



OREGON BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

No. 708 End of the National Emergency and PHE on May 11, 2023

On **January 30, 2023**, the **Biden Administration** announced its intent to end the national emergency and public health emergency (PHE) declarations on **May 11, 2023**, related to the coronavirus disease 2019 (COVID-19) pandemic. These emergency declarations have been in place since early 2020 and gave the federal government flexibility to waive or modify certain requirements in a range of areas, including the Medicare, Medicaid, and CHIP programs, and in private health insurance, as well as to allow for the authorization of medical countermeasures and to provide liability immunity to providers who administer services, among other things.

- **EUAs for COVID-19 Products (including tests, vaccines, and treatments)**

A separate emergency declaration pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) was issued by the secretary of the United States Department of Health and Human Services (HHS) in **February 2020**. Based on this determination, on **March 27, 2020**, the secretary declared that circumstances existed to justify **emergency use authorization (EUA)** of medical countermeasures for COVID-19. An EUA is a mechanism to facilitate availability and use of medical countermeasures that are determined to be safe and effective but have not yet been formally approved. An emergency declaration issued pursuant to Section 564 of the FD&C Act remains in effect until terminated by the HHS secretary. The timing to conclude the EUA is to be determined; it will not conclude on **May 11, 2023**, with the other declarations.

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- **PREP Act Liability Immunity**

A declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), pursuant to Section 319F-3 of the Public Health Service Act (PHS Act), was issued by the secretary of HHS in [March 2020](#). This declaration provides liability immunity for activities related to COVID-19 medical countermeasures. Since then, [10 amendments](#) to the declaration have been issued to extend liability protections related to COVID-19 countermeasures. For a PREP Act emergency determination, the secretary must specify an end date; in this case, it has been set as October 1, 2024, in most cases (although there are some exceptions). On April 14, 2023, HHS announced an [Intent to Amend the Declaration Under the PREP Act for Medical Countermeasures Against COVID-19](#). The final amendment may include extending coverage for certain activities through December 31, 2024. Once the final amendment is published, licensees should review the PREP Act to determine if liability protections related to COVID-19 countermeasures have been extended.

- **FDA Notice Concerning COVID-19-Related Guidance Documents**

On March 10, 2023, Food and Drug Administration (FDA) issued a [notice](#) in the *Federal Register* addressing the agency's [COVID-19-related guidance documents](#), including which of those guidance documents will no longer be in effect after the expiration of the COVID-19 PHE declared under the PHS Act, and which of those guidance documents FDA is revising to temporarily continue in effect. Please review each table in the *Federal Register* notice for a complete list.

- **DEA Announces Proposed Rules for Permanent Telemedicine Flexibilities**

On March 1, 2023, Drug Enforcement Administration (DEA) announced two proposed permanent rules ([Telemedicine Controlled Substance Proposed Rule](#) and [Telemedicine for Prescribing Buprenorphine Proposed Rule](#)) regarding circumstances when controlled substances may be prescribed without an initial in-person medical examination. The public was able to provide comments through March 31, 2023. Final rules are anticipated by May 11, 2023. Additional resources for practitioners can be found here:

- Proposed Rules Summary: [Telemedicine Rules Summary.pdf \(dea.gov\)](#)
- Proposed Rules Highlights for Medical Practitioners: [Telehealth Practitioner Narrative.pdf \(dea.gov\)](#)

- **OAR 855-007 Public Health Emergency Rules**

Most rules in Oregon Administrative Rule (OAR) 855-007 will no longer be in effect when the federal COVID-19 PHE ends on May 11, 2023, per [OAR 855-007-0010\(1\)](#).

No. 709 New CPE Rules – Effective July 1, 2023

In December 2022, the Oregon Board of Pharmacy adopted new rules for continuing pharmacy education (CPE) in [OAR 855-135](#), effective July 1, 2023. The current rules in OAR 855-021 will sunset on June 30, 2023. Requests for Board approval of CPE programs received by the Board prior to July 1, 2023, will be handled per OAR 855-021 and the application processes currently in place. All requests for approval of a CPE program on or after July 1, 2023, must comply with the new rules in OAR 855-135 and the new application processes. The Board will publish a detailed article about how these rule changes affect licensees renewing their license on or after July 1, 2023, in the August 2023 edition of this *Newsletter*.

No. 710 Rulemaking

• **Proposed Permanent Rules Sent to Rulemaking in April for May 23, 2023 Rulemaking Hearing**

In April 2023, the Board sent the following rules to rulemaking to seek public comment and for potential adoption at its June 2023 Board meeting. Please check the Board's rulemaking [page](#) for the most up-to-date information concerning the proposed rules, information on how to provide comments on the proposed rules, and how to [sign up](#) for rulemaking notices.

- [Divisions 006/041/043/045/080/139/141](#) – related to adopted standards by reference
- [Divisions 019/020](#) – related to pharmacist prescriptive authority
- [Divisions 019/041/043/045/080/139/141/143](#) – related to self-inspection form completion date

• **Temporary Rules Adopted in February 2023**

- [Division 045](#) – related to US Pharmacopeia (USP) <795> and USP <797> adopted standards by reference, *effective May 5, 2023. Temporarily permits Drug Outlet pharmacies to implement USP <795> Pharmaceutical Compounding–Nonsterile Preparations (v.11/01/2022) and USP <797> Pharmaceutical Compounding–Sterile Preparations (v.11/01/2022) as an alternative to USP <795> (05/01/2020 v. 2014) and USP <797> (05/01/2020 v. 2008).

No. 711 Compliance: Buprenorphine DATA-Waiver

DEA has updated requirements for buprenorphine. On December 29, 2022, Congress signed the Consolidated Appropriations Act of 2023, removing the federal requirement for practitioners to submit a Notice of Intent or have a waiver to prescribe medications, such as buprenorphine, for the treatment of opioid use disorder. All DEA registrants should be aware of the following:

- 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.

The Consolidated Appropriations Act also introduced new training requirements for all prescribers. These requirements will not go into effect until June 27, 2023. DEA and the Substance Abuse and Mental Health Services Administration are actively working to provide further guidance, and additional information on these requirements will soon be available from DEA. Additionally, these new requirements do not impact the changes related to elimination of the DATA-Waiver Program described above. SAMHSA and DEA have released a separate provision of the Omnibus bill related to [training requirements](#) for DEA registration that becomes effective in June 2023. Visit [SAMHSA.gov](https://www.samhsa.gov) to learn more.

No. 712 Licensing: Reminder – Pharmacist and Pharmacy Technician License Renewals

All pharmacists and pharmacy technicians (PTs) with licenses that expire on June 30, 2023, will need to renew their license in the coming weeks. Here are a few reminders:

- **Registered Pharmacists (RPhs):** During the period from July 1 through June 30 of each biennial license renewal cycle, each pharmacist must have satisfactorily completed 30 hours of CPE **prior to submission** of the license renewal. CPE required for the 2023 renewal include a minimum of at least:
 - two hours in pharmacy and drug law;
 - two hours of CPE credit in patient safety or medication error prevention;
 - one hour in pain management provided by the [Oregon Pain Management Commission \(OPMC\)](#); and
 - two hours of cultural competency CPE either approved by the [Oregon Health Authority](#) under [Oregon Revised Statute 413.450](#) or any cultural competency CPE.

In accordance with [OAR 855-021-0005\(2\)](#), pharmacists applying for the first renewal of their license have to complete CE if they have been licensed by the Board for at least one year prior to July 1 of the renewal period.

- Pharmacists initially licensed between July 1, 2021, and June 30, 2022, must complete the CE requirements for the 2023 renewal.

- Pharmacists initially licensed between July 1, 2022, and June 30, 2023, do not have to complete the CE requirements for the 2023 renewal*.
 - *Effective July 1, 2023, CPE requirements will be found in OAR 855-135 and will apply to all renewals received on July 1, 2023, or later.
- **PTs:** If your PT license expires on June 30, 2023, you must either renew your license for one year to align with the 2024 technician renewal cycle or complete the requirements for a certified Oregon pharmacy technician (COPT) license and have a new COPT license issued prior to June 30, 2023. Additional information on the 2023 renewal of a PT license can be found [here](#).
- **CPE Documentation:** Pharmacists, PTs, and COPTs may upload their CPE completion certificates using [eGov](#) where licensees can maintain their own record and upload documents directly into their profile. Please visit <https://orbop.mylicense.com/EGOV/> and register for a new personal account or, for registered users, log in to access your account. Instructions for creating a new account can be found on the Board [website](#).
 - Once you are logged into your account, click on “Update License Info” or “Renew a License” in the menu and then navigate to “Attach Documents” to upload your CPE certificate into the selected license account.
 - CPE documents that should be uploaded to your electronic licensing record include: cultural competency, contraception certification certificates (RPh only), pain management CPE provided by the OPMC (RPh only), and all non-Accreditation Council for Pharmacy Education-accredited CPE.

No. 713 Well-Being Index for Pharmacy Personnel

Pharmacy personnel well-being as it relates to safe pharmacy practice conditions has been an active area of discussion among the National Association of Boards of Pharmacy® (NABP®), state boards of pharmacy, the American Pharmacists Association (APhA), and other pharmacy organizations. It is widely perceived that conditions in pharmacies over the past several years, including the increased number, volume, and complexity of services provided during the COVID-19 pandemic have contributed to unsafe practice conditions and an inability to provide timely services in many pharmacies. These factors have increased the level of pharmacy staff distress related to their practice. Pharmacy staff identified as being in a state of high distress have been shown to have a two-fold higher risk of making medication errors. Thus, pharmacy staff distress may be directly related to public health and safety.

The [Pharmacy Well-Being Index](#) is a validated self-assessment tool developed at the Mayo Clinic and made available by APhA that measures multiple dimensions of distress and well-being, including quality of life, fatigue, burnout, concern for a recent major medication error, and intent to leave their current job. The self-assessment tool measures six dimensions of distress and well-

being in just nine questions that take less than one minute to complete. Assessments can be completed by pharmacy personnel once per month to provide trends that can be measured over time and compared geographically. You can view analysis ([PWWR Report IV – December 2022](#)) and snapshot ([PWWR Snapshot – December 2022](#)) reports on the website linked above.

All pharmacy personnel may participate in the [Pharmacy Workplace and Well-Being Reporting \(PWWR\)](#) survey, which is anonymous and confidential. APhA and NABP have been providing reports to boards that compare their state to other states in their NABP region. With increased participation in the survey, the data will be more reliable and can serve to assist employers and regulators in making changes to help reduce distress and the potential for medication errors among pharmacy personnel.

No. 714 Free Tools for Safe Pharmacy Practice

Oregon Health & Science University (OHSU) and the Institute for Safe Medication Practices (ISMP) offer valuable tools for safe pharmacy practice.

- **OHSU Medical Library Resources**

Did you know all Oregon-licensed health providers have access to the AccessMedicine Database through the OHSU Library, even if they are not affiliated with OHSU? This database provides information on basic sciences and medicine, including *Harrison's Principles of Internal Medicine* and *Goodman & Gilman's: The Pharmacological Basis of Therapeutics*. To create an OHSU Library account, visit the [OHSU Library Account Application](#) page. Additionally, you can visit the OHSU Biomedical Information Communication Center Library located in Portland, OR, during regular business hours, where you can check out library books and scan or download journal articles free of charge (visit ohsu.edu/library for hours). From the computer stations, you can access nearly all of the resources available at the OHSU Library. This includes thousands of journals and key databases such as CINAHL and ClinicalKey for Nursing, Cochrane Library, OVID MEDLINE, Pediatric Care Online, PsycINFO, and Scopus. To register for this service, visit OHSU's Resources for Oregon-Licensed Health Providers [website](#). Contact the OHSU Library with any questions or to learn more about eligibility to use this service.

- **ISMP's Targeted Medication Safety Best Practices**

The best practice recommendations presented in these guidance documents are based on error reports received through the [ISMP National Medication Errors Reporting Program](#), have been reviewed by an external expert advisory panel, and have been approved by the ISMP Board of Trustees. To access these free resources, you must register with ISMP and log in.

- [Targeted Medication Safety Best Practices for Community Pharmacy](#) – This initiative was recently launched in 2023 and will be updated with additional best practices, as needed, every two years.

- [Community Pharmacy Worksheet](#)
- [Targeted Medication Safety Best Practices for Hospitals](#) – This initiative was first launched in 2014 and is updated with additional best practices, as needed, every two years.
- [Hospital Pharmacy Worksheet](#)

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