

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

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

(b) Definitions.

- (1) "Direct to patient system" or "DTP system" means any delivery system through which a pharmacy dispenses drugs, devices or medical equipment to a patient through any means other than:
 - (A) in-person dispensing to a patient by pharmacy personnel inside a pharmacy,
 - (B) in-person dispensing by delivery to a patient's residence or to a health care provider treating that patient,
 - (C) shipping through common carrier to a patient or to a health care provider treating that patient, or
 - (D) the use of an automated dispensing device by a health care facility pharmacy that is governed by Rule .1419 of this Chapter.

Except as provided in this Rule or one of the exceptions set out 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 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 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 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 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 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 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 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.
 - (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 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.