Second Regular Session
Seventy-fourth General Assembly
STATE OF COLORADO

REVISED

This Version Includes All Amendments Adopted on Second Reading in the Second House

LLS NO. 24-0481.01 Brita Darling x2241

SENATE BILL 24-124

SENATE SPONSORSHIP

Michaelson Jenet and Rich, Buckner, Cutter, Exum, Fenberg, Ginal, Gonzales, Hansen, Hinrichsen, Kirkmeyer, Kolker, Marchman, Mullica, Pelton B., Pelton R., Priola, Roberts, Will, Winter F.

HOUSE SPONSORSHIP

Hartsook and Duran,

Senate Committees
Health & Human Services
Appropriations

House Committees
Health & Human Services

A BILL FOR AN ACT

CONCERNING REQUIRING HEALTH-CARE COVERAGE FOR BIOMARKER TESTING.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at http://leg.colorado.gov.)

The bill requires all individual and group health benefit plans to provide coverage for biomarker testing to guide treatment decisions if the testing is supported by medical and scientific evidence. The bill defines "biomarker testing" as an analysis of a patient's tissue, blood, or other biospecimen for the presence of an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific

HOUSE
Amended 2nd Reading
May 4, 2024

SENATE
3rd Reading Unamended
April 26, 2024

SENATE
Amended 2nd Reading
April 25, 2024

therapeutic intervention. The required testing under the bill does not include biomarker testing for screening purposes or direct-to-consumer genetic tests.

The bill requires the commissioner of insurance to implement biomarker testing coverage for all individual and group health benefit plans issued or renewed on or after January 1, 2026.

Biomarker testing is subject to the health benefit plan's annual deductibles, copayment, or coinsurance but is not subject to any annual or lifetime maximum benefit limit.

Subject to federal authorization and federal financial participation, beginning July 1, 2025, the bill includes coverage for biomarker testing as part of the state medical assistance program to guide treatment decisions if the testing is supported by medical and scientific evidence.

The bill requires the medical assistance program to have a clear, easily accessible appeals process if biomarker testing is denied.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. In Colorado Revised Statutes, 10-16-104, **add** (27) as follows:

10-16-104. Mandatory coverage provisions - definitions - rules. (27) **Biomarker testing.** (a) ALL LARGE GROUP HEALTH BENEFIT PLANS AND, TO THE EXTENT THAT SUCH COVERAGE IS NOT IN ADDITION TO THE BENEFITS PROVIDED PURSUANT TO THE BENCHMARK PLAN, ALL INDIVIDUAL AND SMALL GROUP HEALTH BENEFIT PLANS SHALL PROVIDE COVERAGE FOR BIOMARKER TESTING PURSUANT TO THIS SUBSECTION (27).

(b) COVERAGE MUST INCLUDE BIOMARKER TESTING FOR DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT, AND ONGOING MONITORING OF A COVERED PERSON'S DISEASE OR CONDITION TO GUIDE TREATMENT DECISIONS WHEN THE TEST IS SUPPORTED BY MEDICAL AND SCIENTIFIC EVIDENCE, INCLUDING:

(I) LABELED INDICATIONS FOR AN FDA-APPROVED OR FDA-CLEARED TEST;

(II) INDICATED TESTS FOR AN FDA-APPROVED DRUG;

(III) WARNINGS AND PRECAUTIONS ON FDA-APPROVED DRUG LABELS;

(IV) CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL COVERAGE DETERMINATIONS OR MEDICARE ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE DETERMINATIONS; OR

(V) NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES, CONSENSUS STATEMENTS, AND PEER-REVIEWED STUDIES.

(c) THE COVERAGE REQUIRED BY THIS SUBSECTION (27) IS SUBJECT TO ANNUAL DEDUCTIBLES, COPAYMENTS, OR COINSURANCE REQUIREMENTS UNDER THE HEALTH BENEFIT PLAN BUT IS NOT SUBJECT TO ANY ANNUAL OR LIFETIME MAXIMUM BENEFIT LIMIT.

(d) THE COVERAGE REQUIRED BY THIS SUBSECTION (27) MUST BE PROVIDED IN A MANNER THAT LIMITS UNREASONABLE DISRUPTIONS IN CARE, INCLUDING LIMITING THE NEED FOR MULTIPLE BIOPSIES OR BIOSPECIMEN SAMPLES.

(e) NOTHING IN THIS SUBSECTION (27) SHALL BE CONSTRUED TO REQUIRE COVERAGE FOR BIOMARKER TESTING FOR SCREENING PURPOSES.

(f) A CARRIER MAY REQUIRE PRIOR AUTHORIZATION FOR BIOMARKER TESTING IN THE SAME MANNER THAT PRIOR AUTHORIZATION IS REQUIRED FOR ANY OTHER COVERED BENEFIT AND CONSISTENT WITH SECTION 10-16-112.5.

(g) (I) WITHIN ONE HUNDRED TWENTY DAYS AFTER THE EFFECTIVE DATE OF THIS SECTION, THE DIVISION SHALL SUBMIT TO THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES:

(A) A DETERMINATION AS TO WHETHER THE BENEFIT SPECIFIED IN THIS SUBSECTION (27) IS IN ADDITION TO ESSENTIAL HEALTH BENEFITS AND WOULD BE SUBJECT TO DEFRAYAL BY THE STATE PURSUANT TO 42 U.S.C.

SEC. 18031 (d)(3)(B); AND

(B) A REQUEST THAT THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES CONFIRM THE DIVISION'S DETERMINATION WITHIN SIXTY DAYS AFTER RECEIPT OF THE DIVISION'S REQUEST AND SUBMISSION OF ITS DETERMINATION.

(II) THIS SUBSECTION (27) APPLIES TO, AND THE DIVISION SHALL IMPLEMENT THE PROVISIONS OF THIS SUBSECTION (27) FOR, LARGE EMPLOYER HEALTH BENEFIT PLANS ISSUED OR RENEWED IN THIS STATE ON OR AFTER JANUARY 1, 2025.

(III) THIS SUBSECTION (27) APPLIES TO, AND THE DIVISION SHALL IMPLEMENT THE REQUIREMENTS OF THIS SUBSECTION (27) FOR, INDIVIDUAL AND SMALL GROUP HEALTH BENEFIT PLANS ISSUED OR RENEWED IN THIS STATE TWELVE MONTHS AFTER THE EARLIER OF THE FOLLOWING:

(A) THE DIVISION RECEIVES CONFIRMATION FROM THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES THAT THE COVERAGE SPECIFIED IN THIS SUBSECTION (27) DOES NOT CONSTITUTE AN ADDITIONAL BENEFIT THAT REQUIRES DEFRAYAL BY THE STATE PURSUANT TO 42 U.S.C. SEC. 18031 (d)(3)(B);

(B) THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES HAS OTHERWISE INFORMED THE DIVISION THAT THE COVERAGE DOES NOT REQUIRE STATE DEFRAYAL PURSUANT TO 42 U.S.C. SEC. 18031 (d)(3)(B); OR

(C) MORE THAN THREE HUNDRED SIXTY-FIVE DAYS HAVE PASSED SINCE THE DIVISION SUBMITTED ITS DETERMINATION AND REQUEST FOR CONFIRMATION THAT THE COVERAGE SPECIFIED IN THIS SUBSECTION (27) IS NOT AN ADDITIONAL BENEFIT THAT REQUIRES STATE DEFRAYAL

PURSUANT TO 42 U.S.C. SEC. 18031 (d)(3)(B), AND THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES HAS FAILED TO RESPOND TO THE REQUEST WITHIN THAT PERIOD, IN WHICH CASE THE DIVISION SHALL CONSIDER THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES' UNREASONABLE DELAY A PRECLUSION FROM REQUIRING DEFRAYAL BY THE STATE.

(h) THE COMMISSIONER SHALL IMPLEMENT THIS SUBSECTION (27) AND SHALL ADOPT RULES CONSISTENT WITH AND AS ARE NECESSARY TO IMPLEMENT THIS SUBSECTION (27).

(i) AS USED IN THIS SUBSECTION (27):

(I) "BIOMARKER" 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. "BIOMARKER" INCLUDES GENE MUTATIONS, CHARACTERISTICS OF GENES, OR PROTEIN EXPRESSION.

(II) "BIOMARKER TESTING" MEANS THE ANALYSIS OF A PATIENT'S TISSUE, BLOOD, OR OTHER BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER. "BIOMARKER TESTING" INCLUDES SINGLE-ANALYTE TESTS, MULTIPLEX PANEL TESTS, PROTEIN EXPRESSION, AND WHOLE EXOME, WHOLE GENOME, AND WHOLE TRANSCRIPTOME SEQUENCING. "BIOMARKER TESTING" DOES NOT INCLUDE DIRECT-TO-CONSUMER GENETIC TESTS.

(III) "CONSENSUS STATEMENTS" MEANS STATEMENTS DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF EXPERTS UTILIZING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE AND WITH A CONFLICT OF INTEREST POLICY. CONSENSUS STATEMENTS ARE

DEVELOPED FOR SPECIFIC CLINICAL CIRCUMSTANCES AND ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF OPTIMIZING THE OUTCOMES OF CLINICAL CARE.

(IV) "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS 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:

(A) ESTABLISH STANDARDS OF CARE INFORMED BY A SYSTEMATIC REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND RISKS OF ALTERNATIVE CARE OPTIONS; AND

(B) INCLUDE RECOMMENDATIONS INTENDED TO OPTIMIZE PATIENT CARE.

SECTION 2. Safety clause. The general assembly finds, determines, and declares that this act is necessary for the immediate preservation of the public peace, health, or safety or for appropriations for the support and maintenance of the departments of the state and state institutions.