)~~ ~~(a)(7)~~ of this Rule,
17 the location holding the limited service permit may operate in the absence of a pharmacist only as
18 set out in Rule .1413 of this Chapter.

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

26 (d) A person may serve as the pharmacist-manager or the assistant pharmacist-manager for multiple limited service
27 permits, and may do so while also serving as the pharmacist-manager for a maximum of one permit other than a
28 limited service permit. A person serving multiple limited service permit locations **shall must** fulfill all of that person's
29 duties under State and federal law as to each location.

30 (e) Except as expressly set forth in this Rule, the pharmacist-manager **shall must** provide oversight and supervision
31 as provided elsewhere in this Chapter.

32
33 *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;*

34 *Eff. November 1, 2021;*

35 *Amended Eff. September 1, 2023; 2023; September 1, 2026.*

21 NCAC 46 .1806 is amended as published in 40:20 NCR 1612 as follows:

21 NCAC 46 .1806 TRANSFER OF PRESCRIPTIONS ~~PRESCRIPTION INFORMATION~~

(a) ~~The transfer of original prescription information for the purpose of refill dispensing~~ Transferring prescriptions between pharmacies is permissible ~~between pharmacies~~ subject to the following requirements:

- (1) the transfer is communicated directly from either a pharmacist or certified technician to either a pharmacist or certified technician and not by only one pharmacist or certified technician gaining access to an information file containing data for ~~several locations~~, another pharmacy, unless ~~all locations accessed both pharmacies~~ are under common ownership or ~~accessed~~ the transfer is performed pursuant to contractual agreement of the pharmacies;
- (2) the transferring pharmacist or certified technician deactivates the original prescription; invalidates the prescription and any remaining refills at the transferring pharmacy by marking the word "void" on the face of the prescription or its equivalent;
- (3) the transferring pharmacist or certified technician records; records the name and address of the pharmacy to which it was transferred and the name of the pharmacist or certified technician receiving the prescription information on the reverse of the invalidated prescription;
 - (A) the date of the transfer;
 - (B) the identity of the pharmacist or certified technician transferring the prescription; and
 - (C) the identity of the pharmacy to which the prescription was transferred and the identity of the pharmacist or certified technician receiving it; and
- (4) ~~the transferring pharmacist or certified technician records the date of the transfer and the name of the pharmacist or certified technician transferring the information.~~ the pharmacist or certified technician receiving the transferred prescription records:
 - (A) the date of the original prescription, and the original prescription number;
 - (B) the number of refills authorized and remaining on the prescription;
 - (C) the date of the last fill or refill (if any);
 - (D) the manufacturer or brand of the drug previously dispensed, if the drug is a narrow therapeutic index drug under G.S. 90-85.27;
 - (E) the date of the transfer; and
 - (F) the identity of the pharmacy from which the prescription information was transferred, and the identity of the pharmacist or certified technician transferring the prescription.

(b) ~~The pharmacist or certified technician receiving the transferred prescription information shall reduce to writing the following:~~

- (1) ~~The word "transfer" on the face of the transferred prescription;~~
- (2) ~~All information required to be on a prescription, including:~~
 - (A) ~~Date of issuance of original prescription;~~
 - (B) ~~Number of refills authorized on original prescription;~~

1 ~~(C) — Date and time of transfer;~~

2 ~~(D) — Number of valid refills remaining and date of last refill;~~

3 ~~(E) — Pharmacy's name, address and original prescription number from which the prescription~~
4 ~~information was transferred;~~

5 ~~(F) — Name of transferring pharmacist or certified technician; and~~

6 ~~(G) — Manufacturer or brand of drug dispensed.~~

7 ~~(c) The transferred prescription, as well as the original, must be maintained for a period of three years from the date~~
8 ~~of last refill.~~

9 ~~(d) Dispensing is permitted only within the original authorization for refills and no dispensing on such transfer shall~~
10 ~~occur beyond that authorized on the original prescription. Any dispensing beyond that originally authorized or one~~
11 ~~year, whichever is less, may occur only on a new prescription.~~

12 ~~(e) The requirements of Paragraphs (a) and (b) of this Rule may be facilitated by use of a computer or data system~~
13 ~~without reference to an original prescription document. The system must be able to identify transferred prescriptions~~
14 ~~and prevent subsequent prescription refills at that pharmacy.~~

15 ~~(f) This Rule applies to the transfer of prescriptions issued by prescribers in other states, provided that the~~
16 ~~pharmacist or certified technician receiving the prescription actually knows or reasonably should know that a~~
17 ~~physician-patient relationship exists and dispensing the drug is in the patient's best interests.~~

18 ~~(g) All records pertinent to this Rule shall be readily retrievable.~~

19 ~~(h) A system must be in place that will allow only authorized access by a pharmacist or certified technician to all~~
20 ~~records pertinent to this Rule and will indicate on the prescription record when and by whom such access was made.~~

21 ~~(i) The transfer of original prescription information for the purpose of refill dispensing. Transferring prescriptions~~
22 ~~between device and medical equipment permit holders is permissible ~~between device and medical equipment permit~~~~
23 ~~~~holders~~ so long as the transferring permit holder provides all records and documentation necessary for dispensing~~
24 ~~and does not interfere with the service and claims processing procedures of the receiving permit holder.~~

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26 *History Note: Authority G.S. 90-85.6(a); 90-85.32;*

27 *Eff. December 31, 1985;*

28 *Amended Eff. June 1, 2004; September 1, 1995; July 1, 1992; May 1, 1989;*

29 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*
30 *~~2017.~~ 2017;*

31 *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.

- 1 (15) ~~The labels of any~~ Prescription drugs, devices, and medical equipment ~~dispensed delivered~~ from a
2 DTP system shall be labeled for the individual patient and contain all information required by law,
3 including but not limited to having the dispensing pharmacist identified on the label.
- 4 (16) The home pharmacy shall create and maintain records of dispensing for any prescription drugs,
5 devices, and medical equipment ~~delivered by dispensed in~~ a DTP system in compliance with State
6 and federal law. Any A kiosk shall be connected to the home pharmacy's automated data processing
7 system, and any prescription drugs, devices, or medical equipment ~~delivered dispensed~~ from any a
8 locker shall be recorded in the home pharmacy's recordkeeping system. The recordkeeping system
9 shall be capable of producing a record of all prescription drugs, devices, and medical equipment
10 dispensed from the DTP system.
- 11 (17) The DTP system shall have a means to identify each a patient (or that patient's authorized agent)
12 and release only that patient's prescription drugs, devices, or medical equipment to the patient (or
13 the patient's authorized agent).
- 14 (18) The DTP system shall convey the home pharmacy's offer to counsel a patient as required by Rule
15 .2504 of this Chapter and shall provide the ability for the patient to have an immediate real-time
16 consultation with a pharmacist licensed by this Board and employed by the home pharmacy who
17 has access to all of the home pharmacy's information related to the patient. The communication link
18 shall protect the confidentiality of the patient's information. The home pharmacy shall check the
19 communication link at least daily and the DTP system shall be closed if the link malfunctions or if
20 a licensed pharmacist is not available from the home pharmacy for counseling, unless a licensed
21 pharmacist is physically present at the DTP system. A pharmacist who is responsible for counseling
22 may not provide that service for more than three sites simultaneously. ~~In the event that If~~ the DTP
23 system is placed in the same physical space as the dispensing area of the home pharmacy, this
24 provision may be satisfied ~~when during the time that~~ the pharmacy is open by informing the patient
25 how to receive counseling from a pharmacist in the home pharmacy. If the dispensing pharmacist
26 has determined that the patient should receive counseling before the prescription drug, device, or
27 medical equipment is ~~delivered, dispensed,~~ the DTP system shall provide the ability for the
28 pharmacist to force counseling before the DTP system ~~delivers dispenses~~ the drug, device, or
29 medical equipment.
- 30 (19) The home pharmacy shall record and review any incident involving a complaint, delivery error, or
31 omission regarding a DTP system as part of the home pharmacy's quality assurance program.
- 32 (20) Drugs, devices, or medical equipment that are not picked up by a patient may be returned to stock
33 under the same conditions as if the item had been maintained in the pharmacy, as long as the
34 requirements of this Rule for operating the DTP system have been followed.
- 35 (d) With respect to prescription drugs, devices, or medical equipment dispensed through a kiosk, the following
36 additional requirements shall be met:

- 1 (1) The dispensing pharmacist shall electronically compare via video link the stock bottle, prescription
2 drug dispensed, the strength, and the beyond-use date. The dispensing pharmacist shall verify the
3 entire label for accuracy on the video link.
- 4 (2) The kiosk shall use utilize a barcode system that prints the barcode of the stock bottle or other
5 packaging on the label of the dispensed prescription drug, device, or medical equipment. If the stock
6 bottle or other packaging does not have a barcode, the home pharmacy shall create one. Pharmacy
7 personnel shall scan both the stock bottle or other packaging and the label of the dispensed
8 prescription drug, device, or medical equipment to verify that the item dispensed is the same as the
9 one in the stock bottle or other packaging for each prescription drug, device, or medical equipment
10 dispensed.
- 11 (3) Drugs, Prescription drugs, devices, or medical equipment dispensed by the kiosk shall be packaged
12 only by a licensed manufacturer or repackager, or prepackaged by the home pharmacy in compliance
13 with the Pharmacy Practice Act, Article 4A of Chapter 90 of the General Statutes, Act and this
14 Chapter.
- 15 (4) The home pharmacy shall keep a perpetual inventory of controlled substances that are received and
16 dispensed from each a kiosk.
- 17 (5) The home pharmacy shall not dispense compounded medications through a kiosk.
- 18 (6) The kiosk shall not accept returns of drugs, devices and medical equipment from patients.
- 19 (e) This Rule does not alter the method by which patients or providers shall transmit prescription orders prescriptions
20 to the home pharmacy. Prescriptions Prescription orders may not be collected by the home pharmacy through the DTP
21 system.

22
23 *History Note: Authority G.S. 90-85.6; 90-85.15A; 90-85.21; 90-85.32;*
24 *Eff. September 1, 2023. 2023;*
25 *Amended Eff. September 1, 2026.*

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.

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

- 2 (1) At the alternate delivery site, a pharmacist or a certified technician employed by the pharmacy may
3 personally deliver any drug, device, or medical equipment to the patient or the patient's agent, after
4 that drug, ~~device, device~~ or medical equipment has been previously dispensed by the pharmacy. All
5 physical steps in the dispensing process (other than delivery to the patient) must occur at the
6 pharmacy, ~~including including~~, but not limited ~~to, to~~ filling and patient-specific labeling. No drugs,
7 ~~devices, devices~~ or medical equipment may be maintained at the alternate delivery site, other than
8 completed patient-specific labeled and previously dispensed drugs, devices, or medical equipment
9 that have been transported from the pharmacy to the alternate delivery site to be delivered.
- 10 (2) At the alternate delivery site, a pharmacist or certified pharmacy technician who is an employee of
11 the pharmacy may personally accept a written prescription from the patient or the patient's agent,
12 so long as the prescription is then transmitted to the pharmacy so that all physical steps in the
13 dispensing process may take place in the pharmacy. Patients or their agents may not leave
14 prescriptions at the alternate delivery site, other than by personally delivering them to the pharmacist
15 or certified pharmacy technician.

16 (f) Requirements for Use of Alternate Delivery Site.

- 17 (1) Before a pharmacy delivers drugs, devices, or medical equipment to a patient at an alternate delivery
18 site, the pharmacy shall secure the affirmative consent of the patient to use the alternate delivery
19 site. The pharmacy shall not require patients to pick up their prescriptions from an alternate delivery
20 site, rather than at the pharmacy or through delivery mechanisms otherwise available at the
21 pharmacy.
- 22 (2) To ensure appropriate coordination of patient care, the pharmacy shall notify the alternate delivery
23 site of the anticipated arrival time of the transportation of the drug, device, or medical equipment to
24 the alternate delivery site, the name of the patient for whom the drug, device or medical equipment
25 was dispensed, and any special storage requirements.
- 26 (3) The hours of the alternate delivery site shall be reported to the Board, and the alternate delivery site
27 shall be open during the hours that have been reported to the Board. Emergency closure of the
28 alternate delivery site shall require the pharmacist-manager of the pharmacy to follow the
29 procedures in Rule .2516 of this Chapter.
- 30 (4) The pharmacist or certified pharmacy technician at the alternate delivery site shall convey the
31 pharmacy's offer to counsel a patient as required by Rule .2504 of this Chapter and shall provide the
32 ability for the patient to have an immediate real-time consultation with a pharmacist licensed by this
33 Board and employed by the pharmacy who has access to all of the pharmacy's information related
34 to the patient. The communication link shall protect the confidentiality of the patient's information.
35 A pharmacist who is responsible for counseling may not provide that service for more than three
36 limited service permits simultaneously. A certified pharmacy technician staffing an alternate
37 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.

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

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

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

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

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

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

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

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

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

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

25 (9) Assuring confidentiality of patient information.

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

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

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

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

33
34 *History Note: Authority G.S. 90-85.6; 90-85.15A; 90-85-21; 90-85.21A; 90-85.26;*
35 *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~~

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

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

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

- 8 (1) Permanent closures or temporary closures lasting more than 14 consecutive days, which are instead
9 governed by the provisions of Rule .2502(h) and (i) of this Section;
- 10 (2) Pharmacies located outside the State of North Carolina, which should follow any closure rules of
11 their home states; or
- 12 (3) During the duration of time when the Governor or any county or municipality has declared a state
13 of emergency in the pharmacy's location pursuant to Chapter 166A of the North Carolina General
14 Statutes.

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

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