

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 (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

Amend Pharmacy and Therapeutics Committee rule to remove expiration date and clarity given to safety
Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

January 15, 2014	10:30 a.m.	500 Summer St NE, Salem, OR 97301, Room 137C	Sandy Cafourek
Hearing Date	Time	Location	Hearings Officer

Hearing Date	Time	Location	Hearings Officer
<i>Auxiliary aids for persons with disabilities are available upon advance request.</i>			

RULEMAKING ACTION

Secure approval of new rule numbers (Adopted or Renumbered rules) with the Administrative Rules Unit prior to filing.

ADOPT:

AMEND: 410-121-0111

REPEAL:

RENUMBER:

AMEND & RENUMBER:

Stat. Auth. : ORS 413.042, 414.065, 414.355, 414.360, 414.365, 414.370, 414.380

Other Auth.: HB 2100 and ORS sited

Stats. Implemented: ORS 414.065, Or Law 2011

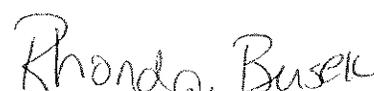
RULE SUMMARY

Rule changes include the removal of expiration date and addition of clarification regarding responsibility of committee to recipient safety.

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.

January 17, 2014

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

		12-10-13
Signature	Printed name	Date

*Hearing Notices published in the Oregon Bulletin must be submitted by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a weekend or legal holiday, upon which the deadline is 5:00 pm the preceding workday. ARC 920-2005

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 (Division)

410

Agency and Division

Administrative Rules Chapter Number

Amend Pharmacy and Therapeutics Committee rule to remove expiration date and clarify given to safety

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

In the Matter of: 410-121-0111

Statutory Authority: ORS 413.042, 414.065, 414.355, 414.360, 414.365, 414.370, 414.380

Other Authority:

Stats. Implemented: ORS 414.065

Need for the Rule(s): Rule changes include the removal of expiration date and addition of clarification regarding responsibility of committee to recipient safety.

Documents Relied Upon, and where they are available: HB2100, and ORS sited.

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 change brings clarity and focus to client safety. Impacts P&T committee's role in alignment with HB 2100.

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:
Minimal to no impact to small business.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:
No additional costs.

c. Equipment, supplies, labor and increased administration required for compliance:
No additional costs.

How were small businesses involved in the development of this rule?

Both the P&T committee and HB 2100 had appropriate public comment opportunities.

Administrative Rule Advisory Committee consulted?: Yes

If not, why?: P&T Committee served as a RAC.


Signature

Rhonda Buser
Printed name

12-10-18
Date

410-121-0111

Pharmacy & Therapeutics Committee

(1) Pursuant to Oregon Laws 2011, chapter 720 (HB 2100), the Drug Use Review Board (DUR Board) is abolished and the tenure of office for the members of the DUR Board expires. The legislature transferred the duties, functions and powers previously vested in the DUR Board to the Pharmacy and Therapeutics (P&T) Committee. This rule is retroactively effective on September 5, 2011, the date the P&T Committee was created and the DUR Board was abolished by HB 2100, and expires on March 15, 2012 or whenever the Oregon Health Authority (Authority) suspends the rule, whichever comes first.

(2) Unless otherwise inconsistent with these administrative rules or other laws, any administrative rule or agency policy with reference to the DUR Board or a DUR Board volunteer, staff or contractor shall be considered to be a reference to the P&T Committee or a P&T Committee volunteer, staff or contractor. The current preferred drug list (PDL), prior authorization process and utilization review process developed by the DUR Board remains in effect until such time as the Authority, after recommendations and advice from the P&T Committee, modifies them through the adoption of new administrative rules or policies and procedures.

(3) The P&T Committee shall advise the Oregon Health Authority (Authority) on the:

(a) Implementation of the medical assistance program retrospective and prospective programs, including the type of software programs to be used by the pharmacist for prospective drug use review and the provisions of the contractual agreement between the state and any entity involved in the retrospective program;

(b) Implementation of the Practitioner Managed Prescription Drug Plan (PMPDP);

(c) Adoption of administrative rules pertaining to the P&T Committee;

(d) Development of and application of the criteria and standards to be used in retrospective and prospective drug use review, and safety edit programs in a manner that ensures that such criteria and standards are based on compendia, relevant guidelines obtained from professional groups through consensus-driven processes, the experience of practitioners with expertise in drug therapy, data and experience obtained from drug utilization review program operations. The P&T Committee must have an open professional consensus process, establish an explicit ongoing process for soliciting and considering input from interested parties, and make timely revisions to the criteria and standards based on this input and scheduled reviews;

(e) Development, selection and application of and assessment for interventions being educational and not punitive in nature for medical assistance program prescribers, dispensers and patients.

(4) The P&T Committee shall make recommendations to the Authority, subject to approval by the Director or the Director's designee, for drugs to be included on any PDL.

adopted by the Authority and on the PMPDP. The P&T Committee shall also recommend all utilization controls, prior authorization requirements or other conditions for the inclusion of a drug on the PDL.

(5) The P&T Committee shall, with the approval of the Director or designee, do the following:

(a) Publish an annual report;

(b) Publish and disseminate educational information to prescribers and pharmacists regarding the P&T Committee and the drug use review programs, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse or inappropriate or medically unnecessary care among prescribers, pharmacists and recipients;

(B) Potential or actual severe or adverse reactions to drugs;

(C) Therapeutic appropriateness;

(D) Overutilization or underutilization;

(E) Appropriate use of generic products;

(F) Therapeutic duplication;

(G) Drug-disease contraindications;

(H) Drug-drug interactions;

(I) Drug allergy interactions;

(J) Clinical abuse and misuse.

(K) Patient safety

(6) Adopt and implement procedures designed to ensure the confidentiality of any information that identifies individual prescribers, pharmacists or recipients and that is collected, stored, retrieved, assessed or analyzed by the P&T Committee, staff of the P&T Committee, contractors to the P&T Committee or the Authority.

Stat. Auth.: ORS 413.042, 414.065, 414.355, 414.360, 414.365, 414.370, 414.380, ~~Or Law 2011, chap. 720 (HB 2100)~~

Stats. Implemented: ORS 414.065, ~~Or Law 2011, chap. 720 (HB 2100)~~