



## NOTICE OF PROPOSED RULEMAKING INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 410  
OREGON HEALTH AUTHORITY  
HEALTH SYSTEMS DIVISION: MEDICAL ASSISTANCE PROGRAMS

**FILED**

02/02/2022 8:56 AM  
ARCHIVES DIVISION  
SECRETARY OF STATE

FILING CAPTION: Requiring CCO Contracted Providers Check The Prescription Drug Monitoring Program (PDMP) Before Prescribing Controlled Substances

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 03/21/2022 5:00 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.*

*A public rulemaking hearing may be requested in writing by 10 or more people, or by a group with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date the Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.*

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### NEED FOR THE RULE(S)

Conformation with requirements in 42 U.S.C. 1396w-3a that are effective October 1, 2021, state Medicaid programs must ensure all prescribing providers check the prescription drug history of a covered individual being treated by the provider through the Oregon Prescription Drug Monitoring Program (PDMP) before prescribing to such individual a controlled substance

### DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

42 U.S.C. 1396w-3a viewable at: <https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section1396w-3a&num=0&edition=prelim>

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

The affect on racial equity was considered. The determination is that there will be no impact from this rule change.

### FISCAL AND ECONOMIC IMPACT:

No fiscal impact to any entity in Oregon. The Department/Authority does not anticipate there will be a fiscal impact from these rule changes.

### 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) None
- (2)
- (a) None
- (b) None
- (c) None

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

None.

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

RAC Exception was granted.

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AMEND: 410-141-3855

RULE SUMMARY: Conformation with requirements in 42 U.S.C. 1396w-3a that effective October 1, 2021, state Medicaid programs must ensure all prescribing providers check the prescription drug history of a covered individual being treated by the provider through the Oregon Prescription Drug Monitoring Program (PDMP) before prescribing to such individual a controlled substance

CHANGES TO RULE:

410-141-3855

Pharmaceutical Services

(1) Prescription drugs are a covered service for conditions that are described in the funded region of the Prioritized List of Health Services, as described in OAR 410-141-3820. MCEs shall pay for covered prescription drugs except:¶¶

(a) As otherwise provided, mental health drugs that are in Standard Therapeutic Class 7 (ataractics-tranquilizers) or Standard Therapeutic Class 11 (psychostimulants-antidepressants) (based on the National Drug Code (NDC) as submitted by the manufacturer to First Data Bank);¶¶

(b) Depakote, Lamictal, and their generic equivalents and those drugs that the Authority specifically carved out from capitation according to section (10) of this rule;¶¶

(c) Drugs covered under Medicare Part D when the member is fully dual eligible; and¶¶

(d) Prescriptions for Physician Assisted Suicide under the Oregon Death with Dignity Act, for which payment is governed by OAR 410-121-0150.¶¶

(2) MCEs may use the statewide Practitioner-Managed Prescription Drug Plan under ORS 414.330 to 414.337.¶¶

(3) MCEs may use a preferred drug list if it allows access to other drug products not on the drug list through prior authorization. ¶¶

(4) As specified in 45 CFR 156.122 and 42 CFR 438.10, MCEs shall publish up-to-date, accurate, and complete preferred drug lists, including any tiering structures, that have been adopted and any coverage criteria or other restrictions on the way certain drugs may be obtained. MCEs shall ensure that: ¶¶

(a) The preferred drug list is easily accessible to members and potential members, state and federal government, and the public;¶¶

(b) The preferred drug list is accessible on the MCE's public website in a machine-readable format through a clearly identifiable web link or tab without requiring a member to access account or policy number;¶¶

(c) Be made available in paper form if requested by a member; and¶¶

(d) If an MCE has more than one plan, members may be easily able to discern which preferred drug list applies to which plan.¶¶

(5) The preferred drug list shall:¶¶

(a) Include Federal Drug Administration (FDA) approved drug products for each therapeutic class sufficient to ensure the availability of covered drugs with minimal prior approval intervention by the provider of pharmaceutical services;¶¶

(b) Include at least one item in each therapeutic class of over-the-counter medications; and¶¶

(c) Be revised periodically to assure compliance with this requirement.¶¶

(6) MCEs shall cover at least one form of contraception within each of the 18 methods identified by the FDA. As set forth in OAR 410-141-3515, the member may refer themselves directly to family planning services without

getting a referral from a PCP or other participating providers.¶

(7) Prior authorization for prescription drug requests shall be addressed by the MCEs as described in OAR 410-141-3835.¶

(8) MCEs shall authorize the provision of a drug requested by the Primary Care Provider or referring provider if the prescriber certifies medical necessity for the drug such as:¶

(a) The equivalent of the drug listed has been ineffective in treatment; or¶

(b) The drug listed causes or is reasonably expected to cause adverse or harmful reactions to the member.¶

(9) MCEs may not authorize payment for any Drug Efficacy Study Implementation (DESI) Less Than Effective (LTE) drugs that have reached the FDA Notice of Opportunity for Hearing (NOOH) stage, as specified in OAR 410-121-0420 (DESI)(LTE) Drug List. DESI LTE drugs are identified by the Covered Outpatient Drug (COD) Status equal to 05 or 06 in the federal "Drug Products in the Medicaid Drug Rebate Program" list available at:

~~https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e¶~~

(10) The Authority shall pay for a drug that is not included in the global budget pursuant to the Pharmaceutical Services program rules (chapter 410, division 121), unless otherwise provided in this rule. An MCE may not reimburse providers for carved-out drugs:¶

(a) An MCE may seek to add drugs to the carve-out list contained in section (1) of this rule by submitting a request to the Authority no later than March 1 of any contract year. The request must contain all the following information:¶

(A) The drug name;¶

(B) The FDA approved indications that identify the drug may be used to treat a severe mental health condition; and¶

(C) The reason the Authority should consider this drug for carve out.¶

(b) If the Authority approves an MCE request for a drug not to be paid within the global budget, the Authority shall exclude the drug from the global budget for the following January contract cycle if the Authority determines that the drug has an approved FDA indication for the treatment of a severe mental health condition such as major depressive, bi-polar, or schizophrenic disorders.¶

(11) MCEs shall submit quarterly encounter data within 45 days after the end of the quarter pursuant to 42 CFR 438.3.¶

(12) MCEs are encouraged to provide payment only for outpatient and physician-administered drugs produced by manufacturers that have valid rebate agreements in place with the CMS as part of the Medicaid Drug Rebate Program. MCEs may continue to have some flexibility in maintaining preferred drug lists regardless of whether the manufacturers of those drugs participate in the Medicaid Drug Rebate Program.¶

(13) MCEs shall utilize a Pharmacy and Therapeutics (P&T) committee and a Drug Use Review (DUR) program. The committees may work in tandem or independent of the other, if all committee requirements for both committee types are met:¶

(a) A P&T committee must maintain written documentation of the rationale for all decisions regarding the drug list development and revisions. The committee shall follow the membership and meeting standards specified in 45 CFR § 156.122(3)(i) and (ii). Meetings shall be held at least quarterly;¶

(b) MCEs shall provide a detailed description of its P&T committee including its DUR functions on an annual basis. The report shall be in the form and manner required by the OHP. The data requested by the Authority shall be calculated to meet federal reporting obligations;¶

(c) The committee in its DUR capacity shall assure prescriptions are appropriate, medically appropriate, and not likely to result in adverse medical results. The committee must be designed to educate prescribers and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. The committee shall include prospective DUR, retrospective DUR, and educational programs as each is defined and described by 42 CFR 456, subpart K and Section 1902(o) of the Social Security Act [42 U.S.C. 1396a(o)]. ¶

(14) As required by ORS 414.328, CCOs shall implement a synchronization policy for the dispensing of prescription drugs to members of the CCO. A "synchronization policy" means a procedure for aligning the refill dates of a patient's prescription drugs so that drugs that are refilled at the same frequency may be refilled concurrently. ¶

(15) Enrolled providers are required to check the Prescription Drug Monitoring Program (PDMP) as defined in ORS 431A.655 before prescribing a schedule II controlled substance pursuant to 42 U.S.C 1396w-3a:¶

(a) Providers shall maintain documentation of the prescription drug history of the individual being treated; and¶

(b) In the case that an enrolled provider is not able to conduct the PDMP check, the providers shall maintain documentation of efforts, including reasons why the provider was unable to conduct the check;¶

(c) The PDMP check does not apply to clients in exempt populations:¶

(A) Individuals receiving hospice care;¶

(B) Individuals receiving palliative care;¶

(C) Individuals receiving cancer treatment;¶

(D) Individuals with sickle cell disease; ¶

(E) Residents of long-term care facilities described in) 42 U.S.C. 1396d, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy in accordance with 42 U.S.C. 1396w-3a(h)(2)(B); and¶

(F) Individuals admitted to an inpatient hospital facility. This exemption shall only apply to schedule II controlled substances provided or administered to the individual admitted to the inpatient hospital facility.¶

(d) PDMP requirements are in accordance with OAR 333-023-0800 to 333-023-0830.

Statutory/Other Authority: ORS 413.042, 414.615, 414.625, 414.635, 414.651

Statutes/Other Implemented: ORS 414.610-414.685