

GUIDANCE TO RULES GOVERNING DIRECT-TO-PATIENT DISPENSING SYSTEMS

[Board Rule 1821](#) authorizes and governs the use of direct-to-patient dispensing (DTP) systems in North Carolina. This FAQ guidance details applicable rules and standards, as well as provides step-by-step instructions on how to obtain a limited-service permit to operate a DTP system not located on the site of an existing pharmacy. Pharmacists who operate DTP systems should also read and understand the full text of the rule itself.

* * *

Q. What is a direct-to-patient dispensing (DTP) system?

A. The rule divides DTP systems into two categories:

(1) A “locker” system, which is a secure container in which pharmacy personnel place labeled patient-specific drugs, devices, or medical equipment to be picked up by the patient.

(2) A “kiosk” system, which is an automated system capable of filling, labeling, and dispensing drugs, devices, and medical equipment to a patient.

DTP system does not include in-person dispensing inside a pharmacy, in-person dispensing by delivery to a patient’s residence or treating provider, shipping through a common carrier to a patient or treating provider, or the use of an automated dispensing device in a health care facility pharmacy in accordance with [Board Rule 1419](#).

Q. I plan to deploy a DTP system on-site at my existing pharmacy. Do I need a separate permit?

A. No. An existing pharmacy permit may deploy a DTP system on-site without acquiring a separate permit. The pharmacy must update its pharmacy services by logging in to the permit through the [Board's Licensure Gateway](#). Step-by-step instructions for performing this update are found below.

The pharmacy must notify the Board within ten (10) days of discontinuing use of a DTP system by logging in to the permit through the [Board's Licensure Gateway](#) and updating the home pharmacy’s services.

Q. I plan to deploy a DTP system off-site from my existing pharmacy. Do I need a separate permit?

A. Yes. If a DTP system will be deployed at a location other than the home pharmacy’s permitted facility, a separate, limited-service permit (LSP) must be obtained. The application process includes identifying the home pharmacy and pharmacist with

responsibility for the off-site DTP system.

The home pharmacy must notify the Board within ten (10) days of discontinuing use of a DTP system by logging in to the permit through the [Board's Licensure Gateway](#) and updating the home pharmacy's services.

If the home pharmacy wishes to relocate a DTP system to another off-site location, it must secure a new LSP for the new site prior to relocation.

Step-by-step instructions for obtaining a DTP system LSP are found below.

General guidance on LSP requirements is found [here](#).

Q. What physical requirements apply to all DTP systems?

A. The following requirements apply to all DTP systems, whether deployed on-site at the home pharmacy or whether deployed off-site of the home pharmacy under a separate LSP:

- (1) A DTP system may only be used by the home pharmacy. Multiple pharmacies may not share a DTP system.
- (2) The home pharmacy shall prohibit access to the DTP system by unauthorized personnel and maintain patient information confidentiality.
- (3) The DTP system shall have a means to identify each patient (or patient's authorized agent) and release only that patient's prescription drugs, devices, or medical equipment to the patient (or patient's authorized agent).
- (4) The DTP system shall convey the home pharmacy's offer to counsel as required by [Board Rule 2504](#). The DTP system shall have the ability to provide the patient with immediate, real-time audio and video consultation with a pharmacist employed by the home pharmacy. The home pharmacy must check the communication link at least daily, and the DTP system must be closed if the link is malfunctioning or a home pharmacy pharmacist is not available to counsel a patient.
- (5) The DTP system shall be under the continuous supervision of a pharmacist employed by the home pharmacy, and this requirement may be satisfied by real-time remote supervision of the system through video and audio connection.
- (6) The DTP system shall display the home pharmacy's name, address, phone number, North Carolina pharmacy permit number, and name of the home pharmacy's pharmacist-manager.
- (7) 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. The home pharmacy shall maintain these recordings for a minimum of 90 days.

(8) The home pharmacy shall develop, maintain, and update at least annually a policy and procedure manual that, at a minimum, covers each topic listed in [Board Rule 1821\(c\)\(9\)](#). These topics include security of the DTP system; determining which drugs, devices, and medical equipment may be dispensed from the DTP system; ensuring that drugs, devices, and medical equipment placed a DTP system are maintained in conditions that prevent adulteration; removal of outdated drugs, devices, and medical equipment; assignment and training of pharmacy personnel who will maintain the DTP system; educating patients on how to use the DTP system – including instructions on what to do if the DTP system is not functioning; and inspecting the DTP system.

(9) The labels of any drugs, devices, or medical equipment dispensed by a DTP system shall be labeled for the individual patient and include all information required by law, including the identification of the dispensing pharmacist.

(10) The home pharmacy shall create and maintain all dispensing records required by State and Federal law. A kiosk-based DTP system must be connected to the home pharmacy's automated data processing system, and all products dispensed from the DTP system (locker or kiosk) must be recorded in the home pharmacy's recordkeeping system. The home pharmacy's recordkeeping system must be capable of producing a record of all items dispensed from the DTP system.

Q: What physical requirements apply to a DTP system deployed off-site by the home pharmacy?

A: In addition to the general requirements governing DTP systems, the following requirements apply to a DTP system that is deployed off-site by the home pharmacy:

(1) The DTP system shall be located 60 miles or fewer from the home pharmacy via the shortest available street route.

(2) A DTP system may be placed in the office of a prescriber: (a) only if the system is under the control of the home pharmacy, which is responsible with all legal compliance; (b) only if the prescriber offers patients a choice of pharmacy; and (c) the home pharmacy neither gives to nor receives from the prescriber compensation for the placement of the DTP system or for any prescriptions filled by the DTP system.

Q: What requirements apply specifically to a kiosk-based DTP system?

A: In addition to the general requirements governing DTP systems (on- and off-site), a kiosk-based DTP system:

(1) May only dispense to a patient after the dispensing pharmacist has electronically compared via video link the stock bottle, drug dispensed, strength, and beyond-use date, as well as verified the entire prescription label for accuracy.

(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 lacks 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 to verify that the dispensed item is the same as the one in the stock bottle or other packaging.

(3) Must be connected in real time to the home pharmacy's automated data processing system.

(4) Drugs, devices, or medical equipment dispensed by the kiosk shall be packaged only by a licensed manufacturer or repackager, or pre-packed by the home pharmacy in compliance with the Pharmacy Practice Act.

(5) Must maintain a perpetual inventory of controlled substances received and dispensed from the kiosk.

(6) Shall not dispense compounded drug products.

(7) Shall not accept returns of drugs, devices, or medical equipment from patients.

Q: What requirements apply to pharmacy personnel who are involved in DTP system operation?

A: All pharmacy personnel who are involved with the operation and maintenance of a DTP system located in North Carolina must be licensed as pharmacists in North Carolina, registered as technicians in North Carolina, or registered as interns in North Carolina, as appropriate.

The dispensing pharmacist on any product provided to a patient via a DTP system located in North Carolina must hold a North Carolina license to practice pharmacy.

Q: What requirements apply to products dispensed from a DTP system?

A: (1) The home pharmacy and responsible pharmacist(s) must ensure that any drug, device, or medical equipment placed in the DTP system is stored in conditions under which the products will not become adulterated.

(2) Controlled substances may be dispensed by a DTP system as long as doing so complies with all North Carolina and federal Controlled Substance Act requirements.

For off-site DTP systems, the home pharmacist must obtain, if and as required by federal law, a DEA registration.

(3) Compounded medications may not be dispensed from a kiosk-based DTP system. Compounded medications may be dispensed from a locker-based DTP system.

Q: What requirements apply to the DTP system dispensing process?

A: (1) Before a home pharmacy dispensed a product to a patient through a DTP system, the pharmacy must obtain the patient's affirmative consent to use of the DTP system.

(2) The home pharmacy must: orient patients on use of the DTP system; notify patients when expected drugs, devices, or medical equipment are not available in the DTP system or when the DTP system is not functioning; and provide timely, alternate dispensing methods when the DTP system is not functional.

(3) The DTP system rule does not alter the methods by which patients or providers transmit prescriptions to the home pharmacy. The home pharmacy may not collect prescriptions through the DTP system.

(4) If controlled substances are dispensed from the DTP system, the home pharmacy must comply with the photo identification requirements of [GS § 90-106.1](#) when dispensing Schedule II medications and visually confirm that the person seeking the dispensation is the same as the person on the photo identification provided.

(5) The dispensing pharmacist at the home pharmacy must verify each prescription, conduct a DUR, and otherwise assure that the product may be safely dispensed to the patient.

(6) The DTP system shall convey the home pharmacy's offer to counsel as required by [Board Rule 2504](#). The DTP system shall have the ability to provide the patient with immediate, real-time audio and video consultation with a pharmacist employed by the home pharmacy. If the DTP system is located on-site at the home pharmacy and the pharmacy is open, the counseling requirements may be satisfied by informing the patient how to receive counseling from an on-site pharmacist.

(7) If the dispensing pharmacist has determined that the patient must receive counseling before the prescription is dispensed, the DTP system must provide the ability for the pharmacist to force counseling before the DTP system dispenses.

(8) A pharmacist responsible for providing counseling through a DTP system may not provide that service for more than three (3) DTP system sites simultaneously.

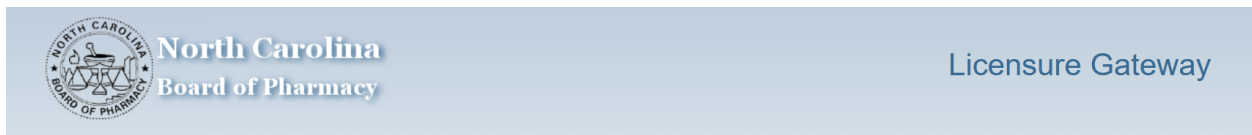
(9) Drugs, devices, and medical equipment not picked up by a patient from a DTP system may be returned to the home pharmacy's stock under the same conditions as if the

item had been maintained in the pharmacy.

(10) The home pharmacy shall record and review any incident involving a complaint, delivery error, or omission regarding the DTP system.

INSTRUCTIONS FOR UPDATING AN EXISTING PHARMACY PERMIT'S SERVICES TO INDICATE USE OF AN ON-SITE DTP SYSTEM

Step 1: Log in to the [Board's Licensure Gateway](#) under the existing pharmacy permit.



Welcome to the Licensure Gateway!

The Gateway is a single portal to manage licenses, permits and registrations associated with the North Carolina Board of Pharmacy. It grants access to printable documents, change of address, online applications and many more features. The Gateway is used to submit all license, permit and registration applications.

- For Pharmacies and DME's click on the [Facility Management](#) tab below.
- For users wishing to manage chain facilities, please click on the [Chain Management](#) tab below.
- All others click on the [Register Now!](#) button below if this is your first time visiting the Licensure Gateway.

The image shows a login form with three tabs: "Personal Licenses", "Facility Management", and "Chain Management". The "Facility Management" tab is selected. The form contains the following fields:

- * Permit Type: A dropdown menu with "Pharmacy" selected.
- * Permit # or Confirmation # (for pending applications): A text input field containing "12345".
- * Password: A password input field with a red question mark icon and masked characters "....".

Below the fields is a green "Login" button. At the bottom of the form are two buttons: "NEW Pharmacy" with a flask icon and "NEW DME" with a calculator icon.

Step 2: Click on the tile View/Update Services



Step 3: Item #4 asks if you have a DTP system on site

4. * Does this pharmacy operate a direct-to-patient dispensing system on site? Yes No

Step 4: If the answer is yes, then indicate which type of DTP system is in use – locker or kiosk (see the FAQs above for definitions or click on the question-mark hover button beside each term).

* Please indicate the type of DTP System:
 Locker ?
 Kiosk ?

Step 5: Add the pharmacist responsible for DTP system oversight by clicking the ADD PHARMACISTS button.

Please identify the pharmacists responsible for the operation of the DTP system. All pharmacists listed must be employed by this pharmacy.

Pharmacists + Add Pharmacist

In the pop-up box, enter only the license number of the pharmacist and click FIND PHARMACIST.

In-State Pharmacist Maintenance

Pharmacist Name:
First Last

Pharmacist License #:
30136

Find Pharmacist

Submit

Click on the drop-down to select the pharmacist, and then click SUBMIT.

In-State Pharmacist Maintenance

Pharmacist Name:
First Last

Pharmacist License #:
30136

Find Pharmacist

Select the Pharmacist

*Pharmacist:
Pharmacist, Test #30136

Submit

123 Apple St. Chapel Hill, NC 27516

The pharmacist will be added to the services page. Repeat Step 5 to add additional pharmacists as necessary.

Please identify the pharmacists responsible for the operation of the DTP system. All pharmacists listed must be employed by this pharmacy.

Pharmacists + Add Pharmacist

Test Pharmacist #30136 🗑️

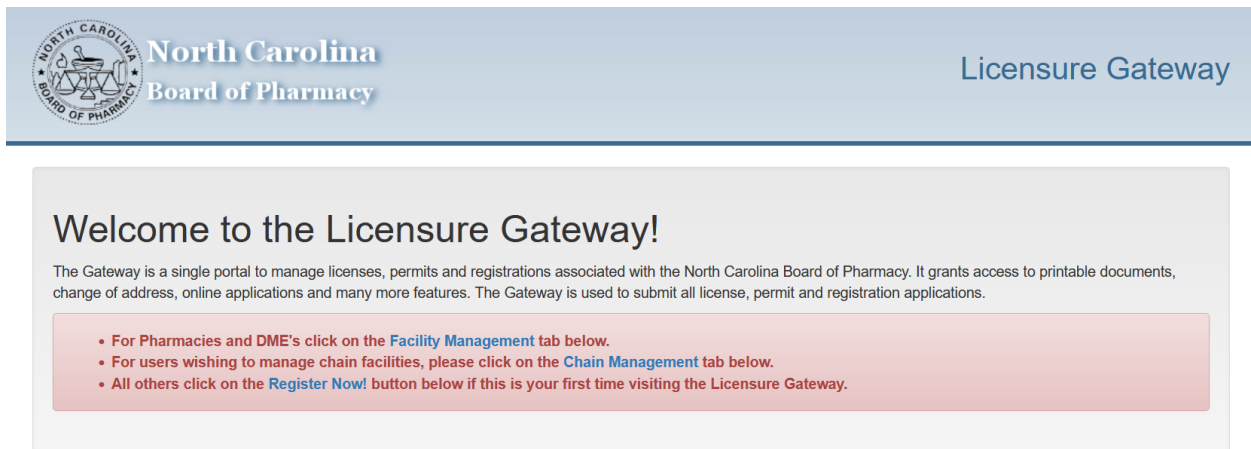
License Status: Active

Practice: Test Pharmacy #14549 - 123 Apple St. Chapel Hill, NC 27516

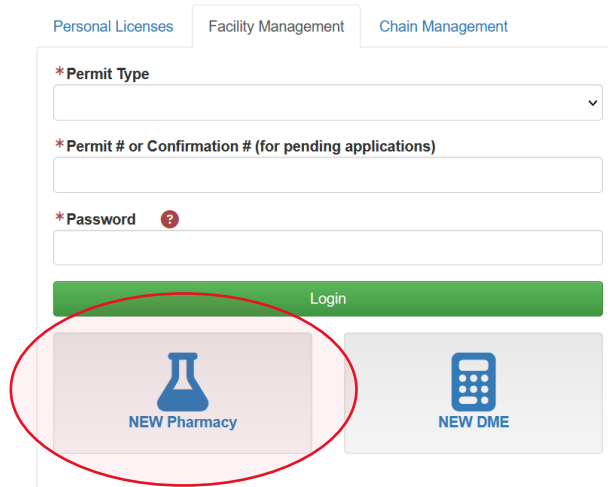
Step 6: Review the remainder of the services update and update as needed. Once complete, click NEXT and the system will display all the answers you provided. After reviewing your answers, click I AGREE under the Terms of Agreement section and click NEXT. Please allow 7-10 business days for the review and processing of the services update.

INSTRUCTIONS FOR OBTAINING A LIMITED SERVICE PERMIT TO OPERATE AN OFF-SITE DTP SYSTEM

Step 1: Navigate to the [Board's Licensure Gateway](#). Under the Facility Management tab, click on NEW PHARMACY



The screenshot shows the top header of the Licensure Gateway with the North Carolina Board of Pharmacy logo and the text "North Carolina Board of Pharmacy" and "Licensure Gateway". Below the header is a large grey box with the heading "Welcome to the Licensure Gateway!". Underneath this heading is a paragraph explaining the gateway's purpose. A red-bordered box contains three bullet points: "For Pharmacies and DME's click on the Facility Management tab below.", "For users wishing to manage chain facilities, please click on the Chain Management tab below.", and "All others click on the Register Now! button below if this is your first time visiting the Licensure Gateway." Below the red box are three tabs: "Personal Licenses", "Facility Management", and "Chain Management".



The screenshot shows the "Facility Management" tab selected. It contains a login form with the following fields: "* Permit Type" (a dropdown menu), "* Permit # or Confirmation # (for pending applications)" (a text input field), and "* Password" (a text input field with a red question mark icon). Below the password field is a green "Login" button. At the bottom of the form are two buttons: "NEW Pharmacy" (with a flask icon) and "NEW DME" (with a calculator icon). The "NEW Pharmacy" button is circled in red.

Step 2: On the Pharmacy Services section of the application, the submitting pharmacist-manager will answer YES to the question whether the application is for a limited service permit.

1. * Limited Service permit? Yes No

Board rule .1616 makes the following pharmacy practices eligible to apply for a limited service permit.

Step 3: Select the DIRECT TO PATIENT DISPENSING SYSTEM category.

Board rule .1616 makes the following pharmacy practices eligible to apply for a limited service permit.

* If YES, please choose which type of permit is operating under:

- Auxiliary Drug Inventory
- Automated Medication System
- Direct To Patient Dispensing System
- Facility Where Only Nurse Practitioners (NPs), Physician Assistants (PAs) Dispense Drugs
- County Health Departments Where Only Registered Nurses Dispense Drugs
- County Health Departments Where Pharmacists Dispense Drugs
- Free and Charitable Clinics
- Critical Access Hospitals

Pharmacy operates a direct-to-patient dispensing system that is not located at the home pharmacy's facility. 21 NCAC 46-1616(a)(3)

Step 4: Enter the “home pharmacy” that will be responsible for operating the off-site DTP system. Enter the home pharmacy’s permit number in the search box, then click SEARCH PHARMACIES. Then click on the drop down to select the home pharmacy.

Please provide the HOME pharmacy that provides medications to this limited service permit. ?

NC Pharmacy Search

Name:

City:

Permit Number:

Search Pharmacies

Select Pharmacy

* Pharmacy:

- Select a Pharmacy -

- Select a Pharmacy -

123 Pharmacy #14544 - 123 Apple St. Chapel Hill, NC 27516

Kiosk ?

Step 5: Indicate which type of DTP system will be used – locker or kiosk (see the FAQs above for definitions or click on the question-mark hover button beside each term).

Select Pharmacy

*Pharmacy:
123 Pharmacy #14544 - 123 Apple St. Chapel Hill, NC 27516

Please select the type of DTP System:
 Locker ?
 Kiosk ?

Step 6: Add the pharmacist responsible for DTP system oversight by clicking the ADD PHARMACISTS button.

Please identify the pharmacists responsible for the operation of the DTP system. All pharmacists listed must be employed by the HOME pharmacy.

Pharmacists

+ Add Pharmacist

In the pop-up box, enter only the license number of the pharmacist and click FIND PHARMACIST.

In-State Pharmacist Maintenance

Pharmacist Name:
First Last

Pharmacist License #:
30136

Find Pharmacist

Submit

Click on the drop-down to select the pharmacist, and then click SUBMIT.

In-State Pharmacist Maintenance

Pharmacist Name:

First Last

Pharmacist License #:

30136

Find Pharmacist

Select the Pharmacist

*Pharmacist:

Pharmacist, Test #30136

Submit

123 Apple St. Chapel Hill, NC 27516

The pharmacist will be added to the services page. Repeat Step 6 to add additional pharmacists as necessary.

Please identify the pharmacists responsible for the operation of the DTP system. All pharmacists listed must be employed by the HOME pharmacy.

Pharmacists + Add Pharmacist

Test Pharmacist #30136

License Status: Active

Practice: 123 Pharmacy #14544 - 123 Apple St. Chapel Hill, NC 27516

Step 7: Complete the remainder of the permit application and submit. The pharmacist-manager (PM) will receive an email with a confirmation number.

Please allow 6-8 weeks for application review. If Board staff needs additional or clarifying information, the PM will be notified via email. Prompt, complete responses from the PM to any requests for additional information will ensure that the application review continues in a timely manner.

Board staff will confirm that all requirements have been met. If so, Board staff issue the permit. The PM will be notified by email, and a permit number will issue. Make sure you follow all instructions provided to you in that email.

Once the permit number issues, it must be used to log in through [Board's Licensure Gateway](#).