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

H.B. NO. 2223

A BILL FOR AN ACT

RELATING TO INSURANCE.

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

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

"**§431:10A- Biomarker testing; coverage.** (a) Each individual or group policy of accident and health or sickness insurance issued or renewed in this State on or after January 1, 2025, shall provide coverage for the services of biomarker testing for the policyholder or any dependent of the policyholder who is covered by the policy for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured's disease or condition to guide treatment decisions when supported by medical and scientific evidence, including but not limited to:

(1) Labeled indications for an FDA-approved or FDA-cleared test;

(2) Indicated tests for an FDA-approved drug;

(3) Warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services national coverage determinations or medicare administrative contractor local coverage determinations; or

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

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

(c) When coverage under this section is restricted for use by a policy, the patient and prescribing health care provider shall have access to clear, readily accessible, and convenient processes to request an exception. The process shall be made readily accessible on the insurer's website.

(d) Coverage under this section may be subject to copayment, deductible, and coinsurance provisions of a policy of accident and health or sickness insurance that are no less favorable than the copayment, deductible, and coinsurance provisions for other medical services covered by the policy.

(e) Every insurer shall provide written notice to its policyholders regarding the coverage required by this section. The notice shall be in writing and prominently positioned in any

literature or correspondence sent to policyholders and shall be transmitted within calendar year 2025 when annual information is made available to policyholders or in any other mailing to policyholders, but in no case later than December 31, 2025.

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

(g) For the purposes of this section:

"Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered. "Biomarkers" include but are not limited to gene mutations, gene characteristics, or protein expression.

"Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. "Biomarker testing" includes but is not limited to single-analyte tests, multi-plex panel tests, protein expression, whole exome, and whole genome and whole transcriptome sequencing.

"Clinical practice guidelines" means guidelines that establish standards of care informed by a systemic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

"Consensus statements" means statements developed by an independent multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and that include a conflict of interest policy, which are aimed at specific clinical circumstances and based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"FDA" means the United States Food and Drug Administration.

"Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and that include a conflict of interest policy."

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

"§432- **Biomarker testing; coverage.** (a) Every individual or group hospital or medical service plan contract issued or renewed in this State on or after January 1, 2025, shall provide coverage for the services of biomarker testing for the subscriber or member or any dependent of the subscriber or member who is covered by the plan contract for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a subscriber's or member's or dependent's disease or condition to guide treatment decisions, when supported by medical and scientific evidence, including but not limited to:

(1) Labeled indications for an FDA-approved or FDA-cleared test;

(2) Indicated tests for an FDA-approved drug;

(3) Warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services national coverage determinations or medicare administrative contractor local coverage determinations; or

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

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

(c) When coverage under this section is restricted for use by a plan contract, the patient and prescribing health care provider shall have access to clear, readily accessible, and convenient processes to request an exception. The process shall be made readily accessible on the mutual benefit society's website.

(d) Coverage under this section may be subject to copayment, deductible, and coinsurance provisions of a plan contract that are no less favorable than the copayment, deductible, and coinsurance provisions for other medical services covered by the plan contract.

(e) Every mutual benefit society shall provide written notice to its subscribers and members regarding the coverage required by this section. The notice shall be in writing and prominently positioned in any literature or correspondence sent to subscribers and members and shall be transmitted within calendar year 2025 when annual information is made available to

subscribers or members or in any other mailing to subscribers or members, but in no case later than December 31, 2025.

(f) For the purposes of this section:

"Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered. "Biomarkers" include but are not limited to gene mutations, gene characteristics, or protein expression.

"Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. "Biomarker testing" includes but is not limited to single-analyte tests, multi-plex panel tests, protein expression, whole exome, and whole genome and whole transcriptome sequencing.

"Clinical practice guidelines" means guidelines that establish standards of care informed by a systemic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

"Consensus statements" means statements developed by an independent multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and that include a conflict of interest policy, which are aimed at specific clinical circumstances and based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"FDA" means the United States Food and Drug Administration.

"Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and that include a conflict of interest policy."

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

"**§432D-23 Required provisions and benefits.** Notwithstanding any provision of law to the contrary, each policy, contract, plan, or agreement issued in the State after January 1, 1995, by health maintenance organizations pursuant to this chapter, shall include benefits provided in sections 431:10-212, 431:10A-115, 431:10A-115.5, 431:10A-116, 431:10A-116.2, 431:10A-116.5, 431:10A-116.6, 431:10A-119, 431:10A-120,

431:10A-121, 431:10A-122, 431:10A-125, 431:10A-126, 431:10A-132, 431:10A-133, 431:10A-134, 431:10A-140, and [~~431:10A-134,~~] 431:10A- and chapter 431M."

SECTION 4. The coverage and benefits to be provided by a health maintenance organization under section 3 of this Act shall take effect for all policies, contracts, plans, or agreements issued or renewed in the State on or after January 1, 2025.

SECTION 5. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 6. This Act shall take effect upon its approval.

INTRODUCED BY: _____

JAN 2 2 2024

H.B. NO. 2223

Report Title:
Health Insurance; Biomarker Testing; Mandatory Coverage

Description:
Beginning 1/1/2025, requires health insurers, mutual benefit societies, and health maintenance organizations to provide coverage for biomarker testing.

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