

# **OREGON STATE** BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

## No. 678 Safe Pharmacy Practice Conditions

Oregon State Board of Pharmacy staff continues to field an unprecedented number of complaints regarding pharmacy practice conditions. In December 2021, the Board released a statement on safe pharmacy practice conditions and requested that a workgroup be formed to inform the Board on this topic. The workgroup held its first meeting in January 2022 and assisted in development of a survey regarding safe pharmacy practice conditions. In February, the survey was sent to all licensees, and responses were collected over a two-week period. Over 2,000 surveys and 500 comments were received during this period. In March and May, the workgroup reviewed the preliminary survey data and comments and began identifying potential targets for future rulemaking. In April, staff provided the Board with a preliminary copy of the survey data; and in June, staff provided the Board with a final copy of the survey data. The workgroup has meetings planned for July and September to review proposed rules to impact pharmacy practice conditions.

# No. 679 Expedited Partner Therapy Updates

The Oregon STD Prevention Program has updated the state's expedited partner therapy (EPT) guidelines. In addition to these updated guidelines and a document summarizing the changes between the 2015 and 2022 guidelines, new educational materials for providers, pharmacists, and partners are also available. The materials listed below are posted on the Oregon Health Authority

(OHA) Public Health Division EPT web page:

- Expedited Partner Therapy for Chlamydia and Gonorrhea: Guidance for Health Care Professionals in Oregon, 2022
- Summary of Changes to EPT Recommendations, 2022
- EPT Fact Sheet for Providers

## National Pharmacy Compliance News

A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

- EPT Fact Sheet for Pharmacists
- Partner Treatment for Chlamydia (English/Spanish)
- Partner Treatment for Gonorrhea (English/Spanish)

Oregon Administrative Rules (OAR) 855-041-4000 and OAR 855-041-4005 (for remote dispensing site pharmacies (RDSPs) OAR 855-139-0725 and OAR 855-139-0730) outline the requirements for dispensing a medication for EPT.

## No. 680 Rulemaking

#### Rule Feedback

There are two primary ways for a licensee, registrant, stakeholder, or the public to provide feedback on rules:

- 1. For rules that are currently in rulemaking, interested parties are encouraged to submit comments and questions on the proposed rules either in writing via pharmacy.rulemaking@bop.oregon.gov or by testifying during a rulemaking hearing (sign-ups are available on the Board's rulemaking page). Deadlines and additional information on submitting comments or testimony is included in the rulemaking notice. Rules currently in rulemaking are posted on the Board's rulemaking page, and only comments received during the rulemaking period or made during the hearing will be included in the record.
- 2. For rules that are **not** currently in rulemaking, interested parties may provide comments and questions via pharmacy.rulemaking@bop.oregon.gov. The agency recognizes that it is useful to have a mechanism to accept submissions of any information related to Board rules that may be unrelated to the specific issues and rules addressed in a rulemaking notice. The agency will not respond to questions or requests regarding issues or rules that are not currently in rulemaking but will review information submitted.

## Permanent Rules Adopted in April 2022

- Division 006/041/139 related to definitions. Amends "Supervision by a Pharmacist":
   adds "Alarm system," "Audiovisual communication system," "Entry system," and
   "Surveillance system." Moves some definitions in Division 041/139 to Division 006:
   "Biosimilar product," "Interchangeable," "Reference biological product," "Repackage," "Still image capture," and "Store and forward."
- Division 020 related to coronavirus disease 2019 (COVID-19) antigen self-test protocol.
   Amends protocol compendia to include COVID-19 antigen self-test.
- Division 020/041/065/139 related to alarm, audiovisual communication, entry, and surveillance systems. Amends the inconsistent use of terms related to "alarm system," "audiovisual communication system," "entry system," and "surveillance system."
- Division 021/025/110 related to certified Oregon pharmacy technician (COPT) and pharmacy technician (PT) licensure. Clarifies the elements of a complete application,

- renewal, and reinstatement of a COPT and PT license. Adds PTs to fees and rate adjustment rules.
- Division 041 related to disclosure of patient information. Amends prohibited practices
  related to disclosure of patient information. Permits disclosure of patient information as
  permitted by federal and state patient confidentiality laws and to the patient or persons
  authorized by the patient. Prohibits accessing or obtaining patient information unless it is
  for the purpose of patient care.
- Division 041/139 related to accurate pharmacy hours and temporary pharmacy closures.
   Requires that pharmacies post accurate hours of operation and update due to temporary or emergency closure.
- Division 080 related to Schedule I exceptions. Amends Schedule I rule by adding exceptions to marijuana and delta-9-tetrahydrocannabinol.
- Division 143 related to pharmacy prescription lockers (PPLs). Rules establish a new drug outlet type of PPL and permit a pharmacy to operate a PPL.

### **Permanent Rules Adopted in June 2022**

- Division 006/041/043/045/080/139 related to standards adopted by reference and definitions. Updates incorporated standards adopted by reference.
- Division 019/025/041 related to 2022 HB 4034 (Section 24) PT/COPT final verification.
   Permits a pharmacist to delegate final verification of drug and dosage form, device, or product to a COPT or PT. Adds and amends general responsibilities of pharmacists, COPT/PTs, and drug outlets. Updates policies and procedures required by pharmacy.
- Division 019/041/139 related to 2021 HB 2359 interpreters. Requires pharmacists
  and interns to work with health care interpreters from the health care interpreter registry
  operated by OHA to provide interpretation services. Modifies patient records requirements
  to include patient's preferred language for communication and prescription labeling. Rules
  effective September 1, 2022.
- Division 019/143 related to PPL. Proactive procedural rule review amendments pursuant to public testimony.
- Division 020 related to pharmacist prescriptive authority tobacco cessation and preexposure prophylaxis (PrEP). Updates protocol compendia with new protocol versions for tobacco cessation and PrEP.
- Division 031 related to public health emergency rules sunset. Repeals intern precepting provision effective during the 2020-2021 academic year.
- Division 041 related to 2022 HB 4034 (Section 18) telework. Permits a PT to engage in

telework. Adds configuration and records requirements for telework.

- Division 041/139 related to permanent pharamacy closure requirements. Updates
  prescription transfer requirements, creates pharmacy permanent closure requirements, and
  requires patient access to pharmacy records.
- Division 080 related to 2022 HB 4034 (Section 1) pseudoephedrine (PSE) or ephedrine (EPH) and interns. Permits an intern to transfer PSE or EPH without a prescription.
- Division 110 related to drug outlet categories. Reorganizes drug outlet categories by registration type.
- Division 139 related to 2022 HB 4034 (Section 19) RDSP. Removes certain personnel and ratio requirements for RDSP.

## No. 681 Compliance: Legal Advice vs Legal Information

The Board frequently receives practice questions from licensees and registrants about the Board's laws and rules. The purpose of this article is to clarify what the Board can and cannot do when it receives this type of inquiry.

## Board staff can provide information about the Board's statutes and rules.

Board staff can point you in the direction of the applicable statutes and rules and provide you with links to statutes and rules that are applicable. Please know that Board staff may not be providing everything that could apply to your specific situation – you should also do your own due diligence by looking through the statutes and rules to see what may apply.

# Board staff may be able to provide other information, such as a *Newsletter* article where the topic has been addressed.

Again, please know that this information is just a starting point. Board staff do not have the resources to research and find all other information that might fit the criteria you are requesting, but if they are aware of something that is easily accessible, staff will provide it.

### Board staff cannot provide legal advice to you.

Legal advice is interpreting and explaining how a law or rule applies to a person's specific situation; legal advice must be provided by an attorney. Board staff can point you to the Board's laws and rules but cannot provide you with legal advice as to how the law or rule applies to a specific situation.

## Board staff cannot tell you what the Board may or may not do in a specific situation.

When the Board receives a complaint, the case is investigated and presented to the Board. The Board issues a notice of proposed action, and the recipient might request a hearing before a final order is considered by the Board, or the matter might settle. Board staff cannot tell you what the Board will or will not do in any specific situation — there is a process by which the Board makes those decisions. If you think that someone is doing something that might violate the Board's laws, Board staff cannot tell you whether it does or not, but you can make a complaint and the matter will be investigated.

#### Resources

- OAR Chapter 855
- Oregon Revised Statues Chapter 689 and Chapter 475
- Public Records Request: Please note that there may be fees associated with the production of records, see standard fee schedule.

## No. 682 Licensing: Technician Renewals Due June 30, 2022

During the period from July 1 through June 30 of each biennial license renewal cycle, each COPT must have satisfactorily completed 20 hours of continuing education (CE) **prior to submission** of the license renewal. A minimum of at least two hours of CE credit must be earned in pharmacy and drug law. A minimum of two hours of CE credit must be earned in patient safety or medication error prevention. The remaining 16 hours of CE credit can be earned on any topic.

Beginning with the 2022-2024 license cycle, all PTs and COPTs must earn two hours of CE credit in cultural competency either approved by OHA under Oregon Revised Statutes 413.450 or any cultural competency. Cultural competency CE credit is not required for the 2022 license renewal.

In accordance with OAR 855-021-0009(2), PTs and COPTs applying for the first renewal of their license must complete CE if they have been licensed by the Board for at least one year prior to July 1 of the renewal period.

- PTs initially licensed between July 1, 2020, and June 30, 2021, do not have to complete the CE requirements for the 2022 renewal.
- COPTs initially licensed between July 1, 2020, and June 30, 2021, must complete the CE requirements for the 2022 renewal.
- COPTs and PTs initially licensed between July 1, 2021, and June 30, 2022, do not have to complete the CE requirements for the 2022 renewal.

## No. 683 REALD and Pharmacies

Pharmacies are reminded to collect and provide race, ethnicity, language, and disability (REALD) information for COVID-19-related encounters according to OAR 943-070. The COVID-19 pandemic has brought social and racial injustice and inequity to the forefront of public health. It has highlighted that health equity is still not a reality as COVID-19 has unequally affected many racial and ethnic communities, putting them more at risk of getting sick and dying from COVID-19. Without good data, the state cannot fully understand the extent to which these communities are being impacted and cannot adjust the state's response to better protect them. In order to address this data gap, during the 2020 first special session, the Legislature passed HB 4212 (see Sections 40-43), which requires certain health care providers, including pharmacists, to collect REALD data from patients during a COVID-19 encounter and report this data to OHA in accordance with Oregon's disease reporting rules,

if reporting is required. A COVID-19 encounter is defined as "an interaction between a patient, or the patient's legal representative, and a health care provider, whether that interaction is in person or through telework, for the purpose of providing health care services related to COVID-19, including but not limited to ordering or performing a COVID-19 test." (HB 4212, Section 40). Health care providers are required to report to OHA, generally within one day, the following:

- All human cases or suspected human cases of the diseases, infections, microorganisms, intoxications, and conditions specified in OAR 333-018-0015, which includes, but is not limited to: Hepatitis B and HIV infection (does not apply to anonymous testing).
- OAR 333-018-0016:
  - · COVID-19 cases
  - COVID-19 hospitalizations
  - COVID-19 deaths
  - · Negative COVID-19 tests
  - · Multisystem inflammatory syndrome in children

The specific requirements for disease reporting and the timelines can be found at OAR 333-018, specifically OAR 333-018-0011, OAR 333-018-0015, and OAR 333-018-0016.

As of January 1, 2022, the collection and reporting of REALD information is required by all health care providers (including pharmacists). The standards for collecting REALD information can be found at OAR 943-070. Enforcement of the collection and reporting REALD requirements began on January 1, 2022. OHA will report noncompliant providers to the Board; and while the Board will work to bring health care providers into compliance, the collection and reporting of REALD information is a priority for the state and will be taken seriously.

You can find data collection templates, guides to asking questions, the full implementation guide, and other resources by navigating to the REALD section on OHA's website. In addition, the Board has a sample REALD standardized patient intake form available on the Public Health & Pharmacy Formulary Advisory Committee web page.

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