



E-News November 2022

Amoxicillin Shortage and Pharmacy Compounding

The Food and Drug Administration (FDA) recently 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 [FDCA](#) provided that all conditions of 503A are met, including a patient-specific prescription. Additionally, Ohio laws and rules require compliance with USP standards (as set forth in [OAC 4729:7-2](#)).

Due to amoxicillin being added to the [FDA Drug Shortages](#) list, the 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 COVID-19 related compounding waivers in effect. For more information on those waivers, visit: www.pharmacy.ohio.gov/COVIDcompound.

Resources for Pharmacists Selling Over-the-Counter Hearing Aids

The 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: <https://www.asha.org/aud/otc-hearing-aid-toolkit/>.

University of Pittsburgh - CHAMP: Championing Hearing Using Accessible Medication Experts at the Community Pharmacy: <https://www.credly.com/org/university-of-pittsburgh/badge/champ-championing-hearing-using-accessible-medication-experts-at-the-community-pharmacy>.

Mandatory Electronic Prescribing of Schedule II Controlled Substances: Safe Harbor Provision

Under current law, prescribers are required to issue an electronic prescription when prescribing a Schedule II controlled substance. The law does include several exceptions which 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 controlled

substance prescription.

For additional information, the Board published a guidance document on the [electronic prescribing of schedule II controlled substances](#), which can be accessed here: www.pharmacy.ohio.gov/C2.

Rule for Stakeholder Feedback – Prohibition on the Use of Quotas - Comment Period Extended to November 14th

In 2020 and 2021, the State of Ohio Board of Pharmacy issued workload surveys to Ohio licensed pharmacists. These surveys formed the basis for the creation of the Board's [Pharmacist Workload Advisory Committee](#) (PWAC).

The PWAC began meeting in October 2021 to review the survey data and present a menu of options for consideration by the Board. As a result of the work of the Committee and feedback from the pharmacist community, the Board is proposing the adoption of a rule to prohibit the use of quotas in the operation of a pharmacy.

Comments on the proposed rule are due by close of business on November 14, 2022. To view the proposed rule and for instructions on how to submit comments, visit: www.pharmacy.ohio.gov/quota.

Required OARRS Review for Gabapentin Prescriptions - Effective 11/15/22

Effective November 15, 2022, OAC 4729:5-5-08 will be amended to require pharmacists to check a patient's 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 Board staff. For example, 24.9% (159,163) of Ohio patients in 2020 received gabapentin from multiple prescribers. [Click here to view the amendments to the rule](#).

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

The U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra recently 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 Prep Now for the 2023 DSCSA Requirements

When Food and Drug Administration (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-prep-now-for-the-2023-dscsa-requirements/>.

Board of Pharmacy Inspection Guides

The State of Ohio Board of Pharmacy is committed to ensuring licensee compliance. As part of this effort, the Board has developed [inspection guides, which 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.

2022 CPE Course

The [2022 CPE course](#) will be expiring and removed from the website on **January 31, 2023**. For those pharmacists and registered pharmacy technicians who have not yet taken advantage of this free law CE, now is the time to do this before it is removed from the website.

To access the 2022 CPE course, visit www.pharmacy.ohio.gov/2022CPE.

A new 2023 quiz (covering 2022 publications) will be posted in early February 2023.

Please note that if you choose to unsubscribe from receiving emails, this unsubscribes you from all emails that are sent by the State of Ohio Board of Pharmacy, including renewal reminders. If you believe you have unsubscribed in error, please email contact@pharmacy.ohio.gov for assistance. If you would like to change the email address, please log into your [eLicense Ohio](#) account to update the email address on file.