HOUSE OF REPRESENTATIVES THIRTY-SECOND LEGISLATURE, 2024 STATE OF HAWAII

H.B. NO. ²²²³ H.D. 1

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 |
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| 2 | amended by adding a new section to article 10A to be |
| 3 | appropriately designated and to read as follows: |
| 4 | " <u>\$431:10A-</u> Biomarker testing; coverage. (a) Each |
| 5 | individual or group policy of accident and health or sickness |
| 6 | insurance issued or renewed in this State on or after January 1, |
| 7 | 2025, shall provide coverage for the medically necessary |
| 8 | services of biomarker testing for the policyholder or any |
| 9 | dependent of the policyholder who is covered by the policy for |
| 10 | the purposes of diagnosis, treatment, appropriate management, or |
| 11 | ongoing monitoring of an insured's disease or condition to guide |
| 12 | treatment decisions when supported by medical and scientific |
| 13 | evidence, including but not limited to: |
| 14 | (1) Labeled indications for an FDA-approved or FDA-cleared |
| 15 | test; |
| 16 | (2) Indicated tests for an FDA-approved drug; |
| 17 | (3) Warnings and precautions on FDA-approved drug labels; |
| | |

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| H.B. NO. | 2223 H.D. 1 |
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| 1 | (4) | Centers for Medicare and Medicaid Services national |
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| 2 | | coverage determinations or medicare administrative |
| 3 | | contractor local coverage determinations; or |
| 4 | (5) | Nationally recognized clinical practice guidelines and |
| 5 | | consensus statements. |
| 6 | (b) | Coverage under this section shall be provided in a |
| 7 | manner th | nat limits disruptions in care, including the need for |
| 8 | multiple | biopsies and consensus statements. |
| 9 | (c) | When coverage under this section is restricted for use |
| 10 | by a poli | cy, the patient and prescribing health care provider |
| 11 | shall hav | ve access to clear, readily accessible, and convenient |
| 12 | processes | to request an exception. The process shall be made |
| 13 | readily a | accessible on the insurer's website. |
| 14 | (d) | Coverage under this section may be subject to |
| 15 | copayment | , deductible, and coinsurance provisions of a policy of |
| 16 | accident | and health or sickness insurance that are no less |
| 17 | favorable | than the copayment, deductible, and coinsurance |
| 18 | provision | as for other medical services covered by the policy. |
| 19 | (e) | Every insurer shall provide written notice to its |
| 20 | policyhol | ders regarding the coverage required by this section. |
| 21 | The notic | e shall be in writing and prominently positioned in any |

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| 1 | literature or correspondence sent to policyholders and shall be |
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| 2 | transmitted within calendar year 2025 when annual information is |
| 3 | made available to policyholders or in any other mailing to |
| 4 | policyholders, but in no case later than December 31, 2025. |
| 5 | (f) This section shall not apply to limited benefit health |
| 6 | insurance as provided in section 431:10A-607. |
| 7 | (g) For the purposes of this section: |
| 8 | "Biomarker" means a characteristic that is objectively |
| 9 | measured and evaluated as an indicator of normal biological |
| 10 | processes, pathogenic processes, or pharmacologic responses to a |
| 11 | specific therapeutic intervention, including known gene-drug |
| 12 | interactions for medications being considered for use or already |
| 13 | being administered. "Biomarkers" include but are not limited to |
| 14 | gene mutations, gene characteristics, or protein expression. |
| 15 | "Biomarker testing" means the analysis of a patient's |
| 16 | tissue, blood, or other biospecimen for the presence of a |
| 17 | biomarker. "Biomarker testing" includes but is not limited to |
| 18 | single-analyte tests, multi-plex panel tests, protein |
| 19 | expression, whole exome, and whole genome and whole |
| 20 | transcriptome sequencing. |



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| 1 | "Clinical practice guidelines" means guidelines that |
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| 2 | establish standards of care informed by a systemic review of |
| 3 | evidence and an assessment of the benefits and risks of |
| 4 | alternative care options and include recommendations intended to |
| 5 | optimize patient care. |
| 6 | "Consensus statements" means statements developed by an |
| 7 | independent multidisciplinary panel of experts utilizing a |
| 8 | transparent methodology and reporting structure and that include |
| 9 | a conflict of interest policy, which are aimed at specific |
| 10 | clinical circumstances and based on the best available evidence |
| 11 | for the purpose of optimizing the outcomes of clinical care. |
| 12 | "FDA" means the United States Food and Drug Administration. |
| 13 | "Nationally recognized clinical practice guidelines" means |
| 14 | evidence-based clinical practice guidelines developed by |
| 15 | independent organizations or medical professional societies |
| 16 | utilizing a transparent methodology and reporting structure and |
| 17 | that include a conflict of interest policy." |
| 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: |

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| 1 | " <u>§</u> 43 | Biomarker testing; coverage. (a) Every |
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| 2 | individua | l or group hospital or medical service plan contract |
| 3 | issued or | renewed in this State on or after January 1, 2025, |
| 4 | shall pro | vide coverage for the medically necessary services of |
| 5 | biomarker | testing for the subscriber or member or any dependent |
| 6 | of the su | bscriber or member who is covered by the plan contract |
| 7 | for the p | urposes of diagnosis, treatment, appropriate |
| 8 | managemen | t, or ongoing monitoring of a subscriber's or member's |
| 9 | or depend | ent's disease or condition to guide treatment |
| 10 | decisions | , when supported by medical and scientific evidence, |
| 11 | including | but not limited to: |
| 12 | (1) | Labeled indications for an FDA-approved or FDA-cleared |
| 13 | | test; |
| 14 | (2) | Indicated tests for an FDA-approved drug; |
| 15 | (3) | Warnings and precautions on FDA-approved drug labels; |
| 16 | (4) | Centers for Medicare and Medicaid Services national |
| 17 | | coverage determinations or medicare administrative |
| 18 | | contractor local coverage determinations; or |
| 19 | (5) | Nationally recognized clinical practice guidelines and |
| 20 | | consensus statements. |

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| 1 | (b) Coverage under this section shall be provided in a |
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| 2 | manner that limits disruptions in care, including the need for |
| 3 | multiple biopsies and consensus statements. |
| 4 | (c) When coverage under this section is restricted for use |
| 5 | by a plan contract, the patient and prescribing health care |
| 6 | provider shall have access to clear, readily accessible, and |
| 7 | convenient processes to request an exception. The process shall |
| 8 | be made readily accessible on the mutual benefit society's |
| 9 | website. |
| 10 | (d) Coverage under this section may be subject to |
| 11 | copayment, deductible, and coinsurance provisions of a plan |
| 12 | contract that are no less favorable than the copayment, |
| 13 | deductible, and coinsurance provisions for other medical |
| 14 | services covered by the plan contract. |
| 15 | (e) Every mutual benefit society shall provide written |
| 16 | notice to its subscribers and members regarding the coverage |
| 17 | required by this section. The notice shall be in writing and |
| 18 | prominently positioned in any literature or correspondence sent |
| 19 | to subscribers and members and shall be transmitted within |
| 20 | calendar year 2025 when annual information is made available to |



| 1 | subscribers or members or in any other mailing to subscribers or |
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| 2 | members, but in no case later than December 31, 2025. |
| 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" include but are not limited to |
| 10 | gene mutations, gene characteristics, or 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 but is not limited to |
| 14 | single-analyte tests, multi-plex panel tests, protein |
| 15 | expression, whole exome, and whole genome and whole |
| 16 | transcriptome sequencing. |
| 17 | "Clinical practice guidelines" means guidelines that |
| 18 | establish standards of care informed by a systemic review of |
| 19 | evidence and an assessment of the benefits and risks of |
| 20 | alternative care options and include recommendations intended to |
| 21 | optimize patient care. |

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| 1 | "Consensus statements" means statements developed by an |
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| 2 | independent multidisciplinary panel of experts utilizing a |
| 3 | transparent methodology and reporting structure and that include |
| 4 | a conflict of interest policy, which are aimed at specific |
| 5 | clinical circumstances and based on the best available evidence |
| 6 | for the purpose of optimizing the outcomes of clinical care. |
| 7 | "FDA" means the United States Food and Drug Administration. |
| 8 | "Nationally recognized clinical practice guidelines" means |
| 9 | evidence-based clinical practice guidelines developed by |
| 10 | independent organizations or medical professional societies |
| 11 | utilizing a transparent methodology and reporting structure and |
| 12 | that include a conflict of interest policy." |
| 13 | SECTION 3. Section 432D-23, Hawaii Revised Statutes, is |
| 14 | amended to read as follows: |
| 15 | "§432D-23 Required provisions and benefits. |
| 16 | Notwithstanding any provision of law to the contrary, each |
| 17 | policy, contract, plan, or agreement issued in the State after |
| 18 | January 1, 1995, by health maintenance organizations pursuant to |
| 19 | this chapter, shall include benefits provided in sections |
| 20 | 431:10-212, 431:10A-115, 431:10A-115.5, 431:10A-116, 431:10A- |
| 21 | 116.2, 431:10A-116.5, 431:10A-116.6, 431:10A-119, 431:10A-120, |

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1 431:10A-121, 431:10A-122, 431:10A-125, 431:10A-126, 431:10A-132, 2 431:10A-133, 431:10A-134, 431:10A-140, and [431:10A-134,] 431:10A- , and chapter 431M." 3 4 SECTION 4. The coverage and benefits to be provided by a 5 health maintenance organization under section 3 of this Act 6 shall take effect for all policies, contracts, plans, or 7 agreements issued or renewed in the State on or after January 1, 8 2025. 9 SECTION 5. (a) The reimbursement for medically necessary 10 services of biomarker testing required under sections 1 and 2 of 11 this Act shall apply to all health plans under the medicaid 12 managed care program in the State. 13 (b) The department of human services shall submit the 14 amendments to the Hawaii medicaid state plan to the Centers for 15 Medicare and Medicaid Services no later than 16 SECTION 6. Statutory material to be repealed is bracketed 17 and stricken. New statutory material is underscored.

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SECTION 7. This Act shall take effect on July 1, 3000;
provided that section 5 shall take effect upon approval of the
Hawaii medicaid state plan by the Centers for Medicare and
Medicaid Services.



Report Title:

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

Description:

Beginning 1/1/2025, 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.

