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Seventy-fourth General Assembly
STATE OF COLORADO

PREAMENDED

This Unofficial Version Includes Committee Amendments Not Yet Adopted on Second Reading

LLS NO. 23-0195.01 Brita Darling x2241

HOUSE BILL 23-1110

HOUSE SPONSORSHIP

Michaelson Jenet and Hartsook, Jodeh

SENATE SPONSORSHIP

Mullica and Rich,

House Committees
Health & Insurance
Appropriations

Senate Committees

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 if the testing is supported by medical and scientific evidence. Biomarker testing is defined 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 therapeutic intervention.

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, 2025.

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.

If a carrier requires prior authorization for biomarker testing, the bill requires the carrier to use an expedited prior authorization process.

Subject to federal authorization and federal financial participation, beginning July 1, 2024, the bill includes coverage for biomarker testing as part of the state medical assistance program if the testing is supported by medical and scientific evidence.

Under the state medical assistance program, the bill requires an expedited utilization review and prior authorization process, as well as an appeal 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** (26) as follows:

10-16-104. Mandatory coverage provisions - definitions - rules. (26) **Biomarker testing.** (a) ALL INDIVIDUAL AND GROUP HEALTH BENEFIT PLANS ISSUED OR RENEWED IN THIS STATE ON OR AFTER JANUARY 1, 2025, SHALL PROVIDE COVERAGE FOR BIOMARKER TESTING PURSUANT TO THIS SUBSECTION (26).

(b) COVERAGE MUST INCLUDE BIOMARKER TESTING FOR DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT, OR ONGOING MONITORING OF A COVERED PERSON'S DISEASE OR CONDITION 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 AND CONSENSUS STATEMENTS.

(c) THE COVERAGE REQUIRED BY THIS SUBSECTION (26) 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 (26) MUST BE PROVIDED IN A MANNER THAT LIMITS UNREASONABLE DISRUPTIONS IN CARE, INCLUDING LIMITING THE NEED FOR MULTIPLE BIOPSIES OR BIOSPECIMEN SAMPLES.

(e) 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.

(f) THE COMMISSIONER SHALL IMPLEMENT THIS SUBSECTION (26) AND SHALL ADOPT RULES CONSISTENT WITH AND AS ARE NECESSARY TO IMPLEMENT THIS SUBSECTION (26).

(g) AS USED IN THIS SUBSECTION (26):

(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 AND IS INCLUSIVE OF DIAGNOSTIC, MONITORING, PROGNOSTIC, PHARMACOGENOMIC, AND PREDICTIVE TESTS. "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.

(V) "URGENT HEALTH-CARE SERVICE" HAS THE SAME MEANING AS SET FORTH IN SECTION 10-16-112.5 (7)(f).

SECTION 2. In Colorado Revised Statutes, 25.5-5-202, **add** (1)(z) as follows:

25.5-5-202. Basic services for the categorically needy - optional services. (1) Subject to the provisions of subsection (2) of this section, the following are services for which federal financial participation is available and that Colorado has selected to provide as optional services under the medical assistance program:

(z) BIOMARKER TESTING, AS SPECIFIED IN SECTION 25.5-5-334.

SECTION 3. In Colorado Revised Statutes, **add** 25.5-5-334 as follows:

25.5-5-334. Biomarker testing - federal authorization - prior authorization - definitions. (1) AS USED IN THIS SECTION, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(a) "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.

(b) "BIOMARKER TESTING" MEANS THE ANALYSIS OF A PATIENT'S TISSUE, BLOOD, OR OTHER BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER AND IS INCLUSIVE OF DIAGNOSTIC, MONITORING, PROGNOSTIC, PHARMACOGENOMIC, AND PREDICTIVE TESTS. "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.

(c) "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.

(d) "FDA" MEANS THE FOOD AND DRUG ADMINISTRATION IN THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES.

(e) "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:

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

(II) INCLUDE RECOMMENDATIONS INTENDED TO OPTIMIZE PATIENT CARE.

(f) "URGENT HEALTH-CARE SERVICE" HAS THE SAME MEANING AS SET FORTH IN SECTION 10-16-112.5 (7)(f).

(2) SUBJECT TO FEDERAL AUTHORIZATION AND FEDERAL FINANCIAL PARTICIPATION, ON AND AFTER JULY 1, 2024, THE MEDICAL

ASSISTANCE PROGRAM MUST INCLUDE BIOMARKER TESTING AS SET FORTH IN SUBSECTIONS (3) AND (4) OF THIS SECTION.

(3) (a) COVERAGE MUST INCLUDE BIOMARKER TESTING FOR DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT, OR ONGOING MONITORING OF A RECIPIENT'S DISEASE OR CONDITION 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 AND CONSENSUS STATEMENTS.

(b) A MANAGED CARE ENTITY, AS DEFINED IN SECTION 25.5-5-403, THAT IS CONTRACTED WITH THE MEDICAL ASSISTANCE PROGRAM TO DELIVER SERVICES SHALL PROVIDE BIOMARKER TESTING IN THE SAME SCOPE, DURATION, AND FREQUENCY AS BIOMARKER TESTING IS PROVIDED TO OTHER PERSONS ENROLLED IN THE MEDICAL ASSISTANCE PROGRAM.

(4) THE MEDICAL ASSISTANCE PROGRAM MUST NOT IMPOSE A LIFETIME LIMIT ON BIOMARKER TESTING FOR A RECIPIENT.

(5) A RECIPIENT AND PROVIDER SHALL HAVE ACCESS TO A CLEAR, READILY ACCESSIBLE, AND CONVENIENT PROCESS TO REQUEST AN APPEAL IF BIOMARKER TESTING IS DENIED. THE PROCESS MUST BE READILY ACCESSIBLE ONLINE TO ALL RECIPIENTS AND PROVIDERS.

SECTION 4. Safety clause. The general assembly hereby finds, determines, and declares that this act is necessary for the immediate preservation of the public peace, health, or safety.