

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

Oregon Health Authority (Authority), Division of Medical Assistance Programs (Division)	410
Agency and Division	Administrative Rules Chapter Number
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RULE CAPTION

Align Rule with Statute to Allow Reimbursement for Brand Name Version of a Covered Drug
Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

RULEMAKING ACTION

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

ADOPT:

AMEND: OAR 410-121-0030

REPEAL: OAR 410-121-0030(T)

RENUMBER:

AMEND & RENUMBER:

Stat. Auth.: ORS 413.032, 413.042, 414.065, 414.325, 414.330 to 414.414, 414.312, 414.316

Other Auth.:

Stats. Implemented: ORS 414.065; 414.325, 414.334, 414.361, 414.369, 414.371, 414.353, 414.354

RULE SUMMARY

Aligns rule with ORS 414.325 to allow the Division to limit reimbursement to a brand name version of a covered drug when its cost is equal to or less than the cost of the generic version after receiving discounted prices and rebates.

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.

December 17, 2015, by 5 p.m. 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

11-7-15
Date

Note: Notices must be submitted by the 15th day of the month to be published in the next month's *Oregon Bulletin*. A Rulemaking Hearing may be requested in writing by 10 or more people, or by an association with 10 or more members, within 21 days following notice publication or 28 days from the date notice was sent to people on the agency's interested party mailing list, whichever is later. In such cases a Hearing Notice must be published in the *Oregon Bulletin* at least 14 days before the hearing.

STATEMENT OF NEED AND FISCAL IMPACT

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

Oregon Health Authority (Authority), Division of Medical Assistance Programs (Division) 410

Agency and Division Administrative Rules Chapter Number

Align Rule with Statute to Allow Reimbursement for Brand Name Version of a Covered Drug

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 410-121-0030

Statutory Authority: ORS 413.032, 413.042, 414.065, 414.325, 414.330 to 414.414, 414.312, 414.316

Other Authority:

Stats. Implemented: ORS 414.065; 414.325, 414.334, 414.361, 414.369, 414.371, 414.353, 414.354

Need for the Rule(s): The Pharmaceutical Services program administrative rules (division 121) govern Division payments for services provided to certain clients. In general, the Division only reimburses pharmacies for generic versions of covered medications. On November 6, 2015 the Division temporarily amended the rule to align with ORS 414.325 to allow the Division to limit reimbursement to a brand name version of a covered drug when its cost is equal to or less than the cost of the generic version after receiving discounted prices and rebates. This filing makes the temporary rule amendment permanent.

The Authority needs to amend OAR 410-121-0030(5) to ensure the safe and appropriate use of cost effective prescription drugs for the Oregon Health Plan's fee-for-service recipients.

Documents Relied Upon, and where they are available: None

Fiscal and Economic Impact:

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)): Amending these rules will have no fiscal impact on the Authority, other state agencies, units of local government, the public, or businesses, including small businesses.

2. Cost of compliance effect on small business (ORS 183.336): none

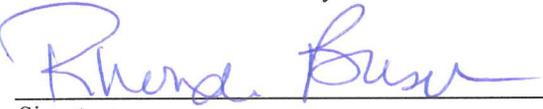
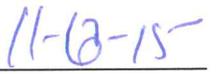
a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule: none

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services: none

c. Equipment, supplies, labor and increased administration required for compliance: none

How were small businesses involved in the development of this rule?

Administrative Rule Advisory Committee consulted?: No. If not, why?: Amending the rule to align with ORS 414.325.

Signature Printed Name Date

410-121-0030

Practitioner-Managed Prescription Drug Plan

(1) The Practitioner-Managed Prescription Drug Plan (PMPDP) is a plan that ensures that OHP fee-for-service clients have access to the most effective prescription drugs appropriate for their clinical conditions at the best possible price:

(a) Licensed health care practitioners, who are informed by the latest peer reviewed research, make decisions concerning the clinical effectiveness of the prescription drugs;

(b) Licensed health care practitioners also consider the client's health condition, personal characteristics, and the client's gender, race, or ethnicity.

(2) PMPDP Preferred Drug List (PDL):

(a) The PDL is the primary tool the Division uses to inform licensed health care practitioners about the results of the latest peer-reviewed research and cost effectiveness of prescription drugs;

(b) The PDL contains a list of prescription drugs that the Division, in consultation with the Drug Use Review (DUR)/Pharmacy & Therapeutics Committee (P&T), has determined represent the most effective drugs available at the best possible price;

(c) The PDL shall include drugs that are Medicaid reimbursable and the Food and Drug Administration (FDA) has determined to be safe and effective.

(3) PMPDP PDL Selection Process:

(a) The Division shall utilize the recommendations made by the P&T that result from an evidence-based evaluation process as the basis for selecting the most effective drugs;

(b) The Division shall ensure the drugs selected in section (3)(a) that are available for the best possible price and shall consider any input from the P&T about other FDA-approved drugs in the same class that are available for a lesser relative price. The Division shall determine relative price using the methodology described in section (4);

(c) The Division shall evaluate selected drugs for the drug classes periodically:

(A) The Division may evaluate more frequently if new safety information or the release of new drugs in a class or other information makes an evaluation advisable;

(B) New drugs in classes already evaluated for the PDL shall be non-preferred until the new drug has been reviewed by the P&T;

(C) The Division shall make all revisions to the PDL using the rulemaking process and shall publish the changes on the Division's Pharmaceutical Services provider rules website.

(4) Relative cost and best possible price determination:

(a) The Division shall determine the relative cost of all drugs in each selected class that are Medicaid reimbursable and that the FDA has determined to be safe and effective;

(b) The Division may also consider dosing issues, patterns of use, and compliance issues. The Division shall weigh these factors with any advice provided by the P&T in reaching a final decision.

(5) Pharmacy providers shall dispense prescriptions in the generic form unless:

(a) The practitioner requests otherwise pursuant to OAR 410-121-0155;

~~(b) The brand name medication is listed as preferred on the PDL.~~

(b) The Division notifies the pharmacy that the cost of the brand name particular drug, after receiving discounted prices and rebates, is equal to or less than the cost of the generic version of the drug.

(6) The exception process for obtaining non-preferred physical health drugs that are not on the PDL drugs shall be as follows:

(a) If the prescribing practitioner in their professional judgment wishes to prescribe a physical health drug not on the PDL, they may request an exception subject to the requirements of OAR 410-121-0040;

(b) The prescribing practitioner must request an exception for physical health drugs not listed in the PDL subject to the requirements of OAR 410-121-0060;

(c) Exceptions shall be granted when:

(A) The prescriber in their professional judgment determines the non-preferred drug is medically appropriate after consulting with the Division or the Oregon Pharmacy Call Center; or

(B) Where the prescriber requests an exception subject to the requirement of section (6)(b) and fails to receive a report of PA status within 24 hours, subject to OAR 410-121-0060.

(7) Table 121-0030-1, PMPDP PDL dated November 1, 2015 is adopted and incorporated by reference and is found at: www.orpdl.org.

Stat. Auth.: ORS 413.032, 413.042, 414.065, 414.325, 414.330 to 414.414, 414.312, 414.316

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