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 Prior Authorization Approval Criteria Guide

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

October 18, 2016 — 500 Summer St. NE, Salem, OR 97301 Room 137D — 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 410-121-0040

REPEAL: OAR 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.: 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: The Authority is amending this rule to update the Oregon Medicaid Fee for Service Prior Authorization Criteria Guide found at http://www.oregon.gov/oha/healthplan/Pages/pharmacy-policy.aspx based on the P&T (Pharmacy and Therapeutic) Committee recommendations.

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.

October 20, by 5 p.m. Send written comments to HSB.Rules@state.or.us

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

Karen Wheeler — Karen Wheeler — 8/25/16

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 (Division) 410

Agency and Division Administrative Rules Chapter Number

Amending Prior Authorization Approval Criteria Guide

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 410-121-0040 and the repeal of OAR 410-121-0040(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 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. The Authority is amending this rule to update the Oregon Medicaid Fee for Service Prior Authorization Criteria Guide found at http://www.oregon.gov/oha/healthplan/Pages/pharmacy-policy.aspx based on the P&T (Pharmacy and Therapeutic) Committee recommendations.

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?: The Pharmacy & Therapeutics Committee meeting held on July 28, 2016 acted as a Rules Advisory Committee meeting for 410-121-0040. If not, why?:

Karen Wheeler Karen Wheeler 8/25/16

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 shall obtain prior authorization (PA) for the drugs and categories of drugs requiring PA in this rule, using the procedures set forth 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 shall meet the following requirements for coverage:

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

(b) Each drug 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 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 Oregon Medicaid Fee-for-Service Prior Authorization Approval Criteria (PA Criteria guide) dated August 26, 2016, adopted and incorporated by reference and found at: http://www.oregon.gov/OHA/healthplan/pages/pharmacy-policy.aspx.

(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. 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 shall be obtained for brand name drugs that have two or more generically equivalent products available and that are not determined Narrow Therapeutic Index drugs by the DUR/P&T Committee:

(a) Immunosuppressant drugs used in connection with an organ transplant 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 shall notify the Authority of patent expiration within 30 days of patent expiration for section (5)(a) to apply;

(c) Criteria for approval are:

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

(B) If section (6)(A) does not apply, the prescribing practitioner shall 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 shall be obtained 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, 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 413.032, 413.042, 414.065, 414.330 to 414.414, 414.312, 414.316

Stats. Implemented: 414.065, 414.334, 414.361, 414.371, 414.353, 414.354