



E-News January 2023

Removal of DATA Waiver (X-Waiver) Requirement

On December 29, 2022, with the signing of the Consolidated Appropriations Act of 2023 (the Act), [Congress eliminated the "DATA-Waiver Program."](#)

All pharmacies should be aware of the following changes that are now in effect:

- 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.
- The Act does not impact existing state laws or regulations that may be applicable.

Separately, the Act also introduced new training requirements for all prescribers that will go into effect later this year. The DEA and SAMHSA are actively working to provide further guidance and DEA will follow up with additional information on these requirements shortly. Importantly, these new requirements do not impact the changes related to elimination of the DATA-Waiver Program described above.

The Board is in the process of reviewing how these changes will impact its current rules and requirements and will be issuing additional guidance.

For DEA-specific questions:

For information regarding DEA's Diversion Control Division, please visit <https://www.DEAdiversion.usdoj.gov>. Please contact the Diversion Control Division Policy Section at ODLP@dea.gov if you seek additional assistance regarding this or any other matter.

Please visit SAMSHA for additional information:

<https://www.samhsa.gov/medication-assisted-treatment/removal-data-waiver-requirement>

<https://www.samhsa.gov/medication-assisted-treatment>

FDA Issues Guidance to Help Increase Supply of Ibuprofen Oral Suspension Products in Hospitals and Health Systems

On January 20, 2023, FDA issued [immediately-in-effect guidance on compounding certain ibuprofen products](#) in an effort to improve the supply of ibuprofen oral suspension products amid record high demand. The guidance describes FDA's regulatory and enforcement priorities regarding the compounding of certain ibuprofen oral suspension products in outsourcing facilities for use in hospitals and health systems.

[The Food and Drug Administration's \(FDA\) final rule](#) for over-the-counter (OTC) hearing aids, which creates a new regulatory class of hearing aids, is now in effect. 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>.

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 the U.S. Food and Drug Administration (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.
- Read the results of a completed test.

This service is available to receive calls Monday through Friday from 10 a.m. - 4 p.m. ET.

Centers for Medicare and Medicaid Services Rule on Electronic Prescribing of Controlled Substances Effective January 1, 2023

As a result of House Bill 193, prescribers are required to issue an electronic prescription when prescribing a Schedule II controlled substance.

As of **January 1, 2023, Medicare Part D plans** require the use of e-prescribing for **all** controlled substance prescriptions. The SUPPORT for Patients and Communities Act (HR6) will require the use of e-prescribing for controlled substances (EPCS) for schedule II-V controlled substances covered under a Medicare Part D prescription drug, or a Medicare advantage prescription drug plan.

For more information on Ohio's requirements for issuing a valid prescription, including electronic prescribing of controlled substances, visit: www.pharmacy.ohio.gov/rx.

For more information on House Bill 193 and prescribing Schedule II controlled substances, please visit www.pharmacy.ohio.gov/c2.

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/>.

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.

CDC Health Alert on High Season Flu Activity

The CDC recently published a Health Advisory stating its estimate that in the 2022-2023 season to date, there have been at least 13 million illnesses, 120,000 hospitalizations, and 7,300 deaths from influenza. While the Food and Drug Administration (FDA) has not indicated shortages of oseltamivir (generic or Tamiflu) in any of its forms (capsules, oral suspension), the CDC has received numerous anecdotal reports of availability issues for generic oseltamivir in some locations.

This Health Alert Network (HAN) Health Advisory provides clinicians and public health officials with guidance for prioritizing oseltamivir for treatment and information on other influenza antivirals that are recommended for treating influenza in areas where oseltamivir is temporarily unavailable. To access the advisory, visit: <https://emergency.cdc.gov/han/2022/han00482.asp>.

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