

1 21 NCAC 46 .1616 is amended **with changes** as published in 37:20 NCR 2030-34 as follows:

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**21 NCAC 46 .1616 LIMITED SERVICE PERMITS**

(a) The following pharmacy practice locations are eligible to apply for "limited service ~~permits~~ **permits,**" which are **pharmacy locations** whose operations are modified by the provisions set forth **in subparagraphs (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;
- ~~(3)~~(4) facilities where drugs are dispensed only by nurse practitioners or physician assistants pursuant to Section .1700 of this Chapter;
- ~~(4)~~(5) county health departments or other governmental entities providing local health services under G.S. 130A-34 where drugs are dispensed only by registered nurses and only pursuant to G.S. 90-85.34A and Section .2400 of this Chapter;
- ~~(5)~~(6) county health departments or other governmental entities providing local health services under G.S. 130A-34 that engage in dispensing beyond that set out in G.S. 90-85.34A and Section .2400 of this Chapter;
- ~~(6)~~(7) free clinics, as defined in G.S. 90-85.44(a)(6); or
- ~~(7)~~(8) critical access hospitals, as defined in G.S. 131E-76.

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

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

- (1) For limited service permits described in Subparagraphs ~~(a)(1) and (a)(1)~~, (2) and (3) of this Rule, either the pharmacist-manager or the assistant pharmacist-manager **must 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), and (3), them, and ensure that the  
3 location holding the permit is permits are operated in compliance with all applicable State and  
4 federal laws.

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

11 (3) For limited service permits described in Subparagraphs (a)(5), (6), and (a)(6), (7) and (8) of this  
12 Rule, either the pharmacist-manager or the assistant pharmacist-manager employed or otherwise  
13 engaged to supply pharmaceutical services may have a flexible schedule of attendance but shall be  
14 present for at least one-half of the hours the pharmacy is open or 20 hours a week, whichever is less.  
15 For the limited service permits described in Subparagraphs (a)(5) and (6) of this Rule, a licensed  
16 pharmacist must shall be present when the pharmacy is open as described in Rule .2502(e) of this  
17 Chapter. For the limited service permits described in Subparagraph (a)(7) of this Rule, the location  
18 holding the limited service permit may operate in the absence of a pharmacist only as set out in Rule  
19 .1413 of this Chapter.

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

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

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

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36 *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;*  
37 *Eff. November 1, 2021; 2021.*



1 21 NCAC 46 .1821 is adopted **with changes** as proposed in 37:20 NCR 2030-34 as follows:

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3 **21 NCAC 46 .1821 DIRECT-TO-PATIENT DELIVERY SYSTEMS**

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

6 (b) Definitions.

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

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

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

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

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

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

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

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

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

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

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

33 (2) The home pharmacy **must shall** notify the Board, in writing, **through the home pharmacy's online**  
34 **permit portal**, prior to **beginning to use using** any DTP system, including the **address and**  
35 **geographical coordinates location** of the DTP system and the licensed pharmacist(s) responsible for  
36 the DTP system. The home pharmacy **must shall** notify the Board prior to moving the DTP system  
37 and **must shall** secure a new limited service permit, if one is required by Subparagraph (c)(1) of this

1 Rule, before operating the DTP system in the new location. The home pharmacy must shall notify  
2 the Board within 10 days after discontinuing the patient use of any DTP system.

3 (3) A DTP system shall be used exclusively by The the home pharmacy. pharmacy shall own or  
4 otherwise have the legal right to sole use of the DTP system.

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

7 (5) A DTP system may be placed in the office of a prescriber only if the DTP system is under the  
8 ownership and control of the home pharmacy, which is responsible for compliance with all laws  
9 regarding the DTP system. The home pharmacy shall maintain the DTP system in the prescriber's  
10 office only if the prescriber must offer offers patients a choice of pharmacy. pharmacy, and neither  
11 the The home pharmacy shall not give compensation to or receive compensation from not the  
12 prescriber may compensate the other for the placement of the DTP system or for any prescriptions  
13 filled by the DTP system.

14 (6) The home pharmacy shall DTP system must be secured to prohibit access to the DTP system and  
15 its contents by unauthorized personnel and to maintain confidentiality of patient information. The  
16 DTP system must shall be under the continuous supervision of a pharmacist employed by the home  
17 pharmacy, which may be satisfied by real-time remote supervision of the pharmacy through video  
18 and audio connections. pharmacy. To qualify as continuous supervision, the pharmacist is not  
19 required to be physically present at the site of the DTP system if the pharmacist electronically  
20 supervises the DTP system.

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

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

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

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

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

35 (C) Maintaining any drugs, devices, and medical equipment at temperatures, humidities and  
36 other environmental conditions to ensure that they do not become adulterated under G.S.

1 106-133 and to ensure that they are transported and stored in accordance with  
2 manufacturer's specifications, if any, for those items.

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

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

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

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

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

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

22 (11) Only pharmacy personnel who are licensed with this Board as pharmacists or registered with this  
23 Board as technicians or pharmacy interns may stock drugs, Drugs, devices, and medical equipment  
24 may be stocked in, or removed from, a DTP system in North Carolina only by pharmacy personnel  
25 who are licensed with this Board as pharmacists or registered with this Board as technicians or  
26 pharmacy interns in, or remove drugs, devices, and medical equipment from the inventory of a DTP  
27 system. The home pharmacy ~~must shall~~ maintain records of any access to the DTP system by  
28 pharmacy personnel stocking or otherwise accessing the DTP system.

29 (12) Before a home pharmacy dispenses drugs, devices and medical equipment to a patient through a  
30 DTP system, the home pharmacy shall secure the affirmative consent of the patient to use the DTP  
31 system. The home pharmacy may use DTP system only with prior approval of the patient.

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

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

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

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

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

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

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

15 (4) The home pharmacy shall keep a perpetual inventory of controlled substances that are received and  
16 dispensed from each 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 **may shall** transmit prescriptions to the home  
20 pharmacy. Prescriptions may not be collected by the home pharmacy through the DTP system.

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