



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 428: Fertility Preservation

A Report to the 2011-2012 California Legislature
April 16, 2011

CHBRP 11-13



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 by statute (California Health and Safety Code, Section 127660, et seq). 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; or (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.

A small 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, as well as Loma Linda University, the University of Southern California, and Stanford University, 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, and 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 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 a small annual assessment on health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available at the CHBRP Web site, www.chbrp.org.

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Analysis of Assembly Bill 428: Fertility Preservation

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 428. In response to a request from the California Assembly Committee on Health on February 15, 2011, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute.

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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:

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Susan Philip, MPP
Director

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 428

The California Assembly Committee on Health requested on February 15, 2011, 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) 428, a bill that would require coverage of fertility preservation services. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.¹

Approximately 21.9 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.² Of the rest of the state's population, a portion is uninsured (and so has no health insurance subject to any benefit mandate) and another portion has 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-level benefit mandates. The California Department of Managed Health Care (DMHC)³ regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers⁴, which offer benefit coverage to their enrollees through health insurance policies. All DMHC-regulated full-service health care service plans and CDI-regulated policies that provide hospital, medical, or surgical benefits would be subject to AB 428. Therefore, the mandate would affect all 21.9 million people who have health insurance subject to state benefit mandates, or 59% of all Californians.

Provisions of AB 428 and Relevant Definitions

AB 428 would require health plans and policies to cover "medically necessary expenses for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause iatrogenic infertility to an enrollee."⁵

Infertility means the diminished ability or the inability to conceive or contribute to conception. Infertility may also be defined in specific terms as the failure to conceive after a year of sexual

¹ CHBRP's authorizing statute is available at: www.chbrp.org/documents/authorizing_statute.pdf.

² CHBRP's estimates are available at http://www.chbrp.org/other_publications/index.php.

³ The DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.

⁴ The 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, Section 106(b) or subdivision (a) of Section 10198.6.

⁵ The version of AB 428 introduced on February 14, 2011, requires that health plans cover fertility preservation services, but requires health policies to offer coverage of such services. On March 10, 2011, the Office of Assembly Member Portantino stated that they will amend the bill to correct a drafting error so that the Insurance Code provisions match the Health and Safety Code provisions. The revised provisions are to clarify that CDI-regulated policies would be mandated to cover fertility preservation services in the same manner the DMHC-regulated plans would be mandated to cover fertility preservation services.

intercourse without contraception. **Iatrogenic** infertility is defined as infertility caused by a medical intervention, including reactions from prescribed drugs or from medical and surgical procedures. This report will not examine other causes of infertility such as underlying medical conditions, genetic defects, or general health and lifestyle status since those causes are not considered “iatrogenic.” Iatrogenic infertility is typically caused by cancer treatments such as radiation, chemotherapy, 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 will focus on fertility preservation among cancer patients since the majority of iatrogenic infertility occurs in cancer patients and the research on fertility preservation has focused almost exclusively on this group.

Patients at risk for iatrogenic infertility differ from patients being treated for infertility in that they need to undergo fertility preservation services *before* they undergo treatments that may put them at risk for becoming infertile. For example, a patient undergoing treatment for cancer would need to freeze his sperm prior to starting treatment for his cancer. At that time, his fertility may be intact, but if he does not take part in fertility preserving treatment, his future ability to father a child may be at risk. If he has coverage for *infertility treatment* (defined below) and not *fertility preservation treatment*, he is ineligible for coverage of those treatments because he does not meet the definition of being infertile prior to undergoing cancer treatments.

A patient may have coverage for *infertility treatment* but may not have coverage for fertility preservation treatment. This bill would not require coverage of infertility treatment. According to current definitions in California law, infertility treatment means “procedures consistent with established medical practices in the treatment of infertility by licensed physicians and surgeons including, but not limited to, diagnosis, diagnostic tests, medication, surgery, and gamete intrafallopian transfer. “In vitro fertilization” means the laboratory medical procedures involving the actual in vitro fertilization process.”⁶ Current California law includes a mandate to offer coverage of infertility treatments (except in vitro fertilization). This means that health plans and insurers are required to *offer* group purchasers the option of buying coverage of infertility treatment but they are not required to cover the service. AB 428 would not affect current coverage rates of infertility services. Therefore, this issue is not directly addressed in this report.

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.

⁶ Section 1374.55 of the Health and Safety Code; Section 10119.6 of the Insurance Code.

Standard Fertility Preservation Services

- Sperm cryopreservation is the collection and freezing of sperm. This is the standard fertility preservation service offered to males at risk for iatrogenic infertility. There is a preponderance of evidence that sperm cryopreservation with sperm collected through ejaculate is an effective method of fertility preservation.
- Embryo cryopreservation involves harvesting eggs followed by in vitro fertilization and freezing of resulting embryos for later implantation. Embryo cryopreservation is the standard fertility preservation service available for females. There is a preponderance of evidence that embryo cryopreservation is an effective method of fertility preservation.
- Ovarian transposition, also called oophoropexy, is a surgical repositioning of ovaries to another location in the body away from the radiation field. There is insufficient evidence to conclude that ovarian transposition 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.
- During cancer treatment with radiation therapy, special shields can be placed over the gonads (ovaries in females and testicles in males) to reduce the dose of radiation delivered to these reproductive organs. There is insufficient evidence that testicular shielding is an effective method of fertility preservation in males. There is also insufficient evidence that ovarian shielding during radiation therapy is an effective method of fertility preservation in females. 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 gonadal shielding to protect their fertility.
- Treatment for gynecological cancers can include surgery to remove the diseased part of the reproductive organs. In cases where fertility preservation is a priority, conservative gynecologic surgery may be used to minimize the amount of tissue removed. Trachelectomy is a treatment for cervical cancer where the cervix is surgically removed while the uterus is preserved. Another conservative surgery for ovarian cancer, preserves the uterus with one ovary. There is a preponderance of evidence that conservative gynecologic surgery is an effective method of fertility preservation measured by pregnancy rates and live births and there is a preponderance of evidence that this surgery has no apparent increase in cancer recurrence or mortality in selected cases.

Experimental Fertility Preservation Services

- Sperm cryopreservation using sperm collected through testicular aspiration or extraction, electroejaculation under sedation, or from a postmasturbation urine sample is considered experimental.
- Oocyte cryopreservation is the harvesting and freezing of unfertilized eggs. Although oocyte cryopreservation is considered experimental per currently available literature, it is being performed at most fertility centers across the nation. Experts expect that it will become standard medical practice within the next few years.

- Testicular tissue cryopreservation is the freezing testicular tissue or germ cells and reimplantation after treatment or maturation. This treatment is considered experimental.
- Ovarian cryopreservation and transplantation is the freezing of ovarian tissue and reimplantation after cancer treatment. This treatment is considered experimental.
- Suppression with hormonal therapies, known as GnRH analogs or antagonists, 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

AB 428 would apply to the 21.9 million enrollees in all DMHC-regulated, privately funded plans and DMHC-regulated, publicly funded plans, as well as all CDI-regulated policies. Standard medical services for fertility preservation include procurement and storage of sperm and embryos. This section presents, first, the current (baseline) benefit coverage, utilization, and costs related to fertility preservation services for patients at risk for iatrogenic infertility, and then provides estimates of the impacts on coverage, utilization, and cost if AB 428 were to be enacted.

Table 1 summarizes the expected benefit coverage, cost, and utilization impacts for AB 428.

Benefit Coverage Impacts

- Approximately 5.4% of the 21.9 million enrollees currently have coverage for fertility preservation services. If enacted, AB 428 would increase this to 100% of enrollees.
- No publicly funded DMHC-regulated plans currently include coverage for fertility preservation services.

Utilization and Per-Unit Cost Impacts

- CHBRP estimates that currently, 1,057 male enrollees use sperm cryopreservation (with 986 paying for the noncovered benefit directly) and 222 female enrollees use embryo cryopreservation (with 188 paying for the noncovered benefit directly).
- If AB 428 is enacted, CHBRP estimates total postmandate utilization to equal 1,263 male enrollees and 578 female enrollees. This is primarily due to the reduction in costs associated for benefits that were previously not covered. This represents a 19% increase among male enrollees (or 205 males) and a 161% increase among female enrollees (or 357 females).
- In total, postmandate, CHBRP estimates a 44% increase in the use of fertility preservation services, as measured by the number of new users.
- The average per-unit cost for sperm cryopreservation and embryo cryopreservation is not expected to change as a result of this mandate. For analytic purposes, CHBRP estimates costs

for one year, but it is highly likely that the sperm and embryos would be cryopreserved for longer than this time period. The average annual per-unit cost for procurement of sperm is estimated to be \$400. The average annual per-unit cost for prescription drugs and the procurement associated with embryo cryopreservation is estimated to be \$14,700.

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 0.00% (for DMHC-regulated Medi-Cal Managed Care plans for ages 65+) to an average of 0.0173% (for CDI-regulated individual policies) in the affected market segments. Increases as measured by PMPM premiums are estimated to range from averages of \$0.00 to \$0.0373.
- In the privately funded large-group market, the premium increases are estimated to range from an average of \$0.0371 PMPM among DMHC-regulated plans to an average of \$0.0362 PMPM among CDI-regulated policies.
- For enrollees in privately funded small-group insurance policies, premiums are estimated to increase by an average of \$0.0373 PMPM for DMHC-regulated plans and by an average of \$0.0278 PMPM for CDI-regulated policies.
- In the privately funded individual market, the premiums are estimated to increase by an average of \$0.0370 PMPM for DMHC-regulated plans and by an average of \$0.0344 PMPM for CDI-regulated policies.
- Among publicly funded DMHC-regulated plans, CHBRP estimates that premiums will increase for Medi-Cal Managed Care Plans, Managed Risk Medical Insurance Board (MRMIB) Plans, and CalPERS HMOs. The increase would range from an average of 0.00% to 0.0125% (or by \$0.00 PMPM to \$0.0323 PMPM).
- Total net health expenditures are projected to increase by \$6.5 million (0.0068%) (Table 1). This is due to an \$8.5 million increase in premiums partially offset by a net reduction in enrollee out-of-pocket expenditures of \$2 million, comprised of a reduction in enrollee expenses for noncovered benefits (\$3.2 million) and an increase in enrollee out-of-pocket expenses for the newly covered benefits (\$1.2 million).
- CHBRP estimates no measurable impact of the mandate on the number of uninsured due to premium increases.

Public Health Impacts

- Loss of fertility can negatively impact the quality of life for cancer survivors of reproductive age. As a result of AB 428, it is expected that the quality of life could improve for some of

the 6,346 cancer patients at risk for iatrogenic infertility each year who would gain coverage for fertility preservation services.

- Although CHBRP is unable to quantify the effects, there would likely be a benefit to patients of reproductive age being treated for autoimmune disorders such as Crohn’s disease, where loss of fertility may result from treatment of their disease.
- AB 428 would decrease expenses paid directly by enrollees who use fertility preservation services by almost \$2 million. Therefore, AB 428 is estimated to reduce financial hardship for enrollees who face the risk of iatrogenic infertility.
- AB 428 is expected to increase utilization of sperm cryopreservation and embryo cryopreservation services. 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 fifteen additional female cancer patients having a biological child as a result of AB 428.
- With 5.4% of enrollees having coverage 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 per embryo cryopreservation and male enrollees are paying an estimated \$400 per sperm cryopreservation. AB 428 is expected to decrease the disparity in the financial burden of expenses related to fertility preservation services borne by females. Based on assumptions on utilization, CHBRP estimates that males and females may likely face similar direct expenses postmandate.
- No evidence was found on potential disparities in the use of fertility preservation treatments by race/ethnicity. Therefore, the extent to which AB 428 would have an impact on disparities is unknown.
- Although cancer is a substantial cause of iatrogenic infertility, premature mortality, and economic loss in California, AB 428 is not expected to result in a reduction in premature death or associated economic loss.

Potential Effects of the Federal Affordable Care Act

The federal “Patient Protection and Affordable Care Act” (P.L.111-148) and the “Health Care and Education Reconciliation Act” (H.R.4872) were enacted in March 2010. These laws (together referred to as the “Affordable Care Act” (ACA)) are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government. The provisions that go into effect during these transitional years would affect the baseline, or current enrollment, expenditures, and premiums. It is important to note that CHBRP’s analysis of specific mandate bills typically address 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 this report.

Essential health benefits offered by qualified health plans in the Exchanges and potential interactions with AB 428

The ACA requires beginning 2014 for states to “make payments...to defray the cost of any additional benefits” required of qualified health plans (QHPs) sold in the Exchange.⁷ Essential health benefits (EHBs) that are required to be offered by QHPs would include ambulatory patient services; hospitalization; and preventive and wellness services and chronic disease management. It is conceivable that EHBs may be defined to include fertility preservation treatment under these EHB categories. However, given that the U.S. Department of Health and Human Services is to ensure that the definition of EHBs “is equal to the scope of benefits provided under a typical employer plan” and given that most large-group and small-group employer plans do not cover this benefit at this time based on CHBRP's analysis of current coverage rates, it is likely that beginning in 2014, AB 428 would incur a fiscal liability for the state for the QHPs offered in the Exchange. This potential liability would depend on three factors (1) differences in the scope of benefits in the final EHB package and the scope of mandated benefits in AB 428; (2) the number of enrollees in QHPs; and, (3) the methods used to define and calculate the cost of additional benefits. All of these factors are unknown at this time, and are dependent upon the details of pending federal regulations, state legislative and regulatory actions, and enrollment into QHPs after the Exchange is implemented.

⁷ Affordable Care Act, 1311(d)(3)(B).

Table 1. AB 428 Impacts on Benefit Coverage, Utilization, and Cost, 2011

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	21,902,000	21,902,000	0	0%
Total enrollees with health insurance subject to AB 428	21,902,000	21,902,000	0	0%
Percentage of enrollees with coverage for the mandated benefit	5.4%	100.0%	94.6%	1,761%
Enrollees with coverage for reproductive material cryopreservation				
Percentage	5.4%	100.0%	94.6%	1,761%
Number	1,176,890	21,902,000	20,725,110	1,761%
Utilization and Cost				
Number of enrollees using services covered by insurance:				
Reproductive material cryopreservation—Sperm	71	1,262	1,191	1,674%
Reproductive material cryopreservation—Embryo (with prescription)	34	578	544	1,590%
Total	105	1,840	1,735	1,647%
Number of enrollees using services not covered by insurance:				
Reproductive material cryopreservation—Sperm	986	-	-986	-100%
Reproductive material cryopreservation—Embryo (with prescription)	188	-	-188	-100%
Total	1,173	-	-1,173	-100%
Total number of enrollees using services:				
Reproductive material cryopreservation—Sperm	1,057	1,262	205	19%
Reproductive material cryopreservation—Embryo (with prescription)	222	578	357	161%
Total	1,279	1,840	562	44%
Average cost per procedure for:				
Reproductive material cryopreservation—Sperm	\$400	\$400	\$0	0%
Reproductive material cryopreservation—Embryo (with prescription)	\$14,700	\$14,700	\$0	0%

Table 1. AB 428 Impacts on Benefit Coverage, Utilization, and Cost, 2011 (Cont'd)

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Expenditures				
Premium expenditures by private employers for group insurance	\$52,713,266,000	\$52,718,175,000	\$4,909,000	0.0093%
Premium expenditures for individually purchased insurance	\$6,724,851,000	\$6,725,731,000	\$880,000	0.0131%
Premium expenditures by persons with group insurance, CalPERS HMOs, Healthy Families Program, AIM, or MRMIP (b)	\$15,173,472,000	\$15,174,868,000	\$1,396,000	0.0092%
CalPERS HMO employer expenditures (c)	\$3,465,785,000	\$3,466,042,000	\$257,000	0.0074%
Medi-Cal Managed Care Plan expenditures	\$8,657,688,000	\$8,658,623,000	\$935,000	0.0108%
MRMIB Plan expenditures (d)	\$1,050,631,000	\$1,050,716,000	\$85,000	0.0081%
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$7,548,415,000	\$7,549,609,000	\$1,194,000	0.0158%
Enrollee expenses for noncovered benefits (e)	\$3,153,000	\$0	-\$3,153,000	-100%
Total Expenditures	\$95,337,261,000	\$95,343,764,000	\$6,503,000	0.0068%

Source: California Health Benefits Review Program, 2011.

Notes: (a) This population includes persons with privately funded and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans, Healthy Families Program, AIM, MRMIP) 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 and enrollee contributions for publicly purchased insurance.

(c) Of the increase in CalPERS employer expenditures, about 58% or \$149,000 would be state expenditures for CalPERS members who are state employees or their dependents.

(d) MRMIB Plan expenditures include expenditures for 874,000 enrollees of the Healthy Families Program, 8,000 enrollees of MRMIP, and 7,000 enrollees of the AIM program.

(e) 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: Reproductive material cryopreservation=This includes associated procurement, storage, and prescription drug costs. AIM=Access for Infants and Mothers; CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health; MRMIB=Managed Risk Medical Insurance Board; MRMIP=Major Risk Medical Insurance Program.

INTRODUCTION

The California Assembly Committee on Health requested on February 15, 2011, 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) 428, a bill that would require coverage of fertility preservation services. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.⁸

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Provisions of AB 428 and Relevant Definitions

The full text of AB 428 can be found in Appendix A.

AB 428 would require health plans and policies to cover "medically necessary expenses for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause iatrogenic infertility to an enrollee." The version of AB 428 introduced on February 14, 2011, requires that health plans cover fertility preservation services, but requires health policies to offer coverage of such services. On March 10, 2011, the Office of Assembly Member Portantino stated that they will amend the bill to correct a drafting error so that the Insurance Code provision matches the Health and Safety Code provisions. The revised provisions are to clarify that CDI-regulated policies would be mandated *to cover* fertility preservation services in the same manner the DMHC-regulated plans would be mandated to cover fertility preservation services. Because of this amendment that is intended to be taken,

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CHBRP's analysis assumes that health policies as well as health plans would be required to cover fertility preservation services.

Infertility means the diminished ability or the inability to conceive or contribute to conception. Infertility may also be defined in specific terms as the failure to conceive after a year of sexual intercourse without contraception. **Iatrogenic** infertility is defined as infertility caused by a medical intervention, including reactions from prescribed drugs or from medical and surgical procedures. This report will not examine other causes of infertility such as underlying medical conditions, genetic defects, or general health and lifestyle status since those causes are not considered "iatrogenic." Iatrogenic infertility is typically caused by cancer treatments such as radiation, chemotherapy, 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 will focus on fertility preservation among cancer patients since the majority of iatrogenic infertility occurs in cancer patients and the research on fertility preservation has focused almost exclusively on this group.

Patients at risk for iatrogenic infertility differ from patients being treated for infertility in that they need to undergo fertility preservation services *before* they undergo treatments that may put them at risk for becoming infertile. For example, a patient undergoing treatment for cancer would need to freeze his sperm prior to starting treatment for his cancer. At that time, his fertility may be intact, but if he does not take part in fertility preserving treatment, his future ability to father a child may be at risk. If he has coverage for *infertility treatment* (defined below) and not *fertility preservation treatment*, he is ineligible for coverage of those treatments because he does not meet the definition of being infertile prior to undergoing cancer treatments.

A patient may have coverage for *infertility treatment* but may not have coverage for fertility preservation treatment. This bill would not require coverage of infertility treatment. According to current definitions in California law, infertility treatment means "procedures consistent with established medical practices in the treatment of infertility by licensed physicians and surgeons including, but not limited to, diagnosis, diagnostic tests, medication, surgery, and gamete intrafallopian transfer. "In vitro fertilization" means the laboratory medical procedures involving the actual in vitro fertilization process."¹² Current California law includes a mandate to offer coverage of infertility treatments (except in vitro fertilization). This means that health plans and insurers are required to *offer* group purchasers the option of buying coverage of infertility treatment but they are not required to cover the service. AB 428 would not affect current coverage rates of infertility services. Therefore, this issue is not directly addressed in this report.

Requirements in other states

CBHRP is unaware of similar mandates in other states.

¹² Section 1374.55 of the Health and Safety Code; Section 10119.6 of the Insurance Code.

Potential Effects of Federal Affordable Care Act

The federal “Patient Protection and Affordable Care Act” (P.L.111-148) and the “Health Care and Education Reconciliation Act” (H.R.4872) were enacted in March 2010. These laws— together referred to as the “Affordable Care Act” (ACA)—are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government.

The provisions that go into effect during the transitional years (2011-2013) would affect the baseline, or current enrollment, expenditures, and premiums. It is important to note that CHBRP’s analysis of specific mandate bills typically address 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 this report. Each of the provisions that have gone into effect by January 2011 has been considered to determine whether they may affect CHBRP’s 2011 Cost and Coverage Model. There are still a number of provisions that have gone into effect for which data are not yet available. Where data allows, CHBRP has made adjustments to the Cost and Coverage model to reflect changes in enrollment and/or baseline premiums. These adjustments are discussed in further detail in Appendix D.

A number of ACA provisions will need regulations and further clarity. One example is the ACA’s requirement for certain health insurance to cover “essential health benefits” (EHBs). Effective 2014, Section 1302(b) will require small-group and individual health insurance, including “qualified health plans” (QHPs) that will be sold in the California Exchange, to cover specified categories of benefits. These EHBs are defined as 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. The Secretary of Health and Human Services (HHS) is charged with defining these categories through regulation, ensuring that the EHB floor “is equal to the scope of benefits provided under a typical employer plan.” In addition, the ACA would allow a state to “require that a qualified health plan offered in [the Exchange] offer benefits in addition to the essential health benefits.” If the state does so, the state must make payments to defray the cost of those additionally mandated benefits, either by paying the individual directly, or by paying the qualified health plan. This ACA requirement could interact with existing and proposed California benefit mandates, especially if California decided to require qualified health plans to cover California-specific mandates, and those mandates were determined to go beyond the EHB floor. Federal regulations regarding which benefits are to be covered under these broad EHB categories and other details, such as how the subsidies for purchasers of qualified health plans are structured, are forthcoming.¹³

¹³ For further discussion on EHBs and potential interaction with state mandates, please see, *California's State Benefit Mandates and the Affordable Care Act's "Essential Health Benefits"* available here: http://www.chbrp.org/other_publications/index.php.

The ACA requires beginning 2014 for states to “make payments...to defray the cost of any additional benefits” required of QHPs sold in the Exchange.¹⁴ EHBs that are required to be offered by QHPs would include ambulatory patient services; hospitalization; and preventive and wellness services and chronic disease management. It is conceivable that EHBs may be defined to include fertility preservation treatment under these EHB categories. However, given that HHS is to ensure that the definition of EHBs are to “is equal to the scope of benefits provided under a typical employer plan” and given that most large-group and small-group employer plans do not cover this benefit at this time based on CHBRP’s analysis of current coverage rates, it is likely that beginning in 2014, AB 428 would incur a fiscal liability for the state for the QHPs offered in the Exchange. This potential liability would depend on three factors (1) differences in the scope of benefits in the final EHB package and the scope of mandated benefits in AB 428; (2) the number of enrollees in QHPs; and, (3) the methods used to define and calculate the cost of additional benefits. All of these factors are unknown at this time, and are dependent upon the details of pending federal regulations, state legislative and regulatory actions, and enrollment into QHPs after the Exchange is implemented.

Background on the Disease or Condition

Incidence and prevalence

As estimates of the prevalence of iatrogenic infertility from all causes do not exist, most literature relies on rates of cancer among men and women of reproductive age as a proxy. In California there are approximately 144,000 new cases of cancer diagnosed annually (ACS, 2010). An estimated 10% of these occur among cancer patients of reproductive age (ACS, 2010). This translates into more than 14,000 cancer cases diagnosed each year in California among patients of reproductive age. Rates of iatrogenic infertility vary by type of cancer type and treatment (Quinn et al., 2011). Using cancer incidence rates by age and gender for the top ten cancers most likely to lead to infertility, and adjusting for the population subject to AB 428, CHBRP calculated that 6,346 cancer patients enrolled in health plans subject to AB 428 would be at risk for infertility due to cancer treatments each year.

Treatment

Fertility preservation services for patients at risk for iatrogenic infertility vary by the age and gender of the patient, the patient’s marital status, cultural and religious beliefs and the type of treatment the patient is undergoing. There are three general categories of treatments used for fertility preservation. One involves freezing reproductive material (sperm, eggs, embryos, testicular tissue, or ovarian tissue) prior to treatment. A second type uses specific methods to try to reduce the harms of cancer treatment on fertility (ovarian transposition, gonadal shielding during radiation, and gonadal suppression with hormonal therapies). The third is to pick the cancer treatment with the lowest likelihood of causing infertility, such as selection of a more conservative surgery to minimize the amount of reproductive tissue lost.

¹⁴ Affordable Care Act, 1311(d)(3)(B).

- **Sperm Cryopreservation:** The collection and freezing of sperm from ejaculate, testicular aspiration or extraction, electroejaculation under sedation, or from a postmasturbation urine sample.
- **Oocyte Cryopreservation:** Harvesting and freezing of unfertilized eggs.
- **Embryo Cryopreservation:** Harvesting eggs followed by in vitro fertilization and freezing of resulting embryos for later implantation.
- **Testicular Tissue Cryopreservation:** Freezing testicular tissue or germ cells and reimplantation after treatment or maturation.
- **Ovarian Cryopreservation and Transplantation:** Freezing of ovarian tissue and reimplantation after cancer treatment.
- **Ovarian Transposition (Oophoropexy):** Surgical repositioning of ovaries away from the radiation field.
- **Gonadal Shielding During Radiation Therapy:** Use of shielding to reduce the dose of radiation delivered to the reproductive organs known as gonads (ovaries in females and testicles in males).
- **Suppression with GnRH Analogs or Antagonists:** Use of hormonal therapies to protect ovarian or testicular tissue during radiation therapy.
- **Conservative Gynecological 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 would surgically remove the cervix while the uterus is preserved.
 - Conservative ovarian cancer surgery: the standard treatment for ovarian cancer is a removal of the uterus (hysterectomy) and removal of both ovaries. The conservative treatment would leave the uterus and one ovary, in cases where the cancer was confined to just one ovary.

MEDICAL EFFECTIVENESS

As indicated in the *Introduction*, AB 428 would mandate coverage of “medically necessary expenses for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause iatrogenic infertility.” Using CHBRP’s methods for analyzing the literature, this analysis relied on a systematic review published in 2006 (Lee et al., 2006) and reviewed studies published in 2006 or later. In addition, the review focuses on the evidence regarding fertility preservation treatments in cancer patients, because they are the types of conditions for which persons in the United States most frequently use fertility preservation services.

Literature Review Methods

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. Web sites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality, the International Network of Agencies for Health Technology Assessment, the National Health Service Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence, and the Scottish Intercollegiate Guideline Network.

The search was limited to abstracts of studies published in English. The medical effectiveness search was limited to studies published from 2006 to present, because the American Society of Clinical Oncology had previously conducted a systematic review on this subject covering literature published from 1987 to 2005 (Lee et al., 2006). Of the 563 articles found in the literature review, 111 were reviewed for potential inclusion in this report, and a total of 22 studies were included in the medical effectiveness review for AB 428. The other articles were eliminated because they did not focus on cancer patients, were of poor quality, or were not reporting on clinical research studies. 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 Table 2, which appears at the end of this section. Descriptive information about the meta-analyses is presented in Appendix C.

This review summarizes findings from the literature on the effectiveness of 12 specific fertility preservation services. Six of these services are considered standard of care, and the focus of the *Medical Effectiveness* section is on these procedures. The other six services 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.

Iatrogenic infertility is typically caused by cancer treatments such as radiation, chemotherapy, 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 review excluded articles based on non-cancer causes of the iatrogenic infertility.

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 group, 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. 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 treatment options, and most of them are very small. It is widely acknowledged among researchers and clinicians in the field that randomized studies are necessary. There are at least five RCTs in progress around the world to assess ovarian suppression with gonadotropin releasing hormone (GnRh) analogs or antagonists as a fertility preservation option for female cancer patients. As the results are not yet available, these studies are not included in this report.

Fertility Preservation Services

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 ASCO review found that the two methods of fertility preservation with the highest likelihood of success are sperm freezing for males and embryo freezing for females (Lee et al., 2006). Other approaches recommended for specific cancer types were transposition of the ovaries, gonadal (ovarian or testicular) shielding during radiation therapy, and conservative surgical approaches for gynecological cancers. The other methods of fertility preservation were labeled as experimental: oocyte [egg] freezing, ovarian or testicular tissue freezing and transplantation, use of hormones to protect the gonads (ovaries or testicles) during chemotherapy, and sperm cryopreservation with alternative methods of collection. CHBRP's literature review and consultation with experts in the field found that these methods are still considered experimental (Lee et al., 2006; Levine et al., 2010). CHBRP will not be drawing conclusions as to the state of the evidence of the medical effectiveness for these treatments that are considered experimental as 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 treatment, diagnosis, the amount of time the patient can wait before starting cancer treatment, and if 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 treatment decisions. This review presents evidence as to the effectiveness of four standard fertility preservation treatments for females: embryo cryopreservation, ovarian shielding during radiation therapy, ovarian transposition, and conservative gynecological surgery (Lee et al., 2006; Levine et al., 2010).¹⁵

Embryo cryopreservation

There are just under 5,000 births in the United States every year from embryo cryopreservation (Lee et al., 2010). Embryo cryopreservation or freezing involves harvesting the patient's eggs, using in-vitro fertilization (IVF) to fertilize the eggs, and freezing any resulting embryos for later implantation. This treatment is targeted at females who have gone through puberty and have mature eggs. The harvesting of the patient's eggs takes place 10 to 14 days from menses as an outpatient surgical procedure, and requires either a partner or donor sperm (Levine et al., 2010).

The medical effectiveness of embryo cryopreservation has been well studied. This is the most successful fertility preservation approach for females and is considered a standard fertility preservation method (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 is in the range of 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 can be more than 60% (Ata et al., 2010; Rodriguez-Macias Wallberg et al., 2009; Seli and Tangir, 2005). Birth rates per embryo transfer using cryopreserved embryos are reported to be in the range of 26% to 28% (Dunn and Fox, 2009; Rodriguez-Macias Wallberg et al., 2009).

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 2006 indicated that the live birth rates from frozen embryo transfers were 34% in women less than 35 years of age, 30% in the 35 to 37 age group, 25% in the 38 to 40 age group, and 21% in the 41 to 42 age group (Lee et al., 2010). In addition, Ata et al. (2010) found that the pregnancy rate following frozen embryo transfer was 34% in women younger than 35 and 19% across all women.

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 (eggs) (Jakimiuk and Grzybowski, 2007). In addition, patients with hormone-sensitive tumors need to avoid the higher estrogen levels induced by ovarian stimulation. Although oocyte collection is possible without ovarian stimulation, the embryo yield is very low (Lee et al., 2006). Therefore, it is necessary for these women to use alternative hormonal stimulation

¹⁵ Although Lee et al. (2006) discusses a class of fertility preservation treatments known as conservative gynecological surgery, the only evidence presented regarding conservative gynecological surgeries was for trachelectomy used for cervical cancer treatment and conservative surgery for ovarian cancer treatment. Other conservative approaches exist, but it was out of the scope of this analysis to discuss them all. 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 428.

approaches that are still experimental so as to not increase their risk of cancer recurrence (Jakimiuk and Grzybowski, 2007; Lee et al., 2006).

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.

Ovarian transposition (oophoropexy)

Oophoropexy or ovarian transposition is the surgical repositioning of the ovaries higher up in the abdomen and away from the radiation field. The aim of the surgery is to minimize the damage to the ovaries caused by pelvic radiation (Levine et al., 2010). This treatment is generally used for female patients receiving pelvic radiation who desire to preserve their fertility (Georgescu et al., 2008).

Oophoropexy has been shown to reduce radiation exposure to the 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 one review reporting a range of 16% to 90% (Seli and Tangir, 2005). In the American Society of Clinical Oncology recommendations on fertility preservation, the rate of fertility preservation is estimated at 50% (Lee et al., 2006). Another review found that ovary function was retained in nearly 90% of patients (Georgescu et al., 2008).

Some considerations for patients contemplating this surgery are that there are many complications to the procedure such as 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 IVF procedure could be performed (Lee et al., 2006).

Of the 11 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 (Level IV) in the hierarchy of evidence described earlier in this section.

There is insufficient evidence to conclude that ovarian transposition 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.

Ovarian shielding during radiation therapy

During radiation treatment for cancer, 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). Although three review

articles recommended the use of ovarian shielding during radiation therapy, no research to support these recommendations were cited (Lee et al., 2006; Gurgan et al., 2008; Levine et al., 2010). 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.

There is insufficient evidence that ovarian shielding during radiation therapy 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 shielding during radiation therapy.

Conservative gynecologic surgery

The recommendations released by the American Society of Clinical Oncology 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 gynecological 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 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). 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., 2010).

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 Tanger, 2005). These rates are comparable to rates observed in women with 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 Tanger, 2005).

The standard treatment for 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).

There is a preponderance of evidence that conservative gynecologic surgery is an effective method of fertility preservation measured by pregnancy rates and live births and there is a preponderance of evidence that this surgery has no apparent increase in cancer recurrence or mortality for specific cases.

Experimental Fertility Preservation Options for Females

Oocyte (egg) cryopreservation

For women who do not have a partner or who do not wish to use a sperm donor, another option for preserving fertility is oocyte cryopreservation. This treatment is appropriate for females who have gone through puberty and have mature eggs. In an outpatient surgical procedure, eggs are removed from the female approximately 10 to 14 days from menses (Levine et al., 2010). It is estimated that birth rates are 2% per oocyte successfully thawed (Dunn and Fox, 2009). A new quick freezing technology called vitrification results in less ice crystallization damage during freezing and thawing (thus a more viable egg) than is experienced in the current slow freeze and thaw method. It is hoped that this advance in technology will vastly improve the viability of the oocytes after thawing. In addition, there is a push in the reproductive medicine profession to treat oocyte cryopreservation as a standard medical procedure (Noyes et al., 2010). However, because the bulk of the published studies still report on the older technique, oocyte cryopreservation is still considered experimental (Lee et al., 2006; Levine et al., 2010; Oktem and Urman, 2010). Therefore, this section does not present a review of the literature or a conclusion as to the overall effectiveness of the procedure.

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 2010, there had been seven babies born through this procedure (Lee et al., 2006; Levine et al., 2010). 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). New techniques are being developed to reduce this risk, but this procedure is still considered experimental (Lee et al.,

2006; Levine et al., 2010). Therefore, this section does not present a conclusion as to the overall effectiveness of the procedure.

Ovarian suppression with GnRH analogs

Gonadotropin releasing hormone (GnRH) analogs 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 Gafer-Gvili, 2010). This treatment 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. The research studies with humans have been small, uncontrolled, and/or retrospective (Lee et al., 2006; Levine et al., 2010). 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 Gafer-Gvili, 2010). In addition, there is some concern that the use of GnRH analogs is not appropriate for women undergoing treatment for breast cancer because it may reduce the tumor sensitivity to chemotherapy (de Ziegler et al., 2010).

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

Table 2. 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 eggs, in vitro fertilization, and freezing of embryos for later implantation.	Postpubertal Females	Average 27% birth rate per embryo transfer (a)	There is a preponderance of evidence that embryo 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% (b)	There is insufficient evidence to conclude that ovarian transposition is an effective method of 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 findings presented	There is insufficient evidence that ovarian shielding during radiation therapy is an effective method of fertility preservation.

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

Treatment	Description	Target Population	Outcomes	Conclusion
Conservative gynecological 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 (c)	There is a preponderance of evidence that trachelectomy is an effective method of fertility preservation
Conservative gynecological 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(d)	There is a preponderance of evidence that conservative ovarian surgery is an effective method of fertility preservation
Experimental Medical Practice				
Oocyte Cryopreservation	Harvesting and freezing of unfertilized eggs.	Postpubertal Females	2% per birth rate oocyte transfer(e)	Experimental treatment, clinicians indicate it is becoming standard of care
Ovarian Cryopreservation and Transplantation	Freezing of ovarian tissue and reimplantation after cancer treatment.	Pre- and Postpubertal (without Systemic Metastasis)	Case reports of seven 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, 2011

Note: The sources for the table are as follows: (a) Dunn and Fox, 2009; Rodriguez-Macias Wallberg et al., 2009; (b) Lee et al., 2006 (c) Beiner and Covens, 2007; Dursun et al., 2007; Eskander et al., 2010; (d) Eskander et al., 2010; (e) Dunn and Fox, 2009; Levine et al., 2010; (f) Levine et al., 2010; (g) Ben-Aharon and Gafer-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 banking (or cryopreservation) 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 extraction or electroejaculation under sedation, but are generally considered experimental (Lee et al., 2006; Levine et al., 2010). Males generally start producing sperm around 13 to 14 years of age,

therefore this treatment is not appropriate for prepubescent males (Levine et al., 2010). Research has indicated that pregnancies with sperm stored between 10 and 28 years can be achieved (Levine et al., 2010).

Studies of the effectiveness of sperm cryopreservation in cancer patients found that this fertility preservation method gives a male cancer patient a reasonable 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).

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

Testicular shielding during radiation therapy

During radiation treatment, a shield can be placed over the testicles to reduce the amount of radiation delivered to the testicles (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 (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).

There is insufficient evidence that testicular shielding is an effective method of fertility preservation in males. 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 (sperm obtained through testicular aspiration or extraction, electroejaculation under sedation, or from a post-masturbation urine sample) but indicated that these methods are uncommon and experimental (Lee et al., 2006). In a study of testicular cancer patients, Delouya et al. (2010) found that in 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 freezing 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).

Testicular suppression with GnRH analogs or antagonists

Gonadotropin releasing hormone (GnRH) analogs or antagonists 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 such as improved sperm count and hormone levels (Lee et al., 2006; van der Kaaij et al., 2010).

<p>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.</p>
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Table 3. 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
Testicular suppression with GnRH analogs or antagonists	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, 2011

Note: The sources for the table are as follows: (a) Hourvitz et al., 2008; van Casteren et al., 2008; (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.

Summary of Findings for Fertility Preservation Treatments

Fertility Preservation Treatments for Females:

- 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.
- There is insufficient evidence to conclude that ovarian transposition 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.

- There is insufficient evidence that ovarian shielding during radiation therapy 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 shielding during radiation therapy.
- There is a preponderance of evidence that conservative gynecologic surgery is an effective method of fertility preservation measured by pregnancy rates and live births with no apparent increase in cancer recurrence or mortality.
- Oocyte cryopreservation, ovarian cryopreservation and transplantation, ovarian suppression with gonadotropin releasing hormone (GnRH) analogs or antagonists are all considered experimental methods of fertility preservation. Therefore, there is insufficient evidence to evaluate their medical effectiveness.
- Although oocyte cryopreservation is considered experimental in the literature, it is being performed at most fertility centers across the nation. Experts expect that it will become standard medical practice within the next few years.

Fertility Preservation Treatments for Males:

- There is a preponderance of evidence that sperm cryopreservation is an effective method of fertility preservation measured by pregnancy rates and live births.
- There is insufficient evidence that gonadal shielding is an effective method of fertility preservation in males. 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.
- Sperm cryopreservation after alternative methods of sperm collection, testicular tissue cryopreservation, and gonad suppression with GnRH analogs or antagonists are all considered experimental methods of fertility preservation. Therefore, there is insufficient evidence to evaluate their medical effectiveness.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

AB 428 would require DMHC-regulated health plan contracts and CDI-regulated insurance policies to include coverage for standard medical services for fertility preservation when a necessary medical treatment poses a risk of iatrogenic infertility to the patient. This bill would apply to enrollees in both DMHC-regulated, privately funded plans and DMHC-regulated, publicly funded plans, as well as all CDI-regulated policies. CHBRP estimates that 21.9 million Californians are currently enrolled in these plans or policies, and would be subject to the mandate.

AB 428 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 radiation and chemotherapy treatment associated with cancer treatment. CHBRP, therefore, estimates the population who would be considered users of fertility preservation to those who face one of the top 10 cancers that associated with treatments that could cause iatrogenic infertility. Furthermore, the population analysis is restricted to those of reproductive age (ages 14-40 for females and ages 12-50 for males). As discussed in the *Medical Effectiveness* section, fertility preservation services 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 two medical procedures that are standard practice in cases in which the patient desires to protect themselves against iatrogenic infertility due to cancer treatments: (1) sperm cryopreservation for men and (2) embryo cryopreservation for women. Radiation shielding is also considered standard practice, but its use and costs are folded in to the normal radiation therapy that occurs as part of cancer treatments. Other services exist, such as egg cryopreservation, ovarian cryopreservation, and ovarian transplantation. However, these services are still considered experimental and are not likely to become standard medical practice during the one-year time frame of this analysis. CHBRP’s cost impact analysis, therefore, focuses on increased coverage and use of sperm cryopreservation and embryo 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 428 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 85.16% of enrollees in the privately funded, CDI-regulated market and 88.53% of enrollees in the privately funded, DMHC-regulated

market. Combined, responses to this survey represent 87.83% of enrollees in the privately funded market subject to state mandates.¹⁶

Currently, 5.4% of the 21.9 million total enrollees in DMHC- or CDI-regulated plans or policies have benefit coverage for fertility preservation services. All of these 1.2 million enrollees who currently have benefit coverage for fertility preservation services are in the large- or small-group market, and there is currently no coverage for fertility preservation services in the individual market.

None of California's publicly funded health insurance programs (i.e., CalPERS HMO, Medi-Cal Managed Care Plans, Managed Risk Medical Insurance Board [MRMIB] Plans) provide coverage for fertility preservation services. Enrollees in the Access for Infants and Mothers (AIM) program were assumed to have no utilization for fertility preservation services from this analysis, since all enrollees are currently pregnant.

Current Utilization Levels

CHBRP estimates that 4,352 men and 1,994 women currently would be recommended to use fertility preservation services, since they are of reproductive age and have one of the top ten types of cancer for which the treatment can cause iatrogenic infertility. This represents 0.029% of the total population of enrollees in DMHC- or CDI-regulated plans or policies. These totals were derived from cancer incidence rates by age, using Surveillance Epidemiology and End Results (SEER) data from the National Cancer Institute from 2005-2007 (Su, 2011).

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. However, the assumptions CHBRP derived from the literature were examined by numerous content experts and reviewers, and it was agreed that these utilization assumptions were the best possible estimate given their own knowledge of the field and the available data.

To calculate the use of sperm cryopreservation by male enrollees who are at risk for iatrogenic infertility, CHBRP relied on a study that found that 24% of men at risk for iatrogenic infertility chose to use sperm cryopreservation (Schover et al., 2002). CHBRP estimates that premandate, 1,057 male enrollees currently use sperm cryopreservation to protect against iatrogenic infertility. Of these, 71 male enrollees are estimated to have coverage for fertility preservation services, while the remainder paid directly for their noncovered fertility preservation services.

To calculate the use of embryo cryopreservation by female enrollees who are at risk for iatrogenic infertility, CHBRP relied on a forthcoming study (Letourneau, et al., 2010) which indicated that 10% of women who face iatrogenic infertility are likely to use fertility preservation services. CHBRP estimates that 222 female enrollees currently use embryo cryopreservation to

¹⁶ CHBRP's analysis of the share of enrollees included in CHBRP's Bill-Specific Coverage Survey of the major carriers in the state is based on "CDI Licenses with HMSR Covered Lives Greater than 100,000" as part of the Accident and Health Covered Lives Data Call, December 31, 2009, by the California Department of Insurance, Statistical Analysis Division, data retrieved from the Department of Managed Health Care's interactive Web site "Health Plan Financial Summary Report," July-September 2010, and CHBRP's Annual Enrollment and Premium Survey.

protect against iatrogenic infertility. Of those, 34 are estimated to have coverage for fertility preservation services while the rest paid 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. The annual costs of sperm and embryo cryopreservation were not included in the short-term, one-year cost model. See *Impact on long-term costs* for further discussion.

For the initial procedure, sperm procurement and cryopreservation costs an average of \$400. Embryo procurement is a surgical procedure and requires a month of prescription drug treatment prior to the actual procedure itself. Taken together, the average cost of the procurement surgery and the fertility drugs is approximately \$14,700.

Current (Baseline) Premiums and Expenditures

Table 4 (at the end of this section) presents per member per month (PMPM) premandate estimates for premiums and expenditures by market segment. Prior to the mandate, total expenditures vary depending on plan type. The lowest average expenditure (\$116.96) was in the DMHC-regulated MRMIB plans, and the highest average expenditure was among the CDI-regulated large group policies (\$560.69).

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

CHBRP estimated no shift in costs among private or public payors 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. 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 currently 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.¹⁷

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.

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 relevant benefit coverage differed from what is 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. As discussed in the public health section, this may be because iatrogenic infertility is concern for treatments associated with relatively rare conditions.

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, once the patient had been informed of their risk of iatrogenic infertility and the availability of sperm and embryo 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). It is possible that the mandate and resulting efforts by advocates to increase awareness of the newly covered benefit may encourage providers to offer these services to their cancer 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 one-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 prices of those services, CHBRP assumes that the unit cost of sperm and embryo cryopreservation would stay the same after the mandate.

¹⁷ Personal communication, S Flocks, California Labor Federation, January 2011.

How Would Utilization Change As a Result of the Mandate?

Estimates from the literature indicate that 7% of the 76% of men (approximately 5% overall) who did not undergo sperm cryopreservation would have utilized the procedure if the cost were reduced (Schover et al., 2002). From this, CHBRP estimated that the postmandate use of sperm cryopreservation would rise to 29% of male enrollees who are cancer patients and are at risk for iatrogenic infertility, or 1,262 male enrollees.

Utilization for embryo cryopreservation for women was assumed to rise to the same level (29%) as that of sperm cryopreservation for men, based on content expert input. CHBRP estimates that 578 female enrollees would use fertility preservation services. In total, utilization of fertility preservation services is estimated to increase to approximately 1,840 enrollees, or 29% of the total 6,346 enrollees who have cancer and would be at risk for iatrogenic infertility.

The utilization increase is small because the choice to undergo sperm or embryo cryopreservation is highly dependent on several other 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 need to start treatment immediately, since embryo cryopreservation delays cancer treatment. The additional invasiveness of the procurement procedure itself can also be a barrier (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 is 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 428 is estimated to increase total net health expenditures by \$6.5 million, or 0.0068% (see Table 1 in *Executive Summary*). This is due to an \$8.46 million increase in premiums to cover the increased utilization of fertility preservation services, partially offset by a net reduction in enrollee out-of-pocket expenditures of \$1.96 million. This is comprised of a reduction in enrollee expenses for noncovered benefits (\$3.15 million) and an increase in enrollee out-of-pocket expenses for the newly covered benefits (\$1.19 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 one-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 428 were enacted, there are potential long-term costs that were not considered as part of CHBRP's one-year, short-term cost model. Cryopreservation of the sperm or embryos incurs annual storage fees. Girasole et al. (2006) found that nationwide, annual maintenance fees ranged from \$0 to \$1200, with a median of \$300. A study by Chang et al. (2006) found that during the 10 years after cryopreserving their sperm prior to cancer treatment, 83% of the 75 patients in the study maintained their storage for the full 10 years. These annual storage fees could add in the long-term to the increase in costs.

In terms of future fertility among those who use cryopreservation, the literature indicates that less than 10% of those who store sperm use it within a 10-year period for reproductive purposes (Chang et al., 2006; Chung et al., 2004; Girasole et al. 2006; van Casteren et al., 2008). In both the Chang et al. and the Chung et al. studies, one successful IVF pregnancy occurred in each. However, the larger study by van Casteren et al. (2008) showed that out of the original 557 men who preserved their sperm, 21 successful pregnancies resulted from a total of 101 attempts to get pregnant using assisted reproductive technologies. The costs of these future procedures may increase health care costs to a small degree, if AB 428 were enacted.

Additionally, health care practitioners may start recommending sperm and embryo 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 428 were enacted, the financial costs to the patient would decrease substantially with the increase in insurance coverage, and oncologists may be more likely to present sperm or embryo cryopreservation to their patients as an option.

Impacts for Each Category of Payor Resulting from the Benefit Mandate

Changes in expenditures and PMPM amounts by payor category

Increases in insurance premiums vary by market segment. Note that the total population in Table 5 reflects the full 21.9 million enrollees in DMHC- or CDI-regulated plans or policies that are subject to AB 428. 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 0.0000% (for DMHC-regulated Medi-Cal Managed Care plans for ages 65+) to an average increase of 0.0173% (for CDI-regulated individual policies) in the affected market segments (Table 5). Increases as measured by PMPM premiums are estimated to range from an average of \$0.0000 (for DMHC-regulated Medi-Cal Managed Care plans for ages 65+) to an average of \$0.0373 (for DMHC-regulated regulated small-group plans).

In the privately funded large-group market, the increase in premiums is estimated to range from an average of \$0.0371 PMPM among DMHC-regulated plan contracts to an average of \$0.0362 PMPM among CDI-regulated policies (Table 5). For enrollees with privately funded small-group

insurance policies, health insurance premiums are estimated to increase by an average of \$0.0373 PMPM for DMHC plan contracts to an average of \$0.0278 PMPM for CDI policies. In the privately funded individual market, the health insurance premiums are estimated to increase by averages of \$0.0370 PMPM and by \$0.0344 PMPM in the DMHC- and CDI-regulated markets, respectively.

Among publicly funded DMHC-regulated health plans, CHBRP estimates that premiums would remain flat or increase slightly for Medi-Cal Managed Care Plans, MRMIB plans, and CalPERS HMOs, with the impact ranging from an average of 0.00% to 0.0125% (\$0.00 to \$0.0323).

There is also a shift in expenditures from enrollees paying for noncovered benefits to premiums. For example, in the large-group DMHC market, an average of \$0.0129 of enrollee expenses for noncovered (measured as PMPM costs) would be expected to shift to the health plan or insurer, partially offset by a \$0.0020 average increase in enrollee expenses for covered benefits. Individuals who currently purchase fertility preservation services would realize savings under the mandate, because full coverage for these services would be available to them if AB 428 were enacted.

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.

Table 4. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2011

	DMHC-Regulated							CDI-Regulated			Total
	Privately Funded Plans (by market)			CalPERS HMOs (b)	Medi-Cal Managed Care Plans		MRMIB Plans (d)	Privately Funded Policies (by market)			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65		Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state Mandates (a)	10,526,000	2,241,000	733,000	831,000	285,000	3,539,000	889,000	397,000	1,118,000	1,343,000	21,902,000
Total enrollees in plans/policies subject to AB 428	10,526,000	2,241,000	733,000	831,000	285,000	3,539,000	889,000	397,000	1,118,000	1,343,000	21,902,000
Average portion of premium paid by Employer	\$317.59	\$267.09	\$0.00	\$347.55	\$346.00	\$176.00	\$98.48	\$375.44	\$270.30	\$0.00	\$65,887,370,000
Average portion of premium paid by Employee	\$82.91	\$83.47	\$399.69	\$86.89	\$0.00	\$0.00	\$13.79	\$122.08	\$64.15	\$199.13	\$21,898,323,000
Total Premium	\$400.51	\$350.57	\$399.69	\$434.44	\$346.00	\$176.00	\$112.27	\$497.52	\$334.45	\$199.13	\$87,785,693,000
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$21.82	\$32.63	\$84.77	\$22.41	\$0.00	\$0.00	\$4.68	\$63.15	\$123.11	\$58.53	\$7,548,415,000
Enrollee expenses for benefits not covered (e)	\$0.01	\$0.01	\$0.01	\$0.01	\$0.00	\$0.01	\$0.00	\$0.01	\$0.01	\$0.01	\$3,153,000
Total Expenditures	\$422.34	\$383.21	\$484.47	\$456.86	\$346.00	\$176.01	\$116.96	\$560.69	\$457.57	\$257.67	\$95,337,261,000

Source: California Health Benefits Review Program, 2011.

Note: (a) This population includes persons insured with private funds (group and individual) and insured with public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans, Healthy Families Program, AIM, MRMIP) enrolled in health plans or policies regulated by the DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance.

(b) Of these CalPERS HMO members, about 58% or 482,000 are state employees or their dependents.

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

(d) MRMIB Plan expenditures include expenditures for 874,000 enrollees of the Healthy Families Program, 8,000 enrollees of MRMIP, and 7,000 enrollees of the AIM program.

(e) 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.

Table 5. Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2011

	DMHC-Regulated							CDI-Regulated			Total
	Privately Funded Plans (by market)			CalPERS HMOs (b)	Medi-Cal Managed Care Plans		MRMIB Plans (d)	Privately Funded Policies (by market)			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65		Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state Mandates (a)	10,526,000	2,241,000	733,000	831,000	285,000	3,539,000	889,000	397,000	1,118,000	1,343,000	21,902,000
Total enrollees in plans/policies subject to AB 428	10,526,000	2,241,000	733,000	831,000	285,000	3,539,000	889,000	397,000	1,118,000	1,343,000	21,902,000
Average portion of premium paid by Employer	\$0.0294	\$0.0285	\$0.0000	\$0.0258	\$0.0000	\$0.0220	\$0.0080	\$0.0273	\$0.0224	\$0.0000	\$6,186,000
Average portion of premium paid by Employee	\$0.0077	\$0.0088	\$0.0370	\$0.0065	\$0.0000	\$0.0000	\$0.0011	\$0.0089	\$0.0053	\$0.0344	\$2,276,000
Total Premium	\$0.0371	\$0.0373	\$0.0370	\$0.0323	\$0.0000	\$0.0220	\$0.0091	\$0.0362	\$0.0278	\$0.0344	\$8,462,000
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$0.0020	\$0.0036	\$0.0080	\$0.0102	\$0.0000	\$0.0072	\$0.0030	\$0.0048	\$0.0109	\$0.0101	\$1,194,000
Enrollee expenses for benefits not covered (e)	-\$0.0129	-\$0.0125	-\$0.0139	-\$0.0139	\$0.0000	-\$0.0100	-\$0.0045	-\$0.0132	-\$0.0123	-\$0.0139	-\$3,153,000
Total Expenditures	\$0.0262	\$0.0284	\$0.0311	\$0.0285	\$0.0000	\$0.0192	\$0.0075	\$0.0278	\$0.0264	\$0.0306	\$6,503,000
Percentage Impact of Mandate											
Insured Premiums	0.0093%	0.0106%	0.0093%	0.0074%	0.0000%	0.0125%	0.0081%	0.0073%	0.0083%	0.0173%	0.0096%
Total Expenditures	0.0062%	0.0074%	0.0064%	0.0062%	0.0000%	0.0109%	0.0064%	0.0050%	0.0058%	0.0119%	0.0068%

Note: (a) This population includes persons insured with private funds (group and individual) and insured with public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans, Healthy Families Program, AIM, MRMIP) enrolled in health plans or policies regulated by the DMHC or CDI. This population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance.

(b) Of these CalPERS members, about 58% or 482,000 are state employees or their dependents.

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

(d) MRMIB Plan expenditures include expenditures for 874,000 enrollees of the Healthy Families Program, 8,000 enrollees of MRMIP, and 7,000 enrollees of the AIM program.

(e) 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.

PUBLIC HEALTH IMPACTS

AB 428 would require coverage for fertility preservation services for iatrogenic infertility, defined as infertility caused by medical treatment including reactions from prescribed drugs or from medical and surgical procedures. Iatrogenic infertility is typically caused by cancer treatments such as radiation, chemotherapy, 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. Fertility preservation treatments considered as standard medical procedures include sperm cryopreservation, embryo cryopreservation, ovarian shielding during radiation treatment, ovarian transposition, and conservative gynecological surgery. This section presents the overall public health impact of AB 428, 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.

Public Health Impacts

As presented in the *Medical Effectiveness* section, there is a preponderance of evidence that embryo cryopreservation, conservative gynecological surgery, and sperm cryopreservation are effective methods of fertility preservation. In addition, there is insufficient evidence to evaluate the effectiveness ovarian transposition or ovarian shielding from radiation. Oocyte cryopreservation, 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 are all considered experimental methods of fertility preservation.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, it is estimated that current utilization of the two most established methods of fertility preservation, embryo and sperm cryopreservation, is 10% and 24% respectively among persons of reproductive age with invasive cancers. With only 5.4% of this population covered for fertility preservation treatments under their current health insurance plan, the vast majority of cancer patients of reproductive age have to pay directly for fertility preservation treatments. It is estimated that currently these expenditures total nearly \$2.8 million for female enrollees to pay for embryo cryopreservation and nearly \$400,000 for male enrollees to pay for sperm cryopreservation.

Research shows that the financial burden faced by cancer patients can be substantial. One study found that 45% of cancer patients with substantial care needs report a sense of financial burden (Emanuel et al., 2000). Cancer treatment can also have significant long-term economic consequences; one study found that one-third of families lose all or most of their savings after a cancer diagnosis (Covinsky et al., 1996). Nonmedical costs due to cancer treatment, such as transportation costs and lost wages, can also result in a substantial burden for cancer patients and their families (Bennett et al., 1998). Cancer patients who are also concerned with maintaining their fertility have an additional burden—not only do they have the burden of their cancer treatments, but they have the burden of paying for their fertility preserving services. AB 428

would decrease expenses paid directly by enrollees who use fertility preservation services by almost \$2 million. Therefore, AB 428 is estimated to reduce financial hardship for enrollees who face the risk of iatrogenic infertility.

The practice guidelines issued by the American Society of Clinical Oncology indicate that all patients of childbearing age should be counseled as to their fertility preservation options prior to starting treatment that could impair their future fertility (Lee et al., 2006). It is estimated that only half of patients of reproductive age are counseled regarding their fertility preservation options, although among breast cancer patients, this rate is closer to three-quarters (Quinn et al., 2009; Partridge et al., 2004). Loss of fertility can negatively impact the quality of life for cancer survivors of reproductive age (Avis et al., 2004; Lee et al., 2006; Wallace et al., 2005). 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). The psychosocial distress and loss of self-esteem facing cancer patients worried about preserving their fertility can lead to a decrease in their overall quality of life (Partridge et al., 2004). In addition, overall quality of life is also impacted by unresolved grief, depression, and anxiety among those who become infertile (Lee et al., 2006). As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section AB 428 would increase coverage for fertility preservation services to over 21.9 million Californians. As a result of this increase, it is expected that the quality of life could improve for those 6,346 enrollees facing iatrogenic infertility each year who would gain coverage for fertility preservation services.

Long-term Public Health Impacts

Outside of the one-year time frame that CHBRP uses for estimating public health impacts, there are some longer-term impacts of AB 428 that should be considered. Although it is impossible to predict these impacts precisely, the numbers presented in this section should be thought of as a general indication of the magnitude of the potential long-term impact. Although AB 428 does not provide coverage for treatments related to trying to conceive using frozen sperm or embryos, CHBRP determined that there was still a potential for increase in the use of frozen reproductive material among enrollees subject to AB 428 who used fertility preservation services covered under the mandate. It was determined that current rates of utilization of frozen embryos and sperm used in the calculations below take into account any potential cost barriers such as insurance coverage for infertility treatments and related direct costs to the patient.

In the *Benefit Coverage, Utilization, and Cost Impacts* section, it is estimated that there would be approximately 205 more males using sperm cryopreservation as a result of AB 428. The literature indicates that approximately 5% of cancer patients that cryopreserve their sperm prior to undergoing cancer treatment end up using their frozen sperm for reproductive purposes (Chung et al., 2004). This number is in the same range as other figures reported internationally of the utilization of cryopreserved sperm for reproductive purposes in males with cancer (Chang et al., 2006; Navarro Medina et al., 2010; Soda et al., 2009). Therefore, 5% of the additional 205 male enrollees using sperm cryopreservation would retrieve their sperm—or approximately 10 more patients. As reported in the *Medical Effectiveness* section, the rate of live births among

cancer patients retrieving their cryopreserved sperm is approximately 50% (Hourvitz et al., 2008; van Casteren et al., 2008). Therefore, long-term impacts of AB 428 are estimated to be approximately five more male cancer patients having biological children each year.

In the *Benefit Coverage, Utilization, and Cost Impacts* section, it is estimated that there could be approximately 357 more female enrollees using embryo cryopreservation as a result of AB 428. It has been estimated that 18% of female cancer patients who cryopreserve embryos ultimately return to thaw these embryos (Michaan et al., 2010). Therefore, as a result of AB 428, approximately 18% of 357 patients who froze embryos could be expected to thaw and transfer embryos – meaning that 64 patients would utilize their frozen embryos. As reported in the *Medical Effectiveness* section, delivery rates per embryo transfer using cryopreserved embryos are reported to be in the range of 26 to 28% (Dunn and Fox, 2009; Rodriguez-Macias Wallberg et al., 2009). Therefore, using a midpoint of 27%, it is estimated that in the long term, AB 428 could result in approximately 17 more female cancer patients having a biological child each year.

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 428 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). Since AB 428 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 428 would decrease the out-of-pocket expenses of patients utilizing fertility preservation services by almost \$2 million. For patients whose expenses decreased, the change would reduce the financial hardship associated with iatrogenic infertility for those persons. There is great disparity in the degree to which males and females face direct expenses and associated financial burden in paying for fertility preservation services. For males, sperm cryopreservation is the standard method of preserving fertility, costing approximately \$400. For females, embryo cryopreservation is the standard method of preserving fertility. This treatment is estimated to cost

\$14,700. Therefore, females are facing costs for preserving fertility that are more than 35 times that faced by males. AB 428 is expected to decrease the disparity in the financial burden of expenses related to fertility preservation services borne by females. Based on assumptions on utilization, CHBRP estimates that males and females may likely face similar direct expenses postmandate.

Impact on Racial/Ethnic Disparities

CHBRP could find no evidence that evaluated the extent to which iatrogenic infertility varied by race/ethnicity. In addition, no evidence was found to the extent to which the use of fertility preservation treatments were used by race/ethnicity since health care claims and utilization data rarely include racial or ethnic identifiers. Therefore, the extent to which AB 428 would have an impact on racial/ethnic disparities is unknown.

Impacts on Premature Death and Economic Loss

Premature death is often defined as death before the age of 75 (Cox, 2006). The overall impact of premature death due to a particular disease can be measured in years of potential life lost prior to age 75 and summed for the population (generally referred to as “YPLL”) (Cox, 2006; Gardner and Sanborn, 1990). In California, it is estimated that there are nearly 102,000 premature deaths each year accounting for more than two million YPLL (Cox, 2006). In order to measure the impact of premature mortality across the population impacted by a proposed mandate, CHBRP first collects baseline mortality rates. Next, the medical effectiveness literature is examined to determine if the proposed mandated benefit impacts mortality. In cases where a reduction in mortality is projected, a literature review is conducted to determine if the YPLL has been established for the given condition. Some diseases and conditions do not result in death and therefore a mortality outcome is not relevant.

Economic loss associated with disease is generally presented in the literature as an estimation of the value of the YPLL in dollar amount (i.e., valuation of a population’s lost years of work over a lifetime). For CHBRP analyses, a literature review is conducted to determine if lost productivity has been established in the literature. In addition, morbidity associated with the disease or condition of interest can also result in lost productivity; either by causing the worker to miss days of work due to their illness or due to their role as a caregiver for someone else who is ill.

Premature Death

Cancer represents the greatest contributor to premature death in California, with 21.1% of all YPLL attributable to cancer (CDPH, 2009). It is estimated that in California in 2007, the YPLL per 100,000 due to cancer was 1,209, translating into nearly 200,000 YPLL each year (CDPH, 2009). Although cancer is a substantial cause of iatrogenic infertility and premature mortality in California, fertility preservation treatments would not be expected to impact premature death. Therefore, AB 428 would not be expected to result in a reduction in premature death.

Economic Loss

The National Institutes of Health have estimated that the overall cost of cancer in 2005 was \$209.9 billion (USCSWG, 2005). Of this, it was estimated that \$74 billion (35%) was for direct medical costs, including health expenditures; while the remaining 65% was attributable to lost productivity due to illness (\$17.5 billion) and premature death (\$118.4 billion) (USCSWG, 2005). Although cancer in California is a substantial cause of lost productivity due to illness and premature death, AB 428 is not expected to result in a reduction of economic loss.

APPENDICES

Appendix A: Text of Bill Analyzed

On February 15, 2011, the Assembly/Senate Committee on Health requested that CHBRP analyze AB 428. Below is the bill language, as it was introduced on February 14, 2011.

On March 10, 2011: The Office of Assembly Member Portantino stated that they will amend the bill language below to have the Insurance Code provision mirror the Health and Safety Code provision so that health policies are required to cover fertility preservation treatment.

California Legislature—2011–12 Regular Session

ASSEMBLY BILL No. 428 **Introduced by Assembly Member Portantino**

February 14, 2011

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 428, as introduced, Portantino. 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 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 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, to read:

1374.551. Every group or individual health care service plan that is issued, amended, or renewed on and after January 1, 2012, 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, to read:

10119.61. Every health insurer that issues, amends, or renews a policy on and after January 1, 2012, that covers hospital, medical, or surgical expenses on a group or individual basis shall offer 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 XIIB 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. Web sites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality, the International Network of Agencies for Health Technology Assessment, the National Health Service Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence, and the Scottish Intercollegiate Guideline Network.

The search was limited to abstracts of studies published in English. The medical effectiveness search was limited to studies published from 2006 to present, because the American Society of Clinical Oncology had previously conducted a systematic review on this subject covering literature published between 1987 to 2005 (Lee et al., 2006). 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.

Two 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. The literature search returned 563 articles, of which 111 were reviewed for inclusion in this report. A total of 22 studies were included in the medical effectiveness review for AB 428.

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. 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
- 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.

The conclusion states that there is “clear and convincing” evidence that an intervention has a favorable effect on an outcome if most of the studies included in a review have strong research designs and report statistically significant and clinically meaningful findings that favor the intervention.

The conclusion characterizes the evidence as “preponderance of evidence” that an intervention has a favorable effect if most, but not all five, criteria are met. For example, for some interventions, the only evidence available is from nonrandomized studies. If most such studies that assess an outcome have statistically and clinically significant findings that are in a favorable direction and enroll populations similar to those covered by a mandate, the evidence would be classified as a “preponderance of evidence favoring the intervention.” In some cases, the preponderance of evidence may indicate that an intervention has no effect or an unfavorable effect.

The evidence is presented as “ambiguous/conflicting” if their findings vary widely with regard to the direction, statistical significance, and clinical significance/size of the effect.

The category “insufficient evidence” of an intervention's effect is used when there is little if any evidence of an intervention's effect.

Search Terms

The search terms used to locate studies relevant to AB 428 were as follows:

MeSH Terms Used to Search PubMed

Antineoplastic Agents/adverse effects
Comparative Effectiveness Research
Costs and Cost Analysis
Ethnic Groups
Fertility/drug effects
Fertility/economics
Fertility/radiation effects
Gonadotropin-Releasing Hormone/therapeutic use
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
Healthcare Disparities
Iatrogenic Disease/economics
Iatrogenic Disease/prevention & control
Infertility
Infertility/drug effects
Infertility/economics
Infertility/epidemiology
Infertility/ethnology
Infertility/etiology
Infertility/surgery
Infertility/therapy
Neoplasms
Neoplasms/complications
Neoplasms/drug therapy
Neoplasms/economics
Neoplasms/radiotherapy
Neoplasms/surgery

Keywords used to search PubMed, Cochrane Library, EconLit, Web of Science, and relevant Web sites

antineoplastic
assisted reproductive techniques
cancer
chemotherapy
cost
cost effective
cost effectiveness
cost of treatment
cost offset
cost savings
cost utility
costs
cryopreservation
demand
direct medical cost
economic*
effective
effectiveness
egg freezing
embryo cryopreservation
embryo preservation
ethnic

ethnicity
expense
expenses
fertility
fertility preservation
financial burden
freez*
freezing
gender
gonad shield*
gonadal shielding
gonadotoxic
gonadotrophin suppression
gonads
gonads shield*
hodgkin*
hodgkin* disease
hodgkins disease
Humans
iatrogenic
Iatrogenic Disease
iatrogenic infertility
incidence
incremental cost effectiveness ratio
infertility
insurance
lymphoma
lymphoma*
neoplasms
oncofertility
oocyte*
oocyte* cryopreservation
oocyte* freez*
oocyte* preserv*
oophoropexy
out-of-pocket
outcome
outcomes
ovarian cryopreservation
ovarian shield*
ovarian suppression
ovarian transplantation
ovarian transposition
pregnancy
Pregnancy Rate
premature menopause

premature ovarian failure
preserv*
prevalence
price
price elasticity
Primary Ovarian Insufficiency
racial
radiation
Radiation Protection
radiation shield*
radiation shield* gonads
radiotherapy
Radiotherapy/adverse effects
Reproductive Techniques, Assisted
Reproductive Techniques, Assisted/utilization
semen cryopreservation
semen freez*
semen preservation
Sex Factors
Socioeconomic Factors
sperm bank*
sperm banking
Sperm Banks
sperm cryopreservation
sperm freez*
sperm preservation
testicular hormonal suppression
testicular shield*
testicular shield* radiation
testicular sperm extraction
testicular suppression
testicular tissue cryopreservation
testicular tissue freez*
testicular tissue preservation
Tissue Preservation
trachelectomy
treatment
treatment-related infertility
treatment cost
Treatment Outcome
unit cost
united states
utilization
Utilization Review

Publication Types:

Case Reports
Clinical Trial
Comparative Study
Controlled Clinical Trial
Evaluation Studies
Guideline
Meta-Analysis
Randomized Controlled Trial
Review

Appendix C: Description of Studies on Fertility Preservation Treatments

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
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	USA, Canada, France, England and Germany
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 carcinoma	Multiple countries
Eskander et al., 2010	Literature review	To summarize the fertility sparing options for patients with cervical, ovarian and endometrial cancer with an emphasis on appropriate patient selection, oncologic, and obstetric outcomes.	Female patients with gynecologic cancer	Multiple countries
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

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

Citation	Type of Study	Study Objective	Population Studied	Location
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, USA
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
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
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, 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 assisted reproductive technologies (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

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

Citation (s)	Research Design	Direction of Effect	Findings	Conclusion
Fertility Options for Females: Embryo cryopreservation				
Lee et al., 2006	American Society of Clinical Oncology Recommendations	Positive	<ul style="list-style-type: none"> • 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 ¹⁸	Review article of 6 studies	Positive	<ul style="list-style-type: none"> • 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	Positive	<ul style="list-style-type: none"> • 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	Positive	<ul style="list-style-type: none"> • 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	Positive	<ul style="list-style-type: none"> • 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.

¹⁸ Although this publication date is 2005 and Lee et al., is 2006, this article came out past the cut off 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	Direction of Effect	Findings	Conclusion
Fertility Options for Females: Ovarian transposition (oophoropexy)				
Lee et al., 2006	American Society of Clinical Oncology Recommendations	Positive	<ul style="list-style-type: none"> 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	Positive	<ul style="list-style-type: none"> 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, 2008	Review article of 3 studies	Positive	<ul style="list-style-type: none"> Reduces radiation exposure to the ovaries to only 5% to 10% of non-transposed 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, 1992	Case series of 18 females	Positive	<ul style="list-style-type: none"> 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.
Fertility Options for Females: Gonadal (ovarian) shielding during radiation therapy				
Lee et al., 2006	American Society of Clinical Oncology Recommendations	Inconclusive	No findings reported.	Gonadal shielding prior to radiation therapy may preserve fertility for selected cancers.
Gurgan et al., 2008	Review article	Inconclusive	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	Inconclusive	No findings reported.	Shielding of the ovaries during radiotherapy is a standard medical practice, but expertise is required.

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

Citation (s)	Research Design	Direction of Effect	Findings	Conclusion
Fertility Options for Females: Conservative gynecological surgery				
Lee et al., 2006	American Society of Clinical Oncology Recommendations	Positive	<ul style="list-style-type: none"> • 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	Positive	<ul style="list-style-type: none"> • 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	Positive	<ul style="list-style-type: none"> • 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	Positive	<ul style="list-style-type: none"> • 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	Positive	<ul style="list-style-type: none"> • 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.
Eskander et al., 2011 (ovarian surgery)	Meta-analysis of 10 ovarian surgery studies with a combined n=626	Positive	<ul style="list-style-type: none"> • 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.

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

Citation (s)	Research Design	Direction of Effect	Findings	Conclusion
Fertility Options for Males: Sperm cryopreservation after masturbation				
Lee et al., 2006	American Society of Clinical Oncology Recommendations	Positive	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	Positive	Cryopreserved sperm from men with cancer was used by 118 couples: <ul style="list-style-type: none"> • 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)	Positive	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	Positive	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	Positive	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.
Fertility Options for Males: Gonadal shielding during radiation therapy				
Lee et al., 2006	American Society of Clinical Oncology Recommendations	Inconclusive	No findings reported.	Gonadal shielding prior to radiation therapy may preserve fertility for selected cancers.
Levine et al., 2010	Review	Inconclusive	No findings reported.	Shielding of the testicles during radiotherapy is a standard medical practice, but expertise is required.

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

This appendix describes data sources, 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 Web site at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

The cost analysis in this report was prepared by the members of cost team, which consists of CHBRP task force members and contributors from the University of California, San Diego, and the University of California, Los Angeles, as well as the contracted actuarial firm, Milliman, Inc. (Milliman). Milliman provides data and analyses per the provisions of CHBRP's authorizing legislation.

Data Sources

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

Health insurance

1. The latest (2009) California Health Interview Survey (CHIS), which is used to estimate health insurance for California's population and distribution by payor (i.e., employment-based, individually purchased, or publicly financed). The biennial CHIS is the largest state health survey conducted in the United States, collecting information from approximately 50,000 households. More information on CHIS is available at <http://www.chis.ucla.edu>.
2. The latest (2010) California Employer Health Benefits Survey is used to estimate:
 - size of firm,
 - percentage of firms that are purchased/underwritten (versus self-insured),
 - premiums for health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and Point of Service Plans [POS]),
 - premiums for health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service plans [FFS]), and
 - premiums for high deductible health plans (HDHPs) for the California population with employment-based health insurance.
 - 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: <http://www.chcf.org/publications/2010/12/california-employer-health-benefits-survey>.

3. 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 <http://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, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed healthcare plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP’s utilization and cost estimates draw on other data, including the following:
 - The MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
 - 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.
 - Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.
 - These data are reviewed for applicability by an extended group of experts within Milliman but are not audited externally.
4. An annual survey by CHBRP of 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 PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC- or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in plans or policies offered by these seven firms represents an estimated 93.7% of the persons with health insurance subject to state mandates. This figure represents an estimated 94.4% of enrollees in full service (non-specialty) DMHC-regulated health plans and an estimated 90.1% of enrollees in full service (non-specialty) CDI-regulated policies.¹⁹

¹⁹ CHBRP analysis of the share of enrollees included in CHBRP’s Bill-Specific Coverage Survey of the major carriers in the state is based on “CDI Licenses with HMSR Covered Lives Greater than 100,000” as part of the Accident and Health Covered Lives Data Call, December 31, 2009, by the California Department of Insurance, Statistical Analysis Division, data retrieved from the Department of Managed Health Care’s interactive Web site “Health Plan Financial Summary Report,” July-September 2010, and CHBRP’s Annual Enrollment and Premium Survey.

Publicly funded insurance subject to state benefit mandates

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 (EOCs) documents publicly available at <http://www.calpers.ca.gov>.
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 CHIS and data maintained by the Department of Health Care Services (DHCS). DHCS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the current scope of benefits. CHBRP assesses enrollment information online at http://www.dhcs.ca.gov/dataandstats/statistics/Pages/RASS_General_Medi_Cal_Enrollment.aspx.
7. Enrollment data for other public programs—Healthy Families Program (HFP), Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (MRMIP)—are estimated based on CHIS and data maintained by the Managed Risk Medical Insurance Board (MRMIB). The basic minimum scope of benefits offered by participating health plans under these programs must comply with all requirements for DMHC-regulated health plans, and thus these plans are affected by state-level benefit mandates. CHBRP does not include enrollment in the Post-MRMIP Guaranteed-Issue Coverage Products as these persons are already included in the enrollment for individual market health insurance offered by DMHC-regulated plans or CDI-regulated insurers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at <http://www.mrmib.ca.gov/>. Average statewide premium information is provided to CHBRP by MRMIB staff.

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.

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 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 one 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://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.
- Several recent 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, while Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and 0.84 percentage point decrease in the number of insured, respectively. The price elasticity of demand for insurance can be calculated from these studies in the following way. First, take the average percentage point decrease in the number of insured reported in these studies in response to a 1% increase in premiums (about -0.088), divided by the average percentage of insured persons (about 80%), multiplied by 100%, i.e., ($\{-0.088/80\} \times 100 = -0.11$). This elasticity converts the *percentage point* decrease in the number of insured into a *percentage* decrease in the number of insured persons for every 1% increase in premiums. 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://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

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 point of service [POS] plans—and non-HMO—including PPO and fee for service [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%.

Potential Effects of the Federal Affordable Care Act

As discussed in the *Introduction*, there are a number of the ACA provisions that have already gone into or will go into effect over the next three years. Some of these provisions affect the baseline or current enrollment, expenditures, and premiums. This subsection discusses adjustments made to the 2011 Cost and Coverage Model to account for the potential impacts of the ACA that have gone into effect by January 2011. It is important to emphasize that CHBRP's analysis of specific mandate bills typically address 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.

CHBRP reviewed the ACA provisions and determined whether and how these provisions might affect:

1. The number of covered lives in California, and specifically the makeup of the population with health insurance subject to state mandates
2. Baseline premiums and expenditures for health insurance subject to state mandates, and

3. Benefits required to be covered in various health insurance plans subject to state mandates

There are still a number of provisions that have gone into effect for which data are not yet available. Where data allows, CHBRP has made adjustments to the 2011 Cost and Coverage model to reflect changes in enrollment and/or baseline premiums and these are discussed here.

Coverage for adult children

PPACA Section 2714, modified by HR 4872, Section 2301, requires coverage for adult children up to age 26 as dependants to primary subscribers on all individual and group policies, effective September 23, 2010. California's recently enacted law, SB 1088 (2010) implements this provision. This could potentially affect both premiums and enrollment in 2011. According to the California Health Interview Survey (CHIS) approximately 22% of Californians aged 19-25 (1,063,000) were estimated to be uninsured at some point in 2009. As a result of the ACA, many of these young adults will likely gain access to health insurance through a parent. This dynamic may diminish the number of uninsured and may also shift some young adults from the individually purchased health insurance market into the group market. The Departments of Treasury, Labor, and Health and Human Services estimate, for 2011, the number of young adults newly covered by his/her parent's plan would be about 0.78 to 2.12 million (using high and low take-up rate assumptions, respectively). Of these young adults, about 0.2 to 1.64 million would have previously been uninsured. The corresponding incremental cost impact to group insurance policies is estimated to be a premium increase of 0.5% to 1.2%. Based on the responses to the Annual Enrollment and Premium survey, there has been an increase of 1% to 1.5% in enrollment for the 19-25 year olds and the increase varies depending on whether the parents were enrolled in the large-group, small-group, or individual markets. Based on analysis of the estimates from the Departments of Treasury, Labor and Health and Human Services as well as CHIS 2009 data, approximately 25% of the increase in enrollment represents a shift from the individual market and approximately 75% were previously uninsured. CHBRP took these estimates into account and adjusted underlying population data since source data did not reflect the effects of this provision, because shift in populations were expected to be significant, and to account for potential lags in enrollment (e.g., due to awareness).

Minimum Medical Loss Ratio requirement

PPACA Section 2718 requires health plans offering health insurance in group and individual markets to report to the Secretary of Health and Human Services the amount of premium revenue spent on clinical services, activities to improve quality, and other non-claim costs. Beginning in 2011, large group plans that spend less than 85% of premium revenue and small-group/individual market plans that spend less than 80% of premium revenue on clinical services and quality must provide rebates to enrollees. According to the Interim Final Rule (45 CFR Part 158), "Issuers will provide rebates to enrollees when their spending for the benefit of policyholders on reimbursement for clinical services and quality improvement activities, in relation to the premiums charged, is less than the MLR standards established pursuant to the statute."²⁰ The requirement to report medical loss ratio is effective for the 2010 plan year, while

²⁰ Department of Health and Human Services, *Interim Final Rule: Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act*. 45 CFR Part 158. December 1, 2010.

the requirement to provide rebates is effective January 1, 2011. The MLR requirement, along with the rebate payment requirement, will affect premiums for 2011, but the effects are unknown and data are not yet available. There is potential for substantial impact on markets with higher administrative costs, including the small and individual group markets. Responses to CHBRP's Annual Enrollment and Premiums Survey indicate that carriers intend to be in compliance with these requirements. For those that may not be in compliance, the requirement to pay rebates is intended to align the MLR retrospectively. Therefore, for modeling purposes, CHBRP has adjusted administrative and profit loads to reflect MLRs that would be in compliance with this provision.

Pre-Existing Condition Insurance Plan (PCIP)

PPACA Section 1101 establishes a temporary high-risk pool for individuals with pre-existing medical conditions, effective 90 days following enactment until January 1, 2014. In 2010, California enacted AB 1887 and SB 227, providing for the establishment of the California Pre-Existing Condition Insurance Plan (PCIP) to be administered by the Managed Risk Medical Insurance Board (MRMIB) and federally funded per Section 1101. MRMIB has projected average enrollment of 23,100 until the end of 2013, when the program will expire. As of December 2010, there were approximately 1,100 subscribers (MRMIB, 2010). The California PCIP is not subject to state benefit mandates,²¹ and therefore this change does not directly affect CHBRP's Cost and Coverage Model. CHBRP has revised its annual update of *Estimates of the Sources of Health Insurance in California*²² to reflect that a slight increase in the number of those who are insured under other public programs that are not subject to state level mandates.

Prohibition of pre-existing condition exclusion for children

PPACA Sections 1201& 10103(e): Prohibits pre-existing condition exclusions for children. This provision was effective upon enactment). California's recently enacted law, AB 2244 (2010) implements this provision. AB 2244 also prohibits carriers that sell individual plans or policies from refusing to sell or renew policies to children with pre-existing conditions. Carriers that do not offer new plans for children are prohibited from offering for sale new individual plans in California for five years.²³ This provision could have had significant premium effects, especially for the DMHC- and CDI-regulated individual markets. The premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision.

Prohibition of lifetime limits and annual benefit limit changes

PPACA Section 2711 prohibits individual and group health plans from placing lifetime limits on the dollar value of coverage, effective September 23, 2010. Plans may only impose annual limits on coverage and these annual limits may be no less than \$750,000 for "essential health benefits." The minimum annual limit will increase to \$1.25 million on Sept. 23, 2011, and to \$2 million Sept. 23, 2012. Earlier in 2010, CHBRP conducted an analysis of SB 890, which sought to prohibit lifetime and annual limits for "basic health care services" covered by CDI-regulated policies. CHBRP's analysis indicated that DMHC-regulated plans were generally prohibited

²¹ Correspondence with John Symkowitz, Legislative Coordinator, MRMIB, October 19, 2010.

²² See: http://www.chbrp.org/other_publications/index.php.

²³ See enacted language at: http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab_2201-2250/ab_2244_bill_20100930_chaptered.pdf

from having annual or lifetime limits. The analysis also indicated that less than 1% of CDI-regulated policies in the state had annual benefit limits and of those, the average annual benefit limit was approximately \$70,000 for the group market and \$100,000 for the individual market. Almost all CDI-regulated policies had lifetime limits in place and the average lifetime limits was \$5 million. After the effective date of the PPACA Section 2711, removal of these limits may have had an effect on premiums. As mentioned, premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision to remove lifetime limits and to increase annual limits for those limited number of policies that had annual limits that fell below \$750,000.

Medi-Cal Managed Care Enrollment: Seniors and Persons with Disabilities

While the PPACA allows states the option to expand coverage to those not currently eligible for Medicaid (Medi-Cal in California), large scale expansions are not expected to be seen during 2011. However, as a result of the 2010-2011 California Budget Agreement, there are expected to be shifts in coverage for seniors and persons with disabilities. Specifically, "Seniors and persons with disabilities who reside in certain counties which have managed care plans, and who are not also eligible to enroll in Medicare, will be required to enroll in a managed care plan under a phased-in process" (LAO, 2010). The Medi-Cal Managed Care enrollment in CHBRP's 2011 Cost and Coverage Model has been adjusted to reflect this change. Baseline premium rates have also been adjusted to reflect an increase in the number of seniors and persons with disabilities in Medi-Cal Managed Care. Information from DHCS indicates these changes will go into effect July 1, 2011, and would affect approximately 427,000 Medi-Cal beneficiaries.²⁴ CHBRP used data from DHCS to adjust enrollment in Medi-Cal Managed Care, and to adjust premiums to account for the change in acuity in the underlying populations (Mercer, 2010).

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 National Cancer Institute (the Surveillance Epidemiology and End Results, or SEER, cancer statistics), and pooling 2005-2007 (Su, 2011), cancer incidence rates were calculated for age bands that captured what would be considered reproductive age for fertility preservation services (Table D-1).

²⁴ Data from the Department of Health Care Services, Medi-Cal Managed Care Division. Received January 14, 2011.

Table D-1. Age Bands Used to Calculate Cancer Incidence Rates in Analysis of AB 428

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 < 40	37 to < 42
	42 to < 47
	47 to < 50

Source: CHBRP, 2011

In its analysis, CHBRP included the types of cancer whose treatments pose the highest iatrogenic infertility risk (Table D-2).

Table D-2. Cancer Types Included in Analysis of AB 428

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: CHBRP, 2011

The utilization rates, both pre- and postmandate, were assumed to be consistent across all age bands and for all types of cancer. While it would have been ideal to model the projected cost impacts for different ages (given the differences in likely desire for fertility) and different types of cancer treatments, no data was available to do so, either in the literature or from content expert input.

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 relied on a study that found that 24% of men at risk for iatrogenic infertility chose to use sperm cryopreservation (Schover et al., 2002).

To calculate the use of fertility preservation services by female enrollees, CHBRP relied on both content expert input and a forthcoming study (Letourneau et al., 2010) which indicated that 10% of women who face iatrogenic infertility are likely to use fertility preservation services.

Estimates from the literature indicate that 7% of the 76% of men (approximately 5% overall) who did not undergo sperm cryopreservation would have utilized the procedure if the cost were reduced (Schover, et al., 2002). From this, CHBRP estimated that the postmandate use of sperm cryopreservation would rise to 29% of male enrollees who are cancer patients and are at risk for

iatrogenic infertility, or 1,262 male enrollees. Utilization for embryo cryopreservation for women was assumed to rise to the same level (29%) as that of men, based on content expert input.

Appendix E: Information Submitted by Outside Parties

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

The following information was submitted by the Office of Assembly Member Anthony Portantino in March 2011.

American Society for Reproductive Medicine. Fertility preservation and reproduction in cancer patients. *Fertility and Sterility*. 2005; 83:1622-8.

Rosen M (2011). Incidence of Reproductive Compromise and Cancer.

The following information was submitted by the Lance Armstrong Foundation in March 2011.

Lee SJ, Schover LR, Partridge AH, Patrizio P, Wallace WH, Hagerty K, Beck LN, Brennan LV, Oktay K. *American Society of Clinical Oncology recommendations on fertility preservation in cancer patients*. *Journal of Clinical Oncology*; 2006. ASCO Special Article [Published Ahead of Print on May 1, 2006 as 10.1200/JCO.2006.06.5888] Vol. 18, No. 24.

Livestrong. *Iatrogenic Infertility Due to Cancer Treatments: A Case for Fertility Preservation Coverage*. Case Study.

Livestrong and Cancer Legal Resource Center. *Health Insurance Coverage for Iatrogenic Infertility*. Position Statement. Available at: <https://www.disabilityrightslegalcenter.org/about/documents/LSCLRCPositionStatementIatrogenicInfertilityFINAL.pdf>. Accessed March 30, 2011.

Pelkonen S, Koivunen R, Gissler M, Nojua-Huttunen S, Suikkari AM, Hyden-Granskog C, Martikainen H, Tiitinen A, Hartikainen AL. Perinatal outcome of children born after frozen and fresh embryo transfer: The Finnish cohort study 1995-2006. *Human Reproduction*. 2010; 25: 914-923.

Ruddy KJ, Gelber S, Tamimi R, Ginsburg ES, Schapira L, Come SE, Meyer ME, Winer EP, Partridge AH. Fertility Concerns in Young Women with Breast Cancer: Results from a Prospective Cohort Study. Submitted to CHBRP with permission from AH Partridge.

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

Wennerholm UB, Soderstrom-Anttila V, Bergh C, Aittomaki K, Hazekamp J, Nygren KG, Selbing A, Loft A. Children born after cryopreservation of embryos or oocytes: A systematic review of outcome data. *Human Reproduction*. 2009; 24: 2158-2172.

The American Society for Reproductive Medicine's (ASRM) Fertility Preservation Special Interest Group (FP-SIG). Letter of support to CHBRP. March 1, 2011.

Submitted information is available upon request.

For information on the processes for submitting information to CHBRP for review and consideration please visit: http://www.chbrp.org/recent_requests/index.php.

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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 and three private universities in California. 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.

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