



# NORTH CAROLINA BOARD OF PHARMACY

*newsletter to promote pharmacy and drug law compliance*

## **Item 2449 – Pharmacy Intern Registration System Is Active**

Revised North Carolina Board of Pharmacy Rule .1503 requires that any person who wishes to serve as a pharmacy intern and obtain practical experience in North Carolina must register with the Board. A person may not, and will not, receive credit for any practical experience required for licensure and obtained in North Carolina unless and until registered as a pharmacy intern. There is no fee for intern registration.

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 and eligible to serve as an intern. Interns may print a Board-issued certificate after completing registration. Pharmacists and pharmacies should also use the [Board's License/Permit Verification tool](#) to confirm intern status.

## **Pharmacy Students**

Most pharmacy interns will be students who are currently enrolled in an Accreditation Council for Pharmacy Education (ACPE)-accredited school of pharmacy. Detailed registration instructions for incoming and currently enrolled students are found [here](#). Note that pharmacy students will need to have three documents for upload to complete a registration:

- (1) a photograph (passport type);
- (2) proof of enrollment from a school of pharmacy; and
- (3) a signed (manual, not electronic) copy of a [Family Educational Rights and Privacy Act Waiver](#) that will authorize the Board to obtain certain enrollment and academic status information from the intern's school of pharmacy.

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**Note:** While the majority of pharmacy students who are acquiring practical experience in North Carolina will be enrolled in a North Carolina-based school of pharmacy, not all will. The intern registration requirement applies to all enrolled pharmacy students acquiring practical experience in North Carolina, whether the school is located in North Carolina or another state.

### ***FPGEC-Certified Graduates of a Foreign School of Pharmacy***

A graduate of a foreign school of pharmacy who has successfully completed the National Association of Boards of Pharmacy® (NABP®) Foreign Pharmacy Graduate Equivalency Examination® and the Test of English as a Foreign Language is eligible for pharmacy intern status and must register to acquire required practical experience. Detailed registration instructions for Foreign Pharmacy Graduate Examination Committee™ (FPGEC®)-certified graduates of a foreign school of pharmacy are available. Note that FPGEC Certification holders will need to have two documents for upload to complete a registration: (1) a photograph (passport type); and (2) NABP-issued FPGEC Certification.

### ***Other Categories of Pharmacy Intern***

Three more categories of persons are required to register as a pharmacy intern, though these are likely to be a small percentage of interns:

**Graduates of an ACPE-Accredited School of Pharmacy Who Are Not Licensed in Any State, Have an Active Application for North Carolina Licensure, But Have Not Yet Passed the Licensure Exams.** Any pharmacy school graduate who, come September 1, 2022, is practicing in a North Carolina pharmacy, has applied for licensure in North Carolina, but has not yet passed the North American Pharmacist Licensure Examination® and Multistate Pharmacy Jurisprudence Examination®, will need to register as an intern. The registration application is accessed through your profile on the [Board's Licensure Gateway](#).

**Pharmacist Licensed in Another State Who Is Gaining Practical Experience Required to Reciprocate to North Carolina.** Occasionally, a pharmacist seeking to reciprocate licensure from another state has been out of practice for a sufficiently long period of time so that some refresher practical experience is required. A reciprocity applicant who falls into this category will be contacted by Board licensing staff when the application is reviewed. Such candidates must register as an intern prior to obtaining refresher practical experience. The registration application is accessed through your profile on the [Board's Licensure Gateway](#).

**Pharmacist With an Inactive North Carolina License Who Is Gaining Practical Experience Required to Reinstate.** Occasionally, a pharmacist seeking to reinstate a North Carolina license has been out of practice for a sufficiently long period of time that some refresher practical experience is required. A reinstatement applicant who falls into this category will be contacted by Board licensing staff when the application is reviewed. Such candidates must register as an intern prior to obtaining refresher practical experience. The registration application is accessed through your profile on the [Board's Licensure Gateway](#).

## ***Item 2450 – It’s Baaaaaaack! Effective October 1, 2022, General Assembly Revives Requirement to Notify Prescribers When Dispensing an Interchangeable Biosimilar***

In 2015, the North Carolina General Assembly amended the Pharmacy Practice Act to clarify that, when authorized by the prescriber, an interchangeable biosimilar product may be substituted by a pharmacist. That statute also directed a pharmacist who acted on the prescriber’s authorization “within a reasonable time” to notify the prescriber of that substitution, including the name and manufacturer of the specific biological product dispensed to the patient. Details on the statute were published in Item 2312 of the Board’s October 2015 *Newsletter*. The notification requirement, however, sunsetted on October 1, 2020.

A provision of the General Assembly’s most recent **appropriations act** has resurrected the notification requirement. Effective October 1, 2022, a pharmacist who, as authorized by the prescriber, dispenses an interchangeable biosimilar to a patient must, within five business days, “communicate to the prescriber the product name and manufacturer of the specific biological product dispensed to the patient.” The statute lists five means of making this communication electronically. An entry into any of the following “that is electronically accessible to the prescriber [by] the pharmacist or a designee is presumed to provide the required communication and notice to the prescriber” [:]

. . . (1) An interoperable electronic medical records system; (2) Electronic prescribing technology; (3) A pharmacy benefit management system; (4) The North Carolina Health Information Exchange Network; (5) A pharmacy record.” Absent one of these methods, the statute says that “the pharmacist or a designee shall provide the required communication to the prescriber by facsimile, telephone, electronic transmission, or other prevailing means.

The statute specifies that there is no required communication to the prescriber if there is no Food and Drug Administration (FDA)-approved interchangeable biosimilar for the product prescribed or if “a refill prescription is not changed from the product dispensed on the prior filling of the prescription.”

FDA’s “**Purple Book**” lists approved biological products, including licensed biosimilar and interchangeable products.

## ***Item 2451 – North Carolina COVID-19 State of Emergency Ended August 15, 2022: Effects on Pharmacy Practice***

The North Carolina coronavirus disease 2019 (COVID-19) state of emergency sunsetted on August 15, 2022. Overall, the end of the North Carolina state of emergency had relatively little effect on pharmacy practice. Details are listed below.

- 1. Board of Pharmacy Waivers.** The Board’s waiver authority is keyed by a state of emergency; so on August 15, the Board’s waiver authority expired. This will, however, have a negligible effect on pharmacy practice:

- i. **Inter- and Intra-Pharmacy Remote Operations.** The Board withdrew the March 17, 2020 expanded emergency services waiver authorizing remote operations effective July 1, 2022, when it began enforcing amended Rule .1816 and new Rule .2515, which authorize and govern inter- and intra-pharmacy remote operations, respectively. See <http://www.ncbop.org/PDF/GuideToInterPharmacyRMOP.pdf> and <http://www.ncbop.org/PDF/GuidanceForIntraPharmacyRMOPServices.pdf>.
- ii. **Cross-Jurisdictional Practice.** Effective December 31, 2020, the Board withdrew the March 10, 2020 emergency services waiver allowing pharmacists and certified technicians in good standing in another state to practice in North Carolina under certain conditions.
- iii. **Temporary Relocation.** The portion of the March 10, 2020 emergency services waiver allowing temporary pharmacy relocations without re-permitting expired on August 15, 2022, when the state of emergency sunsetted.
- iv. **Waiver and Clarification Concerning Pharmacy Intern Status.** The Board's June 16, 2020 waiver and clarification that 2020 pharmacy school graduates retained internship status through December 31, 2020, expired on its own terms on that date. And, in all events, intern status (including that of pharmacy school graduates) is now governed by amended **Rule .1503**.
- v. **CPR Certification for Immunizers.** The executive director's exercise of authority under the March 10, 2020 emergency services waiver to waive enforcement of the requirement that an immunizing pharmacist hold a current provider-level CPR certification ended on August 15, 2022, when the state of emergency sunsetted.
- vi. **Supervision of Immunizing Pharmacy Technicians.** The executive director's December 8, 2020 exercise of authority under the March 10, 2020 emergency services waiver to broaden the definition of "supervision" for immunizing pharmacy technicians was superseded by amended Rule .2507, which incorporated that same supervision standard: The technician:

[e]ither (i) has an Immunizing Pharmacist on site and readily available to assist as needed, or (ii) has another licensed health care provider authorized to administer vaccines on site and readily available to assist as needed and has a supervising pharmacist readily available by phone or other telecommunications method for consultation as needed. [21 North Carolina Administrative Code 46.2507(c)(5) (effective July 1, 2022).]

2. **State Health Director's Standing Orders.** Throughout the COVID-19 state of emergency, North Carolina State Health Director Betsey Tilson has issued a number of COVID-19-related **standing orders**. Those standing orders **remain in effect after the August 15 sunset**. In Session Law 2022-74, the General Assembly continued Dr Tilson's authority to issue statewide standing orders to facilitate the administration of COVID-19 vaccinations, diagnostic tests, or other treatments until rescinded.

**3. PREP Act Declarations.** The United States Department of Health and Human Services Public Readiness and Emergency Preparedness Act (PREP Act) declarations granting pharmacists and pharmacy technicians various authorities **remain in effect after the August 15 sunset**. The PREP Act declarations are keyed to the federal declaration of public health emergency, which did **not** sunset on August 15.

### ***Item 2452 – Changes to Schedule II Controlled Substance Prescriptions***

Board staff has received many calls and emails inquiring about the continued ability for pharmacists to make certain changes to Schedule II prescriptions in consultation with the prescriber (see [Pharmacist FAQs](#)). The source of the angst appears to be as follows: A 2019 presidential executive order required all federal agencies to review and consolidate various informal guidance documents. As a result of this review, the federal Drug Enforcement Administration (DEA) removed informal guidance on its website that concerned changes to Schedule II prescriptions. The National Association of Chain Drug Stores (NACDS) issued a letter describing a private phone call with unnamed DEA officials, during which NACDS interpreted their statements as an “implication” that Schedule II prescriptions may not be altered or changed in any way by a pharmacist.

Whatever was said on this phone call, Board staff disagrees that a pharmacist may not make certain changes to a Schedule II prescription in consultation with the prescriber. The mere fact that informal guidance was withdrawn does not mean that the conduct the informal guidance described is now “illegal.” Nor do statements by individual DEA officials on a private phone call establish a “policy” of any sort. Accordingly, Board staff views the long-standing statement linked above concerning changes to Schedule II prescriptions as appropriate. If DEA issues any formal guidance or proposed rulemaking change on this matter, Board staff will update.

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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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