
Mandatory Health Insurance Coverage for Fertility Preservation Procedures for People of Reproductive Age Diagnosed With Cancer

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

Report No. 12-09
October 2012



THE AUDITOR
STATE OF HAWAI'I

Office of the Auditor

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According to the state Department of Health, 31,389 people in Hawai'i have been diagnosed with cancer between 2005 and 2009. Of this population, 4,690 were 49 or younger and would arguably benefit from H.B. No. 2105.

Recommendations

Responses

Mandatory Health Insurance Coverage for Fertility Preservation Procedures for People of Reproductive Age Diagnosed With Cancer

Report No. 12-09, October 2012

Assessment of proposed mandatory health insurance for fertility preservation procedures

Lack of data makes social and financial impacts difficult to determine

House Concurrent Resolution No. 9, Senate Draft 1, of the 2012 Legislature, asks the Auditor to assess the social and financial effects of mandating health insurance coverage for fertility preservation procedures for people diagnosed with cancer as proposed in House Bill No. 2105, Regular Session of 2012 (H.B. No. 2105). Since treatment for cancer such as radiation and chemotherapy can increase the risk of infertility in both men and women, H.B. No. 2105 would require Hawai'i health insurance providers to include as a benefit established preservation procedures for potential cancer-related infertility in men and women. The procedures covered would be limited to embryo cryopreservation (the freezing of an embryo) and sperm cryopreservation (the freezing of sperm). However, no state currently requires insurance coverage for infertility treatments for people who may become infertile as a result of cancer treatments. Besides Hawai'i, only New Jersey and California have recently proposed legislation mandating coverage similar to H.B. No. 2105.

Since insurance coverage as proposed in H.B. No. 2105 is not generally available, there is insufficient data to assess the social and financial impacts of mandating insurance coverage. Individuals diagnosed with cancer, who may want to preserve their reproductive ability, must seek the service on their own and bear the full costs, which could be upwards of \$10,000. We identified two such individuals from testimony submitted in support of H.B. No. 2105, but we conclude that the the number of people generally utilizing the procedures is unknown and the level of public demand is low. In addition, insurers generally reported that mandated coverage of embryo and sperm cryopreservation would increase premiums and administrative costs.

Expanding coverage raises significant issues for lawmakers

Cancer-related infertility raises issues of patient and offspring welfare that may not arise in other settings. If H.B. No. 2105 is adopted, the Legislature may need to consider other issues, such as the costs related to the preservation of embryos and sperm. Reproduction preservation during cancer treatment also raises a number of ethical issues related to both patient and offspring welfare. According to the American Society for Reproductive Medicine, these issues may include experimental versus established therapies, the ability of minors to give consent, the rights and benefits of the offspring, and posthumous reproduction. For example, what are the rights of a child conceived posthumously to receive an inheritance or Social Security survivors benefits?

Agencies' responses

The Departments of Health, Commerce and Consumer Affairs, and Labor and Industrial Relations opted not to comment on the draft report provided to them.

Mandatory Health Insurance Coverage for Fertility Preservation Procedures for People of Reproductive Age Diagnosed With Cancer

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Submitted by

THE AUDITOR
STATE OF HAWAI'I

Report No. 12-09
October 2012

Foreword

We assessed the social and financial impacts of mandating insurance coverage for fertility preservation procedures for people diagnosed with cancer in Hawai‘i, as proposed by House Bill No. 2105, pursuant to Sections 23-51 and 23-52, Hawai‘i Revised Statutes. The 2012 Legislature requested this assessment through House Concurrent Resolution No. 9, Senate Draft 1.

We acknowledge and appreciate the cooperation of the Departments of Health, Commerce and Consumer Affairs, and Labor and Industrial Relations and other organizations and individuals that we contacted during the course of this assessment.

Marion M. Higa
State Auditor

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Chapter 1

Introduction

House Concurrent Resolution No. 9, Senate Draft 1, of the 2012 Legislature, asks the Auditor to assess the social and financial effects of mandating health insurance coverage for fertility preservation procedures for people diagnosed with cancer as proposed in House Bill No. 2105, Regular Session of 2012 (H.B. No. 2105). We conducted this study 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 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.

Background on Infertility

Infertility in women and men

According to the U.S. Department of Health and Human Services, Office on Women’s Health, infertility is defined as the inability to become pregnant after one year of trying, or after six months if the woman is 35 or older. Women who can become pregnant but are unable to remain pregnant may also be infertile. The Centers for Disease Control and Prevention (CDC), has noted that infertility affects about 10 percent of women (6.1 million) between the ages of 15 and 44 in the United States. The Office on Women’s Health reports that about one-third of infertility cases can be traced to the female, one-third to the male, and one-third to a mixture of male and female factors or unknown sources.

Treatment of infertility often requires a combination of medications, surgery, artificial insemination, and assisted reproductive technologies. Medication can be used to treat ovulation problems in women and infections that may affect sperm count in men. Surgery can be used to remove sperm or clear blockages from the male reproductive tract. Artificial insemination, also known as intrauterine insemination (IUI), is a procedure where the woman is injected with specially prepared sperm. Prior to undergoing IUI, the woman may be treated with medications that stimulate ovulation.

Assisted reproductive technology (ART) as defined by the CDC includes all fertility treatments in which both eggs and sperm are handled. Generally, these procedures involve surgically removing eggs from a woman's ovaries, combining them with sperm, and returning them to the woman's body or donating them to another woman. However, ART does not include treatments in which only sperm are handled such as IUI, or procedures in which the woman takes drugs only for stimulating egg production without the intention of retrieving the eggs. There are three types of ART:

- In vitro fertilization (IVF)—involves extracting a woman's eggs, fertilizing the eggs in a laboratory and then transferring the resulting embryos into the woman's uterus through the cervix;
- Gamete intrafallopian transfer (GIFT)—involves using a laparoscope to guide the transfer of unfertilized eggs and sperm (gametes) into the woman's fallopian tubes;
- Zygote intrafallopian transfer (ZIFT)—involves fertilizing a woman's eggs in the laboratory and then use of a laparoscope to guide the transfer of the fertilized eggs (zygotes) into the woman's fallopian tubes.

According to a November 2011 CDC publication, *2009 Assisted Reproductive Technology Success Rates National Summary and Fertility Clinics Report*, in vitro fertilization is the most common method (99 percent) of ART performed in clinics nationwide. The CDC collected data on the number of clinics, IVF cycles performed, live-birth deliveries, and infants born from 441 out of 484 clinics located throughout the United States. There are four clinics performing ART services in Hawai'i that reported data in 2009 to the CDC:

- Advanced Reproductive Center of Hawai'i;
- IVF Hawai'i;

- Pacific In Vitro Fertilization Institute, Kapi‘olani Medical Center for Women and Children; and
- Tripler Army Medical Center IVF Institute.

The Hawai‘i Reproductive Center operating in Hawai‘i was identified by the CDC for not reporting or verifying data as required by the federal Fertility Clinic Success Rate and Certification Act.

Cancer treatments increase risk for infertility

For men, risk factors for infertility include: heavy alcohol use, drugs, cigarette smoking, age, environmental toxins, kidney disease, and hormone problems. In women, risk factors for infertility include: age; smoking; excessive alcohol use; stress; poor diet; athletic training; excess weight or insufficient weight; sexually transmitted infections; and health problems that cause hormonal changes, such as polycystic ovarian syndrome and primary ovarian insufficiency. Additionally, medicines as well as radiation and chemotherapy treatments for cancer can increase the risk of infertility in both men and women. Permanent infertility or compromised fertility as a result of chemotherapy and radiation are dependent on many factors such as the drug type administered or size and location of the radiation field, dose, and dose intensity, method of administration, disease, as well as the age, sex, and pre-treatment fertility of the patient. In men, chemotherapy can reduce the quantity and quality of sperm, which may result in permanent infertility or compromised fertility. In women, chemotherapy and radiation may damage the ovaries and uterus, which can result in infertility.

Types of fertility preservation procedures

Because cancer treatment often results in reduced fertility, the American Society for Reproductive Medicine and the American Society of Clinical Oncology recommend that physicians inform their cancer patients of the options for fertility preservation and future reproduction prior to receiving treatment. Both groups agree that embryo and sperm cryopreservation are the most established methods of fertility preservation.

Another procedure, oocyte cryopreservation (the freezing of unfertilized eggs), can be used for women who do not have a partner or are unwilling to use donor sperm. However, it is seen as an experimental procedure since its efficacy has yet to be proven. As of 2005, only about 120 infants were born as a result of oocyte cryopreservation. In contrast, according to the CDC, about 7,300 babies were born from frozen embryos in 2009. Exhibit 1.1 details fertility preservation procedures that can be used.

Exhibit 1.1

Description of Fertility Preservation Procedures

Sperm cryopreservation	This procedure, which involves the freezing of sperm, is the most established technique for fertility preservation in men. A procedure known as intracytoplasmic sperm injection (ICSI) involves injecting a single sperm into an egg. This allows for the successful freezing and future use of a small sample of sperm.
Embryo cryopreservation	This method requires the harvesting of eggs, in vitro fertilization, and freezing of embryos to be used for implantation at a later time. This is the most established technique for fertility preservation in women; it has been used for storing extra embryos after in vitro fertilization.
Oocyte cryopreservation	This method requires the harvesting and freezing of unfertilized eggs. The eggs are thawed at a later time and fertilized in vitro. Research shows that unfertilized eggs are more prone to damage during the freezing process than embryos, and that overall pregnancy rates may be lower.

Source: Office of the Auditor

House Bill No. 2105 requires coverage for fertility preservation procedures for those diagnosed with cancer

House Bill No. 2105 would require Hawai‘i health insurance providers to include as a benefit established preservation procedures for cancer-related infertility in men and women. Specifically, the bill adds a new section to Article 10A *Accident and Health or Sickness Insurance Contracts*, Chapter 431, HRS, and amends Chapter 432, HRS, Article 1 *Mutual Benefit Societies*, and the Health Maintenance Organization Act, Chapter 432D, HRS. The measure requires that insurance policies provide coverage for fertility preservation procedures provided the insured is: 1) of reproductive age, and 2) diagnosed with a cancer that may adversely affect fertility or whose cancer treatments do the same. The bill identifies only two fertility preservation procedures—sperm cryopreservation and embryo cryopreservation.

Coverage for in vitro fertilization procedures to treat infertility is available

Hawai‘i’s laws requiring health insurance coverage for in vitro fertilization for married couples experiencing infertility, Sections 431:10A-116.5 and 432:1-604, HRS, were enacted in 1987. These sections require all individual and group accident and health or sickness insurance policies, as well as all individual and group hospital or medical service plan contracts that provide pregnancy-related benefits, to cover in vitro fertilization procedures that conform to guidelines issued by the American College of Obstetricians and Gynecologists or the American Society for Reproductive Medicine. In order to qualify for in vitro fertilization procedure coverage, a married couple must have:

- A history of infertility for at least five years; *or*

- Infertility associated with certain conditions—endometriosis, exposure in utero to diethylstilbestrol (a synthetic nonsteroidal estrogen chemical that may increase the risk of vagina or cervix cancer), blockage or surgical removal of a fallopian tube, or abnormal male factors contributing to infertility.

Mandated coverage in other states

States across the nation currently do not require insurance coverage for infertility treatments for people who may become infertile as a result of cancer treatments. Besides Hawai'i, only two states (New Jersey and California) have recently proposed legislation mandating coverage similar to H.B. No. 2105.

As of March 2012, according to the National Conference of State Legislatures, 15 states including Hawai'i have laws requiring private insurers to cover or offer coverage for varying types of infertility treatment and diagnosis that is not related to cancer treatments. Exhibit 1.2 illustrates these types of mandates.

Exhibit 1.2 Mandated Coverage for Infertility Treatments Available in 15 States

State	Coverage
Arkansas	Requires health insurance companies to cover in vitro fertilization by a facility licensed by the state Department of Health that conforms to guidelines and minimum standards of the American College of Obstetricians and Gynecologists and the American Society for Reproductive Medicine.
California	Requires health care service plan for group contracts and insurers to offer coverage for the treatment of infertility, except in vitro fertilization.
Connecticut	Requires health insurance organizations to provide coverage for medically necessary expenses in the diagnosis and treatment of infertility, including in vitro fertilization procedures.
Hawai'i	Requires all accident and health insurance policies that provide pregnancy-related benefits to include a one-time only benefit for outpatient expenses arising from in vitro fertilization procedures.
Illinois	Requires certain insurance policies that provide pregnancy-related benefits to provide coverage for the diagnosis and treatment of infertility. Coverage includes a variety of procedures including in vitro fertilization and four completed oocyte retrievals.
Louisiana	Prohibits the exclusion of coverage for the diagnosis and treatment of a medical condition otherwise covered by the policy solely because the condition results in infertility. The law does not require insurers to cover fertility drugs, in vitro fertilization or other assisted reproductive techniques.
Maryland	Prohibits certain health insurers that provide pregnancy-related benefits from excluding benefits for all outpatient expenses arising from in vitro fertilization procedures performed.

Massachusetts	Requires general insurance policies, non-profit hospital service corporations, medical service corporations and health maintenance organizations that provide pregnancy related benefits to also provide coverage for the diagnosis and treatment of infertility, including in vitro fertilization.
Montana	Requires health maintenance organizations to cover infertility services as part of basic health services on a prepaid basis.
New Jersey	Requires health insurers to provide coverage for medically necessary expenses incurred in diagnosis and treatment of infertility. Coverage includes medications, surgery, in vitro fertilization and a variety of procedures including four completed egg retrievals per lifetime of the covered person.
New York	Requires certain insurers to cover infertility treatment for women between 21 and 44. Coverage includes hospital, surgical and medical care for diagnosis and treatment of “correctable medical conditions otherwise covered by the policy solely because the medical condition results in infertility.” However, coverage does not include in vitro fertilization, gamete intrafallopian tube transfers, or zygote intrafallopian tube transfers.
Ohio	Requires health maintenance organizations to provide basic health care services, which include infertility services when medically necessary.
Rhode Island	Requires insurers to provide coverage of medically necessary expenses for the diagnosis and treatment of infertility.
Texas	Requires all health insurers to offer and make available coverage for services and benefits for expenses incurred or prepaid for outpatient expenses that may arise from in vitro fertilization procedures, provided the couple has a history of infertility for at least five years or have specified medical conditions resulting in infertility.
West Virginia	Requires health maintenance organizations to cover infertility services.

Source: National Conference of State Legislatures

Like the Hawai‘i Legislature, California and New Jersey legislatures introduced legislation that have proposed to expand existing coverage of infertility caused by cancer treatments. However, neither measure has become law. In 2011, a bill was introduced in California to allow coverage for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause infertility. Unlike H.B. No. 2105, which would cover embryo cryopreservation and sperm cryopreservation, the California bill did not identify a specific preservation procedure to be covered. Also, the target group of people who would benefit from the California legislation is not limited to those undergoing treatment for cancer but those undergoing any necessary medical treatment that may cause infertility.

In 2012, a bill introduced in New Jersey sought to require health insurers to cover medically necessary expenses for preventing infertility in women undergoing chemotherapy or radiation therapy for the treatment of cancer through oocyte cryopreservation. This differs from H.B. No. 2105, in that the target group is women undergoing only chemotherapy

or radiation treatments, and the fertility procedure is limited to oocyte cryopreservation. By contrast, H.B. No. 2105, offers coverage for both men and women diagnosed with cancer, and it covers embryo cryopreservation, which has a more successful pregnancy rate, instead of oocyte cryopreservation which is considered an experimental procedure.

Objectives of the Study

1. Assess the social and financial effects of mandating health insurance coverage for fertility preservation procedures for men and women of reproductive age who have been diagnosed with cancer and will undergo treatment that may adversely affect their ability to procreate.
2. Make recommendations as appropriate.

Scope and Methodology

Our study examined the social and financial effects of mandating health insurance coverage for fertility preservation procedures for persons diagnosed with cancer and subject to cancer treatments as proposed in H.B. No. 2105.

To assess the potential social and financial effects of providing coverage for fertility preservation procedures, we applied the following criteria provided in Section 23-52, HRS, as applicable:

Social impact

1. Extent to which the treatment or service is generally utilized by a significant portion of the population;
2. Extent to which such insurance coverage is already generally available;
3. 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;
4. If coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment;
5. The level of public demand for the treatment or service;
6. The level of public demand for individual or group insurance coverage of the treatment or service;

7. The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts;
8. 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
9. 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.

Financial impact

1. The extent to which insurance coverage of the kind proposed would increase or decrease the cost of the treatment or service;
2. The extent to which the proposed coverage might increase the use of the treatment or service;
3. The extent to which the mandated treatment or service might serve as an alternative for more expensive treatment or service;
4. 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
5. The impact of this coverage on the total cost of health care.

We conducted this study between June 2012 and September 2012 in accordance with the Office of the Auditor's *Manual of Guides* and generally accepted government auditing standards. Those standards require that we plan and perform the study to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our assessment objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our objectives.

Chapter 2

Assessment of Proposed Mandatory Health Insurance for Fertility Preservation Procedures

This study assesses the social and financial impacts of mandating insurance coverage for fertility preservation procedures for people diagnosed with cancer as proposed in House Bill No. 2105, Regular Session of 2012 (H.B. No. 2105). Although improvements in cancer treatment have increased the survival rates of those diagnosed with cancer, treatments such as chemotherapy and radiation often result in reducing a young person's ability to procreate. Currently, sperm cryopreservation (the freezing of sperm) and embryo cryopreservation (the freezing of an embryo) identified in H.B. No. 2105 are the most established procedures for fertility preservation for men and women. Both techniques have been proven to be successful in helping individuals have children after undergoing cancer treatment.

We found that insurance coverage for the two fertility preservation procedures proposed in H.B. No. 2105, is not generally available in Hawai'i or in other states. Therefore, there is insufficient information to determine the social and financial impacts of mandating insurance coverage. Moreover, expanding existing coverage for in vitro fertilization procedures raises significant issues for lawmakers to consider. According to the American Society for Reproductive Medicine, reproduction preservation during cancer raises a number of ethical issues related to both patient and offspring welfare. These issues may include: experimental versus established therapies, the ability of minors to give consent, the welfare of expected children, and posthumous reproduction. For example, what are the rights of a child conceived posthumously to receive an inheritance or Social Security survivors benefits?

Summary of Findings

1. Social and financial impacts are difficult to determine due to a lack of data.
2. Expanding current coverage for in vitro fertilization procedures raises significant issues for lawmakers.

Social and Financial Impacts Are Difficult To Determine Due To a Lack of Data

In order to determine the social and financial impacts of mandating coverage for the fertility preservation procedures—sperm cryopreservation and embryo cryopreservation—proposed in H.B. No. 2105, we surveyed insurance companies, organizations, and unions, and performed a review of the medical literature available on fertility preservation and reproduction in cancer patients. We obtained information from the following insurance companies: Hawai‘i Medical Service Association (HMSA); Kaiser Permanente; Hawai‘i Medical Assurance Association (HMAA); and University Health Alliance (UHA). Of the 17 unions surveyed, three responded: the Hawai‘i Fire Fighters Association, Hawai‘i State Teachers Association, and University of Hawai‘i Professional Assembly. We also surveyed two community organizations, the American Cancer Society and RESOLVE: The National Infertility Organization.

Those surveyed provided little information on both the social and the financial impacts of H.B. No. 2105, since insurance coverage of sperm cryopreservation and embryo cryopreservation procedures for men and women, respectively, diagnosed with cancer is not generally available. Individuals diagnosed with cancer who may want to preserve their reproductive ability must seek the service on their own and bear the full costs, including medications and storage for frozen embryos and sperm. Although we identified two such individuals from testimony submitted in support of H.B. No. 2105, we conclude that the affected population utilizing the procedures is relatively small, the number generally utilizing the procedures is unknown, and the level of public demand is low. Moreover, while the insurers generally reported that mandated coverage of embryo cryopreservation and sperm cryopreservation would increase premiums and administrative costs, only the HMSA ventured to guess the extent of the increase.

Social impact

1. Extent to which the treatment or service is generally utilized by a significant portion of the population:

The population of individuals of reproductive age diagnosed with cancer that may be affected by H.B. No. 2105 is relatively small. According to data provided by the state Department of Health, 31,389 people have been diagnosed with cancer between 2005 and 2009. Of this population, 4,690 people or 14.9 percent were age 49 or younger. This is the age group that would arguably benefit from H.B. No. 2105.

The insurance providers and the organizations we surveyed could not quantify the number of people with cancer who had undergone the fertility preservation procedures identified in H.B. No. 2105. The UHA

responded that none of its members with cancer had undergone fertility preservation procedures. The HMAA was unable to say without a clear definition of reproductive age. The HMSA responded the number utilizing the procedure is unknown since the procedures are not covered. Similarly, Kaiser Permanente did not have the information since procedures are not a covered benefit and the services would be performed in non-Kaiser facilities. Neither the American Cancer Society nor RESOLVE: The National Infertility Organization maintains information on cancer patients who have undergone fertility preservation procedures. From testimonies received by the 2012 Legislature in support of H.B. No. 2105, we identified two individuals who opted to preserve their ability to reproduce following a cancer diagnosis. Because of this lack of data, we conclude that the extent to which sperm and embryo cryopreservation procedures have been generally utilized by a significant portion of the population of 4,690 cancer patients in Hawai‘i is unknown.

2. Extent to which such insurance coverage is already generally available:

Current insurance coverage for in vitro fertilization procedures does not include fertility preservation procedures, such as embryo cryopreservation, oocyte cryopreservation, or sperm cryopreservation. According to Kaiser Permanente, UHA and HMSA, insurance coverage for cryopreservation of embryo, eggs, or sperm is generally not available to people diagnosed with cancer under their plans. The HMAA responded that under most circumstances, these procedures are not covered unless related to state law mandating in vitro fertilization coverage.

3. 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:

The extent to which the lack of coverage results in persons diagnosed with cancer being unable to obtain fertility preservation procedures is unknown. Insurers have reported that since embryo cryopreservation, oocyte cryopreservation, and sperm cryopreservation procedures are generally not covered, members wanting these services would have to bear the full cost of treatment. Although HMSA reported receiving four to five requests per year mostly from mainland oncologists treating its members, it is unknown whether the members decided to bear the costs or forego treatment. Similarly, Kaiser Permanente reported that an estimated one to three patients a year are referred for the procedures, but it is unknown whether the patients actually followed up with the procedures. The UHA reported receiving only one request for sperm cryopreservation several years ago. But again, it had no knowledge about whether the member proceeded with the treatment.

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

The extent to which the lack of coverage results in unreasonable financial hardship is unknown. The costs of these procedures, however, are high. The reported cost of IVF procedures varies, and is usually estimated to cost upwards of \$10,000. According to RESOLVE, the average cost of one IVF cycle, not including the cost of medication, is generally between \$8,000 and \$12,000. Medications for an IVF cycle range from \$3,000 to \$5,000. The HMSA reported that the average cost per female case of IVF is \$8,000. Kaiser Permanente reported that IVF and other infertility treatments can cost from about \$10,000 to \$30,000.

As we noted above, insurance generally does not cover embryo cryopreservation, oocyte cryopreservation, and sperm cryopreservation procedures. People wanting these procedures will have to seek treatment on their own and be responsible for all of these expenses. We have insufficient data to determine the extent to which the lack of coverage results in unreasonable financial hardship. For example, we interviewed the person who testified about conceiving a child posthumously using in vitro fertilization from sperm preserved from her late husband. Although she could not recall the exact costs, we were told she was required to pay about \$10,000 upfront before the treatment could be started. We could not conclude from our interview that the lack of coverage resulted in unreasonable financial hardship. The 2012 Legislature also received testimony from another individual who froze her eggs, and as a result was burdened with a \$6,000 debt even though she received financial aid from the non-profit Livestrong Foundation.

5. The level of public demand for the treatment or service:

The level of public demand for the fertility preservation procedures proposed in H.B. No. 2105 appears to be low. The 2012 Legislature received no more than ten testimonies in support of H.B. No. 2105. For House Draft 1 of that bill extending the effective date to July 1, 2050, the 2012 Legislature received testimony in support from three medical professionals, three private citizens, and one organization. The American Cancer Society informed us it does not capture data specific to fertilization procedures in cancer patients and has not conducted a poll or survey specific to the coverage of fertility preservation. Nor has the organization received any complaints about ensuring that all aspects of cancer treatments are discussed early, including the long-term effects on fertility. Given the fact that there are no states mandating coverage as proposed in H.B. No. 2105, and only two states (New Jersey and California) are considering similar legislation, this low level of public demand may be nationwide.

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

The level of public demand for individual or group insurance coverage of fertility preservation procedures appears to be low. The HMAA reported receiving a total of two requests from its members for coverage in the last two years. The UHA received only one request for sperm cryopreservation. The HMSA received four to five requests for coverage per year primarily from mainland oncologists treating its members. However, the HMSA indicated that if current coverage were expanded to include fertility preservation procedures and the public was made aware of the change in law, the number of inquiries may increase.

Kaiser Permanente estimated that one to three patients are referred but it is not aware of any of its members requesting coverage of the procedure. Kaiser Permanente explained that from an oncology perspective, these procedures have not been a higher priority for patient and physician. Given the illness, one can surmise that fertility preservation may be a lower priority to the patient and physician. Kaiser Permanente estimates that fertility preservation is an issue that arises infrequently—fewer than ten patients a year. Generally, for younger patients where the malignancy is frequently hematologic, the treatment becomes urgent and the chemotherapy must be administered before the time it takes to perform an embryo cryopreservation. For sperm cryopreservation, it could take less time, but understandably, often patients do not want to delay cancer treatment. Notably, Kaiser Permanente’s chemotherapy regimens take into account possible infertility, and its more modern regimens have less impact on fertility, e.g., treatments for Hodgkin lymphoma and breast cancer.

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

The level of interest among collective bargaining organizations is largely unknown, but probably low, since we received responses from only three of 17 unions surveyed. The Hawai‘i Fire Fighters Association, the Hawai‘i State Teacher’s Association, and the University of Hawai‘i Professional Assembly (UHPA) have received no requests from their members for insurance coverage as proposed in H.B. No. 2105. However, the UHPA expressed support for this type of coverage, since its younger faculty is interested in reproductive health and 54 percent of its membership is female.

8. 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):

The impact of providing coverage on morbidity and mortality would be low according to the American Cancer Society, the HMAA and UHA, but the two insurers with the most members, HMSA and Kaiser Permanente, provided no response. The American Cancer Society reported that should mandatory fertilization be covered, the impact to the morbidity and mortality rates among cancer patients would be very little since the procedures are separate from cancer screening, diagnosis, and treatment. The HMAA and UHA reported that morbidity from fertility preservation procedures would be low. The UHA informed us that the impact on morbidity and mortality from sperm cryopreservation should be zero.

9. 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:

The impact of indirect costs upon the costs and benefits of coverage may increase. According to HMAA and Kaiser Permanente, H.B. No. 2105 can be expected to increase indirect costs since the overall costs for delivering health care would increase. The HMAA noted that mandating coverage will prevent resources from being applied to other medical care that may impact a broader base of individuals. The UHA noted that there is a cost associated with the freezing and storage of tissues that may result in an increase in medical expenses. The HMSA was reluctant to provide a response given its problems and concerns with H.B. No. 2105, discussed later in this chapter.

Financial impact

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

According to HMSA, HMAA, and Kaiser Permanente, insurance coverage may increase the cost of fertility preservation procedures, but to what extent is unknown. The HMAA, UHA, and the American Cancer Society could not quantify the costs. The HMSA was the only insurer to provide a rough estimate of the cost for covering fertility preservation procedures, based on assumptions about claims paid and its population—of 7,528 women (15–44) and men (15–64). The insurer calculated a per member per month cost per female with cryotherapy service and in vitro at \$8,000, and \$2,500 per male for cryotherapy and sperm retrieval. The total cost per member per month of \$ 0.84 multiplied by 650,000 members was estimated to be \$546,000 per month or about \$6.6 million a year.

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

Given the fact that undergoing fertility preservation procedures is costly, if coverage were available, there may be an increase in those seeking this type of treatment, but to what extent is unknown. The American Cancer Society anticipates that more cancer patients would likely consider fertility preservation treatment. However, HMAA, Kaiser Permanente, and UHA were unable to estimate whether the coverage of fertility preservation procedures would thereby increase use. Kaiser Permanente and UHA noted that because the service is not covered there is no data and neither could speculate as to how available coverage would have an impact on usage.

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

The two established preservation procedures for cancer-related infertility are embryo cryopreservation and sperm cryopreservation. The HMAA notes that it is highly unlikely that there are other more expensive procedures. The HMSA stated that these fertility procedures would not serve as an alternative for more expensive treatment. Kaiser Permanente could not provide a response regarding other more expensive treatments, and UHA noted that it is unaware of other more extensive procedures that its patients would seek.

4. 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:

In general, insurers reported that the mandated coverage of fertility preservation procedures would increase insurance premiums and administrative costs, but only the HMSA provided an estimate of \$6.6 million, explained in item 1 above. The HMAA and Kaiser Permanente both noted that premiums and administrative costs would increase, but were unable to quantify the amount.

5. The impact of this coverage on the total cost of health care:

The impact of the coverage on the total cost of health care is unknown. The HMAA, Kaiser, and UHA were unable to estimate the financial impact of the bill with any degree of certainty. The HMSA provided an estimate of an increase in cost of \$6.6 million.

Expanding Current Coverage for Future Use of Frozen Embryos and Sperm Raises Significant Issues for Lawmakers

Current coverage for IVF procedure is limited compared to House Bill No. 2105

While in some respects cancer-related infertility is not markedly different from other kinds of infertility, it does raise issues of patient and offspring welfare that may not arise in other settings. For instance, H.B. No. 2105 would expand the current law mandating coverage for in vitro fertilization (IVF) procedures to cover cancer-related infertility for both men and women through the use of sperm cryopreservation and embryo cryopreservation. Should the law include coverage of these procedures, the Legislature may need to consider other issues, such as the costs related to the preservation of embryos and sperm, and the rights and benefits of the offspring.

Currently, insurance coverage of in vitro fertilization procedure is limited to married couples experiencing infertility associated with certain medical conditions. As it stands, Sections 431:10A-116.5 and 432:1-604, HRS, limit the scope of coverage when compared to H.B. No. 2105. Insurance coverage is limited to one IVF cycle per lifetime for married couples and specifies that the embryos created from the IVF procedure consist of sperm and eggs from each spouse. The law also contains a standard of care for facilities performing IVF procedures. Although evaluations and drug therapy associated with IVF are covered, the preservation of embryos, sperm or eggs resulting from IVF is not included as a covered benefit.

The proposed bill for future use expands existing coverage

In 1987, the Legislature mandated health insurance coverage for IVF procedures for married couples experiencing infertility with the passage of Act 332 (SLH 1987), codified in Sections 431:10A-116.5 and 432:1-604, HRS. In order to qualify, married couples must meet certain medical conditions:

- a history of infertility of at least five years' duration; *or*
- infertility related to endometriosis (abnormal growth of uterine tissue), exposure in utero to diethylstilbestrol (a nonsteroidal estrogen that increases risk of vaginal or cervical cancer), blockage or surgical removal of one or both fallopian tubes, or contributing abnormal male factors.

The laws mandating coverage also require the IVF procedures be performed at medical facilities conforming to guidelines of the American College of Obstetricians and Gynecologists or the minimal standards of the American Society for Reproductive Medicine (ASRM). According to two insurance providers (HMSA and Kaiser Permanente), coverage is

limited to those services associated with a one-time only benefit for the IVF procedure including evaluations, drug therapy, and delivery.

While Sections 431:10A-116.5 and 432:1-604, HRS, provide in vitro fertilization coverage for those *currently* experiencing infertility, H.B. No. 2105 addresses potential cancer-related infertility. According to the Ethics Committee of the American Society for Reproductive Medicine, improvements in treating cancer have enabled many younger persons with cancer to survive. For example, the survival rates for testicular cancer, hematologic malignancies, breast cancer, and other cancers that strike young people may be in the 90 to 95 percent range. However, treatment of these cancers often damages the reproductive function of both males and females. The ASRM *Patient’s Fact Sheet on Cancer and Fertility Preservation* explains that lifesaving cancer treatments such as radiation to the ovaries or testicles and cancer drugs, may reduce fertility by destroying eggs and sperm. Permanent infertility or compromised fertility as a result of chemotherapy and radiation are dependent on many factors such as the drug or size and location of the radiation field, dose, dose intensity, method of administration, disease, age, sex, and pre-treatment of the patient.

The proposed H.B. No. 2105 essentially expands the current coverage for IVF procedures for future use to preserve fertility in cancer patients and aid them in reproducing after cancer treatment. The two methods of fertility preservation identified in H.B. No. 2105 are sperm cryopreservation and embryo cryopreservation. However, unlike coverage for IVF procedures, the bill does not specify whose sperm can be used to create the embryo that would be preserved and does not contain a standard of care for performing the fertility preservation procedures. The differences in the extent of coverage, target groups, limits on utilization and standard of care are shown in Exhibit 2.1.

**Exhibit 2.1
Differences in House Bill No. 2105 and Laws Mandating IVF Procedures**

Identifying information required for legislative bills proposing mandatory health insurance under §23-51, HRS	Existing law mandating insurance coverage for IVF procedures, §§431:10A-116.5 and 432:1-604, HRS	Proposed House Bill No. 2105
Specific health service, disease, or provider	In vitro fertilization procedures	Fertility preservation procedures for cancer patients.
Extent of coverage	All outpatient expenses arising from in vitro fertilization procedure, including associated medications, and evaluations associated with the procedure.	Embryo cryopreservation for women and sperm cryopreservation for men.

Covered target groups	Married couples experiencing infertility for at least five-year duration, or infertility associated with endometriosis, diethylstilbestrol, blockage or surgical removal of a fallopian tube, abnormal male factors.	Men and women of reproductive age and diagnosed with cancer or treatment that may adversely affect infertility.
Limits on utilization	Coverage is limited to one IVF procedure per lifetime.	No limits specified for the total number of procedures that can be performed.
Standard of care	American College of Obstetricians and Gynecologists guidelines for in vitro fertilization or the American Society for Reproductive Medicine minimal standards for programs of in vitro fertilization.	None.

Source: Office of the Auditor

Sperm cryopreservation and embryo cryopreservation are the most established methods of fertility preservation according to the ASRM’s ethics committee report, *Fertility Preservation and Reproduction in Cancer Patients*. With advances in assisted reproductive techniques, particularly intracytoplasmic sperm injection, freezing of even one ejaculate before starting cancer treatment provides a plausible chance of conceiving a biological child. Embryo cryopreservation involves the harvesting of eggs, in vitro fertilization, and freezing of embryos to be used for implantation at a later time. This option is available only if there is time before treatment to undergo a cycle of stimulation to obtain eggs and a safe method of ovarian stimulation. Following an IVF cycle, embryos remaining may be cryopreserved for future use. Cryopreservation makes future cycles simpler, less expensive and less invasive than the initial IVF cycle.

Under the current law, cryopreservation of embryos resulting from the IVF procedure is not covered by the insurance carrier. According to ASRM’s Assisted Reproductive Technologies, *A Guide for Patients*, revised in 2011, IVF is a method of assisted reproduction in which a man’s sperm and a woman’s eggs are combined outside the body in a laboratory dish. The fertilized eggs (embryos) may be transferred to a woman’s uterus, where they may implant in the uterine lining and develop. Initially, IVF was used to treat women with blocked, damaged, or absent fallopian tubes. Today, it is used to treat many causes of infertility, such as endometriosis and male factor, or when infertility is unexplained. In November 2011, the Centers for Disease Control reported that IVF accounted for more than 99 percent of assisted

reproductive technologies procedures performed in clinics nationwide in 2009.

Insurance providers raise questions about future rights and costs

The insurers we surveyed found various aspects of H.B. No. 2105 problematic. For example, the HMSA indicated that the federal Affordable Care Act has an enormous effect on new state mandates since mandates enacted after December 31, 2011 are the financial responsibility of the state and cannot be considered part of the essential health benefits package to be offered through the State Exchange.

The proposed bill does not specify who will be responsible for the storage costs and fees associated with embryo cryopreservation and sperm cryopreservation. The HMAA, HMSA, and Kaiser Permanente were concerned with whether the health plan would be required to cover the costs of storage, and the duration that they would be required to pay for storage costs.

Additionally, insurers raised questions about the composition of the embryos cryopreserved under H.B. No. 2105. The current law mandating coverage of IVF specifies that embryos created from the IVF procedure consist of sperm and eggs from each spouse. However, since the proposed bill does not place requirements on the genetic material to be used for the creation of an embryo, both the HMAA and HMSA questioned who would be responsible for providing donor sperm in the event that the woman does not have a partner with whom to create an embryo.

Insurers were also concerned about rights to the preserved sperm and embryos in the event of the donor's death. The ASRM notes that people whose gametes, embryos, or tissue are stored to preserve fertility should give direction for disposition of the tissue in the future. The ASRM recommends that the person should specify what should be done with the preserved gametes, embryos, or gonadal tissue if the donor becomes deceased, does not pay storage fees, or has abandoned the tissue. The HMAA asked, if coverage ceases, who is responsible for the cryopreservation costs? If the woman is unmarried, who is responsible for the donor sperm? The HMAA and HMSA were concerned about whether the health plans were to continue to be responsible to cover the storage costs in the event that the donor passes away. Kaiser Permanente was also concerned with the disposition of the stored embryos and sperm in the event of death. Kaiser Permanente also questioned whether others such as a spouse could use the genetic material posthumously.

Supreme Court case highlights entitlements for offspring conceived posthumously

A recent U.S. Supreme Court decision illustrates entitlement issues confronting states related to children conceived through the use of sperm cryopreservation and IVF after the death of the parent with cancer.

In *Astrue v. Capato*, Robert Capato, who was diagnosed with esophageal cancer, had his sperm frozen and stored prior to undergoing chemotherapy. He did this after being told that chemotherapy may make him sterile, and because he and his wife wanted children. After Mr. Capato passed away, his widow underwent IVF using her husband's frozen sperm and gave birth to twins 18 months after his death.

The case arose because the widow Capato was denied Social Security survivors benefits for her twins by the Social Security Administration. The agency's decision was affirmed by the New Jersey District Court which determined that the Capato twins would qualify for benefits only if they could inherit from their father (the deceased wage earner) under Florida intestacy law, as provided in the Social Security Act. Mr. Capato died in Florida where his will was executed. Under Florida law, a child born posthumously may inherit through intestate succession only if conceived *during* the decedent's lifetime. However, the U.S. Court of Appeals for the Third Circuit reversed the agency's decision, concluding that "the undisputed biological children of a deceased wage earner and his widow" qualify for survivors benefits without regard to state intestacy law.

In May 2012, the Supreme Court ruled that children conceived after their parent's death may receive Social Security benefits only if they qualify to inherit from their deceased parent under state intestacy law. Therefore, states may need to decide whether children who have been conceived posthumously will be entitled to an inheritance from their deceased parent's estate. The Supreme Court noted that some states (California, Colorado, Iowa, Louisiana, and North Carolina) grant inheritance rights to children conceived posthumously, while others (Florida, New York, Georgia, Idaho, Minnesota, South Carolina, and South Dakota) do not.

Conclusion

Since insurance coverage as proposed in H.B. No. 2105 is not generally available, there is insufficient data to assess the social and financial impacts. Therefore, any recommendation would be premature. However, if enacted, H.B. No. 2105 would expand the current law to benefit mostly young people whose cancer treatment is often highly detrimental to both male and female reproductive function. Insurance coverage for the use of in vitro fertilization, sperm

cryopreservation in men, and embryo preservation in women, in the context of cancer-related infertility raises significant issues for lawmakers to consider. Some issues are cost related, while others involve ethical questions and the legal rights of offspring conceived posthumously.

Recommendation

Any recommendation would be premature without sufficient data regarding both the social and financial impacts.

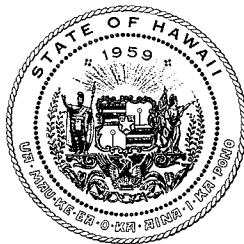
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Responses of the Affected Agencies

Comments on Agency Responses

We submitted a draft copy of this report to the Departments of Health (DOH), Commerce and Consumer Affairs (DCCA), and Labor and Industrial Relations (DLIR) on October 25, 2012. A copy of the transmittal letter to the DOH is included as Attachment 1. Similar letters were sent to the DCCA and DLIR. The departments opted not to respond.

STATE OF HAWAII
OFFICE OF THE AUDITOR
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MARION M. HIGA
State Auditor
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October 25, 2012

COPY

The Honorable Loretta J. Fuddy
Director
Department of Health
Kīna'u Hale
1250 Punchbowl Street
Honolulu, Hawaii 96813

Dear Ms. Fuddy:

Enclosed for your information are three copies, numbered 6 to 8, of our confidential draft report, *Mandatory Health Insurance Coverage for Fertility Preservation Procedures for People of Reproductive Age Diagnosed with Cancer*. We ask that you telephone us by Monday, October 29, 2012, on whether or not you intend to comment on our recommendations. If you wish your comments to be included in the report, please submit them no later than Monday, November 5, 2012.

The Department of Commerce and Consumer Affairs, Department of Labor and Industrial Relations, Governor, and presiding officers of the two houses of the Legislature have also been provided copies of this confidential draft report.

Since this report is not in final form and changes may be made to it, access to the report should be restricted to those assisting you in preparing your response. Public release of the report will be made solely by our office and only after the report is published in its final form.

Sincerely,

A handwritten signature in black ink, appearing to read 'Marion M. Higa', written in a cursive style.

Marion M. Higa
State Auditor

Enclosures