SB 457-1
(LC 3253)
2/3/21 (LHF/ps)

Requested by Senator KNOPP

PROPOSED AMENDMENTS TO
SENATE BILL 457

On page 1 of the printed bill, line 2, delete "creating new provisions; and".

In line 3, delete "414.325, 414.334," and after "414.361," insert "414.605,".

Delete lines 6 through 28 and delete pages 2 through 5.

On page 6, delete lines 1 through 18.

In line 19, delete "4" and insert "1".

In line 25, after "term" insert "but may not serve more than two consecutive terms".

In line 44, delete ", having renown with".

In line 45, delete "respect to the matter".

On page 7, line 6, delete "5" and insert "2".

In line 27, after "review" insert ", including, if requested by the manufacturer, materials related to a drug or a class of drugs that are supplied by a witness".

In line 28, after "(7)" insert "(a)".

After line 34, insert:

"(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.".

After line 38, insert:

"(9) 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.".

In line 39, delete "6" and insert "3".

On page 9, after line 28, insert:

"SECTION 4. 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 pro-

viding 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.".

In line 29, delete "7" and insert "5".

On page 10, line 13, after "reappointment" insert "but may not serve more than two consecutive terms".

In line 18, delete "8" and insert "6".

On page 11, line 15, delete "9" and insert "7".

On page 12, line 29, delete "10" and insert "8".

On page 13, line 10, delete "11" and insert "9".

Delete lines 25 through 45 and delete page 14 and insert:

"SECTION 10. 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.**".