

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
Rules Coordinator	Address
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	Telephone

**RULE CAPTION**

PDL-May 23, July 25, Sept 26, Nov 21, 2013 Jan 30, 2014 DUR/P&T Action, SR Contracts

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

May 15, 2014	10:30 a.m.	500 Summer St. NE, Salem, OR 97301 Conference Rm. 166	Sandy Cafourek
Hearing Date	Time	Location	Hearings Officer

*Auxillary 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, 414.316

Other Auth.: None

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

- Butorphanol Tartrate Spray
- Sumatriptan Succinate
- Peginterferon Alpha-2A
- Peginterferon Alpha-2A Sub Q
- Tricor™
- Trilipix™
- Bacitracin Zinc / Polymyx B Sulfate
- Somatropin (Norditropin®)
- Mesalamine (Lialda®)
- Golimumab (Simponi®)
- Valproic Acid solution
- Interferon Beta-1A / Albumin (Refib™)
- Interferon Beta-1B (Betaseron™)
- Carbidopa / Levodopa tablet ER

Metadate™  
Methylphenidate (Daytrana™)  
Buprenorphine  
Buprenorphine-Naloxone (Suboxone™)  
Buprenorphine HCL / Naloxone (Suboxone™)  
Ipratropium / Albuterol Sulfate (Combivent Respimat™)  
Budesonide (Pulmicort Flexhaler®)  
Budesonide / Formoterol Fumarate (Symbicort®)  
Benzonatate  
Guaifenesin  
Guaifenesin / Codeine Phosphate  
Guaifenesin / Dextromethorphan  
Pseudoephedrine HCL  
Atomoxetine HCL (Strattera®)  
Chlorpromazine HCL  
Fluphenazine Decanoate  
Fluphenazine HCL  
Haloperidol  
Haloperidol Decanoate  
Haloperidol Lactate  
Loxapine HCL  
Loxapine Succinate  
Perhenazine  
Promazine HCL  
Thioridazine HCL  
Thiothixene  
Thiothixene HCL  
Trifluoperazine HCL  
Triflupromazine HCL  
Sofosbuvir (Sovaldi®)  
Simeprevir (Olysio®)  
Estradiol Transdermal patch (Vivelle Dot®, Alora®)

**Non-Preferred:**

Methadone HCL  
Tramadol HCL  
Imitrex®  
Zolmitriptan  
Fenofibrate, Nanocrystallized  
Spinosad (Natroba®)  
Testosterone patch TD24  
Dextroamphetamine Sulfate  
Ciclesonide  
Montelukast Sodium gram pack  
Zafirlukast  
Insulin Lispro (Humalog®)  
Insulin NPL / Insulin Lispro (Humalog Mix 50/50®)  
Insulin NPL / Insulin Lispro (Humalog Mix 75/25®)  
Nadolol  
Captopril  
Captopril/ Hydrochlorothiazide  
Fosinopril Sodium  
Fosinopril/ Hyrdrochlorothiazide  
Moexipril HCL  
Moexipril/ Hydrochlorothiazide  
Quinapril HCL  
Quinapril/ Hydrochlorothiazide  
Trandolapril

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 20, 2014 by 5 p.m.      Send written comments to: [dmap.rules@state.or.us](mailto:dmap.rules@state.or.us)

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



Rhonda Busek

3-21-14

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, Division of Medical Assistance Programs  
Agency and Division

410  
Administrative Rules Chapter Number

PDL-May 23, July 25, Sept 26, Nov 21, 2013 Jan 30, 2014 DUR/P&T Action, SR Contracts

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 repeal of 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 and Therapeutics (P and T) Committee's recommendations made during the May 23, July 25, Sept 26, Nov 21, 2013, and Jan 30, 2014 meetings. The Division also needs to temporarily amend 410-121-0030 to comply with the Supplemental Rebate Contracts effective 1/1/14 with placement on Preferred Drug List (PDL), and the removal of specific Brand names that have not been contracted.

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:**

Butorphanol Tartrate Spray  
Sumatriptan Succinate  
Peginterferon Alpha-2A  
Peginterferon Alpha-2A Sub Q  
Tricor™  
Trilipix™  
Bacitracin Zinc / Polymyx B Sulfate  
Somatropin (Norditropin®)  
Mesalamine (Lialda®)  
Golimumab (Simponi®)  
Valproic Acid solution  
Interferon Beta-1A / Albumin (Refib™)  
Interferon Beta-1B (Betaseron™)  
Carbidopa / Levodopa tablet ER  
Metadate™  
Methylphenidate (Daytrana™)  
Buprenorphine  
Buprenorphine-Naloxone (Suboxone™)  
Buprenorphine HCL / Naloxone (Suboxone™)  
Ipratropium / Albuterol Sulfate (Combivent Respimat™)  
Budesonide (Pulmicort Flexhaler®)  
Budesonide / Formoterol Fumarate (Symbicort®)  
Benzonatate  
Guaifenesin  
Guaifenesin / Codeine Phosphate  
Guaifenesin / Dextromethorphan  
Pseudoephedrine HCL  
Atomoxetine HCL (Strattera®)

Chlorpromazine HCL  
Fluphenazine Decanoate  
Fluphenazine HCL  
Haloperidol  
Haloperidol Decanoate  
Haloperidol Lactate  
Loxapine HCL  
Loxapine Succinate  
Perhenazine  
Promazine HCL  
Thioridazine HCL  
Thiothixene  
Thiothixene HCL  
Trifluoperazine HCL  
Triflupromazine HCL  
Sofosbuvir (Sovaldi®)  
Simeprevir (Olysio®)  
Estradiol Transdermal patch (Vivelle Dot®, Alora®)

**Non-Preferred:**

Methadone HCL  
Tramadol HCL  
Imitrex®  
Zolmitriptan  
Fenofibrate, Nanocrystallized  
Spinosad (Natroba®)  
Testosterone patch TD24  
Dextroamphetamine Sulfate  
Ciclesonide  
Montelukast Sodium gram pack  
Zafirlukast  
Insulin Lispro (Humalog®)  
Insulin NPL / Insulin Lispro (Humalog Mix 50/50®)  
Insulin NPL / Insulin Lispro (Humalog Mix 75/25®)  
Nadolol  
Captopril  
Captopril/ Hydrochlorothiazide  
Fosinopril Sodium  
Fosinopril/ Hydrochlorothiazide  
Moexipril HCL  
Moexipril/ Hydrochlorothiazide  
Quinapril HCL  
Quinapril/ Hydrochlorothiazide  
Trandolapril

Documents Relied Upon, and where they are available: 414.353, 414.354, and Or Law 2011, chapter 720 (HB 2100);  
<http://www.leg.state.or.us/11reg/measpdf/hb2100.dir/hb2100.en.pdf>

**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)): This permanent filing is needed in order for the legislatively mandated Pharmacy and 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.



**410-121-0030**

**Practitioner-Managed Prescription Drug Plan**

(1) The Practitioner-Managed Prescription Drug Plan (PMPDP) is a plan that ensures that 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 (informed by the latest peer reviewed research); make decisions concerning the clinical effectiveness of the prescription drugs;

(b) The licensed health care practitioners also consider the health condition of a client or characteristics of a client, including the client's gender, race or ethnicity.

(2) PMPDP Preferred Drug List (PDL):

(a) The PDL is the primary tool that the Division developed 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 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 drug(s) 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 drug(s);

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

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

(A) Evaluation shall occur more frequently at the discretion of the Division if new safety information or the release of new drugs in a class or other information which 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 or revisions to the PDL, using the rulemaking process and shall publish the changes on the Division's Pharmaceutical Services provider rules wWeb-page.

(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 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 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 in instances:

(A) Where 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 (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 4~~, March 21, 2014 is incorporated in rule by reference and is found on our Web-page at [www.orpdl.org](http://www.orpdl.org).

Stat. Auth.: ORS 409.025, 409.040, 409.110, 414.065, 413.042 and 414.325  
Stats. Implemented: ORS 414.065

~~4/1/14~~