Study of Proposed Mandatory Health Insurance Coverage for Early Access Breast Cancer Screening

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

Report No. 23-03
February 2023

OFFICE OF THE AUDITOR
STATE OF HAWAI‘I

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Foreword

We assessed the social and financial impacts of mandating insurance coverage for early access breast cancer screening as proposed in Senate Bill No. 827, Senate Draft 2, pursuant to 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 2022 Legislature requested this assessment through House Concurrent Resolution No. 33, Senate Draft 1.

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

Leslie H. Kondo
State Auditor

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As we detail in this report, based on our analysis of the bill and our interviews and surveys with insurers and health care providers, the major difference between current mandated insurance coverage and that proposed by the bill is the addition of a baseline mammogram for women ages 35 to 39 who do not have a history of breast cancer or whose mother or sister do not have a history of breast cancer.

Introduction

ACCORDING TO the National Cancer Institute, breast cancer is the most common cancer in women and is the second leading cause of cancer-related death in the United States for women. Incidence and mortality rates vary widely across racial/ethnic populations. Across the nation, non-Hispanic Whites have the highest incidence, followed by African Americans, Asian/Pacific Islanders, American Indian/Alaska Natives, and Hispanics. The University of Hawai‘i Cancer Center has noted that women in Hawai‘i have a higher incidence of breast cancer at 138.9 per 100,000 compared to the national average of 125.9.

Currently, pursuant to Sections 431:10A-116(4), 432:1-605, and 432D-23, Hawai‘i Revised Statutes (HRS), health insurance carriers are required

to provide coverage for screening by low-dose mammography for breast cancer as follows:

A) For women forty years of age and older, an annual mammogram; and

B) For a woman of any age with a history of breast cancer or whose mother or sister has had a history of breast cancer, a mammogram upon the recommendation of the woman's physician.

Senate Bill No. 827, Senate Draft 2 (SB 827, SD 2)[1], introduced during the 2021 Legislative Session, proposes to amend existing mandated health insurance coverage for breast cancer screening to include (proposed revisions underscored):

1) For women ages thirty-five to thirty-nine, inclusive, a baseline mammogram;[2]

2) For women forty years of age and older, an annual mammogram;

3) For women ages thirty to fifty, deemed by a licensed physician or clinician to have an above-average risk for breast cancer, an annual mammogram, provided that a formal risk factor screening assessment is first made and informed by any readily available risk factor modeling tool;

4) For women of any age with a history of breast cancer or whose mother or sister has had a history of breast cancer, a mammogram upon the recommendation of the woman's physician; and

5) For women of any age, any additional or supplemental imaging, such as breast magnetic resonance imaging or ultrasound, deemed medically necessary by an applicable American College of Radiology guideline.[3]

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[1] House Concurrent Resolution No. 33, Senate Draft 1 (2022 Regular Session), requests that the Auditor assess the mandatory insurance coverage proposed in SB 827, SD 2 (2021 Regular Session), and for that reason, this report is based on that version of the bill. We note, however, that there is a more current version of the bill, which is SB 827, SD 2, **House Draft 1**.

[2] Although the term "baseline mammogram" is not defined in the bill, according to an article in the *Journal of the American College of Radiology*, a baseline mammogram is generally the first screening mammogram a woman obtains, which the radiologist can compare to subsequent mammograms. See Robert Horsley, et al., "Baseline Mammography: What is it and Why is it Important? A Cross-Sectional Survey of Women Undergoing Screening Mammography," *Journal of the American College of Radiology*, vol. 16, no. 2, February 2019, pp. 164-169.

[3] We note that the primary changes to coverage proposed in SB 827, SD 2, are

The bill also expands the definition of "low-dose mammography" to include both digital mammography and digital breast tomosynthesis and interpreting and rendering a report by a radiologist or other physician based on the screening.

Pursuant to Section 23-51, HRS, before any legislative measure that mandates health insurance coverage for specific health services, specific diseases, or certain providers of health care services as part of individual or group health insurance policies can be considered, the Auditor must first assess the social and financial effects of the proposed mandated coverage. Through House Concurrent Resolution No. 33, Senate Draft 1 (Regular Session 2022) (HCR 33, SD 1), the Legislature requested the Auditor to conduct this assessment with respect to the mandatory insurance coverage proposed in SB 827, SD 2.

As we detail in this report, based on our analysis of the bill and our interviews and surveys with insurers and health care providers, the major difference between current mandated insurance coverage and that proposed by the bill is the addition of a baseline mammogram for women ages 35 to 39 who do not have a history of breast cancer or whose mother or sister do not have a history of breast cancer. In addition to the baseline mammogram, the bill specifies coverage for an annual mammogram for women ages 30 to 50 deemed by a physician or clinician to have an above-average risk[4] for breast cancer, provided that a formal risk factor screening assessment is first made and informed by any readily available risk factor modeling tool.[5] However, we determined that all major insurers already cover annual mammograms for above-average-risk women of any age as determined by a physician. The bill also specifies coverage for any additional imaging or supplemental imagery, such as breast magnetic resonance imaging or ultrasound, deemed medically necessary by an applicable American College of Radiology guideline; however, any supplemental imaging deemed medically necessary is already required by law to be covered.

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made to Section 431:10A-116(4), HRS, and those corresponding changes are not made to Section 432:1-605, HRS. We assume that this is largely an oversight that will be addressed in future versions of the bill.

[4] Although the modifiers "high," "higher," and "above-average" are used in the various sources we reviewed to describe patients deemed to be at above-average risk for developing breast cancer, we use the term "above-average" throughout this report unless directly quoting a source that references another term.

[5] Kaiser has a narrower definition of "above-average-risk" women than other insurers, requiring that a woman have a mother or sister with a history of breast cancer *and* be within ten years of the age that their mother or sister was when they were first diagnosed. Additionally, Kaiser expressed concern with the term "any readily available risk factor modeling tool" as expressed in SB 827, SD 2, because Kaiser utilizes National Cancer Comprehensive Network-supported risk modeling tools. It is possible that a small number of women not currently considered to be at above-average risk by Kaiser would be eligible for a mammogram under the proposed revisions to SB 827, SD 2.

For these reasons, this report assesses only the social and financial impacts of a baseline mammogram for average-risk women ages 35 to 39.

Objectives of the Study

Pursuant to HCR 33, SD 1, the objectives of this study are to:

1) In accordance with Section 23-52, HRS, assess the social and financial impacts of requiring health insurers, mutual benefit societies, and health maintenance organizations to provide coverage for early access breast cancer screening as proposed in SB 827, SD 2.
2) Assess the impact of the proposed mandatory coverage with respect to Section 1311(d)(3) of the federal Patient Protection and Affordable Care Act (PPACA), that includes but is not limited to the State's obligation to pay for the additional cost of any benefits beyond the essential health benefits of Hawai‘i's qualified health plans under the PPACA.
3) Determine how many qualified health plans are available in Hawai‘i, including plans offered by health maintenance organizations; the individual or group enrollment in these plans; and the actuarial cost of the defrayment to the State for early breast cancer screening.

Scope and Methodology

We surveyed healthcare professional associations and organizations whose members screen and treat women for breast cancer, as well as the major health insurance providers in Hawai‘i, for information necessary for us to complete the assessment of the proposed mandatory health insurance. We conducted this assessment from June 2022 to November 2022 in accordance with Sections 23-51 and 23-52, HRS.

We reviewed the Hawai‘i Association of Health Plans website at www.hahp.org to determine the organizations that provide health insurance to Hawai‘i residents, sending surveys to the following insurance companies that are members of the organization:

1. AlohaCare
2. Hawai‘i Medical Assurance Association
3. Hawai‘i Medical Service Association (HMSA)
4. Hawai‘i-Western Management Group
5. Humana
6. Kaiser Permanente (Kaiser)
7. MDX Hawai‘i

8. ʻOhana Health Plan
9. United Healthcare
10. University Health Alliance (UHA) Health Insurance

We received completed surveys from HMSA, the state's largest insurer, and Kaiser Permanente Hawaiʻi, the second largest insurer, as well as Hawaiʻi Medical Assurance Association/Hawaiʻi-Western Management Group,[6] AlohaCare, UHA, and ʻOhana Health Plan. Humana did not submit a survey response, explaining that it does not have any Hawaiʻi residents on commercial medical plans and that its Medicare plans are required to follow federal Medicare guidelines. United Healthcare also did not complete the survey because its organization in Hawaiʻi mainly deals with Medicaid as a Medicaid contractor for Hawaiʻi's Department of Human Services. As a result, United Healthcare stated that it is bound by whatever coverage the Department of Human Services authorizes. MDX Hawaiʻi did not complete the survey because the company only administers services for Humana and United Healthcare's Medicare Advantage members. Both plans dictate the coverage, and MDX Hawaiʻi must administer the plans accordingly.

Where necessary, we followed up with insurance companies to obtain additional clarification on their survey responses. We also sent a similar survey to a number of clinicians, professional societies, and healthcare providers. Only the Hawaiʻi Radiological Society responded to the survey.

In addition to surveying health insurance providers and health care providers, we also reviewed the testimony submitted in connection with SB 827. Several medical professionals provided research findings from academic studies to support their recommendations for the bill and the resolution. We reviewed the studies cited in testimony for background information on breast cancer and relevant breast cancer screening methods. Our review included a 2019 study written by researchers at the University of Hawaiʻi Cancer Center that was referenced in testimony on HCR 33, SD 1, entitled *The High and Heterogeneous Burden of Breast Cancer in Hawaiʻi: A Unique Multiethnic U.S. Population*.[7] This study evaluated the incidence and mortality trends from 1984-2013 across five major racial/ethnic groups in Hawaiʻi (i.e., Native Hawaiian, White, Japanese, Chinese, and Filipino) using Hawaiʻi's Surveillance, Epidemiology, and Ends Results registry data.

[6] Hawaiʻi-Western Management Group is the third-party administrator for Hawaiʻi Medical Assurance Association.

[7] Leonora Loo, et al., "The High and Heterogeneous Burden of Breast Cancer in Hawaiʻi: A Unique Multiethnic U.S. Population," *Cancer Epidemiology*, vol. 58, February 2019, p. 71.

Other sources for our assessment of the proposed mandatory insurance coverage included data from the National Center for Health Statistics' National Health Interview Survey, the Susan G. Komen Foundation, the National Institute of Health's National Cancer Institute, the Hawai'i Department of Health's Behavioral Risk Factor Surveillance System, the University of Hawai'i Cancer Center, the American Cancer Society, and the screening guidelines from relevant professional organizations such as the U.S. Preventive Services Task Force and the American College of Radiology. Several other academic studies were found through online searches for background information on modern breast cancer detection; the role of ethnicity in breast cancer prevalence and mortality in Hawai'i; the impacts of ethnic disparities on breast cancer prevalence in women in their 40s; women's perceptions of the pros and cons of breast cancer screening, including potential risks and the costs associated with the procedure; and best practices in screening and treatment.

Overview of Early Access Breast Cancer Screening

Prevalence of Breast Cancer Nationwide and in Hawai'i

According to statistics from the National Cancer Institute, breast cancer affects about one in eight (12.9 percent) American women in their lifetime. Breast cancer occurs when malignant (cancer) cells form in the tissue of the breast, such as the lobes, lobules, bulbs, or ducts. Women with a close family member who has had breast cancer are considered above-average risk for developing breast cancer. However, about 75 percent of women diagnosed with breast cancer have no family history of breast cancer.

The Hawai'i Medical Association submitted testimony on HCR 33, asserting that breast cancer is by far the most common cancer among women in Hawai'i, comprising over one-third of all cancer diagnoses. A faculty researcher with the University of Hawai'i Cancer Center testified that there are about 1,200 invasive breast cancer[8] cases a year and 148 deaths per year in Hawai'i from breast cancer. A study published in 2019 by researchers at the University of Hawai'i Cancer Center found a 2.8 percent per year increase in breast cancer diagnoses in Hawai'i between 2006-2014. This study notes that Hawai'i has the fifth highest breast cancer incidence in the nation, but also has the third lowest breast cancer mortality rate in the nation. The researchers suggest that these high rates of breast cancer might be an artifact of the high levels of mammography screening which has been available in Hawai'i for several decades. Data from the Hawai'i Department of Health's Behavioral Risk Factor Surveillance System indicate that

[8] Invasive breast cancer is defined as breast cancer that has spread into surrounding breast tissue.

87 percent of women above the age of 50 have had a mammogram in the past two years.

Breast Cancer Screening Guidelines

The American College of Obstetricians and Gynecologists (ACOG) released a practice bulletin in July 2017 (reaffirmed in 2021) reviewing the major guideline group recommendations for breast cancer screening for average-risk women. The report notes there are differences between the major guideline group recommendations for breast cancer screening and includes information from ACOG, the American Cancer Society (ACS), the National Comprehensive Cancer Network (NCCN), and the U.S. Preventive Services Task Force (USPSTF).

Based on information from the ACOG report, none of the organizations included in the report recommend mammography screening for average-risk women before age 40 and USPSTF does not recommend screening before age 50 for average-risk women.

Exhibit 1 – Recommendations for Breast Cancer Screening in Average-Risk Women

	ACOG	ACS	NCCN	USPSTF
Mammography initiation age	Offer starting at age 40. Initiate at ages 40 to 49 after counseling if patient desires. Recommend no later than age 50.	Offer at ages 40 to 45. Recommend at age 45.	Recommend at age 40.	Recommend at age 50. Individual decision between ages 40 to 49.
Mammography screening interval	Annual or biennial (shared decision making after counseling).	Annual for women ages 40 to 54. Biennial with the option to continue annual screening for women 55 or older.	Annual	Biennial

Source: American College of Obstetricians and Gynecologists.

In addition to the four major guideline groups shown above, the American College of Radiology and the Society of Breast Imaging state that the latest scientific evidence overwhelmingly supports a continued general recommendation of starting annual screening for average-risk women at age 40. The American College of Radiology and the

Society for Breast Imaging further recommend all women have a risk assessment at age 30 to see if screening earlier than age 40 is needed. The Hawai‘i Society for Clinical Oncology submitted testimony on SB 827, SD 2, stating that USPSTF recommendations for biennial mammography screening starting at age 50 are at odds with those of other medical associations such as the American College of Radiology, NCCN, and the American Medical Association.

Both SB 827, SD 2, and HCR 33, SD 1, refer to the USPSTF guidelines. Created in 1984, USPSTF is a panel of independent, volunteer experts in disease prevention and evidence-based medicine who develop recommendations about clinical preventive services. SB 827, SD 2, notes that, if the USPSTF guidelines were implemented, insurance plans would no longer be required to cover annual mammographies for women ages 40 to 49 and that the federal government has delayed implementing the USPSTF guidelines. According to the Chief Medical Officer for HMSA, the state's largest insurer, USPSTF is the gold standard for breast cancer screening and the insurer bases its coverage on the USPSTF guidelines (except as otherwise mandated by Hawai‘i law).

As reflected in Exhibit 1, the current USPSTF guidelines[9] recommend biennial mammography screenings starting at age 50 through 74 for average-risk women. USPSTF found evidence that age is the most important risk factor for breast cancer, meaning that the number of breast cancer deaths increases with age. USPSTF also reviewed research about the *benefits* of mammography screening in women ages 40 to 74 and found that women ages 40 to 49 years benefit the least from mammography screening; women ages 60 to 69 years benefit the most. The increased benefit from mammography screening observed with age is at least partly due to the increase in risk for older women.

However, USPSTF found evidence that mammography screening results in some harms. The most significant harm noted was the overdiagnosis and overtreatment of breast cancer that would otherwise not have become a threat to a woman's health during her lifetime. Mammography screening also poses a risk of false-positive results that lead to unnecessary and invasive follow-up testing. Additionally, USPSTF determined that radiation-induced breast cancer could potentially occur from radiation exposure from mammography screening, although the likelihood of that is very low.

USPSTF recommends that the decision to start screening for breast cancer prior to age 50 should be a personal choice for women, since the benefits still outweigh the harms but to a lesser degree than for older

[9] USPSTF is currently in the process of updating its breast cancer screening guidelines.

women. USPSTF suggests that average-risk women who place a higher value on the potential benefits and harms may choose to begin biennial screening between the ages of 40 and 49.

Breast Cancer Screening Procedures

Doctors screen for breast cancer in a number of ways, but mammography is still the most common form of breast cancer screening.[10]

- **Standard, "Screen Film" Mammography:** A standard, "screen film" mammography is essentially an x-ray image of the breast under compression, typically from 2 different angles (two-dimensional).[11]

- **Digital Mammography:** A digital mammography records the mammographic image onto an electronic file.[12] Digital mammography tends to be more accurate than standard mammography in women under 50 and women with denser breast tissue.[13]

- **Digital Breast Tomosynthesis (DBT):** Tomosynthesis is a newer technology in which 8+ images taken at multiple angles are combined into one or more 3D images.[14] DBT uses 10 percent of the radiation compared with a standard mammogram.[15] Studies suggest that DBT may detect more cases of breast cancer, reduce the screening recall rate, and reduce the number of false-positives detected when compared with digital mammography.[16] In comparison with standard mammography, DBT is particularly effective for identifying breast cancer in women with denser breast tissue.[17] Therefore, DBT is likely to benefit women who begin screening at a younger age, as young women tend to have denser breast tissue.[18]

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[10] Adam Nover, et al., "Modern Breast Cancer Detection: A Technological Review," *International Journal of Biomedical Imaging,* December 2009, p. 2.

[11] Ibid.

[12] Ibid.

[13] Ibid.

[14] Adam Nover, et al., "Modern Breast Cancer Detection: A Technological Review," *International Journal of Biomedical Imaging,* December 2009, p. 5.

[15] Ibid.

[16] Richard Sharpe, et al., "Increased Cancer Detection Rate and Variations in the Recall Rate Resulting from Implementation of 3D Digital Breast Tomosynthesis into a Population-Based Screening Program," *Radiology,* vol. 278, no. 3, March 2016, p. 699.

[17] Debra Monticciolo, et al., "Breast Cancer Screening in Women at Higher-Than-Average Risk: Recommendations from the ACR," *Journal of the American College of Radiology*, vol. 15, January 2018, p. 411.

[18] Ibid.

Risk factor screening assessments

SENATE BILL NO. 827, SD 2 (2021 Regular Session), proposes mandatory health insurance coverage:

"For women ages thirty to fifty, deemed by a licensed physician or clinician to have an above-average risk for breast cancer, an annual mammogram, *provided that a formal risk factor screening assessment is first made and informed by any readily available risk factor modeling tool.*" (Emphasis added.)

Primary care physicians often assess female patients for their individual breast cancer risk. Tools to assess this risk often use a combination of risk algorithms and questions intended to collect personal and family medical histories. Risk factors that are screened for include age, body mass index, family breast cancer history, reproductive risk factors, and other risk factors such as known genetic mutations and prior chest radiation.

Two commonly used risk calculators are the National Cancer Institute Breast Cancer Assessment Tool (BCRAT), or Gail Model, and the International Breast Cancer Intervention Study (IBIS), or Tyrer-Cuzick Risk Model.

The Gail Model allows health care professionals to estimate a woman's risk of developing invasive breast cancer over the next five years in women up to age 90. The tool uses a woman's personal medical and reproductive history and the history of breast cancer among her first-degree relatives (mother, sisters, daughters) to estimate breast cancer risk.

The Gail Model breast cancer screening tool cannot predict whether a woman will get breast cancer. Instead, the tool estimates average-risk of developing breast cancer in the next five years for a group of a women with similar risk factors.

The Tyrer-Cuzick Risk Model breast cancer screening tool considers reproductive history, body composition, and in-depth family history. For patients under the age of 85, a five-year, ten-year, and lifetime risk estimate is available.

In contrast to the Gail Model breast cancer screening tool, the Tyrer-Cuzick Risk Model breast cancer screening tool calculator can be used to qualify patients for supplemental breast cancer screening with MRI. In the office setting, the Gail Model breast cancer screening offers a quick estimate of breast cancer risk, whereas the Tyrer-Cuzick Risk Model breast cancer screening tool is more comprehensive.

- **Breast Magnetic Resonance Imaging (MRI):** A breast MRI uses a magnetic field and radio waves to create an image.[19] It is similar to an ultrasound in its ability to detect cancer. It has a sensitivity rate of nearly 100 percent, meaning a breast MRI catches almost every instance of invasive breast cancer.[20] It is also better at detecting how far the cancer has spread beyond the duct than either ultrasound or mammography.

- **Whole-Breast Ultrasound:** Ultrasound may be indicated for women who qualify for, but are unable to get, a breast MRI.[21] Ultrasound tends to detect cancers which are small (median size 10 mm) and invasive.[22]

[19] Adam Nover, et al., "Modern Breast Cancer Detection: A Technological Review," *International Journal of Biomedical Imaging,* December 2009, p. 3.

[20] Ibid.

[21] Debra Monticciolo, et al., "Breast Cancer Screening in Women at Higher-Than-Average Risk: Recommendations from the ACR," *Journal of the American College of Radiology*, vol. 15, January 2018, p. 408.

[22] Ibid., p. 412.

Current State of Insurance Coverage for Breast Cancer Screening in Hawai‘i

Sections 431:10A-116(4), 432:1-605, and 432D-23, HRS, require health insurers to provide coverage for screening by low-dose mammography for occult breast cancer as follows:

A) For women ***40 years of age and older***, an annual mammogram; and

B) For a woman of any age with a history of breast cancer or whose mother or sister has had a history of breast cancer, a mammogram upon the recommendation of the women's physician.

In reviewing the history of statutory provisions for mammogram screening, we found that, when first enacted in 1990, Sections 431:10A-116(4) and 432:1-605, HRS, required health insurers to provide coverage for a baseline mammogram for women ages 35 to 39, biennial mammograms for women ages 40 to 49, and annual mammograms for women ages 50 and older. These provisions were based on the then-existing guidelines of the American College of Radiology and ACS. At that time, the American College of Radiology guidelines also recommended a mammogram for high-risk women of any age based upon the recommendation of a physician, either due to a personal history of breast cancer or a history of breast cancer of her mother or sister.

Prior to the enactment of Sections 431:10A-116(4) and 432:1-605, HRS, in January of 1990 our office reported on the social and financial impacts of the proposed mandated coverage in Report No. 90-3, *Study of Proposed Mandatory Health Insurance for Mammogram Screening*. In that study, we were unable to provide clear-cut answers about the benefits of mandating coverage for mammography screening. At the time of that study, data from other states were limited because the first laws mandating coverage for mammography screening were only enacted four years before, in 1986.

In 1992, ACS updated its guidelines and eliminated the recommendation that women ages 35 to 39 obtain a baseline mammogram. In 1999, the Legislature amended the mandatory coverage for mammogram screening by eliminating the baseline mammogram for women ages 35 to 39 and expanding coverage for women ages 40 to 49 from biennial to annual screenings (Act 13, Session Laws of Hawaii 1999). This amended mandatory coverage for mammograms correlated with the updated ACS guidelines.

Most of the mandates proposed in SB 827, SD 2, are already covered

According to HMSA and Kaiser, the state's two largest insurers, most of the coverage that SB 827, SD 2, proposes to mandate are already included in their respective health plans, with the exception of baseline mammograms for average-risk women ages 35 to 39. In 2021, HMSA had 773,699 members, representing 70.1 percent of total members for all insurers, and Kaiser had 184,239 members, representing 16.7 percent of total members for all insurers.

Description of Proposed Coverage	HMSA	Kaiser Permanente
Baseline mammograms for women ages 35 to 39.	Covered only for above-average-risk women.	Covered only for above-average-risk women.
Women ages 30 to 50, deemed by a licensed physician or clinician to have an above-average risk for breast cancer, an annual mammogram, provided that a formal risk factor screening assessment is first made and informed by any readily available risk factor modeling tool.	Covered.	Covered.
For women of any age, any additional or supplemental imaging, such as breast magnetic resonance imaging or ultrasound, deemed medically necessary by an applicable American College of Radiology guideline.	Covered.	Covered.
Digital mammography and digital breast tomosynthesis (DBT) and interpreting and rendering a report by a radiologist or other physician based on the screening.	Covered.	Covered, but only available upon request of the patient or physician because not all Kaiser clinics have a DBT machine.

HMSA currently covers baseline mammograms for women ages 35 to 39 who are deemed to be at above-average risk after a risk factor screening assessment. The screening assessment typically involves answering a number of questions regarding the woman's age, whether she has a first-degree relative with a history of breast cancer, and whether she has a history of chest x-rays or other radiation. Kaiser covers baseline mammograms for above-average-risk women ages 35 to 39. The woman is considered to be at above-average risk if her mother or sister had breast cancer *and* if she is within 10 years of the age that their mother or sister was first diagnosed. In addition, coverage is provided for women under the age of 40 who have undergone genetic counseling and are determined to have a greater than 20 percent chance of breast cancer.

HMSA also stated that formal risk factor screening assessments discussed in the bill are not new, but routine standards of care. HMSA allows physicians to use any one of the various risk assessment tools that are available. Kaiser expressed concern that the term "any" readily available risk factor modeling tool was vague. Kaiser's physicians use BRCAPro,[23] which is a risk model that is largely dependent on family history.

Further, the proposed bill prescribes additional or supplemental imaging, MRIs, and ultrasounds, if deemed medically necessary by American College of Radiology guidelines. Both HMSA and Kaiser asserted that they already cover these services. While HMSA's Chief Medical Officer stated that these procedures are covered by HMSA, she expressed concern that the phrase "deemed medically necessary by ACR guidelines*"* may preclude the use of other accepted scientific evidence-based guidelines, such as the USPSTF guidelines.

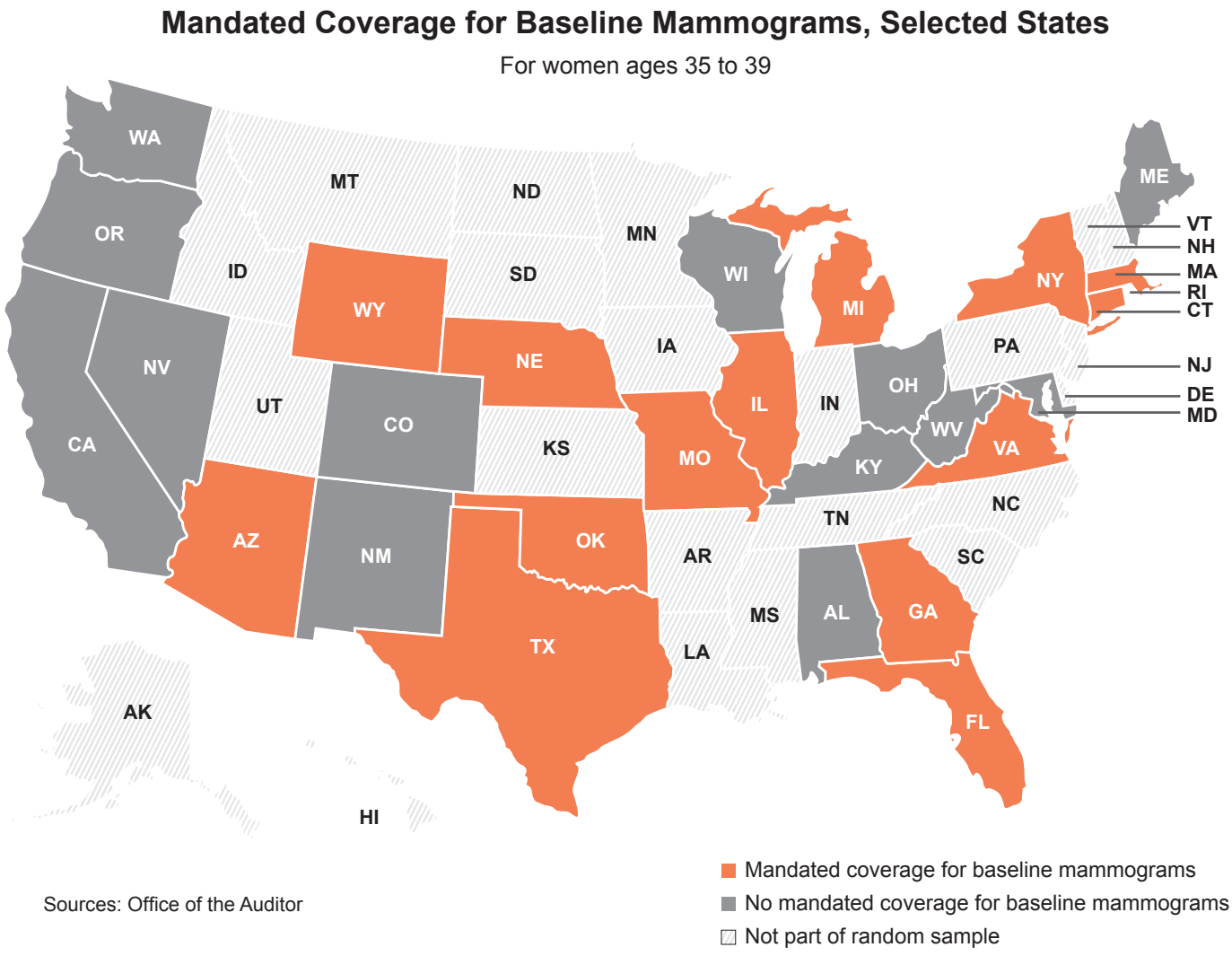
Additionally, the bill expands the definition of "low-dose mammography" to include digital mammography and DBT. Both HMSA and Kaiser said they already cover these services. HMSA's Chief Medical Officer noted that DBT is currently the cutting-edge technology for screening mammography and is covered by HMSA. She asserted that technology evolves rapidly, so specifying coverage for procedures such as DBT may inadvertently exclude coverage for future medical technologies. In her opinion, coverage based on medical necessity as currently defined in the state law allows clinicians to adopt new medical technologies.

[23] BRCAPro is a computer program that uses statistics to predict whether a person has an inherited mutation in the BRCA1 and BRCA2 genes. People who have certain mutations in these genes have a higher-than-normal risk of breast, ovarian, prostate, and other types of cancer. The program is based on personal and family medical histories of breast and ovarian cancer.

Breast Cancer Screening Laws in Other States

We randomly selected a sample of 27 states to research whether they enacted laws to mandate insurance coverage for baseline mammograms for average-risk women ages 35 to 39. We found that 14 of the 27 states sampled mandate such coverage.

Exhibit 2
Map of Selected States That Mandate Coverage for Baseline Mammograms



Sources: Office of the Auditor

Social and Financial Impacts of SB 827, SD 2 (Regular Session 2021)

As previously detailed, the most significant expansion to existing mandatory health insurance coverage proposed by SB 827, SD 2, is the addition of a baseline mammogram for average-risk women ages 35 to 39. The other coverages that the bill proposes are, generally, already covered by insurance. Accordingly, our assessment of the social and financial effects of the proposed mandated coverage focuses on the impact of mandating coverage for baseline mammograms for average-risk women ages 35 to 39.

Social Impacts

The extent to which the treatment or service is generally utilized by a significant portion of the population

It is our understanding that the number of women ages 35 to 39 currently obtaining a baseline mammogram is very small. In other words, baseline mammograms are not generally utilized by a significant portion of women ages 35 to 39. Less than one percent of all mammograms reported by insurers for 2021 were among women ages 35 to 39.

According to the data provided by the insurers we surveyed, in 2021, only 4.6 percent of insured women ages 35 to 39 had a mammogram in the past three years:

Year	No. of Females Ages 35 to 39	No. of Mammograms for Females Ages 35 to 39	Percent
2019	43,520	1,995	4.5%
2020	43,379	1,997	4.6%
2021	44,584	2,063	4.6%

Source: Office of the Auditor based on insurer survey responses.

We note that the data only reflects the number of women ages 35 to 39 whose mammograms were covered by their respective insurers (and, as reported above, most insurers do not currently cover a baseline mammogram for women ages 35 to 39). It does not include women in the age group who paid for a baseline mammogram. However, it is our assumption that the number of women ages 35 to 39 who currently opt to have a baseline mammogram that is not covered by their health insurance is very small.

We also found there is limited nationwide data on the number of women ages 35 to 39 receiving baseline mammograms. Most of the research we reviewed focused on women ages 40 and older. For example, the Centers for Disease Control and Prevention reported that in 2019, 60.2 percent of women ages 40 to 49 had a mammogram within the past two years.

The extent to which such insurance coverage is already generally available

According to our surveys and follow-up interviews with insurers, baseline mammograms for average-risk women ages 35 to 39 are generally *not* covered under standard insurance policies issued in Hawai‘i. Only two of the six insurers currently provide coverage under their standard policies for a baseline mammogram for average-risk women ages 35 to 39. And one of those insurers only issues policies to people under Medicaid and Medicare. Medicare covers a baseline mammogram for all women ages 35 to 39, while Medicaid covers annual mammograms for women ages 40 and over, and women of any age with risk factors.

If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatment

As stated previously, baseline mammograms for women ages 35 to 39 with an average breast cancer risk are not generally covered. However, we do not know the ability of average-risk women ages 35 to 39 to obtain a baseline mammogram.

If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment

We do not understand baseline mammograms to be “treatment;” rather, the baseline mammogram is a preventative procedure, not a “medically necessary” one. According to the insurers, mammograms deemed to be “medically necessary” are already covered; therefore, there is no financial hardship on those women needing “treatment.”

We are unable to determine whether the cost of an elective baseline mammogram would create an “unreasonable financial hardship” for the average woman in Hawai‘i as the term is not defined in the statute. Although the Hawai‘i Radiological Society stated its position that many women in Hawai‘i cannot afford the out-of-pocket expense of screening by mammography or MRI, it did not provide additional detail on how it came to this conclusion that it is unaffordable.

The Hawai‘i Medical Association provided the following information on approximate costs of various breast cancer screening procedures.

Breast Cancer Screening Procedure	Approximate Baseline Cost
Breast Magnetic Resonance Imaging (Bilateral)	$3,916
Breast Ultrasound, Limited (Bilateral)	$990
Digital Breast Tomosynthesis (Bilateral Screen)	$547
Digital Mammography, (Bilateral Screen)	$456
Digital Mammography, Diagnostic (Bilateral)	$753

The level of public demand for the treatment or service

It is difficult to gauge the level of public demand for baseline mammograms for average-risk women ages 35 to 39.

According to figures provided by the six insurers that responded to our survey, in 2021, there was a combined enrollment of 375,023 females ages 35 and over. This included 44,584, or about twelve percent, who were ages 35 to 39, the age group targeted by the proposed mandate.

Exhibit 3 – Enrollment Figures From Surveyed Medical Insurance Providers

Females Ages 30-34			Females Ages 35-39			Females Ages 40-49			Females Ages 50 and up		
2019	2020	2021	2019	2020	2021	2019	2020	2021	2019	2020	2021
62,562	63,328	64,953	43,520	43,379	44,584	84,000	83,798	85,622	250,828	246,843	244,817

Source: Office of the Auditor based on insurer survey responses.

Exhibit 4 shows the total number of women in each age range whose mammograms were covered by insurers between 2019-2021: [24]

Exhibit 4 – Number of Accepted Claims for Mammograms from 2019-2021 Reported by Health Insurers

No. of Mammograms for Females Ages 35 -39			No. of Mammograms for Females Ages 40 – 49			No. of Mammograms for Females Ages 50 and up		
2019	**2020**	**2021**	**2019**	**2020**	**2021**	**2019**	**2020**	**2021**
1,995	1,997	2,063	58,149	41,134	58,039	193,181	168,044	183,561

Source: Office of the Auditor based on insurer survey responses.

Based on the number of mammograms reported by insurers, not all eligible women ages 40 and above receive mammograms even though they are already covered. For example, in 2021, only 58,039 out of 85,622 women between the ages of 40 and 49, or 67.8 percent, received a mammogram. The number increases slightly for women ages 50 and up, as 183,561 of the 244,817 women insured under their policies, or 75 percent, underwent a mammogram. As one insurer noted, it is already difficult to encourage the older population to undergo annual mammogram screenings, so the insurer anticipates that it would be at least equally challenging to get younger patients to do it.

HMSA's Chief Medical Officer was unable to predict how many average-risk women ages 35 to 39 will opt to receive a baseline mammogram if this coverage were offered. The Hawai'i Radiological Society speculated that ten percent of women may opt for a baseline mammogram at age 35 if they are concerned about an earlier average age of breast cancer diagnosis in their ethnic group.

Accordingly, it is difficult to extrapolate with any reasonable certainty from this information the demand for a baseline mammogram among average-risk women ages 35 to 39.

The level of public demand for individual or group insurance coverage of the treatment or service

Three of the six insurers said there is little demand for individual or group insurance coverage of the proposed mandated coverage under SB 827, SD 2, and two said there is no demand.

[24] It is possible that a small number of average-risk women ages 35 to 39 elected to pay out-of-pocket for baseline mammograms, but these women would not be captured by the numbers reported by insurers.

However, based on the information provided by the insurers, we cannot determine the level of demand by average-risk women for a baseline mammogram. The insurers' data only reflects that 44,584 women ages 35 to 39 are covered under policies issued by the insurers but provides no information about the number of insurance claims for baseline mammograms that were rejected or even the number of inquiries about whether those mammograms are covered currently.

The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts

Four of the six insurers stated that there has been no demand from collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts. One insurer stated that the level of interest is very low as their collective bargaining account managers and director have had no requests or complaints from these groups regarding baseline mammograms for average-risk women ages 35 to 39.

We sent a brief survey to five of the larger labor unions in Hawai'i. Only one union responded, stating that there has not been a "flood of requests" from its membership regarding the proposed coverage for baseline mammograms for average-risk women ages 35 to 39.

The impact of providing coverage for the treatment or service (such as morbidity, mortality, quality of care, change in practice patterns, provider competition, or related items)

Based on our review of the testimony and the responses to our surveys of medical organizations and insurers, we found little information on the impact of providing coverage for a baseline mammogram for average-risk women ages 35 to 39 on morbidity, mortality, and quality of care. Most of the academic literature we reviewed for this report discussed screening for women ages 40 and older. For example, a literature review published in the *Journal of the American College of Radiology* found that women who began annual mammography screening at age 40 were less likely to die from breast cancer, were diagnosed at an earlier age, had better surgical options, and were more likely to respond to chemotherapy compared with women who began screening at an older age.[25] The authors found that beginning mammography screening at 40 led to even greater reductions in mortality for minority women than for white women.[26]

[25] Monticciolo, D., et al., "Breast Cancer Screening Recommendations Inclusive of All Women at Average Risk: Update from the ACR and Society of Breast Imaging," *American College of Radiology*, vol. 18, no. 9, September 2021, pp. 1280, 1285.

[26] Ibid., pp. 1280, 1284, 1285.

In contrast, HMSA opined that mandating coverage for a baseline mammogram for average-risk women ages 35 to 39 would likely increase demand for mammograms. HMSA expressed concern that this may increase health care costs and member premiums without improving quality of care. HMSA suggested earlier mammograms may expose women to additional risks such as exposure to radiation and false-positives. HMSA also speculated that wait times for screening could increase.

The impact of any other indirect costs upon the costs and benefits of coverage as may be directed by the legislature or deemed necessary by the auditor in order to carry out the intent of this section

As to the impact of any other indirect costs upon coverage, four of the six insurers stated there would be little demand, one said there would be no demand, and one said there would be a moderate demand. One insurer noted that mandating coverage for average-risk women ages 35 to 39 would increase the volume of mammograms which may result in the need for additional resources, i.e., facilities, equipment, etc.

Financial Impacts

The extent to which insurance coverage of the kind proposed would increase or decrease the cost of the treatment or service

Three insurers stated that there is likely to be no change in the cost of a mammogram, one said a low increase was likely, and another stated that there is likely to be a moderate increase in costs of mammograms. The state's largest insurer opined that mandating insurance coverage for baseline mammograms for average-risk women ages 35 to 39 was not likely to change the cost of each service or treatment.

The Hawai‘i Radiological Society responded to our survey stating that mandating coverage for baseline mammograms for average-risk women ages 35 to 39 would result in only a marginal increase in breast cancer screening costs.

The extent to which the proposed coverage might increase the use of the treatment or service

The Hawai‘i Radiological Society estimated that the total number of mammograms would increase by three to five percent annually if the baseline mammogram for average-risk women ages 35 to 39 was covered by insurance. There was not a consensus among the insurers surveyed regarding the extent to which the proposed coverage might increase the use of the treatment or service of baseline mammograms for average-risk women ages 35 to 39. Three insurers said there would be a

low increase, one said a moderate increase, and another said no change. HMSA, the state's largest insurer, opined that the proposed coverage for baseline mammograms for average-risk women ages 35 to 39 may lead to a low to moderate increase in the overall usage of such services.

Another insurer stated it expects a small increase in the number of average-risk women ages 35 to 39 who would obtain a baseline mammogram, adding that it is already difficult to encourage the older population to undergo mammogram screening, and therefore anticipates it would be at least equally challenging, if not more so, to get younger patients to make use of the additional coverage for baseline mammograms.

We believe it is reasonable to anticipate an increase in the number of baseline mammograms for average-risk women ages 35 to 39 if coverage is mandated because it is likely that more physicians will recommend a baseline mammogram for these patients if covered by insurance. However, from the information we obtained, we are unable to quantify that anticipated increase.

The extent to which the mandated treatment or service might serve as an alternative for more expensive treatment or service

We are unaware of more costly alternatives to the baseline mammogram for average-risk women ages 35 to 39 as proposed in SB 827, SD 2. And, none of the health insurers or healthcare providers who responded to our surveys identified any more costly alternatives.

The Hawai‘i Radiological Society offered its view that, if a woman who elected to have screening before age 40 were to be diagnosed with breast cancer, she would likely be diagnosed at stage 1, with a high probability of being cured or having many years of disease-free life. Hawai‘i Pacific Health testified that early detection of breast cancer via mammography leads to decreased treatment costs. However, those responses relate to the potential savings in treatment costs for breast cancer, rather than more costly alternatives to the baseline mammogram.

The extent to which insurance coverage of the health care service or provider can be reasonably expected to increase or decrease the insurance premium and administrative expenses of policyholders

Three of the insurers surveyed anticipated the proposed mandated coverage for a baseline mammogram would result in a small increase in insurance premiums and administrative expenses, and two other insurers said there would be no change. One insurer estimated that premiums would increase approximately 0.1 to 0.2 percent, assuming that the percentage of women ages 35 to 39 who would get a baseline mammogram would be the same as the percentage of women ages 40 to 49 years who currently get a mammogram.

HMSA opined that mandating insurance coverage for baseline mammograms for average-risk women ages 35 to 39 might increase the cost of premiums due to an increase in the number of services or treatments. Another insurer stated that it anticipates an increase in demand for women in the 35 to 39 age group, which it stated may increase the overall cost of delivering health care.

HMSA estimated the cost of the additional baseline mammograms for average-risk women ages 35 to 39 to be $330,000 for its commercial lines of business. HMSA stated that this is a conservative estimate and does not include any additional follow-up services or procedures that may be necessary after the baseline mammogram.[27]

Using the Hawai‘i Medical Association’s estimated mammogram cost of about $547, and HMSA’s total estimated cost of $330,000, this equates to roughly 603 baseline mammograms for women ages 35 to 39. Since HMSA reported a total of 26,990 women ages 35 to 39 covered by their plans in 2021, this would equate to about two percent of their eligible members. These are purely speculative numbers, intended only to provide the reader with a ballpark estimate of how many mammograms would be covered based upon the estimates of two separate organizations.

None of the insurers anticipate that the premiums and administrative costs would substantially increase if the Legislature was to mandate coverage as proposed in SB 827, SD 2. As noted by HMSA, the costs of mammograms for women ages 30 to 50 with an above-average risk for breast cancer were not factored into the calculations since these screenings are already covered.

[27] In contrast, according to its Condensed 2021 Financial Report, in 2021, HMSA spent $3,396,025,000 on all member medical and hospital claims.

The impact of this coverage on the total cost of health care

Three of the six insurers reported that they expect a low increase in the total cost of health care. Two of the insurers reported that they expect no change to the total cost of health care. One insurer reported that the cost of additional mammography services is expected to be approximately equal to or slightly higher than the expected cost savings for early detection of breast cancer, but the overall impact is expected to be less than 0.1 percent. One insurer estimated that premiums would increase by approximately 0.1. percent to 0.2 percent. UHA reported that it anticipates a negligible impact to the overall cost of treatment, the premium and administrative expense for policyholders, and the total cost of health care. UHA further stated that the overall impact is expected to be less than 0.1 percent.

The insurers did not provide details on the analysis underlying their expectations about the impact of coverage on the total cost of healthcare.

Qualified Health Plans in Hawai‘i

HCR 33, SD 1, asks the Auditor to determine how many qualified health plans are available in Hawai‘i, including plans offered by health maintenance organizations and the individual or group enrollment in these plans.

The PPACA defines a qualified health plan as an insurance plan that is certified by the Health Insurance Marketplace, provides essential health benefits, follows established limits on cost sharing, and meets other requirements such as covering pre-existing conditions and prohibiting annual and lifetime benefit limits. Qualified health plans are specific to the PPACA and apply to people who do not have employer-provided coverage and who do not meet eligibility requirements for Medicare or Medicaid. Qualified health plans are sold on the Health Insurance Marketplace and are also available off-exchange, such as through a broker or directly from the health plan.

In Hawai‘i, only HMSA and Kaiser offer qualified health plans on the Health Insurance Marketplace. HMSA has 12 different individual plans, and Kaiser has 11 different individual plans.

As for the number of individuals enrolled in these plans, according to healthinsurance.org, a non-profit health industry watchdog, during open enrollment for 2021 coverage, 22,903 Hawai‘i residents were enrolled through the state’s Health Insurance Marketplace.

Impact of the Patient Protection and Affordable Care Act (PPACA) on SB 827, SD 2

HCR 33, SD 1, requests the Auditor to include in its assessment the impact of Section 1311(d)(3) of the PPACA on the proposed coverage in SB 827, SD 2. The Auditor is also requested to assess the additional costs to the state that will incur if the legislature mandates coverage for additional benefits for health plans qualified under the PPACA.

The PPACA requires each state to have an essential benefits package that provides coverage for at least ten categories of benefits which include:

1. Ambulatory patient services
2. Emergency services
3. Hospitalization
4. Maternity and newborn care
5. Mental health and substance use disorder services, including behavioral health treatment
6. Prescription drugs
7. Rehabilitative and habilitative services and devices
8. Laboratory services
9. Preventive and wellness services and chronic disease management
10. Pediatric services, including oral and vision care

Sections 1311(d)(3)(B)(i) and (ii) of the PPACA allow a state to require a qualified health plan to offer benefits in addition to the essential health benefits. A benefit required by state action on or before December 31, 2011, is an essential health benefit. A benefit required by state action on or after January 1, 2012, other than for purposes of compliance with Federal requirements, is considered an addition to the essential health benefits. The state must defray the cost to the individual of those added required benefits. The state may make payments to either the individual or directly to the qualified health plan issuer on behalf of the individual. The qualified health plan issuer must quantify the cost attributable to each additional required benefit based on analysis performed in accordance with generally accepted actuarial principles and methodologies conducted by a member of the American Academy of Actuaries.

In his testimony to the House Committee on Consumer Protection and Commerce on SB 827, SD 2, the Hawai‘i Insurance Commissioner stated that the U.S. Department of Health and Human Services confirmed that the proposed increase in the categories of women

required to be covered for mammography screenings is a new mandate, and the State will be responsible for defrayment of the costs of these added benefits to individuals enrolled in the State's *qualified health plan*s.

The State's cost obligation for the additional mandated benefits would only apply to women enrolled in qualified health plans that are certified and sold through the Health Insurance Marketplace. Further, given the fact that in 2021 there were only 22,903 Hawai'i residents enrolled in private individual market plans through the State's health insurance marketplace, the number of average-risk women ages 35 to 39 is likely only a relatively small fraction of the total enrollment.

Conclusion

Hawai'i law currently requires health insurance plans to provide coverage for annual mammograms for women 40 years of age and older. The state's two largest insurers, HMSA and Kaiser, represent that aside from the baseline mammogram for average-risk women ages 35 to 39, many of the proposed revisions in SB 827, SD 2, are already covered under their current health insurance policies. Our analysis suggested that the proposed mandate in SB 827, SD 2, essentially expands the required insurance coverage to include a baseline mammogram for average-risk women ages 35 to 39.

In addition to the baseline mammogram, SB 827, SD 2, specifies coverage for an annual mammogram for women ages 30 to 50 deemed by a physician or clinician to be at an above-average risk for breast cancer, provided that a formal risk factor screening assessment is first made. However, we conclude that this falls under currently mandated coverage. The bill also specifies coverage for any additional imaging or supplemental imagery deemed medically necessary by an applicable American College of Radiology guideline; however, any supplemental imaging deemed medically necessary is already required by law to be covered.

We found that a number of states have enacted laws which mandate insurance coverage for baseline mammograms for women ages 35 to 39. However, none of the major medical organizations that we researched currently recommend mammography screening for average-risk women ages 35 to 39. The U.S. Preventative Services Task Force, as noted earlier in this report, recommends biennial mammograms starting at age 50. The American College of Obstetricians and Gynecologists, American Cancer Society, and the National Comprehensive Cancer Network all recommend offering either annual or biennial mammograms to women starting at age 40. The American College of Radiology and the Society for Breast Imaging further recommend all women have a risk assessment at age 30 to see if screening earlier than age 40 is

needed.

With regard to our analysis of the social impacts set forth in Sections 23-51 and 23-52, HRS, we were unable to determine the level of demand for a baseline mammogram for average-risk women ages 35 to 39. We note that the affected population is a relatively limited one. According to figures provided by the six insurers that responded to our survey, in 2021, there was a combined enrollment of 375,023 females ages 35 and over. This included 44,584, or about twelve percent, who were ages 35 to 39, the age group targeted by the proposed mandate.

In addition, as reflected in the utilization rates provided by the insurers, many women ages 40 and older do not undergo annual mammograms despite it being covered under their policies. As one insurer noted, it is already difficult to encourage the older population to undergo annual mammogram screening; the insurer therefore anticipates that it would be at least equally challenging to get younger patients to do it. Finally, we found little information on the impact of providing coverage for a baseline mammogram for average-risk women ages 35 to 39 on morbidity, mortality, and quality of care; the studies focused on women over 40 years old.

In reviewing the financial impacts of the proposed coverage, in general, the health insurance companies project only very small increases in total healthcare costs and insurance premiums should coverage for a baseline mammogram for average-risk women ages 35 to 39 be mandated.