

---

---

# 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 of accident and health or sickness  
14 insurance restricts coverage under this section, the patient and  
15 prescribing health care provider shall be provided access to a  
16 clear, readily accessible, and convenient process for requesting  
17 an exception. The process for requesting an exception shall  
18 also be readily accessible on the insurer's website.
- 19       (d) Coverage under this section may be subject to the  
20 copayment, deductible, and coinsurance provisions of a policy of  
21 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 medications being considered for use or already  
17 being administered. "Biomarkers" includes 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; that include recommendations intended  
7 to 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:



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's, member's, or dependent's disease or condition, or  
9 to 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 medications being considered for use or already  
9 being administered. "Biomarkers" includes 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; that include recommendations intended  
20 to optimize patient care; and are developed by independent  
21 organizations or medical professional societies using a



1 transparent methodology and reporting structure and with a  
2 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 and that are focused on specific  
7 clinical circumstances and are based on the best available  
8 evidence for the purpose of optimizing the outcomes of clinical  
9 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  
13 than .

14 SECTION 6. 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 7. Statutory material to be repealed is bracketed  
18 and stricken. New statutory material is underscored.



1 SECTION 8. This Act shall take effect on July 1, 3000;  
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.



**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. Effective 7/1/3000. (HD1)

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

