

NORTH CAROLINA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Item 2464 – New Vaccination Authority for Pharmacists, Pharmacy Interns, and Pharmacy Technicians

On May 19, 2023, Governor Roy Cooper signed Session Law (SL) 2023-15 into law. Among other things, the statute amends the North Carolina Pharmacy Practice Act to expand the authority of pharmacists, pharmacy interns, and pharmacy technicians to include vaccine administration.

North Carolina Board of Pharmacy staff has prepared this guidance document. It details this expanded state law vaccination authority, and it discusses how the new state law intersects with two other sources of authority for pharmacist-administered vaccinations – Declarations under the federal Public Readiness and Emergency Preparedness Act (PREP Act) and the state health director's standing orders for pharmacist-administered coronavirus disease 2019 (COVID-19) vaccines.

Item 2465 - Statement Concerning Semaglutide Compounding

Several pharmacists have inquired of Board staff concerning compounding of semaglutide, marketed commercially as Ozempic® and Wegovy®. In general, the federal Drug Quality and

Security Act prohibits the compounding of commercially available drug products, but there are exceptions. This guidance document reviews the circumstances under which federal law permits compounding "essentially a copy" of a commercially available drug product and applies that law to semaglutide compounding specifically.

National Pharmacy Compliance News

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Item 2466 – Federal HHS Announces Extension of Certain PREP Act Declarations Through December 2024

The United States Department of Health and Human Services (HHS) has announced the extension of certain PREP Act Declarations authorizing pharmacists, pharmacy interns, and pharmacy technicians to administer COVID-19 and flu vaccines to patients aged three and older and to perform COVID-19 tests through December 31, 2024. Activities relating to providing COVID-19 countermeasures pursuant to a federal agreement are likewise to be extended to December 31, 2024. Details can be found here.

The PREP Act extension will not, however, extend the federal authorization for COVID-19 vaccination by recently retired providers and students, nor will it extend the ability of pharmacists to administer COVID-19 vaccinations across state lines. Finally, the PREP Act authorization for pharmacists and pharmacy interns to administer routine childhood vaccinations expired with the end of the public health emergency on May 11, 2023.

Item 2464, above, details how new state law authority under SL 2023-15 intersects with PREP Act Declaration extensions.

Item 2467 - Pharmacy Intern Registration Renewals Will Open on August 1, 2023

As reported in the October 2022 Newsletter (Item 2449), a pharmacy intern registration system became 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. This set of frequently asked questions reviews all aspects of the pharmacy intern registration system: NCBOP Pharmacy Intern Registration System.

Pharmacy intern registrations expire on August 31 each year. On August 1, 2023, currently registered pharmacy interns may log in to the Board's Licensure Gateway to renew those registrations. There is no cost for renewal, and Board staff will be communicating with currently registered interns during the summer regarding the renewal process. **Registered interns should make sure that the email address in their Licensure Gateway profile is correct and current to receive reminders and further instructions.**

Item 2468 - North Carolina DHHS Issues Xylazine Exposure Guidance

Xylazine is a veterinary sedative that is not approved for human use. It is increasingly found as a component of drug products sold in the illicit opioid trade. The North Carolina Department of Health and Human Services (DHHS) has issued comprehensive guidance on xylazine, its use, symptoms of xylazine use, treatment modalities, and additional patient information resources. It can be found here.

Item 2469 – One-Time Training Requirement on the Treatment and Management of Patients With SUDs for Practitioners Holding Individual DEA Registrations

Drug Enforcement Administration (DEA) has outlined the requirements for DEA-registered practitioners to meet the new, one-time Medication Access and Training Expansion Act (MATE Act) training requirement that will be tied to their initial or renewal DEA registration, effective June 27, 2023. This requirement applies to practitioners holding individual DEA registrations. A pharmacist who is not an individual DEA registrant – ie, who practices pharmacy under the DEA registration of their employing pharmacy – is not required to obtain this training. But pharmacists such as clinical pharmacist practitioners, who are individual DEA registrants that prescribe controlled substances, are subject to the requirement.

In December 2022, Congress passed the Consolidated Appropriations Act of 2023, which included three bills to help manage and support patients with opioid or substance use disorders (SUDs). The MATE Act, which was part of this legislation, requires new and renewing DEA-registered practitioners to complete a one-time, eight-hour training on opioid or other SUDs. Practitioners must affirm that they have completed this new training requirement by the date of their next-scheduled DEA registration submission on or after June 27, 2023.

There are three ways that practitioners may meet this requirement, which are each outlined in DEA's letter. The letter also defines which accredited groups may provide training to meet the requirement, key points related to the training, and a list of practitioners that have already satisfied the training requirement. Recommendations for curricular elements in SUDs training is also available on the Substance Abuse and Mental Health Services Administration website.

For more information on the MATE Act training requirements, please visit DEA's diversion control website. If you have any additional questions on this issue, please contact the Diversion Control Division Policy Section at ODLP@dea.gov or 571/362-3260.

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