

E-News Update August 2020

HHS Expands Access to Childhood Vaccines during COVID-19 Pandemic

The U.S. Department of Health and Human Services (HHS) <u>issued a third amendment</u> to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks as children across the United States return to daycare, preschool and school.

The federal amendment authorizes State-licensed pharmacists (and pharmacy interns acting under their supervision to administer vaccines, if the pharmacy intern is licensed or registered by his or her State board of pharmacy) to order and administer vaccines to individuals ages three through 18 years, subject to several requirements.

Please be advised that the Board is reviewing the amendment language and will be issuing guidance in the coming days.

Draft Internal Management Rule on Responsible Persons for Public Comment

Acting under the authority of Ohio Revised Code Chapter 4729, the State of Ohio Board of Pharmacy proposes the adoption of an internal management rule regarding responsible persons (RP).

To provide additional context, the Board is seeking to implement general guidance to determine when an RP should also be held accountable for a violation occurring at a licensed TDDD location. This internal management rule was drafted using similar standards adopted by the California Board of Pharmacy: https://www.pharmacy.ca.gov/laws-regs/1760 fdgc.pdf

Please be advised that this rule still permits the Board to consider other factors and is intended to provide general guidance when reviewing cases for citation. The goal of the rule is to ensure consistency across the Board's administrative citation process.

Comments on the proposed rule will be accepted until close of business on September 25, 2020.

Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov.

The proposed rule can be found below or accessed here: www.pharmacy.ohio.gov/proposed

Reminder: Pharmacist Continuing Education (CE) Reporting Requirements

As a reminder, pharmacist license renewal has transitioned to a two-year renewal cycle. The next renewal period will begin Summer 2021.

Effective September 16, 2018, <u>rule 4729:1-5-02 of the Ohio Administrative Code</u> updates the required minimum continuing education units (CEUs) pharmacists are required to obtain and aligns the reporting period to the biennial (two-year) renewal cycle.

Specifically, pharmacists are required to obtain a minimum of 4.0 CEUs (40 hours) every two years prior to license renewal. Every pharmacist, regardless of license number will be on the same reporting cycle beginning with the 2019 renewal. Please refer to the chart in this <u>document</u> for hours required for the 2021 reporting period.

The following provides an overview of the Board's pharmacist continuing education requirements:

- Any format (live, home study) is acceptable
- Minimum 40 hours (4 CEUs) total, which must include:
- Minimum 2 hours medication errors/patient safety (ACPE -05)
- Minimum 2 hours jurisprudence or law (ACPE -03) or Ohio Board of Pharmacy Approved Jurisprudence

• **NOTE:** Only ACPE courses and CE from approved in-state providers (law and provision of volunteer healthcare services) are accepted. Some examples of courses that are not accepted include continuing medical education (CME) and continuing legal education (CLE).

More information about pharmacist CE requirements can be found here: www.pharmacy.ohio.gov/CE

Reminder on Enforcement of USP 797 and USP 795 Compounding Standards

The United States Pharmacopeia (USP) in June 2019 released several new and revised pharmacy compounding standards. Specifically, USP published the final revised version of general chapter <797> and <795>. Due to pending appeals, the effective date of the revised chapters is postponed until further notice.

To ensure compliance, compounding pharmacies are reminded that the Board is conducting compliance inspections using the current version of USP 797 (last revised in 2008) and USP 795 (last revised in 2014) and not the revised version released in June 2019 that is currently on hold pending further review. Please be advised that any change in compounding enforcement standards will be communicated to licensees well in advance of implementation.

For more information about the USP revision process, visit the following links:

For USP 797: https://www.uspnf.com/sites/default/files/usp-pdf/EN/USPNF/revisions/gc-797-rb-notice-20200424.pdf

For USP 795: https://www.uspnf.com/sites/default/files/usp-pdf/EN/USPNF/revisions/gc-795-rb-notice-20200424.pdf

Temporary Extension of Basic Life Support Requirements

To address limited access to basic life-support training recertification, the State of Ohio Board of Pharmacy has adopted the following guidance regarding certifications maintained by Ohio pharmacists and pharmacy interns.

Pharmacists and pharmacy interns whose basic life-support training certification is set to expire on or after March 1, 2020 will be permitted to continue to administer immunizations and dangerous drugs in accordance with section 4729.41 under the following conditions:

- The pharmacist or intern maintains documentation demonstrating their basic life-support training certification expired on or after March 1, 2020.
- The pharmacist or intern obtains recertification no later than December 1, 2020 (formally July 29, 2020).

IMPORTANT: Unless circumstances warrant, the Board **does not** expect to extend this requirement past the new December 1, 2020 deadline. Licensees should plan to have their basic life-support training recertification current by December 1, 2020.

A copy of this updated waiver can be accessed here: http://www.pharmacy.ohio.gov/BLS2020

New Outpatient Pharmacy Rules Effective 12/1/2020

Effective December 1, 2020, new rules for outpatient pharmacies (Chapter 4729:5-5 of the Administrative Code) go into effect. To assist licensees in complying with the new rule chapter, the Board recently published an outpatient pharmacy inspection guide (www.pharmacy.ohio.gov/OPinspect).

The inspection guide aligns with internal guidance used by Board inspectors and allows licensees to conduct self-inspections to ensure compliance. The guide also includes links to the new rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

Outpatient Inspection Guide Continuing Education Opportunity

To assist with the implementation of the new outpatient pharmacy rules, the Board has developed a one-hour jurisprudence quiz. This quiz is intended to test a participant's knowledge of the new outpatient pharmacy rules and provides one contact hour (0.1 CEU) of State of Ohio Board of Pharmacy approved jurisprudence for pharmacists and registered pharmacy technicians.

For more information on the quiz, visit: www.pharmacy.ohio.gov/OPquiz

Pharmacy Personnel Licensure and Registration Requirements Reminder

Ohio Revised Code and Ohio Administrative Code require personnel engaged in the practice of pharmacy or performing the duties of a pharmacy technician to obtain a license or registration with the State of Ohio Board of Pharmacy.

All Ohio pharmacies are strongly encouraged to verify the licensure and registration status of all applicable pharmacy personnel – pharmacists, pharmacy interns, and pharmacy technicians. To verify an individual's license or registration, utilize the self-service, eLicense Ohio license look-up available at www.eLicense.ohio.gov/oh-verifylicense.

Click here for additional guidance on Board of Pharmacy licensure and registration requirements.

Board of Pharmacy Warns of Increasing Extortion Scam Calls During COVID-19

The Board continues to receive reports of calls threatening legal action if an exorbitant fine is not paid immediately over the phone. The callers identify themselves as either Board of Pharmacy or DEA personnel and instruct their victims to pay the "fine" via wire transfer to avoid arrest, prosecution, imprisonment, and license revocation.

The reported scam tactics are continually changing, but share many of the following characteristics:

- Callers use fake names and badge numbers or names of well-known senior officials.
- The tone of calls is urgent and aggressive; callers refuse to speak or leave a message with anyone other than the person for whom they are calling.
- Callers threaten arrest, prosecution, imprisonment, and license revocation.
- Callers demand thousands of dollars via wire transfer or in the form of untraceable gift cards.
- Callers falsify the number on caller ID to appear as a legitimate phone number.
- Callers often ask for personal information, such as social security number or date of birth.
- When calling a medical practitioner, callers often reference National Provider Identifier numbers and/or state license numbers and threaten revocation of their license.

Board of Pharmacy and DEA employees do not contact healthcare providers or members of the public by telephone to demand money or any other form of payment.

Anyone receiving a telephone call from a person purporting to be a DEA or Board of Pharmacy employee seeking money should refuse the demand and report the threat using the Board's online <u>complaint form</u> and the DEA's <u>online form</u>. Reporting scam calls will greatly assist the Board of Pharmacy and DEA in investigating and stopping this criminal activity.