California Health Benefits Review Program

Analysis of Assembly Bill 912: Health Care Coverage: Fertility Preservation

A Report to the 2013–2014 California Legislature April 25, 2013

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

The California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analyses of the medical, financial, and public health impacts of proposed health insurance benefit mandates and proposed repeals of health insurance benefit mandates. CHBRP was established in 2002 to respond to requests from the California Legislature to provide independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates and repeals per its authorizing statute.[1] The program was reauthorized in 2006 and again in 2009. CHBRP's authorizing statute defines legislation proposing to mandate or proposing to repeal an existing health insurance benefit as a proposal that would mandate or repeal a requirement that a health care service plan or health insurer: (1) permit covered individuals to obtain health care treatment or services from a particular type of health care provider; (2) offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition; (3) offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service; and/or (4) specify terms (limits, timeframes, copayments, deductibles, coinsurance, etc.) for any of the other categories.

An analytic staff in the University of California's Office of the President supports a task force of faculty and staff from several campuses of the University of California to complete each analysis within a 60-day period, usually before the Legislature begins formal consideration of a mandate or repeal bill. A certified, independent actuary helps estimate the financial impacts. A strict conflict-of-interest policy ensures that the analyses are undertaken without financial or other interests that could bias the results. A National Advisory Council, drawn from experts from outside the state of California as well as Loma Linda University, the University of Southern California, and Stanford University, and designed to provide balanced representation among groups with an interest in health insurance benefit mandates or repeals, reviews draft studies to ensure their quality before they are transmitted to the Legislature. Each report summarizes scientific evidence relevant to the proposed mandate, or proposed mandate repeal, but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work through an annual assessment on health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available on the CHBRP website, www.chbrp.org.

[1] Available at: www.chbrp.org/documents/authorizing_statute.pdf.

A Report to the 2013–2014 California State Legislature

Analysis of Assembly Bill 912
Health Care Coverage: Fertility Preservation

April 25, 2013

California Health Benefits Review Program
1111 Franklin Street, 11th Floor
Oakland, CA 94607
Tel: 510-287-3876
Fax: 510-763-4253
www.chbrp.org

Additional free copies of this and other CHBRP bill analyses and publications may be obtained by visiting the CHBRP website at www.chbrp.org.

Suggested Citation:

California Health Benefits Review Program (CHBRP). (2013). *Analysis of Assembly Bill 912: Health Care Coverage: Fertility Preservation.* Report to California State Legislature. Oakland, CA: CHBRP.

PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 912. In response to a request from the California Assembly Committee on Health on February 25, 2013, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute.

Sara McMenamin, PhD, of the University of California, San Diego, prepared the medical effectiveness analysis. Stephen L. Clancy, MLS, AHIP, of the University of California, Irvine, conducted the literature search. Diana Cassady, DrPH, and Dominique Ritley, MPH, of the University of California, Davis, prepared the public health impact analysis. Byung-Kwang Yoo, MD, MS, PhD of the University of California, Davis prepared the cost impact analysis. Robert Cosway, FSA, MAAA, and Scott McEachern of Milliman, provided actuarial analysis. H. Irene Su, MD, of the University of California, San Diego, provided technical assistance with the literature review and expert input on the analytic approach. Laura Grossmann, MPH, of CHBRP staff prepared the *Introduction* and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Sylvia Guendelman, PhD, LCSW, of the University of California, Berkeley, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

CHBRP gratefully acknowledges all of these contributions but assumes full responsibility for all of the report and its contents. Please direct any questions concerning this report to:

California Health Benefits Review Program
1111 Franklin Street, 11th Floor
Oakland, CA 94607
Tel: 510-287-3876
Fax: 510-763-4253
Email: chbrpinfo@chbrp.org
www.chbrp.org

All CHBRP bill analyses and other publications are available on the CHBRP website, www.chbrp.org.

Garen Corbett, MS
Director

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 912

The California Assembly Committee on Health requested on February 25, 2013, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 912, fertility preservation. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.[2]

In 2014, CHBRP estimates that approximately 25.9 million Californians (67%) will have health insurance that may be subject to a health benefit mandate law passed at the state level.[3] Of the rest of the state's population, a portion will be uninsured (and so will have no health insurance subject to any benefit mandate), and another portion will have health insurance subject to other state laws or only to federal laws.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state benefit mandates. The California Department of Managed Health Care (DMHC)[4] regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers,[5] which offer benefit coverage to their enrollees through health insurance policies.

Group and individual market DMHC-regulated plans and CDI-regulated policies are subject to AB 912. However, Medi-Cal Managed Care is not subject to AB 912. The regulator, DMHC, and the purchaser, the California Department of Health Care Services, have indicated that by referencing "group" plans, AB 912 would not require compliance from plans enrolling Medi-Cal beneficiaries into Medi-Cal Managed Care.[6,7] Therefore, the mandate would affect the health insurance of approximately 19.4 million enrollees (50% of all Californians).

Developing Estimates for 2014 and the Effects of the Affordable Care Act

The Affordable Care Act (ACA)[8] is expected to dramatically affect health insurance and its regulatory environment in California, with many changes becoming effective in 2014. It is important to note that CHBRP's analysis of proposed benefit mandate bills typically address the marginal effects of the proposed bills—specifically, how the proposed mandate would affect

[2] Available at: www.chbrp.org/docs/authorizing_statute.pdf.
[3] CHBRP's estimates are available at: www.chbrp.org/other_publications/index.php.
[4] The California Department of Managed Care (DMHC) was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code (H&SC) Section 1340.
[5] The California Department of Insurance (CDI) licenses "disability insurers." Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code (IC) Section 106(b) or subdivision (a) of Section 10198.6.
[6] Personal communication, S. Lowenstein, DMHC, March 2013.
[7] Personal communication, C. Robinson, Department of Health Care Services, citing Sec. 2791 of the federal Public Health Service Act, March 2013.
[8] The federal "Patient Protection and Affordable Care Act" (P.L.111-148) and the "Health Care and Education Reconciliation Act" (P.L 111-152) were enacted in March 2010. Together, these laws are referred to as the Affordable Care Act (ACA).

benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these marginal effects are presented in this report. Because expanded enrollment will not occur until January 2014, CHBRP relies on projections from the California Simulation of Insurance Markets (CalSIM) model[9] to help set baseline enrollment for 2014. From this projected baseline, CHBRP estimates the marginal impact of benefit mandates proposed that could be in effect after January 2014.

Bill-Specific Analysis of AB 912

AB 912 would require group and individual market DMHC-regulated plans and CDI-regulated policies to provide coverage for "medically necessary expenses for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause iatrogenic infertility to an enrollee."

Iatrogenic infertility is medically induced infertility caused by a medical intervention used to treat a primary disease or condition. The medical intervention resulting in iatrogenic infertility is often gonadotoxic or surgical treatment. Gonadotoxic treatment includes radiation, chemotherapy, and prescription drugs.

Patients at risk for iatrogenic infertility differ from patients being treated for infertility in that they need to take steps to preserve their fertility prior to undergoing treatment that may put them at risk for becoming infertile. Most cancer patients will not know beforehand if their treatment will lead to infertility or not, so they will need to undergo fertility preservation as a precaution. For example, a patient undergoing treatment for cancer may decide to freeze his sperm prior to starting treatment. Prior to treatment, his fertility may be intact, but if he does not take part in fertility-preserving services, his future ability to father a child may be at risk as treatment may result in iatrogenic infertility.

Analytic Approach and Key Assumptions

Iatrogenic infertility

Iatrogenic infertility is typically caused by cancer treatments, such as radiation and chemotherapy (gonadotoxic treatments) or surgical removal of reproductive organs. Less frequently, fertility is compromised by treatments for autoimmune disorders such as systemic lupus erythematosus, rheumatoid arthritis, or Crohn's disease.

This report focuses on fertility preservation among cancer patients because it is estimated that approximately 90% of iatrogenic infertility is caused by cancer treatment. In addition, there are no recommendations for fertility preservation for patients outside of cancer patients, and thus the research on fertility preservation has focused almost exclusively on this group.

[9] CalSIM was developed jointly and is operated by the University of California, Los Angeles, Center for Health Policy Research and the University of California, Berkeley, Center for Labor Research and Education. The model estimates the impact of provisions in the ACA on employer decisions to offer, and individual decisions to obtain, health insurance.

Coverage for fertility preservation services versus coverage for infertility treatment

Current California law requires group CDI-regulated policies and most group DMHC-regulated plans to *offer* coverage for infertility treatment.[10] An enrollee may have coverage for *infertility treatment* but may not have coverage for *fertility preservation services*, and vice versa.

AB 912 would not require coverage of infertility treatment nor would it affect current coverage rates for infertility treatment. Therefore, this report only looks at coverage for medically necessary fertility preservation services, as would be required under AB 912.

Interaction With Other California Requirements

As just discussed, current California law requires group CDI-regulated policies and most group DMHC-regulated plans to *offer* coverage for infertility treatment.[11,12]

Other existing California state benefit mandates require coverage for various aspects of the screening, diagnosis, and treatment of cancer. However, these existing state benefit mandates do not require coverage for fertility preservation services when iatrogenic infertility may result from cancer treatment.

In addition, DMHC-regulated plans are subject to the Knox-Keene Health Care Service Plan Act of 1975 that requires all health care service plans, except specialized health care service plans, to provide coverage for all medically necessary basic health care services.[13] Medically necessary basic health care services include:

- Physician services;
- Hospital inpatient services and ambulatory care services;
- Diagnostic laboratory and diagnostic and therapeutic radiologic services;
- Home health services;
- Preventive health services;
- Emergency health care services, including ambulance and ambulance transport services, out-of-area coverage, and ambulance transport services provided through the 911 emergency response system; and
- Hospice care.

[10] H&SC Section 1374.55 and IC Section 10119.6.
[11] H&SC Section 1374.55 and IC Section 10119.6.
[12] In 2013, CHBRP was asked to analyze Assembly Bill (AB) 460 (Ammiano) Health Care Coverage: Infertility. This report is available on CHBRP's website at: www.chbrp.org/completed_analyses/index.php.
[13] CHBRP has a resource, *Current Mandates: Health Insurance Benefit Mandates in California State Law*, which includes additional information on basic health care services, available here: www.chbrp.org/other_publications/index.php.

The basic health care services coverage requirement for DMHC-regulated plans interacts with the definition of essential health benefits in California, and thus AB 912, discussed in the "Interaction With the Affordable Care Act" section below.

Requirements in Other States

CHBRP was not able to identify other states with an existing state benefit mandate requiring coverage for fertility preservation services. In the past couple of years, a few states—Connecticut, Hawaii, and New Jersey—have introduced, but not enacted, fertility preservation benefit mandate bills.

Background on Fertility Preservation

- Fertility preservation services provide patients at risk of iatrogenic (medically-induced) infertility with the potential ability to conceive children following treatments that may damage reproductive tissue (e.g., surgery, radiation, chemotherapy, prescription drugs, etc.). In order to preserve reproductive capabilities, fertility preservation services would be decided upon prior to disease treatment.
- Cancer treatments contribute to approximately 90% of iatrogenic infertility cases.
- The definition of reproductive age for purposes of iatrogenic infertility due to cancer treatment is typically under 45 years old. (Some men over 45 years of age may choose to preserve their fertility, and so this may be an underestimate of Californian's affected by iatrogenic infertility.)
- In California, approximately 10% of the 145,000 new cancer cases diagnosed annually occur among cancer patients under the age of 45. A portion of these patients risk iatrogenic infertility as they undergo cancer treatment. The extent to which patients will become infertile after undergoing treatment varies by type of cancer and type of treatment. For example, rates of ovarian failure or 12-month infertility for women who underwent chemotherapy range between 23% and 36% depending on the type of cancer.
- Fertility preservation services fall into three general categories encompassing seven standard procedures: 1) c*ryopreservation* (freezing reproductive tissue) includes sperm cryopreservation, oocyte cryopreservation, and embryo cryopreservation; 2) *harm reduction* includes ovarian transposition (oophoropexy), ovarian shielding during radiation therapy, and testicular shielding during radiation therapy; and 3) *conservative surgery* (cancer therapy modified to preserve reproductive tissue) including the two most common procedures, trachelectomy (i.e., surgical removal of the cervix) and conservative surgery for ovarian cancer.

Medical Effectiveness

The medical effectiveness review focused on the major types of fertility preservation services available to male and female patients undergoing cancer treatments that could compromise their fertility. In the course of performing this review, medical services were categorized as either standard medical care or experimental. Descriptions of both types of fertility preservation

services are provided below, but conclusions regarding the overall effectiveness are only given for standard services.

Of the articles identified in this literature review, very few were randomized controlled trials or large cohort studies. Most were case series of 30 or fewer patients, which are considered to be of low quality in the *Medical Effectiveness* hierarchy of evidence.[14]

CHBRP Terminology for Grading Evidence of Medical Effectiveness

CHBRP uses the following terms to characterize the strength of the evidence it identifies regarding the medical effectiveness of a treatment for which a bill would mandate coverage:

- Clear and convincing evidence;
- Preponderance of evidence;
- Ambiguous/conflicting evidence; and
- Insufficient evidence.

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies included in the medical effectiveness review are consistent in their findings that treatment is either effective or not effective.

A grade of *ambiguous/conflicting evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient* evidence indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

Standard Fertility Preservation Services

- There is a preponderance of evidence that:
    - Sperm cryopreservation (the collection and freezing of sperm) with sperm collected through ejaculate is an effective method of fertility preservation. This is the standard fertility preservation service offered to males at risk for iatrogenic infertility.
    - Embryo cryopreservation (the harvesting of eggs followed by in vitro fertilization and freezing of resulting embryos for later implantation) is an effective method of fertility

[14] More information on the medical effectiveness approach and the hierarchy of evidence is available on CHBRP's website here: www.chbrp.org/analysis_methodology/medical_effectiveness_analysis.php.

preservation. Embryo cryopreservation is the standard fertility preservation service available for females at risk for iatrogenic infertility who have a male partner or who want to use donor sperm.

  - Oocyte (egg) cryopreservation (the collection and freezing of eggs) is an effective method of fertility preservation. This is the standard fertility preservation service offered to females at risk for iatrogenic infertility who do not have a male partner or who do not want to use donor sperm.
  - Trachelectomy (treatment for cervical cancer where the cervix is surgically removed while the uterus is preserved) and ovarian cancer surgery (where the uterus with one ovary can be preserved) are effective methods of conservative gynecologic surgeries (minimal removal of diseased organs to preserve fertility) for fertility preservation. The available evidence indicates that for specific patient populations, these surgeries do not lead to an increase in cancer recurrence or mortality.

- There is insufficient evidence to conclude that:
  - Ovarian transposition or oophoropexy (a surgical repositioning of ovaries to another location in the body away from the radiation field) is an effective method of fertility preservation. Despite this, it stands to reason that under specific circumstances, females undergoing pelvic radiation, where there is a high risk of ovarian failure, may want to consider ovarian transposition as a method of fertility preservation.
  - Testicular or ovarian shielding (shields placed over the testicles or ovaries during cancer treatment with radiation therapy) is an effective method of fertility preservation to reduce the dose of radiation delivered to these reproductive organs. Despite this, it stands to reason that patients undergoing pelvic radiation where there is a high risk of damage to the reproductive organs may want to consider shielding to protect their fertility.
  - A grade of *insufficient* evidence indicates that there is not enough evidence available to know whether or not a treatment is effective—it does not indicate that a treatment is not effective.

<u>Experimental Fertility Preservation Services</u>

The following fertility preservation services are considered experimental:

- Sperm cryopreservation using sperm collected through testicular aspiration or extraction, electroejaculation under sedation, or from a postmasturbation urine sample.
- Testicular tissue cryopreservation is the freezing of testicular tissue or germ cells, and reimplantation after treatment or maturation.
- Ovarian cryopreservation and transplantation is the freezing of ovarian tissue and reimplantation after cancer treatment.
- Ovarian suppression with hormonal therapies, known as gonadotropin-releasing hormone (GnRH) analogs, to protect ovarian or testicular tissue during radiation therapy has been established in animals but is still considered experimental in humans.

Benefit Coverage, Utilization, and Cost Impacts

CHBRP estimates that 19.4 million enrollees are in DMHC-regulated plans and CDI-regulated policies subject to AB 912. Medi-Cal Managed Care Plans are not subject to AB 912. **This section estimates coverage, utilization, and cost impacts for three standard medical services for fertility preservation—the cryopreservation of sperm, embryos, and oocytes (eggs).**[15] This section presents, first, the current (baseline) benefit coverage, utilization, and costs related to fertility preservation services for patients at risk for iatrogenic infertility due to cancer treatment, and then provides estimates of the impacts on coverage, utilization, and cost if AB 912 were to be enacted.

Table 1 summarizes the expected benefit coverage, cost, and utilization impacts for AB 912.

Benefit Coverage Impacts

- Approximately 1.6 million enrollees (8.3%) of the 19.4 million enrollees in DMHC-regulated plans and CDI-regulated policies subject to AB 912 currently have coverage for fertility preservation services. If enacted, AB 912 would increase this to 100% of these enrollees.
- Among California's publicly funded health insurance programs, only California Public Employees' Retirement System Health Maintenance Organizations (CalPERS HMOs) are subject to AB 912. CalPERS HMOs do not currently provide coverage for fertility preservation services, but would be required to if AB 912 were enacted.

Utilization and Per-Unit Cost Impacts

- CHBRP estimates that currently, in a 1-year period, 1,051 male enrollees use sperm cryopreservation, with 947 paying for the noncovered benefit directly, and 72 female enrollees use embryo or oocyte cryopreservation, with 56 paying for the noncovered benefit directly.
- If AB 912 is enacted, CHBRP estimates total 1-year postmandate utilization to equal 1,249 male enrollees and 198 female enrollees. This is primarily due to the reduction in enrollee out-of-pocket costs for benefits that were previously not covered. This represents a 19% increase among male enrollees (or 198 males) and a 175% increase among female enrollees (or 126 females).
- In total, postmandate, CHBRP estimates a 29% increase in the use of fertility preservation services, as measured by the number of new users.
- The average per-unit cost for sperm, embryo, and oocyte cryopreservation is not expected to change as a result of this mandate. For analytic purposes, CHBRP estimates costs for 1 year. The average first-year per-unit cost for sperm cryopreservation is estimated to be

[15] Radiation shielding and conservative gynecologic surgery are considered standard practices. However, for radiation shielding, its use and costs are folded into the normal radiation therapy that occurs as part of cancer treatments, and for conservative gynecologic surgery, it is likely to be covered under a cancer surgery benefit and not fertility preservation coverage, so CHBRP did not estimate coverage, utilization, and cost impacts for these procedures, nor for experimental procedures**.**

$400. The average first-year per-unit cost for embryo and oocyte cryopreservation is estimated to be $14,700 and $11,200, respectively.

- The first-year per-unit costs do not include the long-term costs, e.g., the annual storage costs beyond the first year, but it is highly likely that the sperm, embryos, and oocytes would be stored for longer than this time period. The annual storage costs beyond 2014 are estimated to be $100 for sperm and $300 for embryos and oocytes. The literature on the average storage duration is limited, however a study reported the average storage duration was 3.1 years among 32 male patients (20% of the total study subjects) who discontinued sperm storage.

Cost Impacts

- Increases in per member per month (PMPM) premiums for the newly mandated benefit coverage vary slightly by market segment. Increases as measured by percentage changes in PMPM premiums are estimated to range from an average of 0.0017% (for CDI-regulated small-group policies) to an average of 0.0031% (for CDI-regulated individual policies) in the affected market segments. Increases as measured by PMPM premiums are estimated to be an average of $0.01.
- In the privately funded large-group market, the premium increases are estimated to be an average of $0.01 PMPM among both DMHC-regulated plans and CDI-regulated policies.
- For enrollees in privately funded small-group insurance policies, premiums are estimated to increase by an average of $0.01 PMPM for both DMHC-regulated plans and CDI-regulated policies.
- In the privately funded individual market, the premiums are estimated to increase by an average of $0.01 PMPM for both DMHC-regulated plans and CDI-regulated polices.
- Among publicly funded DMHC-regulated CalPERS HMOs, CHBRP estimates that premiums would increase slightly with the impact of an average of 0.0030% ($0.01 PMPM).
- Total net health expenditures are projected to increase by $2.1 million (0.0015%) (Table 1). This change in expenditures is due to a $2.9 million increase in health insurance premiums plus a 0.3 million increase in enrollee out-of-pocket expenses for newly covered benefits, partially offset by a reduction in out-of-pocket expenses for noncovered benefits ($1.1 million).

Public Health Impacts

- Loss of fertility can negatively impact the quality of life for patients of reproductive age who are treated for cancer. As a result of AB 912, it is expected that the quality of life could improve for some of the 7,650 patients at risk for iatrogenic infertility each year who would gain coverage for fertility preservation services (4,306 males and 3,344 females, see Table 1).

- AB 912 is estimated to reduce the *net* financial burden by almost $750,000 across enrollees who would have paid for previously uncovered fertility preservation services to prevent iatrogenic infertility.
- Based on the evidence reviewed on the medical effectiveness and utilization of these procedures, annual long-term benefits could include an estimated five additional male and four additional female cancer patients having a biological child each year as a result of AB 912. Birth outcomes appear to be similar to those from spontaneous conception and fresh embryo transfer.
- With 8.3% of enrollees currently covered for fertility preservation services, nearly all enrollees using fertility preservation services are directly paying for these treatments. Female enrollees are paying an estimated $14,700 for embryo cryopreservation and $11,200 for oocyte cryopreservation, and male enrollees are paying an estimated $400 for sperm cryopreservation. AB 912 is expected to decrease the disparity in the financial burden of expenses related to fertility preservation services borne by females. CHBRP estimates that females would still be likely to face a greater out-of-pocket expense burden than males postmandate.
- Limited evidence was found on potential disparities in the use of fertility preservation services by race/ethnicity. Therefore, the extent to which AB 912 would have an impact on disparities is unknown.
- Iatrogenic infertility and fertility preservation services do not impact premature mortality, therefore, AB 912 would not be expected to result in a reduction in premature death or economic loss.
- Although time off from work is required for some fertility preservation services, the impact of AB 912 on economic loss related to fertility preservation services is unknown due to lack of data.

Interaction With the Federal Affordable Care Act

Below is an analysis of how this proposed benefit mandate may interact with the ACA's requirement for certain health insurance to cover "essential health benefits" (EHBs).[16]

AB 912 and essential health benefits

For a state benefit mandate to exceed the definition of EHBs in California, triggering the requirement that the state defray the costs for the benefit mandate, the following must be true:

- The state benefit mandate is not covered in the Kaiser Small Group HMO 30 plan that defines the EHB benchmark package in California in 2014 and 2015;

[16] Resources on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.

- The state benefit mandate is not covered under basic health care services, as required by the Knox-Keene Health Care Service Plan Act of 1975 (see the "Interaction With Other California Requirements" section above); and
- The state benefit mandate meets the definition of a benefit mandate that could exceed EHBs as established by federal regulations on EHBs, which states it must be specific to care, treatment, and/or services.[17]

Coverage in the Kaiser Small Group HMO 30 plan. Coverage for medically necessary fertility preservation services are not a covered benefit in the Kaiser Small Group HMO 30 plan, and thus are not included in the EHB benchmark benefit package.

Basic health care services. The Kaiser Small Group HMO 30 plan is a DMHC-regulated plan and, as such, is subject to the Knox-Keene Health Care Service Plan Act of 1975 that requires coverage of medically necessary basic health care services. Therefore, medically necessary basic health care services are a part of the EHB coverage requirement in California.[18] However, fertility preservation services are not seen as medically necessary and so are not required coverage under basic health care services.

Federal definition of state benefit mandates that exceed EHBs. State benefit mandates that are specific to care, treatment, and services meet the federal definition of a state benefit mandate that can exceed EHBs.[19] Fertility preservation services would fall within this definition, and so could exceed EHBs.

For the reasons outlined above—fertility preservations services: 1) are not included in the Kaiser Small Group HMO 30 plan; 2) are not part of required coverage under basic health care services; and 3) do meet the federally definition of a state benefit mandate that can exceed EHBs in 2014 and 2015—AB 912 would require coverage for a new state benefit mandate that appears to exceed the definition of EHBs in California, triggering the requirement that the state defray the costs of coverage for enrollees in qualified health plans (QHPs) in Covered California, the state's health benefits exchange.

Cost of exceeding EHBs. The state is required to defray the additional cost incurred by enrollees in QHPs[20] for any state benefit mandate that exceeds EHBs. As stated above, final rules released by HHS clarify that QHP issuers are responsible for calculating the marginal cost that must be defrayed. However, this rule left state flexibility in how this would be calculated; it could be

[17] Department of Health and Human Services. Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. *Federal Register*, Vol. 78, No. 37. February 25, 2013; 12843. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.
[18] Currently, no CDI-regulated policies are required to cover basic health care services. However, in 2014 CDI-regulated policies subject to the EHB coverage requirement—nongrandfathered small-group and individual market policies—will be required to cover basic health care services.
[19] Essential Health Benefits. Final Rule. 12843.
[20] In California, QHPs are non-grandfathered small-group and individual market DMHC-regulated plans and CDI-regulated policies sold in Covered California, the state's exchange.

based on "either a statewide average or each issuer's actual cost."[21] California has not yet identified which option it will use.

CHBRP is not able to estimate the total number of enrollees in QHPs in 2014, but is able to estimate the marginal change in the PMPM premium that would result from requiring coverage for fertility preservation services in 2014. These estimates reflect a statewide average and not an issuer's actual cost. The marginal change in the PMPM premium that CHBRP estimates would result from AB 912 and that the state would be responsible for defraying for each enrollee in a QHP in Covered California is:

- $0.01 in nongrandfathered small-group and individual market DMHC-regulated plans; and
- $0.01 in nongrandfathered small-group and individual market CDI-regulated policies.

This report presents an evidence-based analysis to provide decision-makers with a more comprehensive understanding of the impacts of AB 912—not only potential costs, such as the cost to defray, but also reviews of the medical effectiveness evidence and estimates of the mandate's public health impacts for Californians.

[21] Essential Health Benefits. Final Rule. 12843.

Table 1. AB 912 Impacts on Benefit Coverage, Utilization, and Cost, 2014

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	25,899,000	25,899,000	0%	0%
Total enrollees with health insurance subject to AB 912	19,382,000	19,382,000	0%	0%
Number of enrollees with coverage for reproductive material cryopreservation	1,617,593	19,382,000	17,764,407	1,098%
Percentage of enrollees with coverage for reproductive material cryopreservation	8.3%	100%	92%	1,098%
Utilization and Cost				
Number of enrollees who are subject to AB 912 and diagnosed with cancer where treatment might result in iatrogenic infertility during child-bearing ages				
Male	4,306	4,306	—	0%
Female	3,344	3,344	—	0%
Number of enrollees using services covered by insurance—reproductive material cryopreservation				
Sperm	104	1,249	1,145	1,101%
Embryo (with Rx)	8	99	91	1,138%
Oocyte (with Rx)	8	99	91	1,138%
Subtotal	120	1,447	1,327	1,106%
Number of enrollees using services not covered by insurance—reproductive material cryopreservation				
Sperm	947	—	−947	−100%
Embryo (with Rx)	28	—	−28	−100%
Oocyte (with Rx)	28	—	−28	−100%
Subtotal	1,003	—	−1,003	−100%
Number of enrollees using services (combining the covered and not covered categories)—reproductive material cryopreservation				
Sperm	1,051	1,249	198	19%
Embryo (with Rx)	36	99	63	175%
Oocyte (with Rx)	36	99	63	175%
Total	**1,123**	**1,447**	**324**	**29%**
Average cost per procedure—reproductive material cryopreservation				
Sperm	$400	$400	—	0%
Embryo (with Rx)	$14,700	$14,700	—	0%
Oocyte (with Rx)	$11,200	$11,200	—	0%

Table 1. AB 912 Impacts on Benefit Coverage, Utilization, and Cost, 2014 (Cont'd)

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Expenditures				
Premium expenditures by private employers for group insurance	$78,385,161,000	$78,387,027,000	$1,866,000	0.0024%
Premium expenditures for individually purchased insurance	$13,639,719,000	$13,640,097,000	$378,000	0.0028%
Premium expenditures by persons with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (b)	$21,272,946,000	$21,273,451,000	$505,000	0.0024%
CalPERS HMO employer expenditures (c)	$4,016,233,000	$4,016,352,000	$119,000	0.0030%
Medi-Cal Managed Care Plan expenditures (exempt from AB 912)	$12,480,492,000	$12,480,492,000	$0	0.0000%
Healthy Families Plan expenditures (exempt from AB 912) (d)	$667,300,000	$667,300,000	$0	0.0000%
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	$14,462,198,000	$14,462,552,000	$354,000	0.0024%
Enrollee expenses for noncovered benefits (e)	$1,105,000	$0	−$1,105,000	−100%
Total expenditures	$144,925,154,000	$144,927,271,000	$2,117,000	0.0015%

Source: California Health Benefits Review Program, 2013.

Notes: (a) This population includes persons with privately funded and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans) health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance.

(b) Premium expenditures by enrollees include employee contributions to employer-sponsored health insurance, health insurance purchased through Covered California, and enrollee contributions for Medi-Cal Managed Care.

(c) Of the increase in CalPERS employer expenditures, about 58%, or $69,000, would be state expenditures for CalPERS members who are state employees or their dependents.

(d) Children in Healthy Families, California's CHIP, will be moved into Medi-Cal Managed Care by January 1, 2014, as part of the 2012–2013 budget.

(e) Includes only those expenses that are paid directly by enrollees to providers for services related to the mandated benefit that are not currently covered by insurance. In addition, this only includes those fertility preservation service expenses that will be newly covered, post-mandate. Other components of expenditures in this table include all health care services covered by insurance such as "Premium expenditures by private employers for group insurance" and "CalPERS HMO employer expenditures."

Key: AB=Assembly Bill; CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; Rx=prescription.

INTRODUCTION

The California Assembly Committee on Health requested on February 25, 2013, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 912, fertility preservation. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.[22]

In 2014, CHBRP estimates that approximately 25.9 million Californians (67%) will have health insurance that may be subject to a health benefit mandate law passed at the state level.[23] Of the rest of the state's population, a portion will be uninsured (and so will have no health insurance subject to any benefit mandate), and another portion will have health insurance subject to other state laws or only to federal laws.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state benefit mandates. The California Department of Managed Health Care (DMHC)[24] regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers,[25] which offer benefit coverage to their enrollees through health insurance policies.

Group and individual market DMHC-regulated plans and CDI-regulated policies are subject to AB 912. However, Medi-Cal Manage Care is not subject to AB 912. The regulator, DMHC, and the purchaser, the California Department of Health Care Services, have indicated that by referencing "group" plans, AB 912 would not require compliance from plans enrolling Medi-Cal beneficiaries into Medi-Cal Managed Care.[26,27] Therefore, the mandate would affect the health insurance of approximately 19.4 million enrollees (50% of all Californians).

Developing Estimates for 2014 and the Effects of the Affordable Care Act

The Affordable Care Act (ACA)[28] is expected to dramatically affect health insurance and its regulatory environment in California, with many changes becoming effective in 2014. Beginning in 2014, an expansion of the Medicaid program to cover people up to 133% of the federal poverty level (FPL)[29] and the availability of subsidized and nonsubsidized health insurance

[22] Available at: www.chbrp.org/docs/authorizing_statute.pdf.
[23] CHBRP's estimates are available at: www.chbrp.org/other_publications/index.php.
[24] The California Department of Managed Care (DMHC) was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code (H&SC) Section 1340.
[25] The California Department of Insurance (CDI) licenses "disability insurers." Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code (IC) Section 106(b) or subdivision (a) of Section 10198.6.
[26] Personal communication, S. Lowenstein, DMHC, March 2013.
[27] Personal communication, C. Robinson, Department of Health Care Services, citing Sec. 2791 of the federal Public Health Service Act, March 2013.
[28] The federal "Patient Protection and Affordable Care Act" (P.L.111-148) and the "Health Care and Education Reconciliation Act" (P.L 111-152) were enacted in March 2010. Together, these laws are referred to as the Affordable Care Act (ACA).
[29] The Medicaid expansion, which California will pursue, is to 133% of the federal poverty level (FPL)—138% with a 5% income disregard.

coverage purchased through newly established state health insurance exchanges are expected to significantly increase the number of people with health insurance in the United States.

State exchanges will sell health insurance in the small-group and individual markets[30] through qualified health plans (QHPs), which will be certified by and sold in a state's exchange. QHPs sold through California's state exchange, Covered California,[31] will be DMHC-regulated plans or CDI-regulated policies, and as such will be subject to California state benefit mandates.

It is important to note that CHBRP's analysis of proposed benefit mandate bills typically address the marginal effects of the proposed bills—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these marginal effects are presented in this report. Because expanded enrollment will not occur until January 2014, CHBRP relies on projections from the California Simulation of Insurance Markets (CalSIM) model[32] to help set baseline enrollment for 2014. From this projected baseline, CHBRP estimates the marginal impact of proposed benefit mandates that could be in effect after January 2014. CHBRP's methods for estimating baseline 2014 enrollment from CalSIM projections are provided in further detail in Appendix D.

Bill-Specific Analysis of AB 912

Bill Language

The full text of AB 912 can be found in Appendix A.

AB 912 would require group and individual market DMHC-regulated plans and CDI-regulated policies to provide coverage for "medically necessary expenses for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause iatrogenic infertility to an enrollee."

Infertility, as defined in the Health and Safety Code (H&SC) and Insurance Code (IC), means "(1) the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility, or (2) the inability to conceive a pregnancy or to carry a pregnancy to a live birth after a year or more of regular sexual relations without contraception."[33] Iatrogenic infertility is medically induced infertility caused by a medical intervention used to treat a primary disease or condition. The medical intervention resulting in iatrogenic infertility is often gonadotoxic or surgical treatment. Gonadotoxic treatment includes radiation, chemotherapy, and prescription drugs.

---

[30] Effective 2017, states may allow large group purchasing through the exchange, which may make some large-group plans and policies subject to EHB requirements [ACA Section 1312(f)(2)(B)].
[31] The California Health Benefits Exchange Authorizing Statute is available here: www.healthexchange.ca.gov/Documents/California%20Codes%20Governing%20the%20Health%20Benefit%20Exchange.pdf.
[32] CalSIM was developed jointly and is operated by the University of California, Los Angeles, Center for Health Policy Research and the University of California, Berkeley, Center for Labor Research. The model estimates the impact of provisions in the ACA on employer decisions to offer, and individual decisions to obtain, health insurance.
[33] H&SC Section 1374.55 and IC Section 10119.6.

Patients at risk for iatrogenic infertility differ from patients being treated for infertility in that they need to take steps to preserve their fertility prior to undergoing treatment that may put them at risk for becoming infertile (see Table 2 below). Most cancer patients will not know beforehand whether their treatment will lead to infertility, so they will need to undergo fertility preservation as a precaution. For example, a patient undergoing treatment for cancer may decide to freeze his sperm prior to starting treatment. Prior to treatment, his fertility may be intact, but if he does not take part in fertility preserving services, his future ability to father a child may be at risk as treatment may result in iatrogenic infertility.

Analytic Approach and Key Assumptions

Iatrogenic infertility

Iatrogenic infertility is typically caused by cancer treatments, such as radiation and chemotherapy—gonadotoxic treatments—or surgical removal of reproductive organs. Less frequently, fertility is compromised by treatments for autoimmune disorders such as systemic lupus erythematosus, rheumatoid arthritis, or Crohn's disease. This report focuses on fertility preservation among cancer patients because it is estimated that approximately 90% of iatrogenic infertility is caused by cancer treatment (Lawrenz et al., 2011). In addition, there are no recommendations for fertility preservation for patients outside of cancer patients (Henes et al., 2012), and thus the research on fertility preservation has focused almost exclusively on this group.

This report does not examine other causes of infertility such as underlying medical conditions, genetic defects, or general health status and lifestyle because those causes are not considered "iatrogenic."

Coverage for fertility preservation services versus coverage for infertility treatment

Current California law requires group CDI-regulated policies and most group DMHC-regulated plans to *offer* coverage for infertility treatment.[34] Under this state benefit mandate, treatment for infertility includes, but is not limited to: diagnosis; diagnostic tests; medication; surgery; and gamete intrafallopian transfers (GIFT). Offering coverage for in vitro fertilization is not required.

An enrollee may have coverage for *infertility treatment* but may not have coverage for *fertility preservation services*, and vice versa. AB 912 would not require coverage of infertility treatment nor would it affect current coverage rates for infertility treatment. Therefore, this report only looks at coverage for medically necessary fertility preservation services, as would be required under AB 912 (see Table 2 below).

[34] H&SC Section 1374.55 and IC Section 10119.6.

Table 2. Definitions of Infertility, Infertility Treatment, Iatrogenic Infertility, and Fertility Preservation and AB 912

	Definition	Would be Covered Under AB 912?
Infertility	(1) The presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility, or (2) The inability to conceive a pregnancy or to carry a pregnancy to a live birth after a year or more of regular sexual relations without contraception.*	No
Infertility treatment	Treatment provided to diagnosis infertility or after a diagnosis of infertility to assist in conception, such as artificial insemination.	
Iatrogenic infertility	Medically-induced infertility caused by a medical intervention used to treat a primary disease or condition, most often cancer.	Yes
Fertility preservation	Services provided to preserve fertility prior to undergoing medical treatments that may cause iatrogenic infertility, such as the freezing of sperm.	

Source: California Health Benefits Review Program, 2013.
Notes: * H&SC Section 1374.55 and IC Section 10119.6.
Key: AB=Assembly Bill.

Interaction With Other California Requirements

As just discussed, current California law requires group CDI-regulated policies and most group DMHC-regulated plans to *offer* coverage for infertility treatment.[35,36,37]

Other existing California state benefit mandates require coverage for various aspects of the screening, diagnosis, and treatment of cancer. However, these existing state benefit mandates do not require coverage for fertility preservation services when iatrogenic infertility may result from cancer treatment.

In addition, DMHC-regulated plans are subject to the Knox-Keene Health Care Service Plan Act of 1975 that requires all health care service plans, except specialized health care service plans, to provide coverage for all medically necessary basic health care services.[38] Medically necessary basic health care services include:

- Physician services;
- Hospital inpatient services and ambulatory care services;
- Diagnostic laboratory and diagnostic and therapeutic radiologic services;
- Home health services;

[35] H&SC Section 1374.55 and IC Section 10119.6.
[36] The current infertility treatment benefit mandate is a "mandate to *offer*," meaning that DMHC-regulated plans and CDI-regulated policies subject to this state benefit mandate are not required to cover infertility treatments, but are required to *offer* group purchasers the option of buying coverage for infertility treatment.
[37] In 2013, CHBRP was asked to analyze Assembly Bill (AB) 460 (Ammiano) Health Care Coverage: Infertility. This report is available on CHBRP's website at: www.chbrp.org/completed_analyses/index.php.
[38] CHBRP has a resource, *Current Mandates: Health Insurance Benefit Mandates in California State Law*, which includes additional information on basic health care services, available here: www.chbrp.org/other_publications/index.php.

- Preventive health services;
- Emergency health care services, including ambulance and ambulance transport services, out-of-area coverage, and ambulance transport services provided through the 911 emergency response system; and
- Hospice care.

The basic health care services coverage requirement for DMHC-regulated plans interacts with the definition of essential health benefits in California, and thus AB 912, as discussed in the "Interaction With the Affordable Care Act" section below.

Requirements in Other States

CHBRP was not able to identify other states with an existing state benefit mandate requiring coverage for fertility preservation services. In the past couple of years, a few states—Connecticut, Hawaii, and New Jersey—have introduced but not enacted fertility preservation benefit mandate bills.

Interaction With the Affordable Care Act

A number of ACA provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how this proposed benefit mandate may interact with requirements in the ACA, including the requirement for certain health insurance to cover "essential health benefits" (EHBs).[39]

Essential Health Benefits

Effective 2014, the ACA requires nongrandfathered small-group and individual market health insurance—including but not limited to QHPs that will be sold in Covered California—to cover 10 specified categories of EHBs.[40] The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options.[41] California has selected the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan as its benchmark plan.[42]

[39] Resources on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.

[40] The 10 specified categories of essential health benefits (EHBs) are: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. [ACA Section 1302(b)].

[41] CCIIO, Essential Health Benefits Bulletin. Available at: http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf. Accessed December 16, 2011.

[42] H&SC Section 1367.005; IC Section 10112.27.

The ACA allows a state to "require that a qualified health plan offered in [an exchange] offer benefits in addition to the essential health benefits."[43] If the state does so, the state must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the QHP. However, as laid out in the Final Rule on EHBs HHS released in February 2013,[44] state benefit mandates enacted on or before December 31, 2011, would be included in the a state's EHBs for 2014 and 2015 and there would be no requirement that the state defray the costs of those state mandated benefits.

For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost. State benefit mandates that could exceed EHBs would "be specific to the care, treatment, and services that a state requires issuers to offer to its enrollees," whereas "state rules related to provider types, cost-sharing, or reimbursement methods" would not meet the definition of state benefit mandates that could exceed EHBs. A state's exchange would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.[45]

AB 912 and essential health benefits

For a state benefit mandate to exceed the definition of EHBs in California, triggering the requirement that the state defray the costs, the following must be true:

- The state benefit mandate is not covered in the Kaiser Small Group HMO 30 plan that defines the EHB benchmark package in California in 2014 and 2015;
- The state benefit mandate is not covered under basic health care services, as required by the Knox-Keene Health Care Service Plan Act of 1975; and
- The state benefit mandate meets the definition of a benefit mandate that could exceed EHBs as established by federal regulations on EHBs (e.g., it is specific to care, treatment, and/or services).[46]

Coverage in the Kaiser Small Group HMO 30 plan. Coverage for medically necessary fertility preservation services are not a covered benefit in the Kaiser Small Group HMO 30 plan, and thus are not included in the EHB benchmark benefit package.

Basic health care services. The Kaiser Small Group HMO 30 plan is a DMHC-regulated plan and, as such, is subject to the Knox-Keene Health Care Service Plan Act of 1975 that requires coverage of medically necessary basic health care services. Therefore, medically necessary basic health care services are a part of the EHB coverage requirement in California.[47] However,

[43] ACA Section 1311(d)(3).
[44] Department of Health and Human Services. Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. *Federal Register*, Vol. 78, No. 37. February 25, 2013; 12843. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.
[45] Essential Health Benefits. Final Rule. 12843.
[46] Essential Health Benefits. Final Rule. 12843.
[47] Currently, no CDI-regulated policies are required to cover basic health care services. However, in 2014 CDI-regulated policies subject to the EHB coverage requirement—nongrandfathered small-group and individual market policies—will be required to cover basic health care services.

fertility preservation services are not seen as medically necessary and so are not required coverage under basic health care services.

Federal definition of state benefit mandates that exceed EHBs. State benefit mandates that are specific to care, treatment, and services meet the federal definition of a state benefit mandate that can exceed EHBs.[48] Fertility preservation services would fall within this definition, and so could exceed EHBs.

For the reasons outlined above—fertility preservations services, 1) are not included in the Kaiser Small Group HMO 30 plan, 2) are not part of required coverage under basic health care services, and 3) do meet the federally definition of a state benefit mandate that can exceed EHBs in 2014 and 2015—AB 912 would require coverage for a new state benefit mandate that appears to exceed the definition of EHBs in California, triggering the requirement that the state defray the costs of coverage for enrollees in QHPs in Covered California.

Cost of exceeding EHBs. The state is required to defray the additional cost incurred by enrollees in QHPs[49] for any state benefit mandate that exceeds EHBs. The *Benefit Coverage, Utilization, and Cost Impacts* section of this report discusses the impact of AB 912 on the per member per month (PMPM) premiums in 2014 in the small-group and individual markets, which are the market segments affected by the EHB coverage requirement and for which the state would have to defray costs for enrollees in QHPs.

This report presents an evidence-based analysis to provide decision-makers with a more comprehensive understanding of the impacts of AB 912—not only potential costs, such as the cost to defray, but also reviews of the medical effectiveness evidence and estimates of the mandate's public health impacts for Californians.

[48] Essential Health Benefits. Final Rule. 12843.

[49] In California, QHPs are non-grandfathered small-group and individual market DMHC-regulated plans and CDI-regulated policies sold in Covered California, the state's exchange.

BACKGROUND ON FERTILITY PRESERVATION

Medical interventions for diseases, such as cancer or lupus, may require the use of treatments that could damage reproductive tissue and result in infertility. Fertility preservation services provide patients at risk of iatrogenic (medically induced) infertility with the ability to conceive children following treatments that may damage reproductive tissue (e.g., radiation, chemotherapy, prescription drugs, surgery, etc.). Cancer treatments contribute to the majority of iatrogenic infertility cases (Lawrenz et al., 2011). In order to preserve reproductive capabilities, fertility preservation services would be decided upon prior to disease treatment (see "Fertility Preservation Services" below for further explanation).

Incidence of Iatrogenic Infertility

Because estimates of the incidence of all-cause iatrogenic infertility do not exist, most literature relies on rates of cancer among men and women of reproductive age as a proxy. The definition of reproductive age for purposes of iatrogenic infertility due to cancer treatment is typically under 45 years old, including children 0–15 years old whose cancer treatment could impact their future fertility (Reinecke et al., 2012). In California, approximately 10% of the 145,000 new cancer cases diagnosed annually occur among cancer patients under the age of 45 (ACS, 2012; CDPH Cancer Surveillance Section, 2011). This translates into more than 14,000 cancer cases diagnosed each year in California among patients of reproductive age. Some men over 45 years of age may choose to preserve their fertility, and so this may be an underestimate of Californian's affected by iatrogenic infertility.

The extent to which patients will become infertile after undergoing treatment varies by type of cancer and type of treatment (Quinn et al., 2011). For example, rates of ovarian failure or 12-month infertility for women who underwent chemotherapy range between 23% and 36% depending on the type of cancer (Letourneau et al., 2012b). Using probabilities of developing cancer by age[50] and gender for the top 10 cancers most likely to lead to infertility (see Appendix D), and adjusting for the population subject to AB 912, CHBRP estimated that 7,650 cancer patients enrolled in health plans subject to AB 912 (4,306 males and 3,344 females, see Table 1) would be at risk for infertility due to cancer treatments each year.

Although the incidence of various cancers is known to disproportionately affect certain minority groups, CHBRP found no evidence that evaluated the extent to which iatrogenic infertility varied by race/ethnicity. Racial and ethnic disparities are discussed in the *Public Health* section.

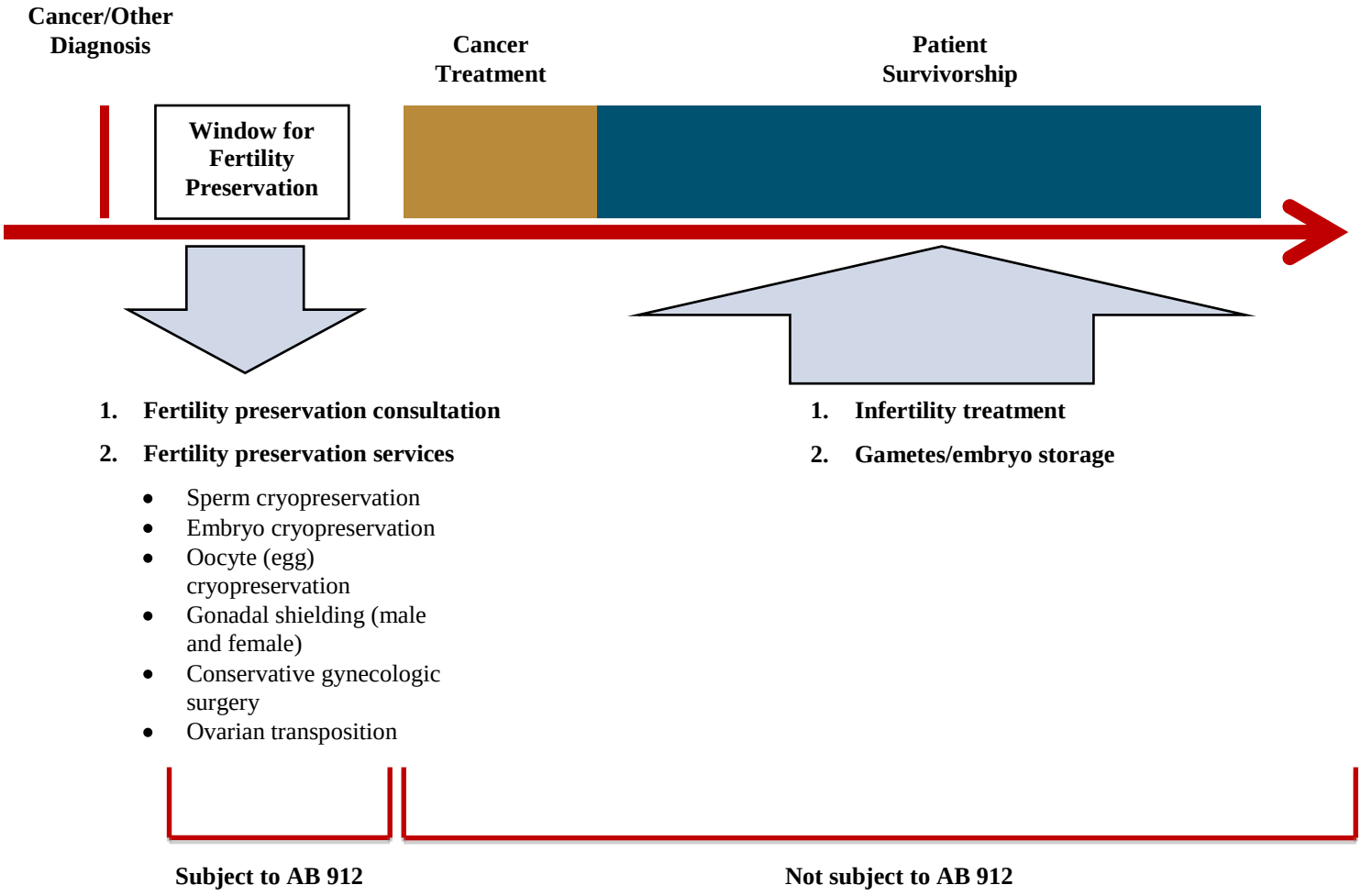
Fertility Preservation Services

The selection of an appropriate fertility preservation service for patients at risk for iatrogenic infertility varies by the age and gender of the patient, the patient's marital status, cultural and religious beliefs, and the type of cancer treatment the patient is undergoing.

[50] Based on content expert input, this analysis is restricted to those of reproductive age, which is defined as ages 13 to 43 years for females and ages 12 to 49 years for males.

Figure 1 shows the continuum of fertility care for cancer patients. Before cancer treatment, patients may choose to preserve their fertility in three main ways (described in Figure 1 and the text below). At some point after cancer treatment, cancer survivors may choose to have a child and retrieve cryopreserved reproductive material to use for artificial insemination or in vitro fertilization; the literature documents 1 to 10 years later (Hallack et al., 1998; Mandelbaum et al., 1998; Oktay and Oktem, 2010). AB 912 impacts the first stage of fertility care: fertility preservation services.

Figure 1. Continuum of Fertility Care for Patients Facing Cancer Treatments



Source: California Health Benefits Review Program, 2013, based on information via personal communication with Dr. Irene Su.

There are three general categories encompassing seven standard[51] fertility preservation services:

- Cryopreservation (freezing reproductive tissue):
  - **Sperm cryopreservation:** Collection and freezing of sperm from ejaculate;
  - **Oocyte cryopreservation:** Harvesting and freezing unfertilized eggs; and
  - **Embryo cryopreservation:** Harvesting eggs followed by in vitro fertilization and freezing resulting embryos for later implantation.
- Harm reduction (gonadal shielding, gonadal suppression, or ovary transposition):
  - **Ovarian transposition (oophoropexy):** Surgical repositioning of ovaries away from the radiation field;
  - **Ovarian shielding during radiation therapy:** Using shielding to reduce the dose of radiation delivered to the ovaries during cancer treatment; and
  - **Testicular shielding during radiation therapy:** Using shielding to reduce the dose of radiation delivered to the testicles during cancer treatment.
- Conservative surgery (cancer therapy modified to preserve reproductive tissue):
  - **Conservative gynecologic surgery:** The two most common procedures are trachelectomy and conservative surgery for ovarian cancer.
    - *Trachelectomy*: The standard treatment for some types of cervical cancer can include a hysterectomy (removal of the uterus). The trachelectomy procedure surgically removes the cervix while preserving the uterus.
    - *Conservative ovarian cancer surgery*: The standard treatment for ovarian cancer is the removal of the uterus (hysterectomy) and removal of both ovaries. The conservative treatment preserves the uterus and one ovary, in cases where cancer was confined to just one ovary.

[51] Testicular tissue cryopreservation, ovarian cryopreservation and transplantation, ovarian suppression with GnRH analogs or antagonist are considered experimental procedures and are not included here.

MEDICAL EFFECTIVENESS

As indicated in the *Introduction*, Assembly Bill (AB) 912 would mandate coverage of "medically necessary expenses for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause iatrogenic infertility." Iatrogenic infertility is typically caused by cancer treatments such as radiation and chemotherapy (gonadotoxic treatments) or surgical removal of reproductive organs. Less frequently, fertility is compromised by treatments for autoimmune disorders such as systemic lupus erythematosus, rheumatoid arthritis, or Crohn's disease. It is estimated that approximately 90% of iatrogenic infertility is caused by cancer treatment (Lawrenz et al., 2011). In addition, there are no recommendations for fertility preservation for patients outside of cancer patients (Henes et al., 2012). Therefore, this review focused on fertility preservation services used in conjunction with cancer treatment. This review is similar to a previously issued California Health Benefits Review Program (CHBRP) report analyzing identical language, and therefore updates the prior literature review with articles published from February 2011 through March 2013 (CHBRP, 2011).

This review summarizes findings from the literature on the effectiveness of 12 specific fertility preservation services. Seven of these services are considered standard of care (embryo cryopreservation, oocyte [egg] cryopreservation [freezing], ovarian transposition, ovarian shielding during radiation therapy, conservative surgical approaches for gynecologic cancers, sperm cryopreservation, and testicular shielding during radiation therapy), and the focus of the *Medical Effectiveness* section is on these procedures. The other five services (ovarian tissue cryopreservation and transplantation, ovarian suppression with hormones during radiation, sperm cryopreservation with alternative methods of collection, testicular tissue cryopreservation, and the use of hormones to protect the testicles during radiation therapy) are considered experimental and are described, but no conclusion as to their overall effectiveness is presented because experimental services have not been, by definition, the subject of rigorous evaluation for effectiveness. Of note, the status of oocyte cryopreservation was changed from experimental to standard since the publication of the 2011 CHBRP report (ASRM, 2013).

Research Approach and Methods

Studies of the effects of fertility preservation services for patients at risk for iatrogenic infertility were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, and Business Source Complete. Websites maintained by the following organizations were also searched: Agency for Healthcare Research and Quality; American Cancer Society; American College of Obstetricians and Gynecologists; Fertile Hope Program; Institute for Clinical Systems Improvement; International Network of Agencies for Health Technology Assessment; National Comprehensive Cancer Network, Inc.; National Guideline Clearinghouse; National Institute for Clinical Excellence; National Institutes of Health; National Health Service Centre for Reviews and Dissemination; Oncofertility Consortium; Scottish Intercollegiate Guideline Network; and World Health Organization.

The search was limited to abstracts of studies published in English. The search was also limited to studies published from 2011 to present because CHBRP had previously conducted thorough literature searches on these topics in 2011 for its analysis of AB 428. Of the 913 articles found in

the literature review, 511 were reviewed for potential inclusion in this report, and a total of 18 studies were added to the medical effectiveness review for AB 912. The other articles were eliminated because they did not focus on cancer patients, were of poor quality, or were otherwise not applicable. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B: Literature Review Methods. Findings from the literature review are summarized in Tables 3 and 4, which appear later on in the *Medical Effectiveness* section. Appendix C includes a table describing the studies that CHBRP reviewed (Table C-1) and a table summarizing evidence of effectiveness (Table C-2).

Methodological Considerations

Many of the studies included in the meta-analyses and systematic reviews that CHBRP assessed are of low quality. CHBRP classifies research by levels I–V. Level I research includes well-implemented randomized controlled trials (RCTs) and cluster RCTs. Level II research includes RCTs and cluster RCTs with major weaknesses. Level III research consists of nonrandomized studies that include an intervention group and one or more comparison groups, time series analyses, and cross-sectional surveys. Level IV research consists of case series and case reports. Level V represents clinical/practical guidelines based on consensus or opinion. Level I and II research consist of studies where the patients have been randomized into different groups whereas levels III, IV, and V comprise observational studies, where no randomization has taken place. High-quality studies are studies that: (1) have sample sizes that are sufficiently large to detect statistically significant differences between the intervention and comparison groups (100 or more subjects); (2) have low attrition rates (less than 20%); (3) have intervention and comparison groups that are statistically equivalent prior to the intervention, with respect to baseline measures of the outcome and important factors associated with the outcome; (4) use controlled before and after designs (i.e., collect data on both the intervention and comparison groups prior to the intervention and after the intervention); and (5) either randomly assign participants to intervention and comparison groups or use instrumental variables, propensity scores, or other sophisticated statistical methods to address selection bias and control for confounders. Using these standards, most of the research related to fertility preservation for cancer patients would be classified as level III and level IV. There are very few RCTs on humans across all the fertility preservation options, and most of them are have very small sample sizes. It is widely acknowledged among researchers and clinicians in the field that larger randomized studies are necessary.

Outcomes Assessed

The medical effectiveness of fertility preservation services was assessed using the following outcomes:

- **Clinical pregnancy rate:** The percentage of attempts that lead to a pregnancy as confirmed by ultrasound early in pregnancy, usually around 7 weeks.
- **Pregnancy rate:** The percentage of attempts that lead to any pregnancy.
- **Cumulative pregnancy rate:** Pregnancy rate across multiple attempts.

- **Birth rate:** The percentage of attempts that result in a birth.
- **Live birth rate:** The percentage of attempts that result in a live birth (excludes still birth).
- **Cumulative birth rate:** Birth rate across multiple attempts.

Intermediate outcomes were also assessed such as post-thaw survival rate of embryos, oocytes, or sperm, fertilization rate, and implantation rate. Adverse outcomes associated with fertility preservation services as measured in the literature were cancer-recurrence rates, preterm delivery rates, miscarriage rates, and rates of chromosomal abnormalities.

Study Findings

This review started with the list of 12 fertility preservation services reviewed in the American Society of Clinical Oncology (ASCO) Recommendations on Fertility Preservation in Cancer Patients (Lee et al., 2006). The findings are broken out by gender and by status (standard or experimental) according to the American Society of Reproductive Medicine (ASRM) and ASCO. These are the leading national organizations of physicians specializing in evidence-based guidelines for cancer care and reproduction care in the United States. Literature regarding standard fertility preservation services was reviewed by CHBRP, and conclusions regarding the medical effectiveness of these services are presented below. This review does not draw conclusions as to the state of the evidence of the medical effectiveness for fertility preservation services that are considered experimental because there is insufficient evidence to evaluate their medical effectiveness.

Standard Fertility Preservation Treatments for Females

Fertility preservation options in females depend on many factors such as patient age, type of cancer diagnosis, prescribed cancer treatment, the amount of time the patient can wait before starting cancer treatment, and whether the cancer has metastasized to the patient's ovaries (Oktem and Urman, 2010). Personal factors such as if the patient has a partner, cultural background, and religious beliefs can also influence fertility preservation decisions. This review presents evidence as to the effectiveness of five standard fertility preservation services for females: embryo cryopreservation; oocyte cryopreservation; ovarian shielding during radiation therapy; ovarian transposition; and conservative gynecologic surgery (ASRM, 2013; Lee et al., 2006; Levine et al., 2010).[52]

Embryo cryopreservation

Embryo cryopreservation involves harvesting the patient's eggs, using in vitro fertilization (IVF) to fertilize the eggs, and freezing any resulting embryos for later implantation. The harvesting of the patient's eggs takes place 10 to 14 days from menses as an outpatient surgical procedure, and requires either partner or donor sperm (Levine et al., 2010). Embryo croypreservation is done as part of infertility treatment to store embryos crated through IVF, and can also be used to store

[52] Levine et al. (2010) list four other standard parenthood options (donor embryos, donor eggs, gestational surrogacy, adoption) that were not considered in this report because they would not be covered under AB 912.

embryos for fertility preservation purposes. There are nearly 10,000 births in the United States every year from embryo cryopreservation (SART, 2013).

Embryo cryopreservation is the most successful fertility preservation approach for females and is considered the standard fertility preservation method for women with a male partner (Ata et al., 2010; Dunn and Fox, 2009; Lee et al., 2006; Rodriguez-Macias Wallberg et al., 2009; Seli and Tangir, 2005). The post-thaw survival rate of embryos ranges between 35% to 90%, while implantation rates are between 8% and 42% (Dunn and Fox, 2009; Rodriguez-Macias Wallberg et al., 2009; Seli and Tangir, 2005). Pregnancy rates per transferred embryo are reported at 19% while cumulative pregnancy rates (pregnancy rate across multiple attempts) can be more than 60% (Ata et al., 2010; Rodriguez-Macias Wallberg et al., 2009; Seli and Tangir, 2005). A recent meta-analysis of three clinical trials found that the clinical pregnancy rate was higher among frozen embryo transfers compared to fresh embryo transfers (relative risk[53] = 1.31, 95% confidence interval [CI] = 1.10–1.56) (Roque et al., 2013).

Birth rates per embryo transfer using cryopreserved embryos have risen from approximately 28% in 2004 to 35% in 2011 (Dunn and Fox, 2009; SART, 2013). The live birth rate from embryo cryopreservation depends on the age of the patient and the number of embryos available (Lee et al., 2006). The Society for Assisted Reproductive Technology/Centers for Disease Control data from 2011 indicated that the percentages of thawed embryo transfers resulting in live births were 39% in women less than 35 years of age, 36% in the 35 to 37 age group, 30% in the 38 to 40 age group, 25% in the 41 to 42 age group, and 17% in the >42 age group (SART, 2013).

Embryo cryopreservation may be limited by several considerations. One consideration with embryo cryopreservation for cancer patients is that it is not always possible to delay the cancer therapy by 2 to 4 weeks in order to stimulate the ovaries to harvest oocytes (Jakimiuk and Grzybowski, 2007). In addition, patients with hormone-sensitive tumors may need to avoid the higher estrogen levels induced by ovarian stimulation, although one small nonrandomized case-control study found no difference in cancer recurrence rates between women who had undergone IVF and those who had not (Azim et al., 2008). Oocyte collection is possible without ovarian stimulation, but the embryo yield is very low (Lee et al., 2006). An additional consideration is that embryo cryopreservation requires the use of sperm from a partner or donor. This may not be acceptable to patients without a partner or who have moral or religious objections to cryopreserving embryos.

The studies mentioned previously all have small sample sizes and were not limited to patients cryopreserving embryos for fertility preservation. Studies comparing infertility procedures between women undergoing gonadotoxic treatments and women seeking IVF for male-factor infertility have mixed results. Although two studies found no difference between these two groups in measures of fertility such as number of oocytes retrieved or number of viable embryos created, another study found differences, especially for women undergoing treatment for hormone-dependent cancer (Domingo et al., 2012; Knopman et al., 2009; Robertson et al., 2011). Therefore, the generalizability of findings from the identified literature is unknown.

[53] The risk ratio (or relative risk) is the ratio of the risk of an event in the two groups.

Summary of findings regarding embryo cryopreservation.

There is a preponderance of evidence that embryo cryopreservation is an effective method of fertility preservation measured by three different outcomes: successful thawing of embryos; successful implantation of embryos; and resulting live births.

Oocyte (egg) cryopreservation

For women who do not have a partner, who do not wish to use a sperm donor, or have objections to freezing embryos, the standard option for preserving fertility is oocyte cryopreservation. This service is appropriate for females who have gone through puberty. In an outpatient surgical procedure, oocytes are removed from the female approximately 10 to 14 days from menses (Levine et al., 2010). A newer flash-freezing technology called vitrification results in less ice crystallization damage during freezing and thawing, resulting in more oocytes that survive the process than with slow-freeze methods. Due to this advance in technology, the viability of oocytes after thawing has greatly improved, leading the ASRM to issue new recommendations in January of 2013 that oocyte cryopreservation should be offered as a standard fertility preservation service to patients facing chemotherapy or other gonadotoxic therapies (ASRM, 2013).

A review of mature oocyte cryopreservation was undertaken by the ASRM in April 2012 (ASRM, 2013). This review identified four randomized controlled trials comparing IVF outcomes using cryopreserved oocytes with outcomes using fresh oocytes (Cobo et al., 2008, 2010; Parmegiani et al., 2011; Rienzi et al., 2010). Across the four studies identified, ASRM found that the oocyte post-thaw survival rate ranged from 90% to 97%, the fertilization rate ranged from 71% to 79%, the implantation rate ranged from 17% to 41%, the clinical pregnancy rate per transfer ranged from 36% to 61%, and the clinical pregnancy rate per thawed oocyte ranged from 4.5% to 12%. The ASRM article reported that these rates compared favorably with fresh oocytes. A meta-analysis published prior to the publication of Parmegiani et al., 2011 included three of the four articles included in the ASRM review (Cobo et al., 2008, 2010; Rienzi et al., 2010). This meta-analysis reported no significant difference in fertilization rates of thawed oocytes (using the vitrification freezing method) versus fresh oocytes (odds ratio[54] = 1.02, 95% CI = 0.91–1.13) (Cobo and Diaz, 2011). Research published after the ASRM literature review was conducted (April 2012) also found no differences between fresh and vitrified warmed oocytes (Forman et al., 2012; Parmegiani et al., 2011). There is limited evidence that rates of chromosomal abnormalities and birth defects in fresh and vitrified oocytes are the same (ASRM, 2013).

The studies mentioned previously have small sample sizes (all but one, n=295, had sample sizes less than 50), and were not limited to patients cryopreserving oocytes for fertility preservation, therefore the generalizability of these findings is unknown.

[54] The odds ratio is the ratio of the chance of an event occurring in one group compared to the chance of it occurring in another group.

Summary of findings regarding oocyte (egg) cryopreservation.

There is a preponderance of evidence that oocyte cryopreservation is an effective method of fertility preservation measured by three different outcomes: successful thawing of oocytes; successful implantation of embryos; and resulting live births.

Ovarian transposition (oophoropexy)

For women undergoing radiation of the pelvis, ovarian transposition (oophoropexy) is used to minimize the damage to the ovaries caused by pelvic radiation (Levine et al., 2010). This surgery involves repositioning the ovaries higher up in the abdomen and away from the radiation field. One study reported that oophoropexy can reduce radiation exposure in transposed ovaries to 5% to 10% of the radiation exposure in nontransposed ovaries (Georgescu et al., 2008). Rates of successful preservation of ovarian function after oophoropexy vary greatly, with a reported range of 16% to 90% (Georgescu et al., 2008; Seli and Tangir, 2005; Thibaud et al., 1992). In the ASCO recommendations on fertility preservation, the rate of fertility preservation is estimated at 50% (Lee et al., 2006).

Adverse outcomes related to this procedure include: the destruction of all or part of the Fallopian tube; chronic ovarian pain; ovarian cyst formation; and migration of the ovaries back to their original position (Lee et al., 2006; Oktem and Urman, 2010). In addition, the ovaries may need to be moved back to the pelvic region before an IVF procedure can be performed (Lee et al., 2006).

Of the articles reviewed in the three review articles referenced above, none were randomized controlled trials or large cohort studies. Most were case series of 20 or fewer patients, which are considered to be of low quality in the hierarchy of evidence described in Appendix B.

Summary of findings regarding ovarian transposition.

There is insufficient evidence as to the effectiveness of ovarian transposition in fertility preservation. A grade of *insufficient* evidence indicates that there is not enough evidence available to know whether or not a treatment is effective—it does not indicate that a treatment is not effective. Despite this, it stands to reason that under specific circumstances, females undergoing pelvic radiation where there is a high risk of ovarian failure may want to consider ovarian transposition as a method of fertility preservation.

Ovarian shielding during radiation therapy

In order to protect the ovaries during cancer treatment with radiation, a special external shield can be placed over the ovaries to minimize the damage caused by radiation. Ovarian shielding is generally used for cervical or vaginal cancer patients undergoing radiation therapy to treat their cancer. Expertise in ovarian shielding is needed to ensure that it is done properly (Levine et al., 2010). In addition, questions remain regarding the correct positioning of the shield, given that not all ovaries are in the exact same location (Fawcett et al., 2012). Although four review articles recommended the use of ovarian shielding during radiation therapy, no research to support these recommendations were cited (Gurgan et al., 2008; Lee et al., 2006; Levine et al., 2010; Rodriguez-Macias Wallberg and Oktay, 2012). In addition, CHBRP's review of the literature did

not find any articles that provided information regarding the effectiveness of ovarian shields to reduce the radiation to the ovaries or potential to preserve fertility.

Summary of findings regarding ovarian shielding.

There is insufficient evidence that ovarian shielding during radiation therapy is an effective method of fertility preservation. A grade of *insufficient* evidence indicates that there is not enough evidence available to know whether or not a treatment is effective—it does not indicate that a treatment is not effective. Despite this, it stands to reason that under specific circumstances, females undergoing pelvic radiation where there is a high risk of ovarian failure may want to consider ovarian shielding during radiation therapy.

Conservative gynecologic surgery

The recommendations released by ASCO indicated that conservative gynecologic surgery should be considered for certain kinds of gynecologic cancers if fertility preservation is desired and conservative surgery is appropriate given the stage of cancer (Lee et al., 2006). The two surgeries included in the recommendations are conservative surgery for cervical cancer (trachelectomy) and conservative surgery for ovarian cancer (Lee et al., 2006). In 2010, a meta-analysis was conducted on the effectiveness of conservative gynecologic surgeries and summarizes the fertility sparing options for patients with cervical and ovarian cancers (Eskander et al., 2011). The evidence of this review and other relevant literature is presented below.

A trachelectomy is a surgical procedure to remove the cervix while preserving the uterus. This procedure is used in place of a hysterectomy (removal of the uterus) as part of cancer treatment for patients wanting to preserve their fertility. This procedure is recommended for early-stage cervical cancer where the cancer has not spread beyond the cervix. It is estimated that half of women of reproductive age diagnosed with cervical cancer are eligible for the procedure (Lee et al., 2006).

Pregnancy rates following trachelectomy procedures range between 41% and 79% (Beiner and Covens, 2007; Dursun et al., 2007; Wellington et al., 2002). Among pregnant women, the live birth rate was calculated across 10 studies as 64%, ranging from 50% to 100% (Eskander et al., 2011). The most common complications from the trachelectomy procedure are higher rates of second trimester miscarriages and preterm deliveries (Beiner and Covens, 2007). Preterm delivery rates (before 37 weeks) were reported in 20% of pregnancies and 10% of women had a second trimester miscarriage (Eskander et al., 2011).

Tumor recurrence rates ranged from 3.9% to 5% while the observed mortality rate ranged from 2% to 3% (Beiner and Covens, 2007; Dursun et al., 2007; Eskander et al., 2011; Seli and Tangir, 2005). These rates are comparable to rates observed in women with a hysterectomy to treat cervical cancer. Therefore, the authors concluded that there are no increased risks of cancer recurrence or mortality to women undergoing trachelectomy for early stage cervical cancer (Beiner and Covens, 2007; Dursun et al., 2007; Eskander et al., 2011; Lee et al., 2006; Seli and Tangir, 2005). These results were confirmed by a meta analysis that found no significant differences in tumor recurrence rate, 5-year cancer survival rate, or surgical complications between women undergoing radical trachelectomy compared to hysterectomy (Xu et al., 2011).

The standard treatment for the type of ovarian cancer classified as a borderline ovarian tumor is removal of the uterus (hysterectomy) and removal of both ovaries. The conservative treatment preserves the uterus and one ovary. This is only possible in cases where the cancer was confined to only one ovary. A meta-analysis of 10 studies with a total of 626 patients with borderline ovarian tumors reported 185 pregnancies and 107 live births. Among pregnant women, the live birth rate was calculated across 9 studies as 75%, ranging from 59% to 100% (Eskander et al., 2011). Tumor recurrence rates ranged from 5% to 32% while only one death was observed across all 10 studies (0.2%) (Eskander et al., 2011). Therefore, the authors concluded that conservative surgery should be considered in young women desiring to preserve their fertility in the appropriate stage of disease and where the tumor can be completely removed (Eskander et al., 2011).

Summary of findings regarding conservative gynecologic surgery.

There is a preponderance of evidence that trachelectomy and conservative ovarian surgery are effective conservative gynecologic surgeries in preserving fertility preservation measured by pregnancy rates and live births. There is a preponderance of evidence that trachelectomy and conservative ovarian surgery have no apparent increase in cancer recurrence or mortality for specific cases.

Experimental Fertility Preservation Options for Females

Ovarian tissue cryopreservation and transplantation

The only option available for freezing reproductive material in prepubescent girls undergoing chemotherapy is ovarian tissue cryopreservation. In this surgical procedure, ovarian tissue is removed and frozen. This allows for the ovarian tissue to be thawed and re-implanted after the patient has finished with her treatment. The first ovarian transplant procedure was performed in 2000, and as of 2012, there had been at least 18 births as a result of this procedure (Dittrich et al., 2012; Lee et al., 2006; Levine et al., 2010). Although the exact denominator is unknown, it is estimated that the pregnancy rate after ovarian tissue cryopreservation and transplantation is approximately 30% (Dolmans et al., 2013). One concern with this procedure is the possibility that cancer cells may be reintroduced when the ovarian tissue is re-implanted (Levine et al., 2010). A review of the literature on the presence of malignant cells in cryopreserved ovarian tissue revealed that approximately 7% of re-implanted tissue is potentially infiltrated by malignant cells (Rosendahl et al., 2013). But, in 33 reported transplants, no related cases of cancer relapse have been reported (Rosendahl et al., 2013).

Ovarian suppression with GnRH analogs

Gonadotropin-releasing hormone (GnRH) analog is an experimental hormonal therapy that causes the ovaries to temporarily shut down during chemotherapy, thus potentially reducing damage to the follicles where eggs develop (Ben-Aharon and Gafter-Gvili, 2010). This service is available to women who have completed puberty and is used in conjunction with chemotherapy, starting a week prior to chemotherapy and continuing for the course of chemotherapy treatment. GnRH analogs do not protect against radiation effects or from very aggressive forms of chemotherapy (Levine et al., 2010).

Much of the research on ovarian suppression with GnRH analogs has been conducted in animals. Although five randomized, prospective studies have been published, they did not confirm the positive results shown in other observational studies, and, overall, the literature is mixed on the impact of the treatment on preserving ovarian function (Ben-Aharon and Gafter-Gvili, 2010; Yang et al., 2013). In addition, there is some concern that the use of GnRH analogs is not appropriate for women undergoing treatment for breast cancer because the hormone treatment may reduce the tumor sensitivity to chemotherapy (de Ziegler et al., 2010).

Summary of findings regarding experimental fertility preservation treatments.

Ovarian tissue cryopreservation and transplantation and ovarian suppression with gonadotropin releasing hormone (GnRH) analogs are considered experimental methods of fertility preservation and there is insufficient evidence to evaluate their medical effectiveness.

Table 3. Summary of Findings From Studies of the Effectiveness of Fertility Preservation Treatments in Females

Treatment	Description	Target Population	Outcomes	Conclusion
Standard Medical Practice				
Embryo cryopreservation	Harvesting oocytes, in vitro fertilization, and freezing of embryos for later implantation.	Postpubertal females	Average 35% birth rate per embryo transfer (a)	There is a preponderance of evidence that embryo cryopreservation is an effective method of fertility preservation.
Oocyte cryopreservation	Harvesting and freezing of unfertilized oocytes.	Postpubertal females	4.5%–12% clinical pregnancy rate per thawed oocyte (b)	There is a preponderance of evidence that oocyte cryopreservation is an effective method of fertility preservation
Ovarian transposition (oophoropexy)	Surgical repositioning of ovaries away from the radiation field.	Pre- and postpubertal females	The rate of fertility preservation is estimated at 50% (c)	There is insufficient evidence as to the impact of ovarian transposition on fertility preservation
Ovarian shielding during radiation therapy	Use of shielding to reduce the dose of radiation delivered to the reproductive organs.	Pre- and postpubertal females	No specific findings provided	There is insufficient evidence that ovarian shielding during radiation therapy is an effective method of fertility preservation
Conservative gynecologic surgery—trachelectomy	Surgical removal of the cervix while preserving the uterus.	Postpubertal females with early-stage cervical cancer	Pregnancy rates ranged between 41% and 79% 64% live birth rate 3.9%–5% cancer recurrence rate and 2%–3% death rate (d)	There is a preponderance of evidence that trachelectomy is an effective method of fertility preservation
Conservative gynecologic surgery for ovarian cancer	Surgical removal of the diseased ovary while preserving the uterus and other ovary.	Postpubertal females with early-stage ovarian cancer	75% live birth rate 18% cancer recurrence rate and 0.2% death rate (e)	There is a preponderance of evidence that conservative ovarian surgery is an effective method of fertility preservation

Table 3. Summary of Findings From Studies of the Effectiveness of Fertility Preservation Treatments in Females (Cont'd)

Treatment	Description	Target Population	Outcomes	Conclusion
Experimental Medical Practice				
Ovarian cryopreservation and transplantation	Freezing of ovarian tissue and reimplantation after cancer treatment.	Pre- and postpubertal (without systemic metastasis)	Case reports of 18 live births (f)	Experimental treatment
Ovarian suppression with GnRH analogs or antagonists	Use of hormonal therapies to protect ovarian tissue during radiation therapy.	Postpubertal females	Unknown success rate (g)	Experimental treatment

Source: California Health Benefits Review Program, 2013.
Note: The sources for the table are as follows: (a) SART, 2013; (b) ASRM, 2013; (c) Lee et al., 2006; (d) Beiner and Covens, 2007; Dursun et al., 2007; Eskander et al., 2011; (e) Eskander et al., 2011; (f) Dittrich et al., 2012; (g) Ben-Aharon and Gafter-Gvili, 2010.
Key: GnRH=gonadotropin-releasing hormone.

Standard Fertility Preservation Treatments for Males

This review presents evidence as to the effectiveness of two standard fertility preservation treatments for males: sperm cryopreservation (sperm banking) and testicular shielding during radiation therapy.

Sperm cryopreservation

Sperm cryopreservation is the most established technique for maintaining fertility in men. In this technique, sperm is collected prior to the initiation of cancer treatment through ejaculation and then frozen. Alternative forms of sperm collection exist such as testicular aspiration or extraction, electroejaculation under sedation, and post-masturbation urine sample, but are generally considered experimental (Lee et al., 2006; Levine et al., 2010). Males start producing sperm after puberty, around 13 to 14 years of age; therefore this treatment is not appropriate for prepubescent males (Levine et al., 2010). Research has indicated that long-term cryopreservation of sperm is possible with reported pregnancies using sperm stored between 10 and 28 years (Levine et al., 2010).

Studies of the effectiveness of sperm cryopreservation in cancer patients found that this fertility preservation method is effective in providing male cancer patients a chance at parenthood (Hourvitz et al., 2008; van Casteren et al., 2008; van der Kaaij et al., 2010). A review by van der Kaaij found an average pregnancy and delivery rate of 54%, with reported rates ranging from 33% to 73% (van der Kaaij et al., 2010). In one study of cancer patients by van Casteren and colleagues (2008), 557 men had their sperm cryopreserved. Thirty-seven patients used assisted reproductive techniques to reproduce using the cryopreserved sperm, yielding a live birth rate of 49%. In an additional study of male cancer patients, Hourvitz and colleagues studied 118 couples using previously cryopreserved sperm from males with cancer. They found that the clinical pregnancy rate was 56.8% and the delivery rate was 50.3% per retrieval (Hourvitz et al., 2008). More recently, Bizet et al. found that of 1,007 patients referred to a sperm bank for sperm

cryopreservation prior to the initiation of cancer treatment, 6.3% later retrieved their sperm for use in reproduction treatment cycles including IVF and artificial insemination, yielding a cumulative birth rate of 46.8% (Bizet et al., 2012).

Summary of findings regarding sperm cryopreservation.

There is a preponderance of evidence that sperm cryopreservation is an effective method of fertility preservation as measured by pregnancy rates and live births.

Testicular shielding during radiation therapy

To protect the testes during radiation treatment, a shield can be placed over the testicles to reduce the amount of radiation they are exposed to (Lee et al., 2006). Research from case series has shown that this treatment is effective in reducing the damage to the testicles, but that it is only possible with selected radiation fields and anatomy (Ishiguro et al., 2007; Lee et al., 2006). In addition, expertise is required to make sure that the shielding does not increase the amount of radiation delivered to the reproductive organs (Lee et al., 2006).

Summary of findings regarding testicular shielding.

There is insufficient evidence that testicular shielding is an effective method of fertility preservation in males. A grade of *insufficient* evidence indicates that there is not enough evidence available to know whether or not a treatment is effective—it does not indicate that a treatment is not effective. Despite this, it stands to reason that under specific circumstances, males undergoing pelvic radiation where there is a high risk of testicular failure may want to consider testicular shielding during radiation therapy.

Experimental Fertility Preservation Treatments for Males

Sperm cryopreservation after alternative methods of sperm collection

The standard protocol for retrieval of male sperm for cryopreservation is to collect ejaculate through masturbation (Lee et al., 2006). In cases where males are unwilling or unable to collect sperm through this process, alternate processes to collect sperm exist. Lee identified three alternative collection methods: 1) sperm obtained through testicular aspiration or extraction; 2) electroejaculation under sedation; or 3) from a post-masturbation urine sample. All three of these alternative sperm collection methods are uncommon and are considered experimental (Lee et al., 2006). In a study of testicular cancer patients, Delouya et al. (2010) found that patients undergoing removal of the testicles were able to retrieve sperm at the time of their surgery with 40% probability of recovering sperm by biopsy of the noncancerous testicle.

Testicular tissue cryopreservation

Testicular tissue cryopreservation is an outpatient surgical procedure where tissue is surgically removed and frozen. It is available for males either before or after puberty, but it is the main option for prepubescent males. This method has produced no live births and is considered experimental (Lee et al., 2006; Levine et al., 2010). Despite this, researchers are calling for the standardization of this treatment so that prepubescent boys undergoing gonadotoxic treatments

may benefit from any future advances in testicular tissue cryopreservation and utilization in fertility preservation (Ruutiainen et al., 2013).

Testicular suppression with GnRH analogs

GnRH analogs are an experimental hormonal therapy that causes the testicles to temporarily shut down during chemotherapy, thus potentially causing a reduction in the damage to the sperm. The efficacy of this method has only been evaluated in very small studies and is considered experimental (Lee et al., 2006; van der Kaaij et al., 2010). Although animal trials have shown promise, only one of seven trials conducted in humans showed positive results on intermediate outcomes such as improved sperm count and hormone levels (Lee et al., 2006; van der Kaaij et al., 2010).

Summary of findings regarding experimental fertility preservation treatments.

Sperm cryopreservation after alternative methods of sperm collection, testicular tissue cryopreservation, and testicular suppression with GnRH analogs or antagonists are all considered experimental methods of fertility preservation, and there is insufficient evidence to evaluate their medical effectiveness.

Table 4. Summary of Findings From Studies of the Effectiveness of Fertility Preservation Treatments in Males

Treatment	Description	Target Population	Outcomes	Conclusion
Standard Medical Practice				
Sperm cryopreservation after masturbation	The collection and freezing of sperm from ejaculate	Postpubertal males	The most established technique for men. 50% delivery rate in couples retrieving sperm (a)	Preponderance of evidence that sperm cryopreservation is effective in preserving male fertility
Testicular shielding during radiation therapy	Use of shielding to reduce the dose of radiation delivered to the testicles	Pre- and postpubertal males	Standard practice, but no evidence on outcomes (b)	Insufficient evidence
Experimental Medical Practice				
Sperm cryopreservation after alternative Methods of sperm collection	Freezing sperm obtained through testicular aspiration or extraction, electroejaculation under sedation, or from a postmasturbation urine sample	Postpubertal males	In testicular cancer patients there is a 40% probability of recovering sperm by random biopsy of the noncancerous testicle (c)	Experimental treatment
Testicular tissue cryopreservation	Freezing testicular tissue or germ cells and re-implantation after treatment or maturation in animals	Pre- and postpubertal males	Experimental, there are no available human success rates (d)	Experimental treatment: at the animal experimental stage

Table 4. Summary of Findings From Studies of the Effectiveness of Fertility Preservation Treatments in Males (Cont'd)

Treatment	Description	Target Population	Outcomes	Conclusion
Testicular suppression with GnRH analogs	Use of hormonal therapies to protect testicular tissue during radiation therapy	Postpubertal males	Experimental, but small, studies show that it is not effective (e)	Experimental treatment

Source: California Health Benefits Review Program, 2013.
Note: The sources for the table are as follows: (a) Hourvitz et al., 2008; van Casteren et al., 2008; Bizet et al., 2012; (b) Lee et al., 2006; Levine et al., 2010; (c) Delouya et al., 2010; (d) Levine et al., 2010; (e) Lee et al., 2006; van der Kaaij et al., 2010.
Key: GnRH=gonadotropin-releasing hormone.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

Assembly Bill (AB) 912 would require group and individual market Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated policies to provide coverage for "medically necessary expenses for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause iatrogenic infertility to an enrollee." This bill would apply to enrollees in CDI-regulated policies and most DMHC-regulated plans; Medi-Cal Managed Care Plans are *not* subject to AB 912. CHBRP estimates approximately 25.9 million enrollees are in DMHC-regulated plans and CDI-regulated policies that can be subject to state benefit mandates. Because Medi-Cal Managed Care Plans are not subject to AB 912, CHBRP estimates there are 19.4 million enrollees in DMHC-regulated plans and CDI-regulated policies subject to AB 912.

AB 912 did not specify the necessary medical treatments that might cause iatrogenic infertility. As discussed in the *Medical Effectiveness* section, the most common and well-known cause is cancer treatments, specifically gonadotoxic treatments (e.g., radiation and chemotherapy treatment) and the surgical removal of reproductive organs. Therefore, CHBRP estimates the population who would be considered users of fertility preservation services are enrollees diagnosed with one of the top 10 cancers associated with treatments that could cause iatrogenic infertility. Furthermore, the population analysis is restricted to those of reproductive age—ages 14 to 43 for females and ages 12 to 49 for males. As discussed in the *Medical Effectiveness* section, fertility preservation services available to those below this age threshold are experimental, and therefore not considered "standard" medical services at this time. Those older than this age range are assumed not to use fertility preservation services.

Fertility preservation services include three medical procedures that are standard practice to protect against iatrogenic infertility: (1) sperm cryopreservation (freezing) for men; (2) embryo cryopreservation for women; and (3) oocyte (egg) cryopreservation for women. Radiation shielding and conservative gynecologic surgery are also considered standard practices. However, for radiation shielding, its use and costs are folded into the normal radiation therapy that occurs as part of cancer treatments, and for conservative gynecologic surgery, it is likely to be covered under a cancer surgery benefit and not fertility preservation coverage. Other services exist, such as ovarian tissue cryopreservation and transplantation, ovarian suppression, and (surgical) ovarian transposition. However, these services are still considered experimental and are not likely to become standard medical practice during the 1-year time frame of this analysis. **Therefore, CHBRP's cost impact analysis focuses on increased coverage and use of sperm cryopreservation, embryo cryopreservation, and oocyte cryopreservation only.**

This section presents, first, the current (baseline) benefit coverage, utilization, and costs related to fertility preservation services when patients are at risk for iatrogenic infertility, and then provides estimates of the impacts on coverage, utilization, and cost if AB 912 were enacted. For further details on the underlying data sources and methods, please see Appendix D at the end of this document.

Current (Baseline) Benefit Coverage, Utilization, and Cost

Current coverage of fertility preservation services when patients are at risk for iatrogenic infertility was determined by a survey of the seven largest providers of health insurance coverage in California. CHBRP conducts a bill-specific coverage survey of California's largest health plans and insurers. Responses to this survey represented 90.2% of enrollees in the privately funded, CDI-regulated market and 92.2% of enrollees in the privately funded, DMHC-regulated market. Combined, responses to this survey represent 91.7% of enrollees in the privately funded market subject to state mandates.

Currently, 1.6 million enrollees (8.3%) of the 19.4 million enrollees in DMHC-regulated plans or CDI-regulated policies subject to AB 912 have benefit coverage for fertility preservation services. All of these 1.6 million enrollees who currently have benefit coverage for fertility preservation services are in the large-group, small-group, or the individual market.

Among California's publicly funded health insurance programs, only CalPERS HMOs are subject to AB 912. Currently, CalPERS HMOs do not provide coverage for fertility preservation services.

Current Utilization Levels

CHBRP estimates that 4,306 men and 3,344 women (7,650 enrollees) would be currently eligible to use fertility preservation services, since they are of reproductive age and have one of the top 10 types of cancer for which the treatment can cause iatrogenic infertility. This represents 0.040% of the total population of enrollees in DMHC-regulated plans or CDI-regulated policies subject to AB 912. These totals were derived by applying age- and gender-specific cancer incidence rates, based on Surveillance Epidemiology and End Results (SEER) data from the National Cancer Institute from 2007–2009, to the insured California population subject to AB 912.

Estimates of those who use fertility preservation services were not available using the SEER data, and the body of literature on this topic is thin. CHBRP derived utilization assumptions from the available literature, which were examined by content experts and reviewers, and it was agreed that these assumptions were the best possible estimates given their own knowledge of the field and the available data.

To calculate the utilization rate of sperm cryopreservation by male enrollees who are at risk for iatrogenic infertility, CHBRP relied on a study (Schover et al., 2002). Schover et al. found that:

- 24% of men without insurance coverage at risk for iatrogenic infertility chose to use sperm cryopreservation; and
- 29% of men with insurance coverage at risk for iatrogenic infertility chose to use sperm cryopreservation.

On the basis of the carrier survey, CHBRP estimated that currently 8.3% of male enrollees have coverage for sperm cryopreservation. Therefore, CHBRP estimates that premandate, 1,051 male enrollees currently use sperm cryopreservation to protect against iatrogenic infertility. Of these,

104 male enrollees are estimated to have coverage for fertility preservation services, whereas the remainder pay directly for their noncovered fertility preservation services.

To calculate the use of embryo and oocyte cryopreservation by female enrollees without coverage for fertility preservation services who are at risk for iatrogenic infertility, CHBRP relied on a study (Letourneau et al., 2012a). Adjusting the age distribution of this study to be consistent with the females enrollees in DMHC-regulated plans and CDI-regulated policies subject to AB 912 (see Appendix D for further details), CHBRP estimated that the proportion of female enrollees at risk for iatrogenic infertility choosing to use fertility preservation services who do not have coverage for fertility preservation services was 3.6%: 1.8% for embryo cryopreservation and 1.8% for oocyte cryopreservation. On the basis of content expert input, CHBRP estimated that utilization increases to 11.8% with coverage for fertility preservation services: 5.9% for embryo cryopreservation and 5.9% for oocyte cryopreservation.

CHBRP estimated that currently 8.3% of female enrollees have coverage for embryo and oocyte cryopreservation based on the carrier survey. Therefore, CHBRP estimates that premandate, 72 female enrollees currently use fertility preservation services to protect against iatrogenic infertility: 36 female enrollees currently use embryo cryopreservation, and 36 female enrollees currently use oocyte cryopreservation. Of those, 16 enrollees are estimated to have coverage for fertility preservation services, whereas the rest, 56 female enrollees, pay directly for their noncovered fertility preservation services.

Current Average Cost of Fertility Preservation Services

Currently, the per-unit costs vary depending on whether the procurement and storage services are for men or for women. Both face initial charges for the procurement procedure, along with annual fees for storage. CHBRP estimated costs during 2014 only. Therefore, the annual storage costs beyond 2014 of sperm ($100), embryos ($300), and oocytes ($300) were not included in the CHBRP short-term (1-year) cost model (see the "Impact on Long-Term Costs" section below for further discussion).

Sperm cryopreservation costs an average of $400 (including the first-year storage cost). Both embryo and oocyte procurement are surgical procedures and require several weeks of prescription drug treatment prior to the actual surgical procedure itself. The cost of embryo cryopreservation is $14,700, which includes $2,500 for the prescription drug treatment and $12,200 for the surgical procedure, which includes in vitro fertilization (IVF) and the cost of the first-year storage. The cost of oocyte cryopreservation is approximately $11,200, which includes $2,500 for the prescription drug treatment and $8,700 for the surgical procedure and the first-year storage. Oocyte cryopreservation costs are a little less than embryo cryopreservation because the former does not require an oocyte fertilization procedure (IVF) or embryo culture in the laboratory for 3–5 days prior to freezing.

AB 912 does not provide coverage for assisted reproductive technologies (ART) (Figure 1) using thawed reproductive material that had been cryopreserved. Therefore, CHBRP does not include the cost of these post-thaw services in its estimates.

Current (Baseline) Premiums and Expenditures

Table 5.1 (at the end of this section) presents premandate per member per month (PMPM) estimates for premiums and expenditures by market segment. Prior to the mandate, total expenditures vary depending on plan type. The lowest average expenditure ($468.83) was in the CDI-regulated individual policies, and the highest average expenditure was among the CDI-regulated small-group policies ($821.91).

Like Table 5.1, Table 5.2 also presents premandate PMPM estimates for premiums and expenditures by market segment, comparing grandfathered plans or policies and nongrandfathered ones in the small-group and individual markets. Total expenditures PMPM appears moderately greater among nongrandfathered plans or policies than grandfathered ones, with the difference being around $60–$70 PMPM.

The Extent to Which Costs Resulting From Lack of Coverage Are Shifted to Other Payers, Including Both Public and Private Entities

CHBRP estimated no shift in costs among private or public payers as a result of current coverage. Nearly all fertility preservation services are currently paid for entirely by the enrollee or by some other source since these benefits are not typically covered by insurance. Some assistance with these costs from charities and foundations does exist, but is limited and based on household income. These extra funds were not considered separately in the model, as they are included under "Enrollee expenses for noncovered benefits" in Table 1.

Public Demand for Benefit Coverage

Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- Considers the bargaining history of organized labor; and
- Compares the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and so not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions do not include discussions of fertility preservation services in their health insurance negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.[55]

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. The CalPERS PPOs provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate, and generally do not cover fertility preservation services.

[55] Personal communication, S. Flocks, California Labor Federation, January 2011.

To further investigate public demand, CHBRP used the bill-specific coverage survey. In the survey, CHBRP asked carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the proposed benefit coverage differed from what is currently offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences, and self-insured plans generally do not cover fertility preservation services as well.

Given that fertility preservation services are not widely covered by self-insured plans nor are they specifically discussed during union negotiations, it is not likely that demand for these services are widespread.

Impacts of Mandated Benefit Coverage

How Would Changes in Benefit Coverage Related to the Mandate Affect the Availability of the Newly Covered Treatment/Service, the Health Benefit of the Newly Covered Treatment/Service, and the Per-Unit Cost?

Impact on access and health treatment/service availability

CHBRP found no information about lack of access to fertility preservation services beyond the high cost, assuming the patient had been informed of their risk of iatrogenic infertility and the availability of sperm, embryo, or oocyte cryopreservation. However, an initial barrier does exist in that health providers often downplay the risk of infertility and either recommend against or fail to mention the existence of fertility preservation services (Achille et al., 2006; Letourneau et al., 2012a). It is possible that enactment of the mandate combined with efforts by advocates to increase awareness of the newly covered benefit may encourage more providers to offer these services to their patients who are at risk for iatrogenic infertility. This possible increase in utilization is likely to occur over the long term and cannot be measured within a 1-year time frame, and therefore is not included in the cost model.

Impact on per-unit cost

As there is no evidence in the literature that increasing coverage for fertility preservation services increases the price of those services, CHBRP assumes that the unit costs of sperm, embryo, and oocyte cryopreservation would stay the same after the mandate.

How Would Utilization Change As a Result of the Mandate?

As discussed previously, CHBRP estimates the utilization rate of sperm cryopreservation to be 29% for male enrollees with coverage for fertility preservation services (Schover et al., 2002). If AB 912 were enacted, CHBRP estimates that 1,249 male enrollees at risk for iatrogenic infertility would use fertility preservation services. Therefore, 197 additional male enrollees would use fertility preservation services were AB 912 to be enacted.

Also as previously discussed, on the basis of a study (Letourneau et al., 2012a) and content expert input, CHBRP estimates that the utilization rate of fertility preservation services for women with coverage for fertility preservation services is 11.8%, with half of the women using embryo cryopreservation (5.9%), and the other half using oocyte cryopreservation. If AB 912 were enacted, CHBRP estimates that 198 female enrollees at risk for iatrogenic infertility would

use fertility preservation services. Therefore, 126 additional female enrollees would use fertility preservation services if AB 912 were enacted.

In total, utilization of fertility preservation services is estimated to increase from 1,123 to approximately 1,447 out of the total 7,650 enrollees who would have cancer and be at risk for iatrogenic infertility.

The utilization increase is small because the choice to undergo sperm, embryo, or oocyte cryopreservation is highly dependent on several factors beyond cost. For men, these include the man's perceived own risk of infertility due to treatment, recommendations from health providers, and desire for children in the future (Achille et al., 2006). For women, these factors include those for men as well as the importance of starting treatment immediately, as embryo and oocyte cryopreservation delays the start of cancer treatment, and the potential impact of drugs used to stimulate the ovaries on the cancer. The additional invasiveness of the procurement procedure itself can also be a barrier for women (Gardino et al., 2010).

To What Extent Would the Mandate Affect Administrative and Other Expenses?

CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost proportion of premiums would remain unchanged. All health plans and insurers include a component for administration and profit in their premiums. CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and CDI-regulated policies would remain proportional to the increase in premiums.

Impact of the Mandate on Total Health Care Costs

Changes in total expenditures

AB 912 is estimated to increase total net health expenditures by $2.1 million, or 0.0015% (see Table 1 in the *Executive Summary*). This change in expenditures is due to a $2.9 million increase in health insurance premiums plus a 0.3 million increase in enrollee out-of-pocket expenses for newly covered benefits, partially offset by a reduction in out-of-pocket expenses for noncovered benefits ($1.1 million).

Potential cost offsets or savings in the short-term

In some cases, an increase in cost due to an expansion in benefit coverage is accompanied by a decrease in the cost for other health care services, known as a "cost offset." There is not sufficiently strong evidence to support health cost savings within the 1-year time frame of this cost analysis. Therefore, CHBRP does not estimate a cost offset in the first year following implementation.

Impact on long-term costs

If AB 912 were enacted, there are potential long-term costs that were not considered as part of CHBRP's 1-year, short-term cost model. In the short-term CHBRP cost model, the first-year storage cost is included in the costs ($14,700, $11,200, and $400 for embryo, oocyte, and sperm cryopreservation, respectively) shown in Table 1. Cryopreserved sperm, embryos, or oocytes incur annual storage fees. Girasole et al. (2007) found that nationwide, annual maintenance fees

ranged from $0 to $1,200, with a median cost of $300. The annual sperm storage cost was $100 based on content expert input. The literature on the average storage duration is limited. A study by Chung et al. (2004) reported the average storage duration was 3.1 years among 32 male patients (20% of the total study subjects) who discontinued sperm storage. These annual storage fees could add in the long term to the increase in costs to both health plans and policies and enrollees.

In terms of future fertility among those who use cryopreservation, some enrollees may retrieve their frozen sperm, embryos, or oocytes for reproductive purposes. The costs of these future procedures are not included in the short-term CHBRP cost model, nor are they required as coverage under AB 912, but they may increase long-term total health care costs at the state level if AB 912 were enacted.

Additionally, health care practitioners may start recommending sperm, embryo, and oocyte cryopreservation to their reproductive-age patients who will be undergoing cancer treatments at higher rates, which may lead to higher utilization in the long term. Schover et al. (2002) found that perceptions of high costs related to sperm cryopreservation was one of the key barriers leading to 48% of oncologists never or rarely mentioning sperm cryopreservation as an option to their patients. If AB 912 were enacted, the financial costs to the patient would decrease with the increase in insurance coverage, and oncologists may be more likely to present sperm, embryo, or oocyte cryopreservation to their patients as an option.

Impacts for Each Category of Payer Resulting from the Benefit Mandate

Changes in expenditures and PMPM amounts by payer category

Increases in insurance premiums vary by market segment. Note that the total population in Table 6.1 reflects the full 19.4 million enrollees in DMHC-regulated plans or CDI-regulated policies that are subject to AB 912. The premium increases are estimated to be spread among all enrollees in all plans or policies, regardless of whether they are at risk for iatrogenic infertility or whether the enrollees would possibly use fertility preservation services.

Increases as measured by percentage changes in PMPM premiums are estimated to range from an average increase of 0.0017% (for CDI-regulated small-group policies) to an average increase of 0.0031% (for CDI-regulated individual policies) in the affected market segments (Table 6.1). Increases as measured by PMPM premiums are estimated to be an average of $0.01 for both CDI-regulated policies and DMHC-regulated plans, including CalPERS HMOs.

In the privately funded large-group market, the increase in premiums is estimated to be an average of $0.01 PMPM among both DMHC-regulated plans and CDI-regulated policies (Table 6.1). For enrollees with privately funded small-group insurance policies, health insurance premiums are estimated to increase by an average of $0.01 PMPM for both DMHC-regulated plans and CDI-regulated policies. In the privately funded individual market, health insurance premiums are estimated to increase by an average of $0.01 PMPM in both DMHC-regulated plans and CDI-regulated policies.

Among publicly funded DMHC-regulated CalPERS HMOs, CHBRP estimates that premiums would increase slightly, with an average increase of 0.0030% ($0.01 PMPM).

There is also a shift in expenditures from enrollees paying for noncovered benefits to premiums. For example, in the individual DMHC market, an average of $0.01 of enrollee expenses for noncovered benefits (measured as PMPM costs) would be expected to shift to the health plan or insurer. Individuals who currently pay out-of-pocket for fertility preservation services would realize savings under the mandate because full coverage for these services would be available to them if AB 912 were enacted.

Table 6.2 (at the end of this section) also presents impacts of the mandate on PMPM premiums and total expenditures by market segments, comparing grandfathered plans or policies and nongrandfathered ones in the small-group and individual markets. The mandate impacts on both insured premium and total expenditure PMPM were greater among nongrandfathered plans or policies than grandfathered ones in small-group markets. On the other hand, these impacts were smaller among nongrandfathered plans or policies than grandfathered ones in individual markets.

Impacts on the Uninsured and Public Programs As a Result of the Cost Impacts of the Mandate

Changes in the number of uninsured persons as a result of premium increases

CHBRP estimates premium increases of less than 1% for each market segment. CHBRP does not anticipate loss of health insurance, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of health insurance, changes in employer contribution rates, changes in take-up of health insurance by employees, or purchase of individual market policies, due to the small size of the increase in premiums after the mandate. This premium increase would not have a measurable impact on number of persons who are uninsured.

Impact on public programs as a result of premium increases

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs or on utilization of covered benefits in the publicly funded insurance market.

Cost of Exceeding Essential Health Benefits

As explained in the *Introduction,* fertility preservations services are not included in the essential health benefits (EHBs) package as defined in California for 2014 and 2015. The state is required to defray the additional cost incurred by enrollees in qualified health plans (QHPs)[56] in Covered California, the state's health benefits exchange, for any state benefit mandate that exceeds the EHBs. Coverage for fertility preservation services, as would be required if AB 912 were enacted, would trigger this requirement and the state would need to defray the costs.

Final rules released by the U.S. Department of Health and Human Services (HHS) clarify that QHP issuers are responsible for calculating the marginal cost that must be defrayed. However, this rule left state flexibility in how this would be calculated; it could be based on "either a

[56] In California, QHPs are nongrandfathered small-group and individual market DMHC-regulated plans and CDI-regulated policies sold in Covered California, the state's exchange.

statewide average or each issuer's actual cost."[57] California has not yet identified which option it will use.

Table 6.2 in the *Benefit Coverage, Utilization, and Cost Impacts* section of this report shows the impact of AB 912 on the PMPM premiums in the small-group and individual markets, which are the market segments affected by the EHB coverage requirement. CHBRP is not able to estimate the total number of enrollees in QHPs in 2014, but this table provides the marginal change in the premium that would result from requiring coverage for fertility preservation services. These estimates reflect a statewide average and not an issuer's actual cost. The marginal change in the PMPM premium that CHBRP estimates would result from AB 912 and that the state would be responsible for defraying for each enrollee in a QHP in Covered California is:

- $0.01 in nongrandfathered small-group and individual market DMHC-regulated plans; and
- $0.01 in nongrandfathered small-group and individual market CDI-regulated policies (see Table 6.2).

[57] Essential Health Benefits. Final Rule. 12843.

Table 5.1 Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2014

	DMHC-Regulated							CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			CalPERS HMOs (b)	Medi-Cal Managed Care Plans			Privately Funded Plans (by Market) (a)			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65	Medi-Cal/Formerly Healthy Families Program (d)	Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state mandates (e)	11,289,000	2,479,000	1,029,000	854,000	688,000	5,203,000	626,000	539,000	1,315,000	1,877,000	25,899,000
Total enrollees in plans/policies subject to AB 912	11,289,000	2,479,000	1,029,000	854,000	0	0	0	539,000	1,315,000	1,877,000	19,382,000
Average portion of premium paid by employer	$437.53	$313.63	$0.00	$391.90	$279.00	$163.00	$88.83	$483.35	$421.89	$0.00	$95,549,186,000
Average portion of premium paid by employee	$83.30	$169.52	$546.88	$97.98	$0.00	$0.00	$8.79	$135.14	$190.22	$305.75	$34,912,666,000
Total premium	$520.83	$483.15	$546.88	$489.88	$279.00	$163.00	$97.62	$618.49	$612.11	$305.75	$130,461,851,000
Enrollee expenses for covered benefits (deductibles, copays, etc.)	$28.54	$46.99	$109.38	$25.99	$0.00	$0.00	$4.51	$87.22	$209.80	$163.07	$14,462,198,000
Enrollee expenses for benefits not covered (f)	$0.00	$0.00	$0.01	$0.01	$0.00	$0.00	$0.00	$0.00	$0.00	$0.01	$1,105,000
Total expenditures	$549.37	$530.15	$656.27	$515.87	$279.00	$163.00	$102.13	$705.72	$821.91	$468.83	$144,925,155,000

Source: California Health Benefits Review Program, 2013.

Note: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, inside and outside the exchange.

(b) As of September 30, 2012, 57.5%, or 469,000 CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2014.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who also have Medicare coverage.

(d) Children in Healthy Families, California's CHIP, will be moved into Medi-Cal Managed Care by January 1, 2014, as part of the 2012–2013 budget.

(e) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

(f) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

Table 5.2 Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures in Small and Individual Markets by Grandfathered Status, California, 2014

	Privately Funded DMHC-Regulated					Privately Funded CDI-Regulated				
	Small Group		Individual Market			Small Group		Individual Market		
	Grand-fathered	Nongrand-fathered	Grand-fathered	Nongrand-fathered	Nongrand-fathered Exchange	Grand-fathered	Nongrand-fathered	Grand-fathered	Nongrand-fathered	Nongrand-fathered Exchange
Total enrollees in plans/policies subject to state mandates (a)	231,000	2,248,000	575,000	38,000	416,000	51,000	1,264,000	762,000	95,000	1,020,000
Total enrollees in plans/policies subject to AB 912	231,000	2,248,000	575,000	38,000	416,000	51,000	1,264,000	762,000	95,000	1,020,000
Average portion of premium paid by employer	$276.03	$317.50	$0.00	$0.00	$0.00	$391.24	$423.12	$0.00	$0.00	$0.00
Average portion of premium paid by employee	$149.20	$171.61	$520.69	$580.06	$580.06	$176.40	$190.78	$283.62	$320.88	$320.88
Total premium	$425.23	$489.11	$520.69	$580.06	$580.06	$567.64	$613.90	$283.62	$320.88	$320.88
Enrollee expenses for covered benefits (deductibles, copays, etc.)	$40.89	$47.62	$104.14	$116.01	$116.01	$194.56	$210.41	$151.26	$171.14	$171.14
Enrollee expenses for benefits not covered (b)	$0.00	$0.00	$0.01	$0.01	$0.01	$0.00	$0.00	$0.00	$0.01	$0.01
Total expenditures	$466.12	$536.73	$624.83	$696.08	$696.08	$762.20	$824.32	$434.89	$492.02	$492.02

Source: California Health Benefits Review Program, 2013.

Note: (a) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

(b) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

Table 6.1 Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2014

	DMHC-Regulated							CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			CalPERS HMOs (b)	Medi-Cal Managed Care Plans			Privately Funded Plans (by Market) (a)			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65	Medi-Cal/Formerly Healthy Families Program (d)	Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state mandates (e)	11,289,000	2,479,000	1,029,000	854,000	688,000	5,203,000	626,000	539,000	1,315,000	1,877,000	25,899,000
Total enrollees in plans/policies subject to AB 912	11,289,000	2,479,000	1,029,000	854,000	0	0	0	539,000	1,315,000	1,877,000	19,382,000
Average portion of premium paid by employer	$0.01	$0.01	$0.00	$0.01	$0.00	$0.00	$0.00	$0.01	$0.01	$0.00	$1,985,000
Average portion of premium paid by employee	$0.00	$0.00	$0.01	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.01	$882,000
Total premium	$0.01	$0.01	$0.01	$0.01	$0.00	$0.00	$0.00	$0.01	$0.01	$0.01	$2,867,000
Enrollee expenses for covered benefits (deductibles, copays, etc.)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.01	$354,000
Enrollee expenses for benefits not covered (f)	$0.00	$0.00	−$0.01	−$0.01	$0.00	$0.00	$0.00	$0.00	$0.00	−$0.01	−$1,105,000
Total expenditures	$0.01	$0.01	$0.01	$0.01	$0.00	$0.00	$0.00	$0.01	$0.01	$0.01	$2,115,000
Percentage Impact of Mandate											
Insured premiums	0.0024%	0.0026%	0.0024%	0.0030%	0.0000%	0.0000%	0.0000%	0.0020%	0.0017%	0.0031%	0.0022%
Total expenditures	0.0016%	0.0017%	0.0016%	0.0020%	0.0000%	0.0000%	0.0000%	0.0013%	0.0011%	0.0021%	0.0015%

Source: California Health Benefits Review Program, 2013.

Note: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, inside and outside the exchange.

(b) As of September 30, 2012, 57.5%, or 469,000, CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2014.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who also have Medicare coverage.

(d) Children in Healthy Families, California's CHIP, will be moved into Medi-Cal Managed Care by January 1, 2014, as part of the 2012–2013 budget.

(e) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

(f) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

Table 6.2 Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures in Small and Individual Markets by Grandfathered Status, California, 2014

	Privately Funded DMHC-Regulated					Privately Funded CDI-Regulated				
	Small Group		Individual Market			Small Group		Individual Market		
	Grand-fathered	Nongrand-fathered	Grand-fathered	Nongrand-fathered	Nongrand-fathered Exchange	Grand-fathered	Nongrand-fathered	Grand-fathered	Nongrand-fathered	Nongrand-fathered Exchange
Total enrollees in plans/policies subject to state mandates (a)	231,000	2,248,000	575,000	38,000	416,000	51,000	1,264,000	762,000	95,000	1,020,000
Total enrollees in plans/policies subject to AB 912	231,000	2,248,000	575,000	38,000	416,000	51,000	1,264,000	762,000	95,000	1,020,000
Average portion of premium paid by employer	$0.00	$0.01	$0.00	$0.00	$0.00	$0.00	$0.01	$0.00	$0.00	$0.00
Average portion of premium paid by employee	$0.00	$0.00	$0.01	$0.01	$0.01	$0.00	$0.00	$0.01	$0.01	$0.01
Total premium	$0.01	$0.01	$0.01	$0.01	$0.01	$0.00	$0.01	$0.01	$0.01	$0.01
Enrollee expenses for covered benefits (deductibles, copays, etc.)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.01	$0.01
Enrollee expenses for benefits not covered (b)	$0.00	$0.00	−$0.01	−$0.01	−$0.01	$0.00	$0.00	$0.00	−$0.01	−$0.01
Total expenditures	$0.01	$0.01	$0.01	$0.01	$0.01	$0.00	$0.01	$0.01	$0.01	$0.01
Percentage Impact of Mandate										
Insured premiums	0.0017%	0.0027%	0.0025%	0.0022%	0.0023%	0.0000%	0.0018%	0.0033%	0.0030%	0.0031%
Total expenditures	0.0011%	0.0018%	0.0017%	0.0015%	0.0015%	0.0000%	0.0012%	0.0021%	0.0020%	0.0020%

Source: California Health Benefits Review Program, 2013.
Note: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, inside and outside the exchange.
(b) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.
Key: CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

PUBLIC HEALTH IMPACTS

Assembly Bill (AB) 912 would require group and individual market Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated policies to provide coverage for "medically necessary expenses for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause iatrogenic infertility to an enrollee." In line with the rest of this report, the public health analysis focuses on the cancer patient population, and acknowledges that other persons with diseases at risk of iatrogenic infertility may also clinically qualify for fertility preservation services.

This section presents the overall public health impact of AB 912 followed by an analysis examining the potential for reduction in gender and racial/ethnic disparities in health outcomes and the potential for the mandate to reduce premature death and societal economic losses.

As presented in the *Medical Effectiveness* section, there is a preponderance of evidence that embryo cryopreservation (freezing of embryos), oocyte (egg) cryopreservation, conservative gynecologic surgery, and sperm cryopreservation are effective methods of fertility preservation. In addition, there is insufficient evidence to evaluate the effectiveness of ovarian transposition, ovarian shielding from radiation, and testicular shielding from radiation. The following treatments are considered experimental: ovarian tissue cryopreservation and transplantation; ovarian suppression with gonadotropin-releasing hormone (GnRH) analogs or antagonists; sperm cryopreservation after alternative methods of sperm collection; testicular tissue cryopreservation; and testicular suppression with GnRH analogs or antagonists.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP estimates that 8.3% of enrollees in DMHC-regulated plans and CDI-regulated policies subject to AB 912 are currently covered for fertility preservation services. CHBRP cites literature stating that current utilization of the three most established methods of fertility preservation—embryo, oocyte, and sperm cryopreservation—*without* insurance coverage is 1.8%, 1.8%, and 24% respectively, among persons of reproductive age with invasive cancers. For enrollees *with* coverage for fertility preservation services, utilization is estimated to be 5.9% for both embryo and oocyte cryopreservation and 29% for sperm cryopreservation. CHBRP estimates the treatment cost premandate for female enrollees (for embryo and oocyte cryopreservation) to be $932,000 and $420,000 for male enrollees (for sperm cryopreservation), for a total annual treatment cost of $1.35 million.

Research shows that the overall financial burden faced by cancer patients can be substantial (Bennett et al., 1998; Covinsky et al., 1996; Emanuel et al., 2000). For most cancer patients who are concerned with maintaining their fertility, they also have the burden of paying for their fertility preserving services. AB 912 would decrease the net enrollee expenses for fertility preservation services by almost $0.75 million annually (from $1.1 million to $354,000 annually, Table 1).

CHBRP estimates that AB 912 would reduce the net financial burden by almost $750,000 across enrollees who would have paid for fertility preservation services to prevent iatrogenic infertility.

The practice guidelines issued by the American Society of Clinical Oncology (ASCO) indicate that all patients of childbearing age should be counseled about their fertility preservation options prior to starting treatment that could impair their future fertility (Lee et al., 2006). One study found that half of the patients of reproductive age are counseled regarding their fertility preservation options, although among breast cancer patients, this rate is closer to three-quarters (Partridge et al., 2004; Quinn et al., 2009). The rate of fertility preservation counseling may be less than 50% for patients who are under 18 and are in puberty (Kohler et al., 2011). There are many reasons for the relatively low referral rates for fertility preservation, and perceived costs may be one. Schover et al. (2002) found that perceptions of high costs related to sperm cryopreservation was one of the key barriers leading to 48% of oncologists never or rarely mentioning sperm cryopreservation as an option to their patients. This finding suggests that AB 912 could increase physician referrals for fertility preservation.

AB 912 could potentially increase the rate of physician referrals for fertility preservation by eliminating out-of-pocket costs for cancer patients.

Loss of fertility can negatively impact the quality of life for cancer survivors of reproductive age, including unresolved grief, depression, and anxiety (Avis et al., 2004; Lee et al., 2006; Wallace et al., 2005). For instance, one survey of breast cancer patients of reproductive age documented that 39% were very concerned about their fertility, 18% were somewhat concerned, 16% were a little concerned, and 27% were not concerned at all (Partridge et al., 2004). Distress regarding iatrogenic infertility can persist for many years, as demonstrated by one study that contacted women 10 years after they received cancer treatment (Canada and Schover, 2012).

AB 912 would potentially improve the quality of life for a portion of the 7,650 enrollees facing iatrogenic infertility each year who would opt for fertility preservation services.

Long-Term Public Health Impacts

The long-term impacts of AB 912 (beyond the 1-year time frame for CHBRP analyses) could yield an additional number of live births annually. AB 912 does not provide coverage for assisted reproductive technologies (ART) (Figure 1) using thawed reproductive material that had been cryopreserved; however CHBRP estimates an increase in the use of fertility preservation services among enrollees subject to AB 912 that could result in increased use of ART for conception in the long term. In calculating estimates for increased use of treatment for conception, CHBRP assumed that utilization rates of cryopreserved embryos, oocytes, and sperm account for potential cost barriers such as insurance coverage for infertility treatments and related direct costs to the patient.

The *Benefit Coverage, Utilization, and Cost Impacts* section estimated that there would be approximately 198 more males using sperm cryopreservation as a result of AB 912. About 5% of cancer patients who cryopreserve their sperm retrieve their frozen sperm for reproductive purposes (Bizet et. al., 2012; Chung et al., 2004). This percentage is similar to other international rates of utilization of cryopreserved sperm (Chang et al., 2006; Navarro Medina et al., 2010; Soda et al., 2009). Therefore, as a result of AB 912, approximately 10 more patients who froze sperm could be expected to retrieve and use their cryopreserved sperm. As reported in the

Medical Effectiveness section, the rate of live births among cancer patients retrieving their cryopreserved sperm is approximately 50% (Bizet et. al., 2012; Hourvitz et al., 2008; van Casteren et al., 2008). Therefore, CHBRP estimates that five more male cancer patients would produce biological children per year. (For further details on how these estimates were calculated, please see Appendix F at the end of this document.)

The long-term impacts of AB 912 are estimated to result in approximately five more male cancer patients producing biological children each year.

The *Benefit Coverage, Utilization, and Cost Impacts* section shows an estimated 63 more female enrollees using embryo cryopreservation as a result of AB 912. About 18% of female cancer patients who cryopreserve embryos ultimately return to thaw these embryos (Michaan et al., 2010). Therefore, as a result of AB 912, approximately 11 more patients who froze embryos could be expected to thaw and transfer embryos. As reported in the *Medical Effectiveness* section, delivery rates using cryopreserved embryos are reported to be 35% (SART, 2013). Therefore, CHBRP estimates that about 4 female cancer patients per year could become pregnant and deliver.

The *Benefit Coverage, Utilization, and Cost Impacts* section shows an estimated 63 more female enrollees using oocyte cryopreservation as a result of AB 912. However, CHBRP was unable to locate any published studies on the rate that cancer patients return to thaw and use the oocytes, and so is unable to calculate the rate of live births that may occur as a result of AB 912.

CHBRP estimates that, in the long term, AB 912 could result in approximately four more female cancer patients becoming pregnant and delivering each year using embryo cryopreservation. The long-term public health impact of AB 912 for women using oocyte cryopreservation is unknown.

CHBRP found few studies focusing on another long-term public health outcome: the health of children born using assisted reproductive technologies that involve cryopreservation. Those who did study this population reported similar perinatal outcomes for fresh and frozen embryo transfers and spontaneous conception. Specifically, they found the cryopreservation process did not affect child development or growth (Aflatoonian et al., 2010; Wennerholm et al., 1997, 1998). Aflatoonian et al., measured prematurity, low birthweight, stillbirth, neonatal death, and major malformation. Wennerholm et al. studied gestational age, preterm birth, major malformations, and mortality and followed up 18 months later to study growth, chronic illness, major malformations, and development. Additionally, two systematic literature reviews assessed the evidence from more than 40 studies of children born as a result of assisted reproductive technologies. The authors concluded that ART-conceived children are generally healthy and develop similarly to those children conceived spontaneously; however, ART-conceived children appear to be at higher risk for low birth weight (Ludwig et al., 2006; Basatemur et al., 2008). Low birth weight can lead to developmental delays and other health problems. However, single births resulting from assisted reproductive technologies are likely to be full-term pregnancies and have birth weights in the healthy range. The authors caution that the research is somewhat limited in that most of the evidence is available for younger children, not older children and young adults, and there are no prospective studies yet available to shed more light on the long-term health implications of this new medical technology.

Impact on Gender and Racial Disparities

Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: *A health disparity/inequality is a particular type of difference in health or in the most important influences of health that could potentially be shaped by policies; it is a difference in which disadvantaged social groups (such as the poor, racial/ethnic minorities, women or other groups that have persistently experienced social disadvantage or discrimination) systematically experience worse health or great health risks than more advantaged groups* (Braveman, 2006).

CHBRP investigated the effect that AB 912 would have on health disparities by gender, race, and ethnicity. Evaluating the impact on racial and ethnic disparities is particularly important because racial and ethnic minorities report having poorer health status and worse health indicators (KFF, 2007). One important contributor to racial and ethnic health disparities is differential rates of insurance, where minorities are more likely than whites to be uninsured; however disparities still exist within the insured population (Kirby et al., 2006; Lillie-Blanton and Hoffman, 2005). Because AB 912 would only affect the insured population, a literature review was conducted to determine whether there are gender, racial, or ethnic disparities associated with the prevalence and treatment of iatrogenic infertility outside of disparities attributable to differences between insured and uninsured populations.

Impact on Gender Disparities

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, AB 912 would decrease the out-of pocket expenses of patients utilizing fertility preservation services by almost $0.75 million. This is comprised of a reduction in enrollee expenses for noncovered benefits ($1.1 million) and an increase in enrollee out-of-pocket expenses for the newly covered benefits ($0.3 million). For males, sperm cryopreservation is the standard method of preserving fertility, costing approximately $400. For females, oocyte and embryo cryopreservation are the standard methods of preserving fertility. These cryopreservation treatments are estimated to cost $11,200 (oocyte) and $14,700 (embryo). Therefore, females are facing costs for preserving fertility that are more than 28–35 times that faced by males. The utilization rates of these services were assumed to increase from 24% (without coverage) to 29% (with coverage) among males and from 3.6% (without coverage) to 11.8% (with coverage; combining embryo and oocyte cryopreservation) among females.

AB 912 is expected to decrease the gender disparity by reducing females' financial burden of fertility preservation services. CHBRP estimates that females would still be likely to face a greater out-of-pocket expense burden than males postmandate.

Impact on Racial/Ethnic Disparities

CHBRP could find no evidence that evaluated the extent to which iatrogenic infertility varied by race/ethnicity. Only a handful of recently published studies examine racial and ethnic disparities regarding fertility preservation services, and all of these studies were conducted with women cancer patients. For instance, Goodman and colleagues found that 30% of eligible White women were referred for a fertility preservation consultation compared to 17% of eligible African American women, 13% of eligible Asian American women, and no Hispanic women (out of 19

eligible). After controlling for other factors such as income and education, White women were still more than twice as likely to be referred for fertility preservation consultation compared to women of color (Goodman et al., 2012). Letourneau investigated the utilization of fertility preservation services among cancer patients, and found that white women were slightly more likely to use services compared to Hispanic women, but the difference was not statistically significant (Letourneau et al., 2012c). This finding is in contrast to Lee's study which found no difference in utilization of fertility preservation services by race/ethnicity (Lee et al., 2011).

Because of the limited number of studies on disparities in the use of fertility preservation services by race/ethnicity, the extent to which AB 912 would have an impact on disparities is unknown.

Impacts on Premature Death and Economic Loss

Premature Death

Although cancer is a substantial cause of premature mortality in California, fertility preservation services do not address premature mortality. As stated in the *Medical Effectiveness* section, there is no evidence that women undergoing conservative gynecologic surgery have worse cancer treatment outcomes compared to those women who do not undergo fertility preservation services.

The enactment of AB 912 would not be expected to result in a reduction in premature death because fertility preservation treatments are unrelated to premature mortality.

Economic Loss

Although cancer in California is a substantial cause of lost productivity due to illness, and fertility preservation services may require some time off from work to accommodate medical visits (e.g., oocyte and embryo banking require multiple doctor visits over 2–3 weeks and 1 day off for surgery; transposition may require a 1 week off of work for surgery), CHBRP found no estimates of fertility preservation-related economic loss. Therefore, the impact of AB 912 on economic loss associated with fertility preservation is unknown.

The impact of AB 912 on economic loss related to fertility preservation services is unknown due to lack of data.

Summary

CHBRP estimates that coverage of fertility preservation services for iatrogenic infertility could result in about nine live births on an annual basis. Though the number of births in California would be small, these births would have significant impact for the families involved.

APPENDICES

Appendix A: Text of Bill Analyzed

On February 25, 2013, the Assembly Committee on Health requested that CHBRP analyze AB 912.

ASSEMBLY BILL 912

Introduced by Assembly Member Quirk-Silva

FEBRUARY 22, 2013

An act to add Section 1374.551 to the Health and Safety Code, and to add Section 10119.61 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 912, as introduced, Quirk-Silva. Health care coverage: fertility preservation.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Under existing law, a health care service plan and a health insurer are required to offer group coverage for the treatment of infertility, as defined.

This bill would require a health care service plan and a health insurer to provide, on a group and individual basis, coverage for medically necessary expenses for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause iatrogenic infertility to an enrollee or insured.

Because the bill would specify additional requirements for a health care service plan under the act, the willful violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1374.551 is added to the Health and Safety Code, immediately following Section 1374.55, to read:

1374.551. Every group or individual health care service plan that is issued, amended, or renewed on and after January 1, 2014, that provides hospital, medical, or surgical coverage shall include coverage for medically necessary expenses for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause iatrogenic infertility to an enrollee.

SEC. 2. Section 10119.61 is added to the Insurance Code, immediately following Section 10119.6, to read:

10119.61. Every health insurer that issues, amends, or renews a policy on and after January 1, 2014, that covers hospital, medical, or surgical expenses on a group or individual basis shall include coverage for medically necessary expenses for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause iatrogenic infertility to an insured.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review conducted for this report. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, Publication Types, and Keywords, follows.

Studies of the effects of fertility preservation treatments for patients at risk iatrogenic infertility were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, and Business Source Complete. Websites maintained by the following organizations were also searched: Agency for Healthcare Research and Quality; American Cancer Society; American College of Obstetricians and Gynecologists; Fertile Hope Program; Institute for Clinical Systems Improvement; International Network of Agencies for Health Technology Assessment; National Comprehensive Cancer Network, Inc.; National Guideline Clearinghouse; National Institute for Clinical Excellence; National Institutes of Health; National Health Service Centre for Reviews and Dissemination; Oncofertility Consortium; Scottish Intercollegiate Guideline Network; and World Health Organization.

The search was limited to abstracts of studies published in English. The medical effectiveness search was limited to studies published from 2011 to present, because CHBRP had previously reviewed this literature using the same search terms in 2011 for the AB 428 analysis. The literature on the effectiveness of fertility preservation treatments did not include any randomized controlled trials. The majority of the papers returned were case reports or systematic reviews. Findings from the literature review are summarized in Tables 2 and 3, which appears in the *Medical Effectiveness* section.

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

Abstracts for 913 articles, of which 511 were reviewed for inclusion in this report. A total of 18 new studies were included in the medical effectiveness review for AB 912.

Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach.*[58] To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and

[58] Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- Clear and convincing evidence;
- Preponderance of evidence;
- Ambiguous/conflicting evidence; and
- Insufficient evidence.

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *ambiguous/conflicting evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient* evidence indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

Search Terms (* indicates truncation of the word stem)

PubMed

Medical Subject Headings (MeSH)—PubMed

Antineoplastic Agents/adverse effects
Continental Population Groups
Cost of Illness
Cost Sharing
Costs and Cost Analysis
Cryopreservation
economics [Subheading]
Ethnic Groups
Fertility
Fertility Preservation
Gonads/drug effects
Gonads/radiation effects
Health Services Needs and Demand/economics

Health Services Needs and Demand/statistics and numerical data
Health Services Needs and Demand/utilization
Health Status Disparities
Iatrogenic Disease
Iatrogenic Disease/economics
Infertility
Infertility/economics
Infertility/epidemiology
Infertility/ethnology
Infertility/etiology
Insurance Coverage
Menopause, Premature
Minority Health
Neoplasms
Neoplasms/complications
Neoplasms/drug therapy
Neoplasms/radiotherapy
Neoplasms/surgery
Neoplasms/therapy
Oocyte Retrieval
Organ Sparing Treatments
Pregnancy
Pregnancy Outcome
Pregnancy Rate
Primary Ovarian Insufficiency
Quality of Life
Radiotherapy/adverse effects
Reproductive Techniques, Assisted
Reproductive Techniques, Assisted/economics
Reproductive Techniques, Assisted/statistics and numerical data
Semen Preservation
Sperm Banks
Sperm Retrieval
supply and distribution [Subheading]
Treatment Failure
Treatment Outcome
utilization [Subheading]
Utilization Review

Keywords—PubMed

abnormal
access
access barriers
accessibil*
benefit
benefit cap
birth defect
burden*
cancer
cervicectomy
co-payment
coinsurance
conservative
copayment
cost
cost analysis
cost benefit
cost effective
cost effectiveness
cost of treatment
cost offset
cost savings
cost sharing
cost utility
costs
coverage
cryopreservation
deductible
delivery
demand
demographic
demographics
disparities
disparity
egg
eggs
embryo
embryos
ethnic
ethnicity
expenditure
extraction
fertility
fertility preservation
fertility sparing
financial
freeze
freezing
frozen
gender
generosity
gnrh
gnrha
gonad
gonadal
gonadotropin releasing hormone
gonads
health care
iatrogenic
iatrogenic infertility
incidence
incremental cost effectiveness ratio
infertility
insurance
karyotype
loss
mandate
mandates
men
oncofertility
oocyte
oocyte retrieval
oocytes
oophoropexy
out-of-pocket
outcome assessment
ovarian
ovarian transposition
patient
patients
payment
pregnancy
premature menopause
premature ovarian failure
preservation
prevalence
price
price elasticity
quality of life
racial
retrieval
risk
safe
semen
sexism
shielding
spending
sperm banking
sperm banks
sperm extraction
sperm retrieval
suppression
surgery
testes
testicular
tier
trachelectomy
treatment
treatment-related infertility
treatment cost
treatment related
unit cost
utilisation
utilization
vitrification
women

Business Source Complete, EconLit, & Cochrane Library
Keywords

cancer
cervicectomy
conservative cancer surgery
cryopreservation
egg
eggs
embryo
embryos
fertility
fertility preservation
fertility sparing
freeze
freezing
gnrh
gnrha
gonad
gonadal
Gonadotropin Releasing
Hormone
gonads
iatrogenic infertility
infertility
oncofertility
oocyte
oocyte retrieval
oocytes
oophoropexy
organ sparing
ovarian
ovarian failure
ovarian transposition
pregnancy
premature menopause
premature ovarian failure
preserv*
preservation
preservation sperm extraction
semen
shielding
sperm
Sperm Bank*
sperm extraction
sperm retrieval
suppression
testes
testicular
trachelectomy
treatment-related infertility

Web of Science
Keywords
abnormal
absenteeism
access
accessibility
benefit cap
benefit caps
birth
birth defect
cancer
co-payment
coinsurance
cost
cost barriers
cost effective
cost effectiveness
cost sharing
costs
cryopreservation
deductible
delivery
demand
disparities
disparity
economic
economic loss
egg
eggs
embryo
embryos
ethnic
ethnicity
expenditure
fertility
fertility preserv*
fertility preservation
financial burden*
freeze
freezing
frozen
gender
gnrh
gnrha
gonad
gonadal
gonadotropin releasing
hormone
gonads
iatrogenic infertility
incidence
insurance
karyotype
long term outcome
long term outcomes
oncofertility
oocyte
oocyte retrieval
oocytes
oophoropexy
out-of-pocket
out of pocket
ovarian
payment
pregnancy
preserv*
preservation
prevalence
price
price elasticity
public health
quality of life
risk
safe
semen
spending
sperm
sperm bank*
sperm extraction
sperm retrieval
suppression
testicular
treatment-related infertility
utilisation
utilization
vitrification

Appendix C: Summary Findings on Medical Effectiveness

Appendix C describes the meta-analyses, systematic reviews, and individual studies on fertility preservation treatments that were analyzed by the medical effectiveness team. Table C-1 provides a description of each of the studies included in the *Medical Effectiveness* section including the type of study, the study objective, the population studied, and the location of the study. Table C-2 provides additional information on the findings from each of the studies.

Table C-1. Summary of Published Studies on Effectiveness of Fertility Preservation Treatments

Citation	Type of Study	Study Objective	Population Studied	Location
ASRM, 2013	Literature review of 4 randomized control trials	To document and provide recommendations regarding the current technology, clinical outcomes, and risks of mature oocyte cryopreservation.	Females cryopreserving oocytes	United States, Spain
Ata et al., 2010	Literature review	To review the currently available literature on the cryopreservation of unfertilized oocytes and embryos.	Female cancer patients	Europe
Beiner and Covens, 2007	Meta-analysis of 7 studies	To assess the effects of radical vaginal trachelectomy as a method of fertility preservation for cervical cancer.	Females with cervical cancer that received trachelectomy	United States, Canada, and Europe
Bizet et al., 2012	Retrospective analysis	To analyze sperm cryopreservation activity and outcomes for 1,007 patients referred to cryopreserve sperm before cancer treatment.	Male cancer patients	France
Cobo and Diaz, 2011	Meta-analysis of 3 randomized control trials	To conduct a systematic review of the literature of RCTs assessing the efficacy of oocyte vitrification	Females undergoing ovarian stimulation and oocyte cryopreservation	Multiple countries
Dunn and Fox, 2009	Literature review	To outline the risks of infertility from breast cancer treatment, and to illustrate current techniques in preserving fertility in breast-cancer patients who wish to become pregnant after treatment is concluded.	Women with breast cancer	Multiple countries
Dursun et al., 2007	Literature review	To present a review of the most recent articles about radical vaginal trachelectomy.	Postpubertal females with early-stage cervical cancer	Multiple countries
Eskander et al., 2011	Literature review	To summarize the fertility sparing options for patients with cervical, ovarian and endometrial cancer.	Female patients with gynecologic cancer	Multiple countries
Formal et al., 2012	Paired randomized control trial	To assess the impact of oocyte vitrification by comparing vitrified and fresh oocytes.	Female patients at an academic medical center	United States

Table C-1. Summary of Published Studies on Effectiveness of Fertility Preservation Treatments (Cont'd)

Citation	Type of Study	Study Objective	Population Studied	Location
Georgescu et al., 2008	Literature review	To summarize the options for trying to preserve fertility in female cancer patients	Female cancer patients	Multiple countries
Gurgan et al., 2008	Literature review	To describe and review the pregnancy and assisted reproduction techniques in men and women after cancer treatment	Male and female cancer patients	Multiple countries
Hourvitz et al., 2008	Retrospective consecutive study	To investigate the efficacy of IVF–intracytoplasmic sperm injection (ICSI) in patients who cryobanked semen before cancer treatment	118 couples undergoing IVF-ICSI using pretreatment frozen sperm	Israel, United States
Lee et al., 2006	Literature review	To develop guidance to practicing oncologists about available fertility preservation methods and related issues in people treated for cancer	Male and female cancer patients	Multiple countries
Levine et al., 2010	Literature review	Assessing fertility preservation options for adolescent and young adult survivors of cancer	Adolescent and young adult males and females with cancer	Multiple countries
Parmegiani et al., 2011	Randomized control trial	To assess the safety of UV sterilization of liquid nitrogen and hermetical cryostorage of human oocytes by comparing outcomes of cryopreserved and fresh oocytes	Women <41 years old with more than 5 mature oocytes retrieved	Italy
Rodriguez-Macias Wallberg et al., 2009	Literature review	To review the clinical aspects of fertility preservation options in female cancer patients	Female cancer patients	Multiple countries
Roque et al., 2013	Meta-analysis of 3 clinical trials	To examine the available evidence comparing frozen to fresh embryos in terms of pregnancy rate and miscarriage	Infertility patients	Not provided
Seli and Tangir, 2005	Literature review	To discuss available fertility preservation options and discuss recently published data on experimental methods	Female cancer patients	Multiple countries
Thibaud et al., 1992	Case series of 18 females	To evaluate the effect of ovarian transposition during childhood or adolescence	Adolescent female cancer patients	France
van Casteren et al., 2008	Retrospective data analysis	To assess the use rate and ART outcome of the cryopreserved semen of cancer patients with an average follow-up of 7 years	Male cancer patients who were referred for semen cryopreservation between 1983 and 2004	Netherlands
van der Kaaij et al., 2010	Review article	To summarize data and fertility preservation options on fertility after chemotherapy in adult Hodgkin lymphoma patients	Adult Hodgkin lymphoma patients	Multiple countries

Source: California Health Benefits Review Program, 2013.
Key: ART=assisted reproductive technologies; IVF=in vitro fertilization; UV=ultraviolet.

Table C-2. Summary of Findings From Studies of the Effectiveness of Fertility Preservation Treatments

Citation (s)	Research Design	Findings	Conclusion
Fertility Options for Females: Embryo cryopreservation			
Lee et al., 2006	American Society of Clinical Oncology recommendations	• The method of fertility preservation for female patients with the highest likelihood of success is embryo freezing • Pregnancy rates are encouraging.	Embryo cryopreservation is considered an established fertility preservation method as it has routinely been used for storing surplus embryos after in vitro fertilization for infertility treatment.
Seli and Tangir, 2005[59]	Review article of 6 studies	• The post-thaw survival rate of embryos is in the range of 35%–90% • Implantation rates are between 8%–30% • Cumulative pregnancy rates can be more than 60%.	Embryo cryopreservation is an established technique with a well-defined success rate.
Dunn and Fox, 2009	Review article of 3 studies	• The transfer of two to three cryopreserved embryos at a time results in a pregnancy rate of 20% to 30%. • Average live birth rate of 27.7% per embryo transfer cycle in the United States.	Embryo cryopreservation remains the best known option for fertility preservation in women with early stage breast cancer whose fertility may be compromised by chemotherapy.
Rodriguez-Macias Wallberg et al., 2009	Review article of 2 studies	• Implantation rate following transfer of frozen-thawed embryos is up to 42%. • 59% pregnancy rate • 26% live birth rate.	Embryo freezing is a clinically accepted procedure.
Ata et al., 2010	Review article of 2 studies	• Pregnancy rate of 34% following frozen embryo transfer in women younger than 35 years • Overall pregnancy rate of 19%	Embryo cryopreservation is the most established fertility preservation technique if the patient has a partner and sufficient amount of time before cancer treatment.
Roque et al., 2013	Meta-analysis of 3 clinical trials	• Ongoing pregnancy rate frozen vs. fresh: RR=1.32 95% CI=1.10–1.59 • Clinical pregnancy rate frozen vs. fresh: RR=1.31 95% CI=1.10–1.56 • Miscarriage rate frozen vs. fresh: RR=0.83 95% CI=0.43–1.60	Compared to fresh embryos, cryopreserved embryos resulted in higher pregnancy rates and similar miscarriage rates.

[59] Although this publication date is 2005 and Lee et al. is 2006, this article came out past the cutoff point for inclusion in the Lee et al., 2006, review and is not included in that publication.

Table C-2. Summary of Findings From Studies of the Effectiveness of Fertility Preservation Treatments (Cont'd)

Citation (s)	Research Design	Findings	Conclusion
Fertility Options for Females: Oocyte (egg) cryopreservation			
ASRM, 2013	Review article of 4 randomized control trials	• Oocyte post-thaw survival range: 90%–97% • Fertilization rates range: 71%–79% • Implantation rates range: 17%–41% • Clinical pregnancy rates per transfer range: 36%–61% • Clinical pregnancy rates per thawed oocyte range: 4.5%–12%	Oocyte cryopreservation is recommended for patients facing iatrogenic infertility.
Forman et al., 2012	Randomized control trial	• Pregnancy rate per embryo transferred (vitrified vs. fresh): RR=0.93, 95% CI=0.57–1.52 • Embryonic genetic abnormalities (vitrified vs. fresh): RR=0.95, 95% CI=0.48–1.89	Oocyte cryopreservation using vitrification has similar implantation rates and no evidence of increased chromosomal abnormalities.
Parmegiani et al., 2011	Randomized control trial	• Fertilization rate 88.3% (fresh) vs. 84.9% (cryopreserved) • Pregnancy rate per cycle: 12.9% (fresh) vs. 35.5% (cryopreserved)	No significant differences on main outcome measures were observed between the fresh and cryopreserved-warmed oocytes.
Cobo and Diaz, 2011	Meta-analysis of 3 randomized control trials	• Fertility rate of vitrified and thawed oocytes vs. fresh oocytes: OR=1.02, 95% CI=0.91–1.13	No significant difference in fertilization rates between thawed and fresh oocytes.
Fertility Options for Females: Ovarian transposition (oophoropexy)			
Lee et al., 2006	American Society of Clinical Oncology recommendations	• The overall success rate as judged by preservation of short-term menstrual function is approximately 50%.	Transposition of the ovaries may preserve fertility in selected cancers.
Seli and Tangir, 2005	Review article of 3 studies	• Procedure has been successful in 16%–90% of reported cases.	Ovarian transposition is a relatively simple, minimally invasive and effective procedure that should be offered to reproductive-age patients who need pelvic radiation.
Georgescu et al., 2008	Review article of 3 studies	• Reduces radiation exposure to the ovaries to only 5% to 10% of nontransposed ovaries. • For women under age 40, 88.6% retained ovarian function and 89% of pregnancies were spontaneous with 75% occurring without repositioning the ovaries.	Ovarian transposition remains the standard of care for women undergoing pelvic radiation.
Thibaud et al., 1992	Case series of 18 females	• Ovarian function was maintained in 7 of 18 patients undergoing ovarian transposition (39%)	This study showed that ovarian function could be maintained in a small group of women.

Table C-2. Summary of Findings from Studies of the Effectiveness of Fertility Preservation Treatments (Cont'd)

Citation (s)	Research Design	Findings	Conclusion
Fertility Options for Females: Gonadal (ovarian) shielding during radiation therapy			
Lee et al., 2006	American Society of Clinical Oncology recommendations	No findings reported	Gonadal shielding prior to radiation therapy may preserve fertility for selected cancers.
Gurgan et al., 2008	Review article	No findings reported	Whenever possible, shielding the gonads may effectively reduce the adverse effects of radiotherapy on gonadal functions.
Levine et al., 2010	Review article	No findings reported	Shielding of the ovaries during radiotherapy is a standard medical practice, but expertise is required.
Fertility Options for Females: Conservative gynecologic surgery			
Lee et al., 2006	American Society of Clinical Oncology Recommendations	• Should be considered for certain kinds of gynecologic cancers if fertility preservation is desired and conservative surgery is appropriate, given the stage of cancer	Previous research is generally limited in size, but they do not indicate any obvious increased risk of conservative gynecologic surgery
Seli and Tangir, 2005	Meta-analysis of trachelectomy studies with a combined n=319	• 147 pregnancies with a 67% birth rate • Recurrence = 4.1% • Mortality = 2.5% • Comparable to early-stage cervical cancer treated with hysterectomy	Trachelectomy offers tremendous opportunity for women to preserve their fertility while hoping for long-term survival.
Eskander et al., 2011 (trachelectomy)	Meta-analysis of 10 trachelectomy studies with a combined n=582	• There were 257 pregnancies reported with a 64% live birth rate. • There were 23 cancer recurrences (3.9%) and 12 deaths (2%).	Selected patients with early-stage cervical cancer can benefit from fertility preserving surgical interventions
Beiner and Covens, 2007 (trachelectomy)	Meta-analysis of 7 trachelectomy studies with a combined n=548	• Of women attempting pregnancy, pregnancy rates were 41%–79%. • Preterm delivery rate (before 37 weeks) was approximately 20%. • 10% of pregnancies had a second trimester miscarriage. • Tumor recurrence rate of 5% and a mortality rate of 3% are comparable to rates observed with hysterectomy.	Trachelectomy is well established as a safe and feasible procedure for patients with early stage cervical cancer, with low morbidity, recurrence, and mortality rates.
Dursun et al., 2007 (trachelectomy)	Meta-analysis of 7 trachelectomy studies with a combined n=520	• A 70% pregnancy rate was reported in the women who wanted to conceive following trachelectomy. • Recurrence and death rates (4.2% and 2.8%, respectively) of trachelectomy seem to be comparable to hysterectomy.	Trachelectomy is a valid uterus-conserving surgery for women of reproductive age who have early-stage cervical carcinoma.

Table C-2. Summary of Findings From Studies of the Effectiveness of Fertility Preservation Treatments (Cont'd)

Citation (s)	Research Design	Findings	Conclusion
Eskander et al., 2011 (ovarian surgery)	Meta-analysis of 10 ovarian surgery studies with a combined n=626	• There were 185 pregnancies reported with a 75% live birth rate. • There were 111 cancer recurrences (18%) and 1 death (0.2%).	Fertility preservation should be considered in young patients desiring future childbearing who are appropriately staged and in whom the primary tumor can be completely removed.
Fertility Options for Males: Sperm cryopreservation after masturbation			
Lee et al., 2006	American Society of Clinical Oncology recommendations	No findings reported	The most established technique for fertility preservation in men, as shown in large cohort studies of men with cancer.
Hourvitz et al., 2008	Retrospective consecutive study	Cryopreserved sperm from men with cancer was used by 118 couples: • 56.8% pregnancy rate per retrieval • 50.3% delivery rate per retrieval	High pregnancy and delivery rates using cryopreserved sperm from cancer patients should encourage all reproductive-age males to freeze semen immediately after diagnosis.
van Casteren et al., 2008	Retrospective data analysis (n=37)	7.5% of the cancer survivors have used their banked semen, which led to live births in 49% of the couples.	Semen cryopreservation is a reliable method to preserve fertility potential and gives couples a reasonable chance of achieving parenthood.
Levine et al., 2010	Review article	Long-term follow-up studies have demonstrated successful pregnancies with sperm stored between 10 and 28 years.	The most reliable and well-established means of preserving fertility in males is cryopreservation of sperm before the onset of cytotoxic therapy.
van der Kaaij et al., 2010	Review article	Pregnancy and delivery rate of at least 54% has been demonstrated with cryopreserved semen (ranging from 33% to 73%). Longer storage did not correlate with lower pregnancy rates.	Semen cryopreservation before start of treatment is the easiest and safest option and widely available.
Bizet et al., 2012	Retrospective analysis	57 of 1,080 patients (6%) retrieved their cryopreserved sperm for use in IVF resulting in 46.8% cumulative birth rate.	There is a high level of successful sperm storage and utilization of cryopreserved sperm let to a good chance at pregnancy.
Fertility Options for Males: Gonadal shielding during radiation therapy			
Lee et al., 2006	American Society of Clinical Oncology recommendations	No findings reported	Gonadal shielding prior to radiation therapy may preserve fertility for selected cancers.
Levine et al., 2010	Review	No findings reported	Shielding of the testicles during radiotherapy is a standard medical practice, but expertise is required.

Source: California Health Benefits Review Program, 2013.
Key: CI = confidence interval; IVF = in vitro fertilization; RR=risk ratio.

Appendix D: Cost Impact Analysis: Data Sources, Caveats, and Assumptions

This appendix describes data sources, estimation methodology, as well as general and mandate-specific caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP website at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, San Diego, the University of California, Los Angeles, the University of California, Davis, and University of California, Berkeley, as well as the contracted actuarial firm, Milliman, Inc. (Milliman).[60]

Data Sources

In preparing cost estimates, the cost team relies on a variety of data sources as described below.

Baseline model

1. The California Simulation of Insurance Markets (CalSIM) is used to project health insurance status of Californians aged 64 and under in 2014. CalSIM is a microsimulation model that projects the effects of the Affordable Care Act on firms and individuals.[61] CalSIM relies on national Medical Expenditure Panel Survey (MEPS) Household Component and Person Round Plan, California Health Interview Survey (CHIS) 2009, and California Employer Health Benefits Survey data.
2. California Health Interview Survey (2011) data is used to estimate the number of Californians aged 65 and older, and the number of Californians dually eligible for both Medi-Cal and Medicare coverage. CHIS 2011 is also used to determine the number of Californians with incomes below 400% of the federal poverty level. CHIS is a continuous survey that provides detailed information on demographics, health insurance coverage, health status, and access to care. CHIS 2011 surveyed approximately 23,000 households and is conducted in multiple languages by the UCLA Center for Health Policy Research. More information on CHIS is available at www.chis.ucla.edu.
3. The latest (2012) California Employer Health Benefits Survey is used to estimate:
    a. Size of firm;
    b. Percentage of firms that are purchased/underwritten (versus self-insured);
    c. Premiums for health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and point of service [POS] plans); and

[60] CHBRP's authorizing legislation requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact (www.chbrp.org/docs/authorizing_statute.pdf).
[61] UC Berkeley Center for Labor Research and Education and UC Los Angeles Center for Health Policy Research. *Methodology & Assumptions, California Simulation of Insurance Markets (CalSIM) Version 1.7*, June 2012. Available at www.healthpolicy.ucla.edu/pubs/files/calsim_methods.pdf. Accessed October 19, 2012.

d. Premiums for health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service [FFS] plans).

This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. Information on the CHCF/NORC data is available at: www.chcf.org/publications/2010/12/california-employer-health-benefits-survey.

4. Milliman data sources are relied on to estimate the premium impact of mandates. Milliman's projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States. See www.milliman.com/expertise/healthcare/products-tools/milliman-care-guidelines/index.php. Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed health care plans, generally those characterized as preferred provider organization (PPO) plans. The HCGs currently include claims drawn from plans covering 37 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following:

    a. The MarketScan databases, which reflects the health care claims experience of employees and dependents covered by the health benefit programs of large employers. These claims data are collected from approximately 100 different insurance companies, Blue Cross Blue Shield plans, and third party administrators. These data represent the medical experience of insured employees and their dependents for active employees, early retirees, individuals with COBRA continuation coverage, and Medicare-eligible retirees with employer-provided Medicare Supplemental plans. No Medicaid or Workers Compensation data are included.

    b. An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2010 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2010 experience.

    c. Ingenix MDR Charge Payment System, which includes information about professional fees paid for health care services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.

    d. These data are reviewed for applicability by an extended group of experts within Milliman but are not audited internally.

5. Premiums and enrollment in DMHC-regulated health plans and CDI-regulated policies by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their dependents who receive their benefits through CalPERS. Enrollment information is provided for DMHC-regulated health care service plans covering non-Medicare beneficiaries—about 74% of CalPERS total

enrollment. CalPERS self-funded plans—approximately 26% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOC) documents publicly available at www.calpers.ca.gov. For the 2013 model, CHBRP assumes CalPERS's enrollment in 2014 will not be affected by the ACA.

6. Enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System plans) is estimated based on data maintained by the Department of Health Care Services (DHCS). CHBRP assesses enrollment information online at: www.dhcs.ca.gov/dataandstats/statistics/Pages/RASB_Medi-Cal_Enrollment_Trends.aspx. Starting with the 2013 model, the most recent Medi-Cal enrollment data from DHCS is projected to 2014 based on CalSIM's estimate of the impact of the Medi-Cal expansion in 2014.

Estimate of Premium Impact of Mandates

7. CHBRP's Annual Enrollment and Premium Survey collects information from the seven largest providers of health insurance in California (Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and United Healthcare/PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC-regulated or CDI-regulated), grandfathered and nongrandfathered status, and average premiums. Enrollment in plans or policies offered by these seven insurers represent an estimated 97.5% of the persons with health insurance subject to state mandates. This figure represents an estimated 97.9% of enrollees in full-service (nonspecialty) DMHC-regulated health plans and an estimated 96.1% of enrollees in full-service (nonspecialty) CDI-regulated policies.

   For CHBRP reports analyzing specific benefit mandates, CHBRP surveys the seven major carriers on current coverage relevant to the benefit mandate. CHBRP reports the share of enrollees—statewide and by market segment—reflected in CHBRP's bill-specific coverage survey responses. The proportions are derived from data provided by CDI and DMHC. CDI provides data by market segment (large, small, and individual) based on "CDI Licenses With HMSR Covered Lives Greater Than 100,000" as part of the Accident and Health Covered Lives Data Call September 30, 2011, by the California Department of Insurance, Statistical Analysis Division. The Department of Managed Health Care's interactive website "Health Plan Financial Summary Report," July–September 2012, provides data on DMHC-regulated plans by segment.[62]

The following table describes the data sources mentioned above, and the data items that they inform.

[62] CHBRP assumes DMHC-regulated PPO group enrollees and POS enrollees are in the large-group segment. http://wpso.dmhc.ca.gov/flash/.

Table D-1. Population and Cost Model Data Sources and Data Items

Data Source	Items
California Simulation of Insurance Markets (CalSIM)	Uninsured, age: 0–17; 18–64 Medi-Cal (non-Medicare) (a), age: 0–17; 18–64 Other public (b), age: 0–64 Individual market, age: 0–17; 18–64 Small group, age: 0–17; 18–64 Large group, age: 0–17; 18–64
California Health Interview Survey, 2011 (CHIS, 2011)	Uninsured, age: 65+ Medi-Cal (non-Medicare), age: 65+ Other public, age: 65+ Employer-sponsored insurance, age: 65+
CalPERS data, annually, enrollment as of September 30	CalPERS HMO and PPO enrollment • Age: 0–17; 18–64; 65+ HMO premiums
California Employer Survey, conducted annually by NORC and funded by CHCF	Enrollment by HMO/POS, PPO/indemnity self-insured, fully insured, Premiums (not self-insured) by: • Size of firm (3–25 as small group and 25+ as large group) • Family vs. single • HMO/POS vs. PPO/indemnity vs. HDHP employer vs. employer premium share
DHCS administrative data for the Medi-Cal program, annually, 11-month lag from the end of November	Distribution of enrollees by managed care or FFS distribution by age: 0–17; 18–64; 65+ Medi-Cal Managed Care premiums
CMS administrative data for the Medicare program, annually (if available) as of end of September	HMO vs. FFS distribution for those 65+ (noninstitutionalized)
CHBRP enrollment survey of the seven largest health plans in California, annually as of end of September	Enrollment by: • Size of firm (2–50 as small group and 51+ as large group), • DHMC vs. CDI regulated • Grandfathered vs. nongrandfathered Premiums for individual policies by: • DMHC vs. CDI regulated • Grandfathered vs. nongrandfathered
Department of Finance population projections, for intermediate CHIS years	Projected civilian, noninstitutionalized CA population by age: 0–17; 18–64; 65+
Medical trend influencing annual premium increases	Milliman estimate

Notes: (a) Includes children previously enrolled in Healthy Families, California's CHIP. By January 1, 2014, children enrolled in Healthy Families will be transitioned into Medi-Cal as required in the 2012–2013 state budget agreement.
(b) Includes individuals dually eligible for Medi-Cal and Medicare.
Key: CDI=California Department of Insurance; CHCF=California HealthCare Foundation; CHIS= California Health Interview Survey; CMS=Centers for Medicare & Medicaid Services; DHCS=Department of Health Care Services; DMHC=Department of Managed Health Care; FFS=fee-for-service; HMO=health maintenance organization; NORC=National Opinion Research Center; PPO=preferred provider organization.

Projecting the Effects of the Affordable Care Act in 2014

This subsection discusses adjustments made to CHBRP's Cost and Coverage Model to account for the potential impacts of the ACA effective January 2014. It is important to emphasize that CHBRP's analysis of specific mandate bills typically addresses the marginal effects of the mandate bill—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, *holding all other factors constant*. CHBRP's estimates of these marginal effects are presented in the *Benefit Coverage, Utilization, and Cost Impacts* section of this report.

Baseline premium rate development methodology—2014 post-ACA

Mandate bills introduced during 2013 would, if passed, become effective in 2014. Many significant provisions of the Affordable Care Act also become effective in 2014. In many cases, provisions required in the ACA would become effective on the same date as a mandate proposed to California law.

CHBRP's analyses of mandates effective in 2014 assume that carriers implement the new ACA provisions first. The baseline premiums reflect the estimated 2014 premium levels costs *after* carriers have implemented the 2014 ACA provisions. The estimated cost impact of a proposed mandate is then calculated relative to this post-ACA baseline.

The key components of the baseline model for utilization and expenditures are estimates of the per member per month (PMPM) values for each of the following:

- Insurance premiums PMPM;
- Gross claims costs PMPM;
- Member cost sharing PMPM; and
- Health care costs paid by the health plan.

For each plan type, we first obtained an estimate of the insurance premium PMPM by taking the 2012 reported premium from the above-mentioned data sources and trending that value to 2014. CHBRP uses trend rates published in the Milliman Health Cost Guidelines to estimate the health care costs for each plan segment in 2014.

In 2014, 4 plan segments in the previous CHBRP model[63] were split into 12 segments. Each of the two small-group segments (CDI-regulated and DMHC-regulated), and individual segments (CDI-regulated and DMHC-regulated) were split into: grandfathered non-exchange, nongrandfathered non-exchange, and exchange groups in order to separately calculate the impact of ACA and specific mandates that may apply differently to these three subgroups. The premium rate information received from NORC did not split the premiums based on grandfathered or exchange status. The 2012 CHBRP Annual Enrollment and Premium Survey asked the seven

[63] In the past, CHBRP's model has reflected large-group, small-group, and individual market segments. These market segments were further subdivided by regulator: DMHC-regulated and CDI-regulated. The four plan segments refer to the small and individual market subdivisions by regulator.

largest insurance carriers in California to provide their average premium rates separately for grandfathered and nongrandfathered plans. The ratios from the carrier survey data are then applied to the NORC aggregate premium rates, to estimate premium rates for grandfathered and nongrandfathered plans that were consistent with the NORC results.

The marginal impact of ACA on 2014 premiums was established as follows:

- For nongrandfathered small-group and individual market segments, a 3% increase in medical costs is applied to reflect the total cost of requiring each plan to cover the essential health benefits.
- For nongrandfathered small-group plans, a 5% increase in medical costs is applied to reflect the other additional costs of ACA (e.g., age rating, health status, increased premium taxes and fees, change in actuarial value, etc.).
- For DMHC-regulated individual plans and CDI-regulated individual policies, an increase of 20% and 31%, respectively, in medical costs is applied to reflect the other additional costs of ACA.

The remaining three values were then estimated by the following formulas:

- Health care costs paid by the health plan = insurance premiums PMPM × (1 − profit/administration load).
- Gross claims costs PMPM = health care costs paid by the health plan ÷ percentage paid by health plan
- Member cost sharing PMPM = gross claims costs × (1 − percentage paid by health plan)

In the above formulas, the quantity "profit/administration load" is the assumed percentage of a typical premium that is allocated to the health plan's administration and profit. These values vary by insurance category, and under the ACA, are limited by the minimum medical loss ratio requirement. CHBRP estimated these values based on Milliman's knowledge of the health care market.

In the above formulas, the quantity "percentage paid by health plan" is the assumed percentage of gross health care costs that are paid by the health plan, as opposed to the amount paid by member cost sharing (deductibles, copays, etc.). In ACA terminology, this quantity is known as the plan's "actuarial value." These values vary by insurance category. For each insurance category, Milliman estimated the member cost sharing for the average or typical plan in that category. Milliman then priced these plans using the Milliman Health Cost Guidelines to estimate the percentage of gross health care costs that are paid by the carrier.

Medi-Cal Managed Care: CHBRP is unable to project EHB-related marginal impact on Medi-Cal Managed Care premiums for the following reasons:

- **Newly eligible:** California has not yet decided on Medi-Cal's EHBs;

- **Currently eligible:** The ACA does not coverage of EHBs for individuals currently eligible for Medicaid.

Therefore, premiums for both newly eligible and currently eligible Medi-Cal enrollees, have been calculated using 2012 premium rates provided to CHBRP by DHCS.

General Caveats and Assumptions

The projected cost estimates are estimates of the costs that would result if a certain set of assumptions were exactly realized. Actual costs will differ from these estimates for a wide variety of reasons, including:

- Prevalence of mandated benefits before and after the mandate may be different from CHBRP assumptions.
- Utilization of mandated benefits (and, therefore, the services covered by the benefit) before and after the mandate may be different from CHBRP assumptions.
- Random fluctuations in the utilization and cost of health care services may occur.
- The impact of ACA on the mandated benefit cost may be different from CHBRP assumptions.

Additional assumptions that underlie the cost estimates presented in this report are:

- Cost impacts are shown only for plans and policies subject to state benefit mandate laws.
- Cost impacts are only for the first year after enactment of the proposed mandate.
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of the premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for 1 year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts, please see: http://chbrp.org/documents/longterm_impacts08.pdf.
- Several studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew et al., 2005; Glied and Jack, 2003; Hadley, 2006). Chernew et al. (2005) estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, whereas Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and a 0.84 percentage point decrease in the number of insured, respectively. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the simplifying assumption that the elasticity is the same across different types of markets. For more information on

CHBRP's criteria for estimating impacts on the uninsured, please see: http://chbrp.org/documents/uninsured_010109.pdf.

There are other variables that may affect costs, but which CHBRP did not consider in the cost projections presented in this report. Such variables include, but are not limited to:

- Population shifts by type of health insurance: If a mandate increases health insurance costs, some employer groups and individuals may elect to drop their health insurance. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefit plans: To help offset the premium increase resulting from a mandate, subscribers/policyholders may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and policies and enrollees, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). CHBRP did not include the effects of such potential benefit changes in its analysis.
- Adverse selection: Theoretically, individuals or employer groups who had previously foregone health insurance may now elect to enroll in a health plan or policy, postmandate, because they perceive that it is to their economic benefit to do so.
- Medical management: Health plans and insurers may react to the mandate by tightening medical management of the mandated benefit. This would tend to dampen the CHBRP cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., PPO plans).
- Geographic and delivery systems variation: Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the health insurance types CHBRP modeled (HMO—including HMO and POS plans—and non-HMO—including PPO and FFS policies), there are likely variations in utilization and costs by type. Utilization also differs within California due to differences in the health status of the local population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between providers and health plans or insurers. Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, CHBRP has estimated the impact on a statewide level.
- Compliance with the mandate: For estimating the postmandate coverage levels, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the coverage requirements of the bill. Therefore, the typical postmandate coverage rates for populations subject to the mandate are assumed to be 100%.

Bill Analysis-Specific Caveats and Assumptions

CHBRP estimated utilization of fertility preservation services, both pre- and postmandate, using cancer incidence rates grouped by age bands, the peer-reviewed literature, and input from content experts. Using data from the 2007-2009 National Cancer Institute (the Surveillance Epidemiology and End Results, or SEER, cancer statistics), cancer incidence rates were calculated for age bands that captured what would be considered reproductive age for fertility preservation services (Table D-2).

Table D-2. Age Bands Used to Calculate Cancer Incidence Rates in Analysis of AB 912

Females	Males
14 to <19	12 to <17
19 to <24	17 to <22
24 to <29	22 to <27
29 to <34	27 to <32
34 to <39	32 to <37
39 to <44	37 to <42
	42 to <47
	47 to <50

Source: California Health Benefits Review Program, 2013.

In its analysis, CHBRP included the types of cancer whose treatments pose the highest iatrogenic infertility risk (Table D-3).

Table D-3. Cancer Types Included in Analysis of AB 912

Females	Males
Colon and rectum—in situ and malignancy	Male genital system—malignancy
Breast—in situ and malignancy	Hodgkin lymphoma
Cervix—malignancy only	Non-Hodgkin lymphoma
Ovarian	Leukemia
Hodgkin lymphoma	Colon—malignancy only
Non-Hodgkin lymphoma	Brain/CNS—malignancy only
Leukemia	
Uterine	
Brain/CNS	

Source: California Health Benefits Review Program, 2013.
Key: CNS=central nervous system.

The utilization rates, both pre- and postmandate, were assumed to be consistent across all types of cancer due to the very limited relevant data in the literature or from content expert input. Also, these utilization rates, both pre- and postmandate, were assumed to be consistent across all age bands for males. For females, CHBRP estimated age-band specific utilization rates as detailed below.

Estimates of those who use fertility preservation services were not available using the SEER data. The body of literature on this topic is also thin. CHBRP estimated the utilization rate of sperm cryopreservation to increase from 24% (without insurance coverage) to 29% with insurance coverage (Schover et al., 2002). This insurance coverage effect on the utilization, 5 percentage points, was estimated as follows. In this study, 24% of males at risk for iatrogenic infertility utilized sperm cryopreservation and 76% did not. 7% of the latter group (76% of

males) was estimated to be approximately 5% overall and would have utilized the cryopreservation if the cost were reduced (Schover et al., 2002). From these, CHBRP estimated that the postmandate use of sperm cryopreservation would rise from 1,051 (when 8.3% of male enrollees had insurance coverage for sperm cryopreservation) to 1,249 (when 100% had insurance coverage) of male enrollees who are cancer patients and are at risk for iatrogenic infertility.

To calculate the use of fertility preservation services by female enrollees, CHBRP relied on both content expert input and a published study (Letourneau et al., 2012a), which indicated that 4% of women who face iatrogenic infertility without coverage are likely to use fertility preservation services and that this would rise to 12.9% with coverage. CHBRP applied the unique utilization rate for each of six age bands indicated in Table D-2, adjusting the age distribution of the study (Letourneau et al., 2012a) to be consistent with the entire enrollees subject to AB 912. From this, CHBRP estimated that the combined utilization rate for embryo and oocyte cryopreservation for women in DMHC-regulated plans and CDI-regulated policies subject to AB 912 who face iatrogenic infertility would be 3.6% without coverage, and that this would rise to 11.8% with coverage. For instance the baseline utilization rate ranged from 2.8% (for aged 39–43) to 5.2% (aged 34–38). After the bill mandate, the utilization rate is assumed to rise 9.2% (for aged 39-43) to 16.4% (aged 34–38). Based on Letourneau et al. and content expert input, CHBRP assumed that half of these utilization rates are for embryo cryopreservation and half are for oocyte cryopreservation. Consequently, CHBRP estimates that 198 female enrollees would use fertility preservation services postmandate.

In total, utilization of fertility preservation services is estimated to increase to 1,447 (from 1,123) out of the total 7,650 enrollees who have cancer and would be at risk for iatrogenic infertility.

Appendix E: Information Submitted by Outside Parties

In accordance with CHBRP policy to analyze information submitted by outside parties during the first 2 weeks of the CHBRP review, the following parties chose to submit information.

The following information was submitted by the Office of Assembly Member Quirk-Silva in March 2013.

American Society of Clinical Oncology (ASCO). Available at: www.asco.org. Accessed March 6, 2013.

American Society of Clinical Oncology (ASCO). ASCO University. 2010 ASCO Annual Meeting. Available at: meetinglibrary.asco.org/subcategories/2010+ASCO+Annual+Meeting. Accessed March 6, 2013.

American Society of Clinical Oncology (ASCO). ASCO University. 2010 ASCO Annual Meeting. Abstracts. Available at: meetinglibrary.asco.org/abstracts?vmview=abst_detail_view. Accessed March 6, 2013.

California Department of Public Health (CDPH). California Pregnancy-Associated Mortality Review (CA-PAMR). 2013. Available at: www.cdph.ca.gov/data/statistics/Pages/CaliforniaPregnancy-AssociatedMortalityReview.aspx. Accessed March 6, 2013.

California Department of Public Health (CDPH). Chronic Disease Surveillance and Research Branch (CDSRB). 2013. Available at: www.cdph.ca.gov/programs/csrb/Pages/default.aspx. Accessed March 6, 2013.

Callaghan WM, Creanga AA, Kuklina EV. Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. *Obstetrics and Gynecology.* 2012;120:1029-1036.

Tuncalp O, Hindin MJ, Souza JP, Chou D, Say L. The prevalence of maternal near miss: a systematic review. *British Journal of Obstetrics and Gynaecology.* 2012;119:653-661.

Submitted information is available upon request.

For information on the processes for submitting information to CHBRP for review and consideration please visit: www.chbrp.org/requests.html.

Appendix F: Public Health Calculations

These are the calculations used to derive the estimated live births attributable to AB 912.

Impact on Men:

Number of additional men using cryopreservation postmandate: 198. The *Benefit Coverage, Utilization, and Cost Impacts* section estimated that there would be approximately 198 more males using sperm cryopreservation as a result of AB 912.

Proportion of men who eventually retrieve frozen sperm: 5%. About 5% of cancer patients who cryopreserve their sperm retrieve their frozen sperm for reproductive purposes (Bizet, et. al., 2012; Chung et al., 2004). This percentage is similar to other international rates of utilization of cryopreserved sperm (Chang et al., 2006; Navarro Medina et al., 2010; Soda et al., 2009).

Proportion of live births using cryopreserved sperm: 50%. As reported in the *Medical Effectiveness* section, the rate of live births among cancer patients retrieving their cryopreserved sperm is approximately 50% (Bizet, et. al., 2012; Hourvitz et al., 2008; van Casteren et al., 2008).

Expected outcomes of the bill: Five percent of the additional 198 male enrollees using sperm cryopreservation would retrieve their sperm ($0.05 \times 198 = 9.90$), and 50% of those attempts would result in live births ($9.9 \times 0.5 = 4.95$), or about five live births.

Impact on Women:

Number of additional women using embryo cryopreservation postmandate: 63. The *Benefit Coverage, Utilization, and Cost Impacts* section shows an estimated 63 more female enrollees using embryo cryopreservation as a result of AB 912.

Proportion of women who eventually retrieve frozen embryos: 18%. About 18% of female cancer patients who cryopreserve embryos ultimately return to thaw these embryos (Michaan et al., 2010).

Proportion of live births using cryopreserved embryos: 35%. As reported in the *Medical Effectiveness* section, delivery rates using cryopreserved embryos are reported to be 35% (SART, 2013). *Expected outcomes of the bill*: Eighteen percent of the additional women enrollees using embryo cryopreservation would retrieve the embryo ($0.18 \times 63 = 11.34$), resulting in a birthrate of 35% ($11 \times 0.35 = 3.85$), or four live births.

CHBRP was unable to locate any published studies on the rate that cancer patients return to thaw and use the oocytes, and so is unable to calculate rate of live births that may occur as a result of AB 912.

REFERENCES

Achille MA, Rosberger Z, Robitaille R, et al. Facilitators and obstacles to sperm banking in young men receiving gonadotoxic chemotherapy for cancer: the perspective of survivors and health care professionals. *Human Reproduction (Oxford, England)*. 2006:21:3206-3216.

Aflatoonian A, Mansoori Moghaddam F, Mashayekhy M, Mohamadian F. Comparison of early pregnancy and neonatal outcomes after frozen and fresh embryo transfer in ART cycles. *Journal of Assisted Reproduction and Genetics*. 2010;27:695-700.

American Cancer Society (ACS), California Department of Public Health, California Cancer Registry. *California Cancer Facts and Figures 2013.* Oakland, CA: American Cancer Society, California Division; October 2012.

Ata B, Chian R, Tan SL. Cryopreservation of oocytes and embryos for fertility preservation for female cancer patients. *Best Practice & Research Clinical Obstetrics and Gynaecology*. 2010;24:101-112.

Azim AA, Costantini-Ferrando M, Oktay K. Safety of fertility preservation by ovarian stimulation with letrozole and gonadotropins in patients with breast cancer: a prospective controlled study. *Journal of Clinical Oncology*. 2008;26:2630-2635.

Avis NE, Crawford S, Manuel J. Psychosocial problems among younger women with breast cancer. *Psychooncology.* 2004;13:295-308.

Basatemur E, Sutcliffe A. Follow-up of children born after ART. *Placenta*. 2008;29:(suppl B):135-140.

Beiner ME, Covens A. Surgery insight: radical vaginal trachelectomy as a method of fertility preservation for cervical cancer. *Nature Reviews: Clinical Oncology*. 2007;4:353-361.

Ben-Aharon I, Gafter-Gvili A. Pharmacological interventions for fertility preservation during chemotherapy: a systematic review and meta-analysis. *Breast Cancer Research and Treatment*. 2010;122:803-811.

Bennett CL, Weinberg PD, Lieberman JJ. Cancer insurance policies in Japan and the United States. *Western Journal of Medicine*. 1998;168:17-22.

Bizet P, Saias-Magnan J, Jouve E, et al. Sperm cryopreservation before cancer treatment: a 15-year monocentric experience. *Reproductive Biomedicine Online*. 2012;24:321-330.

Braveman P. Health disparities and health equity: concepts and measurement. *Annual Review of Public Health*. 2006;27:167-194.

California Department of Public Health (CDPH), Cancer Surveillance Section, 2011. Five-Year Incidence and Mortality Counts and Average Annual Age-Specific and Crude Rates per 100,000 Persons by Age, Race/Ethnicity, and Sex, California, 2005-2009*, All Cancer Combined. Available at: www.ccrcal.org/pdf/AnnualReport/1988_2009_ALL.pdf. Accessed March 22, 2013.

California Health Benefits Review Program (CHBRP). *Analysis of Assembly Bill 428: Fertility Preservation*. Report to the California State Legislature. Oakland, CA: CHBRP; 2011.

Canada AL, Schover LR. The psychosocial impact of interrupted childbearing in long-term female cancer survivors. *Psychooncology.* 2012;21:134-143.

Chang HC, Chen SC, Chen J, Hsieh JT. Initial 10-year experience of sperm cryopreservation services for cancer patients. *Journal of the Formosan Medical Association.* 2006;105:1022-1026.

Chernew M, Cutler M, Keenan PS. Increasing health insurance costs and the decline in insurance coverage. *Health Services Research*. 2005;40:1021-1039.

Chung K, Irani J, Knee G, Efymow B, Blasco L, Patrizio P. Sperm cryopreservation for male patients with cancer: an epidemiological analysis at the University of Pennsylvania. *European Journal of Obstetrics & Gynecology and Reproductive Biology*. 2004;113:S7-S11.

Cobo A, Diaz C. Clinical application of oocyte vitrification: a systematic review and meta-analysis of randomized controlled trials. *Fertility and Sterility*. 2011;96:277-285.

Cobo A, Kuwayama M, Pérez S, Ruiz A, Pellicer A, Remohí J. Comparison of concomitant outcome achieved with fresh and cryopreserved donor oocytes vitrified by the Cryotop method. *Fertility and Sterility*. 2008;89:1657-1664.

Cobo A, Meseguer M, Remohí J, Pellicer A. Use of cryo-banked oocytes in an ovum donation programme: a prospective, randomized, controlled, clinical trial. *Human Reproduction (Oxford, England)*. 2010;25:2239-2246.

Covinsky KE, Landefeld CS, Teno J, et al., SUPPORT investigators. Is economic hardship on the families of the seriously ill associated with patient and surrogate care preferences? *Archives of Internal Medicine*. 1996;156:1737-1741.

de Ziegler D, Streuli I, Vasilopoulos I, Decanter C, This P, Chapron C. Cancer and fecundity issues mandate: a multidisciplinary approach. *Fertility and Sterility*. 2010;93:691-696.

Delouya G, Baazeem A, Boman JM, Violette P, Saad F, Zini A. Identification of spermatozoa in archived testicular cancer specimens: implications for bench side sperm retrieval at orchiectomy. *Urology*. 2010:75:1436-1440.

Dittrich R, Lotz L, Keck G, et al. Live birth after ovarian tissue autotransplantation following overnight transportation before cryopreservation. *Fertility and Sterility*. 2012;97:387-390.

Dolmans MM, Jadoul P, Gilliaux S, et al. A review of 15 years of ovarian tissue bank activities. *Journal of Assisted Reproduction and Genetics*. 2013;30:305-314.

Domingo J, Guillén V, Ayllón Y, et al. Ovarian response to controlled ovarian hyperstimulation in cancer patients is diminished even before oncological treatment. *Fertility and Sterility*. 2012;97:930-934.

Dunn L, Fox KR. Techniques for fertility preservation in patients with breast cancer. *Current Opinion in Obstetrics and Gynecology*. 2009:21:68-73.

Dursun P, LeBlanc E, Nogueira MC. Radical vaginal trachelectomy (Dargent's operation): a critical review of the literature. *European Journal of Surgical Oncology*. 2007;33:933-941.

Emanuel EJ, Fairclough DL, Slutsman J, Emanuel LL. Understanding economic and other burdens of terminal illness: The experience of patients and their caregivers. *Annals of Internal Medicine*. 2000;132:451-459.

Eskander RN, Randall LM, Berman ML, Tewari KS, Disaia PJ, Bristow RE. Fertility preserving options in patients with gynecologic malignancies. *American Journal of Obstetrics and Gynecology*. 2011;205:103-110.

Fawcett SL, Gomez AC, Barter SJ, Ditchfield M, Set P. More harm than good? The anatomy of misguided shielding of the ovaries. *British Journal of Radiology*. 2012;85:e442-e447.

Forman EJ, Li X, Ferry KM, Scott K, Treff NR, Scott RT Jr. Oocyte vitrification does not increase the risk of embryonic aneuploidy or diminish the implantation potential of blastocysts created after intracytoplasmic sperm injection: a novel, paired randomized controlled trial using DNA fingerprinting. *Fertility and Sterility.* 2012;98:644-649.

Gardino SL, Sfekas A, Dranove D. Anticipating ovarian tissue cryopreservation in the health-care marketplace: a willingness to pay assessment. *Cancer Treatment and Research*. 2010:156:363-370.

Georgescu ES, Goldberg JM, du Plessis SS, Agarwal A. Present and future fertility preservation strategies for female cancer patients. *Obstetrical and Gynecological Survey*. 2008;63:725-732.

Girasole CR, Cookson MS, Smith JA Jr., Ivey BS, Roth BJ, Chang SS. Sperm banking: use and outcomes in patients treated for testicular cancer. *British Journal of Urology International*. 2007,99:33-36.

Glied S, Jack K. *Macroeconomic Conditions, Health Care Costs and the Distribution of Health Insurance*. Cambridge, MA: National Bureau of Economic Research. October 2003. NBER Working Paper (W10029). Available at: www.nber.org/papers/W10029. Accessed August 2, 2010.

Goodman LR, Balthazar U, Kim J, Mersereau JE. Trends of socioeconomic disparities in referral patterns for fertility preservation consultation. *Human Reproduction (Oxford, England)*. 2012;27:2076-2081.

Gurgan T, Salman C, Demirol A. Pregnancy and assisted reproduction techniques in men and women after cancer treatment. *Placenta*. 2008;29:s152-s159.

Hadley J. The effects of recent employment changes and premium increases on adults' insurance coverage. *Medical Care Research and Review*. 2006;63:447-476.

Hallak J, Hendin B, Thomas A, Agarwal A. Investigation of fertilizing capacity of cryopreserved spermatozoa from patients with cancer. *Journal of Urology*. 1998;159:1217-1220.

Henes M, Henes JC, Neunhoeffer E, et al. Fertility preservation methods in young women with systemic lupus erythematosus prior to cytotoxic therapy: experiences from the FertiPROTEKT network. *Lupus*. 2012;21:953-958.

Hourvitz A, Goldschlag DE, Davis OK, Veeck Gosden L, Palermo GD, Rosenwaks Z. Intracytoplasmic sperm injection (ICSI) using cryopreserved sperm from men with malignant neoplasm yields high pregnancy rates. *Fertility and Sterility*. 2008:90:557-563.

Ishiguro H, Yasuda Y, et al. Gonadal shielding to irradiation is effective in protecting testicular growth and function in long-term survivors of bone marrow transplantation during childhood or adolescence. *Bone Marrow Transplant*. 2007;39:483-490.

Jakimiuk AJ, Grzybowski W. Ovarian tissue preservation, present and clinical perspectives. *Gynecological Endocrinology*. 2007;23:87-93.

Kaiser Family Foundation (KFF). Key Facts: Race, Ethnicity and Medical Care, 2007 Update. January 2007. Available at: www.kff.org/minorityhealth/upload/6069-02.pdf. Accessed March 2009.

Kirby JB, Taliaferro G, Zuvekas SH. Explaining racial and ethnic disparities in health care. *Medical Care*. 2006;44(suppl):I64-I72.

Knopman JM, Noyes N, Talebian S, Krey LC, Grifo JA, Licciardi F. Women with cancer undergoing ART for fertility preservation: a cohort study of their response to exogenous gonadotropins. *Fertility and Sterility*. 2009;91:1476-1478.

Kohler TS, Kondapalli LA, Shah A, Chan S, Woodruff TK, Brannigan RE. Results from the survey for preservation of adolescent reproduction (SPARE) study: gender disparity in delivery of fertility preservation message to adolescents with cancer. *Journal of Assisted Reproduction and Genetics*. 2011;28:269-277.

Lawrenz B, Jauckus J, Kupka MS, Strowitzki T, von Wolff M. Fertility preservation in >1,000 patients: patient's characteristics, spectrum, efficacy and risks of applied preservation techniques. *Archives of Gynecology and Obstetrics.* 2011;283:651-656.

Lee S, Heytens E, Moy F, Ozkavukcu S, Oktay K. Determinants of access to fertility preservation in women with breast cancer. *Fertility and Sterility*. 2011;95:1932-1936.

Lee SJ, Schover LR, Partridge AH, et al. American Society of Clinical Oncology recommendations on fertility preservation in cancer patients. *Journal of Clinical Oncology*. 2006:24:2917-2931.

Levine J, Canada A, Stern CJ. Fertility preservation in adolescents and young adults with cancer. *Journal of Clinical Oncology*. 2010:28:4831-4841.

Letourneau JM, Ebbel EE, Katz PP, et al. Pretreatment fertility counseling and fertility preservation improve quality of life in reproductive age women with cancer. *Cancer*. 2012a;118:1710-1717.

Letourneau JM, Ebbel EE, Katz PP, et al. Acute ovarian failure underestimates age-specific reproductive impairment for young women undergoing chemotherapy for cancer. *Cancer.* 2012b;118:1933-1939.

Letourneau JM, Smith JF, Ebbel EE, et al. Racial, socioeconomic, and demographic disparities in access to fertility preservation in young women diagnosed with cancer. *Cancer.* 2012c;118:4579-4588.

Lillie-Blanton M, Hoffman C. The role of health insurance coverage in reducing racial/ethnic disparities in health care. *Health Affairs (Millwood)*. 2005;24:398-408.

Ludwig AK, Sutcliffe AG, Diedrich, K, Ludwig M. Post-neonatal health and development of children born after assisted reproduction: a systematic review of controlled studies. *European Journal of Obstetrics, Gynecology, and Reproductive Biology*. 2006;127:3-25.

Mandelbaum J, Belaïsch-Allart J, Junca AM, Antoine JM, Plachot M, Alvarez S, Alnot MO, Salat-Baroux J. Cryopreservation in human assisted reproduction is now routine for embryos but remains a research procedure for oocytes. *Human Reproduction*. 1998;13(suppl 3):161-174.

Michaan N, Ben-David G, Ben-Yosef D, et al. Ovarian stimulation and emergency in vitro fertilization for fertility preservation in cancer patients. *European Journal of Obstetrics, Gynecology, and Reproductive Biology*. 2010;149:175-177.

Navarro Medina P, Barroso Deyne E, Castillo Suárez M, et al. An analysis of our experience in cryopreservation of semen from cancer patients [Spanish]. *Actas Urológicas Españolas*. 2010;34:101-105.

Oktay K, Oktem O. Ovarian cryopreservation and transplantation for fertility preservation for medical indications: report of an ongoing experience. *Fertility and Sterility*. 2010;93(3):762-768.

Oktem O, Urman B. Options of fertility preservation in female cancer patients. *Obstetrical and Gynecological Survey*. 2010:65:531-542.

Parmegiani L, Cognigni GE, Bernardi S, et al. Efficiency of aseptic open vitrification and hermetical cryostorage of human oocytes. *Reproductive Biomedicine Online*. 2011;23:505-512.

Partridge AH, Gelber S, Peppercorn J, et al. Web-based survey of fertility issues in young women with breast cancer. *Journal of Clinical Oncology*. 2004;22:4174-4183.

Practice Committees of the American Society of Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology. Mature oocyte cryopreservation: a guideline. *Fertility and Sterility.* 2013;99:37-43.

Quinn GP, Vadaparampil ST, Lee JH, et al. Physician referral for fertility preservation in oncology patients: a national study of practice behaviors. *Journal of Clinical Oncology*. 2009;27:5952-5957.

Reinecke JD, Kelvin JF, Arvey SR, et al. Implementing a systematic approach to meeting patients' cancer and fertility needs: a review of the Fertile Hope Centers of Excellence Program. *Journal of Clinical Oncology*. 2012;28:1284-1286.

Rienzi L, Romano S, Albricci L, et al. Embryo development of fresh 'versus' vitrified metaphase II oocytes after ICSI: a prospective randomized sibling-oocyte study. *Human Reproduction*. 2010;25:66-73.

Robertson AD, Missmer SA, Ginsburg ES. Embryo yield after in vitro fertilization in women undergoing embryo banking for fertility preservation before chemotherapy. *Fertility and Sterility*. 2011;95:588-591.

Rodriguez-Macias Wallberg KA, Keros V, Hovatta O. Clinical aspects of fertility preservation in female patients. *Pediatric Blood & Cancer*. 2009;53:254-260.

Rodriguez-Macias Wallberg KA, Oktay K. Options on fertility preservation in female cancer patients. *Cancer Treatment Reviews*. 2012;38:354-361.

Roque M, Lattes K, Serra S, et al. Fresh embryo transfer versus frozen embryo transfer in in vitro fertilization cycles: a systematic review and meta-analysis. *Fertility and Sterility*. 2013;99:156-162.

Rosendahl M, Greve T, Andersen CY. The safety of transplanting cryopreserved ovarian tissue in cancer patients: a review of the literature. *Journal of Assisted Reproduction and Genetics*. 2013;30:11-24.

Ruutiainen T, Miller S, Caplan A, Ginsberg JP. Expanding access to testicular tissue cryopreservation: an analysis by analogy. *American Journal of Bioethics.* 2013;13(3):28-35.

Schover LR, Brey K, Lichtin A, Lipshultz L, Jeha SI. Oncologists' attitudes and practices regarding banking sperm before cancer treatment. *Journal of Clinical Oncology.* 2002;20:1890-1897.

Seli E, Tangir J. Fertility preservation options for female patients with malignancies. *Current Opinion in Obstetrics and Gynecology*. 2005;17:299-308.

Society of Assisted Reproductive Technology (SART). Clinic Summary Report: All SART Member Clinics. 2013. Available at: www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?ClinicPKID=0. Accessed April 2, 2013.

Soda T, Okubo K, Ichioka K, et al. Sperm cryopreservation for cancer patients: 5-year experience in a private hospital in Japan [Japanese]. *Hinyokika Kiyo*. 2009;55:9-13.

Thibaud E, Ramirez M, Brauner R, et al. Preservation of ovarian function by ovarian transposition preformed before pelvic irradiation during childhood. *Journal of Pediatrics.* 1992;121:880-884.

van Casteren NJ, van Santbrink EJ, van Inzen W, Romijn JC, Dohle GR. Use rate and assisted reproduction technologies outcome of cryopreserved semen from 629 cancer patients. *Fertility and Sterility*. 2008:90:2245-2250.

van der Kaaij MEA, van Echten-Arends J, Simons AHM, Kluin-Nelemans HC. Fertility preservation after chemotherapy for Hodgkin lymphoma. *Hematological Oncology*. 2010;28:168-179.

Wallace WH, Anderson RA, Irvine DS. Fertility preservation for young patients with cancer: who is at risk and what can be offered? *Lancet Oncology*. 2005;6:209-218.

Wennerholm UB, Hamberger L, Nilsson L, Wennergren M, Wikland M, Bergh C. Obstetric and perinatal outcome of children conceived from cryopreserved embryos. *Human Reproduction (Oxford, England)*. 1997;12:1819-1825.

Wennerholm UB, Albertsson-Wikland K, Bergh C, et al. Postnatal growth and health in children born after cryopreservation as embryos. *The Lancet*. 1998;351:1085-1090.

Wethington SL, Cibula D, Duska LR, et al. An international series on abdominal radical trachelectomy: 101 patients and 28 pregnancies. *International Journal of Gynecological Cancer*. 2012;22:1251-7.

Xu L, Sun FQ, Wang ZH. Radical trachelectomy versus radical hysterectomy for the treatment of early cervical cancer: a systematic review. *Acta Obstetricia et Gynecologica Scandinavica.* 2011;90:1200-9.

Yang B, Shi W, Yang J, et al. Concurrent treatment with gonadotropin-releasing hormone agonists for chemotherapy-induced ovarian damage in premenopausal women with breast cancer: A meta-analysis of randomized controlled trials. *Breast* 2013; 22: 150-7.

California Health Benefits Review Program Committees and Staff

A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature. The level of involvement of members of the CHBRP Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, Milliman Inc., to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit. Milliman also helped with the initial development of CHBRP methods for assessing that impact.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

Faculty Task Force

Todd Gilmer, PhD, *Vice Chair for Cost*, University of California, San Diego
Joy Melnikow, MD, MPH, *Vice Chair for Public Health*, University of California, Davis
Ed Yelin, PhD, *Vice Chair for Medical Effectiveness*, University of California, San Francisco
Susan L. Ettner, PhD, University of California, Los Angeles
Theodore Ganiats, MD, University of California, San Diego
Sheldon Greenfield, MD, University of California, Irvine
Sylvia Guendelman, PhD, LCSW, University of California, Berkeley

Task Force Contributors

Wade Aubry, MD, University of California, San Francisco
Diana Cassady, DrPH, University of California, Davis
Janet Coffman, MPP, PhD, University of California, San Francisco
Gina Evans-Young, University of California, San Francisco
Margaret Fix, MPH, University of California, San Francisco
Brent Fulton, PhD, University of California, Berkeley
Jennifer Kempster, MS, University of California, San Diego
Shana Lavarreda, PhD, MPP, University of California, Los Angeles
Stephen McCurdy, MD, MPH, University of California, Davis
Sara McMenamin, PhD, University of California, San Diego
Ninez Ponce, PhD, University of California, Los Angeles
Dominique Ritley, MPH, University of California, Davis
Meghan Soulsby, MPH, University of California, Davis
Chris Tonner, MPH, University of California, San Francisco
Byung-Kwang (BK) Yoo, MD, MS, PhD, University of California, Davis

National Advisory Council

Lauren LeRoy, PhD, Fmr. President and CEO, Grantmakers In Health, Washington, DC, *Chair*

Stuart H. Altman, PhD, Professor of National Health Policy, Brandeis University, Waltham, MA
Deborah Chollet, PhD, Senior Fellow, Mathematica Policy Research, Washington, DC
Joseph P. Ditré Esq, Executive Director, Consumers for Affordable Health Care, Augusta, ME
Allen D. Feezor, Fmr. Deputy Secretary for Health Services, North Carolina Department of Health and Human Services, Raleigh, NC
Charles "Chip" Kahn, MPH, President and CEO, Federation of American Hospitals, Washington, DC
Jeffrey Lerner, PhD, President and CEO, ECRI Institute Headquarters, Plymouth Meeting, PA
Trudy Lieberman, Director, Health and Medicine Reporting Program, Graduate School of Journalism, City University of New York, New York City, NY
Donald E. Metz, Executive Editor, Health Affairs, Bethesda, MD
Marilyn Moon, PhD, Vice President and Director, Health Program, American Institutes for Research, Silver Spring, MD
Carolyn Pare, CEO, Buyers Health Care Action Group, Bloomington, MN
Michael Pollard, JD, MPH, Senior Fellow, Institute for Health Policy Solutions, Washington, DC
Christopher Queram, President and CEO, Wisconsin Collaborative for Healthcare Quality, Madison, WI
Richard Roberts, MD, JD, Professor of Family Medicine, University of Wisconsin-Madison, Madison, WI
Frank Samuel, LLB, Former Science and Technology Advisor, Governor's Office, State of Ohio, Columbus, OH
Patricia Smith, President and CEO, Alliance of Community Health Plans, Washington, DC
Prentiss Taylor, MD, Corporate Medical Director, Advocate At Work, Advocate Health Care, Chicago, IL
J. Russell Teagarden, Vice President, Clinical Practices and Therapeutics, Medco Health Solutions, Inc, Brookfield, CT
Alan Weil, JD, MPP, Executive Director, National Academy for State Health Policy, Washington, DC

CHBRP Staff

Garen Corbett, MS, Director
John Lewis, MPA, Associate Director
Laura Grossmann, MPH, Principal Policy Analyst
Hanh Kim Quach, Principal Policy Analyst
Nimit Ruparel, Graduate Health Policy Intern
Karla Wood, Program Specialist

California Health Benefits Review Program
University of California
Office of the President
1111 Franklin Street, 11th Floor
Oakland, CA 94607
Tel: 510-287-3876 Fax: 510-763-4253
chbrpinfo@chbrp.org
www.chbrp.org

The California Health Benefits Review Program is administered by the Division of Health Sciences and Services at the University of California, Office of the President. The Division is led by John D. Stobo, MD, Senior Vice President.