

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

Oregon Health Authority (OHA), Division of Medical Assistance Programs (Division)	410
Agency and Division	Administrative Rules Chapter Number
Sandy Cafourek	(503) 945-6430
Rules Coordinator	Telephone

RULE CAPTION

Amending PDL March 26, May 28, July 30, 2015 DUR/P&T Action

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

December 15, 2015	10:30 a.m.	500 Summer St. NE, Salem, OR 97301 Room 137C	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: 410-121-0030

REPEAL: 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, and 414.316

Other Auth.: None

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

RULE SUMMARY

The Pharmaceutical Services Program administrative rules (Division 121) govern Division payments for services provided to certain clients. The Division needs to amend rules as follows:

410-121-0030:

Preferred:

Viekiera Pak™

Laxative drug class

Polyethylene glycol 3350

Lactulose

Senna products

Bulk forming laxatives less than \$1/unit

Osmotic laxatives less than \$1/unit

Surfactant, stimulant, and saline laxatives

Isosorbide dinitrate – capsule ER

Nitroglycerin – capsule ER

Adalimumab (Humira Pediatric Crohn's™)

Calcium Citrate – tablet

Buprenorphine HCL / Naloxone HCL

Dexmethylphenidate HCL

Chlorpromazine HCL

Fluphenazine HCL

Dabigatran

Rivaroxaban

Apixaban
Edoxaban
Linezolid
Tobramycin (Tobi Poldhaler™)
Tobramycin / Nebulizer (Kitabis™ Pak)
All rectal subclass products
All acetaminophen with codeine products
Ibuprofen containing products
Hydrocodone APAP solution
Metoprolol Succinate

Cilostazol
Fluticasone Propionate
Amlodipine-Olmesartan
Enalapril-Hydrochlorothiazide
Lisinopril-Hydrochlorothiazide
Losartan-Hydrochlorothiazide
Metoprolol Succinate-Hydrochlorothiazide
Olmesartan-Amlodipine-Hydrochlorothiazide
Olmesartan-Hydrochlorothiazide
Propranolol-Hydrochlorothiazide

Non-Preferred:

Bulk forming laxatives \$1/unit or more
Osmotic laxatives \$1/unit or more
Lubricant laxatives
Cimetidine – tablet
Spinosad

Semprivir Sodium
Tedizolid Phosphate
Ivacaftor (Kalydeco™)
All Butalbital subclass products

Pirfenidone
Nintedanib Esylate
All other agents in Intranasal Allergy
Ketoconazole
All other products in Combination Antihypertensives class

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 written comments to: dmap.rules@state.or.us

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


Signature

Rhonda Busek
Printed name

10/30/15
Date

Note: Hearing Notices must be submitted by the 15th day of the month to be published in the next month's *Oregon Bulletin*.

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 Assistance Programs

410

Agency and Division

Administrative Rules Chapter Number

Amending PDL March 26, May 28, July 30, 2015 DUR/P&T Action

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 410-121-0030 and the repeal of OAR 410-121-0030(T)

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

Other Authority: None

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. The Division temporarily amended 410-121-0030 per the Drug Use Review (DUR) Pharmacy & Therapeutics (P&T) Committee's recommendations made during the March 26, May 28, July 30, 2015 meeting.

The Authority needs to implement changes to the Preferred Drug List to ensure the safe and appropriate use of cost effective prescription drugs for the Oregon Health Plan's fee-for-service recipients.

410-121-0030:

Preferred:

Viekiera Pak™

Laxative drug class

Polyethylene glycol 3350

Lactulose

Senna products

Bulk forming laxatives less than \$1/unit

Osmotic laxatives less than \$1/unit

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Buprenorphine HCL / Naloxone HCL

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Fluphenazine HCL

Dabigatran

Rivaroxaban

Apixaban

Edoxaban

Linezolid

Tobramycin (Tobi Poldhaler™)

Tobramycin / Nebulizer (Kitabis™ Pak)

All rectal subclass products

All acetaminophen with codeine products

Ibuprofen containing products

Hydrocodone APAP solution

Metoprolol Succinate

Cilostazol

Fluticasone Propionate

Amlodipine-Olmesartan

Enalapril-Hydrochlorothiazide

Lisinopril-Hydrochlorothiazide

Losartan-Hydrochlorothiazide
Metoprolol Succinate-Hydrochlorothiazide
Olmesartan-Amlodipine-Hydrochlorothiazide
Olmesartan-Hydrochlorothiazide
Propranolol-Hydrochlorothiazide

Non-Preferred:

Bulk forming laxatives \$1/unit or more
Osmotic laxatives \$1/unit or more
Lubricant laxatives
Cimetidine – tablet
Spinosad

Semprivir Sodium
Tedizolid Phosphate
Ivacaftor (Kalydeco™)
All Butalbital subclass products

Pirfenidone
Nintedanib Esylate
All other agents in Intranasal Allergy
Ketoconazole
All other products in Combination Antihypertensives class

Documents Relied Upon, and where they are available: 414.353, 414.354, and Or Law 2011, chapter 720 (HB 2100),:
http://www.oregon.gov/pers/docs/2011_legislation/hb2100.en.pdf

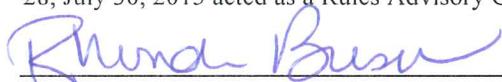
Fiscal and Economic Impact: None

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)): This permanent filing is needed in order for the legislatively mandated Pharmacy & Therapeutics Committee to convene and conduct official business under the auspices of the Oregon Health Authority. It is also necessary for the health and safety of Oregon Health Plan recipients receiving drugs and prior authorizations.
2. Cost of compliance effect on small business (ORS 183.336): Small businesses will not be affected by this rule.
 - a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule: Small businesses will not be affected by this rule.
 - b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services: There is no anticipated increase.
 - c. Equipment, supplies, labor and increased administration required for compliance: There is no anticipated increase.

How were small businesses involved in the development of this rule? Small businesses were not involved in the development of this rule as it will not affect them.

Administrative Rule Advisory Committee consulted?: The Pharmacy & Therapeutics Committee meeting held on March 26, May 28, July 30, 2015 acted as a Rules Advisory Committee meeting for 410-121-0030. If not, why?:


Signature

Rhonda Busek
Printed name

10/30/15
Date

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

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.

(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 ~~October 4~~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

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