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## E-News Update May 2021

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### **Pfizer COVID-19 Vaccinations by Pharmacy Personnel to Individuals Who are 12 Years Old**

Individuals ages 12 and older are now eligible to receive the Pfizer vaccine, which is the only COVID-19 vaccine currently authorized for use for people ages 12-17.

Ohio law permits pharmacists and pharmacy interns to administer any FDA-approved or FDA-licensed COVID-19 vaccines (including those under an EUA) to any of the following:

- Individuals 13 years or older (no prescription required)
- Individuals between ages 7 through 12 (prescription required)

Please be advised that the Federal PREP Act authorization, which preempts state law, may be utilized to provide FDA-authorized COVID-19 vaccines to individuals who are 12 and do not have a valid prescription. For more information about the Federal PREP Act requirements for pharmacy personnel, please visit: [www.pharmacy.ohio.gov/covidvaccine](http://www.pharmacy.ohio.gov/covidvaccine).

[Legislation is pending](#) to permit individuals ages 7-12 to receive a COVID-19 vaccination at a pharmacy without a prescription under Ohio law. The bill ([HB 6](#)) is expected to be signed by early next week and will take effect immediately upon signature. Once signed, the Board will issue updated guidance to all licensees.

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### **Clarification on New HHS Buprenorphine Practice Guidelines**

To get evidenced-based treatment to more Americans with opioid use disorder, the Department of Health and Human Services (HHS) released new buprenorphine practice guidelines that among other things, remove a longtime requirement tied to training, which some practitioners have cited as a barrier to treating more people.

Please be advised that this change **still requires a prescriber to obtain a DEA-X waiver** to prescribe buprenorphine for opioid use disorder. The Board has posted a one-page fact sheet to assist prescribers and pharmacists in understanding this change. The fact sheet can be [accessed here](#).

Prescribers and pharmacists may also find more information about the changes using the [Quick Start Guide](#) and [FAQs](#) provided by HHS.

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### **Virtual Informational Session on New HHS Buprenorphine Practice Guidelines - May 21, 2021**

There is a free webinar, hosted by Get Waivered and California Bridge, that can help providers with completion of the Notice of Intent (NOI) Process, as well as answer any questions about the waiver process and administering buprenorphine. The event is being held May 21st, 2021 from 3-4 pm EST. Additional information and registration form can be found at: <https://getwaivered.com/remote>.

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### **Board of Pharmacy Now Accepting Applications for Pharmacist Workload Advisory Committee**

On April 20, 2021, the State of Ohio Board of Pharmacy approved the formation of a Pharmacist Workload Advisory Committee (PWAC). The formation of the committee is in response to the release of a July 2020 workload survey conducted by the Board ([www.pharmacy.ohio.gov/workload](http://www.pharmacy.ohio.gov/workload)).

The purpose of the advisory committee is to promote patient safety and compliance with Ohio laws

and rules by analyzing survey and other data and make recommendations to the Board to address pharmacist working conditions. PWAC recommendations may include changes to Board of Pharmacy rules as well as statutory changes.

As indicated in the resolution creating the committee (see: [www.pharmacy.ohio.gov/workload](http://www.pharmacy.ohio.gov/workload)), the Board is seeking to appoint two Ohio-licensed pharmacist members and one Ohio-certified pharmacy technician.

To be considered for an appointment, all interested applicants must submit a completed [application](#) no later than **June 4, 2021**. Submission instructions are included in the application, which can be accessed here: [www.pharmacy.ohio.gov/PWACapp](http://www.pharmacy.ohio.gov/PWACapp). The committee will have regular monthly meetings that last up to 2-3 hours so please consider this time commitment when preparing your application.

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### Rules for Public Comments

Acting under the authority of the Ohio Revised Code Chapter 4729, the State of Ohio Board of Pharmacy proposes the adoption of rules regarding distribution of compounded human drug products interstate.

The purpose of the proposed rules is to ensure Ohio can comply with the US Food and Drug Administration's (FDA) standard memorandum of understanding (MOU) that addresses interstate distribution of compounded drugs.

Under the [MOU](#), pharmacy compounders that distribute more than 50% of their compounded human drug products interstate will be identified by the states. States will be required to report certain information about these compounders to the FDA.

The 50% threshold merely triggers the information-sharing requirements; it does not limit the quantity of compounded drugs for humans that an individual compounding pharmacy may distribute outside its home state.

If a state does not enter into the MOU with FDA, a pharmacist, pharmacy, or physician in that state cannot sell more than 5% of its total compounding prescription orders across state lines.

For more information about the MOU, please see the following resources:

- [Memorandum of Understanding Addressing Certain Distributions of Compounded Drugs: Questions and Answers](#)
- [FDA MOU Full Text](#)

A copy of the rules can be accessed here: [www.pharmacy.ohio.gov/proposed](http://www.pharmacy.ohio.gov/proposed).

Comments on the proposed rules will be accepted until close of business on May 27, 2021.

Please send all comments to the following email address: [rulecomments@pharmacy.ohio.gov](mailto:rulecomments@pharmacy.ohio.gov).

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