

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 Prior Authorization Guide – May 23, July 25, Sept. 26, 2013, and Jan 30, March 27, 2014 DUR/P&T Action

**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:** 410-121-0040

**REPEAL:** 410-121-0040(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.:

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:

410-121-0040:

- Hydroxyprogesterone Caproate (Makena®) – new criteria
- Analgesics, Non-Steroidal Anti-Inflammatory Drugs – updated criteria
- Antiemetics – updated criteria
- Anti-Parkinsons Agents – updated criteria
- Cysteamine Delayed Release – new criteria
- Fentanyl Transmucosal, Buccal, and Sprays – updated criteria
- Hepatitis C Oral Protease Inhibitors / Triple Therapy – updated criteria
- Incretin Enhancers – updated criteria
- Incretin Mimetics – updated criteria
- LABA / ICS Inhalers – updated criteria
- Mipomersen and Lomitapide – new criteria
- Naltrexone Extended Release Inj (Vivitrol®) – new criteria

- Omega-3 fatty acids – new criteria
- Oral MS Drugs – updated criteria
- Oral Direct Factor Xa Inhibitor – updated criteria
- Oral Direct Thrombin Inhibitor – updated criteria
- Repository Corticotropin Injection (Acthar Gel®) – new criteria
- Roflumilast – updated criteria
- Sofosbuvir (Sovaldi®)
- Saproterin – updated criteria
- Skeletal Muscle Relaxants – updated criteria

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.

What date do we want?

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

	<i>JUDY MOHR PETERSON</i>	<i>05/08/2014</i>
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*.

**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 Prior Authorization Guide – May 23, July 25, Sept. 26, 2013, and Jan 30, March 27, 2014 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: OAR 410-121-0040

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

Other Authority:

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

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 410-121-0040 per the Drug Use Review (DUR) Pharmacy & Therapeutics (P&T) Committee's recommendations made during the May 23, July 25, Sept 26, 2013, Jan 30, and March 27, 2014 meetings.

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

410-121-0040:

- Hydroxyprogesterone Caproate (Makena®) new criteria
- Analgesics, Non-Steroidal Anti-Inflammatory Drugs – updated criteria
- Antiemetics – updated criteria
- Anti-Parkinsons Agents – updated criteria
- Cysteamine Delayed Release – new criteria
- Fentanyl Transmucosal, Buccal, and Sprays – updated criteria
- Hepatitis C Oral Protease Inhibitors / Triple Therapy – updated criteria
- Incretin Enhancers – updated criteria
- Incretin Mimetics – updated criteria
- LABA / ICS Inhalers – updated criteria
- Mipomersen and Lomitapide – new criteria
- Naltrexone Extended Release Inj (Vivitrol®) – new criteria
- Omega-3 fatty acids – new criteria
- Oral MS Drugs – updated criteria
- Oral Direct Factor Xa Inhibitor – updated criteria
- Oral Direct Thrombin Inhibitor – updated criteria
- Repository Corticotropin Injection (Acthar Gel®) – new criteria
- Roflumilast – updated criteria
- Saproterin – updated criteria
- Sofosbuvir (Sovalid®) – new criteria
- Skeletal Muscle Relaxants – updated criteria
- Sodium-Glucose Co-Transporter 2 (SGLT2) – new criteria

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 & 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 410-121-0040.

If not, why?:



Signature



Printed name

Date



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

## 410-121-0040

### Prior Authorization Required for Drugs and Products

(1) Prescribing practitioners are responsible for obtaining prior authorization (PA) for the drugs and categories of drugs requiring PA in this rule, using the procedures required in OAR 410-121-0060.

(2) All drugs and categories of drugs, including, but not limited to, those drugs and categories of drugs that require PA as described in this rule, are subject to the following requirements for coverage:

(a) Each drug ~~must~~ shall be prescribed for conditions funded by Oregon Health Plan (OHP) in a manner consistent with the Oregon Health Services Commission's Prioritized List of Health Services (OAR 410141-0480 through 410-141-0520). If the medication is for a non-covered diagnosis, the medication shall not be covered unless there is a co-morbid condition for which coverage would be extended. The use of the medication ~~must~~ shall meet corresponding treatment guidelines, be included within the client's benefit package of covered services, and not otherwise excluded or limited;

(b) Each drug ~~must~~ shall also meet other criteria applicable to the drug or category of drug in these pharmacy provider rules, including PA requirements imposed in this rule.

(3) The Oregon Health Authority (Authority) may require PA for individual drugs and categories of drugs to ensure that the drugs prescribed are indicated for conditions funded by OHP and consistent with the Prioritized List of Health Services and its corresponding treatment guidelines (see OAR 410-141-0480). The drugs and categories of drugs that the Authority requires PA for this purpose are found in the OHP Fee-For-Service Pharmacy PA Criteria Guide (PA Criteria Guide) dated ~~March 21~~ May 1, 2014, incorporated in rule by reference and found on our Web page at: <http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/clinical.html>

(4) The Authority may require PA for individual drugs and categories of drugs to ensure medically appropriate use or to address potential client safety risk associated with the particular drug or category of drug, as recommended by the Pharmacy & Therapeutics Committee (P&T) and adopted by the Authority in this rule (see OAR 410-121-0100 for a description of the DUR program). The drugs and categories of drugs for which the Authority requires PA for this purpose are found in the Pharmacy PA Criteria Guide.

(5) New drugs shall be evaluated when added to the weekly upload of the First DataBank drug file:

(a) If the new drug is in a class where current PA criteria apply, all associated PA criteria shall be required at the time of the drug file load;

(b) If the new drug is indicated for a condition below the funding line on the Prioritized List of Health Services, PA shall be required to ensure that the drug is prescribed for a condition funded by OHP;

(c) PA criteria for all new drugs shall be reviewed by the DUR/P&T Committee.

(6) PA is required for brand name drugs that have two or more generically equivalent products available and that are NOT determined Narrow Therapeutic Index drugs by the Oregon DUR/P&T Committee:

(a) Immunosuppressant drugs used in connection with an organ transplant ~~must~~shall be evaluated for narrow therapeutic index within 180 days after United States patent expiration;

(b) Manufacturers of immunosuppressant drugs used in connection with an organ transplant ~~must~~shall notify the department of patent expiration within 30 days of patent expiration for (5)(a) to apply;

(c) Criteria for approval are:

(A) If criteria established in subsection (3) or (4) of this rule applies, follow that criteria;

(B) If (6)(A) does not apply, the prescribing practitioner must document that the use of the generically equivalent drug is medically contraindicated; and provide evidence that either the drug has been used and has failed or that its use is contraindicated based on evidence-based peer reviewed literature that is appropriate to the client's medical condition.

(7) PA is required for non-preferred Preferred Drug List (PDL) products in a class evaluated for the PDL except in the following cases:

(a) The drug is a mental health drug as defined in OAR 410-121-0000;

(b) The original prescription is written prior to 1/1/10;

(c) The prescription is a refill for the treatment of seizures, cancer, HIV<sub>1</sub> or AIDS; or

(d) The prescription is a refill of an immunosuppressant.

(8) PA may not be required:

(a) When the prescription ingredient cost plus the dispensing fee is less than the PA processing fees as determined by the Authority;

(b) For over-the-counter (OTC) covered drugs when prescribed for conditions covered under OHP or;

(c) If a drug is in a class not evaluated from the Practitioner-Managed Prescription Drug Plan under ORS 414.334.

Stat. Auth.: ORS Chap. 409.110, 413.042, 414.065, 414.325, and 414.334

Stats. Implemented: 414.065

| 4/1/14