

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

RULE CAPTION

Amending PDL January 29, 2015 DUR/P&T Action

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

May 15, 2015	10:30 a.m.	500 Summer St. NE, Salem, OR 97301 Room 166	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:

Guaifenesin/Codeine Phosphate Syrup
nitroglycerin Capsule ER
Lovenox ®- Brand Only Vial
Cholestyramine(with Sugar) Powd Pack
Cholestyramine/Aspartame Powd Pack
Aspirin Tab Chew
Aspirin Tablet DR
Spinosad Suspension
Insulin Detemir * INSULN PEN
Humulin70-30™
Humulin 70/30 KWIKPEN™
Humalog mix 50-50™
Humalog mix 75-25™
Humulin R™
Humulin N™
Oxybutynin Patch TDSW
Etanercept (Enbrel™) vial
Galantamine HBR Cap24H Pel
Memantine HCL Tab Ds Pk

Polymyxin B Sulf/Trimethoprim Drops
Dorzolamide/Timolol/PF
Neomycin/Polymyxin B Sulf/HC Drop/Susp
Buprenorphine Naloxone (Zubsolv™)
Proventil HFA
Calcium Acetate Capsule
Bupropion HCL Tab ER 24H
Escitalopram Oxalate Solution
Fluphenazine decanoate vial
Haloperidol decanoate ampul
Haloperidol decanoate vial
Haloperidol lactate ampul
Haloperidol lactate vial
TBO- Filgrastim syringe
Ledipasvir/ Sofosbuvir (Harvoni™)
Gentamicin/ Prednisol AC Drops Susp
Gentamicin/ Prednisol AC Oint. (G)
Neo/ Polymyx B Sulf/ Dexameth Oint. (G)
Cefuroxime Axetil Susp Recon

Non-Preferred:

Salsalate
Oxycodone/acetaminophen Capsules
Benicar®
Benicar HCT®
isosorbide dinitrate capsule ER
Hydrochlorothiazide Solution
triamterene
Estrogens, Conj., Synthetic A
Metformin HCL Tab ER 24
Estrogens, conjugated Cream (G)
Lipase/Protease/Amylase
Cimetidine
Neomy sulf/bacitrac zn/poly/HC
Pilocarpine HCL Gel (Gram)
chlorpromazine, Multiple products
Fluphenazine, Multiple products
Haloperidol, Multiple products
Loxapine, Multiple products
Perphenazine, Multiple products
Promazine, Multiple products
Thioridazine, Multiple products
Thiothixene, Multiple products
Trifluoperazine, Multiple products

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.

May 18 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

DAVID SIMARD
Printed name

4/15/2015
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 January 29, 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 May 29, July 31, and Sept. 23, Nov. 20, 2014, Jan. 29, 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:

Imitrex® - Brand only

Tobramycin (Bethkis)

Calcium Acetate

Anafranil – Brand only

Escitalopram Oxalate

Imipramine HCL

Acamprosate Calcium

Amiloride HCL

Naltrexone HCL

Pulmonary Drug Reorganization removed COPD, Asthma Controllers, Asthma Rescue

(New Drug class names)

Combination Inhalers

Inhaled Anticholinergics

Inhaled Corticosteroids

Inhaled Long Acting Bronchodilators

Miscellaneous Pulmonary Drugs

Short Acting Bronchodilators

Tazarotene (Tazorac®)

Fenofibrate

Epinephrine Injection

Estradiol

Legend Prenatal Vitamins

Risperidone Microspheres

Guaifenesin/Codeine Phosphate Syrup

nitroglycerin Capsule ER

Lovenox ®- Brand Only Vial

Cholestyramine(with Sugar) Powd Pack

Cholestyramine/Aspartame Powd Pack

Aspirin Tab Chew
Aspirin Tablet DR
Spinosad Suspension
Insulin Detemir * INSULN PEN
Humulin70-30 TM
Humulin 70/30 KWIKPEN TM
Humalog mix 50-50 TM
Humalog mix 75-25 TM
Humulin R TM
Humulin N TM
Oxybutynin Patch TDSW
Etanercept (Enbrel TM) vial
Galantamine HBR Cap24H Pel
Memantine HCL Tab Ds Pk
Polymyxin B Sulf/Trimethoprim Drops
Dorzolamide/Timolol/PF
Neomycin/Polymyxin B Sulf/HC Drop/Susp
Buprenorphine Naloxone (ZubsolvTM)
Proventil HFA
Calcium Acetate Capsule
Bupropion HCL Tab ER 24H
Escitalopram Oxalate Solution
Fluphenazine decanoate vial
Haloperidol decanoate ampul
Haloperidol decanoate vial
Haloperidol lactate ampul
Haloperidol lactate vial
TBO- Filgrastim syringe
Ledipasvir/ Sofosbuvir (HarvoniTM)
Gentamicin/ Prednisol AC Drops Susp
Gentamicin/ Prednisol AC Oint. (G)
Neo/ Polymyx B Sulf/ Dexameth Oint. (G)
Cefuroxime Axetil Susp Recon

Non-Preferred:

Clomipramine HCL

Niacin

TricorTM – Brand only

TrilipixTM - Brand only

Golimumab (Simponi®)

Bendroflumethiazide

Boceprevir (Victrelis®)

Memantine HCL (Namenda XR®)

NPH, Human Insulin Isophane

Telaprevir (Incivek®)

Salsalate

Oxycodone/acetaminophen Capsules

Benicar®

Benicar HCT®

isosorbide dinitrate capsule ER

Hydrochlorothiazide Solution

triamterene

Estrogens, Conj., Synthetic A

Metformin HCL Tab ER 24

Estrogens, conjugated Cream (G)

Lipase/Protease/Amylase

Cimetidine

Neomy sulf/bacitrac zn/poly/HC

Pilocarpine HCL Gel (Gram)
chlorpromazine, Multiple products
Fluphenazine, Multiple products
Haloperidol, Multiple products
Loxapine, Multiple products
Perphenazine, Multiple products
Promazine, Multiple products
Thioridazine, Multiple products
Thiothixene, Multiple products
Trifluoperazine, Multiple products

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?: Yes. The Pharmacy & Therapeutics Committee meeting held on May 29, July 31, and Sept. 23, Nov. 20, 2014, Jan. 29, 2015 acted as a Rules Advisory Committee meeting for 410-121-0030. If not, why?:


Signature

DAVID SAMUITT 4/15/2015
Printed name 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 of the Oregon Health Plan shall 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) ~~The licensed~~ Licensed health care practitioners also consider the client's health condition ~~of a client or, personal characteristics of a client, including, and~~ the client's gender, race, or ethnicity.

(2) PMPDP Preferred Drug List (PDL):

(a) The PDL is the primary tool the Division ~~developed~~ 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 ~~(as defined in 410-121-0000 (cc) consists~~ 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 ~~determine~~ 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) ~~Evaluation shall occur~~The Division may evaluate more frequently at the discretion of the Division if new safety information or the release of new drugs in a class or other information that 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 changes of~~ 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 ~~subject~~pursuant to the regulations outlined in 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 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 ~~in instances~~when:

(A) ~~Where the~~The prescriber in their professional judgment determines the non-preferred drug is medically appropriate after consulting with the Division or the Oregon Pharmacy Help Desk; 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 ~~March 4~~April 18, 2015 is adopted and incorporated in rule by reference and is found on the Division's website 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