



OREGON BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

No. 701 New Contraception Protocol Effective

At the December 2022 Oregon Board of Pharmacy meeting, the Board adopted a revised contraception protocol, **effective February 1, 2023.**

What is happening? The contraception prescribing process has changed from the process in place since its inception in 2016 to a new process effective February 1, 2023. Under the new process, the contraception protocol was transferred from the 2015 House Bill (HB) 2879 Contraception Workgroup to the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC).

Why is it happening? To streamline and consolidate pharmacist prescribing rules, the Board is in the process of moving all pharmacist prescribing services to the PHPFAC. Prior to this move, there was not an effective way for pharmacists to provide feedback on the protocol. Under the PHPFAC, pharmacists can submit feedback utilizing the Feedback Form on the PHPFAC [web page](#).

When did it happen? As of February 1, 2023, pharmacists must use the revised contraception protocol (v. 12/2022) found on the Board's PHPFAC [web page](#).

What has changed? The updated contraception [protocol](#) contains six documents:

1. Cover Page – Contains information on the statutory authority and purpose for prescribing contraception, standardized elements, required pharmacist education/training, references, and resources.

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2. Patient Intake Form (required) – This required document is an updated version of the Self-Screening Risk Questionnaire. Major changes include:

- New background information section to determine if the patient qualifies for pharmacist contraception prescribing.
- Updated contraception history section to assess if and which type of contraception is appropriate for the patient.
- Required pregnancy screen section. This section is now required and not optional.
- Reorganized medical health and history section.
- Required pharmacist section to complete at the end of the visit.

3. Assessment Pathway (required) – This required document is an updated version of the Contraceptive Algorithms.

- Major changes to Algorithm A – Oral, Vaginal, and Transdermal Contraception with Combined Hormonal Contraceptives and Progestin Only Pills (POP) include:
 - Step 1: Incorporation of background information section from patient intake form into first step of algorithm.
 - Step 3: Removal of specific list of drugs to consider. The pharmacist must utilize the United States Medical Eligibility Criteria (US MEC) to determine if any drugs are US MEC category 3 or 4 and, if so, make appropriate referrals to a primary care or women’s health care practitioner.
 - Step 4: If prescribing a POP, a patient may have a blood pressure > 140/90.
 - Step 7: Requires referral to a primary care or women’s health care practitioner for any unexplained vaginal bleeding that worries the patient, and/or a blood pressure \geq 140/90.
 - Step 8: Incorporates required visit summary into last step of algorithm.
- Major Changes to Algorithm B – Injectable Contraception – Depot Medroxyprogesterone (DMPA) include:
 - Step 1: See changes listed under Algorithm A.
 - Step 3: See changes listed under Algorithm A. In addition, any unexplained vaginal bleeding that worries patient (Patient Intake Form #15) – requires a referral.
 - Step 6: Permits a pharmacist to prescribe DMPA SQ for self-administration by the patient. Requires observation of first self-administration.
 - Step 8: See changes listed under Algorithm A.

4. Prescription Template (optional) – This is an optional document for the pharmacist to utilize when prescribing contraception.
5. Provider Fax (required) – This document must be faxed to the patient’s identified health care provider within five days of the visit.
6. Patient Visit Summary (required) – This document must be provided to the patient at the completion of the visit.

Rule Changes Effective February 1, 2023:

- Oregon Administrative Rules (OARs) 855-019-0400, 855-019-0405, 855-019-0410, 855-019-0415, 855-019-0425, 855-019-0430, and 855-019-0435 related to contraceptive prescribing are repealed.
- OAR 855-020-0110 is modified to ensure that training and education requirements have been met prior to engaging in prescribing, and requirements for retaining copies of the training and education are outlined in rule.
- OAR 855-020-0120 adds language that prohibits prescribing drugs or devices when the formulary and protocol compendia requires a referral to a non-pharmacist provider and adds that a pharmacist must not require, but may allow, a patient to schedule an appointment with the pharmacist for prescribing or administering of an injectable hormonal contraceptive or the prescribing or dispensing of a self-administered hormonal contraceptive.

What do I need to do? Pharmacists need to:

1. Review the updated protocol and be aware of significant changes from the previous version.
2. Obtain updated **protocol** documents (v. 12/2022) and begin using on February 1, 2023.
3. Discard all copies of contraception protocol documents (v. 2017/2018) after end of business on January 31, 2023. Do not discard any records associated with prescribing. Records created prior to February 1, 2023, must be retained according to OAR 855-019-0435 (for five years). Records created on or after February 1, 2023, must be retained per OAR 855-020-0110 (for seven years).
4. Review the **amended rules** in OAR 855-020 as all of the rules in this division will now apply to the prescribing of contraception effective February 1, 2023.
5. Follow future Board rulemaking as the contraception protocol will be updated more regularly under the PHPFAC. You can sign up for **rulemaking notices** to receive notifications of proposed and adopted rules.

No. 702 USP Chapters <795> and <797> Revisions

The final revised US Pharmacopeia (USP) Compounding General Chapters <795> and <797> were published on November 1, 2022, and become official on November 1, 2023. The Board anticipates adopting the new USP <795> and <797> standards by reference in rule prior to November 1, 2023.

The final revised USP Compounding General Chapters <795> and <797> are available for download in the *United States Pharmacopeia – National Formulary 2023*, Issue 1 through the online [USP Compounding Compendium](#). The USP Compounding Compendium is available by subscription only. Copies are available for inspection in the Board office, per OAR 855-010-0021(2). All pharmacies are required to comply with OAR 855-041-1035 related to Minimum Equipment Requirements. Pharmacies providing compounding services (including flavoring and the use of FIRST® compounding kits) should review and comply with rules including, but not limited to:

- [OAR 855-045](#): Drug Compounding
- [OAR 855-041-1035](#): Minimum Equipment Requirements

(1) Each retail drug outlet and institutional drug outlet must have the following:

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, **standards adopted by reference (e.g. USP) based on services offered by the outlet** and a minimum of three years of the Board of Pharmacy quarterly newsletters;

(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and **standards adopted by reference (e.g. USP) based on services offered by the outlet; (emphasis added)**

(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).

Below is a list of resources and education you may find helpful.

Resources Available:

- Summary of Updates to the Compounding Chapters
 - [USP <795> and <797> Fact Sheet](#)
- Frequently Asked Questions (FAQs) for each General Chapter
 - [<795> FAQs](#)
 - [<797> FAQs](#)

- Summary of Comments and USP Compounding Expert Committee Responses
 - [<795> Commentary](#)
 - [<797> Commentary](#)

Education Courses:

USP offers [educational programs](#) to support the adoption of the updated standards. Stay informed on USP compounding standards and associated initiatives and educational materials by [signing up](#) for USP Healthcare Quality and Safety updates.

No. 703 Rulemaking

Licensees are encouraged to review rules added, amended, and repealed during the December 2022 and February 2023 Board meetings.

Permanent Rules Adopted in December 2022

- **Division 019** – related to 2022 HB 4034 duties of a pharmacist – Effective December 21, 2022. Amendments remove conflict between Board regulations and revised telemedicine statutes in 2022 HB 4034. Amendments include removing “not result solely from a questionnaire or an internet-based relationship” and adding “issued pursuant to a valid patient-practitioner relationship” in OAR 855-019-0210(2)(a).
- **Division 139** – related to 2022 HB 4034 prohibited practices – Effective December 21, 2022. Amendment removes language that states a Retail Drug Outlet Remote Dispensing Site Pharmacy may not “Deliver a prescription.” Per 2022 HB 4034, the Board may not establish standards for telepharmacy that are more restrictive than standards for the delivery of in-person pharmacy services, including standards regarding prescription and dispensation of drugs.
- **Division 019** – related to 2022 HB 4096 out-of-state volunteer pharmacist – Effective December 21, 2022. Creates the necessary requirements for a pharmacist to practice pharmacy in Oregon without compensation for a specified amount of time without being required to obtain licensure in Oregon as required 2022 HB 4096.
- **Division 062** – related to drug distribution agent – Effective December 21, 2022. Amends the current drug distribution agent registration due date from August 31 to reflect the proper due date of September 30 to provide clarity to licensees and registrants.
- **Divisions 010/019/020** – related to pharmacist prescriptive authority – Effective February 1, 2023.

- Updates **post-exposure prophylaxis (PEP)**, **pre-exposure prophylaxis (PrEP)**, and **travel medication** protocols.
- Adds **COVID-19 antiviral (Paxlovid™)*** and **contraception** to the protocol compendium.
 - Repeals language in Division 019 related to contraceptives.
 - Adds language that a pharmacist must not require but may allow a patient to schedule an appointment with the registered pharmacist for prescribing or administering an injectable hormonal contraceptive or prescribing or dispensing a self-administered hormonal contraceptive.

*See February 2023 temporary rule below.
- Moves rule related to committee requirements for PHPFAC from Division 020 to 010. Adopts language related to “ensuring training and education requirements have been met prior to engaging in prescribing and requirements for retaining copies of the training and education.”
- **Divisions 021/135** – related to continuing pharmacy education (CPE) – Effective July 1, 2023. Creates new Division 135 that includes definitions, requirements for applicants, instructors, renewal requirements for licensees, and audits to reflect current requirements and standards related to CPE. Repeals Division 021 CPE rules in their entirety.
- **Divisions 019/141** – related to pharmacy prescription kiosk (PPK) – Effective February 15, 2023. Establishes a new registration type for PPK. Adds new Division 141, which contains requirements for the operation of a PPK by a PPK affiliated pharmacy.
- **Division 006** – related to definitions – Effective December 21, 2022. Amends clinical pharmacy agreement definition to match definition in Oregon Revised Statutes (ORS) 689.005, adds definition for “Drug Regimen Review” or “DRR,” adds definition for “Good Standing,” and adds definition for “Pharmacist.”
- **Division 041** – related to prescription labeling expiration date – Effective December 21, 2022. Amendments allow prescription drugs dispensed in manufacturer’s container to be labeled with the expiration date on the container and not limited to one year.

Permanent Rules Adopted in February 2023

- **Divisions 019/041** – related to safe pharmacy practice conditions: pharmacist autonomy, outlet requirements – Effective February 14, 2023. Incorporates rules to address safe pharmacy practice conditions.

- **Division 110** – related to PPK registration fee – Effective February 15, 2023. Registration fee for PPK.
- **Division 019** – related to definitions – Effective February 14, 2023. Repeals definitions in OAR 855-019-0110, except for “Counseling.”

Temporary Rules Adopted in February 2023

- **Division 020** – related to protocols for COVID-19 monoclonal antibody and COVID-19 antiviral – Effective February 10, 2023. Temporarily suspends statewide drug therapy management protocols for COVID-19 monoclonal antibody and COVID-19 antiviral due to:
 - COVID-19 monoclonal antibody – REGEN-COV
 - REGEN-COV (casirivimab and imdevimab) is not currently authorized in any US region.
 - COVID-19 antiviral – Paxlovid
 - Under Oregon State laws, pharmacists cannot diagnose. The current Paxlovid emergency use authorization (EUA) requires a diagnosis to prescribe Paxlovid, which is not required in the Board’s Paxlovid protocol (based on the EUA dated October 27, 2022) and appears to be preempted by federal law.

No. 704 Licensing – Pharmacists: Update Your Address and/or Contact Information – Pharmacist Continuing Education Deadlines and Biennial Renewals Coming Soon!

The 2023-2025 pharmacist license renewal is coming soon. Has your address or contact information (eg, email address or phone) changed since your last renewal? You can log in to your [eGov](#) account at any time to view your information on file; update your address, contact information and employment information; and order certified copies of your license. Instructions on how to link to your account and log in to the eGov system are available on the Board’s [website](#).

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 (see [ORS 689.285](#) and [OAR 855-021](#)). The following CPE credits must be earned:

- a minimum of two hours in pharmacy and drug law;
- a minimum of two hours in patient safety or medication error prevention;

- one hour in [pain management](#), provided by the Pain Management Commission of the Oregon Health Authority (OHA);
- two hours in cultural competency either [approved by the OHA](#) under ORS 413.450 or any cultural competency CPE; and
- the remaining 23 hours can be earned on any topic.

In accordance with [OAR 855-021-0005\(2\)](#):

- Pharmacists applying for the first renewal of their license must complete CPE 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, 2022, and June 30, 2023, do not have to complete the CPE requirements for the 2023 renewal.
- Pharmacists initially licensed between July 1, 2023, and June 30, 2025, must complete the CPE requirements for the 2025 renewal.

No. 705 Board Member Opportunities

There is one opportunity for an interested pharmacist to serve on the Board. The position will be available for appointment effective July 1, 2023. Please apply by March 13, 2023, for consideration. Each position is appointed by the governor, and each Board member serves at the pleasure of the governor. The Board encourages all interested and qualified individuals to apply sooner rather than later, as the governor's office may close the applicant pool without notice. For more information, including qualifications and how to apply, please review [ORS 689.115](#) and visit the Board's [website](#).

No. 706 PHPFAC – Opportunities

There are currently three opportunities for interested persons to serve on the PHPFAC. The Board has the following committee member opportunities available:

- One pharmacist member position is currently vacant. Please apply now if interested.
- One advanced practice registered nurse member position is currently vacant. Please apply now if interested.
- Two physician member positions are currently vacant. Please apply now if interested.

Each position is appointed by the governor, and each committee member serves at the pleasure of the governor. The Board encourages all interested and qualified individuals to apply sooner rather than later, as the governor's office may close the applicant pool without notice. For more

information, including qualifications and how to apply, please review [ORS 689.649](#) and visit the Board's [website](#).

No. 707 Executive Director Announces Retirement

Executive Director Joe Schnabel has announced his intent to retire in summer of 2023. If you or someone you know would like additional information or to apply for this position, the posting will be available in the Oregon Workday system and through the Board's website in the coming weeks.

We thank Joe for his dedicated service to the Board and the citizens of Oregon. We wish him well in his retirement.

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