Proposed Mandatory Health Insurance Coverage for Fertility Preservation Procedures for Cancer Patients

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

Report No. 22-16
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OFFICE OF THE AUDITOR
STATE OF HAWAI‘I

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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

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

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Foreword

Through Senate Concurrent Resolution No. 241, Senate Draft 1 (2022 Regular Session), the Legislature requested we assess the social and financial impacts of mandating insurance coverage for standard fertility preservation services for those persons who have been diagnosed with cancer that may, or whose treatment may, adversely affect their fertility, as proposed in House Bill No. 2242 and Senate Bill No. 3308, both introduced during the 2022 session. Pursuant to Section 23-51, Hawai‘i Revised Statutes, before the Legislature considers a measure that mandates health insurance coverage for specific health services, diseases, or providers, the Office of the Auditor is required to assess the social and financial effects of the proposed coverage. We initiated the assessment but, for the reasons described herein, are unable to complete the requested work.

We appreciate the cooperation and assistance of the American Society for Reproductive Medicine, the American Society of Clinical Oncology, the Hawai‘i State Department of Health, and other organizations and individuals we contacted during the course of this assessment.

Leslie H. Kondo
State Auditor

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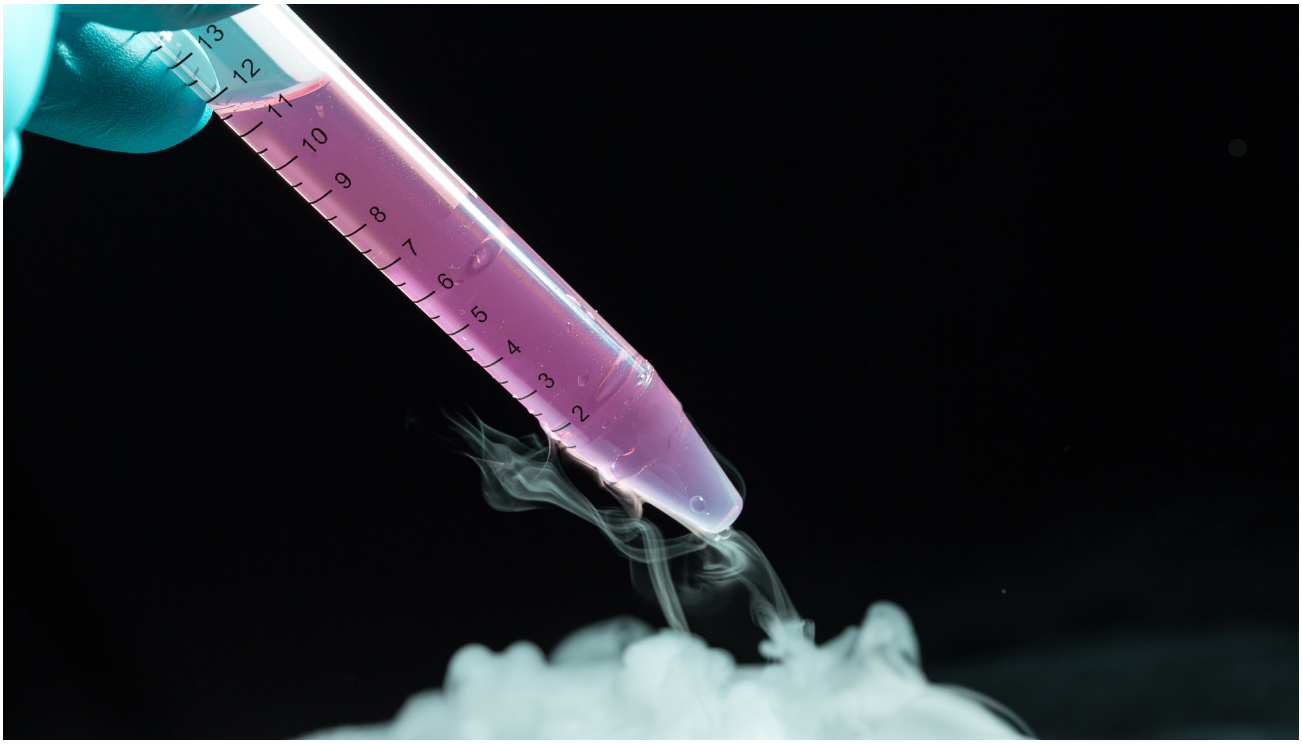

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Introduction

SENATE CONCURRENT RESOLUTION NO. 241, Senate Draft 1 (SCR 241, SD 1), of the 2022 Legislature, requests the Auditor to assess the social and financial effects of mandating health insurance coverage for "standard fertility preservation services" for insureds who have been diagnosed with cancer that may, or whose treatment may, adversely affect their fertility, as proposed in House Bill No. 2242 (HB 2242) and Senate Bill No. 3308 (SB 3308), both introduced in the Regular Session of 2022.

We conducted this assessment in accordance with Sections 23-51 and 23-52, Hawai'i Revised Statutes (HRS).

HB 2242 and SB 3308 do not include the minimum information needed to conduct the assessment required by Section 23-52, HRS.

House Bill No. 2242 and Senate Bill No. 3308

SCR 241, SD 1, designates HB 2242 and SB 3308 as specific bills that have been introduced in the legislature, as required by Section 23-51, HRS,

the statute governing concurrent resolutions requesting a social and financial assessment of proposed mandatory health insurance coverage. Both bills propose specific coverage parameters that would require health insurers, mutual benefit societies, and health maintenance organizations to provide coverage for "standard fertility preservation services" for the insured, provided that:

1. The insured is diagnosed with a cancer that may, or whose treatment may, adversely affect the fertility of the insured; and

2. The standard fertility preservation services are deemed reasonably necessary for the insured.

HB 2242 and SB 3308 both define "standard fertility preservation services" as procedures consistent with established medical practices and professional guidelines published by the American Society for Reproductive Medicine,[1] or the American Society of Clinical Oncology,[2] or as defined by the Hawai'i Department of Health, including the storage of sperm or oocytes for one year.

The term "reasonably necessary" is not defined in HB 2242 or SB 3308, nor is it defined in Chapters 431, 432, 432D, or 432E, HRS.

Objectives of Study

1. Assess the social and financial effects of mandating health insurance coverage for standard fertility preservation services for insureds who have been diagnosed with cancer that may, or whose treatment may, adversely affect their fertility.

2. Make recommendations as appropriate.

[1] The American Society for Reproductive Medicine describes itself as a multidisciplinary organization dedicated to the advancement of science and practice of reproductive medicine.

[2] The American Society of Clinical Oncology is a network of oncology professionals who care for people living with cancer.

Scope and Methodology

We researched existing medical practices and professional guidelines and contacted the three organizations identified in HB 2242 and SB 3308 to request each entity's definition of "standard fertility preservation services."

We interviewed representatives of the American Society for Reproductive Medicine (ASRM) and the American Society of Clinical Oncology (ASCO) to verify that the services were consistent with established medical practices and professional guidelines published by ASRM and ASCO. We also reviewed ASCO's written testimony to the 2022 Legislature in support of SCR 241, SD 1. In addition, we requested the Department of Health (DOH) to provide any definition for "standard fertility preservation services" it may have.

Sections 23-51 and 23-52, Hawai'i Revised Statutes

Section 23-51, HRS, requires passage of a concurrent resolution requesting a social and financial 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 statute also requires that the concurrent resolution designate a specific bill that has been introduced in the Legislature and includes, at a minimum, information identifying the:

- Specific health service, disease, or provider that would be covered;
- Extent of the coverage;
- Target groups that would be covered;
- Limits on utilization, if any; and
- Standards of care.

Section 23-52, HRS, requires the Auditor's report to the Legislature assessing the impact of proposed mandated coverage to include at the minimum and to the extent that information is available, the following:

Social Impact

- The extent to which the treatment or service is generally utilized by a significant portion of the population;
- The extent to which such insurance coverage is already generally available;

- 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;
- If coverage is not generally available, the extent to which lack of coverage results in unreasonable financial hardship on those persons needing treatment;
- The level of public demand for the treatment or service;
- The level of public demand for individual or group insurance coverage of the treatment or service;
- The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts;
- 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); and
- The impact of any other indirect costs upon the costs and benefits of the coverage as may be directed by the Legislature or deemed necessary by the Auditor in order to carry out the intent of Section 23-52, HRS.

Financial Impact

- The extent to which insurance coverage of the kind proposed would increase or decrease the cost of the treatment or service;
- The extent to which the proposed coverage might increase the use of the treatment or service;
- The extent to which the mandated treatment or service might serve as an alternative for more expensive treatment or service;
- 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 policy holders; and
- The impact of this coverage on the total cost of health care.

Standard Fertility Preservation Services

HB 2242 and SB 3308 provide that the mandated coverage for "standard fertility preservation services" means procedures consistent with established medical practices and professional guidelines published by ASRM or ASCO, or as defined by DOH.

ASCO's State Advocacy Specialist explained that the organization considers "standard fertility preservation services" to be "procedures to preserve fertility as outlined and established according to the professional guidelines published by ASCO"; the organization considers the term to include "the full scope of services or treatments, without any exclusions or limitations, as defined in the most recent professional guidelines established by ASCO." According to ASCO, "standard" services or treatments are those not considered "experimental" by the organization.

We interviewed the current chair of ASRM's Practice Committee and ASRM's Public Policy Specialist to confirm which fertility preservation services or procedures are considered "standard fertility preservation services." ASRM's Practice Committee develops practice guidelines, guidance, and committee opinions following evidence-based practice within ASRM and the medical community.

All information included in ASRM's Practice Committee publications is considered "established medical practices and professional guidelines." The ASRM Practice Committee opinion, *Fertility preservation in patients undergoing gonadotoxic therapy or gonadectomy: a committee opinion* (2019), removed the "experimental" label from ovarian tissue cryopreservation. That publication is more recent than ASCO's 2018 publication, *Fertility Preservation in Patients With Cancer: ASCO Clinical Practice Guideline Update*, which still deemed ovarian tissue cryopreservation to be experimental.

To determine if DOH has a definition for "standard fertility preservation services," we requested the department's definition of "standard fertility preservation services." DOH's Office of the Deputy Director of Health Resources Administration confirmed the department has no definition for "standard fertility preservation services."

The table below summarizes services included in established medical practice and professional guidelines published by ASRM and ASCO, which HB 2242 and SB 3308 use to define the term "standard fertility preservation services." The bills also refer to "standard fertility preservation services" as that term may be defined by Hawai‘i's DOH, so we include in the table the response we received from the DOH Health Resources Administration confirming DOH does not have a definition of "standard fertility preservation services."

Exhibit 1: Services included in "standard fertility preservation services"

<table>
<tr><th>American Society for Reproductive Medicine (ASRM)</th><th>American Society of Clinical Oncology (ASCO)</th><th>Hawai'i State Department of Health (DOH)</th></tr>
<tr><td colspan="2">Embryo Cryopreservation is the freezing and storing of embryos obtained by ovarian stimulation, oocyte (egg) retrieval, and in vitro fertilization. Both sperm and oocytes are needed to create the embryo, and sperm or oocytes could be obtained from donors.</td><td rowspan="4">According to the Hawai'i State Department of Health, Health Resources Administration Office, DOH has no definition for "standard fertility preservation services" because there are no Department of Health programs relating to fertility preservation.</td></tr>
<tr><td colspan="2">Sperm Cryopreservation is the collection, freezing, and storage of semen. Sperm is usually collected through masturbation; however, if patients are unable to do this, additional techniques may be utilized. Sperm banking (storage) is the storage of sperm in a repository; HB 2242 and SB 3308 limit storage to one year.</td></tr>
<tr><td colspan="2">Oocyte Cryopreservation is the freezing and storing of oocytes which are obtained through two procedures, ovarian stimulation and egg retrieval. Ovarian stimulation is a pharmacological treatment that induces the development of ovarian follicles that allows providers to retrieve multiple oocytes at follicular aspiration. Oocyte banking (storage) is the storage of these oocytes in a repository for future use. HB 2242 and SB 3308 limit storage to one year.</td></tr>
<tr><td>Ovarian Tissue Cryopreservation is the process of slow-freezing of tissue surgically removed from the ovary with the intention of preserving reproductive capacity. The process of obtaining ovarian cortical tissue prior to ovarian failure or cancer treatment may include a surgical procedure and cryopreservation using either a slow-cool technique or vitrification. This is the only way to preserve oocytes in prepubertal females.</td><td>Not included in ASCO's established professional guidelines.</td></tr>
</table>

"Reasonably Necessary"

Pursuant to Section 23-51, HRS, any legislative measure that proposes to mandate health insurance coverage for specific health services must identify, among other things, the specific health services that would be covered and the extent of the coverage. Here, the extent of the proposed mandated coverage is limited to where (1) the "insured is diagnosed with a cancer that may, or whose treatment may, adversely affect the fertility of the insured" and (2) the "standard fertility preservation services are deemed reasonably necessary for the insured." HB 2242 and SB 3308 require that, for the mandatory health insurance coverage to be activated, both conditions must be satisfied.

We note, however, that the term "reasonably necessary," is not defined in the two bills themselves. In addition, the term is not defined in Chapters 431, 432, or 432D, HRS, sections of the HRS amended by HB 2242 and SB 3308, nor in Chapter 432E, HRS, the Patients' Bill of Rights and Responsibilities Act (a Hawai'i statute that defines "medical necessity" in the context of health insurance determinations).

We asked ASCO, Hawai'i Society of Clinical Oncology (Hawai'i Chapter of ASCO), Alliance for Fertility Preservation[3], Hawai'i Medical Service Association, Kaiser Permanente Hawai'i, 'Ohana Health Plan, United Healthcare Community Plan Hawai'i, UHA Health Insurance, Hawai'i Western Management Group (Third Party Administrator for Hawai'i Medical Assurance Association), AlohaCare, and Humana for their understanding of the term "reasonably necessary."[4] While many noted that "medically necessary" or "medical necessity" is a commonly used term, none of the organizations or insurers were able to define "reasonably necessary." Three of the health insurance providers further stated that "reasonably necessary" was not a commonly used insurance term.

What is "Medically Necessary"?

PURSUANT TO SECTION 432E-1.4, HRS, a health intervention is medically necessary if it is recommended by the treating physician or licensed health care provider, is approved by the health plan's medical director or physician designee, and is:

(1) For the purpose of treating a medical condition;

(2) The most appropriate delivery or level of service, considering potential benefits and harms to the patient;

(3) Known to be effective in improving health outcomes; provided that:

  (a) Effectiveness is determined by scientific evidence;

  (b) If no scientific evidence exists, then by professional standards of care; and

  (c) If no professional standards of care exists or if they exist but are outdated or contradictory, then by expert opinion; and

(4) Cost-effective for the medical condition being treated compared to alternative health interventions, including no intervention.

[3] Alliance for Fertility Preservation is a nonprofit organization dedicated to expanding fertility resources for cancer patients and survivors.

[4] Humana chose not to comment.

Without a clear definition of the term, we are unable to determine the extent of the proposed coverage – specifically, when an insured is entitled to coverage for fertility preservation services. Without that understanding, we are unable to assess the social and financial impacts of the mandatory health insurance coverage, including the extent to which insurance coverage can be reasonably expected to increase or decrease insurance premiums and total cost of health care. Without a clear understanding of the extent of the coverage, we are also unable to assess the public demand for fertility preservation services for which the bills propose to mandate insurance coverage. Additionally, insureds and insurers must be able to determine when standard fertility preservation services are deemed to be "reasonably necessary" for an insured such that the mandatory insurance coverage is applicable.

Conclusion

HB 2242 and SB 3308 do not include the minimum information needed to conduct the assessment required by Section 23-52, HRS. For that reason, we are unable to assess the social and financial effects of mandating the health insurance coverage, in accordance with Sections 23-51 and 23-52, HRS. Under the bills, the term "reasonably necessary" acts as a scoping mechanism for the proposed coverage. But the meaning of "reasonably necessary" is unclear. Without a clear definition of the term, it is impossible to assess the social and financial effects of mandating the proposed health insurance coverage. In addition, without a consistent description of what services are considered to be "standard fertility preservation services," we do not have enough information to identify the extent of the proposed coverage.