SENATE BILL 435
By Reeves

HOUSE BILL 484

By Martin B

AN ACT to amend Tennessee Code Annotated, Title 56 and Title 71, relative to coverage of biomarker testing.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 56, Chapter 7, Part 23, is amended by adding the following as a new section:

(a) As used in this section:

(1) "Biomarker":

(A) Means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered; and

(B) Includes gene mutations, characteristics of genes, and protein expression;

(2) "Biomarker testing":

(A) Means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker; and

(B) Includes single-analyte tests, multi-plex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing;

(3) "Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent

methodology and reporting structure that includes a conflict of interest policy, that is aimed at specific clinical circumstances, and that bases the statement on the best available evidence for the purpose of optimizing the outcomes of clinical care;

(4) "Health benefit plan" means health insurance coverage as defined in § 56-7-109;

(5) "Health insurer" means a health insurance entity as defined in § 56-7-109; and

(6) "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by an independent organization or professional medical society utilizing a transparent methodology and reporting structure that includes a conflict of interest policy, and that establishes standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options, including recommendations intended to optimize patient care.

(b) A health insurer that issues, amends, delivers, or renews a contract or agreement for a health benefit plan to take effect on or after January 1, 2026, shall include coverage for biomarker testing pursuant to subsection (c).

(c) A health benefit plan must provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

(1) Labeled indications for a federal food and drug administration (FDA)-approved or FDA-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 national coverage determinations or medicare administrative contractor local coverage determinations; or

(5) Nationally recognized clinical practice guidelines and consensus statements.

(d) A health insurer shall ensure that biomarker testing coverage under this section is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(e) If utilization review, including, but not limited to, prior authorization is required, then the health insurer, nonprofit health service plan, health maintenance organization, utilization review entity, or a third party acting on behalf of an organization or entity subject to this section must approve or deny a prior authorization request and notify the enrollee, the enrollee's healthcare provider, and each entity requesting authorization of the service within seventy-two (72) hours of a non-urgent request or within twenty-four (24) hours of an urgent request.

(f) A patient and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy or an adverse utilization review determination of a health insurer, nonprofit health service plan, or health maintenance organization. The process must be made readily accessible on the public website of the health insurer, nonprofit health service plan, or health maintenance organization.

SECTION 2. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following as a new section:

(a) As used in this section:

(1) "Biomarker" has the same meaning as defined in SECTION 1;

(2) "Biomarker testing" has the same meaning as defined in SECTION 1;

(3) "Consensus statement" has the same meaning as defined in SECTION 1;

(4) "Health benefit plan" means health insurance coverage as defined in § 56-7-109;

(5) "Health insurer" means a health insurance entity as defined in § 56-7-109;

(6) "Nationally recognized clinical practice guideline" has the same meaning as defined in SECTION 1; and

(7) "TennCare health benefit plan" means a health benefit plan issued by a health insurer pursuant to an agreement with the bureau of TennCare to provide health insurance coverage for an enrollee in the medical assistance program.

(b) A TennCare health benefit plan that is issued, amended, or renewed to take effect on or after January 1, 2026, must provide coverage for biomarker testing.

(c) Biomarker testing must be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

(1) Labeled indications for a federal food and drug administration (FDA)-approved or FDA-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 national coverage determinations or medicare administrative contractor local coverage determinations; or

(5) Nationally recognized clinical practice guidelines and consensus statements.

(d) A health insurer that issues a TennCare health benefit plan shall provide biomarker testing within the same scope, and at the same duration and frequency, that other TennCare benefits are provided to enrollees.

(e) If utilization review, including, but not limited to, prior authorization is required, then the health insurer, nonprofit health service plan, health maintenance organization, utilization review entity, or a third party acting on behalf of an organization or entity subject to this section must approve or deny a prior authorization request and notify the enrollee, the enrollee's healthcare provider, and each entity requesting authorization of the service within seventy-two (72) hours of a non-urgent request or within twenty-four (24) hours of an urgent request.

(f) An enrollee and participating provider must have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy of, or an adverse utilization review by, a health insurer that issues a TennCare health benefit plan. The process must be made readily accessible on the public website of TennCare and each health insurer that issues TennCare health benefit plans.

(g) The director of TennCare is authorized to seek any federal waiver the director deems necessary to effectuate this section.

SECTION 3. The commissioner of commerce and insurance is authorized to promulgate rules to effectuate Section 1 of this act. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 4. This act takes effect upon becoming a law, the public welfare requiring it.

House Finance, Ways, and Means 1

Amendment No. 2 to HB0484

Hicks G
Signature of Sponsor

AMEND Senate Bill No. 435* House Bill No. 484

by deleting all language after the enacting clause and substituting:

SECTION 1. Tennessee Code Annotated, Title 56, Chapter 7, Part 23, is amended by adding the following as a new section:

56-7-2369.

(a) As used in this section:

(1) "Biomarker":

(A) Means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered; and

(B) Includes gene mutations, characteristics of genes, and protein expression;

(2) "Biomarker testing":

(A) Means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker; and

(B) Includes single-analyte tests, multi-plex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing;

(3) "Health benefit plan" means health insurance coverage as defined in § 56-7-109 that is offered under a state or local insurance program pursuant to title 8, chapter 27;

(4) "Health insurer" means a health insurance entity, as defined in § 56-7-109, that offers a health benefit plan; and

(5) "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by an independent organization or professional medical society utilizing a transparent methodology and reporting structure that includes a conflict of interest policy, and that establishes standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options, including recommendations intended to optimize patient care.

(b) A health insurer that issues, amends, delivers, or renews a contract or agreement for a health benefit plan to take effect on or after January 1, 2027, shall include coverage for biomarker testing pursuant to subsection (c).

(c) A health benefit plan must provide coverage for biomarker testing when ordered by a healthcare provider for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring to guide treatment decisions for an enrollee's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

(1) Labeled indications for a federal food and drug administration (FDA)-approved or FDA-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 national coverage determinations or medicare administrative contractor local coverage determinations; or

(5) Nationally recognized clinical practice guidelines.

(d) A health insurer shall ensure that biomarker testing coverage under this section is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(e) This section does not require coverage of biomarker testing for the purpose of screening asymptomatic individuals.

(f) If utilization review, including, but not limited to, prior authorization, is required, then the health insurer, nonprofit health service plan, health maintenance organization, utilization review entity, or a third party acting on behalf of an organization or entity subject to this section must approve or deny a prior authorization request and notify the enrollee, the enrollee's healthcare provider, and each entity requesting authorization of the service in accordance with state law.

(g) A patient and prescribing practitioner must have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy or an adverse utilization review determination of a health insurer, nonprofit health service plan, or health maintenance organization. The process must be made readily accessible on the public website of the health insurer, nonprofit health service plan, or health maintenance organization.

(h) This section does not limit a health insurer's ability to require prior authorization or other utilization management techniques.

SECTION 2. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following as a new section:

(a) As used in this section:

(1) "Biomarker" has the same meaning as defined in § 56-7-2369;

(2) "Biomarker testing" has the same meaning as defined in § 56-7-2369;

(3) "Health benefit plan" means health insurance coverage as defined in § 56-7-109;

(4) "Health insurer" means a health insurance entity as defined in § 56-7-109;

(5) "Nationally recognized clinical practice guideline" has the same meaning as defined in § 56-7-2369; and

(6) "TennCare health benefit plan" means a health benefit plan issued by a health insurer pursuant to an agreement with the bureau of TennCare to provide health insurance coverage for an enrollee in the medical assistance program.

(b) A TennCare health benefit plan that is issued, amended, or renewed on or after January 1, 2027, must provide coverage for biomarker testing when medically necessary pursuant to § 71-5-144.

(c) Biomarker testing must be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

(1) Labeled indications for a federal food and drug administration (FDA)-approved or FDA-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 national coverage determinations or medicare administrative contractor local coverage determinations; or

(5) Nationally recognized clinical practice guidelines.

(d) A health insurer that issues a TennCare health benefit plan that covers biomarker testing shall provide biomarker testing within the same scope, and at the same duration and frequency, that other TennCare benefits are provided to enrollees.

(e) If utilization review, including, but not limited to, prior authorization, is required, then the health insurer, nonprofit health service plan, health maintenance organization, utilization review entity, or a third party acting on behalf of an organization or entity subject to this section must approve or deny a prior authorization request and notify the enrollee, the enrollee's healthcare provider, and each entity requesting authorization of the service in accordance with 42 CFR Part 438.

(f) An enrollee and participating provider must have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy of, or an adverse utilization review by, a health insurer that issues a TennCare health benefit plan. The process must be made readily accessible on the public website of TennCare and each health insurer that issues TennCare health benefit plans.

(g) The director of TennCare is authorized to seek any federal waiver the director deems necessary to effectuate this section.

(h)

(1) The commissioner of commerce and insurance shall compile a report on the usage of covered biomarker testing and cost savings generated pursuant to this section, based upon data reported to the department of commerce and insurance by health insurers.

(2) The commissioner may establish reporting standards by rule for the purpose of compiling data necessary to complete the report required by this subsection (h). The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(3) No later than February 1, 2029, the commissioner shall deliver a copy of the report to the chief clerk of the senate, the chief clerk of the house of representatives, and the legislative librarian. The report may be delivered by electronic means.

SECTION 3. The commissioner of commerce and insurance may promulgate rules to effectuate SECTION 1 of this act. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 4. This act takes effect upon becoming a law, the public welfare requiring it.