

Enrolled
House Bill 2306

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CHAPTER

AN ACT

Relating to prescription drugs; creating new provisions; amending ORS 414.325, 414.351 and 414.364; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. Section 2 of this 2015 Act is added to and made a part of ORS 414.351 to 414.414.

SECTION 2. (1)(a) If necessary to avoid overutilization by a recipient of medical assistance, the Oregon Health Authority may restrict, for 18 months or less, the recipient's pharmacy choices for filling and refilling prescriptions to a mail order pharmacy that contracts with the authority, a retail pharmacy selected by the recipient and a specialty pharmacy selected by the recipient, if the recipient:

- (A) Uses three or more pharmacies in a six-month period;
- (B) Fills prescriptions from more than one prescriber for the same or comparable medications for the same time period;
- (C) Alters a prescription; or
- (D) Exhibits behaviors or patterns of behavior that the Pharmacy and Therapeutics Committee has identified as indicative of intentional overutilization or misuse.

(b) This subsection does not apply to a recipient who:

- (A) Is a member of a coordinated care organization;
- (B) Has Medicare drug coverage, in addition to medical assistance, but no other drug coverage;
- (C) Is a child in the custody of the Department of Human Services; or
- (D) Is a patient in a hospital or other medical institution or a resident in a long term care facility.

- (c) The authority shall prescribe by rule:
 - (A) Exceptions to the limitation imposed under paragraph (a) of this subsection; and
 - (B) The conditions under which a recipient who is restricted under paragraph (a) of this subsection may change to a different pharmacy.

(2) The authority may conduct prospective drug utilization review, in accordance with rules adopted under ORS 414.361, prior to payment for drugs for a patient who has filled prescriptions for more than 15 drugs in the preceding six-month period.

SECTION 3. ORS 414.325 is amended to read:
414.325. (1) As used in this section:

(a) "Legend drug" means any drug requiring a prescription by a practitioner, as defined in ORS 689.005.

(b) "Mental health drug" means a type of legend drug defined by the Oregon Health Authority by rule that includes, but is not limited to:

(A) Therapeutic class 7 ataractics-tranquilizers; and

(B) Therapeutic class 11 psychostimulants-antidepressants.

(c) "Urgent medical condition" means a medical condition that arises suddenly, is not life-threatening and requires prompt treatment to avoid the development of more serious medical problems.

(2) The authority shall reimburse the cost of a legend drug prescribed for a recipient of medical assistance only if the legend drug:

(a) Is on the drug list of the Practitioner-Managed Prescription Drug Plan adopted under ORS 414.334;

(b) Is in a therapeutic class of non-sedating antihistamines and nasal inhalers, as defined by the authority by rule, and is prescribed by an allergist for the treatment of:

(A) Asthma;

(B) Sinusitis;

(C) Rhinitis; or

(D) Allergies; or

(c) Is prescribed and dispensed under this chapter by a licensed practitioner at a rural health clinic for an urgent medical condition and:

(A) There is no pharmacy within 15 miles of the clinic;

(B) The prescription is dispensed for a patient outside of the normal business hours of any pharmacy within 15 miles of the clinic; or

(C) No pharmacy within 15 miles of the clinic dispenses legend drugs under this chapter.

(3) The authority shall pay only for drugs in the generic form unless an exception has been granted by the authority through the prior authorization process adopted by the authority under subsection (4) of this section.

(4) Notwithstanding subsection (2) of this section, the authority shall provide reimbursement for a legend drug that does not meet the criteria in subsection (2) of this section if:

(a) It is a mental health drug.

(b) The authority grants approval through a prior authorization process adopted by the authority by rule.

(c) The prescriber contacts the authority requesting prior authorization and the authority or its agent fails to respond to the telephone call or to a prescriber's request made by electronic mail within 24 hours.

(d) After consultation with the authority or its agent, the prescriber, in the prescriber's professional judgment, determines that the drug is medically appropriate.

(e) The original prescription was written prior to July 28, 2009, or the request is for a refill of a prescription for:

(A) The treatment of seizures, cancer, HIV or AIDS; or

(B) An immunosuppressant.

(f) It is a drug in a class not evaluated for the Practitioner-Managed Prescription Drug Plan adopted under ORS 414.334.

(5) Notwithstanding subsections (1) to (4) of this section, the authority is authorized to:

(a) Withhold payment for a legend drug when federal financial participation is not available;

(b) Require prior authorization of payment for drugs that the authority has determined should be limited to those conditions generally recognized as appropriate by the medical profession; and

(c) Withhold payment for a legend drug that is not a funded health service on the prioritized list of health services established by the Health Evidence Review Commission under ORS [414.720] **414.690**.

(6) Notwithstanding ORS 414.334, the authority may conduct prospective drug utilization review [prior to payment for drugs for a patient whose prescription drug use exceeded 15 drugs in the preceding six-month period] **in accordance with ORS 414.351 to 414.414.**

(7) Notwithstanding subsection (3) of this section, the authority may pay a pharmacy for a particular brand name drug rather than the generic version of the drug after notifying the pharmacy that the cost of the particular brand name drug, after receiving discounted prices and rebates, is equal to or less than the cost of the generic version of the drug.

(8)(a) Within 180 days after the United States patent expires on an immunosuppressant drug used in connection with an organ transplant, the authority shall determine whether the drug is a narrow therapeutic index drug.

(b) As used in this subsection, “narrow therapeutic index drug” means a drug that has a narrow range in blood concentrations between efficacy and toxicity and requires therapeutic drug concentration or pharmacodynamic monitoring.

(9) The authority shall appoint an advisory committee in accordance with ORS 183.333 for any rulemaking conducted pursuant to this section.

SECTION 4. ORS 414.325, as amended by section 8, chapter 827, Oregon Laws 2009, is amended to read:

414.325. (1) As used in this section:

(a) “Legend drug” means any drug requiring a prescription by a practitioner, as defined in ORS 689.005.

(b) “Urgent medical condition” means a medical condition that arises suddenly, is not life-threatening and requires prompt treatment to avoid the development of more serious medical problems.

(2) A licensed practitioner may prescribe such drugs under this chapter as the practitioner in the exercise of professional judgment considers appropriate for the diagnosis or treatment of the patient in the practitioner’s care and within the scope of practice. Prescriptions shall be dispensed in the generic form pursuant to ORS 689.515 and pursuant to rules of the Oregon Health Authority unless the practitioner prescribes otherwise and an exception is granted by the authority.

(3) Except as provided in subsections (4) and (5) of this section, the authority shall place no limit on the type of legend drug that may be prescribed by a practitioner, but the authority shall pay only for drugs in the generic form unless an exception has been granted by the authority.

(4) Notwithstanding subsection (3) of this section, an exception must be applied for and granted before the authority is required to pay for minor tranquilizers and amphetamines and amphetamine derivatives, as defined by rule of the authority.

(5)(a) Notwithstanding subsections (1) to (4) of this section and except as provided in paragraph (b) of this subsection, the authority is authorized to:

(A) Withhold payment for a legend drug when federal financial participation is not available; and

(B) Require prior authorization of payment for drugs that the authority has determined should be limited to those conditions generally recognized as appropriate by the medical profession.

(b) The authority may not require prior authorization for therapeutic classes of nonsedating antihistamines and nasal inhalers, as defined by rule by the authority, when prescribed by an allergist for treatment of any of the following conditions, as described by the Health Evidence Review Commission on the funded portion of its prioritized list of services:

- (A) Asthma;
- (B) Sinusitis;
- (C) Rhinitis; or
- (D) Allergies.

(6) The authority shall pay a rural health clinic for a legend drug prescribed and dispensed under this chapter by a licensed practitioner at the rural health clinic for an urgent medical condition if:

- (a) There is not a pharmacy within 15 miles of the clinic;

(b) The prescription is dispensed for a patient outside of the normal business hours of any pharmacy within 15 miles of the clinic; or

(c) No pharmacy within 15 miles of the clinic dispenses legend drugs under this chapter.

(7) Notwithstanding ORS 414.334, the authority may conduct prospective drug utilization review [prior to payment for drugs for a patient whose prescription drug use exceeded 15 drugs in the preceding six-month period] **in accordance with ORS 414.351 to 414.414.**

(8) Notwithstanding subsection (3) of this section, the authority may pay a pharmacy for a particular brand name drug rather than the generic version of the drug after notifying the pharmacy that the cost of the particular brand name drug, after receiving discounted prices and rebates, is equal to or less than the cost of the generic version of the drug.

(9)(a) Within 180 days after the United States patent expires on an immunosuppressant drug used in connection with an organ transplant, the authority shall determine whether the drug is a narrow therapeutic index drug.

(b) As used in this subsection, “narrow therapeutic index drug” means a drug that has a narrow range in blood concentrations between efficacy and toxicity and requires therapeutic drug concentration or pharmacodynamic monitoring.

SECTION 5. ORS 414.351 is amended to read:

414.351. As used in ORS 414.351 to 414.414:

(1) “Compendia” means those resources widely accepted by the medical profession in the efficacious use of drugs, including the following sources:

(a) The American Hospital Formulary Service drug information.

(b) The United States Pharmacopeia drug information.

(c) The American Medical Association drug evaluations.

(d) Peer-reviewed medical literature.

(e) Drug therapy information provided by manufacturers of drug products consistent with the federal Food and Drug Administration requirements.

(2) “Criteria” means the predetermined and explicitly accepted elements based on compendia that are used to measure drug use on an ongoing basis to determine if the use is appropriate, medically necessary and not likely to result in adverse medical outcomes.

(3) “Drug-disease contraindication” means the potential for, or the occurrence of, an undesirable alteration of the therapeutic effect of a given prescription because of the presence, in the patient for whom it is prescribed, of a disease condition or the potential for, or the occurrence of, a clinically significant adverse effect of the drug on the patient’s disease condition.

(4) “Drug-drug interaction” means the pharmacological or clinical response to the administration of at least two drugs different from that response anticipated from the known effects of the two drugs when given alone, which may manifest clinically as antagonism, synergism or idiosyncrasy. Such interactions have the potential to have an adverse effect on the individual or lead to a clinically significant adverse reaction, or both, that:

(a) Is characteristic of one or any of the drugs present; or

(b) Leads to interference with the absorption, distribution, metabolism, excretion or therapeutic efficacy of one or any of the drugs.

(5) “Drug use review” means the programs designed to measure and assess on a retrospective and a prospective basis, through an evaluation of claims data, the proper utilization, quantity, appropriateness as therapy and medical necessity of prescribed medication in the medical assistance program.

(6) “Intervention” means an action taken by the Oregon Health Authority with a:

(a) Prescriber or pharmacist to inform about or to influence prescribing or dispensing practices; or

(b) **Recipient, prescriber or pharmacist to inform about or to influence the** utilization of drugs.

(7) “Overutilization” means the use of a drug in quantities or for durations that put the recipient at risk of an adverse medical result.

- (8) "Pharmacist" means an individual who is licensed as a pharmacist under ORS chapter 689.
- (9) "Prescriber" means any person authorized by law to prescribe drugs.
- (10) "Prospective program" means the prospective drug use review program described in ORS 414.369.
- (11) "Retrospective program" means the retrospective drug use review program described in ORS 414.371.
- (12) "Standards" means the acceptable prescribing and dispensing methods determined by compendia, in accordance with local standards of medical practice for health care providers.
- (13) "Therapeutic appropriateness" means drug prescribing based on scientifically based and clinically relevant drug therapy that is consistent with the criteria and standards developed under ORS 414.351 to 414.414.
- (14) "Therapeutic duplication" means the prescribing and dispensing of two or more drugs from the same therapeutic class such that the combined daily dose puts the recipient at risk of an adverse medical result or incurs additional program costs without additional therapeutic benefits.
- (15) "Underutilization" means that a drug is used by a recipient in insufficient quantity to achieve a desired therapeutic goal.

SECTION 6. ORS 414.364 is amended to read:

414.364. In appropriate instances, interventions developed under ORS 414.361 (1)(d) may include the following:

- (1) Information disseminated to prescribers and pharmacists to ensure that they are aware of the duties and powers of the Pharmacy and Therapeutics Committee.
- (2) Written, oral or electronic reminders of recipient-specific or drug-specific information that are designed to ensure recipient, prescriber and pharmacist confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care.
- (3) Face-to-face discussions between experts in drug therapy and the prescriber or pharmacist who has been targeted for educational intervention.
- (4) Intensified reviews or monitoring of selected prescribers or pharmacists.
- (5) Educational outreach through the retrospective program focusing on improvement of prescribing and dispensing practices.
- (6) The timely evaluation of interventions to determine if the interventions have improved the quality of care.
- (7) The review of case profiles before the conducting of an intervention.

(8) The actions specified in section 2 of this 2015 Act.

SECTION 7. This 2015 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2015 Act takes effect on its passage.

Passed by House February 6, 2015

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Timothy G. Sekerak, Chief Clerk of House

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Tina Kotek, Speaker of House

Passed by Senate June 8, 2015

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Peter Courtney, President of Senate

Received by Governor:

.....M,....., 2015

Approved:

.....M,....., 2015

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Kate Brown, Governor

Filed in Office of Secretary of State:

.....M,....., 2015

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Jeanne P. Atkins, Secretary of State