

Secretary of State
NOTICE OF PROPOSED RULEMAKING HEARING*
A Statement of Need and Fiscal Impact accompanies this form.

Oregon Health Authority, Division of Medical Assistance Programs (Division)	410
Agency and Division	Administrative Rules Chapter Number
Sandy Cafourek	500 Summer St NE, Salem, OR 97301
Rules Coordinator	Address
	Telephone

RULE CAPTION

Preferred Drug List Requirements

Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

June 15, 2016	10:30 a.m.	500 Summer St NE, Salem, OR 97301, Room 137B	Sandy Cafourek
Hearing Date	Time	Location	Hearings Officer

Auxiliary aids for persons with disabilities are available upon advance request.

RULEMAKING ACTION

Secure approval of new rule numbers (Adopted or Renumbered rules) with the Administrative Rules Unit prior to filing.

ADOPT:

AMEND: OAR 410-141-3070

REPEAL:

RENUMBER:

AMEND & RENUMBER:

Stat. Auth.: ORS 413.042, 414.615, 414.625, 414.635 & 414.651

Other Auth.:

Stats. Implemented: ORS 414.610-414.685

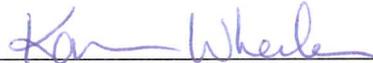
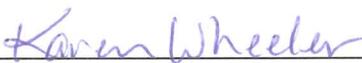
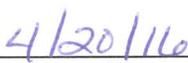
RULE SUMMARY

The Division's rule requires CCOs to demonstrate that they are able to provide coordinated care service efficiently, effectively, and economically. This rule provides CCOs with the framework for the Preferred Drug List Requirements under the Oregon Health Plan in the managed care environment.

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

June 17, 2016 Send comments to dmap.rules@state.or.us

Last Day for Public Comment (Last day to submit written comments to the Rules Coordinator)

		
Signature	Printed name	Date

*Hearing Notices published in the Oregon Bulletin must be submitted by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a weekend or legal holiday, upon which the deadline is 5:00 pm the preceding workday. ARC 920-2005

Secretary of State
STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

Oregon Health Authority, Division of Medical Assistant Programs (Division)
Agency and Division

410

Administrative Rules Chapter Number

Preferred Drug List Requirements

Rule Caption (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

In the Matter of: The amendment of OAR 410-141-3070

Statutory Authority: ORS 413.042, 414.615, 414.625, 414.635 & 414.651

Other Authority:

Stats. Implemented: ORS 414.610-414.685

Need for the Rule(s): The Division's rule requires CCOs to demonstrate that they are able to provide coordinated care service efficiently, effectively, and economically. This rule provides CCOs with the framework for the Preferred Drug List Requirements under the Oregon Health Plan in the managed care environment.

Documents Relied Upon, and where they are available: None

Fiscal and Economic Impact: None anticipated

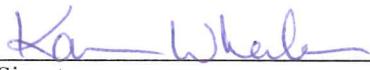
Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)): None anticipated
2. Cost of compliance effect on small business (ORS 183.336):
 - a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule: None anticipated
 - b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services: None anticipated
 - c. Equipment, supplies, labor and increased administration required for compliance: Amending these rules will not add additional reporting, record keeping, or other administrative activities.

How were small businesses involved in the development of this rule? Small businesses were invited to participate in the RAC.

Administrative Rule Advisory Committee consulted?: Yes, RAC 3/10/16.

If not, why?:


Signature

Karen Wheder
Printed name

4/20/16
Date

Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310.

410-141-3070

Pharmaceutical Preferred Drug List Requirements

(1) Prescription drugs are a covered service based on the funded Condition/Treatment Pairs. CCOs shall pay for 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), & ~~11~~ (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 sections (8) and (9) of this rule;

(c) Any applicable co-payments;

(d) For drugs covered under Medicare Part D when the client is fully dual eligible.

(2) CCOs may use the statewide Practitioner-Managed Prescription Drug Plan under ORS 414.330 to 414.337. CCOs may use a restrictive drug list as long as it allows access to other drug products not on the drug list through some process such as prior authorization (PA). The 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.

(3) CCOs shall provide their participating providers and their pharmacy subcontractor with:

(a) Their drug list and information about how to make non-drug listed requests;

(b) Updates made to their drug list within 30 days of a change that may include, but are not limited to:

(A) Addition of a new drug;

(B) Removal of a previously listed drug; and

(C) Generic substitution.

~~(4) If a drug cannot be approved within the 72-hour time requirement for prior authorization and the medical need for the drug is immediate, CCOs must provide, within 24 hours of receipt of the drug prior authorization request, for the dispensing of at least a 72-hour supply of a drug that requires prior authorization.~~

(4) Preauthorization for prescription drugs marked for urgent review shall be reviewed within 24 hours. If an urgent preauthorization for a prescription drug cannot be completed within 24 hours, the CCO shall provide for the dispensing of at least a 72-hour supply if there is an immediate medical need for the drug. All requests, including those not marked urgent, shall be reviewed and decision rendered within 72 hours of original receipt of the preauthorization request.

(5) CCOs shall authorize the provision of a drug requested by the Primary Care Provider or referring provider if the approved 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.

(6) Prescriptions for Physician Assisted Suicide under the Oregon Death with Dignity Act are excluded. Payment is governed by OAR 410-121-0150.

(7) CCOs may not authorize payment for any Drug Efficacy Study Implementation (DESI) Less Than Effective (LTE) drugs ~~which that~~ have reached the FDA Notice of Opportunity for Hearing (NOOH) stage, as specified in OAR 410-121-0420 (DESI)(LTE) Drug List. ~~The DESI LTE drug list is available at:~~
~~<http://www.cms.hhs.gov/MedicareDrugRebateProgram/12-LTEIRSDrugs.asp>~~

(8) A CCO may seek to add drugs to the 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 of the following information:

(a) The drug name;

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

(c) The reason that the Authority should consider this drug for carve out.

(9) If a CCO requests that a drug not 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.

(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). A CCO may not reimburse providers for carved-out drugs.

(11) CCOs shall submit quarterly utilization data within 60 days of the date of service as part of the CMS Medicaid Drug Rebate Program requirements pursuant to Section 2501 of the Affordable Care Act.

(12) CCOs 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. CCOs may continue to have some flexibility in maintaining formularies of drugs regardless of whether the manufacturers of those drugs participate in the Medicaid Drug Rebate Program.

Stat. Auth.: ORS 413.042, 414.615, 414.625, 414.635 & 414.651

Stats. Implemented: ORS 414.610–414.685