



NORTH CAROLINA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Item 2477 – Licenses/Permits/Registrations Not Renewed for 2024 Are Now Expired

All licenses, permits, and registrations (other than pharmacy intern registrations) expire on December 31 annually. State statute provides a 60-day period after expiration before a license, permit, or registration holder is deemed to be engaged in the unlicensed practice of pharmacy. The 60-day clock is now ticking. Be sure you renew!

North Carolina Board of Pharmacy licensing staff will continue to send frequent reminders and instructions electronically. All license, permit, and registration holders should ensure that they have provided the Board with a current email address to receive these reminders and instructions.

Item 2478 – Board Implements DTP Dispensing Rules

The Board has completed its rulemaking on the authorization for and regulation of the use of direct-to-patient (DTP) dispensing systems. [Board Rule 21 North Carolina Administrative Code \(NCAC\) 46.1821](#) provides that authorization and the standards that apply to the use of DTP systems. [Board Rule 21 NCAC 46.1616](#) authorizes limited service permits to be issued for the operation of a DTP system when the system is not located at the site of the home pharmacy.

Board staff has completed programming to implement a limited service permit application for an off-site DTP system, as well as for an existing pharmacy to notify the Board that it will deploy an on-site DTP system.

Detailed guidance on the rules and standards governing DTP systems, as well as step-by-step instructions

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to add an on-site DTP system to an existing pharmacy's services or to apply for an off-site DTP system limited service permit, can be found [here](#).

The general limited service permit [guidance document](#) has also been updated to include information on DTP system permits.

Item 2479 – Immunizing Pharmacists' Authority to Administer COVID-19 and Flu Vaccines to Pediatric Patients

A number of pharmacists have reached out to Board staff about immunizing pharmacist authority to administer flu and COVID-19 vaccines to pediatric patients. With all of the recent changes to North Carolina law and Public Readiness and Emergency Preparedness Act (PREP Act) declarations, it can be confusing. Here is the skinny on flu and COVID-19 vaccine authority:

1. PREP Act declarations authorizing pharmacists to administer flu and COVID-19 vaccines to patients ages three and older are still in effect and will be until December 31, 2024.
2. State law now allows immunizing pharmacists to administer flu and COVID-19 vaccines to patients ages seven and older pursuant to protocol and parental permission. State law allows immunizing pharmacists to administer any Advisory Committee on Immunization Practices-recommended vaccine to patients ages six and older pursuant to a prescription and parental permission.
3. For flu and COVID-19, immunizing pharmacists can administer to patients ages three and older and can do so under their own authority under the PREP Act. Immunizing pharmacists can also use [Dr Betsey Tilson's statewide standing order](#) to do this for the COVID-19 vaccine (which typically makes billing and record keeping easier). These paths are available until December 31, 2024.
4. After December 31, 2024, immunizing pharmacists can administer flu and COVID-19 vaccines pursuant to protocol, but only to patients ages seven and older or pursuant to a prescription for patients ages six and older.

For a comprehensive overview of immunizing pharmacist authority, see the frequently asked question guidance [here](#).

Item 2480 – Reminder: Revised USP Chapters <795> and <797> Became Effective November 1, 2023

United States Pharmacopeia (USP) has published chapter revisions for USP <795> and <797> for nonsterile and sterile compounding. USP has also published the newly developed Chapter <825>, which sets standards for compounding radiopharmaceuticals. These chapters, along with USP Chapter <800> Handling of Hazardous Drugs, became enforceable for compounding operations on November 1, 2023.

You can find additional resources on these USP chapters here:

- [USP <795>](#)
- [USP <797>](#)
- [USP <800>](#)
- [USP <825>](#)

With respect to USP Chapter <800> and **non-compounding** activities involving hazardous medications, pharmacists are reminded:

The Board views compliance with USP <800> for non-compounding activities involving hazardous medications as a best practice. As pharmacists know, USP Chapter <800> standards are designed to protect pharmacists, pharmacy staff, patients, and the public from the harmful effects of exposure to hazardous medications.

As USP Chapter <800> standards for non-compounding activities become commonly followed, North Carolina law is likely to reflect them as a standard of practice. In that case, failure to comply may be evidence of negligence. Therefore, you are encouraged to evaluate (and continue to reevaluate) to what extent compliance reflects the appropriate standard of care. Board staff will continue to make observations during inspections to help identify potential risks of handling hazardous medications and provide education on how to comply with USP Chapter <800> standards to minimize risk to pharmacy staff, patients, and the public. These observations regarding USP Chapter <800> compliance in non-compounding activities involving hazardous medications will not, by themselves, serve as bases for disciplinary action by the Board. The Board's full position statement may be found [here](#).

Board staff has created helpful educational resources that address the identification of hazardous drugs, instructions on conducting an assessment of risk, and templates for non-compounding pharmacies to develop standard operating procedures addressed in USP <800>. The resources can be found [here](#).

Item 2481 – Reminder: Process for Submitting Working Conditions Complaints

The Board's Enforcement department has created a workplace conditions-specific complaint form. The complaint form – hosted in the Licensure Gateway system and available to any pharmacist who logs in as an easy-to-use tile selector and fillable online form – guides the complainant through a series of questions designed to elicit sufficient information to facilitate workplace condition investigations.

Item 2482 – Reminder: Allowable Technician Ratios and Pharmacist-Manager Responsibilities

North Carolina Pharmacy Practice Act General Statute 90-85.15A(c) states that:

A pharmacist may not supervise more than two pharmacy technicians unless the pharmacist-manager receives written approval from the Board. The Board may not allow a pharmacist to supervise more than two pharmacy technicians unless the additional pharmacy technicians are certified pharmacy technicians.

A pharmacist-manager's request for a 1:3, 1:4, or 1:5 pharmacist-to-technician ratio may be allowed by Board staff without formal Board action as long as the pharmacist-manager demonstrates that the pharmacy employs a sufficient number of certified technicians to meet the permitted ratio. A pharmacist-manager's request for a 1:6 or higher pharmacist-to-technician ratio must be considered by the full Board.

More detail on the Board's process, as well as instructions on how to submit a pharmacist-to-technician ratio request, can be found [here](#).

Item 2483: NC DHHS Medicaid Expansion Includes Website, Toolkit, and Sign-Up Form

Beginning December 1, 2023, more North Carolinians became eligible to obtain health coverage through NC Medicaid. North Carolina Department of Health and Human Services (NC DHHS) needs your help to ensure that North Carolinians know who is eligible and how to apply. NC DHHS has a new website, a bilingual toolkit, and a sign-up form to stay updated on the most current information about how more North Carolinians will be able to get health coverage through NC Medicaid. Please use these tools and share them with your networks and communities. Read more [here](#).

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