



# NORTH CAROLINA BOARD OF PHARMACY

*newsletter to promote pharmacy and drug law compliance*

## ***Item 2453 – License, Permit, and Registration Renewal Period Opened on November 1***

The annual license, permit, and registration renewal period opened on November 1, 2022, through the North Carolina Board of Pharmacy’s [Licensure Gateway](#).

All licenses, permits, and registrations issued by the Board expired on December 31, 2022 (except for pharmacy intern registrations – see Item 2449 in the Board’s [October 2022 Newsletter](#)). Under North Carolina law, a license, permit, or registration holder is not deemed to be engaging in the unlicensed practice of pharmacy until the credential has been expired for 60 days. This is the source of the so-called “grace period,” which runs through March 1, 2023.

Again, a Board credential not renewed by December 31, 2022, is expired. To avoid a credential going inactive, if you have not already, be sure to renew prior to March 1, 2023.

## ***Item 2454 – Updated Guidance on OTC Syringe Sales by Pharmacies***

The North Carolina Department of Health and Human Services and the North Carolina Harm Reduction Coalition, in consultation with Board staff, have updated their guidance for over-the-counter (OTC) syringe sales by pharmacies. This guide provides comprehensive legal, public health, and practical advice for pharmacists and pharmacies.

The revised guidance can be found [here](#).

## ***Item 2455 – Solicitations to Pharmacists From Companies Claiming to Pay for Survey Participation***

Several pharmacists have contacted Board staff concerning solicitations

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received from a company purporting to offer pharmacists payment for participating in research surveys. The solicitations state “We received your information from the North Carolina Board of Pharmacy that you are a licensed Pharmacist licensed [sic] in North Carolina with License Number #####.”

Pharmacist license numbers are public information and widely available. Board staff is concerned, however, that these solicitations are worded in a way intended to convey that the Board is working with the soliciting company or otherwise endorses its programs. **This is not true.** The Board has no such involvement with this company or any other. Pharmacists should consider these solicitations accordingly.

### ***Item 2456 – State and Federal Law Applicable to ‘Walk-In’ IV Therapy Clinics***

Board staff has fielded several inquiries from various licensed medical professionals concerning clinics that offer walk-in intravenous (IV) therapy services. Board staff has produced a [guidance document](#) that sets forth the North Carolina law governing the need for pharmacy permits and preparation of sterile drug products.

Board staff also strongly recommends that any medical professional who is considering operating an IV therapy clinic should consult with their own licensing board.

### ***Item 2457 – FDA Announces Additional Temporary Enforcement Discretion With Respect to Clozapine REMS Requirements***

In November 2021, Food and Drug Administration (FDA) announced certain enforcement discretion with respect to Clozapine Risk Evaluation and Mitigation Strategies (REMS) requirements. On November 2, 2022, FDA stated that it is temporarily exercising additional enforcement discretion on this matter:

FDA is aware health care professionals and patients continue to experience ongoing difficulties with the Clozapine REMS program, including issues with patient access to clozapine for patients recently discharged from an inpatient setting. To address the concern that inpatient pharmacies are only allowed to dispense a 7-days’ supply of clozapine to the patient upon discharge, FDA does not intend to object if:

- Inpatient pharmacies dispense a days’ supply of clozapine that aligns with the patient’s monitoring frequency (e.g., weekly monitoring = 7 days’ supply, twice monthly monitoring = 14 days’ supply, monthly monitoring = 30 days’ supply) upon discharge from an inpatient facility.

FDA continues to exercise the enforcement discretion announced in November 2021, including that FDA does not intend to object if:

- Pharmacists dispense clozapine without a REMS dispense authorization (RDA).
- Wholesalers ship clozapine to pharmacies and health care settings without confirming enrollment in the REMS.

Board staff will continue to update pharmacists on this matter as FDA issues additional or different guidance. More information is available [here](#).

### **Item 2458 – Reminder: Pharmacy Intern Registration System Is Active**

Effective September 1, 2022, North Carolina pharmacists and pharmacies that host pharmacy interns as part of an academic experiential program or host/employ pharmacy interns outside of an academic experiential program must verify that the would-be intern is, in fact, registered. Interns may print a Board-issued certificate after completing registration. Further details and instructions may be found [here](#) and in Item 2449 of the Board's [October 2022 Newsletter](#).

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*Jack W. "Jay" Campbell IV, JD, RPh - State News Editor*

*Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor*

*Megan Pellegrini - Publications and Editorial Manager*

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**6015 Farrington Rd, Suite 201 | Chapel Hill, NC 27517 | 919/246-1050 | Fax: 919/246-1056 | [www.ncbop.org](http://www.ncbop.org)**

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