

Certificate and Order for Filing
TEMPORARY ADMINISTRATIVE RULES
A Statement of Need and Justification accompanies this form.

I certify that the attached copies* are true, full and correct copies of the TEMPORARY Rule(s) adopted on upon filing by the
Date prior to or same as filing date.

Oregon Health Authority (OHA), Division of Medical Assistance Programs (Division) 410
Agency and Division Administrative Rules Chapter Number

Cheryl Peters 503-945-6527 503-947-5221 cheryl.peters@state.or.us
Rules Coordinator Telephone Fax email

Communications Unit, 3rd Fl., DHS Bldg., 500 Summer St. NE-E35, Salem, Or. 97301-0177
Address

to become effective upon filing **through** 10/15/2012 .
Date upon filing or later A maximum of 180 days including the effective date.

RULEMAKING ACTION

Rule Filing Caption: Clarification of prior authorization requirements for new drugs.

AMEND: 410-121-0040

Statutory Authority: ORS 413.032, 413.042, 414.065, 414.325, 414.334, 414.361, 414.369 and 414.371

Other Authority: None.

Statutes Implemented: ORS 414.325, 414.334, 414.361, 414.369 and 414.371

Subject Matter: The Division needs to temporarily amend OAR 410-121-0040 to clarify prior authorization requirements for new drugs under the Oregon Health Plan (OHP). Based on comments received by the agency after it amended OAR 410-121-0040 for an effective date of January 1, 2012, the Division determined that there was some confusion related to the prior authorization requirements for new drugs under the OHP and the application of ORS 414.325. Consequently, the Division is amending its rule to provide clear guidelines for OHP clients and OHP providers on the prior authorization requirements for new drugs and the Division's process for developing those prior authorization criteria for new drugs.

410-121-0040: Revert language in 5(a-c) back to language that became effective on January 1, 2012

The Division intends to permanently adopt rule revisions through the standard rule process which will allow for input from stakeholders and the public.

Authorized Signers: _____
Judy Mohr Peterson, Jean Donovan or Sandy Wood Date

Secretary of State
Statement of Need and Justification

A Certificate and Order for Filing Temporary Administrative Rules accompanies this form.

Oregon Health Authority (OHA), Division of Medical Assistance Programs (Division) 410
Agency and Division Administrative Rule Chapter Number

In the Matter of: The temporary amendment of rules that govern payment for the Pharmaceutical Services Program. The Division temporarily amends OAR 410-121-0040.

Rule Filing Caption: Clarification of prior authorization requirements for new drugs.

Statutory Authority: ORS 413.032, 413.042, 414.065, 414.325, 414.334, 414.361, 414.369 and 414.371

Other Authority:

Statutes Implemented: ORS 414.325, 414.334, 414.361, 414.369 and 414.371

Need for Rule(s): The Pharmaceutical Services Program administrative rules govern Division payments for services provided to certain clients. The Division needs to temporarily amend OAR 410-121-0040 to clarify prior authorization requirements for new drugs under the Oregon Health Plan (OHP). Based on comments received by the agency after it amended OAR 410-121-0040 for an effective date of January 1, 2012, the Division determined that there was some confusion related to the prior authorization requirements for new drugs under the OHP and the application of ORS 414.325. Consequently, the Division is amending its rule to provide clear guidelines for OHP clients and OHP providers on the prior authorization requirements for new drugs and the Division's process for developing those prior authorization criteria for new drugs.

Justification of Temporary Rule(s): The Division finds that its failure to act promptly in adopting this temporary rule will result in serious prejudice to the public interest and the interests of affected parties because OHP clients and OHP providers may not be clear on which new drugs are subject to prior authorization requirements and thus must be submitted to the Division in order to receive reimbursement from OHP. Failure to immediately amend the rules may result in the submission of unnecessary prior authorization requests from OHP providers, possible delays in pharmacies filling prescriptions for OHP recipients, possible delays in reimbursement of claims, and the administrative burden and cost in reviewing unnecessary prior authorization requests. Through this temporary amendment of the rule, the Division will avoid these potential issues by removing any perceived inconsistency within the rules or with statutory law.

Documents Relied Upon, and where these can be viewed or obtained: ORS 414.325 viewable at:
<http://www.leg.state.or.us/ors/414.html>

Other Agencies affected: None.

Authorized Signers: _____
Judy Mohr Peterson, Jean Phillips or Sandy Wood Date

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 Oregon Health Services Commission's 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 OHP Fee-For-Service Pharmacy PA Criteria Guide (PA Criteria Guide) dated April 9, 2011, 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 Drug Use Review (DUR) / 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) PA is required for all new drugs added to the National Drug Data File (NDDF):~~

~~(a) The new drug will be prioritized to be presented to the P & T Committee after the drug's NDDF add date. The P & T Committee will make additional drug specific recommendations to the Authority regarding PA criteria, if any, that should be adopted for the new drug:~~

~~(i) If the new drug is in a class where current PA criteria apply, all PA criteria associated with that class shall be required at the time the new drug is added to the NDDF;~~

~~(ii) 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;~~

~~(b) PA for the new drug under section (5) of this rule remains in effect until such time as the Authority makes a determination regarding the applicability of PA criteria for the new drug or six months elapse from the drug's NDDF add date without a decision regarding PA criteria for that drug, whichever occurs first;~~

~~(c) Oral oncology medications, anti-retrovirals, and family planning drugs are excluded from the PA requirements in section (5) of this rule.~~

(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 Chap. 409.110, 413.042, 414.325, s414.065, and 414.334

Stats. Implemented: 414.065

4-19-12 (T)