

OREGON STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

No. 671 New Rules for Telework

On December 14, 2021, the Oregon State Board of Pharmacy adopted rules to permit telework, which is defined as the practice or assistance in the practice of pharmacy physically located outside of a registered drug outlet when working as an employee of an Oregon-registered drug outlet in a telework site. The telework rules became effective December 16, 2021, and can be found in Oregon Administrative Rules (OAR) 855-041-3200 through OAR 855-041-3250. In addition, the definition of "supervision by a pharmacist" was amended to include a reference to the new telework rules.

Per OAR 855-041-3205:

- (1) "Telework" means the practice or assistance in the practice of pharmacy physically located outside of a registered drug outlet when working as an employee of an Oregon registered drug outlet in a telework site.
- (2) "Telework Site" means a location that is not a registered drug outlet where an Oregon licensed Pharmacist may practice pharmacy and an Intern or Certified Oregon Pharmacy Technician may assist in the practice of pharmacy as employees of an Oregon registered drug outlet.

The adopted rules in OAR 855-041-3200 through OAR 855-041-3250 permit a pharmacist, intern, or certified Oregon pharmacy technician (COPT) to work remotely at a secured off-site, non-pharmacy location on behalf of a drug outlet and provide regulatory requirements for registration, supervision, confidentiality, technology, personnel, environment and security, policies and procedures, and records.

As a result of the coronavirus disease 2019 (COVID-19) pandemic and the need to facilitate physical distancing in pharmacies, in March 2020 the Board modified the definition of "supervision by a pharmacist" to permit remote supervision of a pharmacy technician (PT), COPT, or intern to perform specific remote processing functions at a secure off-site, non-pharmacy location (also known as public health emergency (PHE) remote processing). For the duration of the PHE, a pharmacist may supervise a PT, COPT, or intern performing the following remote processing functions only:

- Prescription order entry;
- · Other data entry; and
- Insurance processing of prescriptions and medication orders.

When the Oregon PHE ends, the allowance for PHE remote processing will also end.

Per OAR 855-006-0005:

(33) "Supervision by a pharmacist" means being stationed within the same work area, except as authorized under OAR 855-041-3200 through OAR 855-041-3250, as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action. During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.

No. 672 New Temporary Rules: Accurate Hours of Operation, Temporary/ Emergency/Permanent Pharmacy Closures, and PT and COPT Licensure

To protect the public by assisting the public in accessing their medication, the Board has adopted four temporary rules:

- 1. Division 041- related to accurate pharmacy hours:
 - OAR 855-041-1015(3): Requires pharmacies to post accurate hours of operation.
 Accurate pharmacy operating hours must be posted at each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (eg, website, social media, mobile applications) for patients and prescribers so they can seek alternate sources of prescription medication when a pharmacy is closed.
 Effective November 19, 2021.
- 2. Division 041- related to temporary, emergency, and permanent pharmacy closures:
 - OAR 855-041-1092(1) and OAR 855-041-1092(2-5): During the COVID-19 pandemic, pharmacies are experiencing an increase in temporary closures due to extenuating circumstances (eg, illness, staffing shortages). Posting notification of the estimated time the pharmacy will be closed and providing alternative options for prescription pick-up (eg, another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions) must be made available to patients and providers to ensure timely access to prescription medication. Pharmacies must notify the board if the temporary closure lasts more than two consecutive business days. Effective December 10, 2021. Regarding permanent pharmacy closures, the temporary rule provides a list of items that must be

completed prior to, on the date of or within 24 hours, and within 30 calendar days of the permanent pharmacy closure. Effective February 11, 2022.

- 3. Division 021/025/110 related to PT and COPT licensure:
 - Clarifies licensure qualifications, elements of a complete application and renewal/reinstatement requirements for PTs and COPTs; revises PT license fees; allows PT to renew or reinstate their license; adds continuing education (CE) requirements for PTs. Effective February 11, 2022.

These rules will be considered for permanent adoption at the April 2022 (accurate hours, temporary closure, and PT and COPT licensure) and June 2022 (permanent closure) Board meetings.

No. 673 Rulemaking Updates

Licensees are encouraged to review rules added, amended, and repealed during the December 2021 Board meeting. The Board adopted the following permanent rules in December:

- Division 006 related to definitions. Added definitions for adulterated, misbranded, and official compendium. Effective December 10, 2021.
- Division 007 related to compliance with Oregon Health Authority (OHA) COVID-19 rules. Requires compliance with OHA rules to control the communicable disease COVID-19. Effective December 10, 2021.
- Division 007/041/045/065 related to United States Pharmacopeia (USP), labeling, repackaging. Updates pharmacy minimum equipment requirements, modifies expiration date on labeling, adopts USP standards by reference, removes definition of repackaging/repackager from Division 065, and adds definition of repackaging to Division 041. Effective December 16, 2021.
- Division 010 related to Board administration and policies. Modifies amount of compensation paid to Board members and Public Health and Formulary Advisory Committee members of the Board as required by 2021 House Bill (HB) 2992. Requires Board to pay compensation and expenses to certain members with adjusted gross income below threshold outlined in Oregon Revised Statute (ORS) 292.495. Provides that members may decline to accept compensation or reimbursement. Additional procedural rules revisions to ensure clarity and transparency and to promote patient safety. Effective December 16, 2021.
- Division 019/021 related to pain management CE. Amends pharmacist continuing pharmacy education (CPE) requirements to align with the directives set forth in 2021 HB 2078, related to pain management education. Removes the one-time, six-hour pain CPE requirement and requires one hour of pain management CPE, provided by the Pain Management Commission of the OHA upon initial licensure and with each renewal. Effective January 1, 2022.

- Division 019/139 related to remote dispensing site pharmacy/telepharmacy. Permits
 a pharmacist to be designated as pharmacist-in-charge (PIC) of up to three pharmacies
 without written approval by the Board. Outlines the registration, personnel, security,
 drug procurement/storage/loss/disposal/return, sanitation, minimum equipment,
 technology, supervision, pharmacist utilization, nonprescription drugs, controlled
 substances (CS), nonsterile compounding, prescriptions, dispensing, labeling, policies/
 procedures, records, and pharmacy service for remote dispensing site pharmacies in
 alignment with 2021 Senate Bill 629. Effective January 1, 2022.
- Division 020 related to pharmacist prescriptive authority COVID-19 monoclonal antibody (mAb), HIV Post-exposure Prophylaxis (PEP) and HIV Pre-exposure Prophylaxis (PrEP). Clarifies that the face-to-face requirement only applies to physical assessment components of patient care process (collect, assess, plan, implement, and follow-up). Permanently adopts new COVID-19 mAb to the Protocol Compendia. Amends protocol versions of HIV PEP and HIV PrEP in the Protocol Compendia. Effective December 10, 2021.
- Division 041 related to telework. Rules permit a pharmacist, intern, or COPT to work remotely at a secured off-site, non-pharmacy location on behalf of a drug outlet. Effective December 16, 2021.
- Division 041 related to Technician Checking Validation Program (TCVP). Repeals rules permitting TCVP. Effective October 1, 2022.
- Division 041/080 related to pseudoephedrine (PSE)/ephedrine (EPH). Reschedules
 PSE and EPH from Schedule III to Schedule V. Allows transfer of PSE or EPH by a
 pharmacist, COPT, or PT without prescription as permitted by 2021 HB 2648. Additional
 procedural rules revisions to ensure clarity, transparency, and patient safety. Effective
 January 1, 2022.
- Division 043 related to supervising physician dispensing outlet (SPDO). Allows physician assistant to dispense prescription drugs as permitted by 2021 HB 3036 and ensures rules reflect updates to statutes, including ORS 678.390, concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs. Amends dispensing practitioner drug outlet (DPDO) and community health clinic (CHC) requirements for dispensing and drug delivery including permitting DPDO or CHC to mail or deliver a drug. Additional procedural rules revisions to ensure clarity, transparency, and patient safety. Effective January 1, 2022.
- Division 043 related to SPDO. Repeals SPDO registration type in alignment with 2021 HB 3036. Effective March 31, 2022.
- Division 060/110 related to prescription drug monitoring program fee increase.
 Addresses fee changes pursuant to 2021 HB 2074 and 2021 HB 3036. Repeals pharmacist license (the North American Pharmacist Licensure Examination®)

re-examination fee; increases pharmacist licensing by reciprocity fee of \$25 to \$100. Decreases pharmacist licensing by score transfer fee of \$250 to \$50. Effective January 1, 2022.

In December 2021, the Board adopted a temporary rule, OAR 855-006-0005(33), which amended the definition of "Supervision by a Pharmacist" to include a provision for telework. OAR 855-020-0300(2)(C)(d) added COVID-19 mAb therapy to the Protocol Compendia. These rules will be considered for permanent adoption at the April 2022 Board meeting.

The Board is proposing to permanently adopt the following rules. 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 006/041/139 related to definitions
- Division 020 related to COVID-19 antigen self-test
- Divisions 020/041/065/139 related to alarm, audiovisual communication, entry, and surveillance systems
- Divisions 021/025/110 related to PT and COPT licensure
- Division 041 related to disclosure of patient information
- Divisions 041/139 related to accurate pharmacy hours and temporary pharmacy closures
- Divisions 041/139 related to drug storage
- Division 080 related to Schedule I exceptions
- Division 143 related to pharmacy prescription lockers

No. 674 Compliance Updates

Limited English Proficiency: Full Implementation Now Required

The Board adopted Limited English Proficiency (LEP) rules on January 1, 2021, requiring pharmacists to label prescriptions for patients with LEP in both English and the patient's preferred language. In the February 2021 edition of this *Newsletter*, the Board recognized the implementation challenges posed by the new LEP regulations and encouraged all drug outlets dispensing medications for patient self-administration to operationalize these labeling capabilities as soon as possible to realize their benefits to patient safety and health equity.

Compliance officers continue to find Oregon pharmacies that have not appropriately implemented policies and procedures to comply with OAR 855-041-1132. The most frequent observations include not using directions in both languages on the prescription label, having some, but not all, of the required 14 languages available, and not having signage updated to include translated prescription label availability.

All pharmacists, PICs, and drug outlets have the responsibility to ensure compliance with these rules, including:

- Appropriate equipment and supplies as required in OAR 855-041-1035.
- Posting signage in a location easily seen by the public where prescriptions are
 dispensed or administered that provides notification in each of the languages required
 in OAR 855-041-1132 of the right to free, competent oral interpretation and translation
 services, including translated prescription labels, for patients who are of limited English
 proficiency.
- Creating and implementing policies and procedures that operationalize these rules.
- Maintaining dispensing records (which include the label as dispensed) for three years.

During the first year of implementation, the Board exercised enforcement discretion in recognition of known implementation challenges. Enforcement discretion has now ended and full implementation of the LEP statute and rules is required.

No. 675 Technicians Must Work Under the Supervision, Direction, and Control of a Pharmacist at All Times

PTs and COPTs must work under the supervision, direction, and control of a pharmacist (ORS 689.225(4) and ORS 689.486(6)). Do you, as a PT or COPT, know:

- · Which pharmacist is supervising, directing, and controlling your work at all times?
 - If you are unsure, you should ask your employer who this is.
- That a pharmacist must verify your work if the task requires judgment?
 - If you are unsure, ask the pharmacist who is supervising you if the task requires judgment and verification.

The Board has adopted a definition of supervision of PTs:

OAR 855-006-0005(33), which states:

"Supervision by a pharmacist" means being stationed within the same work area, except as authorized under OAR 855-041-3200 through OAR 855-041-3250, as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action. During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.

Other rules concerning supervision of PTs and COPTs include:

OAR 855-025-0025

- (2) Pharmacy Technicians or Certified Oregon Pharmacy Technicians must be supervised by a Pharmacist.
- (4) Work performed by Pharmacy Technicians and Certified Oregon Pharmacy Technicians assisting the Pharmacist to prepare medications must be verified by a Pharmacist prior to release for patient use. Verification must be documented, available and consistent with the standard of practice.

OAR 855-025-0040

- (2) Only persons licensed with the Board as a Pharmacy Technician or Certified Oregon Pharmacy Technician, acting in compliance with all applicable statutes and rules and under the supervision of a Pharmacist, may assist in the practice of pharmacy. . .
- (3) In order to protect the public, safety, health and welfare, Pharmacy Technicians or Certified Oregon Pharmacy Technicians shall not:
 - (e) Perform any task that requires the professional judgment of a Pharmacist;

No. 676 Licensing

Licensing updates include reminders about the 2022-2024 licensing cycle for PTs and COPTs, as well as data on licensees by type.

Reminders for PTs with licenses expiring on June 30, 2022, and all COPTs: Update your contact information!

- PTs: If your license expires on June 30, 2022, you must either renew your PT license or complete the requirements for a COPT license and have a new COPT license issued prior to June 30, 2022. Additional information on renewing a PT license can be found here.
- COPTs: The 2022-2024 license renewal is coming soon; you must renew by June 30, 2022.

Has your address or contact information changed since your license was issued or renewed? You can log in to your eGov account at any time to view your information on file, update your contact or employment information, and order certified copies of your license. Instructions on how to link to your account and log into the eGov system are available on the Board's website.

Licensure Trends

Board staff often receive requests related to license renewals or how many licenses exist. Data on license renewal for 2021 and from previous years are provided on the next page:

Pharmacist

| Year | New | Renewed | Not Renewed | Renewed% | Active |
|------|-----|---------|-------------|----------|--------|
| 2010 | 435 | 5,027 | 194 | 96% | 5,670 |
| 2011 | 464 | 5,300 | 162 | 97% | 5,670 |
| 2012 | 465 | 5,536 | 238 | 96% | 5,914 |
| 2013 | 488 | 5,766 | 248 | 96% | 6,223 |
| 2014 | 591 | 6,105 | 272 | 96% | 6,538 |
| 2015 | 653 | 6,482 | 242 | 96% | 6,961 |
| 2016 | 633 | - | - | - | 7,602 |
| 2017 | 651 | 7,123 | 639 | 92% | 7,657 |
| 2018 | 513 | - | - | - | 8,267 |
| 2019 | 652 | 7,697 | 754 | 91% | 8,232 |
| 2020 | 523 | - | - | - | 8,787 |
| 2021 | 517 | 8,073 | 943 | 90% | 8,457 |

Interns

| Year | New | Renewed | Not Renewed | Renewed% | Active |
|------|-----|---------|-------------|----------|--------|
| 2010 | 496 | - | - | - | 932 |
| 2011 | 280 | - | - | - | 887 |
| 2012 | 261 | 301 | 64 | 82% | 903 |
| 2013 | 274 | 197 | 39 | 83% | 884 |
| 2014 | 268 | 209 | 106 | 66% | 926 |
| 2015 | 349 | 211 | 142 | 60% | 842 |
| 2016 | 345 | 201 | 108 | 65% | 862 |
| 2017 | 320 | 209 | 98 | 68% | 980 |
| 2018 | 305 | 203 | 130 | 61% | 875 |
| 2019 | 285 | 193 | 135 | 59% | 836 |
| 2020 | 245 | 194 | 132 | 60% | 889 |
| 2021 | 250 | 191 | 131 | 59% | 754 |

Certified Oregon Pharmacy Technician

| Certified Oregon Pharmacy Technician | | | | | |
|--------------------------------------|-----|---------|-------------|-----------|--------|
| Year | New | Renewed | Not Renewed | Renewed % | Active |
| 2010 | 871 | 4,963 | 648 | 88% | 5,326 |
| 2011 | 715 | 5,172 | 549 | 90% | 5,440 |
| 2012 | 807 | 5,410 | 622 | 90% | 5,732 |
| 2013 | 767 | 5,688 | 555 | 91% | 5,909 |
| 2014 | 746 | 5,804 | 629 | 90% | 6,031 |
| 2015 | 628 | 5,736 | 787 | 88% | 5,933 |
| 2016 | 598 | 5,726 | 663 | 90% | 5,978 |
| 2017 | 691 | - | - | - | 6,629 |
| 2018 | 604 | 5,643 | 926 | 86% | 6,272 |
| 2019 | 572 | - | - | - | 6,788 |
| 2020 | 443 | 5,682 | 1,222 | 82% | 6,911 |
| 2021 | 528 | - | - | - | 6,645 |

All Licensees and Registrants

| Year | New | Active |
|------|-------|--------|
| 2010 | 3,679 | 21,638 |
| 2011 | 5,268 | 22,359 |
| 2012 | 5,341 | 23,329 |
| 2013 | 5,318 | 24,396 |
| 2014 | 5,487 | 25,191 |
| 2015 | 6,269 | 26,121 |
| 2016 | 5,882 | 27,501 |
| 2017 | 6,306 | 28,519 |
| 2018 | 6,260 | 29,449 |
| 2019 | 6,035 | 30,228 |
| 2020 | 5,100 | 31,021 |
| 2021 | 5,838 | 30,975 |

% PT vs. COPT

| Year | Active | PT% | CPT% |
|------|--------|-----|------|
| 2010 | 6,146 | 13% | 87% |
| 2011 | 6,425 | 15% | 85% |
| 2012 | 6,507 | 12% | 88% |
| 2013 | 6,691 | 12% | 88% |
| 2014 | 6,759 | 11% | 89% |
| 2015 | 6,926 | 14% | 86% |
| 2016 | 7,340 | 19% | 81% |
| 2017 | 8,095 | 18% | 82% |
| 2018 | 7,668 | 18% | 82% |
| 2019 | 8,149 | 17% | 83% |
| 2020 | 8,300 | 17% | 83% |
| 2021 | 8,173 | 19% | 81% |

Pharmacy Technician

| Year | New | Renewed | Active |
|------|-------|---------|--------|
| 2010 | 1,039 | - | 820 |
| 2011 | 844 | - | 985 |
| 2012 | 844 | - | 775 |
| 2013 | 818 | - | 782 |
| 2014 | 795 | - | 728 |
| 2015 | 1,017 | - | 993 |
| 2016 | 1,053 | - | 1,362 |
| 2017 | 1,028 | - | 1,466 |
| 2018 | 816 | - | 1,396 |
| 2019 | 978 | - | 1,361 |
| 2020 | 889 | - | 1,389 |
| 2021 | 1,178 | - | 1,528 |

No. 677 Board Member News: A New Board Member and Current Opportunities

Kathleen "Kat" Chinn has been appointed to the Board as a public board member by Governor Kate Brown. Chinn is a family nurse practitioner with the PeaceHealth Senior Health and Wellness Center in Eugene, OR. She received her associate degree in nursing from Lane Community College and her bachelor of science in nursing and master's degrees from Oregon Health & Science University. Chinn has over 20 years of nursing experience and resides in Eugene. She recently completed eight years as a member of the Oregon Board of Nursing and four years as a committee member on this board's Public Health and Pharmacy Formulary Advisory Committee. Her term on the Board of Pharmacy began on November 19, 2021, and ends February 29, 2024. The Board and staff welcome Chinn to the Board and look forward to continuing to work with her in her new role.

There are periodic opportunities for interested persons to serve on the Board. The Board has the following member opportunities available:

- One pharmacist member position applications due March 4, 2022
- One public member position

Each position is appointed by Governor Kate Brown, and each Board member serves at the pleasure of the governor. If you are interested in applying to serve on the Board, please visit the Board Member Opportunities web page, review ORS 689.115, and apply through the governor's Boards and Commissions website.

National Pharmacy Compliance News Now Available!

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

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