

e-News November 2024

FDA Announced Extended Use Dates of Parenteral Drug Products

FDA announced extended use dates for some parenteral drug products, after a review of the stability data submitted by Baxter International. Providers and patients that have the lot numbers in stock will be able to use them through the corresponding new use dates to help with supply. The following extended use dates are supported for specific lot numbers **indicated in the linked table**.

For more information, visit the FDA's website: https://www.fda.gov/drugs/updates-2024-hurricane-season/hurricane-helene-baxters-manufacturing-recovery-north-carolina

FDA Announces Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medicines

The Drug Enforcement Administration (DEA) in concert with the Department of Health and Human Services (HHS) is issuing a third extension of telemedicine flexibilities for the prescribing of controlled medications, through December 31, 2025. To read the full text of the rule, visit the Federal Register's website: https://www.federalregister.gov/documents/2024/11/19/2024-27018/third-temporary-extension-of-covid-19-telemedicine-flexibilities-for-prescription-of-controlled

FDA Reminds Compounders to Use Ingredients Suitable for Sterile Compounding

FDA is reminding compounders to only produce sterile drugs using components that are suitable for compounding drugs intended to be sterile.

The agency is aware of compounders using food-grade nicotinamide adenine dinucleotide (NAD+) sold by repackagers to make intravenous products. Ingredients identified as food grade are not suitable for compounding sterile drugs without appropriate processing, due to the high risk of contamination with microbes and endotoxins, which can harm patients.

The agency encourages compounders to know your bulks and excipient suppliers and know whether the ingredient is appropriate for use in drugs. Additionally, repackagers should ask

compounders about whether the ingredient is intended for use in drugs to help ensure the ingredient is used appropriately.

For more information, visit the FDA's website: https://www.fda.gov/drugs/human-drug-compounding/fda-reminds-compounders-use-ingredients-suitable-sterile-compounding

Board Extends Deadline to Submit Accessible Services to December 6, 2024

OAC 4729:5-2-05 requires all outpatient pharmacies located in Ohio to submit notification to the Ohio Board of Pharmacy of the types of language translation services, hearing impairment services, and vision impairment services they offer to patients using the Board's accessible services reporting webpage. Pharmacies are required to use this webpage to notify the Board of these accessible services. To submit the services offered by your pharmacy, visit: www.pharmacy.ohio.gov/ASreport

For more information, definitions of the types of accessible services offered, and a step-by-step guide on how to submit and edit your pharmacy's accessible services, visit: https://www.pharmacy.ohio.gov/accessreport. If you have any additional questions, please contact the Board via contact@pharmacy.ohio.gov.

IMPORTANT DEADLINE UPDATE: The deadline to submit notification of accessible services has been extended to December 6, 2024. All outpatient pharmacies in Ohio now have until this date to submit initial notification of accessible services to the Board.

REMINDER FOR LARGE CHAINS: For companies that must report for multiple pharmacy locations, you can bulk report for all your pharmacy licenses using the webpage. **NOTE:** After your initial bulk submission to report accessible services, you will be unable to make changes for your pharmacies using bulk editing. Any further accessible services updates will have to be made individually for each pharmacy location.

2025 Law and Responsible Person Review Virtual Presentations

Join the Ohio Board of Pharmacy for presentations throughout 2025 to learn about the latest developments in pharmacy laws and rules.

2025 Law Review topics will include:

- Duty to Report and Continuous Quality Improvement
- Minimum standards for outpatient pharmacies
- Updates to state and federal laws and rules
- Hot topics and drug diversion trends

Responsible Person Roundtable topics will include:

- How should an RP handle duty to report and establish a continuous quality improvement program?
- Updates to state and federal laws and rules
- Hot topics and drug diversion trends

Responsible Person 101 topics will include:

- Duties and responsibilities of a responsible person
- · General requirements of a terminal distributor of dangerous drugs
- An overview of resources available for a responsible person

For presentation dates and times and a link to sign up, visit: https://www.pharmacy.ohio.gov/documents/licensing/ce/rplaw/2025%20law%20review%20communication.pdf

DSCSA Dispenser Guide

The Board would like to remind licensees about the Dispenser Guide to Achieving Drug Supply Chain Security Act Compliance document developed by NABP. This guide was developed to assist dispensers in establishing processes to comply with the Drug Supply Chain Security Act (DSCSA) law enacted November 27, 2013. To access the document, visit: www.pharmacy.ohio.gov/DSCSADispenserGuide.

Be Vigilant - Watch Out for Scammers!

BOARD STAFF DO NOT ASK FOR MONEY OVER THE PHONE OR VIA EMAIL TO RESOLVE PENDING INVESTIGATIONS. WHEN IN DOUBT, PLEASE CONTACT THE BOARD IF YOU BELIEVE YOU ARE THE TARGET OF A SCAM.

The Ohio Board of Pharmacy continues to learn that licensees are being targeted by scammers who claim to work for various governmental agencies (Board of Pharmacy, DEA, FBI, Department of Justice, etc.) to obtain money from the target. The Board strongly encourages licensees to be alert to avoid scammers.

Scammers may try to initiate contact via phone calls, emails, faxes, and letters purporting to originate from various state and federal agencies that include allegations of drug trafficking and threats of suspension against the target's license.

Board of Pharmacy investigators will not ask for fine payment or personal/sensitive information over the phone and will never contact licensees via fax. As a reminder, administrative fines issued by the Board are not paid via gift cards or cryptocurrency. If the Board of Pharmacy is conducting an investigation and that individual faces action against their license, they will receive an official notice of opportunity for a hearing either via certified mail, personal service, or electronic registered mail.

If you are contacted by a scammer, please report this information using the Board's online complaint form: www.pharmacy.ohio.gov/complaint. Additionally, reports should be made to your local law enforcement agency.

If you receive any suspicious calls or correspondence purporting to be from the Board of Pharmacy, we encourage you to call (614-466-4143) or email (contact@pharmacy.ohio.gov) the Board to confirm its legitimacy.



People call, text, and chat the 988 Lifeline to talk about a lot of emotional needs—not just thoughts of suicide. Whatever your reason, the #988Lifeline is there to help. There is hope.

Ohio Board of Pharmacy

Mike DeWine, Governor | Steven W. Schierholt, Executive Director