Secretary of State

NOTICE OF PROPOSED RULEMAKING HEARING

A Statement of Need and Fiscal Impact accompanies this form.

Oregon Health Authority, Division of Medical Assistance Programs	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- May 23, July 25, Sept 26, 2013 and Jan 30, 2014 DUR/P&T Action, and SR Contract updates.

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

June 17, 2014	10:30 am	500 Summer Street NE, Salem, Oregon 97301 Rm 137B	Sandy Cafourek
Hearing Date	Time	Location	Hearings Officer

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.:

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:

- 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®)
- Tobi® - Brand only

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.

June 20, 2014, 5 pm

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

Signature | Printed name | Date

05/08/14

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 | 410

Agency and Division | Administrative Rules Chapter Number

Amending PDL- May 23, July 25, Sept 26, 2013 and Jan 30, 2014 DUR/P&T Action, and SR Contract updates

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

In the Matter of: OAR 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: 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 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:

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- Fluphenazine HCL
- Haloperidol
- Haloperidol Decanoate
- Haloperidol Lactate
- Loxapine HCL
- Loxapine Succinate
- Perhenazine
- Promazine HCL
- Thioridazine HCL
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- Insulin NPL / Insulin Lispro (Humalog Mix 75/25®)
- Nadolol
- Captopril
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- Moexipril HCL
- Moexipril/ Hydrochlorothiazide
- Quinapril HCL
- Quinapril/ Hydrochlorothiazide
- Trandolapril

Documents Relied Upon, and where they are available: 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 & 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 May 23, July 25, Sept 26, Nov 21, 2013 Jan 30, 2014 acted as a Rules Advisory Committee meeting for 410-121-0030.

If not, why?:

Signature | 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~~ 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 w~~W~~eb 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 May 1, 2014 is incorporated in rule by reference and is found on our w~~W~~eb-page at www.orpdl.org.

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

~~5/1/14~~