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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
12/22/2023 8:54 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Pharmacists; Collaborative Drug Therapy Management (CDTM)

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 01/24/2024 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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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: 01/24/2024
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: 618712182
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 January 24, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Relocates and existing CDTM rules from Division 019 into Division 115.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Division 115 Pharmacists Permanent Administrative Order
https://www.oregon.gov/pharmacy/Documents/Div_115_Pharmacists_BP_16-2023TrackedChanges.pdf

https://www.oregon.gov/pharmacy/Documents/Div_115_Supervision_Counseling_PIC_Qualifications_BP_31-2023TrackedChanges.pdf

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

The proposed rule is not expected to affect racial equity in this state.

FISCAL AND ECONOMIC IMPACT:

No anticipated fiscal and economic impact. Licensees, registrants and interested parties may provide fiscal and economic impact statements during the open comment period.

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).

(1) The proposed new rule has no additional economic impact on state agencies, units of local government, or the public.
(2)(a) The proposed rule amendments applies to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP &IP) registrants identify as a small business.
(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.
(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

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

Licensees and registrants who identify as a small business will receive an email notice of proposed rulemaking via GovDelivery and will have an opportunity to provide public comment on the proposed rule for the board's consideration.

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

The board directed staff to convene a CDTM – CPA Workgroup consisting of Subject Matter Experts with expertise related to CDTMs/CPAs to assist with the development of rule amendments. The CDTM/CPA workgroup held a meeting on 5/4/2023 and reviewed and provided input on amendments related to CDTM and CPAs. The board reviewed and discussed the proposed amendments to the rules at the October 2023 board meeting, sent the rules to rulemaking in November 2023, but decided not to adopt the proposed rules in December 2023. Thus, the proposed rule for the January 2024 rulemaking copies the currently enacted language in OAR 855-019-0260 into the new Division 115.

ADOPT: 855-115-0315

RULE SUMMARY: Relocates existing CDTM rules from OAR 855-019-0260 to OAR 855-115-0315. The board adopted Division 115 Pharmacists rules in August, October and December 2023, effective 3/1/2024 which replaces Division 019. Division 019 needs to be repealed effective 3/1/2024 to allow Division 115 rules to become effective.

CHANGES TO RULE:

855-115-0315
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;¶
(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