



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Executive Summary
Analysis of Assembly Bill 428:
Fertility Preservation

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

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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.

ACKNOWLEDGMENTS

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.

Theodore Ganiats, MD, Erik Groessl, PhD, Meghan Maiya, MA, and Sara McMenamin, PhD, all of the University of California, San Diego, prepared the medical effectiveness analysis. Stephen L. Clancy, MLS, AHIP, of the University of California, Irvine, conducted the literature search. Theodore Ganiats, MD and Sara McMenamin, PhD, of the University of California, San Diego, prepared the public health impact analysis. Shana Lavarreda, PhD, MPP, of the University of California, Los Angeles, prepared the cost impact analysis. Robert Cosway, FSA, MAAA, of Milliman, provided actuarial analysis. H. Irene Su, MD of the University of California, San Diego, and Scott Zeitlin, MD, of the University of California, Los Angeles, provided technical assistance with the literature review and expert input on the analytic approach. Susan Philip, MPP, of CHBRP staff prepared the introduction and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

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California Health Benefits Review Program Committees and Staff

A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses 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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