
A BILL FOR AN ACT

RELATING TO INSURANCE.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

1 SECTION 1. Chapter 431, Hawaii Revised Statutes, is
2 amended by adding a new section to article 10A to be
3 appropriately designated and to read as follows:

4 **"§431:10A- Biomarker testing; coverage.** (a) Each
5 individual or group policy of accident and health or sickness
6 insurance issued or renewed in the State on or after January 1,
7 2027, shall provide coverage for biomarker testing for the
8 policyholder, or any dependent of the policyholder who is
9 covered by the policy, for purposes of diagnosis, treatment,
10 appropriate management, or ongoing monitoring of an insured
11 person's disease or condition, or to guide treatment decisions
12 when supported by medical and scientific evidence, including:

13 (1) Labeled indications for a test approved or cleared by
14 the United States Food and Drug Administration;
15 (2) Indicated tests for a drug approved by the United
16 States Food and Drug Administration;



1 (3) Warnings and precautions on the label of a drug
2 approved by the United States Food and Drug
3 Administration;
4 (4) National coverage determinations from the Centers for
5 Medicare and Medicaid Services or local coverage
6 determinations from a medicare administrative
7 contractor; or
8 (5) Nationally recognized clinical practice guidelines and
9 consensus statements.

10 (b) Coverage under this section shall be provided in a
11 manner that limits disruptions in care, including the need for
12 multiple biopsies.

13 (c) If a policy of accident and health or sickness
14 insurance restricts coverage under this section, the insurer
15 shall provide the patient and prescribing health care provider
16 with a clear, readily accessible, and convenient process for
17 requesting an exception. The process for requesting an
18 exception shall also be readily accessible on the insurer's
19 website.

20 (d) Coverage under this section may be subject to the
21 copayment, deductible, and coinsurance provisions of a policy of



1 accident and health or sickness insurance; provided that the
2 terms shall be no less favorable than the copayment, deductible,
3 and coinsurance provisions for other medical services covered by
4 the policy.

5 (e) Annual information that is made available to
6 policyholders shall include information concerning the coverage
7 required by this section.

8 (f) This section shall not apply to limited benefit health
9 insurance as provided in section 431:10A-607.

10 (g) For the purposes of this section:

11 "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 a
14 specific therapeutic intervention, including known gene-drug
15 interactions for medications being considered for use or already
16 being administered. "Biomarker" includes gene mutations, gene
17 characteristics, and protein expression.

18 "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;



1 multi-plex panel tests; protein expression; and whole exome,
2 whole genome, and whole transcriptome sequencing.

3 "Clinical practice guidelines" means guidelines that
4 establish standards of care informed by a systemic review of
5 evidence and an assessment of the benefits and risks of
6 alternative care options; include recommendations intended to
7 optimize patient care; and are developed by independent
8 organizations or medical professional societies using a
9 transparent methodology and reporting structure and with a
10 conflict-of-interest policy.

11 "Consensus statements" means statements developed by an
12 independent multidisciplinary panel of experts using a
13 transparent methodology and reporting structure and with a
14 conflict-of-interest policy and that are focused on specific
15 clinical circumstances and are based on the best available
16 evidence for the purpose of optimizing the outcomes of clinical
17 care."

18 SECTION 2. Chapter 432, Hawaii Revised Statutes, is
19 amended by adding a new section to article 1 to be appropriately
20 designated and to read as follows:



§432:1- Biomarker testing; coverage. (a) Each individual or group hospital or medical service plan contract issued or renewed in the State on or after January 1, 2027, shall provide coverage for biomarker testing for the subscriber or member, or any dependent of the subscriber or member who is covered by the plan contract, for purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a subscriber's, member's, or dependent's disease or condition, or to guide treatment decisions when supported by medical and scientific evidence, including:

(1) Labeled indications for a test approved or cleared by the United States Food and Drug Administration;

(2) Indicated tests for a drug approved by the United States Food and Drug Administration;

(3) Warnings and precautions on the label of a drug approved by the United States Food and Drug Administration;

(4) National coverage determinations from the Centers for Medicare and Medicaid Services or local coverage determinations from a medicare administrative contractor; or



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

3 (b) Coverage under this section shall be provided in a
4 manner that limits disruptions in care, including the need for
5 multiple biopsies.

6 (c) If a plan contract restricts coverage under this
7 section, the mutual benefit society shall provide the patient
8 and prescribing health care provider with access to a clear,
9 readily accessible, and convenient process for requesting an
10 exception. The process for requesting an exception shall also
11 be readily accessible on the mutual benefit society's website.

12 (d) Coverage under this section may be subject to the
13 copayment, deductible, and coinsurance provisions of a plan
14 contract; provided that the terms shall be no less favorable
15 than the copayment, deductible, and coinsurance provisions for
16 other medical services covered by the plan contract.

17 (e) Annual information that is made available to
18 subscribers and members shall include information concerning the
19 coverage required by this section.

20 (f) For the purposes of this section:



1 "Biomarker" means a characteristic that is objectively
2 measured and evaluated as an indicator of normal biological
3 processes, pathogenic processes, or pharmacologic responses to a
4 specific therapeutic intervention, including known gene-drug
5 interactions for medications being considered for use or already
6 being administered. "Biomarker" includes gene mutations, gene
7 characteristics, and protein expression.

8 "Biomarker testing" means the analysis of a patient's
9 tissue, blood, or other biospecimen for the presence of a
10 biomarker. "Biomarker testing" includes single-analyte tests,
11 multi-plex panel tests, protein expression, and whole exome,
12 whole genome, and whole transcriptome sequencing.

13 "Clinical practice guidelines" means guidelines that
14 establish standards of care informed by a systemic review of
15 evidence and an assessment of the benefits and risks of
16 alternative care options; include recommendations intended to
17 optimize patient care; and are developed by independent
18 organizations or medical professional societies using a
19 transparent methodology and reporting structure and with a
20 conflict-of-interest policy.



1 "Consensus statements" means statements developed by an
2 independent multidisciplinary panel of experts using a
3 transparent methodology and reporting structure and with a
4 conflict-of-interest policy and that are focused on specific
5 clinical circumstances and are based on the best available
6 evidence for the purpose of optimizing the outcomes of clinical
7 care."

8 SECTION 3. Section 432D-23, Hawaii Revised Statutes, is
9 amended to read as follows:

10 **"S432D-23 Required provisions and benefits.**

11 Notwithstanding any provision of law to the contrary, each
12 policy, contract, plan, or agreement issued in the State after
13 January 1, 1995, by health maintenance organizations pursuant to
14 this chapter, shall include benefits provided in sections
15 431:10-212, 431:10A-115, 431:10A-115.5, 431:10A-116, 431:10A-
16 116.2, 431:10A-116.5, 431:10A-116.6, 431:10A-119, 431:10A-120,
17 431:10A-121, 431:10A-122, 431:10A-125, 431:10A-126, 431:10A-132,
18 431:10A-133, 432:10-134, 431:10A-140, and [431:10A-134,]
19 431:10A-, and chapter 431M."

20 SECTION 4. The coverage and benefits to be provided by a
21 health maintenance organization under section 3 of this Act



1 shall take effect for all policies, contracts, plans, or
2 agreements issued or renewed in the State on or after
3 January 1, 2027.

4 SECTION 5. (a) The reimbursement required by sections 1
5 and 2 of this Act for biomarker testing services shall apply to
6 all health plans under the State's medicaid managed care
7 program.

8 (b) The department of human services shall submit the
9 necessary amendments to the Hawaii medicaid state plan to the
10 Centers for Medicare and Medicaid Services no later
11 than .

12 SECTION 6. This Act shall be exempt from the requirements
13 of sections 23-51 and 23-52, Hawaii Revised Statutes.

14 SECTION 7. This Act does not affect rights and duties that
15 matured, penalties that were incurred, and proceedings that were
16 begun before its effective date.

17 SECTION 8. Statutory material to be repealed is bracketed
18 and stricken. New statutory material is underscored.

19 SECTION 9. This Act shall take effect upon its approval;
20 provided that section 5 shall take effect upon the approval of



- 1 the Hawaii medicaid state plan by the Centers for Medicare and
- 2 Medicaid Services.
- 3

INTRODUCED BY: 



S.B. NO. 2390

Report Title:

Health Insurance; Mutual Benefit Societies; Health Maintenance Organizations; Medicaid; Biomarker Testing; Mandatory Coverage

Description:

Beginning 1/1/2027, requires health insurers, mutual benefit societies, health maintenance organizations, and health plans under the State's Medicaid managed care program to provide coverage for biomarker testing.

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