SECOND REGULAR SESSION

SENATE BILL NO. 1795

103RD GENERAL ASSEMBLY

INTRODUCED BY SENATOR WEBBER.

7393S.01I KRISTINA MARTIN, Secretary

AN ACT

To amend chapters 208 and 376, RSMo, by adding thereto three new sections relating to biomarker testing.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Chapters 208 and 376, RSMo, are amended by adding thereto three new sections, to be known as sections 208.1450, 376.1194, and 376.1195, to read as follows:

208.1450. 1. The MO HealthNet program shall cover biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a participant's disease or condition to guide treatment decisions when the test provides clinical utility to the patient as demonstrated by medical and scientific evidence, including, but not limited to:

(1) Labeled indications for a test approved or cleared by the U.S. Food and Drug Administration (FDA) or indicated tests for an FDA approved drug;

(2) Centers for Medicare and Medicaid Services national coverage determinations or Medicare administrative contractor local coverage determinations; or

(3) Nationally recognized clinical practice guidelines.

2. MO HealthNet managed care organizations contracted to deliver services to participants shall provide biomarker

testing at the same scope, duration, and frequency as MO HealthNet otherwise provides to participants.

3. Nothing in this section shall be construed to require coverage of biomarker testing for screening purposes.

4. As used in this section, the following terms shall mean:

(1) "Biomarker", a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. A biomarker is not an assessment of how a patient feels, functions, or survives;

(2) "Biomarker testing", the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests and multi-plex panel tests performed at a participating in-network laboratory facility that is either CLIA certified or CLIA waived by the federal Food and Drug Administration.

376.1194. For purposes of this section and section 376.1195, the following terms shall mean:

(1) "Biomarker", a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. A biomarker is not an assessment of how a patient feels, functions, or survives;

(2) "Biomarker testing", the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes, but is not limited

to, single-analyte tests and multi-plex panel tests performed at a participating in-network laboratory facility that is either CLIA certified or CLIA waived by the U.S. Food and Drug Administration;

(3) "Clinical utility", the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision;

(4) "Nationally recognized clinical practice guidelines", evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

376.1195. 1. Health insurers, nonprofit health service plans, and health maintenance organizations issuing, amending, delivering, or renewing a health insurance contract on or after August 28, 2026, shall include coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition to guide treatment decisions when the test provides clinical utility to the patient as demonstrated by medical and scientific evidence, including, but not limited to:

(1) Labeled indications for a test approved or cleared by the U.S. Food and Drug Administration or indicated tests for an FDA approved drug;

(2) Centers for Medicare and Medicaid Services national coverage determinations or Medicare administrative contractor local coverage determinations; or

(3) Nationally recognized clinical practice guidelines.

2. Such coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

3. The patient and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of this section. Such process shall be made readily accessible on the health insurer's, nonprofit health service plan's, or health maintenance organization's website.

4. Nothing in this section shall be construed to require coverage of biomarker testing for screening purposes.

5. The department of commerce and insurance shall adopt rules as necessary to effectuate the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2026, shall be invalid and void.

✓