



NORTH CAROLINA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Item 2459 – COVID-19 PREP Act Declarations Expire on May 11, 2023

On February 9, 2023, the United States Department of Health and Human Services (HHS) announced that the federal public health emergency (PHE) for the coronavirus disease 2019 (COVID-19) will expire on May 11, 2023. With the end of the PHE, various declarations issued under the Public Readiness and Emergency Preparedness Act (PREP Act) will sunset. HHS has published a [Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap](#).

As pharmacists know, a number of those declarations expanded pharmacists' authority to order and administer (and, in the case of pharmacy technicians, administer) certain vaccines, as well as pharmacists' authority to order and administer certain COVID-19 treatments. When those authorizations sunset on May 11, 2023, pharmacist (and pharmacy technician) authority will revert to that found in North Carolina law. This [guidance document](#) discusses the chief differences among North Carolina law and PREP Act-granted authority. Pharmacists should be aware that the vaccination authority (for pharmacists and pharmacy technicians) granted under the PREP Act was broader than that allowed under North Carolina law, and that, while new North Carolina law granted qualifying immunizing pharmacists the authority to initiate certain types of drug therapy, it did not grant authority to initiate COVID-19 treatment.

As the PHE sunset approaches, North Carolina Board of Pharmacy staff will continue to provide transition updates on the Board's website, www.ncbop.org. Board staff will also advise of any proposed legislation introduced in the North Carolina General Assembly to retain PREP Act-granted authorities as a matter of state law.

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Item 2460 – Congress Eliminates the DATA-Waiver Program and the Requirement for DATA-Waiver ‘X’ DEA Registration Numbers on Prescriptions for Buprenorphine for OUD

On December 29, 2022, with the signing of the Consolidated Appropriations Act of 2023 (the Act), Congress eliminated the “DATA-Waiver Program.” Section 1262 of the Act removes the federal requirement for practitioners to submit a Notice of Intent (NOI), or have a waiver, to prescribe medications like buprenorphine for the treatment of opioid use disorder (OUD). With this provision effective immediately, the Substance Abuse and Mental Health Services Administration will no longer be accepting NOIs or waiver applications.

All practitioners who have a current Drug Enforcement Administration (DEA) registration that includes Schedule III authority may now prescribe buprenorphine for OUD in their practice if permitted by applicable state law. North Carolina rules and laws do not conflict with this new authority for prescribing of buprenorphine for OUD with a current DEA registration.

DEA issued an [informational document](#) that states:

DEA fully supports this significant policy reform. In this moment, when the United States is suffering tens of thousands of opioid-related drug poisoning deaths every year, the DEA’s top priority is doing everything in our power to save lives. Medication for opioid use disorder helps those who are fighting to overcome opioid use disorder by sustaining recovery and preventing overdoses. At DEA, our goal is simple: we want medication for opioid use disorder to be readily and safely available to anyone in the country who needs it. The elimination of the X-Waiver will increase access to buprenorphine for those in need.

All DEA registrants should be aware of the following:

- A DATA-Waiver registration is no longer required to treat patients with buprenorphine for opioid use disorder.
- Going forward, all prescriptions for buprenorphine only require a standard DEA registration number. The previously used DATA-Waiver registration numbers are no longer needed for any prescription.
- There are no longer any limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine.

Separately, the Act also introduced new [training requirements](#) for all prescribers. These requirements will not go into effect until June 27, 2023. DEA-registered practitioners are required to complete a one-time, eight-hour training requirement on the treatment and management of patients with opioids and other substance use disorders. Importantly, these new requirements do not impact the changes related to elimination of the DATA-Waiver Program described above.

Item 2461 – Board Implements Additional Feature for Pharmacy Intern Registration System

As reported in the Board's [October 2022 Newsletter](#) (Item 2449), a pharmacy intern registration system became effective on September 1, 2022. North Carolina pharmacists and pharmacies who host pharmacy interns as part of an academic experiential program or who 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.

In February 2023, the intern registration system added an online method for pharmacy interns to record, and obtain certification of, experiential hours acquired outside of an academic program. This system replaces the paper affidavit process previously used by interns and preceptors to record and certify such experience.

An overview of this new recording system, as well as detailed instructions for interns, can be found here: [Recording and Obtaining Certification for Experiential Pharmacy Practice Hours Obtained Outside of an Academic Curriculum](#).

North Carolina pharmacists who precept pharmacy interns have already begun receiving email notifications that an intern has claimed experiential hours that require preceptor certification. A detailed overview of the preceptor notification-and-certification system, as well as instructions for use, is available here: [A Preceptor's Guide to Confirming a Pharmacy Intern's Claimed Experiential Hours](#).

Some key emphasis points for preceptors:

- Pharmacy interns should **not** record experiential hours obtained through introductory pharmacy practice experiences and advanced pharmacy practice experiences in a PharmD curriculum. The Board accepts certification of experiential hours obtained during the PharmD curriculum from the pharmacy school.
- For many reasons, pharmacists should maintain a current, valid email address on their Board profile. Pharmacists who precept pharmacy interns should specifically do so to ensure that notifications of claimed experiential hours are timely received and reviewed.
- The Board relies on preceptors to ensure that claimed experiential hours are correct. If a preceptor denies an intern's claimed hours, the intern will be notified that they should reach out to the preceptor to resolve any concerns or correct any mistakes. The intern will have the ability to resubmit a denied claim with corrected or additional information.

This set of frequently asked questions reviews all aspects of the pharmacy intern registration system: [NCBOP Pharmacy Intern Registration System](#).

Item 2462 – Oxycodone 'Recall' Fraud Alert

The Pharmaceutical Cargo Security Coalition is warning pharmacies and others of a fraud scam in which pharmacies and other health care facilities receive a letter, spoofed to appear that it is

from a legitimate pharmaceutical distributor, claiming that a “precautionary” manufacturer recall of oxycodone hydrochloride is being conducted. At least one fraudulent notice assigns a National Drug Code (0406853001) to the “recalled” product.

If a pharmacy or any pharmacy staff member receives any type of communication referring to any type of a recall, please document as much information about the notice as possible. The pharmacy should then reach out to a known contact of its distributor to determine if the request is legitimate. If a request is not legitimate, please contact law enforcement. Pharmacy staff may also reach out to Chuck Forsaith at the Healthcare Distribution Alliance, by email at cforsaith@hda.org, or by phone at 401/623-1344.

Item 2463 – Update to Statewide Standing Order for Qualified Immunizing Pharmacists to Initiate Hormonal Contraceptive Therapy

North Carolina State Health Director Betsey Tilson issued an amended hormonal contraceptive standing order for qualified immunizing pharmacists. The change to the standing order, at bullet point 3, now clarifies that, while a seated blood pressure must be obtained at the time of the patient’s assessment, that measurement may be performed by qualified personnel or device – and not only by the pharmacist. The updated standing order and all current standing orders for pharmacists are found here: [North Carolina Department of Health and Human Services Standing Orders for Pharmacists](#).

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