



STATE OF OHIO BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

From the Director's Desk

Effective November 15, 2022, Ohio Administrative Code (OAC) 4729:5-5-08 was amended to require pharmacists to check a patient's Ohio Automated Rx Reporting System (OARRS) report prior to dispensing medications containing gabapentin.

This rule is intended to address an increase in the overutilization of gabapentin as reported by OARRS and State of Ohio Board of Pharmacy staff. For example, 24.9% (159,163) of Ohio patients in 2020 received gabapentin from multiple prescribers. The total days of overlap were 7,122,238, meaning, on average, those receiving overlapping gabapentin got an additional 20.8 days' worth of medication.

You can view the amendments to the rule by visiting www.pharmacy.ohio.gov/gaba.

On behalf of the Board, thank you for all that you do to help keep Ohioans safe and healthy.

Sincerely,

Steven W. Schierholt, Esq
Executive Director
State of Ohio Board of Pharmacy

National Pharmacy Compliance News

A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

[Read National News](#)

Resources for Pharmacists Selling OTC Hearing Aids

Food and Drug Administration (FDA) **has released a final rule** for over-the-counter (OTC) hearing aids by creating a new regulatory class of hearing aids. While OTC hearing aids will be widely available at lower costs to many adults with self-perceived mild to moderate hearing loss, they are not right for everyone.

Pharmacists who may be assisting patients in the purchase of OTC hearing aids should familiarize themselves with the requirements of FDA's rule. To assist pharmacists and patients, the Board would like to highlight the following resources:

- [American Speech-Language-Hearing Association – Over-the-Counter Hearing Aid Toolkit](#)
- [University of Pittsburgh – CHAMP: Championing Hearing Using Accessible Medication Experts at the Community Pharmacy](#)

Mandatory Electronic Prescribing of Schedule II CS: Safe Harbor Provision

Under current law, prescribers are required to issue an electronic prescription when prescribing a Schedule II controlled substance (CS). The law does include several exceptions that still allow prescribers to issue a written prescription in specified circumstances.

Please note that this law includes a “safe harbor” provision that does not require a pharmacist to verify any exceptions prior to dispensing a written Schedule II CS prescription.

For additional information, the Board published a guidance document on the [electronic prescribing of Schedule II CS](#).

HHS Amends PREP Act Declaration Increasing Workforce Authorized to Administer Mpox Vaccines

In October 2022, United States Department of Health and Human Services (HHS) Secretary Xavier Becerra amended the Public Readiness and Emergency Preparedness Act (PREP Act) declaration for smallpox medical countermeasures to expand the categories of providers authorized to administer vaccines and therapeutics against smallpox, [monkeypox virus](#), and other orthopoxviruses in a declared emergency.

For more information, visit <https://www.hhs.gov/about/news/2022/10/03/hhs-amends-prep-act-declaration-increasing-workforce-authorized-to-administer-monkeypox-vaccines.html>.

How Pharmacies Can Prepare Now for the 2023 DSCSA Requirements

When FDA enacted the [Drug Supply Chain Security Act](#) (DSCSA) in 2013, it set a 10-year timeline for full implementation (November 2023). The National Association of Boards of Pharmacy® developed a resources page to assist pharmacies in preparing for the implementation of DSCSA. For more information, visit <https://nabp.pharmacy/news/blog/how-pharmacies-can-prepare-now-for-the-2023-dscsa-requirements/>.

Board of Pharmacy Inspection Guides

The Board is committed to ensuring licensee compliance. As part of this effort, the Board has developed **inspection guides** that can be found on the Board's website. These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections or gap analyses to maintain compliance. The guides also include links to rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

Please visit www.pharmacy.ohio.gov/Inspection to access the guides.

Amoxicillin Shortage and Pharmacy Compounding

FDA added amoxicillin to its list of drugs that are experiencing shortages. Amoxicillin, specifically the Amoxicillin Oral Powder for Suspension, was added to the **FDA Drug Shortages** list on October 28, 2022.

As a result, this drug may be compounded under section 503A of the **Federal Food, Drug, and Cosmetic Act** provided that all conditions of 503A are met, including a patient-specific prescription. Additionally, Ohio laws and rules require compliance with US Pharmacopeia (USP) standards (as set forth in **OAC 4729:7-2**).

Because of amoxicillin being added to the **FDA Drug Shortages** list, FDA does not consider the drug product to be commercially available. For more information regarding FDA guidance on essential copies, visit <https://www.fda.gov/media/98973/download>.

In addition to pharmacy compounding, amoxicillin that is in shortage may also be produced by registered outsourcing facilities. For more information on outsourcing facilities, visit www.pharmacy.ohio.gov/drugshortage.

As a reminder, the Board has several coronavirus disease 2019 (COVID-19)-related compounding waivers in effect. For more information on those waivers, visit www.pharmacy.ohio.gov/COVIDcompound.

State of Ohio Announces Partnership to Provide COVID-19 Testing Assistance for Ohioans Who Are Blind or Have Low Vision

The Ohio Department of Health and Opportunities for Ohioans with Disabilities recently announced their partnership with Be My Eyes and Accessible Pharmacy Services to offer a solution for Ohioans who are blind or have low vision in self-administering COVID-19 tests.

At-home COVID-19 tests have become the standard method of testing; however, individuals who are blind or have low vision face challenges self-administering these tests.

Ohio residents can now call a state-sponsored support line through the [Be My Eyes](#) phone app to receive assistance taking any at-home COVID-19 test authorized by FDA, by [downloading the free Be My Eyes app](#) for [Apple](#) or [Android](#) smartphones.

Once on the app, the user should select “State of Ohio COVID Testing.” The user will be connected to an experienced customer support representative from Accessible Pharmacy Services. These representatives have helped hundreds of Be My Eyes users administer a variety of at-home medical tests. The customer support representative can help individuals read print information or instructions included in an at-home COVID-19 test, provide step-by-step guidance while taking the test, and read the results of a completed test.

This service is available to receive calls Monday through Friday from 10 AM – 4 PM ET.

Centers for Medicare & Medicaid Services Rule on EPCS Now in Effect

As a result of House Bill (HB) 193 passing last year, prescribers are required to issue an electronic prescription when prescribing a Schedule II CS.

As of **January 1, 2023, Medicare Part D** plans require the use of e-prescribing for **all** CS prescriptions. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act will require the use of electronic prescriptions for controlled substances (EPCS) for Schedule II-V CS covered under a Medicare Part D prescription drug or a Medicare advantage prescription drug plan. For more information, visit www.pharmacy.ohio.gov/CMSepcs.

For more information on Ohio’s requirements for issuing a valid prescription, including EPCS, visit www.pharmacy.ohio.gov/rx.

For more information on HB 193 and prescribing Schedule II CS, please visit www.pharmacy.ohio.gov/c2.

Revised USP <797> and USP <795> Published

On November 1, 2022, [USP published](#) revisions to the chapters on compounding nonsterile and sterile preparations. Please be advised that while the new chapters have been published, the Board is continuing to enforce the versions of USP <797> and <795> that were in effect prior to these revisions.

Licensees should be aware that the Board is unable to enforce these revisions until the compounding references rule ([OAC 4729:7-1-01](#)) is updated to reflect the new version of these standards. Licensees and stakeholders will have the opportunity to provide feedback on any changes to Ohio’s compounding requirements when changes are proposed. To sign up for updates on the Board’s proposed rules, visit <https://www.pharmacy.ohio.gov/RSS/Subscription>.

Pharmacies are reminded that USP <800> (hazardous drug compounding) and USP <825> (radiopharmaceuticals) are being enforced in Ohio.

For more information on hazardous drug compounding, visit www.pharmacy.ohio.gov/pharmcompound.

For more information on compounding of radiopharmaceuticals, visit www.pharmacy.ohio.gov/nuclear.

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