STATE OF OHIO BOARD OF PHARMACY

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Board Publishes Comments on Proposed Rest Break Rule

In December 2022, the Board published a proposed rule requiring mandatory breaks and rest periods for pharmacy personnel. The Board will be reviewing these comments at a future meeting and determining next steps. A copy of all the comments can be accessed here: www.pharmacy.ohio.gov/RBcomments.

Electronic Prescribing for Controlled Substances Program Guidance Regarding the Role of the Pharmacy and Pharmacist

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.

REMINDER: Compliance actions for prescriptions for beneficiaries in a long-term care (LTC) facility will begin January 1, 2025.

The Centers for Medicare and Medicaid Services recently issued program guidance regarding the roles of the pharmacy and pharmacist, which are outlined below:

1. There are no compliance requirements for pharmacists or pharmacies in the CMS EPCS Program, as all compliance requirements are limited to prescribers of controlled substances under Medicare Part D.
2. A pharmacist is not required or otherwise obligated to verify that a prescriber has a "waiver" from the CMS EPCS Program prior to dispensing a controlled substance under Medicare Part D.
3. A pharmacist is not required or otherwise obligated to verify that a prescriber or prescription qualifies for an exception from the CMS EPCS Program requirements prior to dispensing a controlled substance under Medicare Part D.
4. The CMS EPCS Program does not limit or impede in any way pharmacists or pharmacies from dispensing covered Part D drugs including controlled substances from valid written, oral or faxed prescriptions that are consistent with current laws and regulations, including state EPCS mandates or Drug Enforcement Agency (DEA) requirements.

For more information, visit: https://www.cms.gov/Medicare/E-Health/Eprescribing.

FDA Updates Draft Guidance to Help Increase Supply of Children's Ibuprofen

The FDA recently revised the immediately-in-effect guidance on compounding certain ibuprofen oral suspension products. The FDA published this update to address increased demand for fever-reducing medications among state licensed pharmacies, in addition to hospitals and health-systems. The revision addresses the provision of such products to state

licensed pharmacies (including those within hospitals and health systems), and to applicable federal facilities, for dispensing to patients following receipt of a patient-specific prescription.

On January 20th, the FDA issued the initial guidance in an effort to improve the supply of pediatric ibuprofen amid record high demand. The U.S. is currently experiencing a significant number of infections from three viruses: COVID-19, respiratory syncytial virus (RSV) and influenza, any of which can cause fevers in young children.

Generally, outsourcing facilities cannot compound a copy of an FDA-approved medicine unless it appears on the FDA shortage webpage, but this guidance explains the FDA's regulatory and enforcement priorities regarding the compounding of certain ibuprofen oral suspension products in outsourcing facilities for administration in hospitals, health systems, state licensed pharmacies and federal facilities.

More information on the updated guidance can be found here.

Medical Board Adopts New Telehealth Rules

The State Medical Board adopted new telehealth rules that will become effective on **February 28, 2023.** These rules implement the requirements of the telehealth statute (R.C. 4743.09) for the following Medical Board health care professionals: physicians (MD, DO, and DPM), physician assistants, dietitians, respiratory care professionals, and genetic counselors.

The Medical Board recently posted a summary of the new rules, which can be accessed here.

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

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/.

Cultural Competency Continuing Education

To provide effective communication with patients, pharmacy professionals must learn to accurately assess their own level of cultural competency and develop methods to improve those skills. Cultural competency can foster a greater understanding and appreciation of diverse patient populations, giving pharmacy professionals additional information and insight to enrich patient care. The skills developed with cultural competency allow healthcare providers to understand and respect a patient's cultural identity. This includes effective communication and appropriate interactions with patients from various ethnic and/or cultural groups.

While there is no requirement to complete continuing education relating to this subject, the Board strongly encourages its licensees to consider these important learning opportunities. More information about continuing education can be found here: www.pharmacy.ohio.gov/cultural.
