House Bill 2499

Sponsored by Representative NOSSE (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 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 commission 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

Relating to services paid for by medical assistance; amending ORS 414.353, 414.354, 414.361, 414.605, 414.688, 414.689, 414.690, 414.695, 414.698 and 414.701.

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

SECTION 1. ORS 414.353 is amended to read:

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

(2) The Director of the Oregon Health Authority shall appoint the members of the committee, who shall serve at the pleasure of the director for a term of three years. An individual appointed to the committee may be reappointed upon completion of the individual's term **but may not serve more than two consecutive terms**. The membership of the committee shall be composed of the following:

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

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

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

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

(4) A member of the committee or of an advisory committee shall declare a conflict 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.

interest if the member has a public or professional stake in any matter before the committee or advisory committee, such as having published an article regarding the matter or receiving compensation directly or indirectly connected with the matter. In addition, a member must abstain from voting on any matter that may impact the compensation, reimbursement, financial standing or performance of the member or the member's employer.

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

SECTION 2. 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. **Advisory committees are subject to the requirements in subsections (6) and (7) of this section and members may not serve for more than two consecutive years.**

(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 other times and places specified by the call of the director or a majority of the members of the committee. No less than [*30*] **45** days prior to a meeting the committee shall post to the [*authority*] **authority's** website **and to the website of the committee**:

(a) The agenda for the meeting;

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

(c) Background materials and supporting documentation provided to committee members with respect to drugs and drug classes that are before the committee for review**, including, if requested by the manufacturer, materials related to a drug or a class of drugs that are supplied by a witness**.

(7)**(a)** The committee shall provide appropriate opportunity for public testimony at each regularly scheduled committee meeting. Immediately prior to deliberating on any recommendations 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. **The committee shall provide each witness with a meaningful opportunity to testify. The committee may not impose word limits on written testimony and, if a witness is given a time limit, questions from the committee members may not count against the witness's time limit.**

(b) When considering the addition or restriction of a newly approved drug or class of drugs, the committee shall make reasonable efforts to proactively solicit and consider testimony from patients afflicted by the disease or condition for which the drug or class of drugs is prescribed.

(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.

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)**(a)** 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 coverage of a drug.

(b) The committee shall annually review and discuss drugs and classes of drugs that have been made subject to utilization controls or other measures that create barriers to physicians prescribing the drugs or drug classes. The committee shall permit public input and shall review access barriers to determine whether the positions of the drugs on the Practitioner-Managed Prescription Drug Plan should be changed based on new evidence or patient needs.

(4) In making recommendations under subsection (3) of this section, the committee may use any

information the committee deems appropriate**, subject to ORS 414.701**. The recommendations must be based upon the following factors in order of priority:

(a) Safety and efficacy of the drug.

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

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

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

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

[*(c) Except as provided in subsection (6) of this section, a recommendation approved 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 seven days after the date that the director's decision is published on the website.*]

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

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

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

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

(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 by rule. A rule adopted by the director approving, disapproving or modifying any recommendation of the committee, 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 30 days after the date that the final rule is published.

(6) The director shall reconsider any rule approving, disapproving or modifying 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 final rule is published on the website. Any amendments to a rule approving, disapproving or modifying the recommendation of the committee must be in accordance with ORS chapter 183.

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

SECTION 4. ORS 414.361, as amended by section 4, chapter 628, Oregon Laws 2021, is amended to read:

414.361. (1) The Pharmacy and Therapeutics Committee shall advise the Oregon Health Author-

ity 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)**(a)** 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 coverage of a drug.

(b) The committee shall annually review and discuss drugs and classes of drugs that have been made subject to utilization controls or other measures that create barriers to physicians prescribing the drugs or drug classes. The committee shall permit public input and shall review access barriers to determine whether the positions of the drugs on the Practitioner-Managed Prescription Drug Plan should be changed based on new evidence or patient needs.

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

(a) Safety and efficacy of the drug.

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

(c) For mental health drugs, the recommendations of the Mental Health Clinical Advisory Group.

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

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

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

[*(c) Except as provided in subsection (6) of this section, a recommendation approved 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 seven days after the date that the director's decision is published on the website.*]

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

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

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

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

(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 by rule. A rule adopted by the director approving, disapproving or modifying any recommendation of the committee, 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 30 days after the date that the final rule is published.

(6) The director shall reconsider any rule approving, disapproving or modifying 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 final rule is published on the website. Any amendments to a rule approving, disapproving or modifying the recommendation of the committee must be in accordance with ORS chapter 183.

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

SECTION 5. ORS 414.605 is amended to read:

414.605. (1) The Oregon Health Authority shall adopt by rule safeguards for members enrolled in coordinated care organizations that protect against underutilization of services and inappropriate denials of services. In addition to any other consumer rights and responsibilities established by law, each member:

(a) Must be encouraged to be an active partner in directing the member's health care and services and not a passive recipient of care.

(b) Must be educated about the coordinated care approach being used in the community, including the approach to addressing behavioral health care, and provided with any assistance needed regarding how to navigate the coordinated health care system.

(c) Must have access to advocates, including qualified peer wellness specialists, peer support specialists, personal health navigators, and qualified community health workers who are part of the member's care team to provide assistance that is culturally and linguistically appropriate to the member's need to access appropriate services and participate in processes affecting the member's care and services.

(d) Shall be encouraged within all aspects of the integrated and coordinated health care delivery system to use wellness and prevention resources and to make healthy lifestyle choices.

(e) Shall be encouraged to work with the member's care team, including providers and community resources appropriate to the member's needs as a whole person.

(f) Shall have access to all pharmaceutical treatments and technologies that are available to medical assistance recipients who are not members of coordinated care organizations, under the conditions established by the Health Evidence Review Commission or the Pharmacy and Therapeutics Committee, unless a coordinated care organization has established a process that, at a minimum, complies with the process and procedures applicable to the commission and the committee.

(2) The authority shall establish and maintain an enrollment process for individuals who are dually eligible for Medicare and Medicaid that promotes continuity of care and that allows the member to disenroll from a coordinated care organization that fails to promptly provide adequate services and:

(a) To enroll in another coordinated care organization of the member's choice; or

(b) If another organization is not available, to receive Medicare-covered services on a fee-for-service basis.

(3) Members and their providers and coordinated care organizations have the right to appeal decisions about care and services through the authority in an expedited manner and in accordance with the contested case procedures in ORS chapter 183.

(4) A health care entity may not unreasonably refuse to contract with an organization seeking to form a coordinated care organization if the participation of the entity is necessary for the organization to qualify as a coordinated care organization.

(5) A health care entity may refuse to contract with a coordinated care organization if the reimbursement established for a service provided by the entity under the contract is below the reasonable cost to the entity for providing the service.

(6) A health care entity that unreasonably refuses to contract with a coordinated care organization may not receive fee-for-service reimbursement from the authority for services that are available through a coordinated care organization either directly or by contract.

(7)(a) The authority shall adopt by rule a process for resolving disputes involving:

(A) A health care entity's refusal to contract with a coordinated care organization under subsections (4) and (5) of this section.

(B) The termination, extension or renewal of a health care entity's contract with a coordinated care organization.

(b) The processes adopted under this subsection must include the use of an independent third

party arbitrator.

(8) A coordinated care organization may not unreasonably refuse to contract with a licensed health care provider.

(9) The authority shall:

(a) Monitor and enforce consumer rights and protections within the Oregon Integrated and Coordinated Health Care Delivery System and ensure a consistent response to complaints of violations of consumer rights or protections.

(b) Monitor and report on the statewide health care expenditures and recommend actions appropriate and necessary to contain the growth in health care costs incurred by all sectors of the system.

SECTION 6. ORS 414.688 is amended to read:

414.688. (1) As used in this section:

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

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

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

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

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

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

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

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

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

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

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

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

(4) Members of the commission serve for a term of [*four*] **two** years at the pleasure of the Governor. A member is eligible for reappointment **but may not serve more than two consecutive terms**.

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

SECTION 7. ORS 414.689 is amended to read:

414.689. (1) The Health Evidence Review Commission shall select one of its members as chairperson and another as vice chairperson, for terms and with duties and powers the commission determines necessary for the performance of the functions of the offices.

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

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

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

(5) If the commission or an advisory committee lacks current clinical or treatment expertise with respect to an issue, technology, treatment or procedure under consideration, or at the request of an interested outside party, the chairperson shall appoint one or more medical experts who have the required expertise. A medical expert who is appointed at the request of an interested outside party shall be in addition to medical experts appointed at the commission's request. The medical experts shall have full voting rights with respect to recommendations on topics for which they were appointed. The medical experts may participate in meetings but may not vote on other topics addressed by the commission.

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

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

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

SECTION 8. ORS 414.690 is amended to read:

414.690. (1) The Health Evidence Review Commission shall regularly solicit **and provide meaningful opportunity for** testimony and information from stakeholders representing consumers,

advocates, providers, carriers and employers in conducting the work of the commission.

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

(a) The agenda for the meeting; and

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

(A) A drug or drug class review;

(B) A technology review; and

(C) Coverage guidance.

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

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

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

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

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

(c) Shall consider both the clinical effectiveness and cost-effectiveness of health services, including drug therapies, in determining their relative importance using peer-reviewed medical literature as defined in ORS 743A.060.

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

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

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

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

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

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

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

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

service, the commission shall report to the Emergency Board to request the funding.

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

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

SECTION 9. ORS 414.695 is amended to read:

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

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

(B) "Medical technology" does not include a prescription drug or a prescription drug delivery device that is filled with a prescription drug at the point of sale.

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

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

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

(4) The commission shall present its preliminary findings at a public hearing and shall solicit testimony and information from health care consumers. The commission shall give strong consideration to the recommendations of the advisory committee and public testimony in developing its assessment.

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

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

SECTION 10. ORS 414.698 is amended to read:

414.698. (1) The Health Evidence Review Commission shall conduct comparative effectiveness research of medical technologies selected in accordance with ORS 414.695. The commission may conduct the research by comprehensive review of the comparative effectiveness research undertaken by recognized state, national or international entities. The commission may consider evidence relating to prescription drugs that is relevant to a medical technology assessment but may not conduct a drug **review, a drug** class evidence review or medical technology assessment [*solely*] of a prescription drug **that has been approved by the United States Food and Drug Administration**.

The commission shall disseminate the research findings to health care consumers, providers and third-party payers and to other interested stakeholders.

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

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

SECTION 11. ORS 414.701 is amended to read:

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

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

(a) Shall, in instances in which data from a randomized controlled trial does not exist or is insufficient, consider the totality of available evidence and utilize any relevant, well-designed, rigorous, peer-reviewed research including but not limited to observational research studies, research studies using real-world data, research studies used to inform national clinical guidelines or other research studies accepted by the United States Food and Drug Administration;

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

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

(3) As used in subsection (2) of this section, "real-world data" means data relating to patient health status or the delivery of health care that is routinely collected from a variety of sources, including but not limited to electronic health records, medical claims data, product or disease registries, patient-generated data or data gathered from other sources such as mobile devices.