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ARCHIVES DIVISION
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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
06/16/2023 12:38 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Proactive procedural rule review; Creates new Division 115 for Pharmacists

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/26/2023 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Portland ,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 07/26/2023
TIME: 9:30 AM
OFFICER: Rachel Melvin

HEARING LOCATION
ADDRESS: Oregon Board of Pharmacy - Virtual Meeting , 800 NE Oregon St., Suite 150 , Portland , OR 97232

REMOTE MEETING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 627978258
SPECIAL INSTRUCTIONS:
This hearing meeting will be held virtually via Microsoft Teams.
If you wish to present oral testimony virtually during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your first and last name, email address and phone number to pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.
You must submit written comments before 4:30PM on July 26, 2023. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Creates new Division 115 for Pharmacists. Relocates, reorganizes and amends existing Pharmacists rules from Divisions 019, 020, and 041. After the board permanently adopts and publishes Division 115, repeals Division 019 on the effective date of Division 115.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

OBOP 2022-2026 Strategic Plan https://www.oregon.gov/pharmacy/Documents/OBOP_Strategic_Plan_2022-2026.pdf
Alkhateeb, Fadi M., et al. "Review of National and International Accreditation of Pharmacy Programs in the Gulf Cooperation Council Countries." American Journal of Pharmaceutical Education 82.10 (2018). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6325464/
FPGEC Certification Candidate Application Bulletin Spring 2022-Spring 2023. National Association of Boards of Pharmacy. //read.nxtbook.com/nabp/bulletin/fpgec_2022/cover.html
ACPE List of Programs Accredited by State https://www.acpe-accredit.org/accredited-programs-by-state/, see +For International for information on Lebanese American University

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STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

Reorganizing proposed rules may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated. Ensuring licensees and registrants can easily locate licensure and compliance requirements will positively impact all Oregonians in all communities.

FISCAL AND ECONOMIC IMPACT:

On 5/24/2023, board staff sent out a fiscal impact request via GovDelivery to licensees, registrants, and stakeholders requesting estimated fiscal impacts associated with compliance, implementation, and operations of rules to be considered by the board at the June 2023 board meeting.

Based on multiple responses received from licensees, registrants, and stakeholders, we estimate the following fiscal and economic impact for rules included in this rulemaking filing:
- For prescriptions that are delivered, the cost to provide interactive counseling, reattempt to counsel if unable to counsel prior to delivery, and to document such counseling/attempts = $25K-$55M/year
- For clinical pharmacy record storage, the cost to retain records for 7 years = $75K/year
- For Pharmacists, the time associated with attending a PIC training class = $700-$2K/year
- For requiring PIC to be employed by the Drug Outlet pharmacy = $200K/year

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COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved in the development of proposed revisions to these rules.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

Board staff suggests reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

RULES PROPOSED:

855-115-0001, 855-115-0005, 855-115-0010, 855-115-0015, 855-115-0020, 855-115-0025, 855-115-0030, 855-115-0035, 855-115-0040, 855-115-0045, 855-115-0050, 855-115-0060, 855-115-0065, 855-115-0070, 855-115-0105, 855-115-0110, 855-115-0115, 855-115-0120, 855-115-0125, 855-115-0130, 855-115-0140, 855-115-0145, 855-115-0150, 855-115-0200, 855-115-0210, 855-115-0300, 855-115-0305, 855-115-0310, 855-115-0315, 855-115-0320, 855-115-0330, 855-115-0335, 855-115-0340, 855-115-0345, 855-115-0350

ADOPT: 855-115-0001

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-019-0100 to OAR 855-115-0001 related to applicability.

CHANGES TO RULE:

855-115-0001
Applicability
(1) This Division applies to any Pharmacist who engages in the practice of pharmacy.¶
(2) Only persons licensed with the board as a Pharmacist may practice pharmacy and must act in compliance with statutes and rules unless exempt under ORS 689.225. ¶
(3) A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the board in accordance with the following rules, except that a Pharmacist located in another state who is working for an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with the out-of-state pharmacy dispensing of a drug into Oregon, is not required to be licensed by the board.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.255

ADOPT: 855-115-0005

RULE SUMMARY: Proposed rule revises and relocates the existing definition of "Counseling" from OAR 855-019-0110 and adds definition of "Drug utilization review or "DUR" to OAR 855-115-0005.

CHANGES TO RULE:

855-115-0005
Definitions
(1) "Counseling" or "Counsel" means an interactive communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.¶
(2) "Drug utilization review" or "DUR" means evaluation of a prescription to identify and resolve potential problems through the review of information provided to the Pharmacist by the patient, patient's agent, prescriber and the patient's record.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

ADOPT: 855-115-0010

RULE SUMMARY: Proposed new rule related to qualifications for licensure as a Pharmacist.

CHANGES TO RULE:

855-115-0010
Licensure: Qualifications - General
(1) Before licensure as a Pharmacist, an applicant must meet the qualifications required that are applicable to their method of licensure;¶
(a) Examination or Score Transfer in OAR 855-115-0020; or¶
(b) Reciprocity in OAR 855-115-0025.¶
(2) If residing in the United States, proof of citizenship, legal permanent residency or qualifying visa, as required by 8 USC 1621.¶
(3) Foreign pharmacy graduates must also meet the requirements of OAR 855-115-0015 prior to applying for a Pharmacist license.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151

ADOPT: 855-115-0015

RULE SUMMARY: Proposed rule revises and relocates rule from OAR 855-019-0150 to OAR 855-115-0015 related to licensure qualifications for pharmacist with a pharmacy degree from a foreign college or school of pharmacy.

CHANGES TO RULE:

855-115-0015
Licensure: Qualifications - Foreign Pharmacy Graduate Education
(1) An applicant for pharmacist licensure who graduated from a foreign school, college, or program of pharmacy must meet the following educational requirements:¶
(a) Obtain certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC); and¶
(b) Submit evidence of 1440 hours in pharmacy practice as an intern or pharmacist in the United States or its jurisdiction.¶
(2) (1)(a) is not required for graduates of:¶
(a) A Canadian Council for Accreditation of Pharmacy Programs (CCAPP) accredited pharmacy program located in Canada or its jurisdiction with a curriculum taught in English and who graduated between 1993 and June 30, 2004.¶
(b) The ACPE-accredited program at the Lebanese American University in Byblos, Lebanon with a Doctor of Pharmacy degree and graduated after 2002.¶
(3) If (1)(a) is required, an applicant must not count internship hours or practice as a pharmacist towards the requirement in (1)(b) that was completed before achieving the FPGEC certification.¶
(4) Once the educational qualifications in this rule are met, an applicant must also comply with the requirements for licensure in OAR 855-115-0020 for examination or score transfer or OAR 855-115-0025 for reciprocity.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.255

ADOPT: 855-115-0020

RULE SUMMARY: Proposed rule revises and relocates existing rule from OAR 855-019-0120 to OAR 855-115-0020 related to pharmacist licensure qualifications for examination or score transfer applicants.

CHANGES TO RULE:

855-115-0020
Licensure: Qualifications - Examination or Score Transfer
(1) To receive licensure as a Pharmacist by examination or score transfer, an applicant must meet the following requirements:¶
(a) Provide evidence in the form of an official transcript from an Accreditation Council for Pharmacy Education (ACPE) accredited college or school of pharmacy or compliance with OAR 855-115-0015 that: ¶
(A) A degree has been conferred; and¶
(B) The applicant has completed a minimum of 1440 hours in an Internship Program as that term is defined in OAR 855-031-0005.¶
(b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts;¶
(c) Pass the Oregon Multistate Pharmacy Jurisprudence Examination (MPJE) exam. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts; and¶
(d) Complete one hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority.¶
(2) An applicant who has obtained their professional degree outside the United States is not eligible for licensure via examination or score transfer until they have met the requirements of OAR 855-115-0015.¶
(3) An applicant applying via score transfer must request the National Association of Boards of Pharmacy to transfer their NAPLEX score to Oregon.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 413.590, ORS 689.151, ORS 689.285

ADOPT: 855-115-0025

RULE SUMMARY: Proposed rule revises and relocates existing rule from OAR 855-019-0130 to OAR 855-115-0025 related to pharmacist licensure qualifications by reciprocity.

CHANGES TO RULE:

855-115-0025
Licensure: Qualifications - Reciprocity
(1) An applicant for licensure as a Pharmacist by reciprocity must meet the requirements of ORS 689.265 and provide evidence of the following requirements:¶
(a) Be a graduate, as shown by an official transcript, of an ACPE accredited college or school of pharmacy or compliance with OAR 855-115-0015;¶
(b) Have passed the NAPLEX;¶
(c) Have passed the Oregon MPJE. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts;¶
(d) Proof that each Pharmacist license granted to the applicant is not suspended, revoked, canceled or otherwise completely restricted from the practice of pharmacy for any reason except nonrenewal or the failure to obtain required continuing education credits in any state where the applicant is licensed but not engaged in the practice of pharmacy; and¶
(e) Have either:¶
(A) Been engaged in the practice of pharmacy for period of at least 12 months including a minimum of 1440 hours of work experience as a licensed Pharmacist. Evidence supporting this work experience must be provided at time of application; or¶
(B) Completed 1440 hours in an Internship Program as that term is defined in OAR 855-031-0005¶
within the 12 month period immediately before the date of application. Evidence must be provided at time of application.¶
(2) An applicant who has obtained their professional degree outside the United States and jurisdiction is not eligible for licensure by reciprocity until they have met the requirements of OAR 855-115-0015.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.265, ORS 689.405

ADOPT: 855-115-0030

RULE SUMMARY: Proposed new rule adds licensure requirements for applicants applying for a pharmacist license.

CHANGES TO RULE:

855-115-0030
Licensure: Application
(1) An application for licensure as a Pharmacist may be accessed on the board website.¶
(2) The board may issue a license to a qualified applicant after the receipt of:¶
(a) Evidence of compliance with OAR 855-115-0020 or 855-115-0025; ¶
(b) A completed application including:¶
(A) Payment of the fee prescribed in OAR 855-110;¶
(B) A current, passport regulation size photograph (full front, head to shoulders);¶
(C) Personal identification or proof of identity; and¶
(D) Certificate of completion for the one hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority; ¶
(c) A completed national fingerprint-based background check; and¶
(d) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.¶
(3) Penalties may be imposed for: ¶
(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;¶
(b) Failure to disclose any requested information on the application;¶
(c) Failure to respond to requests for information resulting from the application; and¶
(d) Any other grounds found in ORS 689.405.¶
(4) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications. ¶
(5) The license of a Pharmacist expires June 30 in odd numbered years and may be renewed biennially.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.225, ORS 689.285

ADOPT: 855-115-0035

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-019-0122 and OAR 855-019-0170 to OAR 855-115-0035 related to requirements for licensure renewal or licensure reinstatement for pharmacists.

CHANGES TO RULE:

855-115-0035
Licensure: Renewal or Reinstatement
(1) An applicant for renewal of a Pharmacist license must: ¶
(a) Pay the biennial license fee required in OAR 855-110;¶
(b) Complete the continuing pharmacy education requirements as outlined in OAR 855-135; ¶
(c) Be subject to a criminal background check; and ¶
(d) Provide a written description and documentation regarding all conduct that is required to be disclosed.¶
(2) A Pharmacist who fails to renew their license by the expiration date and whose license has been lapsed for 12 months or less may apply to renew their license and must pay a late fee required in OAR 855-110. ¶
(3) A person who fails to renew their license by the expiration date and whose license has been lapsed for greater than 12 months may apply to reinstate their Pharmacist license as follows:¶
(a) Apply per OAR 855-115-0030;¶
(b) Provide certification of completion of the continuing pharmacy education requirement in OAR 855-135 for all years in which the license was lapsed; and ¶
(c) Meet the requirements below, if applicable.¶
(4) A person must take and pass the Oregon MPJE if their pharmacist license has been lapsed for more than three years. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts.¶
(5) If the Pharmacist license has been lapsed for more than five years and the person has not maintained an active pharmacist license in another US state or jurisdiction, a person must comply with (4) and take and pass the NAPLEX. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts.¶
(6) In lieu of reinstatement, a person may apply for licensure via reciprocity if the person has maintained an active pharmacist license in good standing in another US state or jurisdiction.¶
(7) A person whose Pharmacist license has been retired for more than 12 months need only pay the annual license fees for the year in which they seek a license, however they must also complete the requirements in (3). ¶
(8) A person whose Pharmacist license has been suspended, revoked or restricted has the right, at reasonable intervals, to petition to the board for reinstatement of such license pursuant to ORS 689.445 and in conjunction with the application process identified in OAR 855-115-0030.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.275, ORS 689.445

ADOPT: 855-115-0040

RULE SUMMARY: Proposed new rule adds requirements for pharmacists who wish to lapse their license.

CHANGES TO RULE:

855-115-0040
Licensure: Lapse
(1) A Pharmacist may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.¶
(a) Lapse of a license is not discipline.¶
(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.¶
(c) A person must not practice pharmacy if their license is lapsed.¶
(d) A person may apply for renewal or reinstatement of their license according to OAR 855-115-0035.¶
(2) If a Pharmacist requests to lapse their license prior to the expiration date, the following applies:¶
(a) The license remains in effect until the board accepts the lapse.¶
¶
(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.¶
(c) The board will not accept the lapse if an investigation of or disciplinary action against the licensee is pending.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

ADOPT: 855-115-0045

RULE SUMMARY: Proposed new rule adds requirements for pharmacists who wish to retire their license.

CHANGES TO RULE:

855-115-0045
Licensure: Retire
(1) A Pharmacist may request that the board retire their license if the Pharmacist is in good standing, has been licensed as a Pharmacist for at least 20 years and is no longer practicing pharmacy.¶
(a) A retired license is not considered discipline.¶
(b) The board has continuing authority under ORS 689.153.¶
(c) A person must not practice pharmacy if the license is retired.¶
(d) A person may apply for renewal or reinstatement according to OAR 855-115-0035.¶
(2) If a Pharmacist requests to retire their license prior to the expiration date of the license, the following applies:¶
(a) The license remains in effect until the board accepts the request to retire the license.¶
(b) If the board accepts the request to retire the license, the board will notify the licensee of the date the license is no longer active.¶
(c) The board will not accept the request to retire the license if an investigation of or disciplinary action against the licensee is pending.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

ADOPT: 855-115-0050

RULE SUMMARY: Proposed new rule adds requirements for pharmacists who wish to voluntarily surrender their license.

CHANGES TO RULE:

855-115-0050
Licensure: Voluntary Surrender
A Pharmacist may request that the board accept the voluntary surrender of their license.¶
(1) A voluntary surrender of a license is discipline. ¶
(2) The license remains in effect until the board accepts the surrender.¶
(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a board representative. The termination date is the date the order is signed by all parties and served on the licensee. ¶
(4) The licensee must cease practicing pharmacy from the date the license terminates.¶
(5) A voluntarily surrendered license cannot be renewed. A former licensee who wants to obtain a license must apply for reinstatement per OAR 855-115-0035 unless the final order prohibits the licensee from doing so.¶
(6) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

ADOPT: 855-115-0060

RULE SUMMARY: Proposed rule relocates existing rule from OAR 855-019-0123 to OAR 855-115-0060 related to requirements for pharmacist's who wish to register with the board for limitation on liability.

CHANGES TO RULE:

855-115-0060
Registration: In-State Volunteer
(1) A Pharmacist may register with the board for the limitation on liability provided by ORS 676.340, which provides a licensee with specific exemptions from liability for the provision of pharmacy services without compensation under the terms of the law.¶
(2) A no cost registration may be issued by the board upon receipt of a completed application. Registration requires submission of a signed form provided by the board in accordance with ORS 676.345(2).¶
(3) Registration will expire at the licensee's next license renewal date and may be renewed biennially. It is the licensee's responsibility to ensure his or her active registration in this program.¶
(4) Nothing in this section relieves licensee from the responsibility to comply with board regulations and still may be subject to disciplinary actions.¶
(5) Pharmacists providing care under the provisions of ORS 676.340 and ORS 676.345 remain subject to the board complaint investigation process articulated in ORS 676.175.
Statutory/Other Authority: ORS 676.340, ORS 689.205
Statutes/Other Implemented: ORS 676.340, ORS 689.345

ADOPT: 855-115-0065

RULE SUMMARY: Proposed rule relocates existing rule OAR 855-019-0124 to OAR 855-115-0065 related to notification requirements for out-of-state volunteer pharmacists.

CHANGES TO RULE:

855-115-0065
Notification: Out-of-State Volunteer
(1) A pharmacist who is not licensed in Oregon may, without compensation and in connection with a coordinating organization or other entity, practice pharmacy for 30 days each calendar year. The pharmacist is not required to apply for licensure or other authorization from the board to practice pharmacy under this section.¶
(2) To practice pharmacy under this section, the pharmacist who is not licensed in Oregon must submit on a form prescribed by the board, at least 10 days prior to commencing practice in this state, to the board:¶
(a) Proof that the pharmacist is in good standing and is not the subject of an active disciplinary action in any jurisdiction in which the Pharmacist is authorized to practice;¶
(b) An acknowledgement that the pharmacist must provide services only within the scope of practice of pharmacy and will provide services pursuant to the scope of practice of this state or the health care practitioner's licensing agency, whichever is more restrictive;¶
(c) An attestation that the pharmacist will not receive compensation for practice in this state;¶
(d) The name and contact information of the coordinating organization or other entity through which the Pharmacist will practice; and¶
(e) The dates on which the pharmacist will practice in this state.¶
(3) Except as otherwise provided, a pharmacist practicing under this section is subject to the laws and rules governing the pharmacy profession that the pharmacist is authorized to practice and to disciplinary action by the appropriate health professional regulatory board.
Statutory/Other Authority: ORS 689.205, 2022 HB 4096
Statutes/Other Implemented: ORS 689.151, ORS 689.315, 2022 HB 4096

ADOPT: 855-115-0070

RULE SUMMARY: Proposed rule relocates existing rule OAR 855-019-0160 to OAR 855-115-0070 related to notification requirements for nuclear pharmacists.

CHANGES TO RULE:

855-115-0070
Notification: Nuclear Pharmacists
In order to qualify under these rules as a nuclear Pharmacist, a Pharmacist must :¶
(1) Meet minimum standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Radiation Protection Services of the Department of Human Services; and¶
(2) Be a Pharmacist licensed to practice in Oregon; and¶
(3) Submit to the Board of Pharmacy either:¶
(a) Evidence of current certification in nuclear pharmacy by the Board of Pharmacy Specialties; or¶
(b) Evidence that they meet both the following:¶
(A) Certification of a minimum of six month on-the-job training under the supervision of a qualified nuclear Pharmacist in a nuclear pharmacy providing radiopharmaceutical services; and¶
(B) Certification of completion of a nuclear pharmacy training program in a college of pharmacy or a nuclear pharmacy training program approved by the board.¶
(4) Receive a letter of notification from the board that the evidence submitted by the Pharmacist meets the above requirements and has been accepted by the board.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151

ADOPT: 855-115-0105

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-019-0200 to OAR 855-115-0105 related to general responsibilities for pharmacists.

CHANGES TO RULE:

855-115-0105
Responsibilities: General
When practicing pharmacy per ORS 689, each Pharmacist must: ¶
(1) Use that degree of care, skill, diligence and reasonable professional judgment that is exercised by a careful and prudent Pharmacist in the same or similar circumstances;¶
(2) Be responsible for their own actions, however, this does not absolve the pharmacy from responsibility for the Pharmacist's actions;¶
(3) Be responsible for the actions of each Intern, Certified Oregon Pharmacy Technician, Pharmacy Technician and non-licensed pharmacy personnel under their supervision; ¶
(4) Ensure compliance with all state and federal laws and rules governing the practice of pharmacy;¶
(5) Control each aspect of the practice of pharmacy;¶
(6) Perform appropriately the duties of a Pharmacist;¶
(7) Ensure access to reference material and equipment needed based on the services provided; ¶
(8) Ensure services are provided with required interpretation and translation per ORS 689.564;¶
(9) Ensure services occur in a sanitary, secure and confidential environment; ¶
(10) Be clearly identified as a Pharmacist in all interactions and communications (e.g., nametag, phone interaction, chart notations);¶
(11) Display in plain sight the Pharmacist license within the pharmacy or place of business to which it applies; ¶
(12) Engage in a continuous quality improvement program; and¶
(13) Review, adhere to and enforce written policies and procedures. The review must:¶
(a) Occur prior to engaging in the practice of pharmacy; ¶
(b) Occur with each update; and¶
(c) Be documented and records retained according to OAR 855-104-0055.
Statutory/Other Authority: ORS 689.205, 2022 HB 4034
Statutes/Other Implemented: ORS 689.025, ORS 689.151, ORS 689.155, ORS 689.564, ORS 689.645, ORS 689.682, ORS 689.689, 2022 HB 4034

ADOPT: 855-115-0110

RULE SUMMARY: Proposed new rule adds compliance requirements for pharmacists regarding confidentiality.

CHANGES TO RULE:

855-115-0110
Responsibilities: Confidentiality
Each Pharmacist must comply with OAR 855-104-0015 regarding confidentiality.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-115-0115

RULE SUMMARY: Proposed rule revises and relocates portions of existing rule OAR 855-019-0205 to OAR 855-104-0010 and OAR 855-115-0115 related to a pharmacist's duty to report.

CHANGES TO RULE:

855-115-0115
Responsibilities: Duty to Report
Each Pharmacist must report to the board as required by OAR 855-104-0010. In addition, unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, a Pharmacist must report to the board without undue delay, but within 1 business day of:¶
(1) Confirmed significant drug loss; or ¶
(2) Any loss related to suspected drug theft of a controlled substance.
Statutory/Other Authority: ORS 689.205, ORS 689.455
Statutes/Other Implemented: ORS 676.150, ORS 689.151, ORS 689.155, ORS 689.455

ADOPT: 855-115-0120

RULE SUMMARY: Proposed rule revises and relocates portions of existing rule OAR 855-019-0200 to OAR 855-115-0120 related to pharmacist responsibilities for licensed and non-licensed personnel.

CHANGES TO RULE:

855-115-0120
Responsibilities: Personnel
(1) When practicing pharmacy per ORS 689, each Pharmacist must:¶
(a) Ensure personnel that require licensure have been granted and maintain licensure with the board;¶
(b) Ensure licensed personnel work within the duties permitted by their licensure;¶
(c) Ensure non-Pharmacist personnel only perform duties they are licensed and trained to perform;¶
(d) Know the identity of each Intern under their supervision, and Certified Oregon Pharmacy Technician and Pharmacy Technician under their supervision, direction and control at all times;¶
(e) Ensure each Intern only practices pharmacy under the supervision of a Pharmacist as outlined in OAR 855-120 including any applicable ratios;¶
(f) Ensure each Certified Oregon Pharmacy Technician and Pharmacy Technician only assists in the practice of pharmacy under the supervision, direction, and control of a Pharmacist as outlined in OAR 855-125;¶
(g) Ensure licensed personnel do not engage in prohibited practices as outlined for Interns in OAR 855-120-0150 and for Certified Oregon Pharmacy Technicians and Pharmacy Technicians in OAR 855-125-0150;¶
(h) Ensure non-licensed personnel do not practice or assist in the practice of pharmacy;¶
(i) Ensure initial and ongoing training is completed that is commensurate with the tasks that the Pharmacist and persons under their supervision will perform, prior to the performance of those tasks;¶
(j) Ensure continued competency in tasks that are performed by the Pharmacist and persons under their supervision; and ¶
(k) Ensure that the supervision of non-Pharmacist personnel does not exceed their capacity to safely supervise based on the workload and services being provided.¶
(2) When engaging in the practice of pharmacy per ORS 689, each Pharmacist may delegate the practice of pharmacy to other health care providers who are appropriately trained and authorized to perform the delegated tasks.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-115-0125

RULE SUMMARY: Proposed rule revises and relocates portions of existing rule OAR 855-019-0200 to OAR 855-115-0125 related to pharmacist requirements for being responsible for drugs, records and security while practicing pharmacy.

CHANGES TO RULE:

855-115-0125
Responsibilities: Drugs, Records and Security
When practicing pharmacy per ORS 689, each Pharmacist must:¶
(1) Ensure the security of prescription drugs, pharmacy and patient records including:¶
(a) Provide adequate safeguards against loss, theft, or diversion; and¶
(b) Ensure only persons authorized by the Pharmacist access the areas where prescription drugs, pharmacy and patient records are stored by restricting access;¶
(2) Ensure that all records are maintained in accordance with state and federal laws and rules;¶
(3) Only receive drugs from an Oregon Registered Drug Outlet (e.g., Wholesaler, Manufacturer or Pharmacy);¶
(4) Comply with the drug storage rules for pharmacies in OAR 855-041-1036;¶
(5) Ensure drugs and devices that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or identified as suspect or illegitimate, or otherwise unfit for dispensing or administration must be documented, quarantined and physically separated from other drugs and devices until they are destroyed or returned to the supplier;¶
(6) Ensure each compounded drug is prepared in compliance with OAR 855-045;¶
(7) Ensure all computer equipment used for the practice of pharmacy:¶
(a) Establishes and maintains a secure connection to patient information to which they have access;¶
(b) Prevents unauthorized access to patient information; and¶
(c) Is configured so information from any patient records are not duplicated, downloaded, or removed from the electronic database if accessed remotely;¶
(8) Document accurately and maintain records in the practice of pharmacy including, but not limited to:¶
(a) Services provided; ¶
(b) The date, time and identification of the licensee and the specific activity or functions performed; and¶
(c) Maintain records pertaining to the acquisition, storage, dispensing or administration, and disposal of drugs and devices; and¶
(9) Ensure reporting of data as required by federal and state regulations, including but not limited to:¶
(a) ALERT Immunization Information System (ALERT-IIS) per ORS 433.090, ORS 433.092, ORS 433.094, ORS 433.095, ORS 433.096, ORS 433.098, ORS 433.100, ORS 433.102, ORS 433.103, and ORS 433.104;¶
(b) Communicable diseases per ORS 433.004; and¶
(c) Vaccine Adverse Event Reporting System (VAERS) per 21 CFR 600.80 (v. 04/01/2022).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-115-0130

RULE SUMMARY: Proposed rule revises and relocates portions of existing rules in OAR 855-019-0200 and OAR 855-019-0210 to OAR 855-115-0130 related to pharmacists responsibilities when practicing pharmacy for a Drug Outlet.

CHANGES TO RULE:

855-115-0130
Responsibilities: Drug Outlet
(1) When practicing pharmacy per ORS 689 for a Drug Outlet, each Pharmacist must:¶
(a) Be responsible for the daily conduct, operation, management and control of the Drug Outlet pharmacy;¶
(b) Ensure that only a Pharmacist has access to the Drug Outlet pharmacy when the pharmacy is closed, except as permitted in OAR 855-041-6310;¶
(c) Ensure each prescription contains all the elements required in OAR 855-041 or OAR 855-139; ¶
(d) Ensure the patient record contains the elements required in OAR 855-041 or OAR 855-139;¶
(e) Ensure prescriptions, prescription refills, and drug orders are dispensed:¶
(A) Accurately;¶
(B) To the correct party;¶
(C) Pursuant to a valid prescription; ¶
(D) Pursuant to a valid patient-practitioner relationship; and ¶
(E) For a legitimate medical purpose;¶
(f) Ensure the Drug Outlet pharmacy is operated in a professional manner at all times; ¶
(g) Ensure the drug outlet reports data as required by federal and state regulations, including but not limited to:¶
(A) Prescription Drug Monitoring Program (PDMP) per ORS 413A.890, ORS 413A.895, ORS 413A.896, ORS 413A.898, and OAR 333-023;¶
(B) Death with Dignity per ORS 127.800, ORS 127.805, ORS 127.810, ORS 127.815, ORS 127.820, ORS 127.825, ORS 127.830, ORS 127.835, ORS 127.840, ORS 127.845, ORS 127.850, ORS 127.855, ORS 127.860, ORS 127.865, ORS 127.870, ORS 127.875, ORS 127.880, ORS 127.885, ORS 127.890, ORS 127.892, ORS 127.895, ORS 127.897, and OAR 333-009;¶
(C) Controlled substances per 21 CFR 1301.74 (v. 04/01/2022); and¶
(D) Listed chemicals per 21 CFR 1310.05 (v. 04/01/2022); and¶
(2) A Pharmacist who utilizes licensees remotely, must comply with OAR 855-041-3200 through OAR 855-041-3250.¶
(3) When engaging in the practice of pharmacy per ORS 689, each Pharmacist may delegate final verification of drug and dosage form, device, or product to a Certified Oregon Pharmacy Technician or Pharmacy Technician per ORS 689.005 when the following conditions are met:¶
(a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification;¶
(b) The Certified Oregon Pharmacy Technician or Pharmacy Technician does not use discretion in conducting final verification;¶
(c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and¶
(d) Ensure the Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-115-0140

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-019-0220 to OAR 855-115-0140 related to Drug Utilization Review (DUR).

CHANGES TO RULE:

855-115-0140
Drug Utilization Review (DUR)
(1) A Pharmacist must complete a drug utilization review (DUR) by reviewing the patient record prior to dispensing each prescription drug or device for the purpose of identifying the following:¶
(a) Over-utilization or under-utilization;¶
(b) Therapeutic duplication;¶
(c) Drug-disease contraindications;¶
(d) Drug-drug interactions;¶
(e) Incorrect drug dosage or formulation;¶
(f) Inappropriate duration of treatment;¶
(g) Drug-allergy interactions; and¶
(h) Drug abuse or misuse.¶
(2) Upon recognizing a concern with any of the items in (1)(a)-(h), the Pharmacist must take steps to mitigate or resolve the problem and document the steps taken and outcome.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

ADOPT: 855-115-0145

RULE SUMMARY: Proposed rule revises and relocates existing rule from OAR 855-019-0230 to OAR 855-115-0145 related to counseling. Clarifies circumstances that require counseling, adds requirements for counseling when a prescription is delivered to a patient for self-administration, and adds requirements for documentation of attempts to counsel.

CHANGES TO RULE:

855-115-0145
Counseling
(1) For each prescription, the pharmacist must determine the manner and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient. ¶
(2) The pharmacist must counsel the patient or patient's agent on the use of a drug or device:¶
(a) Upon request; ¶
(b) When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy;¶
(c) When there has been a change in the dose, formulation, or directions;¶
(d) When the prescription has been transferred to the Drug Outlet pharmacy by oral, written or electronic means; or¶
(e) For any refill that the pharmacist deems counseling is necessary. ¶
(3) When communicating (e.g., counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the pharmacist must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the pharmacist is proficient in the patient's preferred language.¶
(4) For a prescription delivered outside of a Drug Outlet Pharmacy to a patient for self-administration, the pharmacist must:¶
(a) Attempt to provide counseling prior to delivery as required in (1) and (2);¶
(b) Reattempt to provide counseling by end of the next business day if counseling does not occur prior to delivery to the patient; and¶
(c) Provide drug information in a format accessible by the patient, including information on how to contact the pharmacist with the delivery. ¶
(5) A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused,¶
(a) Only a pharmacist can accept a patient's or patient's agent's request not to be counseled, when counseling is required.¶
(b) The pharmacist may choose not to release the prescription until counseling has been completed.¶
(6) A pharmacist must initiate and provide counseling under conditions that maintain patient privacy and confidentiality.¶
(7) The pharmacist that attempts counseling, provides counseling or accepts the request not to be counseled must document their identity, each attempt to counsel and the outcome at the time of the attempt or interaction.¶
(8) Additional forms of drug information (e.g., Medication Guide, Patient Package Inserts, Instructions for Use) must be used to supplement counseling when required by federal law or rule. ¶
(9) Counseling on a new prescription may include, but is not limited to, the following elements:¶
(a) Name and description of the drug;¶
(b) Dosage form, dose, route of administration, and duration of drug therapy;¶
(c) Intended use of the drug and expected action;¶
(d) Special directions and precautions for preparation, administration, and use by the patient;¶
(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;¶
(f) Techniques for adherence and self-monitoring drug therapy;¶
(g) Proper storage and appropriate disposal method(s) of unwanted or unused medication;¶
(h) Refill information;¶
(i) Action to be taken in the event of a missed dose; and¶
(j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.¶
(10) Counseling on a refill prescription may include, but is not limited to, the following elements:¶
(a) Name and purpose of the medication;¶
(b) Directions for use, including technique;¶

(c) Perceived side effects; and¶
(d) Adherence.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

ADOPT: 855-115-0150

RULE SUMMARY: Proposed new rule adds pharmacist prohibited practices.

CHANGES TO RULE:

855-115-0150
Prohibited Practices
Pharmacists must not:¶
(1) Engage in the dispensing, distribution or delivery of drugs unless working for a registered Drug Outlet pharmacy.¶
(2) Possess personally or store drugs other than in a registered Drug Outlet pharmacy except for those drugs legally prescribed for the personal use of the Pharmacist or when the Pharmacist possesses or stores the drugs in the usual course of business and within the Pharmacist's scope of practice.¶
(3) Diagnose.¶
(4) Engage in any form of discrimination, harassment, intimidation, or assault.¶
(5) Permit any Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician to perform any task in which the supervising Pharmacist is not trained or qualified to perform.¶
(6) Permit any non-licensed pharmacy personnel to perform any function that constitutes the practice of pharmacy as defined in ORS 689 or the assistance of the practice of pharmacy. Non-licensed personnel may only perform functions permitted by the Pharmacist providing supervision.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-115-0200

RULE SUMMARY: Proposed rule revises and relocates portions of existing rule in OAR 855-019-0300 to OAR 855-115-0200 related to Pharmacist-in-Charge (PIC) qualifications and limitations. The PIC training course is a free 3-hour virtual meeting.

CHANGES TO RULE:

855-115-0200
Pharmacist-in-Charge: Qualifications and Limitations
Effective July 1, 2025, in order to be a Pharmacist-in-Charge (PIC), a Pharmacist must:¶
(1) Complete a board-provided PIC training course as described below:¶
(a) A Pharmacist with 1500 hours or more of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training course within two years prior to appointment as PIC or within 90-days after appointment.¶
(b) A Pharmacist with less than 1500 hours of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training prior to the appointment.¶
(2) Complete a board-provided PIC training course at least every five years.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

ADOPT: 855-115-0210

RULE SUMMARY: Proposed rule revises and relocates portions of existing rule in OAR 855-019-0300 to OAR 855-115-0210 related to the responsibilities of a Pharmacist-in-Charge of a Drug Outlet pharmacy.

CHANGES TO RULE:

855-115-0210
Pharmacist-in-Charge: Responsibilities
(1) In addition to the responsibilities of a Pharmacist outlined in OAR 855-115, a Pharmacist-in-Charge of a Drug Outlet pharmacy must:¶
(a) Be actively engaged in pharmacy activities at the Drug Outlet pharmacy;¶
(b) Be physically present at the Drug Outlet pharmacy on a regular basis for a sufficient amount of time as needed to ensure Drug Outlet pharmacy compliance;¶
(c) Be responsible for the ongoing conduct, operation, management and control of the Drug Outlet pharmacy; ¶
(d) Establish, maintain, and enforce written policies and procedures governing the practice of pharmacy that are compliant with federal and state laws and rules;¶
(e) Ensure maintenance of complete and accurate records;¶
(f) Establish, maintain and enforce a continuous quality improvement program;¶
(g) Develop, implement and submit a plan of correction for observations noted on an inspection within the time allowed by the board;¶
(h) Complete an annual self-inspection of the pharmacy using the Self-Inspection Form provided by the board, by July 1 each year and within 15 days of becoming PIC. The completed self-inspection forms must be signed and dated by the PIC and retained for three years from the date of completion; ¶
(i) Ensure a controlled substance inventory with discrepancy reconciliation is accurately completed and documented; and¶
(j) For all controlled drugs either prior to the opening or after the close of business on the inventory date:¶
(A) Within 15 days of a change in PIC; and¶
(B) At least every 367 days; and¶
(i) For all Schedule II controlled drugs:¶
(ii) At least every 93 days in a Retail Drug Outlet Pharmacy; and¶
(iii) At least every 31 days in an Institutional Drug Outlet Pharmacy.¶
(2) The PIC of a Drug Outlet pharmacy affiliated with the following Drug Outlet types must also comply with the PIC responsibilities as outlined in: ¶
(a) Pharmacy Prescription Kiosk in OAR 855-141; ¶
(b) Pharmacy Prescription Locker in OAR 855-143; and ¶
(c) Remote Dispensing Site Pharmacy in OAR 855-139.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

ADOPT: 855-115-0300

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-019-0240 to OAR 855-115-0300 related to pharmacist consulting practice.

CHANGES TO RULE:

855-115-0300
Services: Consulting Practice
(1) A Pharmacist who provides services to an Oregon licensed healthcare facility must perform all duties and functions required by the healthcare facility's licensure as well as by any relevant federal and state laws and rules.¶
(2) A Pharmacist who provides services to a correctional facility, long term care facility, community-based care facility, hospital drug room, or charitable pharmacy that does not have additional Pharmacist service requirements under the terms of its licensure with any other state agency, must provide services that include but are not limited to the following:¶
(a) Provide the facility with policies and procedure relating to security, storage and distribution of drugs within the facility;¶
(b) Provide guidance on the proper documentation of drug administration or dispensing; and¶
(c) Provide educational materials or programs as requested.¶
(3) A Pharmacist who provides services to an Oregon licensed healthcare provider must follow all state and federal laws and rules related to the practice of pharmacy. ¶
(4) A Pharmacist must maintain appropriate records of their services in (2) - (4) for three years and make them available to the board for inspection.¶
(5) A Pharmacist may store health protected records outside an Oregon licensed facility as permitted in OAR 855-104-0055. ¶
(6) Records and documents must be retained according to OAR 855-104-0055.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

ADOPT: 855-115-0305

RULE SUMMARY: Proposed rule revises and relocates portions of existing rules in OAR 855-019-0265, OAR 855-019-0270, OAR 855-019-0280, and OAR 855-019-0290 to OAR 855-115-0305 related to pharmacist requirements for the administration of vaccines, drugs or devices.

CHANGES TO RULE:

855-115-0305
Services: Administration of Vaccines, Drugs, or Devices
(1) In accordance with ORS 689.645 and ORS 689.655, a Pharmacist may administer a vaccine, drug or device as specified in this rule.¶
(2) A Pharmacist who administers a vaccine, drug or device must:¶
(a) Prior to administration of an injectable drug or device, receive practical training on the injection site and administration technique that is utilized;¶
(A) For vaccines, the training:¶
(i) May include programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the board; and ¶
(ii) Must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.¶
(B) For orally administered drugs, training is not required; and¶
(C) Records of training must be retained according to OAR 855-104-0055.¶
(b) Hold active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years. The most current CPR certification record must be retained according to OAR 855-104-0055;¶
(c) Ensure that any drug administered to a patient was stored in accordance with the drug storage rules for pharmacies in ORS 855-041-1036; ¶
(d) Observe, monitor, report, and otherwise take appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the vaccine, drug or device; ¶
(e) Ensure that vaccine, drug or device administration is documented in the patient's permanent record; and¶
(f) Ensure records and documents are retained according to OAR 855-104-0055. Records of administration must include but are not limited to:¶
(A) Patient identifier;¶
(B) Vaccine, drug or device and strength;¶
(C) Route and site of administration;¶
(D) Date and time of administration; and¶
(E) Pharmacist identifier.¶
(3) For vaccines only, the requirements in (2) and the following apply, the Pharmacist must:¶
(a) Follow the guidance in the Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit (v. 4/12/2022);¶
(b) Have access to a current copy of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases" (v. 8/2021);¶
(c) Give the appropriate Vaccine Information Statement (VIS) to the patient or patient's agent with each dose of vaccine covered by these forms. The Pharmacist must ensure that the patient or patient's agent is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the vaccine;¶
(d) Report all vaccinations administered to the ALERT IIS in accordance with OAR 333-049-0050, and for COVID-19 immunizations, in accordance with OAR 333-047-1000; and¶
(e) Report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient.¶
(4) The Pharmacist must be acting:¶
(a) Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice; or¶
(b) In accordance with a statewide drug therapy management protocol per OAR 855-115-0345 or clinical pharmacy agreement or collaborative drug therapy management agreement per OAR 855-115-0315; or¶
(c) In accordance with a written administration protocol issued by the Oregon Health Authority and approved by the board.¶

(5) The Pharmacist may administer a drug or device in conjunction with training the patient or the patient's agent how to administer or self-administer the drug or device. ¶
(6) Except as required in (2), records and documents must be retained according to OAR 855-104-0055.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.655

ADOPT: 855-115-0310

RULE SUMMARY: Proposed new rule adds requirements for Pharmacists who order and receive laboratory tests.

CHANGES TO RULE:

855-115-0310
Services: Laboratory
(1) A Pharmacist must only order and receive laboratory test when:¶
(a) Managing drug therapy pursuant to the terms of a clinical pharmacy agreement or collaborative drug therapy management agreement with a provider under OAR 855-115-0315;¶
(b) Providing patient care services pursuant to the terms of the post diagnostic formulary listed in OAR 855-115-0340 that is developed under ORS 689.645 and adopted by the board under ORS 689.649; ¶
(c) Providing patient care services pursuant to and as allowed by the terms of a protocol listed in OAR 855-115-0345 that is developed under ORS 689.645 and adopted by the board under ORS 689.649;¶
(d) Permitted under a Health Screen Testing Permit pursuant to ORS 438.010(8); ORS 438.060; ORS 438.130(2); ORS 438.150(5), (6) and (7); OAR 333-024-0370, OAR 333-024-0375, OAR 333-024-0380, OAR 333-024-0385, OAR 333-024-0390, OAR 333-024-0395 and OAR 333-024-0400; or¶
(e) Monitoring a therapeutic response or adverse effect to drug therapy under ORS 689.005.¶
(2) A pharmacy may perform a laboratory test as permitted under ORS 689.661.¶
(3) Records and documents must be retained according to OAR 855-104-0055.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 438.010, ORS 438.060, ORS 438.130, ORS 438.150, ORS 689.151, ORS 689.155, ORS 689.649, ORS 689.661

ADOPT: 855-115-0315

RULE SUMMARY: Proposed rule relocates existing rule OAR 855-019-0260 to OAR 855-115-0315 related to Collaborative Drug Therapy Management services.

CHANGES TO RULE:

855-115-0315
Services: Collaborative Drug Therapy Management
(1) As used in this rule "Collaborative Drug Therapy Management" (CDTM) means the participation by a practitioner and a Pharmacist in the management of drug therapy pursuant to a written agreement that includes information on the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:¶
(a) Is agreed to by one practitioner and one Pharmacist; or¶
(b) Is agreed to by one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee, and one or more Pharmacists.¶
(2) A Pharmacist shall engage in collaborative drug therapy management with a practitioner only under a written arrangement that includes:¶
(a) The identification, either by name or by description, of each of the participating Pharmacists;¶
(b) The identification, by name or description, of each of the participating practitioners or group of practitioners;¶
(c) The name of the principal pharmacist and practitioner who are responsible for development, training, administration, and quality assurance of the arrangement; ¶
(d) The types of decisions that the pharmacist is allowed to make, which may include:¶
(A) A detailed description of the types of diseases, drugs, or drug categories involved, and the activities allowed in each case;¶
(B) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities;¶
(C) A detailed description of the activities the pharmacist is to follow including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the practitioner concerning specific decisions made. In addition to the agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system; and¶
(D) Circumstances which will cause the pharmacist to initiate communication with the practitioner, including but not limited to the need for a new prescription order and a report of a patient's therapeutic response or any adverse effect.¶
(e) Training requirement for Pharmacist participation and ongoing assessment of competency, if necessary;¶
(f) Quality assurance and periodic review by a panel of the participating Pharmacists and practitioners;¶
(g) Authorization by the practitioner for the pharmacist to participate in collaborative drug therapy; and¶
(h) A requirement for the collaborative drug therapy arrangement to be reviewed and updated, or discontinued at least every two years.¶
(3) The collaborative drug therapy arrangement and associated records must be kept on file in the pharmacy and made available to any appropriate health licensing board upon request.¶
(4) Nothing in this rule shall be construed to allow therapeutic substitution outside of the CDTM agreement.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

ADOPT: 855-115-0320

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-019-0250 to OAR 855-115-0320 related to requirements for Pharmacists who provide Medication Therapy Management (MTM) services.

CHANGES TO RULE:

855-115-0320
Services: Medication Therapy Management
(1) Medication Therapy Management (MTM) is a distinct service or group of services that is intended to optimize the therapeutic outcomes of a patient. Medication Therapy Management can be an independent service provided by a Pharmacist or can be in conjunction with the provision of a medication product with the objectives of:¶
(a) Enhancing appropriate medication use;¶
(b) Improving medication adherence;¶
(c) Increasing detection of adverse drug events;¶
(d) Improving collaboration between practitioner and Pharmacist; and¶
(e) Improving outcomes.¶
(2) A Pharmacist that provides MTM services must ensure that they are provided according to the individual needs of the patient and may include but are not limited to the following:¶
(a) Performing or otherwise obtaining the patient's health status assessment;¶
(b) Developing a medication treatment plan for monitoring and evaluating the patient's response to therapy;¶
(c) Monitoring the safety and effectiveness of the medication therapy;¶
(d) Selecting, initiating, modifying or administering medication therapy in consultation with the practitioner where appropriate;¶
(e) Performing a medication review to identify, prevent or resolve medication related problems;¶
(f) Monitoring the patient for adverse drug events;¶
(g) Providing education and training to the patient or the patient's agent on the use or administration of the medication where appropriate;¶
(h) Documenting the delivery of care, communications with other involved healthcare providers and other appropriate documentation and records as required. Such records must:¶
(A) Be accurate; ¶
(B) Identify the person who completed each action;¶
(C) Records and documents must be retained according to OAR 855-104-0055. ¶
(i) Providing necessary services to enhance the patient's adherence with the therapeutic regimen; and¶
(j) Integrating the medication therapy management services within the overall health management plan for the patient.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

ADOPT: 855-115-0330

RULE SUMMARY: Proposed rule revises and relocates portions of existing rule OAR 855-020-0105 and OAR 855-020-0110 to OAR 855-115-0330 related to pharmacist prescribing practices for the Formulary or Protocol Compendia.

CHANGES TO RULE:

855-115-0330
Services: Prescribing - Formulary or Protocol Compendia
(1) A Pharmacist located and licensed in Oregon may prescribe and dispense a FDA-approved drug and device included on either the Formulary or Protocol Compendia, set forth in this Division. ¶
(2) A Pharmacist may submit a concept, on a form prescribed by the board to the Public Health and Pharmacy Formulary Advisory Committee for consideration, for the addition of a drug or device to the Formulary Compendia or the development of a protocol for the Protocol Compendia. A Pharmacist may provide feedback on the Formulary or Protocol Compendia on a board prescribed form and located on the board website.¶
(3) A Pharmacist must only prescribe a drug or device consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations.¶
(4) The Pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond their expertise by consulting with or referring patients to another health care provider.¶
(5) For each drug or device the Pharmacist prescribes via the Formulary or Protocol Compendia, the Pharmacist must:¶
(a) Ensure training and education requirements have been met prior to engaging in prescribing activities. A copy of all required training and education must be retained according to OAR 855-104-0055; ¶
(b) Collect subjective and objective information about the patient's health history and clinical status. If prescribing pursuant to the Formulary Compendia in OAR 855-115-0340, a diagnosis from the patient's healthcare provider is required. ¶
(c) Assess the information collected in (b). Any physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means.¶
(d) Create an individualized patient-centered care plan that utilizes information obtained in the assessment to evaluate and develop a care plan; ¶
(e) Implement the care plan, to include:¶
(A) Addressing medication and health-related problems and engaging in preventive care strategies;¶
(B) Initiating, modifying, discontinuing, or administering medication therapy as permitted by the Formulary or Protocol Compendia;¶
(C) Providing education and self-management training to the patient or caregiver;¶
(D) Contributing to coordination of care, including the referral or transition of the patient to another health care professional; and¶
(E) Scheduling follow-up care as needed to achieve goals of therapy.¶
(f) Monitor and evaluate the effectiveness of the care plan and make modifications to the plan; and¶
(g) Provide notification to the patient's identified primary care provider or other care providers when applicable within five business days following the prescribing of a Formulary or Protocol Compendia drug or device.¶
(6) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use an audiovisual communication system to conduct the consultation.¶
(7) All records and documents must be retained according to OAR 855-104-0055 and must be made available to the patient and provider upon request.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

ADOPT: 855-115-0335

RULE SUMMARY: Proposed rule revises and relocates existing rule from OAR 855-020-0120 to OAR 855-115-0335 related to prescribing prohibited practices for pharmacists.

CHANGES TO RULE:

855-115-0335
Services: Prescribing - Prohibited Practices
(1) A Pharmacist must not prescribe a drug or device via the Formulary or Protocol Compendia:¶
(a) To self; or¶
(b) When the compendia requires referral to non-Pharmacist provider.¶
(2) A Pharmacist must not require, but may allow, a patient to schedule an appointment with the Pharmacist for the prescribing or administering of an injectable hormonal contraceptive or the prescribing or dispensing of a self-administered hormonal contraceptive.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

ADOPT: 855-115-0340

RULE SUMMARY: Proposed rule relocates existing rule OAR 855-020-0200 to OAR 855-115-0340 related to the Formulary Compendium.

CHANGES TO RULE:

855-115-0340
Services: Prescribing - Formulary Compendium
A Pharmacist may prescribe, according to OAR 855-115-0330 and OAR 855-115-0335, a FDA-approved drug and device listed in the following compendium, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis must be documented. Devices and supplies:¶
(1) Diabetic blood sugar testing supplies;¶
(2) Injection supplies;¶
(3) Nebulizers and associated supplies;¶
(4) Inhalation spacers;¶
(5) Peak flow meters;¶
(6) International Normalized Ratio (INR) testing supplies;¶
(7) Enteral nutrition supplies; ¶
(8) Ostomy products and supplies; and¶
(9) Non-invasive blood pressure monitors.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

ADOPT: 855-115-0345

RULE SUMMARY: Proposed rule relocates existing rule from OAR 855-020-0300 to OAR 855-115-0345 related to the Protocol Compendium.

CHANGES TO RULE:

855-115-0345
Services: Prescribing - Protocol Compendium
A Pharmacist may prescribe, according to OAR 855-115-0330 and OAR 855-115-0335, FDA-approved drugs and devices listed in the following compendium, pursuant to a statewide drug therapy management protocol. ¶
(1) Continuation of therapy including emergency refills of insulin (v. 06/2023)¶
(2) Conditions¶
(a) Cough and cold symptom management¶
(A) Pseudoephedrine (v. 06/2021);¶
(B) Benzonatate (v. 06/2021);¶
(C) Short-acting beta agonists (v. 06/2021);¶
(D) Intranasal corticosteroids (v. 06/2021);¶
(b) Vulvovaginal candidiasis (VVC) (v. 06/2021);¶
(c) COVID-19 Antigen Self-Test (v. 12/2021);¶
(3) Preventative care¶
(a) Emergency Contraception (v. 06/2021);¶
(b) Male and female condoms (v. 06/2021);¶
(c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT (v. 06/2022);¶
(d) Travel Medications (v. 06/2023);¶
(e) HIV Post-exposure Prophylaxis (PEP) (v. 06/2023);¶
(f) HIV Pre-exposure Prophylaxis (PrEP) (v.06/2023); and¶
(g) Contraception (v. 06/2023).¶
[Publications: Publications referenced are available from the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649, ORS 689.689

ADOPT: 855-115-0350

RULE SUMMARY: Proposed rule relocates existing rule from OAR 855-019-0460 to OAR 855-115-0350 related to Naloxone prescribing.

CHANGES TO RULE:

855-115-0350
Services: Prescribing Practices - Naloxone
(1) A Pharmacist, having determined that there is an identified medical need, can prescribe naloxone and the necessary medical supplies to administer naloxone for opiate overdose:¶
(a) When dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME); ¶
(b) To an individual seeking naloxone; ¶
(c) To an entity seeking naloxone.¶
(2) The Pharmacist must determine that the individual (or the individual on behalf of an entity) seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.¶
(3) The Pharmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.¶
(4) The Pharmacist must dispense the naloxone product in a properly labeled container.¶
(5) Naloxone may not be prescribed without offering to provide oral counseling to the authorized recipient, which may include dose, effectiveness, adverse effects, storage conditions, and safety.¶
(6) The Pharmacist must document the encounter and the prescription, and maintain records for three years.¶
(7) Any person, having once lawfully obtained naloxone may possess, distribute or administer it for the purpose of reversing opiate overdose.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682, ORS 689.684