

**Second Regular Session  
Seventy-fourth General Assembly  
STATE OF COLORADO**

**PREAMENDED**

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

LLS NO. 24-0481.01 Brita Darling x2241

**SENATE BILL 24-124**

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**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**,

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**Senate Committees**

Health & Human Services  
Appropriations

**House Committees**

Health & Human Services

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**A BILL FOR AN ACT**

101 **CONCERNING REQUIRING HEALTH-CARE COVERAGE FOR BIOMARKER**  
102 **TESTING.**

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**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

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.  
*Capital letters or bold & italic numbers indicate new material to be added to existing law.*  
*Dashes through the words or numbers indicate deletions from existing law.*

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.

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

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

4 **10-16-104. Mandatory coverage provisions - definitions -**  
5 **rules. (27) Biomarker testing. (a) ALL LARGE GROUP HEALTH BENEFIT**  
6 **PLANS AND, TO THE EXTENT THAT SUCH COVERAGE IS NOT IN ADDITION TO**  
7 **THE BENEFITS PROVIDED PURSUANT TO THE BENCHMARK PLAN, ALL**  
8 **INDIVIDUAL AND SMALL GROUP HEALTH BENEFIT PLANS SHALL PROVIDE**  
9 **COVERAGE FOR BIOMARKER TESTING PURSUANT TO THIS SUBSECTION (27).**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 (I) "BIOMARKER" MEANS A CHARACTERISTIC THAT IS OBJECTIVELY  
12 MEASURED AND EVALUATED AS AN INDICATOR OF NORMAL BIOLOGICAL  
13 PROCESSES, PATHOGENIC PROCESSES, OR PHARMACOLOGIC RESPONSES TO  
14 A SPECIFIC THERAPEUTIC INTERVENTION, INCLUDING KNOWN GENE-DRUG  
15 INTERACTIONS FOR MEDICATIONS BEING CONSIDERED FOR USE OR  
16 ALREADY BEING ADMINISTERED. "BIOMARKER" INCLUDES GENE  
17 MUTATIONS, CHARACTERISTICS OF GENES, OR PROTEIN EXPRESSION.

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


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

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

4 (IV) "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES"  
5 MEANS EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES DEVELOPED BY  
6 INDEPENDENT ORGANIZATIONS OR MEDICAL PROFESSIONAL SOCIETIES  
7 UTILIZING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE  
8 AND WITH A CONFLICT OF INTEREST POLICY. CLINICAL PRACTICE  
9 GUIDELINES:

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

13 (B) INCLUDE RECOMMENDATIONS INTENDED TO OPTIMIZE PATIENT  
14 CARE.

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