LC 3071
2013 Regular Session
2/15/13 (LHF/ps)

D R A F T

SUMMARY

Modifies meeting requirements for Pharmacy and Therapeutics Committee of Oregon Health Authority.

Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to drug reviews by the Oregon Health Authority; amending ORS 414.354, 414.356 and 414.361; and declaring an emergency.

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

SECTION 1. ORS 414.354 is amended to read:

414.354. (1) Except as provided in ORS 414.356, the Pharmacy and Therapeutics Committee shall operate in accordance with ORS chapter 192. The committee shall annually elect a chairperson from the members of the committee.

(2) A committee member is not entitled to compensation but is entitled to reimbursement for actual and necessary travel expenses incurred in connection with the member's duties, pursuant to ORS 292.495.

(3) A quorum consists of six members of the committee.

(4) The committee may establish advisory committees to assist in carrying out the committee's duties under ORS 414.351 to 414.414, with the approval of the Director of the Oregon Health Authority.

(5) The Oregon Health Authority shall provide staff and support services to the committee.

(6) The committee shall meet no less than four times each year at a place, day and hour determined by the director. The committee also shall meet at

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

other times and places specified by the call of the director or a majority of the members of the committee. No less than 30 days prior to a meeting the committee shall post to the authority website:

(a) The agenda for the meeting;

(b) A list of the drug classes to be considered at the meeting; [*and*]

(c) The name of any drug to be discussed by the committee for the purpose of recommending the drug's inclusion on or exclusion from the Practitioner-Managed Prescription Drug Plan adopted by the Oregon Health Authority under ORS 414.334; and

[*(c)*] **(d)** Background materials and supporting documentation provided to committee members with respect to drugs and drug classes that are before the committee for review **and any other documents to be considered by the committee, except for confidential documents that will be considered exclusively in an executive session under ORS 414.356**.

(7) **Drug use reviews shall be considered separately from consideration of whether to recommend a drug for inclusion on or exclusion from the Practitioner-Managed Prescription Drug Plan.** The committee shall provide appropriate opportunity for public testimony at each regularly scheduled committee meeting. Immediately prior to deliberating on any [*recommendations*] **committee action** regarding a drug or a class of drugs, the committee shall accept testimony, in writing or in person, that is offered by a manufacturer of those drugs or another interested party.

(8) The committee may consider more than 20 classes of drugs at a meeting only if:

(a) There is no new clinical evidence for the additional class of drugs; and

(b) The committee is considering only substantial cost differences between drugs within the same therapeutic class.

(9) If the committee will be discussing an agenda item during an executive session, the agenda must specify the basis under ORS 414.356 (1) for meeting in executive session.

SECTION 2. ORS 414.356 is amended to read:

414.356. (1) Notwithstanding ORS 192.610 to 192.690, the Pharmacy and Therapeutics Committee shall meet in an executive session for purposes of:

(a) Reviewing the prescribing or dispensing practices of individual physicians or pharmacists;

(b) Discussing drug use review data pertaining to individual physicians or pharmacists;

(c) Reviewing profiles of individual patients; or

(d) **Subject to subsection (3) of this section,** reviewing confidential drug pricing information, including substantial cost differences between drugs within the same therapeutic class, that is necessary for the committee to make final recommendations under ORS 414.361 or to comply with ORS 414.414.

(2) A meeting held in executive session is subject to the requirements of ORS 192.650 (2).

(3) The committee may meet in executive session for purposes of subsection (1)(d) of this section only after the committee finds that the uses, safety and efficacy of the drugs under consideration within the same therapeutic class are comparable enough that a substantial difference in the net cost, after deducting rebates, reimbursements and other applicable cost reductions, would be the determining factor in the committee's recommendation to include a drug on the Practitioner-Managed Prescription Drug Plan.

SECTION 3. ORS 414.361 is amended to read:

414.361. (1) The Pharmacy and Therapeutics Committee shall advise the Oregon Health Authority on:

(a) Adoption of rules to implement ORS 414.351 to 414.414 in accordance with ORS chapter 183.

(b) Implementation of the medical assistance program retrospective and prospective programs as described in ORS 414.351 to 414.414, 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.

(c) Development of and application of the criteria and standards to be used in retrospective and prospective drug use review 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 committee shall have an open professional consensus process for establishing and revising criteria and standards. Criteria and standards shall be available to the public. In developing recommendations for criteria and standards, the committee shall establish an explicit ongoing process for soliciting and considering input from interested parties. The committee shall make timely revisions to the criteria and standards based upon this input in addition to revisions based upon scheduled review of the criteria and standards. Further, the drug utilization review standards shall reflect the local practices of prescribers in order to monitor:

(A) Therapeutic appropriateness.

(B) Overutilization or underutilization.

(C) Therapeutic duplication.

(D) Drug-disease contraindications.

(E) Drug-drug interactions.

(F) Incorrect drug dosage or drug treatment duration.

(G) Clinical abuse or misuse.

(H) Drug allergies.

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

(2) In reviewing retrospective and prospective drug use, the committee may consider only drugs that have received final approval from the federal Food and Drug Administration.

(3) The committee shall make recommendations to the authority, subject

to approval by the Director of the Oregon Health Authority or the director's designee, for drugs to be included on any preferred drug list adopted by the authority and on the Practitioner-Managed Prescription Drug Plan. The committee shall also recommend all utilization controls, prior authorization requirements or other conditions for the inclusion of a drug on a preferred drug list.

(4) In making recommendations under subsection (3) of this section, the committee may use any information the committee deems appropriate. The recommendations must be based upon **and include committee findings on** the following factors in order of priority:

(a) The use or uses for the drug that have been approved by the federal Food and Drug Administration.

[*(a)*] **(b) The** safety and efficacy of the drug.

[*(b)*] **(c)** The **impact of prior authorization requirements or other restrictions on access to drugs on the** ability of Oregonians to [*access*] **obtain** effective prescription drugs that are appropriate for their clinical conditions.

[*(c)*] **(d)** Substantial differences in the **net** costs of drugs within the same therapeutic class**, after deducting all rebates and reimbursements that reduce the net cost to the authority**.

(5) The committee shall post a recommendation to the website of the authority no later than 30 days after the date the committee approves the recommendation. The director shall approve, disapprove or modify any recommendation of the committee as soon as practicable, shall publish the decision on the website and shall notify persons who have requested notification of the decision. A recommendation adopted by the director, in whole or in part, with respect to the inclusion of a drug on a preferred drug list or the Practitioner-Managed Prescription Drug Plan may not become effective less than 60 days after the date that the director's decision is published.

(6) The director shall reconsider any decision to adopt or modify a recommendation of the committee with respect to the inclusion of a particular

drug on a preferred drug list or the Practitioner-Managed Prescription Drug Plan, upon the request of any interested person filed no later than 30 days after the director's decision is published on the website. The decision on reconsideration shall be sent to the requester and posted to the website without undue delay.

SECTION 4. This 2013 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2013 Act takes effect on its passage.
