

January 3, 2025

VIA EMAIL

The Honorable Ronald D. Kouchi
Senate President
415 South Beretania Street
Hawaii State Capitol, Room 409
Honolulu, Hawaii 96813

VIA EMAIL

The Honorable Nadine K. Nakamura
Speaker, House of Representatives
415 South Beretania Street
Hawaii State Capitol, Room 431
Honolulu, Hawaii 96813

Re: *Assessment of Proposed Mandatory Health Insurance Coverage For Medically Necessary Biomarker Testing, Report No. 25-01*

Dear President Kouchi and Speaker Nakamura:

Please find attached Report No. 25-01, *Assessment of Proposed Mandatory Health Insurance Coverage For Medically Necessary Biomarker Testing*, along with a copy of the Auditor's Summary. This report is being issued pursuant to House Concurrent Resolution No. 53 of the 2024 Legislative Session, which requested the State Auditor to assess the social and financial effects of the mandated coverage as proposed in House Bill No. 2223, House Draft 1, also introduced in the 2024 Legislative Session.

The report is accessible through our website at:
<http://files.hawaii.gov/auditor/Reports/2025/25-01.pdf>.

The summary is also accessible through our website at:
<http://files.hawaii.gov/auditor/Overviews/2025/25-01AuditorSummary.pdf>.

If you or other Legislators have questions about the report or would like a printed version of the report, please let me know.

Very truly yours,

Leslie H. Kondo
State Auditor

LHK:dmah

Attachments

ec/attach: Members of the Senate
Members of the House of Representatives
Carol Taniguchi, Senate Chief Clerk
Brian Takeshita, House Chief Clerk

Auditor's Summary

Assessment of Proposed Mandatory Health Insurance Coverage For Medically Necessary Biomarker Testing

Report No. 25-01



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WE WERE REQUESTED BY THE LEGISLATURE through House Concurrent Resolution No. 53 (Reg. Session 2024), to assess the social and financial effects of mandating health insurance coverage for medically necessary biomarker testing as proposed in House Bill No. 2223, House Draft 1 (Reg. Session 2024) (HB 2223, HD 1) and in accordance with Sections 23-51 and 23-52, Hawai'i Revised Statutes. HB 2223, HD 1 proposed that every individual or group policy or medical service plan contract issued or renewed in Hawai'i on or after January 1, 2025 provide coverage for medically necessary "biomarker testing."

Biomarker testing is the analysis of a patient's tissue, blood, or other bodily fluid to identify a biomarker or group of biomarkers. A biomarker is a biological characteristic indicative of a particular disease, condition, or treatment response. Biomarkers can help health providers diagnose, treat, and monitor a patient's disease or condition.

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We found that health insurance policies issued in the State of Hawai'i currently provide coverage for medically necessary biomarker testing. Hawai'i's Patients' Bill of Rights and Responsibilities Act, Chapter 432E, HRS, mandates coverage for health interventions that are medically necessary, which include medically necessary biomarker testing. All insurers that responded to our survey agreed that their policies are already required to include coverage for medically necessary biomarker testing. We determined that there will be no social or financial impacts caused by the mandate requiring that health insurance policies provide coverage for medically necessary biomarker testing, as proposed in HB 2223, HD 1.

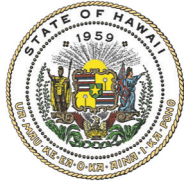
Assessment of Proposed Mandatory Health Insurance Coverage For Medically Necessary Biomarker Testing

A Report to the Governor
and the Legislature of
the State of Hawai'i

Report No. 25-01
January 2025



OFFICE OF THE AUDITOR
STATE OF HAWAII



OFFICE OF THE AUDITOR STATE OF HAWAII

Constitutional Mandate

Pursuant to Article VII, Section 10 of the Hawai'i State Constitution, the Office of the Auditor shall conduct post-audits of the transactions, accounts, programs and performance of all departments, offices, and agencies of the State and its political subdivisions.

The Auditor's position was established to help eliminate waste and inefficiency in government, provide the Legislature with a check against the powers of the executive branch, and ensure that public funds are expended according to legislative intent.

Hawai'i Revised Statutes, Chapter 23, gives the Auditor broad powers to examine all books, records, files, papers and documents, and financial affairs of every agency. The Auditor also has the authority to summon people to produce records and answer questions under oath.

Our Mission

To improve government through independent and objective analyses.

We provide independent, objective, and meaningful answers to questions about government performance. Our aim is to hold agencies accountable for their policy implementation, program management, and expenditure of public funds.

Our Work

We conduct performance audits (also called management or operations audits), which examine the efficiency and effectiveness of government programs or agencies, as well as financial audits, which attest to the fairness of financial statements of the State and its agencies.

Additionally, we perform procurement audits, sunrise analyses and sunset evaluations of proposed regulatory programs, analyses of proposals to mandate health insurance benefits, analyses of proposed special and revolving funds, analyses of existing special, revolving, and trust funds, and special studies requested by the Legislature.

We report our findings and make recommendations to the Governor and the Legislature to help them make informed decisions.

For more information on the Office of the Auditor, visit our website:
<https://auditor.hawaii.gov>

Foreword

We assessed the social and financial impacts of mandating health insurance coverage for medically necessary biomarker testing as proposed in House Bill No. 2223, House Draft 1 (Reg. Session 2024), in accordance with Sections 23-51 and 23-52, Hawai'i Revised Statutes (HRS). Section 23-51, HRS, requires passage of a concurrent resolution requesting an impact assessment by the Auditor before any legislative measure mandating health insurance coverage for a specific health service, disease, or provider can be considered. The Legislature requested this assessment through House Concurrent Resolution No. 53 (Reg. Session 2024).

We wish to express our appreciation for the cooperation and assistance extended to us by the State's health plan providers as well as other organizations and individuals we contacted during the course of our work.

Leslie H. Kondo
State Auditor

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Assessment of Proposed Mandatory Health Insurance Coverage For Medically Necessary Biomarker Testing

Introduction

House Concurrent Resolution No. 53 and House Bill No. 2223, House Draft 1

Through House Concurrent Resolution No. 53 (Reg. Session 2024) (HCR 53), the Legislature requested that the Office of the Auditor assess the social and financial effects of mandating health insurance coverage for medically necessary biomarker testing as proposed in House Bill No. 2223, House Draft 1 (Reg. Session 2024) (HB 2223, HD 1) and in accordance with Sections 23-51 and 23-52, Hawai‘i Revised Statutes (HRS). HB 2223, HD 1 proposed that every individual or group policy or medical service plan contract issued or renewed in Hawai‘i on or after January 1, 2025 provide coverage for medically necessary “biomarker testing,” as that term is defined in the bill. Biomarker testing is the analysis of a patient’s tissue, blood, or other bodily fluid to identify a biomarker or group of biomarkers. Biomarkers,

Biomarkers, which are a characteristic of a patient’s biology, can help health providers diagnose, treat, and monitor a patient’s disease or condition.

which are a characteristic of a patient's biology, can help health providers diagnose, treat, and monitor a patient's disease or condition.

We determined that there will be no social or financial impacts caused by the mandate requiring that health insurance policies provide coverage for medically necessary biomarker testing, as proposed in HB 2223, HD 1. Health insurance policies issued in the State of Hawai'i currently provide coverage for medically necessary biomarker testing. Hawai'i's Patients' Bill of Rights and Responsibilities Act, Chapter 432E, HRS, mandates coverage for health interventions that are medically necessary, which include medically necessary biomarker testing. The insurers that provide health insurance in the State confirmed in responses to our surveys that the proposed mandate will not expand the health insurance coverage beyond what is currently provided under their policies.

Objectives

In accordance with Sections 23-51 and 23-52, HRS, the objectives of this study are to assess the social and financial impacts of mandating health insurance coverage of medically necessary biomarker testing services for the purpose of diagnosis, treatment, management, or monitoring of a disease or condition to guide treatment decisions when supported by medical and scientific evidence.

Scope and Methodology

In preparing this report, we reviewed testimony relating to House Bill 2223 (Reg. Session 2024)¹ and surveyed health insurance providers². We researched the Patient Protection and Affordable Care Act, Hawai'i's Prepaid Health Care Act, Hawai'i's Patients' Bill of Rights and Responsibilities Act, and publications by medical organizations, the media, and government agencies, including the American Medical Association, the National Institutes of Health, and the Centers for Medicare and Medicaid Services. Finally, we met with representatives of the Insurance Division of the Hawai'i Department of Commerce and Consumer Affairs (DCCA Insurance Division). We conducted this assessment from September 2024 through December 2024 and in accordance with Sections 23-51 and 23-52, HRS.

¹ We note that the House Committee on Health and Homelessness amended House Bill 2223 by, among other things, specifying that the mandated coverage would be for "medically necessary" biomarker testing services. HB 2223, HD 1, however, was not heard by the House Committee on Consumer Protection and Commerce, the next committee to which the bill was referred. For that reason, the written testimony did not address the condition that the mandated coverage for biomarker testing services be medically necessary.

² The health insurance providers that responded to our survey were Hawai'i Medical Service Association (HMSA), Kaiser Permanente Hawaii (Kaiser Permanente), University Health Alliance, 'Ohana Health Plan, and Hawai'i Medical Assurance Association, as reported by its administrator Hawai'i-Western Management Group.

Background on Biomarkers and Biomarker Testing

Biomarkers

A biomarker is a biological characteristic indicative of a particular disease, condition, or treatment response. Biomarkers include biological molecules, gene mutations, gene characteristics, radiographic abnormalities, and similar measurable characteristics found in blood, tissue, or other bodily fluids. A biomarker may also be more than a single gene, molecule, or other indicator; it may be a grouping, pattern, or sequence of such indicators – such as a pattern of DNA chemical tags that, when arranged in that pattern, suggest a likelihood of developing asthma. In some instances, it is the level of a substance, as opposed to that substance’s mere existence, that is the biomarker – such as a high level of a hormone that suggests the development of breast cancer.

Importantly, many biomarkers are not disease indicators at all, but are signs of how well or poorly a patient is likely to react to a treatment, such as in rheumatoid arthritis patients who undergo a biomarker test to determine responsiveness to certain therapies. When a biomarker can be monitored to assess the status of a disease or medical condition, or for evidence of exposure to a medical product or environmental agent, it is a monitoring biomarker. Other biomarkers have been described as prognostic, safety, and susceptibility/risk biomarkers. Worldwide, as of October 16, 2024, there are at least 34,483 known biomarkers.

Biomarker Testing

Biomarker testing is the analysis of a patient’s tissue, blood, or other specimen for the presence of a biomarker.³ It is used to obtain information specific to a patient’s condition, to help doctors choose effective therapies and drugs, and otherwise to inform care. Biomarker testing is used to diagnose and tailor treatments for diseases and conditions including: pancreatic cancer, ovarian cancer, breast cancer, prostate cancer, melanoma, hypertension, hyperlipidemia, lupus, rheumatoid arthritis, preeclampsia, sickle cell disease, Alzheimer’s disease, Parkinson’s disease, and amyotrophic lateral sclerosis (also known as Lou Gehrig’s disease). Biomarker testing may also help identify a specific form of disease – such as a specific subtype of a type of cancer.

Aside from assisting providers in diagnosing conditions and pinpointing effective treatment, biomarker testing is also used for overall disease prognosis, management, and monitoring. Biomarker testing can also

³ We note that the broad definition of biomarker testing may include a routine blood test ordered as part of an insured’s annual check-up examination.

facilitate organ and tissue transplantation by providing early detection of whether a patient’s immune system is fighting or rejecting a donated organ – informing doctors of whether and how much to modify immunosuppressive therapy. In the U.S., biomarker tests are identified by, and billed according to, a string of alphanumeric characters known as a Healthcare Common Procedure Codes System code, in a list maintained by the Centers for Medicare and Medicaid Services.

Proposed Mandatory Insurance Coverage

HB 2223, HD 1 proposes to amend the Hawai‘i Insurance Code to mandate insurance coverage for “medically necessary services of biomarker testing.” It is intended to ensure comprehensive coverage of biomarker testing “for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a person’s disease or condition to guide treatment decisions when supported by medical and scientific evidence.”⁴

The bill defines biomarker testing as “the analysis of a patient’s tissue, blood, or other biospecimen for the presence of a biomarker.” It also defines biomarker as “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.” However, HB 2223, HD 1 does not specify any particular set of biomarker codes or otherwise target the biomarkers or biomarker tests for any particular diseases or conditions.

The bill also contains provisions that include:

- (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

⁴ The House Committee on Health & Homelessness amended the original bill by specifying that the mandated coverage is for biomarker testing services that are medically necessary. The Committee, however, did not otherwise amend the coverage section of the bill, leaving the original version’s requirement that biomarker testing be covered “when supported by medical and scientific evidence.” The type of medical and scientific evidence required to trigger coverage is further defined in the bill to include label indications, determinations by Centers for Medicare and Medicaid Services, and guidelines of national recognition. It appears the requirement that the biomarker testing be medically necessary renders those factors moot. The statutory definition of medical necessity takes into consideration the types of medical and scientific evidence listed in the bill. See Sidebar, “Determination of Medical Necessity and Appeal Process” on page 6. For that reason, we did not assess, separately, the impacts caused by the requirement that the testing be supported by medical and scientific evidence.

to clear, readily accessible, and convenient processes to request an exception. The process shall be made readily accessible on the insurer's website.

It is unclear whether, and to what extent, these provisions mandate coverage beyond what is already required under the medical necessity standard. No further definitions are provided in these provisions. For example, the bill does not define or describe whether "policy" in subsection (c) refers to the language of an insurance policy or contract as opposed to a policy decision made by an insurer. Therefore, we did not consider the social and financial impacts, if any, of these provisions which were included in the original version of the bill before the amendment adding "medically necessary."

Mandating Health Insurance Coverage for Biomarker Testing Should Have No Impact, as Medically Necessary Services are Already Required to be Covered

The mandated health insurance coverage as proposed in HB 2223, HD 1 will likely have no social or financial impact on insurers or their insureds. We found that biomarker testing is already included in health insurance policies issued in Hawai'i.

The bill's mandated coverage for medically necessary biomarker testing services is redundant of the coverage already required by Hawai'i's Patients' Bill of Rights and Responsibilities Act. Specifically, Section 432E-1.4, HRS, states that a health intervention shall be covered if recommended by the treating licensed health care provider and "determined by the health plan's medical director to be medically necessary." See "Determination of Medical Necessity and Appeal Process" on page 6. All insurers that responded to our survey agreed that their policies are already required to include coverage for medically necessary biomarker testing. We note that Section 432E-1.4, HRS, requires coverage of a medically necessary health intervention "not specifically excluded," which indicates that without mandated coverage, an insurer could specifically exclude medically necessary biomarker testing.

Determination of Medical Necessity and Appeal Process

MEDICAL NECESSITY is defined in Section 432E-1.4(b), HRS, which is part of Hawai'i's Patients' Bill of Rights and Responsibilities Act. Under that section, to be medically necessary, a health intervention must be:

- recommended by a treating physician or licensed healthcare provider;
- approved by the health plan's medical director or physician designee;
- for the purpose of treating a medical condition;
- be the most appropriate delivery of service, considering harms and benefits to the patient;
- known to improve health outcomes, as determined by scientific evidence, professional standards of care, or expert opinion; and
- cost-effective compared to alternatives, including having no intervention.

As noted above, medical necessity is determined by the insurer's medical director – in approving or denying a claim – but the insured can appeal a determination that the recommended health intervention is not medically necessary. First, an insured may utilize an insurer's internal appeals process. If the insured continues to be denied coverage, the insured may file a request for an external review. The insurer initially determines whether the case is eligible for external review. If the insurer determines that the case is ineligible, the insured may appeal that eligibility determination to the DCCA Insurance Division, whose commissioner determines whether the case meets state standards for external review. If external review is approved – whether by the insurer or by the commissioner – the DCCA Insurance Division assigns the review to an Independent Review Organization, which will render a determination on medical necessity. These processes may be expedited in cases involving urgent health risks, where Section 432E-35, HRS, requires each step prior to a final determination to be completed "immediately."

According to some insurers, many of the claims that they denied were because they were duplicate claims or there were other administrative issues.⁵ Total claims submitted for 2023, 2022, and 2021 numbered 36,974, 24,328 and 23,928, respectively, and covered persons represented over 81 percent of Hawai‘i’s resident population.

The social impacts caused by the mandated coverage for biomarker testing proposed in HB 2223, HD 1 should be immaterial, if any, in light of existing coverage of medically necessary services under Section 432E-1.4, HRS. The proposed coverage should not result in any impact on biomarker testing usage or on morbidity, mortality, quality of care, or other health measures in the State. Insurer survey responses indicate minimal if any social impact. Insurers either responded that the bill should cause minimal to no increase in usage or were unclear as to usage, and three insurers agreed it should have no impact on morbidity, mortality, quality of care, or other health measures in the State. None of the responding insurers were aware of any inquiries specific to biomarker testing, either concerning coverage or with respect to any bargaining agreement.

The financial impact of HB 2223, HD 1 likewise should be immaterial, if any. We expect there will be little to no increase in testing costs, insurance premiums, or overall health care costs, as biomarker testing should already be covered as medically necessary. Insurers either asserted that HB 2223, HD 1 should cause minimal to no increase in premiums or did not give a definite answer; three predicted little to no increase in biomarker testing service costs. Insurers were generally unsure as to whether the bill would affect overall health care costs, three stating that costs typically tend to increase with new mandates, but without further elaboration.

Pursuant to Section 23-52, HRS, we assessed the social and financial effects of mandating health insurance coverage for medically necessary biomarker testing, as provided in HB 2223, HD 1. For the reasons explained above, we conclude that the coverage that HB 2223, HD 1 seeks to mandate is already mandated by existing law and already provided by Hawai‘i’s plan providers.

⁵ HMSA and Kaiser Permanente both noted that many denials of coverage were due to administrative error, such as incorrect coding or gender entry, untimely or duplicate filings, and coverage by another insurer. HMSA – whose membership equals more than double that of all the other four insurers, combined – added that denied claims are generally resubmitted and paid.

