ENGROSSED SENATE
BILL NO. 513

By: Rosino and Garvin of the Senate

and

Miller, Fugate, and Stinson of the House

An Act relating to biomarker testing; defining terms; requiring coverage of biomarker testing under certain conditions; requiring certain contract to be provided with policy; directing plan to limit disruptions in care with certain evidence; requiring plan to publish accessible process on certain website for certain requests; construing provision; amending 56 O.S. 2021, Section 4002.6, as amended by Section 10, Chapter 395, O.S.L. 2022 (56 O.S. Supp. 2022, Section 4002.6), which relates to the state Medicaid program; clarifying certain prior authorization requirement; updating statutory language; defining terms; requiring certain coverage and provision of biomarker testing; stipulating prior authorization requirements for biomarker testing; directing creation of process to request exceptions to certain coverage policies; providing for codification; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 6060.5a of Title 36, unless there is created a duplication in numbering, reads as follows:

A. As used in this section:

1. "Biomarker" means a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal

process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition or for other purposes. Biomarkers shall include but are not limited to gene mutation or protein expression;

2. "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing shall include but not be limited to single-analyte tests, multiplex panel tests, gene or protein expression, and whole exome, whole genome, and whole transcriptome sequencing;

3. "Consensus statement" means a statement that:

a. is developed by an independent, multidisciplinary panel of experts that use a transparent methodology and reporting structure that includes a conflict of interest policy,

b. is based on the best available evidence for the purpose of optimizing clinical care outcomes, and

c. is aimed at specific clinical circumstances;

4. "Health benefit plan" means a plan as defined pursuant to Section 6060.4 of Title 36 of the Oklahoma Statutes; and

5. "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that:

a. are developed by independent organizations or medical professional societies using a transparent methodology

and reporting structure and a conflict of interest policy, and

b. establish standards of care that are informed by a systemic review of evidence and an assessment of the benefits and costs of alternative care options that includes recommendations intended to optimize patient care.

B. Any health benefit plan, including the Oklahoma Employees Insurance Plan, that is offered, issued, or renewed in this state on or after the effective date of this act shall provide coverage for biomarker testing. A contract provided with a health benefit plan under this section shall include biomarker testing for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured's disease or condition to guide treatment decisions when the biomarker test is supported by medical and scientific evidence including, but not limited to:

1. Labeled indications for tests that are approved or cleared by the United States Food and Drug Administration;

2. Indicated tests for a drug that is approved by the United States Food and Drug Administration;

3. Warnings and precautions on United States Food and Drug Administration approved drug labels;

4. Centers for Medicare and Medicaid Services national coverage determinations or Medicare administrative contractor local coverage determinations; or

5. Nationally recognized clinical practice guidelines and consensus statements.

C. A health benefit plan shall ensure that coverage is provided in a manner that limits disruptions in care, including the need for multiple biopsies and biospecimen samples.

D. An insured and a prescribing practitioner shall have access to a clear, readily available, and convenient process to request an exception to a coverage policy of a health benefit plan under this subsection. The process shall be readily accessible on the plan's website. This subsection shall not be construed to require a separate process if the health benefit plan's existing process complies with this subsection.

SECTION 2. AMENDATORY 56 O.S. 2021, Section 4002.6, as amended by Section 10, Chapter 395, O.S.L. 2022 (56 O.S. Supp. 2022, Section 4002.6), is amended to read as follows:

Section 4002.6. A. A contracted entity shall meet all requirements established by the Oklahoma Health Care Authority pertaining to prior authorizations. The Authority shall establish requirements that ensure timely determinations by contracted entities when prior authorizations are required including expedited

review in urgent and emergent cases that at a minimum meet the criteria of this section.

B. A contracted entity shall make a determination on a request for an authorization of the transfer of a hospital inpatient to a post-acute care or long-term acute care facility within twenty-four (24) hours of receipt of the request.

C. A contracted entity shall make a determination on a request for any member who is not hospitalized at the time of the request within seventy-two (72) hours of receipt of the request; provided, that if the request does not include sufficient or adequate documentation, the review and determination shall occur within a time frame and in accordance with a process established by the Authority. The process established by the Authority pursuant to this subsection shall include a time frame of at least forty-eight (48) hours within which a provider may submit the necessary documentation.

D. A contracted entity shall make a determination on a request for services for a hospitalized member including, but not limited to, acute care inpatient services or equipment necessary to discharge the member from an inpatient facility within one (1) business day of receipt of the request.

E. Notwithstanding the provisions of subsection C of this section, a contracted entity shall make a determination on a request as expeditiously as necessary and, in any event, within twenty-four

(24) hours of receipt of the request for service if adhering to the provisions of subsection C or D of this section could jeopardize the member's life, health or ability to attain, maintain or regain maximum function. In the event of a medically emergent matter, the contracted entity shall not impose limitations on providers in coordination of post-emergent stabilization health care including pre-certification or prior authorization.

F. Notwithstanding any other provision of this section, a contracted entity shall make a determination on a request for inpatient behavioral health services within twenty-four (24) hours of receipt of the request.

G. A contracted entity shall make a determination on a request for covered prescription drugs that are required to be prior authorized by the Authority within twenty-four (24) hours of receipt of the request. The contracted entity shall not require prior authorization on any covered prescription drug for which the Authority does not require prior authorization.

H. A contracted entity shall make a determination on a request for coverage of biomarker testing in accordance with Section 3 of this act.

I. Upon issuance of an adverse determination on a prior authorization request under subsection B of this section, the contracted entity shall provide the requesting provider, within seventy-two (72) hours of receipt of such issuance, with reasonable

opportunity to participate in a peer-to-peer review process with a provider who practices in the same specialty, but not necessarily the same sub-specialty, and who has experience treating the same population as the patient on whose behalf the request is submitted; provided, however, if the requesting provider determines the services to be clinically urgent, the contracted entity shall provide such opportunity within twenty-four (24) hours of receipt of such issuance. Services not covered under the state Medicaid program for the particular patient shall not be subject to peer-to-peer review.

~~I.~~ J. The Authority shall ensure that a provider offers to provide to ~~an enrollee~~ a member in a timely manner services authorized by a contracted entity.

~~J.~~ K. The Authority shall establish requirements for both internal and external reviews and appeals of adverse determinations on prior authorization requests or claims that, at a minimum:

1. Require contracted entities to provide a detailed explanation of denials to Medicaid providers and members;

2. Require contracted entities to provide a prompt opportunity for peer-to-peer conversations with licensed clinical staff of the same or similar specialty which shall include, but not be limited to, Oklahoma-licensed clinical staff upon adverse determination; and

3. Establish uniform rules for Medicaid provider or member appeals across all contracted entities.

SECTION 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 4003 of Title 56, unless there is created a duplication in numbering, reads as follows:

A. As used in this section:

1. "Biomarker", "biomarker testing", "consensus statement", and "nationally recognized clinical practice guidelines" shall have the same meaning as provided by Section 1 of this act; and

2. "Contracted entity" shall have the same meaning as provided by Section 4002.2 of Title 56 of the Oklahoma Statutes.

B. The state Medicaid program shall cover biomarker testing in accordance with the requirements provided by this section.

C. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a member's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

1. Labeled indications for a Food and Drug Administration (FDA)-approved or -cleared test;

2. Indicated tests for an FDA-approved drug;

3. Warnings and precautions on FDA-approved drug labels;

4. Centers for Medicare and Medicaid Services (CMS) national coverage determinations or Medicare Administrative Contractor (MAC) local coverage determinations; or

5. Nationally recognized clinical practice guidelines and consensus statements.

D. Contracted entities under the state Medicaid program shall provide biomarker testing at the same scope, duration, and frequency as the Medicaid program otherwise provides to members.

E. If prior authorization is required for biomarker testing, the contracted entity shall approve or deny a prior authorization request and notify the member, the member's provider, and any entity requesting authorization of the service within seventy-two (72) hours for non-urgent requests or within twenty-four (24) hours for urgent requests.

F. The member and the member's provider shall have access to clear, readily accessible, and convenient processes to request an exception to a coverage policy for biomarker testing of the state Medicaid program. The process shall be made readily accessible to all participating providers and members online.

SECTION 4. This act shall become effective January 1, 2024.

Passed the Senate the 6th day of March, 2023.

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Presiding Officer of the Senate

Passed the House of Representatives the ____ day of _____, 2023.

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Presiding Officer of the House of Representatives