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 Prior Authorization Guide DUR/P&T Action Nov 20, 2014 Meeting

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

February 17, 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: 410-121-0040

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.: 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:

410-121-0040:

ADHD Safety Edits – updated criteria
Analgesics Non-Steroidal – updated criteria
Antiemetics – updated criteria
Benzodiazepines – new criteria
CNS Sedative Non-Benzodiazepines – updated criteria
LABA ICS Inhalers – updated criteria
Naltrexone Extended Release Inj. (Vivitrol®) – updated criteria
Nutritional Supplements (Oral Administration Only) – 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.

February 19, 2015 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)

Rhonda Busek	Rhonda Busek	12-31-14
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 — 410

Agency and Division — Administrative Rules Chapter Number

Amending Prior Authorization Guide DUR/P&T Action Nov 20, 2014 Meeting

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 410-121-0040(T)

Statutory Authority: ORS 413.032, 413.042, 414.065, 414.325, and 414.330 to 414.414
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 410-121-0040 per the Drug Use Review (DUR) Pharmacy & Therapeutics (P&T) Committee's recommendations made during the Nov 20, 2014 meeting. 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:
ADHD Safety Edits – updated criteria
Analgesics Non-Steroidal – updated criteria
Antiemetics – updated criteria
Benzodiazepines – new criteria
CNS Sedative Non-Benzodiazepines – updated criteria
LABA ICS Inhalers – updated criteria
Naltrexone Extended Release Inj. (Vivitrol®) – updated criteria
Nutritional Supplements (Oral Administration Only) – updated criteria
Skeletal Muscle Relaxants – updated criteria

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?: The Pharmacy & Therapeutics Committee meeting held on Nov 20, 2014 acted as a Rules Advisory Committee meeting for 410-121-0040. If not, why?:

Rhonda Busell — Rhonda Busell — 12-31-14

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 be prescribed for conditions funded by 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 shall not be covered unless there is a co-morbid condition for which coverage would be extended. The use of the medication must 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 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 Oregon Medicaid Fee-For-Service Prior Authorization Approval Criteria (PA Criteria guide) dated ~~October 14, 2014~~January 1, 2015, 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 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 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 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, 141.325, 414.330 to 414.414, 414.312, 414.316

Stats. Implemented: 414.065, 414.325, 414.334, 414.361, 414.371, 414.353, 414.354