

1 ENGROSSED HOUSE AMENDMENT

TO

2 ENGROSSED SENATE BILL NO. 513

By: Rosino and Garvin of the
Senate

3

and

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Miller, Fugate, and Stinson
of the House

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

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20 AUTHOR: Add the following House Coauthors: Sneed, Burns, Davis,
Newton, McEntire, Williams, Cantrell, McCall, Bennett,
21 Hilbert, Stark, Randleman, Marti, Roe, Tedford, Lowe
(Dick), Munson, Boles, Manger, Roberts, and Baker

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23 AMENDMENT NO. 1. Strike the title, enacting clause, and entire bill
and insert:

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1 "An Act relating to biomarker testing; defining
2 terms; requiring coverage of biomarker testing under
3 certain conditions; requiring certain contract to be
4 provided with policy; directing plan to limit
5 disruptions in care with certain evidence; requiring
6 plan to publish accessible process on certain website
7 for certain requests; construing provision; amending
8 56 O.S. 2021, Section 4002.6, as amended by Section
9 10, Chapter 395, O.S.L. 2022 (56 O.S. Supp. 2022,
10 Section 4002.6), which relates to the state Medicaid
11 program; clarifying certain prior authorization
12 requirement; updating statutory language; defining
13 terms; requiring certain coverage and provision of
14 biomarker testing; stipulating prior authorization
15 requirements for biomarker testing; directing
16 creation of process to request exceptions to certain
17 coverage policies; providing for codification; and
18 providing an effective date.

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

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

23 A. As used in this section:

24 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.

1 Biomarker testing shall include but not be limited to single-analyte
2 tests, multiplex panel tests, gene or protein expression, and whole
3 exome, whole genome, and whole transcriptome sequencing;

4 3. "Clinical utility" means the test result provides
5 information that is used in the formulation of a treatment or
6 monitoring strategy that informs a patient's outcome and impacts the
7 clinical decision. The most appropriate test may include both
8 information that is actionable and some information that cannot be
9 immediately used in the formulation of a clinical decision;

10 4. "Consensus statement" means a statement that:

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

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

17 c. is aimed at specific clinical circumstances;

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

20 6. "Nationally recognized clinical practice guidelines" means
21 evidence-based clinical practice guidelines that:

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

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1 and reporting structure and a conflict of interest
2 policy, and

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

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

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

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

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

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

4 5. Nationally recognized clinical practice guidelines and
5 consensus statements.

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

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

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

19 Section 4002.6 A. A contracted entity shall meet all
20 requirements established by the Oklahoma Health Care Authority
21 pertaining to prior authorizations. The Authority shall establish
22 requirements that ensure timely determinations by contracted
23 entities when prior authorizations are required including expedited
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1 review in urgent and emergent cases that at a minimum meet the
2 criteria of this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 A. As used in this section:

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

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

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

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

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

18 2. Indicated tests for an FDA-approved drug;

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

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

23 5. Nationally recognized clinical practice guidelines and
24 consensus statements.

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

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

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

15 SECTION 4. This act shall become effective January 1, 2024."
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1 Passed the House of Representatives the 20th day of April, 2023.

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4 _____
5 Presiding Officer of the House of
6 Representatives

7 Passed the Senate the ____ day of _____, 2023.

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10 Presiding Officer of the Senate
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1 ENGROSSED SENATE
2 BILL NO. 513

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13 requests; construing provision; amending 56 O.S.
14 2021, Section 4002.6, as amended by Section 10,
15 Chapter 395, O.S.L. 2022 (56 O.S. Supp. 2022, Section
16 4002.6), which relates to the state Medicaid program;
17 clarifying certain prior authorization requirement;
18 updating statutory language; defining terms;
19 requiring certain coverage and provision of biomarker
20 testing; stipulating prior authorization requirements
21 for biomarker testing; directing creation of process
22 to request exceptions to certain coverage policies;
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24 effective date.

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24 other body fluids, or tissues that is a sign of a normal or abnormal

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2 see how well the body responds to a treatment for a disease or
3 condition or for other purposes. Biomarkers shall include but are
4 not limited to gene mutation or protein expression;

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

10 3. "Consensus statement" means a statement that:

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

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

17 c. is aimed at specific clinical circumstances;

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

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

22 a. are developed by independent organizations or medical
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3 b. establish standards of care that are informed by a
4 systemic review of evidence and an assessment of the
5 benefits and costs of alternative care options that
6 includes recommendations intended to optimize patient
7 care.

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

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

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

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

1 4. Centers for Medicare and Medicaid Services national coverage
2 determinations or Medicare administrative contractor local coverage
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7 in a manner that limits disruptions in care, including the need for
8 multiple biopsies and biospecimen samples.

9 D. An insured and a prescribing practitioner shall have access
10 to a clear, readily available, and convenient process to request an
11 exception to a coverage policy of a health benefit plan under this
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16 SECTION 6. AMENDATORY 56 O.S. 2021, Section 4002.6, as
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19 Section 4002.6. A. A contracted entity shall meet all
20 requirements established by the Oklahoma Health Care Authority
21 pertaining to prior authorizations. The Authority shall establish
22 requirements that ensure timely determinations by contracted
23 entities when prior authorizations are required including expedited
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1 review in urgent and emergent cases that at a minimum meet the
2 criteria of this section.

3 B. A contracted entity shall make a determination on a request
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5 post-acute care or long-term acute care facility within twenty-four
6 (24) hours of receipt of the request.

7 C. A contracted entity shall make a determination on a request
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12 time frame and in accordance with a process established by the
13 Authority. The process established by the Authority pursuant to
14 this subsection shall include a time frame of at least forty-eight
15 (48) hours within which a provider may submit the necessary
16 documentation.

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

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

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

8 F. Notwithstanding any other provision of this section, a
9 contracted entity shall make a determination on a request for
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16 authorization on any covered prescription drug for which the
17 Authority does not require prior authorization.

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

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

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

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

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

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

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

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

1 SECTION 7. NEW LAW A new section of law to be codified
2 in the Oklahoma Statutes as Section 4003 of Title 56, unless there
3 is created a duplication in numbering, reads as follows:

4 A. As used in this section:

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

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

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

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

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

18 2. Indicated tests for an FDA-approved drug;

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

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

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24 consensus statements.

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

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

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

15 SECTION 8. This act shall become effective January 1, 2024.

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

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3 _____
4 Presiding Officer of the Senate

5 Passed the House of Representatives the ____ day of _____,
6 2023.

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9 Presiding Officer of the House
10 of Representatives