
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 2026, 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 restricts coverage under this section, the
14 patient and prescribing health care provider shall be provided
15 access to a clear, readily accessible, and convenient process
16 for requesting an exception. The process for requesting an
17 exception shall also be readily accessible on the insurer's
18 website.

19 (d) Coverage under this section may be subject to the
20 copayment, deductible, and coinsurance provisions of a policy
21 for accident and health or sickness insurance; provided that the



1 terms shall be no less favorable than the copayment, deductible,
2 and coinsurance provisions for other medical services covered by
3 the policy.

4 (e) Within calendar year 2026, and in no case later than
5 December 31, 2026, each insurer shall provide written notice to
6 its policyholders regarding the coverage required by this
7 section. The notice shall be prominently featured in any
8 literature or correspondence sent annually to policyholders.

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

11 (g) For the purposes of this section:

12 "Biomarker" means a characteristic that is objectively
13 measured and evaluated as an indicator of normal biological
14 processes, pathogenic processes, or pharmacologic responses to a
15 specific therapeutic intervention, including known gene-drug
16 interactions for mediations being considered for use or already
17 being administered. Biomarkers include gene mutations, gene
18 characteristics, and protein expression.

19 "Biomarker testing" means the analysis of a patient's
20 tissue, blood, or other biospecimen for the presence of a
21 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 and that include recommendations
7 intended to optimize patient care. Clinical practice guidelines
8 are developed by independent organizations or medical
9 professional societies using a transparent methodology and
10 reporting structure and with a 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. Consensus statements are focused
15 on specific clinical circumstances and are based on the best
16 available evidence for the purpose of optimizing the outcomes of
17 clinical 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:



1 "§432:1- Biomarker testing; coverage. (a) Each
2 individual or group hospital or medical service plan contract
3 issued or renewed in the State on or after January 1, 2026,
4 shall provide coverage for biomarker testing for the subscriber
5 or member, or any dependent of the subscriber or member who is
6 covered by the plan contract, for purposes of diagnosis,
7 treatment, appropriate management, or ongoing monitoring of a
8 subscriber, member, or dependent's disease or condition, or to
9 guide treatment decisions when supported by medical and
10 scientific evidence, including:

- 11 (1) Labeled indications for a test approved or cleared by
12 the United States Food and Drug Administration;
- 13 (2) Indicated tests for a drug approved by the United
14 States Food and Drug Administration;
- 15 (3) Warnings and precautions on the label of a drug
16 approved by the United States Food and Drug
17 Administration;
- 18 (4) National coverage determinations from the Centers for
19 Medicare and Medicaid Services or local coverage
20 determinations from a medicare administrative
21 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 patient and prescribing health care provider shall
8 be provided access to a clear, readily accessible, and
9 convenient process for requesting an exception. The process for
10 requesting an exception shall also be readily accessible on the
11 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) Within calendar year 2026, and in no case later than
18 December 31, 2026, each mutual benefit society shall provide
19 written notice to its subscribers and members regarding the
20 coverage required by this section. The notice shall be



1 prominently featured in any literature or correspondence sent
2 annually to subscribers and members.

3 (f) For the purposes of this section:

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

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

16 "Clinical practice guidelines" means guidelines that
17 establish standards of care informed by a systemic review of
18 evidence and an assessment of the benefits and risks of
19 alternative care options and include recommendations intended to
20 optimize patient care. Clinical practice guidelines are
21 developed by independent organizations or medical professional



1 societies using a transparent methodology and reporting
2 structure and with a conflict-of-interest policy.

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

10 SECTION 3. Section 432D:23, Hawaii Revised Statutes, is
11 amended to read as follows:

12 **"§432D-23 Required provisions and benefits.**

13 Notwithstanding any provision of law to the contrary, each
14 policy, contract, plan, or agreement issued in the State after
15 January 1, 1995, by health maintenance organizations pursuant to
16 this chapter, shall include benefits provided in sections
17 431:10-212, 431:10A-115, 431:10A-115.5, 431:10A-116,
18 431:10A-116.2, 431:10A-116.5, 431:10A-116.6, 431:10A-119,
19 431:10A-120, 431:10A-121, 431:10A-122, 431:10A-125, 431:10A-126,
20 431:10A-132, 431:10A-133, 431:10A-134, 431:10A-140, and
21 [~~431:10A-134~~,] 431:10A- , and chapter 431M."



1 SECTION 4. The coverage and benefits to be provided by a
2 health maintenance organization under section 3 of this Act
3 shall take effect for all policies, contracts, plans, or
4 agreements issued or renewed in the State on or after
5 January 1, 2026.

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

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

13 SECTION 6. This Act does not affect rights and duties that
14 matured, penalties that were incurred, and proceedings that were
15 begun before its effective date.

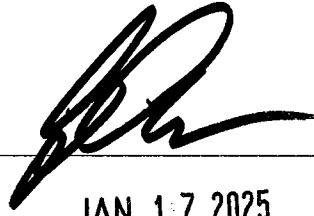
16 SECTION 7. Statutory material to be repealed is bracketed
17 and stricken. New statutory material is underscored.



1 SECTION 8. This Act shall take effect upon its approval;
2 provided that section 5 shall take effect upon the approval of
3 the Hawaii medicaid state plan by the Centers for Medicare and
4 Medicaid Services.

5

INTRODUCED BY:



A handwritten signature in black ink, appearing to be 'R. H.', is written over a horizontal line.

JAN 17 2025



H.B. NO. 553

Report Title:

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

Description:

Beginning 1/1/2026, 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.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.

