Secretary of State

NOTICE OF PROPOSED RULEMAKING HEARING

A Statement of Need and Fiscal Impact accompanies this form.

Oregon Health Authority (OHA), Health Systems Division, Medical Assistance Programs (Division)	410
Agency and Division	Administrative Rules Chapter Number

Sandy Cafourek	500 Summer St NE, Salem, OR 97301	(503) 945-6430
Rules Coordinator	Address	Telephone

RULE CAPTION

Amending PDL November 19, 2015, January 28, 2016 DUR/P&T Action

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 410-121-0030

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, 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:
Budesonide
Exenatide Pen Injector

Guaifenesin (Mucinex™)
Daclatasvir Dihydrochloride
Elviteg/ Cobi/ Emtric/ Tenofo Ala (Genvoya™)
Rivaroxaban (Xarelto™)
Insulin Lispro Protamin / Lispro

Non-Preferred:
Ciclesonide Nasal Spray/ Pump

Ombita/ Paritap/ Riton/ Dasabuvir (Viekira Pak™)
Amantadine HCL
Rimantadine HCL
Bupropion HCL
Amphetamine Sulfate
Tobramycin
TOBI

Due to changes in supplemental rebate contracts, the following changes were made:
Removed Pegasys™
Added Sovaldi™
Added Evotaz™
Added Eliquis™
Added Pradaxa™
Removed Androgel™
Added Janumet™
Removed Humalog™
Removed Humalog Mix 50/50™
Removed Humalog Mix 75/25™
Removed Humulin R™
Removed Humulin N™
Removed Humulin 70/30™
Removed Makena™
Removed Apriso™
Removed Exelon™
Removed Capaxone™
Removed Avonex™
Removed Betaseron™
Removed Stalevo™
Removed Zubsolv™
Removed Bethkis™
Added Renagel™

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, 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)

Karen Wheeler Karen Wheeler 4/25/16

Signature Printed name Date

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

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, Health Systems Division, Medical Assistance Programs	410
Agency and Division	Administrative Rules Chapter Number

Amending PDL November 19, 2015, January 28, 2016 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 needs to amend 410-121-0030 per the Drug Use Review (DUR) Pharmacy & Therapeutics (P&T) Committee's recommendations made during the November 19, 2015, and January 28, 2016, 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:
Budesonide
Exenatide Pen Injector

Guaifenesin (Mucinex™)
Daclatasvir Dihydrochloride
Elviteg/ Cobi/ Emtric/ Tenofo Ala (Genvoya™)
Rivaroxaban (Xarelto™)
Insulin Lispro Protamin / Lispro

Non-Preferred:
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Ombita/ Paritap/ Riton/ Dasabuvir (Viekira Pak™)
Amantadine HCL
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Removed Humalog Mix 50/50™
Removed Humalog Mix 75/25™
Removed Humulin R™
Removed Humulin N™
Removed Humulin 70/30™

Removed Makena™
Removed Apriso™
Removed Exelon™
Removed Capaxone™
Removed Avonex™
Removed Betaseron™
Removed Stalevo™
Removed Zubsolv™
Removed Bethkis™
Added Renagel™

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):

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?: Yes. The Pharmacy & Therapeutics Committee meeting held on November 19, 2015 acted as a Rules Advisory Committee meeting for 410-121-0030. If not, why?:

Signature	Printed name	Date
Karen Wheeler	Karen Wheeler	4/28/16

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 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 ~~January 1~~May 1, 2016, 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