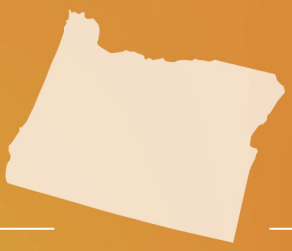
NOVEMBER 2023



OREGON BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

No. 723 New Rules for Pharmacists, Interns/Preceptors, Certified Oregon Pharmacy Technicians/Pharmacy Technicians, Board Administration, and Universal Rules – Effective March 1, 2024

At the August 2023 Oregon Board of Pharmacy meeting, the Board adopted five new divisions of Oregon Administrative Rules (OARs) in Chapter 855. These new divisions revise and replace existing divisions, as shown below.

New Division	Replaced Division*
102 – Board Administration	10 – Board Administration & Policies
104 – Universal Rules	1 – Procedural Rules
115 – Pharmacists	19 – Pharmacists
120 – Interns/Preceptors	31 – Interns
125 – Certified Oregon Pharmacy Technicians/ Pharmacy Technicians	25 – Certified Oregon Pharmacy Technicians/ Pharmacy Technicians

**It is anticipated that the Board will motion to repeal these divisions via rulemaking at the December 2023 Board meeting.*

These rule changes are part of the Board's 2022-2026 Strategic Plan to proactively review and update rules to provide clear expectations to licensees and registrants to promote compliance and patient safety. Each licensee is encouraged to:

1. Read the new rules. Since the rules are not effective until March 1, 2024,

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the rules do not currently appear in the Oregon Administrative Rules Database for Chapter 855. The new rules can be viewed on the Board's rulemaking web page or by clicking on the links in the Rule Revision Navigation Chart.

2. Review the Navigation Chart **for OAR Chapter 855 rule revisions.** This chart has been created to help licensees and registrants understand the new rule divisions. The chart does not cover every detail of each rule change but provides a high-level overview of the changes. In addition, not every new rule corresponds exactly to an old rule.

3. Attend one of the virtual informational sessions on the new rules that will be held by the Board. Licensees and registrants will receive an email notification of the dates and times for these virtual sessions once they are determined. It is anticipated that these sessions will occur in early 2024.

No. 724 Coming Soon! Updated and New Rules Related to Short-Acting Opioid Antagonists and Immunizations

At the October 2023 Board meeting, the Board considered revised rules related to short-acting opioid antagonists (eg, naloxone, nalmefene) and immunizations.

- **Short-Acting Opioid Antagonists:** The Board has adopted amendments to existing rules in OAR 855-019, OAR 855-041, OAR 855-043, OAR 855-044, and OAR 855-139 related to naloxone by utilizing the newly defined term "short-acting opioid antagonist" instead of "naloxone," per directives of 2023 House Bill (HB) 2395. In addition, existing rules for pharmacies, dispensing practitioner drug outlets (DPDOs), correctional facilities (CFs), community health clinics (CHCs), and charitable pharmacies have been amended by incorporating the labeling exemption that applies when a prescriber personally dispenses a short-acting opioid antagonist in the form of a nasal spray, per directives of 2023 Senate Bill (SB) 450. Both OAR 855-041-2340 Naloxone and OAR 855-139-0720 Naloxone General Requirements were repealed, as these requirements can be found in other existing rules. At the same time, the Board adopted new rules in OAR 855-115 with similar language and intent, effective March 1, 2024. Please note that there are no requirements for pharmacists to have additional training, certification, or licensure by the Board to prescribe naloxone.

- **Immunizations:** Due to recently adopted legislation, the Board considered new and revised rules related to immunizations at the October 2023 Board meeting. The Board motioned to send these rules to rulemaking. The proposed rules, **if adopted** at the December 2023 Board meeting, will permit a pharmacist or intern to administer an influenza vaccine to a person who is six months of age or older per 2023 HB 2278, beginning January 1, 2024.

  In addition, the proposed rules, **if adopted,** will permit an appropriately trained and qualified certified Oregon pharmacy technician (COPT) and pharmacy technician (PT) to perform the physical act of administering vaccines under the supervision of an appropriately trained and qualified pharmacist pursuant to 2023 HB 2486, beginning January 1, 2024.

Prior to administration of a vaccine, the COPT or PT must receive practical training that includes infection control, recognition of anatomical landmarks, and competency in hands-on administration technique and hold active CPR certification. CPR certification must be issued by the American Heart Association, the American Red Cross, or any other equivalent program that is specific to the age and population receiving the vaccine, contain a hands-on training component, and be valid for not more than three years. The proposed rules also:

- Remove the requirement for the pharmacist to "give" a Vaccine Information Statement (VIS) to the patient and ensure that it was read by/to the patient and, alternatively, requires the pharmacist to "ensure" that each patient receives a VIS.
- Add pharmacist requirements for supervising interns, COPTs, and PTs who administer a vaccine, which include the pharmacist being immediately available to the vaccinator.
- Require each Drug Outlet Pharmacy to have policies and procedures for COPT/PT administration of vaccines and the disposal of drugs and/or devices, including hazardous and pharmaceutical waste.

The proposed rules, **if adopted,** also prohibit a COPT/PT working at a Remote Dispensing Site Pharmacy to administer a vaccine. At the same time, the Board motioned to send new rules to rulemaking in OAR 855-115 and OAR 855-125 with similar language and a proposed effective date of March 1, 2024.

No. 725 Rulemaking

Licensees are encouraged to review rules added, amended, repealed, and sent to rulemaking during the October 2023 Board meeting.

- **Rules Adopted in October 2023**
  - Division 007 – related to compliance with Oregon Health Authority COVID-19 rules. Repeals COVID-19-related rule no longer in effect.
  - Divisions 019/041/043/044/139 – related to short-acting opioid antagonists – Amends existing rules related to naloxone by utilizing the newly defined term "short-acting opioid antagonist" instead of "naloxone," per directives of 2023 HB 2395. Amends existing rules for pharmacies, DPDOs, CFs, CHCs, and charitable pharmacies by incorporating the labeling exemption that applies when a prescriber personally dispenses a short-acting opioid antagonist in the form of a nasal spray, per directives of 2023 SB 450. Repeals OAR 855-041-2340 Naloxone and OAR 855-139-0720 Naloxone General Requirements, as these requirements can be found in other existing rules.

- Division 045 – related to United States Pharmacopeia (USP) <795> and USP <797> standards adopted by reference. 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).
- Division 115 – related to short-acting opioid antagonist. Proposed rule incorporates the newly defined term "short-acting opioid antagonist" from 2023 HB 2395 and incorporates the labeling exemption that applies when a prescriber personally dispenses a short-acting opioid antagonist in the form of a nasal spray, per directives of 2023 SB 450.

- **Proposed Permanent Rules Sent to Rulemaking in October for November 21, 2023 Rulemaking Hearing.** The following rules are open for public comment via rulemaking and will be considered by the Board for potential adoption at its December 2023 Board meeting.
  - Divisions 019/025/041/139 – related to pharmacist/COPT/PT administration of vaccines
  - Division 020 – related to vaccination protocols – protocol compendium
    - Each proposed protocol may be viewed here.
  - Division 041 – related to Drug Outlet requirements
  - Division 080 – related to Schedule II prescriptions
  - Divisions 115/125 – related to pharmacist/COPT/PT administration of vaccines
  - Division 115 – related to pharmacist applicability, definitions, supervision, counseling, PIC qualifications and limitations, CPA and CDTM
  - Division 125 – related to pharmacy technician prohibited practices

No. 726 Compliance: Updated Inspection Processes, Requests for Additional On-Site Inspections, and a Reminder About Prescriptions From Veterinarians

This article covers the updated pharmacy inspection process that became effective in October 2023, explains what to do if an outlet needs additional on-site inspections, and reminds licensees that a veterinarian does not have a National Provider Identifier (NPI).

- **Updated Inspection Processes Effective October 2023**

  Board compliance officers (COs) routinely inspect pharmacies on a biennial basis, usually without notice. As of October 2023, COs are utilizing a new Board-approved, updated inspection process. As part of this process, a CO will notify the pharmacist-in-charge (PIC) and the outlet of a two-week window during which they plan to inspect the pharmacy.

Please make sure that each pharmacist and outlet has updated their work email and outlet inspection email addresses in e-Gov. Instructions on how to do this are available in article #727 of this *Newsletter.*

All Board COs are licensed pharmacists with more than five years of active pharmacy practice experience. As such, they understand the demands of pharmacy workflow and workload, and strive to minimize disruption during inspections. While it may be easier and more efficient to conduct an inspection with the PIC present, this is not always possible. Board staff requests that PICs ensure that all pharmacy staff members are aware of the notified inspection window and can assist with the inspection process as needed.

COs use the self-inspection form (SIF) as a guide for inspections. This is why the SIF is often called the "open-book test." If the PIC has carefully completed the SIF, including the checklist, and organized the relevant records, the on-site inspection can and should be a positive and productive experience for the PIC and pharmacy staff. If the CO identifies an observation during the inspection, it will be documented in the inspection report. In the new Board-approved inspection process, the CO will no longer issue "Non-Compliance Notifications" or "Deficiency Notifications." Instead, observations will be documented in the inspection report, and the CO will indicate either "Response Required" or "No Response Required."

If "No Response Required" is indicated, the inspection report will be finalized by the CO and provided to the PIC and the outlet. If a "Response Required" is indicated, the CO will provide the PIC and outlet with the opportunity to respond to the observations from the inspection. The Board will review each response and determine the next steps at the next applicable Board meeting. The PIC and outlet will be notified of the Board's decision. Please note that this process has many moving parts, and the time to completion is dependent on many factors, including licensee/registrant response time, the next applicable Board meeting deadline, and the time needed for Board staff to prepare documents after the Board meeting. The CO will keep the PIC and pharmacy updated on the timeline of the process.

Finally, a completed on-site inspection is not a declaration that the pharmacy is in full compliance with all regulations and standards of practice. During an inspection, it is impossible to review and evaluate every aspect of a pharmacy's compliance. The PIC is responsible for ensuring that the pharmacy and staff maintain compliance and is the person that the Board holds accountable for all questions regarding the pharmacy.

- **Requests for Additional On-Site Inspections**

  The Board has experienced a significant increase in workload in recent years, and has reorganized processes to ensure that the safety, health, and welfare of Oregonians remains its top priority. During this time, the Board moved to a biennial inspection cycle, meaning that all pharmacies are inspected once every two years. After this process was implemented, the Board received requests from outlets for additional on-site inspections.

The Board does not have the resources to provide additional inspections. If an outlet needs an additional inspection as part of its registration renewal in another state, the Board recommends that they coordinate with that state to meet its renewal process requirements. NABP's Verified Pharmacy Program® (VPP®) is the most widely recognized, multistate uniform inspection program accepted by state boards of pharmacy across the nation. This coordination may include the need to identify an approved third-party vendor to conduct an inspection that meets that state's requirements.

- **NPI Requests for Veterinary Prescriptions**

  Veterinarians continue to report that some pharmacies routinely request the veterinarian's NPI when processing prescriptions for animal patients. An NPI is a unique identification number for human health care providers for billing Medicare and Medicaid. Veterinarians are not eligible for NPIs because they do not meet the regulatory definition of "health care provider" as defined in 45 Code of Federal Regulations 160.103.

  Veterinarians also report that some pharmacies routinely ask for the veterinarian's Drug Enforcement Administration (DEA) number for non-controlled substance prescriptions as an alternative to an NPI. The DEA strongly opposes using a DEA number for non-controlled substances, as it would lead to a weakened registration system and defeat the purpose of the DEA number.

  To confirm prescriptive authority or the validity of a prescription, pharmacists may consider asking for the veterinarian's state veterinary license number or another identifier. If the lack of an NPI or DEA number creates a problem for the pharmacy computer processing or billing systems, the pharmacy staff should work with their leadership and information technology services to address the issue. The Board encourages pharmacists to prioritize patient care and ensure that computer systems and automated processes do not interfere with the provision of safe and effective care. Delays in care resulting from information system problems should be avoided, if possible.

No. 727 Licensing: How to Update Outlet Contact Information and Pharmacist Work Email in e-Gov

To update and confirm any registration- or license-related information, please log in to the e-Gov account associated with the license/registration.

To update your outlet's PIC/consultant pharmacist work email and inspection contact email:

1. Log in to your appropriate eGov account.
2. Using the left-hand menu, select "Update License Info & Upload Documents."
3. Select the appropriate license and click "Continue."
4. Using the left-hand menu, select "Information Update."

5. Enter the PIC or consultant pharmacist email address in the "PIC/Consultant Pharmacist Work Email" field.
6. Enter the person who should be contacted concerning an inspection of the outlet in the "Outlet Inspection Contact Email" box and click "Save."
7. Click "Continue" on the Document Upload page.
8. Once all checklist items have been completed, click "Continue," or, in the left-hand menu, select "Finish."
9. Review the information on the Summary page to confirm that everything is correct.
10. Click "Submit Attestation." A copy of this update will be added to the Board's licensing file.

How to update your pharmacist work email:

1. See steps 1-3 above.
2. Using the left-hand menu, select "Demographics."
3. Under Physical Address in the "Email" field, enter your personal email. This email cannot be your work email.
4. Click "Save & Continue."
5. Using the left-hand menu, select "Information Update."
6. Under "Employment Related Contact Information" in the "Work email" field, enter your work email. If you do not have a work email, please enter "None" and click "Save."
7. See steps 7-10 above.

No. 728 Minutes for Board-Related Meetings

At the August 2023 Board meeting, the Board authorized staff to discontinue drafting written meeting minutes for all future Board-related meetings and, instead, post the meeting recordings along with a meeting summary on the Board website. The meeting summaries include roll calls, meeting agenda items with timestamps, and all motions with votes. The Board will retain the meeting audio recording as the official record of the meeting, consistent with Oregon Revised Statute 192.650, and post the meeting audio recording on the Board's website along with the meeting summary.

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