

Senate Bill 457

Sponsored by Senator KNOPP (Presession filed.)

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced**.

Modifies required coverage of prescription drugs in medical assistance program.

Modifies membership requirements and duties of Pharmacy and Therapeutics Committee and Health Evidence Review Commission and advisory committees appointed for committee and commission. Reduces term of committee members from four years to two years.

Modifies timelines for Pharmacy and Therapeutics Committee to make recommendation and for Oregon Health Authority to act on recommendation. Requires decision approving, disapproving or modifying recommendation of committee to be adopted by rule.

A BILL FOR AN ACT

1
2 Relating to the scope of services paid for by medical assistance; creating new provisions; and
3 amending ORS 414.325, 414.334, 414.353, 414.354, 414.361, 414.688, 414.689, 414.690, 414.695,
4 414.698 and 414.701.

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

6 **SECTION 1.** ORS 414.325 is amended to read:

7 414.325. (1) As used in this section:

8 (a) "Legend drug" means any drug requiring a prescription by a practitioner, as defined in ORS
9 689.005.

10 (b) "**Mental health drug**" means a type of legend drug defined by the Oregon Health Au-
11 **thority by rule that includes, but is not limited to:**

12 (A) **Therapeutic class 7 ataractics-tranquilizers; and**

13 (B) **Therapeutic class 11 psychostimulants-antidepressants.**

14 [(b)] (c) "Urgent medical condition" means a medical condition that arises suddenly, is not life-
15 threatening and requires prompt treatment to avoid the development of more serious medical prob-
16 lems.

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

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

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

28 **(2) The authority shall reimburse the cost of a legend drug prescribed for a recipient of**

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.

1 **medical assistance only if the legend drug:**

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

4 (b) **Is in a therapeutic class of nonседating antihistamines and nasal inhalers, as defined**
5 **by the authority by rule, and is prescribed by an allergist for the treatment of:**

6 (A) **Asthma;**

7 (B) **Sinusitis;**

8 (C) **Rhinitis; or**

9 (D) **Allergies; or**

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

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

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

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

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

19 (4) **Notwithstanding subsection (2) of this section, the authority shall provide re-**
20 **imbursement for a legend drug that does not meet the criteria in subsection (2) of this sec-**
21 **tion if:**

22 (a) **It is a mental health drug.**

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

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

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

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

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

33 (B) **An immunosuppressant.**

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

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

38 [(A)] (a) **Withhold payment for a legend drug when federal financial participation is not avail-**
39 **able; [and]**

40 [(B)] (b) **Require prior authorization of payment for drugs that the authority has determined**
41 **should be limited to those conditions generally recognized as appropriate by the medical**
42 **profession[.]; and**

43 (c) **Withhold payment for a legend drug that is not a funded health service on the prior-**
44 **itized list of health services established by the Health Evidence Review Commission under**
45 **ORS 414.690.**

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

5 ***[(A) Asthma;]***

6 ***[(B) Sinusitis;]***

7 ***[(C) Rhinitis; or]***

8 ***[(D) Allergies.]***

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

11 ***[(a) There is not a pharmacy within 15 miles of the clinic;]***

12 ***[(b) The prescription is dispensed for a patient outside of the normal business hours of any phar-***
 13 ***macy within 15 miles of the clinic; or]***

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

15 **[(7)] (6)** Notwithstanding ORS 414.334, the authority may conduct prospective drug utilization
 16 review in accordance with ORS 414.351 to 414.414.

17 **[(8)] (7)** Notwithstanding subsection (3) of this section, the authority may pay a pharmacy for a
 18 particular brand name drug rather than the generic version of the drug after notifying the pharmacy
 19 that the cost of the particular brand name drug, after receiving discounted prices and rebates, is
 20 equal to or less than the cost of the generic version of the drug.

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

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

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

29 **SECTION 2.** ORS 414.325, as amended by section 1 of this 2021 Act, is amended to read:

30 414.325. (1) As used in this section:

31 (a) “Legend drug” means any drug requiring a prescription by a practitioner, as defined in ORS
 32 689.005.

33 ***[(b) “Mental health drug” means a type of legend drug defined by the Oregon Health Authority by***
 34 ***rule that includes, but is not limited to:]***

35 ***[(A) Therapeutic class 7 ataractics-tranquilizers; and]***

36 ***[(B) Therapeutic class 11 psychostimulants-antidepressants.]***

37 **[(c)] (b)** “Urgent medical condition” means a medical condition that arises suddenly, is not life-
 38 threatening and requires prompt treatment to avoid the development of more serious medical prob-
 39 lems.

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

42 ***[(a) Is on the drug list of the Practitioner-Managed Prescription Drug Plan adopted under ORS***
 43 ***414.334;]***

44 ***[(b) Is in a therapeutic class of nonsedating antihistamines and nasal inhalers, as defined by the***
 45 ***authority by rule, and is prescribed by an allergist for the treatment of:]***

1 [(A) *Asthma;*]

2 [(B) *Sinusitis;*]

3 [(C) *Rhinitis; or*]

4 [(D) *Allergies; or*]

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

7 [(A) *There is no pharmacy within 15 miles of the clinic;*]

8 [(B) *The prescription is dispensed for a patient outside of the normal business hours of any phar-*
9 *macy within 15 miles of the clinic; or*]

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

11 [(3) *The authority shall pay only for drugs in the generic form unless an exception has been*
12 *granted by the authority through the prior authorization process adopted by the authority under sub-*
13 *section (4) of this section.*]

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

16 [(a) *It is a mental health drug.*]

17 [(b) *The authority grants approval through a prior authorization process adopted by the authority*
18 *by rule.*]

19 [(c) *The prescriber contacts the authority requesting prior authorization and the authority or its*
20 *agent fails to respond to the telephone call or to a prescriber's request made by electronic mail within*
21 *24 hours.*]

22 [(d) *After consultation with the authority or its agent, the prescriber, in the prescriber's profes-*
23 *sional judgment, determines that the drug is medically appropriate.*]

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

26 [(A) *The treatment of seizures, cancer, HIV or AIDS; or*]

27 [(B) *An immunosuppressant.*]

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

30 **(2) A licensed practitioner may prescribe such drugs under this chapter as the practi-**
31 **tioner in the exercise of professional judgment considers appropriate for the diagnosis or**
32 **treatment of the patient in the practitioner's care and within the scope of practice. Pre-**
33 **scriptions shall be dispensed in the generic form pursuant to ORS 689.515 and pursuant to**
34 **rules of the Oregon Health Authority unless the practitioner prescribes otherwise and an**
35 **exception is granted by the authority.**

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

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

43 **(5)(a) Notwithstanding subsections (1) to (4) of this section and except as provided in para-**
44 **graph (b) of this subsection, the authority is authorized to:**

45 [(a)] **(A) Withhold payment for a legend drug when federal financial participation is not avail-**

1 able; **and**

2 [(b)] **(B)** Require prior authorization of payment for drugs that the authority has determined
 3 should be limited to those conditions generally recognized as appropriate by the medical
 4 profession[; *and*].

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

7 **(b) The authority may not require prior authorization for therapeutic classes of nonse-**
 8 **dating antihistamines and nasal inhalers, as defined by rule by the authority, when pre-**
 9 **scribed by an allergist for treatment of any of the following conditions, as described by the**
 10 **Health Evidence Review Commission on the funded portion of its prioritized list of services:**

11 **(A) Asthma;**

12 **(B) Sinusitis;**

13 **(C) Rhinitis; or**

14 **(D) Allergies.**

15 **(6) The authority shall pay a rural health clinic for a legend drug prescribed and dis-**
 16 **persed under this chapter by a licensed practitioner at the rural health clinic for an urgent**
 17 **medical condition if:**

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

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

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

22 [(6)] **(7)** Notwithstanding ORS 414.334, the authority may conduct prospective drug utilization
 23 review in accordance with ORS 414.351 to 414.414.

24 [(7)] **(8)** Notwithstanding subsection (3) of this section, the authority may pay a pharmacy for a
 25 particular brand name drug rather than the generic version of the drug after notifying the pharmacy
 26 that the cost of the particular brand name drug, after receiving discounted prices and rebates, is
 27 equal to or less than the cost of the generic version of the drug.

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

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

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

36 **SECTION 3.** ORS 414.334 is amended to read:

37 414.334. (1) The Oregon Health Authority shall adopt **and maintain** a Practitioner-Managed
 38 Prescription Drug Plan [*for*] **consisting of:**

39 **(a) A preferred drug list for drugs prescribed in the medical assistance program for which**
 40 **the costs are reimbursed on a fee-for-service basis; and**

41 **(b) A partially aligned preferred drug list for coordinated care organizations that consists**
 42 **of portions of the Practitioner-Managed Prescription Drug Plan preferred drug list that apply**
 43 **to certain drugs or therapeutic classes of prescription drugs paid for from a coordinated care**
 44 **organization’s global budget.**

45 **(2)** The purpose of the plan is to ensure that [*enrollees in the medical assistance program*] **med-**

1 **ical assistance recipients** receive the most effective prescription drug available at the best possible
2 price.

3 [(2)] (3) In adopting the plan, the authority shall consider recommendations of the Pharmacy and
4 Therapeutics Committee.

5 [(3)] (4) The authority shall consult with representatives of the regulatory boards and associ-
6 ations representing practitioners who are prescribers under the medical assistance program and
7 ensure that practitioners receive educational materials and have access to training on the
8 Practitioner-Managed Prescription Drug Plan.

9 [(4)] (5) Notwithstanding the Practitioner-Managed Prescription Drug Plan adopted by the au-
10 thority, a practitioner may prescribe any drug that the practitioner indicates is medically necessary
11 for [*an enrollee*] **a recipient** as being the most effective available.

12 [(5)] (6) [*An enrollee*] **A recipient** may appeal to the authority a decision of a practitioner, **a**
13 **coordinated care organization** or the authority to [*not provide*] **deny coverage of** a prescription
14 drug requested by the [*enrollee*] **recipient**.

15 [(6)] (7) This section does not limit the decision of a practitioner as to the scope and duration
16 of treatment of chronic conditions, including but not limited to arthritis, diabetes and asthma.

17 **(8) The authority shall update the partially aligned preferred drug list regularly through**
18 **a collaborative process engaging all of the coordinated care organizations.**

19 **SECTION 4.** ORS 414.353 is amended to read:

20 414.353. (1) There is created an 11-member Pharmacy and Therapeutics Committee responsible
21 for advising the Oregon Health Authority on the implementation of the retrospective and prospec-
22 tive programs and on the Practitioner-Managed Prescription Drug Plan.

23 (2) The Director of the Oregon Health Authority shall appoint the members of the committee,
24 who shall serve at the pleasure of the director for a term of [*three*] **two** years. An individual ap-
25 pointed to the committee may be reappointed upon completion of the individual's term. The mem-
26 bership of the committee shall be composed of the following:

27 (a) Five persons licensed as physicians under ORS 677.100 to 677.228 and actively engaged in
28 the practice of medicine in Oregon, who may be from among persons recommended by organizations
29 representing physicians;

30 (b) Four persons licensed in and actively practicing pharmacy in Oregon who may be from
31 among persons recommended by organizations representing pharmacists whether affiliated or unaf-
32 filiated with any association; and

33 (c) Two persons who are not physicians or pharmacists.

34 (3) If the committee [*determines that it*] lacks current clinical or treatment expertise with respect
35 to a particular therapeutic class, or at the request of an interested outside party, the director shall
36 appoint one or more medical experts otherwise qualified as described in subsection (2)(a) of this
37 section who have such expertise. **A medical expert who is appointed at the request of an in-**
38 **terested outside party shall be in addition to any medical expert appointed at the committee's**
39 **request.** The medical experts shall have full voting rights with respect to recommendations made
40 under ORS 414.361 (3) and (4). The medical experts may participate **in meetings** but may not vote
41 [*in*] **on** any other activities of the committee.

42 (4) **A member of the committee or of an advisory committee shall declare a conflict of**
43 **interest if the member has a public or professional stake in any matter before the committee**
44 **or advisory committee, such as a published article regarding the matter, having renown with**
45 **respect to the matter or receiving compensation directly or indirectly connected with the**

1 **matter. In addition, a member must abstain from voting on any matter that may impact the**
 2 **compensation, reimbursement, financial standing or performance of the member or the**
 3 **member's employer.**

4 [(4)] (5) The director shall fill a vacancy on the committee by appointing a new member to serve
 5 the remainder of the unexpired term.

6 **SECTION 5.** ORS 414.354 is amended to read:

7 414.354. (1) Except as provided in ORS 414.356, the Pharmacy and Therapeutics Committee shall
 8 operate in accordance with ORS chapter 192. The committee shall annually elect a chairperson from
 9 the members of the committee.

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

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

14 (4) The committee may establish advisory committees to assist in carrying out the committee's
 15 duties under ORS 414.351 to 414.414, with the approval of the Director of the Oregon Health Au-
 16 thority. **Advisory committees are subject to the requirements in subsections (6) and (7) of this**
 17 **section and members may not serve for more than two consecutive years.**

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

19 (6) The committee shall meet no less than four times each year at a place, day and hour deter-
 20 mined by the director. The committee also shall meet at other times and places specified by the call
 21 of the director or a majority of the members of the committee. No less than [30] **45** days prior to a
 22 meeting the committee shall post to the [authority] **authority's website and to the website of the**
 23 **committee:**

24 (a) The agenda for the meeting;

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

26 (c) Background materials and supporting documentation provided to committee members with
 27 respect to drugs and drug classes that are before the committee for review.

28 (7) The committee shall provide appropriate opportunity for public testimony at each regularly
 29 scheduled committee meeting. Immediately prior to deliberating on any recommendations regarding
 30 a drug or a class of drugs, the committee shall accept testimony, in writing or in person, that is
 31 offered by a manufacturer of those drugs or another interested party. **The committee shall provide**
 32 **each witness with a meaningful opportunity to testify. The committee may not impose word**
 33 **limits on written testimony and, if a witness is given a time limit, questions from the com-**
 34 **mittee members may not count against the witness's time limit.**

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

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

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

39 **SECTION 6.** ORS 414.361 is amended to read:

40 414.361. (1) The Pharmacy and Therapeutics Committee shall advise the Oregon Health Author-
 41 ity on:

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

43 (b) Implementation of the medical assistance program retrospective and prospective programs
 44 as described in ORS 414.351 to 414.414, including the type of software programs to be used by the
 45 pharmacist for prospective drug use review and the provisions of the contractual agreement between

1 the state and any entity involved in the retrospective program.

2 (c) Development of and application of the criteria and standards to be used in retrospective and
 3 prospective drug use review in a manner that ensures that such criteria and standards are based
 4 on compendia, relevant guidelines obtained from professional groups through consensus-driven pro-
 5 cesses, the experience of practitioners with expertise in drug therapy, data and experience obtained
 6 from drug utilization review program operations. The committee shall have an open professional
 7 consensus process for establishing and revising criteria and standards. Criteria and standards shall
 8 be available to the public. In developing recommendations for criteria and standards, the committee
 9 shall establish an explicit ongoing process for soliciting and considering input from interested par-
 10 ties. The committee shall make timely revisions to the criteria and standards based upon this input
 11 in addition to revisions based upon scheduled review of the criteria and standards. Further, the drug
 12 utilization review standards shall reflect the local practices of prescribers in order to monitor:

13 (A) Therapeutic appropriateness.

14 (B) Overutilization or underutilization.

15 (C) Therapeutic duplication.

16 (D) Drug-disease contraindications.

17 (E) Drug-drug interactions.

18 (F) Incorrect drug dosage or drug treatment duration.

19 (G) Clinical abuse or misuse.

20 (H) Drug allergies.

21 (d) Development, selection and application of and assessment for interventions that are educa-
 22 tional and not punitive in nature for medical assistance program prescribers, dispensers and pa-
 23 tients.

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

26 (3) The committee shall make recommendations to the authority, subject to approval by the Di-
 27 rector of the Oregon Health Authority or the director's designee, for drugs to be included on any
 28 preferred drug list adopted by the authority and on the Practitioner-Managed Prescription Drug
 29 Plan. The committee shall also recommend all utilization controls, prior authorization requirements
 30 or other conditions for the coverage of a drug.

31 (4) In making recommendations under subsection (3) of this section, the committee may use any
 32 information the committee deems appropriate, **subject to ORS 414.701**. The recommendations must
 33 be based upon the following factors in order of priority:

34 (a) Safety and efficacy of the drug.

35 (b) The ability of Oregonians to access effective prescription drugs that are appropriate for their
 36 clinical conditions.

37 (c) Substantial differences in the costs of drugs within the same therapeutic class.

38 *[(5)(a) No later than seven days after the date on which the committee makes a recommendation*
 39 *under subsection (3) of this section, the committee shall publish the recommendation on the website of*
 40 *the authority.]*

41 *[(b) As soon as practicable after the committee makes a recommendation, the director shall decide*
 42 *whether to approve, disapprove or modify the recommendation, shall publish the decision on the website*
 43 *and shall notify persons who have requested notification of the decision.]*

44 *[(c) Except as provided in subsection (6) of this section, a recommendation approved by the director,*
 45 *in whole or in part, with respect to the inclusion of a drug on a preferred drug list or the*

1 *Practitioner-Managed Prescription Drug Plan may not become effective less than seven days after the*
 2 *date that the director's decision is published on the website.]*

3 *[(6)(a) The director may allow the immediate implementation of a recommendation described in*
 4 *subsection (5)(c) of this section if the director determines that immediate implementation is necessary*
 5 *to protect patient safety or to comply with state or federal requirements.]*

6 *[(b) The director shall reconsider any decision to approve, disapprove or modify a recommendation*
 7 *described in subsection (5)(c) of this section upon the request of any interested person filed no later than*
 8 *seven days after the director's decision is published on the website of the authority. The director's de-*
 9 *termination regarding the request for reconsideration shall be sent to the requester and posted to the*
 10 *website without undue delay. Upon receipt of a request for reconsideration, the director may:]*

11 *[(A) Delay the implementation of the recommendation pending the reconsideration process; or]*

12 *[(B) Implement the recommendation if the director determines that delay could reasonably result*
 13 *in harm to patient safety or would violate state or federal requirements.]*

14 **(5) The committee shall post a recommendation to the website of the authority no later**
 15 **than 30 days after the date the committee approves the recommendation. The director shall**
 16 **approve, disapprove or modify any recommendation of the committee by rule. A rule adopted**
 17 **by the director approving or modifying any recommendation of the committee, in whole or**
 18 **in part, with respect to the inclusion of a drug on a preferred drug list or the Practitioner-**
 19 **Managed Prescription Drug Plan may not become effective less than 30 days after the date**
 20 **that the final rule is published.**

21 **(6) The director shall reconsider any rule adopting or modifying a recommendation of the**
 22 **committee with respect to the inclusion of a particular drug on a preferred drug list or the**
 23 **Practitioner-Managed Prescription Drug Plan, upon the request of any interested person filed**
 24 **no later than 30 days after the final rule is published on the website. Any amendments to a**
 25 **rule adopting or modifying the recommendation of the committee must be in accordance with**
 26 **ORS chapter 183.**

27 **(7) The authority shall appoint an advisory committee as described in ORS 183.333 (7) for**
 28 **the adoption of rules under subsections (1)(a), (5) and (6) of this section.**

29 **SECTION 7.** ORS 414.688 is amended to read:

30 414.688. (1) As used in this section:

31 (a) "Practice of pharmacy" has the meaning given that term in ORS 689.005.

32 (b) "Retail drug outlet" has the meaning given that term in ORS 689.005.

33 (2) The Health Evidence Review Commission is established in the Oregon Health Authority,
 34 consisting of 13 members appointed by the Governor in consultation with professional and other
 35 interested organizations, and confirmed by the Senate, as follows:

36 (a) Five members must be physicians licensed to practice medicine in this state who have clin-
 37 ical expertise in the areas of family medicine, internal medicine, obstetrics, perinatal health,
 38 pediatrics, disabilities, geriatrics or general surgery. One of the physicians must be a doctor of
 39 osteopathic medicine, and one must be a hospital representative or a physician whose practice is
 40 significantly hospital-based.

41 (b) One member must be a dentist licensed under ORS chapter 679 who has clinical expertise
 42 in general, pediatric or public health dentistry.

43 (c) One member must be a public health nurse.

44 (d) One member must be a behavioral health representative who may be a social services
 45 worker, alcohol and drug treatment provider, psychologist or psychiatrist.

1 (e) Two members must be consumers of health care who are patient advocates or represent the
2 areas of indigent services, labor, business, education or corrections.

3 (f) One member must be a complementary or alternative medicine provider who is a chiropractic
4 physician licensed under ORS chapter 684, a naturopathic physician licensed under ORS chapter 685
5 or an acupuncturist licensed under ORS chapter 677.

6 (g) One member must be an insurance industry representative who may be a medical director
7 or other administrator.

8 (h) One member must be a pharmacy representative who engages in the practice of pharmacy
9 at a retail drug outlet.

10 (3) No more than six members of the commission may be physicians either in active practice or
11 retired from practice.

12 (4) Members of the commission serve for a term of *[four]* **two** years at the pleasure of the Gov-
13 ernor. A member is eligible for reappointment.

14 (5) Members are not entitled to compensation, but may be reimbursed for actual and necessary
15 travel and other expenses incurred by them in the performance of their official duties in the manner
16 and amounts provided for in ORS 292.495. Claims for expenses shall be paid out of funds available
17 to the Oregon Health Authority for purposes of the commission.

18 **SECTION 8.** ORS 414.689 is amended to read:

19 414.689. (1) The Health Evidence Review Commission shall select one of its members as chair-
20 person and another as vice chairperson, for terms and with duties and powers the commission de-
21 termines necessary for the performance of the functions of the offices.

22 (2) A majority of the members of the commission constitutes a quorum for the transaction of
23 business.

24 (3) The commission shall meet at least four times per year at a place, day and hour determined
25 by the chairperson. The commission also shall meet at other times and places specified by the call
26 of the chairperson or of a majority of the members of the commission. **The commission shall pro-
27 vide an opportunity for public testimony, in writing and in person, at each regularly sched-
28 uled meeting of the commission. The commission shall provide each witness with a
29 meaningful opportunity to testify. The commission may not impose word limits on written
30 testimony and, if a witness is given a time limit, questions from the commission members
31 may not count against the witness's time limit.**

32 (4) The commission *[may use advisory committees or subcommittees whose]***shall consult with an
33 advisory committee in making coverage or guidance determinations, including determining
34 priorities for mental health care and chemical dependency. The members of advisory com-
35 mittees** are appointed by the chairperson of the commission subject to approval by a majority of
36 the members of the commission. The advisory committees or subcommittees may contain experts
37 appointed by the chairperson and a majority of the members of the commission. The conditions of
38 service of the experts will be determined by the chairperson and a majority of the members of the
39 commission. **Advisory committees are subject to the requirements in ORS 414.690 (2) and (3)
40 and of this section, and members may not serve for more than two consecutive years.**

41 (5) **If the commission or an advisory committee lacks current clinical or treatment ex-
42 pertise with respect to an issue, technology, treatment or procedure under consideration,
43 or at the request of an interested outside party, the chairperson shall appoint one or more
44 medical experts who have the required expertise. A medical expert who is appointed at the
45 request of an interested outside party shall be in addition to medical experts appointed at the**

1 **commission's request. The medical experts shall have full voting rights with respect to rec-**
 2 **ommendations on topics for which they were appointed. The medical experts may participate**
 3 **in meetings but may not vote on other topics addressed by the commission.**

4 **(6) A member of the commission or of an advisory committee shall declare a conflict of**
 5 **interest if the member has a public or professional stake in any matter before the commis-**
 6 **sion or advisory committee, such as a published article regarding the matter, having renown**
 7 **with respect to the matter or receiving compensation directly or indirectly connected with**
 8 **the matter. In addition, a member must abstain from voting on any matter that may impact**
 9 **the compensation, reimbursement, financial standing or performance of the member or the**
 10 **member's employer.**

11 **(7) In rulemaking conducted under ORS 414.690 and 414.695, the commission shall appoint**
 12 **an advisory committee in accordance with ORS 183.333 (7), which may not include any**
 13 **member of the commission or of any other advisory committee.**

14 [(5)] (8) The Oregon Health Authority shall provide staff and support services to the commission.

15 **SECTION 9.** ORS 414.690 is amended to read:

16 414.690. (1) The Health Evidence Review Commission shall regularly solicit **and provide**
 17 **meaningful opportunity for** testimony and information from stakeholders representing consumers,
 18 advocates, providers, carriers and employers in conducting the work of the commission.

19 **(2) No less than 45 days prior to a meeting, the Oregon Health Authority shall post to**
 20 **the authority's website and to the website of the commission:**

21 **(a) The agenda for the meeting; and**

22 **(b) A list of all recommendations before the commission for review, including, but not**
 23 **limited to:**

24 **(A) A drug or drug class review;**

25 **(B) A technology review; and**

26 **(C) Coverage guidance.**

27 [(2)] (3) The commission shall actively solicit public involvement through a public meeting pro-
 28 cess to guide health resource allocation decisions, **in which the public is invited to testify in**
 29 **writing and in person. The authority shall post to the commission's website and provide each**
 30 **commission member with the written comments received from the public no later than 48**
 31 **hours after the close of the public comment period.**

32 [(3)] (4) The commission shall [*develop and maintain*] **adopt by rule** a list of health services
 33 ranked by priority, from the most important to the least important, representing the comparative
 34 benefits of each service to the population to be served. The list must be submitted by the commission
 35 pursuant to subsection [(5)] (6) of this section and is not subject to alteration by any other state
 36 agency.

37 [(4)] (5) In order to encourage effective and efficient medical evaluation and treatment, the
 38 commission:

39 (a) May include clinical practice guidelines in its prioritized list of services. The commission
 40 shall actively solicit testimony and information from the medical community and the public to build
 41 a consensus on clinical practice guidelines developed by the commission.

42 (b) May include statements of intent in its prioritized list of services. Statements of intent should
 43 give direction on coverage decisions where medical codes and clinical practice guidelines cannot
 44 convey the intent of the commission.

45 (c) Shall consider both the clinical effectiveness and cost-effectiveness of health services, in-

1 cluding drug therapies, in determining their relative importance using peer-reviewed medical litera-
2 ture as defined in ORS 743A.060.

3 [(5)] (6) The commission shall report the prioritized list of services to the [*Oregon Health*] au-
4 thority for budget determinations by July 1 of each even-numbered year.

5 [(6)] (7) The commission shall make its report during each regular session of the Legislative
6 Assembly and shall submit a copy of its report to the Governor, the Speaker of the House of Rep-
7 resentatives and the President of the Senate.

8 [(7)] (8) The commission may alter the list, **through rulemaking**, during the interim only as
9 follows:

10 (a) To make technical changes to correct errors and omissions;

11 (b) To accommodate changes due to advancements in medical technology or new data regarding
12 health outcomes;

13 (c) To accommodate changes to clinical practice guidelines; and

14 (d) To add statements of intent that clarify the prioritized list.

15 [(8)] (9) If a service is deleted or added during an interim and no new funding is required, the
16 commission shall report to the Speaker of the House of Representatives and the President of the
17 Senate. However, if a service to be added requires increased funding to avoid discontinuing another
18 service, the commission shall report to the Emergency Board to request the funding.

19 [(9)] (10) The prioritized list of services remains in effect for a two-year period beginning no
20 earlier than October 1 of each odd-numbered year.

21 **(11) In addition to rulemaking procedures required by ORS chapter 183, the commission**
22 **shall post to the authority's website the proposed rules containing the list of ranked health**
23 **services, clinical practice guidelines, statements of intent adopted by the commission and its**
24 **report under subsection (6) of this section. The posting shall solicit public comment on the**
25 **rules. No later than 48 hours after the close of the public comment period, the authority**
26 **shall post to the website and provide each member of the commission the public comments**
27 **received. The final rules may not take effect until at least 30 days after the final rules are**
28 **published.**

29 **SECTION 10.** ORS 414.695 is amended to read:

30 414.695. (1) As used in this section and ORS 414.698:

31 (a)(A) "Medical technology" means medical equipment and devices, medical or surgical proce-
32 dures and techniques used by health care providers in delivering medical care to individuals, and
33 the organizational or supportive systems within which medical care is delivered.

34 **(B) "Medical technology" does not include a prescription drug or a prescription drug de-**
35 **livery device that is filled with a prescription drug at the point of sale.**

36 (b) "Medical technology assessment" means evaluation of the use, clinical effectiveness and cost
37 of a technology in comparison with its alternatives.

38 (2) The Health Evidence Review Commission shall develop a medical technology assessment
39 process. The Oregon Health Authority shall direct the commission with regard to medical technol-
40 ogies to be assessed and the timing of the assessments.

41 (3) The commission shall appoint and work with an advisory committee whose members have the
42 appropriate expertise to conduct a medical technology assessment.

43 (4) The commission shall present its preliminary findings at a public hearing and shall solicit
44 testimony and information from health care consumers. The commission shall give strong consider-
45 ation to the recommendations of the advisory committee and public testimony in developing its as-

1 sessment.

2 **(5) The commission shall adopt final recommendations by rule, in accordance with ORS**
 3 **chapter 183 and ORS 414.690 (11).**

4 ~~[(5)]~~ **(6)** To ensure that confidentiality is maintained, identification of a patient or a person li-
 5 censed to provide health services may not be included with the data submitted under this section,
 6 and the commission shall release such data only in aggregate statistical form. All findings and con-
 7 clusions, interviews, reports, studies, communications and statements procured by or furnished to
 8 the commission in connection with obtaining the data necessary to perform its functions is confi-
 9 dential pursuant to ORS 192.338, 192.345 and 192.355.

10 **SECTION 11.** ORS 414.698 is amended to read:

11 414.698. (1) The Health Evidence Review Commission shall conduct comparative effectiveness
 12 research of medical technologies selected in accordance with ORS 414.695. The commission may
 13 conduct the research by comprehensive review of the comparative effectiveness research undertaken
 14 by recognized state, national or international entities. The commission may consider evidence re-
 15 lating to prescription drugs that is relevant to a medical technology assessment but may not conduct
 16 a drug **review, a drug** class evidence review or medical technology assessment [*solely*] of a pre-
 17 scription drug **that has been approved by the United States Food and Drug Administration.**
 18 The commission shall disseminate the research findings to health care consumers, providers and
 19 third-party payers and to other interested stakeholders.

20 (2) The commission shall develop or identify and shall disseminate evidence-based health care
 21 guidelines for use by providers, consumers and purchasers of health care in Oregon.

22 (3) The Oregon Health Authority shall vigorously pursue health care purchasing strategies that
 23 adopt the research findings described in subsection (1) of this section and the evidence-based health
 24 care guidelines described in subsection (2) of this section.

25 **SECTION 12.** ORS 414.701 is amended to read:

26 414.701. (1) **The Legislative Assembly finds that randomized controlled trials for therapies,**
 27 **treatments and medical interventions provide valuable insight into clinical efficacy, but the**
 28 **inclusion and exclusion of specific criteria, by design, often limit the enrollment in the trials**
 29 **of a significant percentage of patients with certain diseases despite the unmet medical needs**
 30 **of such patients. In light of the significant advances in precision medicine, clinicians can**
 31 **leverage a host of phenotypic, molecular and genetic data to guide treatment decisions. In**
 32 **certain clinical situations, including but not limited to identification of rare disease**
 33 **mutations or combinations of mutations, testing the efficacy of a treatment with a tradi-**
 34 **tional randomized controlled trial may be impossible or unethical.**

35 (2) The Health Evidence Review Commission, in ranking health services or developing guide-
 36 lines under ORS 414.690 or in assessing medical technologies under ORS 414.698, and the Pharmacy
 37 and Therapeutics Committee, in considering a recommendation for a drug to be included on any
 38 preferred drug list or on the Practitioner-Managed Prescription Drug Plan[,]:

39 **(a) Shall utilize well-designed, rigorous observational research studies in instances in**
 40 **which data from a randomized controlled trial does not exist or is insufficient, including but**
 41 **not limited to certain head-to-head comparisons or analyses of long term safety and adher-**
 42 **ence to medication regimens;**

43 **(b) May not rely solely on the results of comparative effectiveness research; and**

44 **(c) Shall implement distinct and appropriate processes for the evaluation of individualized**
 45 **treatment for patients who have a disease or condition that affects fewer than 200,000 people**

1 **in the United States.**

2 **SECTION 13. The amendments to ORS 414.325 by section 2 of this 2021 Act become op-**
3 **erative on January 1, 2026.**

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