California Health Benefits Review Program

Analysis of California Assembly Bill 767
Infertility

A Report to the 2019-2020 California State Legislature April 18, 2019

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Key Findings:

Analysis of California Assembly Bill 767
Infertility

Summary to the 2019–2020 California State Legislature, April 18, 2019

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

AT A GLANCE

The version of California Assembly Bill (AB) 767 analyzed by CHBRP would require coverage of infertility treatments, including in vitro fertilization (IVF), and mature oocyte cryopreservation (OC).

1. CHBRP estimates that, in 2020, of the 24.5 million Californians enrolled in state-regulated health insurance, 14.6 million of them will have insurance subject to AB 767.
2. **Benefit coverage.** Benefit coverage for infertility treatments, including IVF, would increase from 4.3% premandate to 100% postmandate. Benefit coverage of planned OC would increase from 0% premandate to 100% postmandate. AB 767 would likely exceed EHBs.
3. **Utilization.** Utilization of infertility services would increase between 9% for diagnostic tests and 350% for IVF with intracytoplasmic sperm injection (ICSI). Utilization of planned OC is expected to increase from 0% to between 2% and 5%.
4. **Expenditures.** AB 767 would increase total net annual expenditures by $627,288,000 or 0.39% due to a $537,777,000 increase in total health insurance premiums, adjusted by decrease in enrollee expenses for covered and/or noncovered benefits.
    a. Enrollees with uncovered expenses at baseline would receive on the whole a $133,897,000 reduction in their out-of-pocket spending for covered and noncovered expenses.
    b. Per member per month premiums would increase between $2.76 for enrollees in CalPERS HMOs (an increase of 0.47%) and $3.72 in the DMHC-regulated small group market (an increase of 0.68%).
5. **Medical effectiveness.**
    a. There is a *preponderance of evidence* that IVF is an effective treatment for infertility.

AT A GLANCE, CONT.

    b. There is a *preponderance of evidence* that IVF is associated with certain maternal harms.
    c. There is cl*ear and convincing evidence* that IVF can lead to multiple gestation and preterm delivery. However, these outcomes can be mitigated by single embryo transfers.
    d. CHRBP found a *preponderance of evidence* that IVF mandates are associated with lower numbers of embryos transferred per cycle, lead to fewer births per cycle, and a reduction in overall harms of IVF.
6. **Public health.** The number of pregnancies resulting from infertility treatments in the first year postmandate will increase the number of pregnancies by 6,000 (from 7,000 to 13,000) and the number of live births by 5,000 (from 6,000 to 11,000).
7. **Long-term impacts.** For each cohort of females electing to undergo mature OC for the prevention of age-related infertility in a given year, CHBRP estimates the long-term marginal impact of AB 767 would yield about 685 more live births among these women over a 20 year period.

CONTEXT

Infertility is the inability to have a child and is a complex condition that can take many forms. Approximately 12% of women aged 15–44 experience infertility and approximately 9% of men aged 19–44 report some type of infertility.

The cost of undergoing infertility treatments such as assisted reproductive technology (ART) can be a prohibitive factor for couples and individuals faced with infertility.[1]

[1] Refer to CHBRP's full report for full citations and references.

BILL SUMMARY

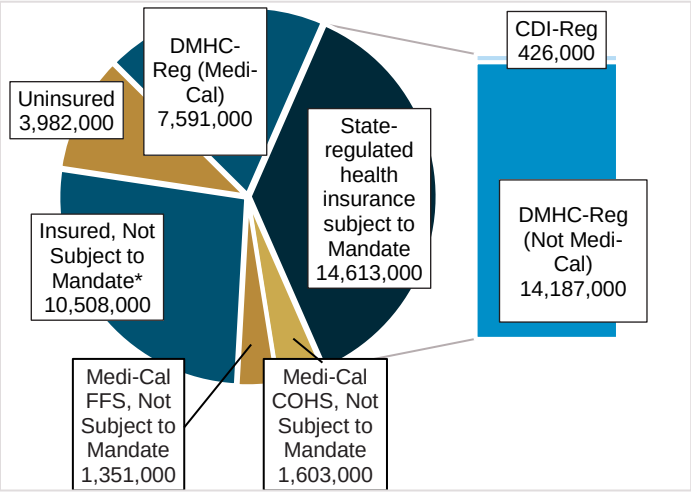
Current law requires most group health plans and policies to offer coverage for infertility services, excluding in vitro fertilization. AB 767 would require group health plans and policies, excluding the individual market and Medi-Cal, to provide coverage for infertility treatments, including in vitro fertilization (IVF), and mature oocyte cryopreservation (OC).

AB 767 defines infertility as the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility. "Treatment of infertility" includes 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, gamete intrafallopian transfer, and in vitro fertilization.

Mature OC is a form of fertility preservation. While fertility preservation usually refers to the preservation of fertility in advance of medical procedures that can lead to iatrogenic infertility (medically caused infertility), such as treatment for cancer or during sex transition, AB 767 could expand coverage of mature OC to a woman seeking to preserve her fertility for age-related reasons or to women seeking to preserve their fertility if they experience other medical conditions, such as endometriosis.

Figure A notes how many Californians have health insurance that would be subject to AB 767.

Figure A. Health Insurance in CA and AB 767



Source: California Health Benefits Review Program, 2019.
Notes: *Medicare beneficiaries, enrollees in self-insured products, etc.

IMPACTS

Revision

The initially released version of these Key Findings (April 18) referenced an incorrect figure (see the updated full report for more). This version has been updated using the correct total expenditures impact figure, 0.39%.

Benefit Coverage, Utilization, and Cost

To capture the full cost of coverage of infertility services for each year, CHBRP included the cost of pregnancies and births resulting from infertility services in year 1 into year 1 cost estimates.

No utilization data are available for planned OC in MarketScan claims data. There are no studies that estimate utilization of OC for non-iatrogenic or planned use, thus the approach to CHBRP's estimation of utilization change postmandate due to AB 767's coverage of mature OC included an estimate of potential increase in utilization per CHBRP's content expert. The estimates of utilization change do not include planned fertility preservation, however CHBRP offers an estimate of potential cost increase if a modest proportion of females of reproductive age opt to use the service in the *Planned Oocyte Cryopreservation* section.

Benefit Coverage

Currently, 4.3% of enrollees with health insurance that would be subject to AB 767 in DMHC-regulated plans or CDI-regulated policies have coverage for infertility treatments, including in vitro fertilization. No enrollees currently have coverage for mature OC as defined by AB 767. Benefit coverage for infertility treatments and planned OC would increase to 100% postmandate.

Utilization

In California, there are approximately 53,000 users of female diagnostic tests at baseline and about the same number of users of medications for infertility (i.e., only medications and no other service). IUI baseline utilization is about 9,000 users annually. IVF services alone (i.e., without ICSI) is estimated to have about 2,000 users and ICSI, which is done with IVF, is 2,000 users annually. For males, at baseline there are 25,000 users of diagnostic tests and 11,000 users of any male treatment.

Pent-up demand is assumed to occur given the financial burden currently cited by couples hoping to use infertility services but are unable to because of cost barriers. It is assumed that utilization in the first and second year would be 10% greater. Pent-up demand for infertility services likely dissipates over time and utilization reaches a steady state after a few years postmandate.

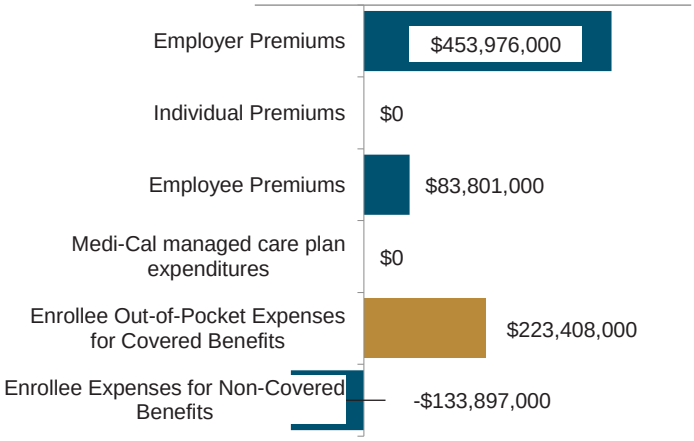
Expenditures

AB 767 would increase total net annual expenditures by $627,288,000 or 0.39% for enrollees with DMHC-regulated group plans and CDI-regulated group policies. This is due to a $537,777,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by an increase in enrollee expenses for covered expenses and a decrease in enrollee expenses for noncovered benefits.

CHBRP estimates that enrollees with uncovered expenses at baseline would receive on the whole a $133,897,000 reduction in their out-of-pocket spending for covered and noncovered expenses associated with AB 767's coverage of infertility services.

Per member per month (PMPM) premiums would increase between $2.76 among CalPERS HMOs (an increase of 0.47%) and $3.72 in the DMHC-regulated small-group market (an increase of 0.68%). Total expenditures would increase between 0.33% in the CDI-regulated large-group market and 0.64% in the DMHC-regulated small-group market.

Figure B. Expenditure Impacts of AB 767



Source: California Health Benefits Review Program, 2019.

Planned Oocyte Cryopreservation

CHBRP did not find any source of data on baseline utilization for planned OC or likely changes postmandate. CHBRP estimates that if 2% of women aged 25–37 years used planned OC services, the total expenditures would increase by $319,683,000. If a higher share of women aged 25–37 used planned OC (5%), total expenditures would increase by $799,197,000. This assumes the average cost for OC is $10,078.

Medi-Cal

AB 767 does not apply to Medi-Cal enrollees and therefore there is no measurable impact.

CalPERS

CalPERS employer expenditures are projected to increase by $14,539,000 for coverage of infertility treatments. Total premiums would increase by $2.76 PMPM (0.47%) and total expenditures would increase by $3.38 PMPM (0.53%).

Number of Uninsured in California

Because the change in average premiums does not exceed 1% for any market segment for coverage of infertility treatments, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 767.

However, should 5% of female enrollees aged 25–37 use mature OC services as a form of fertility preservation, premiums would increase by more than 1% for enrollees in group and CalPERS HMO plans (premium increases for private employers for group insurance increase 1.24% and CalPERS HMO 1.31%). It is unclear how the increase in premiums translates into uninsurance since not all of the increase is transferred to the enrollee.

Medical Effectiveness

CHBRP found a *preponderance of evidence* that IVF is an effective treatment for infertility, resulting in increased pregnancy rates and live birth rates. There is also a *preponderance of evidence* that planned OC is an effective treatment for infertility, resulting in pregnancies and live births.

CHBRP found a *preponderance of evidence* that IVF is associated with certain maternal harms, including ovarian hyperstimulation syndrome and thromboembolism. There is also *clear and convincing evidence* that IVF can lead to multiple gestation and preterm delivery. However, it is important to note that multiple gestation is associated with higher numbers of embryos transferred per cycle, and that preterm delivery is associated with multiple gestation — these outcomes can be mitigated by single embryo transfers.

CHRBP found a *preponderance of evidence* that IVF mandates are associated with lower numbers of embryos transferred per cycle. There is also a *preponderance of evidence* that IVF mandates lead to fewer births per cycle (due to the decreased number of embryos transferred per cycle), and a reduction in overall harms of IVF (i.e., lower rates of multiple gestation, preterm deliveries, and low-birthweight births).

Public Health

CHBRP estimates that the number of pregnancies resulting from infertility treatments in the first year postmandate will increase the number of pregnancies by 6,000 (from 7,000 to 13,000) and the number of live births by 5,000 (from 6,000 to 11,000).These estimates are supported by a preponderance of evidence that infertility treatments, including IVF, are medically effective and that health insurance benefit mandates are effective in increasing utilization of treatments for infertility, including IVF.

Although CHBRP found evidence that engaging in infertility treatments may result in short-term psychosocial harms, evidence-based literature also indicates that the inability to have wanted children is itself associated with stress, anxiety, depression, and quality of life deficits that are likely to decrease upon the achievement of a successful pregnancy through treatment. Therefore, it stands to reason that mental health and quality of life would improve for the additional 5,000 persons and couples who would have a live birth resulting from infertility treatments postmandate.

Disparities

Barriers in fertility treatment access related to sexual orientation are reduced with the change in language defining infertility to be more inclusive, however barriers remain as the bill does not cover donor materials (sperm or eggs) or gestational carriers (surrogates) that are required for same-sex couples. Cost-related barriers to infertility treatment would be significantly reduced for those covered by the bill, however cost sharing could still represent a significant cost barrier.

Long-Term Impacts

In the short-term, the aggregate pregnancy and birth rate is expected to increase postmandate due to increased utilization of infertility services. In the longer term, it is possible that the coverage of infertility services results in encouraging couples to undergo infertility treatment earlier than they would normally and where pregnancy might be achieved naturally.

For each cohort of females electing to undergo mature OC for the prevention of age-related infertility in a given year, CHBRP estimates the long-term marginal impact of AB 767 would yield about 685 more live births among these women over a 20-year period.

Although AB 767 would decrease the financial burden of planned OC services in the short term, AB 767 would not cover future storage costs, which can range from range from $100 to $1,500 per year (average $300/year). These additional uncovered costs may have an impact on the demand for these services, but the magnitude of this effect is unknown.

Essential Health Benefits and the Affordable Care Act

AB 767 would require coverage for a new state benefit mandate that appears to exceed the definition of EHBs in California. A state that requires QHPs to offer benefits in excess of the EHBs must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the QHP.

CHBRP estimates that the state would potentially be required to defray the following amounts due to AB 767:

- $6.43 PMPM for each QHP enrollee in a small-group DMHC-regulated plans; and
- $7.10 PMPM for each QHP enrollee in a small-group CDI-regulated policy.

CHBRP estimates that this translates to a state-responsibility of $51,823,000 total, which includes:

- $50,801,000 in payments to DMCH-regulated small group plans; and
- $1,023,000 in payments to CDI-regulated small group policies.

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Infertility

April 18, 2019

California Health Benefits Review Program
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REVISION HISTORY

Date	Description of Revisions
May 10, 2019	In the initially released version of this report (April 18), one summary table, Table 6, correctly indicated a 0.39% impact. However, the other summary tables, Table 1 & 9, were in error, indicating a 0.49% impact. All tables and text in this version have been updated to indicate the correct 0.39% impact.

The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit-related legislation. The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact. Content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications are available at www.chbrp.org.

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Table 1. AB 767 Impacts on Benefit Coverage, Utilization, and Cost, 2020

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
Benefit coverage				
Total enrollees with health insurance subject to state benefit mandates (a)	24,490,000	24,490,000	0	0%
Total enrollees with health insurance subject to AB 767	14,613,000	14,613,000	0	0%
Percentage of enrollees with coverage for infertility services, including IVF	4.3%	100%	96%	2247%
Number of enrollees with coverage for infertility services, including IVF	622,600	14,613,000	96%	2247%
Percentage of enrollees with coverage for mature oocyte cryopreservation	0%	100%	100%	100%
Number of enrollees with coverage for mature oocyte cryopreservation	0	14,613,000	100%	100%
Utilization and unit cost				
Female - Number of enrollees using:				
Diagnostic tests	53,000	58,000	5,000	9%
Medications only	14,000	17,000	3,000	21%
IVF	2,000	7,000	5,000	250%
ICSI-IVF	2,000	9,000	7,000	350%
IUI	9,000	10,000	1,000	11%
Male - Number of enrollees using:				
Diagnostic tests	25,000	27,000	2,000	8%
Treatment	11,000	12,000	1,000	9%
Average per unit cost				
Diagnostic tests	$458	$458	$0	0%
Medications only	$5,486	$5,486	$0	0%
IVF	$15,331	$15,331	$0	0%
ICSI-IVF	$28,773	$28,773	$0	0%
IUI	$6,593	$6,593	$0	0%
Male diagnostic tests	$81	$81	$0	0%
Male treatment	$635	$635	$0	0%
Pregnancy				
# of pregnancies due to infertility services (all types)	7,000	13,000	6,000	86%
# of live birth deliveries due to infertility services (single, twin, multiples)	6,000	11,000	5,000	83%
Average annual cost of pregnancy and delivery from infertility services (single, twin, multiples)	$37,000	$39,000	2,000	5%
Expenditures				
Premiums by payer				

Private employers for group insurance	$86,438,375,000	$86,877,812,000	$439,437,000	0.51%
CalPERS HMO employer expenditures (b) (c)	$3,098,551,000	$3,113,090,000	$14,539,000	0.47%
Medi-Cal Managed Care Plan expenditures	$28,492,273,000	$28,492,273,000	$0	0%
Enrollees with individually purchased insurance	$12,045,324,000	$12,045,324,000	$0	0%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (c)	$14,476,394,000	$14,560,195,000	$83,801,000	0.58%
Enrollee expenses				
For covered benefits (deductibles, copayments, etc.) (d)	$14,750,880,000	$14,974,288,000	$223,408,000	1.51%
For noncovered benefits (e)	$133,897,000	$0	-$133,897,000	-100.00%
Total expenditures	$159,435,694,000	$160,062,982,000	$627,288,000	0.39%

Source: California Health Benefits Review Program, 2019.

Notes: For estimates of the impact of mature oocyte cryopreservation coverage, refer to the *Benefit, Cost, and Utilization* section.

(a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.[2]

(b) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care.

(d) Enrollee out-of-pocket expenses for covered benefits for IVF and ICSI services (not including associated pregnancies) is $42,829,000, at baseline and $168,182,000 postmandate, resulting in an increase of 293%; for all other infertility services, out-of-pocket expenses at baseline is $14,708,051,000 and $14,806,106,000 postmandate, a 0.67% increase.

(e) Includes only expenses 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 would be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organizations; ICSI = intracytoplasmic sperm injection; IUI = intrauterine insemination; IVF = in vitro fertilization

[2] For more detail, see *Estimates of Sources of Health Insurance in California*, available at http://chbrp.com/analysis_methodology/cost_impact_analysis.php.

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[3] conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 767 (Wicks), Infertility. AB 767 was amended on April 9, 2019, and the new language is incorporated below.

Bill-Specific Analysis of AB 767, Infertility

Bill Language Summary

AB 767 would require group health plans and policies, excluding individual market plans and policies and Medi-Cal, to *provide* coverage for infertility treatments, including in vitro fertilization (IVF), and mature oocyte cryopreservation (OC). The full text of AB 767 as amended can be found in Appendix A.

Current law requires most group health plans and policies to *offer* coverage for infertility services, excluding IVF.

Definition of infertility

Current law[4] defines infertility as:

(1) "the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility, or

(2) the inability to conceive a pregnancy or to carry a pregnancy to a live birth after a year or more of regular sexual relations without contraception."

AB 767 amends the definition of infertility by removing the second clause.

Treatment for infertility

Current law defines "treatment for infertility" as 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. AB 767 adds IVF to the list of treatments.

Mature oocyte cryopreservation

AB 767 requires plans and policies to also cover mature OC, which the bill defines as procedures consistent with established medical practices, including laboratory medical procedures, involving induction, egg retrieval, and freezing of the egg. Mature OC is used for fertility preservation purposes. AB 767 as introduced defines "preventive fertility care treatment" as procedures consistent with established medical practices in the treatment of fertility care, which is rendered by a licensed physician and surgeon, to prevent the inability to conceive a child. However, this definition was removed from the version of AB 767 amended on April 9, 2019.

[3] CHBRP's authorizing statute is available at http://chbrp.org/faqs.php.
[4] H&SC Section 1374.55 and IC Section 10119.6.

Discrimination clause

Current law includes a non-discrimination clause that states "coverage for the treatment of infertility shall be offered, and if purchased, provided without discrimination on the basis of age, ancestry, color, disability, domestic partner status, gender, gender expression, gender identity, genetic information, marital status, national origin, race, religion, sex, or sexual orientation." This clause remains unchanged in AB 767.

Religious exemption

Current law states that any employer that is a religious organization is not required to offer coverage for forms of infertility treatment in a manner inconsistent with the religious organization's religious and ethical principles. AB 767 eliminates this exemption.

Relevant Populations

If enacted, AB 767 would affect the health insurance of approximately 14,613,000 enrollees (37% of all Californians). This represents 60% percent of the 24.5 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law — health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would affect the health insurance of enrollees in DMHC-regulated large- and small-group plans and CDI-regulated large- and small-group policies. AB 767 does not apply to the health insurance of enrollees in the individual market or Medi-Cal.

Among the 14.6 million Californians with insurance impacted by AB 767, there are approximately 3.43 million women of reproductive age, ages 15 to 44.[5] As described in the *Background* section, there is no upper age bound for men, although reproductive capacity declines beginning around age 60. There are 4.89 million men ages 18 to 60. More information about the populations likely to use infertility treatments and mature OC is included in the *Background* section.

Interaction With Existing Requirements

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

California Policy Landscape

California law and regulations

Current California law requires most group CDI-regulated policies and most DMHC-regulated plans to *offer* coverage for infertility treatment, except IVF. "Mandate to offer" means all health care service plans and health insurers selling health insurance subject to the mandate are required to offer coverage for the benefit for purchase. The health plan or insurer may comply with the mandate either (1) by including the benefit as standard in its health insurance products, or (2) by offering coverage for the benefit separately at an additional cost (e.g., a rider). "Mandate to cover" means that all health insurance subject to the law must cover the benefit.

[5] While women above age 44 may use infertility treatments and be able to conceive, ages 15 to 44 is a commonly used range when discussing women of reproductive age. (ACOG, 2014b)

CHBRP reviewed the state's Independent Medical Review (IMR) determinations for inclusion of infertility services. Of note, three IMRs in the last 10 years overturned the decision of the health plan for enrollees requesting coverage of consultations for infertility services. Seven health plans' decisions were upheld in instances where enrollees requested coverage of infertility treatments either due to insufficient medical evidence or advanced maternal age and the likelihood of success.

Similar requirements in other states

Currently, 14 states have laws that require insurance companies to cover infertility treatment and two states — California and Texas — have laws that require insurance companies to offer coverage for infertility treatment. States that require coverage of infertility treatment are: Arkansas, Connecticut, Hawaii, Illinois, Louisiana, Maryland, Massachusetts, Montana, New Jersey, New York, Ohio, Rhode Island, and West Virginia, and most recently Delaware, which passed legislation in 2018 (NCSL, 2018). In 2019, New York amended its existing mandate through a budget measure in the 2020 state budget that mandates certain large-group insurance plans cover IVF, and requires all private insurance companies to cover medically necessary egg freezing. The Connecticut, New Jersey, and Rhode Island mandates are closest to the proposed AB 767 legislation, with the exception of planned OC, which is not included those states' mandates.

While most states with laws requiring insurance companies to offer or provide coverage for infertility treatment include coverage for IVF, California and Louisiana have laws that specifically exclude coverage for the procedure.

Other examples of unique state laws are Louisiana and New York's previous law, which prohibit the exclusion of coverage for a medical condition otherwise covered solely because the condition results in infertility; Minnesota, which specifies that medical assistance will not provide coverage for fertility drugs when specifically used to enhance fertility; and Utah, which requires insurers providing coverage for maternity benefits to also provide an indemnity benefit for adoption or infertility treatments.

Limits on infertility coverage in other states that mandate coverage include applying dollar lifetime caps, and limiting the number of treatment cycles covered.

- Connecticut allows four cycles of ovulation induction, a lifetime maximum coverage of three cycles of intrauterine insemination, and a lifetime maximum coverage of two cycles of IVF, GIFT, ZIFT or low tubal ovum transfer, with not more than two embryo implantations per cycle.
- Hawaii requires that only one cycle of IVF be covered.
- Illinois mandates that each patient is covered for up to four egg retrievals. However, if a live birth occurs, two additional egg retrievals will be covered, with a lifetime maximum of six retrievals covered.
- New York covers up to three IVF cycles.
- Rhode Island limits coverage to a lifetime cap of $100,000.

Federal Policy Landscape

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 767 may interact with requirements of the ACA as presently

exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[6]

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law and regulations.

Essential Health Benefits

State health insurance marketplaces, such as Covered California, are responsible for certifying and selling qualified health plans (QHPs) in the small-group and individual markets. QHPs are required to meet a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.[7,8]

States may require QHPs to offer benefits that exceed EHBs.[9] However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the QHP.[10,11] State rules related to provider types, cost-sharing, or reimbursement methods would *not meet* the definition of state benefit mandates that could exceed EHBs.[12]

AB 767 and EHBs

AB 767 could be interpreted to exceed the EHBs for the following reasons:

- AB 767 would apply to small-group QHPs in Covered California.
- The state's benchmark plan (Kaiser Foundation Health Plan Small Group HMO 30) excludes coverage for infertility treatments. Thus, this service would not appear to be considered an essential health benefit for the state of California.

[6] The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories of EHBs. Resources on EHBs and other ACA impacts are available on the CHBRP website: http://www.chbrp.org/other_publications/index.php.
[7] The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options. CCIIO, Information on Essential Health Benefits Benchmark Plans. Available at: https://www.cms.gov/cciio/resources/data-resources/ehb.html.
[8] H&SC Section 1367.005; IC Section 10112.27.
[9] ACA Section 1311(d)(3).
[10] State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov\fdsys\pkg\FR-2013-02-25\pdf\2013-04084.pdf.
[11] However, as laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs and there would be no requirement that the state defray the costs of those state mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.
[12] Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.

- The federal definition of a state benefit mandate that can exceed EHBs is "specific to the care, treatment, and services that a state requires issuers to offer to its enrollees."[13] AB 767 would appear to meet this federal definition.

As outlined above, AB 767 would require coverage for a new state benefit mandate that appears to exceed the definition of EHBs in California.

Analytic Approach and Key Assumptions

Definition of Infertility for Analysis of AB 767

There are multiple definitions of infertility (see details below):

- The current infertility treatment mandate includes a definition of infertility;
- AB 767's definition of infertility;
- The medical policies for DMHC-regulated plans and CDI-regulated policies include definitions of infertility;
- The National Survey on Family Growth (NSFG) defines infertility; and
- The American Society of Reproductive Medicine (ASRM) defines infertility.[14]

Current infertility treatment mandate. As stated previously, the current infertility treatment mandate defines infertility as either: "(1) the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility, or (2) the inability to conceive a pregnancy or to carry a pregnancy to a live birth after a year or more of regular sexual relations without contraception." AB 767 removes the second clause of this definition.

Medical policies. The medical policies of DMHC-regulated plans and CDI-regulated insurers are not identical in how they define infertility, but the medical policies generally define infertility for heterosexual couples as the inability to achieve conception after having frequent, unprotected intercourse for at least a year, or for 6 months for a woman over the age of 35. For a single woman, infertility is defined as the inability to achieve conception after having 6 to 12 cycles of artificial insemination, generally within a 1-year period. Sometimes, the language for the definition of infertility for a single woman includes the words "medically supervised" artificial insemination.

American Society for Reproductive Medicine. The ASRM defines infertility as a disease. The definition of infertility is "the failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination" (ASRM, 2013).

National Survey on Family Growth. The NSFG defines fecundity as the ability of a woman or couple to have a child (Chandra et al., 2013), and then defines "impaired fecundity," which encompasses their definition of infertility.

[13] Essential Health Benefits Final Rule. Federal Register, Vol. 87, No. 27. February 25, 2013. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.
[14] There are likely further definitions of infertility beyond those listed here. These definitions are addressed in this report because they directly relate to AB 767 and/or the data and literature discussed in the report.

DHMC-regulated plans and CDI-regulated policies are subject to the Health and Safety Code and Insurance Code, respectively, which includes one definition of infertility, and DMHC-regulated plans and CDI-regulated insurers include other definitions of infertility in their medical policies, which generally align with the ASRM definition. However, because much of the information and data presented in the *Background on Infertility* section of this report and the literature reviewed in the *Medical Effectiveness* section of this report rely on the NSFG, the definitions used by the NSFG inform much of this report. The NSFG definitions of impaired fecundity and infertility are discussed in more depth in the *Background on Infertility* section.

Definition for men and women in same-sex relationships. The National Institute for Health and Clinical Excellence (NICE) recently released updated clinical guidelines on assessment and treatment for people with fertility problems. Included in the guidelines are definitions for when men and women in same-sex relationships not having vaginal intercourse should be eligible for assessment and possible treatment for infertility. Specifically, the clinical guidelines state that "for same-sex couples, failure to conceive after 6 cycles of [artificial insemination] within the 12 past months should be the indication for further assessment" (NICE, 2013).

When using "infertility" throughout this report, CHBRP refers to AB 767's definition of infertility, "the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility," unless otherwise specified.

By removing the medical component from the definition of infertility, the diagnosis of infertility is left solely to the provider. This may result in more enrollees receiving a diagnosis of "infertility" earlier than they would have previously or when they would not have received a diagnosis at all, and enrollees would potentially use higher-intensity treatments sooner than they would have previously, as well.

Mature Oocyte Cryopreservation for the Analysis of AB 767

Mature OC is a form of fertility preservation, as defined above. While fertility preservation usually refers to the preservation of fertility in advance of medical procedures that can lead to iatrogenic infertility (medically caused infertility), such as treatment for cancer or during sex transition, the lack of definition of fertility preservation in AB 767 as amended could result in a much broader interpretation. The lack of a definition for fertility preservation, in combination with the non-discrimination clause included in current law, could expand coverage of mature OC to a woman seeking to preserve her fertility for age-related reasons or to women seeking to preserve their fertility if they experience other medical conditions, such as endometriosis. CHBRP's analysis of AB 767 analyzes only the impacts of expanding OC services to women not seeking these services for iatrogenic reasons. This report refers to non-iatrogenic fertility preservation as "planned oocyte cryopreservation," in accordance with guidance from the ASRM (2018).

Information about fertility preservation related to iatrogenic infertility and projected impacts of coverage of fertility preservation services is included in CHBRP's April 2019 analysis of SB 600 Fertility Preservation.[15]

Religious Exemption

CHBRP does not provide legal analysis and is unable to analyze the impacts of the removal of the religious exemption.

[15] CHBRP reports are available at http://chbrp.org/completed_analyses/index.php.

Other Key Assumptions

- CHBRP assumes all non-experimental infertility treatments and planned OC would need to be covered for a plan to be in compliance with AB 767. More information about non-experimental infertility treatments is included in the *Background on Infertility* section.

- CHBRP assumes AB 767 does not require coverage of donor materials (oocytes or semen), surrogacy services, or storage of frozen materials unless included as part of the infertility treatment (such as during IVF), as this is not stated in the bill language.

- AB 767 does not provide a definition of "demonstrated condition." CHBRP assumes this to encompass a diagnosis of infertility and apply to couples in same-sex relationships and single women. Single men are not included as a "demonstrated condition" because a surrogate would be required to "treat infertility" and both surrogacy and semen cryopreservation are not included as a covered service within AB 767.

- Gamete intrafallopian transfer (GIFT) and zygote intrafallopian transfer (ZIFT), while specified as required treatments for infertility, are no longer performed. These procedures have been replaced by IVF. Therefore, CHBRP does not incorporate utilization of GIFT and ZIFT into the cost impact projections and does not discuss these procedures in the *Background, Medical Effectiveness, or Public Health* sections.

BACKGROUND ON INFERTILITY

Infertility is the inability to have a child and is a complex condition that can take many forms. In order for a live baby to be born without medical intervention, several conditions must be met:

- An egg (oocyte) must be released from an ovary;
- Sperm must join with (fertilize) the egg;
- A fertilized egg must be able to move through the fallopian tube toward the uterus;
- The fertilized egg must attach (implant) to the lining of the uterus to begin pregnancy; and
- The fertilized egg must develop to an embryo and then fetus in the uterus and be gestated (carried) until live birth occurs.

Infertility may result from a problem with any one of these steps, or a combination of several steps.

Persons attempting to have a child may experience *primary infertility* (physical difficulties having a first child) or *secondary infertility* (having had at least one child, but experiencing difficulty having another), either of which may be related to the inability to become pregnant or successfully carry a pregnancy to term.

There are important differences between male and female reproductive biology that impact infertility. Women are born with a finite number of eggs (oocytes) that mature with the onset of menarche (median age 12 years) and decrease in number and quality until the onset of menopause, beyond which women are not able to naturally bear children; this is generally referred to as the female reproductive range. National datasets of in vitro fertilization (IVF) use show that less than 1% of women initiating IVF at age 44 or older will have a live birth; however, women up to the age of menopause, average age 51 in the US, may experience fertility treatment success using donor materials (ACOG, 2014b). In contrast, males become able to produce sperm during puberty (median age 12 years) and, according to the American Society for Reproductive Medicine (ASRM), retain optimal reproductive capabilities until 60 years of age.[16]

Definitions of Infertility

As described in the *Policy Context* section, there are many definitions of infertility that vary in specificity depending on the population or context to which they are applied.

In most clinical contexts, infertility is defined as the inability to become pregnant after 12 months of trying to conceive without contraceptives. Some clinical definitions specify a shorter timeframe (6 months) for women aged 35 years and older or separately define infertility for single women wishing to become pregnant (ASRM, 2013). In demographic contexts, infertility is often broadly defined as the inability to become or remain pregnant among reproductive-aged women. In some public health or social justice contexts, infertility is considered to meet the legal definition of a disability or disease, since the inability to have children is an impairment of a basic human function (ASRM, 2013). In other instances, infertility is only described among persons currently attempting to become pregnant or only among heterosexual

[16] Men produce sperm throughout their lives, and it is thought that there is no maximum age at which it is not possible for a male to father a child.

married and cohabitating persons, thereby excluding single women, same-sex couples, persons who may be infertile but have stopped trying to become pregnant, or persons who experienced infertility in the past.

In the context of AB 767, infertility is defined as "the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility." In taking a condition-related approach, this definition recognizes infertility in enrollees regardless of their conception-related intentions and for whom timeframe restrictions are not meaningful, such as single women, same-sex couples, and persons who are surgically sterile for non-contraceptive reasons.[17]

Causes and Risk Factors of Infertility

Medical Causes

There are numerous medical causes of infertility, and an individual can have more than one cause of infertility. Within a couple, one or both partners can have a cause of infertility. In the United States, results from a prospective cohort study of almost 400 women presenting at eight infertility practices showed that 58% of infertility cases were attributable to female factors, 7% were attributable to male factors, 31% were attributable to both male and female factors, and 4% were not directly attributable to either partner (Smith et al., 2011).

Treatments for infertility can target the cause of infertility, and many treatments, including IVF, are options for a number of different causes of infertility. Infertility in persons with iatrogenic causes (i.e., cancer treatments and sex transition) are addressed in another 2019 CHBRP analysis (SB 600) and will not directly be addressed here.

Common causes of infertility among *females* are:

- **Ovarian factors** (ovulatory and/or oocyte disorders): Issues with the eggs or release of eggs. Ovulation disorders include infrequent ovulation (oligoovulation) and absent ovulation (anovulation). Polycystic ovarian disorder (PCOS) is the most common cause; other causes include primary ovarian insufficiency (previously called premature ovarian failure or premature menopause), other hormonal disorders, other chronic conditions, and oocyte aging. Oocyte aging (i.e., age-related infertility) is an expected decline in the quality and quantity of oocytes (eggs) as a woman ages. This begins when a woman is 30–35, and is significant by age 40.
- **Tubal factors** (fallopian tube abnormalities): Blocked fallopian tubes inhibit transport of oocytes and sperm though the fallopian tube. Tubal abnormalities are often caused by pelvic inflammatory disease, which results from infections such as Chlamydia or gonorrhea. Endometriosis is also a cause of blocked fallopian tubes.
- **Uterine factors**: Can cause problems with pregnancy implantation and ability to carry a pregnancy to a term live birth. These include uterine leiomyomata (fibroids), which are benign smooth muscle tumors within the uterus that develop over time, and congenital (present from birth) uterine anomalies.

[17] This CHBRP analysis draws on many informational sources regarding infertility and related treatments that rely on differing definitions of infertility; therefore, the term "infertility" is used broadly throughout this report to refer to the inability to conceive or carry a pregnancy. Distinctions in definitions due to data sources are described and cited when necessary.

- **Endometriosis**: A chronic condition in which endometrium (the lining of the uterus) implants inappropriately outside the uterus. This can block the fallopian tubes or uterus cavity, and damage the ovaries, which can lead to impaired fertilization and implantation outcomes.
- **Immune factors**: Antiphospholipid syndrome (APS) leads to the immune system rejecting early pregnancy or to placental damage, resulting in recurrent pregnancy loss.
- **Genetic causes**: The most common genetic cause of female infertility is Turner syndrome (45,X), which is the absence or abnormality of one of the two X chromosomes that women have, and leads to ovarian failure in most women with this syndrome. Genetic causes in the fertilized egg, embryo, and fetus can also lead to miscarriage.
- **Unexplained infertility**: A diagnosis of exclusion, when testing for the above conditions is negative and no specific cause of infertility can be found. Fertility treatments are still possible even when female factor infertility cannot be explained.

Common causes of infertility among *males* are:

- **Sperm-related factors**:
    - *Sperm motility and morphology disorders*: Defective sperm production, impaired sperm motility, and low count lead to a lack of sperm available to reach and fertilize the egg. There are multiple causes of sperm dysfunction or inadequate production. These include congenital (present at birth, such as missing or undescended testes), trauma to the testicles, varicoceles, genetic causes (chromosomal disorders, such as Klinefelter syndrome), infections (such as mumps), medications and/or toxin exposure, chronic health conditions (including cancer and treatments for cancer, renal failure, celiac disease, and sickle cell disease), and other causes of hormonal dysfunction.
    - *Sperm transport issues*: Includes abnormalities of the epididymis and the vas deferens (including absence of the vas deferens, as in cystic fibrosis), and defective ejaculation or ejaculatory ducts. These disorders can be congenital (present at birth) or caused by trauma or infection.
- **Unexplained infertility**: When semen analyses are normal, but pregnancy cannot be achieved with a woman who had normal infertility testing, unexplained infertility (idiopathic infertility) is considered the cause. Fertility treatments are still possible even when male factor infertility cannot be explained.

Relationship Status

Persons in same-sex relationships or who are not in a relationship also are unable to achieve pregnancy without additional intervention as they lack either the male or female components necessary for fertilization and pregnancy. These persons could have the above medical causes of infertility as well.

Evaluation and Treatment of Infertility

Diagnostic Evaluation

Diagnostic evaluation for infertility is clinically recommended for couples that have not become pregnant after a year of unprotected intercourse, or 6 months of unprotected intercourse for women over 35 years

of age. Single women or women who are in same-sex relationships who are planning on attempting insemination might also benefit from a diagnostic evaluation.

Diagnostic evaluation typically starts with a thorough medical examination as well as a discussion of sexual, reproductive, and family history. Depending on the results of this preliminary evaluation, females are assessed for ovulatory function, ovarian reserve, uterine abnormalities, tubal patency (fallopian tube functioning), or peritoneal factors (endometriosis or pelvic adhesions) (ASRM, 2015a). After preliminary evaluation, males are evaluated using a semen analysis, endocrine evaluation, post-ejaculation urinalysis, or ultrasonography of the scrotum or genital tract to identify structural abnormalities (ASRM, 2015b). A diagnostic evaluation can effectively identify the source of the infertility problem in 70% of cases. In the 30% where infertility cannot be identified, a protocol for treatment of unspecified infertility is recommended (ASRM, 2015a).

In the 2006–2010 cycle of the National Survey of Family Growth (NSFG), 7.3% of women and 5.3% of men aged 25–44 years reported that either they or their partners had ever undergone tests to diagnose infertility (Chandra et al., 2014; NSFG, 2017).

Treatments for Infertility

As described in Table 2, there are a number of treatment options for women and men seeking medical help to achieve a pregnancy, including medical advice, medications, surgery, artificial insemination, and assisted reproductive technology (ART), which includes IVF.

In the 2006–2010 cycle of the NSFG, 12.5% of women aged 25–44 years reported ever having any medical help to get pregnant (including treatment among their partners). Among the same cohort of women, 9.4% received advice, 5.8% reported using ovulation drugs, 1.3% had surgery or treatment of blocked fallopian tubes, 1.7% had artificial insemination, and 0.7% had ever used any form of assisted reproductive technologies (Chandra et al., 2014).

Table 2. Common Infertility Treatment Options by Category

Treatment	Description
Advice	Medical advice usually includes information about how to measure biological readiness (such as ovulation) and time sexual intercourse to optimize the chances of conception in a given month.
Medications	Medications are usually used in instances of abnormal ovarian function. In general, medications are used to time or stimulate the release of oocytes (ovulation) or stimulate greater egg production.[18]
Surgery	With the advent of IVF, surgery is becoming a less common infertility treatment option.

[18] Common medications (generic then common brand names) include: clomiphene citrate (Clomid), Serophene); metformin (Glucophage, Glumetza); follicle-stimulating hormone (FSH) (Bravelle, Follistim, Gonal-F); human chorionic gonadotropin (hCG) (Pregnyl, Profasi, Novarel, Ovidrel); human menopausal gonadotropin (hMG) (Menopur, Repronex); dopamine agonists; gonadotropin-releasing hormone (GnRH) (Factrel, Lutrepulse); GnRH agonists (Lupron, Zoladex, Synarel); GnRH antagonists (Ganirelix, Cetrotide); aromatase inhibitors (letrozole, anastrozole, exemestane); letrozole, and dexamethasone (Decadron).

Treatment	Description
Tubal repair	Surgery on the fallopian tubes is generally performed to treat blockages that may prevent the transfer of oocytes or sperm, such as in the instance of tubal scarring or desire for a tubal ligation reversal.
Uterine fibroid removal	Surgery to remove fibroids from the uterus that could interfere with fertility.
Endometriosis excision or ablation	Procedure to remove or destroy deposits of endometrial tissue where they do not belong in the genital tract and abdomen, and that can interfere with fertility.
Vasectomy or tubal ligation reversal	Men with prior vasectomies or women with prior tubal ligations may have a surgery to reattach the vas deferens or fallopian tubes and thereby allow the sperm and eggs to travel without impediment to allow fertilization.
Artificial Insemination	The deliberate introduction of semen into the uterus (also known as intrauterine insemination [IUI]) is another method for treating infertility, in the case of male factor or unexplained infertility. IUI is also a potential option for single women or same-sex couples wishing to conceive. ICI (intracervical insemination) is another lesser-used approach to artificial insemination that is an option in certain situations in which sperm is placed inside the vagina against the cervix.
Assisted Reproductive Technologies (ART)	ART is defined as any procedure in which both the oocyte (egg) and sperm are handled.
In vitro fertilization (IVF)	IVF is a multicomponent process in which mature eggs (oocytes) are retrieved from the ovaries and then combined (fertilized) with sperm in a culture dish in a laboratory. The resulting embryos are then transferred into the uterus. This is the most common form of ART. (a)
Intracytoplasmic sperm injection (ICSI) as part of IVF	An assistive IVF procedure wherein a single sperm is injected into a mature egg (as compared with allowing sperm to fertilize eggs on their own in a culture dish) as part of IVF. ICSI is often used for couples with male factor infertility.

Source: Centers for Disease Control and Prevention, 2019.

Note: This table only presents information on commonly used treatments for infertility and, therefore, should not be used as a comprehensive source. (a) Less commonly used forms of ART include zygote intrafallopian tube transfer (ZIFT) and gamete intrafallopian tube transfer (GIFT).

Treatment considerations for same-sex couples and single persons

For two women in a relationship or single women, donor sperm will be needed, and in some cases IUI or IVF. For two men in a relationship or men who are single, donor eggs and a gestational carrier (surrogate) with IVF will be needed (Greenfeld and Seli, 2016). As stated in the *Policy Context* section, the use of donor materials and gestational carriers are not explicitly included in AB 767 and therefore CHBRP has assumed they are not required to be covered.

Preventive Infertility Treatments

In addition to detection and treatment of infertility, AB 767 mandates coverage for mature oocyte cryopreservation (OC) — a procedure in which viable, unfertilized eggs (oocytes) are frozen and preserved for future fertilization and implantation via IVF — which is generally performed in two instances:

1) Prior to a medical treatment known to cause infertility, such as chemotherapy for cancer (also known as iatrogenic infertility); or

2) As an elective procedure, known as "planned oocyte cryopreservation," in which women choose to have their eggs frozen to increase the likelihood of having viable eggs in the event they experience difficulty conceiving when they are ready to become pregnant (Hirshfeld-Cytron et al., 2012).

Since fertility preservation for iatrogenic infertility is the focus of another 2019 CHBRP analysis (SB 600), discussion of mature OC in this analysis will refer only to persons utilizing planned OC. For information about iatrogenic infertility incidence and related fertility preservation utilization, see CHBRP's April 2019 analysis of SB 600 at www.CHBRP.org.

According to the ASRM, planned OC is potentially beneficial for women facing non-immediate threats to their fertility. These threats may include conditions such as endometriosis, polycystic ovarian syndrome, or age-related fertility loss (ASRM, 2018). National estimates of planned OC use are not available, but individual studies indicate that awareness and use of planned OC has increased and the average age of initiation has decreased in the past decade (Argyle et al., 2016; Goldman et al., 2014; Mucowski et al., 2014).

Treatment-Associated Financial Burden

As compared with other developed countries, the cost of undergoing ART is highest in the United States. Chambers et al. (2009) assessed the cost of ART in 2003 for 10 highly developed countries, taking into account differences in regulatory structure and the relative value of currency. A 2009 study showed that the cost of one standard cycle of IVF was $12,513 (2006 USD) in the United States compared to $3,956 in Japan, and the cost of one live birth with IVF was $41,132 in the US compared to $24,329 in Japan. Similarly, one cycle of IVF in the United States accounted for up to 50% of a couple's annual disposable income as compared with 6% in Australia (Chambers et al., 2009). Due to these high costs, Chambers et al. (2009) estimated that only 24% of the demand for ART in 2003 was being met in the United States, whereas Australia and Scandinavia demonstrated almost no unmet demand.

More recent data from a cohort of couples recruited from eight community and academic endocrinology clinics in California indicates that out-of-pocket costs are significant and may impact overall utilization of infertility treatments. Based on cost diaries, Wu et al. (2014) estimated that the median out-of-pocket cost of infertility treatments ranges from $912 for medications alone, up to $19,234 for one cycle of IVF, with each additional cycle of IVF costing $6,995. Further analysis of the same cohort found that, on average, couples undergo 3.7 cycles of IVF, which means that an average couple utilizing IVF might accrue up to $40,219 in out-of-pocket treatment costs for infertility treatment. Costs were even higher for couples utilizing donor eggs (Katz et al., 2011). In addition to oocyte retrieval and IVF, persons undergoing planned OC generally also need to pay out of pocket for frozen storage costs, which range from $100 to $1,500 per year (average $300/year) (Mesen et al., 2015). Treatments for infertility are also complex and time-consuming, with one study estimating that a single cycle of IVF could account for 15.6 work-day equivalents, mostly in administrative time (Wu et al., 2013).

For current, California-specific estimates of treatment costs, demand, and utilization, please see Table 1 and the *Benefit Coverage, Utilization, and Cost Impacts* section.

Prevalence of Infertility and Impaired Fecundity in the United States

This section presents prevalence estimates of infertility and impaired fecundity from the CDC's National Survey of Family Growth (NSFG).[19] As defined by the NSFG, "infertility" is a subset of the broader term "impaired fecundity." Whereas ***impaired fecundity is the difficulty conceiving or carrying a pregnancy to term*** among women of any relationship status or sexual orientation within a 3-year period, ***infertility is specific to difficulty conceiving*** within a 1-year period among women who have been continuously married to, or cohabitating with, an opposite-sex partner (Chandra et al., 2013). In contrast, AB 767 is broadly inclusive of all persons experiencing infertility, regardless of timeframe, marital status, or cause and, therefore, more closely aligns with the NSFG's definition of impaired fecundity.[20]

Females

Results from the 2011–2015 cycle of the NSFG (Table 3) indicate that just over 12% of all women aged 15–44 years in the United States have impaired fecundity and almost 7% of married or cohabitating women are infertile (NSFG, 2017).

As described by Table 3, prevalence and age-related trends of infertility have remained fairly consistent across the past three cycles of the NSFG (encompassing 13 years of data), with overall slightly lower rates reported for both outcomes in the 2006–2010 cycle. However, a report of all NSFG cycles from 1982 to 2010 indicates that the prevalence of impaired fecundity significantly increased from 8.4% in 1982 to 11.8% in 2002, driven primarily by an increase in the number of women for whom it is physically difficult or dangerous to have a baby. In contrast, the prevalence of infertility among married and cohabitating women has steadily decreased, from 8.5% in 1982 to an all-time low of 6% in the 2006–2010 NSFG cycle (Chandra et al., 2013).

Table 3. Prevalence of Infertility and Impaired Fecundity Among Women Aged 15–44 Years by Age Group National Survey of Family Growth Cycles 2002, 2006-2010, 2011-2015

	Infertility [(a)] (%)			Impaired Fecundity (%)		
	2002	2006-2010	2011-2015	2002	2006-2010	2011-2015
Overall	**7.4**	**6.0**	**6.7**	**11.8**	**10.9**	**12.1**
Age Group (years)						
15–29	6.3	5.0	5.8	8.4	8.9	9.0
30–34	8.1	4.6	6.3	14.1	12.2	14.0
35–39	5.7	7.8	6.5	12.1	13.9	15.2
40–44	9.4	6.2	8.0	17.9	12.5	16.2

[19] The NSFG consists of nationally representative data gathered from in-person interviews with males and females aged 15–44 years, administered by trained interviewers. Only one person per household was interviewed.
[20] Persons who are surgically sterile for *non-contraceptive* reasons (e.g., cancer treatment) but still have a potentially viable uterus are not included in the NSFG's estimates of impaired fecundity but may be eligible to receive infertility treatment under the proposed mandate.

Source: National Survey of Family Growth (2017)

Note: Estimates of infertility and impaired fecundity may reflect the fertility status of a respondent's partner as well their own. (a) NSFG estimates infertility only among married or cohabiting women and their opposite sex partners aged 15–44 years.

Males

Currently, there is no national registry that systematically collects information about males and the true prevalence of infertility among males in the United States is unknown. Although the NSFG estimates several measures of impaired fertility among married or cohabitating males aged 15–44 years[21] it should be noted that there are no completely analogous measures of infertility or impaired fecundity for males as compared with females and male participation in the NSFG is low (Chandra et al., 2013; Mehta et al., 2016). At the time of this report, estimates of impaired fertility from the 2011–2015 NSFG were not yet available; however, 9.4% of men aged 15–44 years reported some type of impaired fertility in the 2006–2011 NSFG; of those, a little over half (5.2%) of men were subfertile and just under half (4.2%) were non-surgically sterile (Chandra et al., 2013).

A more recent survey conducted in Great Britain found that 10.1% of males aged 16–75 years surveyed between 2010 and 2012 had experienced infertility[22] at some point in their lives. Among this cohort of men, increased prevalence of infertility was associated with increased socioeconomic status, later cohabitation with a partner, and — among men with children — becoming parents at an older age (Datta et al., 2016).

Disparities[23] and Social Determinants of Health[24] in Infertility

Per statute, CHBRP includes discussion of disparities and social determinants of health (SDoH) as it relates to infertility. Disparities are differences between groups that are modifiable. CHBRP found literature identifying disparities by race/ethnicity, marital status/sexual orientation, and socioeconomic status.

Disparities

Race or ethnicity

According to a pooled analysis of race and ethnicity data over three cycles of the NSFG (2002, 2006–2010, and 2011–2013), overall infertility and impaired fecundity rates are highest among Hispanic and non-Hispanic black women; however, utilization of infertility treatments is highest among non-Hispanic white women (Chandra et al., 2013; Craig et al., 2019). In the 2006–2010 NSFG, the most recent cycle for which race and ethnicity data are available, non-Hispanic white women reported almost twice the

[21] Male NSFG respondents are limited to the same age range as the women respondents (15–44 years); however, according to the American Society for Reproductive Medicine (ASRM), males retain optimal reproductive capabilities until 60 years of age and do not have a maximum age at which it is not possible to father a child.
[22] Defined by unsuccessfully attempting pregnancy for a year or longer.
[23] Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population. Wyatt et al., 2016.
[24] CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from Healthy People 2020, 2015; CDC, 2014). See CHBRP's SDoH white paper for further information: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

utilization rate of medical help to get pregnant (15%) as compared with non-Hispanic black women (8.0%) or Hispanic women (7.6%) (Chandra et al., 2014).

Furthermore, in a cumulative analysis of several NSFG cycles, Janitz et al. (2018) observed that non-Hispanic black women respondents were significantly less likely to undergo infertility testing, seek medical advice for infertility, or utilize infertility treatments as compared with non-Hispanic white women after adjusting for age and income. Although Hispanic women reported less use of infertility treatments as compared with non-Hispanic women, these differences were not statistically significant; however, Hispanic women were significantly more likely to seek medical advice or infertility testing (Janitz et al., 2018). In addition to being less likely to seek medical help for infertility overall, Chin et al. (2015) observed that, on average, black women who do utilize medical help for infertility wait twice as long to seek care after an infertility diagnosis as compared with white women (i.e., 2 years versus 1 year).

Studies of data from the Society for Assisted Reproductive Technology (SART) Clinic Outcome Reporting System (CORS) database suggest that when black, Hispanic, and Asian women access ART for infertility treatment, they experience less success as compared with non-Hispanic white women. In a systematic review of studies using SART CORS data from 1999-2007, Wellons et al. (2012) found that black, Asian, and Hispanic women had significantly lower live birth rates resulting from ART as compared with white women; and black and Hispanic women were significantly less likely than white women to opt for a single embryo transfers meaning that they may have had increased risk of multiple pregnancies (likely due to the higher costs associated with multiple single-embryo cycles compared to a single multiple-embryo transfer cycle), which have been associated with poor maternal and perinatal outcomes (see Harms discussion in the *Public Health Impacts* section). In addition, individual studies describing ART outcome disparities by racial or ethnic groups have shown that black women are significantly more likely to experience miscarriages after ART and Asian women are less likely to conceive a pregnancy from ART as compared with white women, which may, in part, be driving the lower birth rates observed among these groups overall (Fujimoto et al., 2010; Purcell et al., 2007; Quinn and Fujimoto, 2016; Seifer et al., 2008).

It has been suggested that increased rates of obesity, tubal factor infertility associated with endometriosis or infections, and fibroid-related uterine factor infertility observed among minority women may contribute to the previously discussed disparity in treatment outcomes, but cannot explain the full magnitude of the difference (Humphries et al., 2016; Insogna and Ginsburg, 2018).

Marital status and sexual orientation

As described previously, single persons and same-sex couples need to utilize infertility treatments, including donor materials, in order to have biological children. Although estimates vary widely, use of fertility treatments among same-sex couples and single persons is increasing. According to the NSFG, almost half of all births (49%) between 2011 and 2015 were to single or unmarried women, as compared with 38% in 2002 (NSFG, 2017). Similarly, retrospective studies of gay and lesbian couples have documented increases in fertility treatment use since the early 2000s ranging from 21% among lesbians seeking artificial insemination with donor sperm to a 21-fold increase among gay and single men undergoing ART (Carpinello et al., 2016; Grover et al., 2013). Despite these increases, advocates and professional groups, such as the ASRM, recognize that same-sex couples and single persons face disproportionate barriers to infertility treatment as compared with opposite-sex couples.

Same-sex couples and single persons are sometimes subject to definitional barriers that mediate their utilization of infertility treatments. Single or same-sex oriented persons may themselves be fertile or fecund but are not able to conceive a child with their spouses or partners; however, lacking a biologically compatible partner is not always recognized as cause of infertility in most clinical contexts or in major

demographic surveys, like the NSFG, which may impact how insurance coverage is applied to these populations (Daar et al., 2015; Daar, 2008; National LGBT Health Education Center, 2019).

Same-sex couples and single persons need to use donor materials, including gestational carriers (surrogates), which pose an additional cost burden beyond the previously discussed expense of standard infertility treatments. At a minimum, female same-sex couples and single women attempting to conceive need to undergo artificial insemination with donor sperm whereas male same-sex couples and single men typically need to engage a gestational carrier (surrogate) and use donor eggs via IVF (with ICSI) to have biological children. The average cost of insemination with donor sperm is estimated at around $5,000 and the cost of IVF with donor eggs has been estimated to be around $38,000 for a live birth; gestational carrier (surrogacy) arrangements are very costly, ranging from $80,000 to $140,000 depending on medical and legal expenses (Katz et al., 2011; National LGBT Health Education Center, 2019). Note that use of donor materials is not exclusive to same-sex couples and single persons, but it is always required for these populations.

Finally, same-sex couples and single persons may experience informational deficits regarding to reproduction procedures. CHBRP identified two studies that reviewed a representational sample of ART clinic websites in the United States, of which only about half (45.5%–53%) contained content specific to LGBT or single-person reproduction. Western clinic websites had the second highest rate of LGBT-specific content (66%) after the Northeast (72%) (Jin and Dasgupta, 2016; Wu et al., 2017).

Socioeconomic status

Greil et al. (2011) analyzed data from 2,162 respondents to the National Survey on Fertility Barriers (NSFB) and found that having higher income, greater educational attainment, and private insurance were all independently associated with higher odds of medical service use for infertility. Among women recruited from high- and low-resource infertility clinics in California, Ho et al. (2017) observed that lower income and educational levels were significantly associated with longer durations of untreated infertility. With each level of education attained (e.g., high school diploma vs. some college) patients presented for infertility care approximately 3.5 months earlier; as compared with patients who did not attend college, patients with a college education presented 8.4 months earlier on average. A similar pattern was observed with respect to income in the same study wherein patients with an annual income greater than $100,000 sought infertility care approximately 6 months earlier than patients with incomes below $100,000 (Ho et al., 2017).

CHBRP also found evidence suggesting that socioeconomic factors mediate documented disparities in use of infertility treatments by race and ethnicity. Missmer et al. (2011) surveyed over 1,300 women receiving infertility treatments about barriers to treatment and found that African American women were 8 times more likely than white or Asian American women to report difficulty getting treatment for infertility due to income and Hispanic women were about 6 times more likely to report income-related barriers. In addition, African American and Hispanic women were significantly more likely to have difficulty taking time off for appointments, a significant component of successful infertility treatment.

Disparities in infertility treatment outcomes by socioeconomic status have also been documented. Among approximately 800 women recruited from eight fertility clinics in California, women with college educations had almost twice the odds of achieving a pregnancy as compared with women without a degree after controlling for age, demographic factors, and fertility factors. Similarly, women with an annual income greater than $60,000 had 3 to 5 times the odds of achieving a pregnancy compared to women with incomes less than $60,000 (Smith et al., 2011).

Social Determinants of Health (SDoH)

SDoH include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography). With respect to AB 767, CHBRP found literature regarding the impact of cultural beliefs and discrimination on the prevalence of infertility treatment use and outcomes.

Discrimination

CHBRP found evidence suggesting that discrimination may contribute to disparities in infertility treatment. A study of over 1,300 women receiving infertility treatments at a university-based fertility center found that, compared to whites, African American and Hispanic women felt it was more difficult to obtain infertility treatment, and this difficulty was a direct result of their race or ethnicity (Missmer et al., 2011).

Infertility-associated discrimination is also present on a system level. Gurmankin et al. (2005) surveyed nearly 369 assisted reproductive technology (ART) clinics across the country to assess the opinions of clinic directors on access-to-service issues in comparison to their clinic policy. They found that 53% and 48% of clinic directors would be very likely to turn away single men pursuing parenthood and male same-sex couples planning to engage a surrogate, respectively. In contrast, clinic directors were less likely to express intent to deny services to single women (20%) and female same-sex couples pursuing insemination with donor sperm (17%).

Cultural beliefs

Missmer et al. (2011) surveyed over 1,300 women receiving infertility treatments and reported numerous cultural differences in access to infertility care. Compared with whites, African American and Hispanic women reported more difficulty finding a physician they felt comfortable with and that their race or ethnicity made it more difficult to obtain treatment. Similarly, Catholic women were 9 times more likely than Protestant women to report that difficulty obtaining treatment was specifically due to their religion (Missmer et al., 2011). Moreover, among 2,162 women participating in the National Survey of Family Barriers, Greil et al. (2011) observed that compared to white women, black, Hispanic, and Asian women were more likely to express ethical concerns about infertility treatments, such as artificial insemination (with partner or donor sperm), which was associated with significantly lower odds of seeking treatment for infertility (OR, 0.77;$p<0.0001$). Black and Hispanic respondents also had lower scores with respect to the perceived importance of motherhood as compared with white respondents, which was associated with significantly greater odds of receiving tests or treatment for infertility.

Community-related social stigma may also be a reason racial and ethnic minority populations seek out infertility treatments less often than non-Hispanic whites do. Greil et al. (2011) analyzed data from the NSFB and found that black and Hispanic women reported infertility-related stigma more frequently than whites and Asians and were less likely to seek treatment as a result of encouragement from a partner or family member. Similarly, in a survey of women receiving infertility treatments, Missmer et al. (2011) found that African American women were up to 4 times more likely than white women to be concerned with failing to conceive naturally and the social stigma of infertility. Compared to white women, Asian American women were 7 times as likely to be concerned with social stigma of infertility; women of Chinese descent were nearly 60 times as likely to name social stigma as a significant worry or concern in seeking infertility treatment.

Societal Impact of Infertility in the United States

As described previously, infertility is a common condition and the presence of infertility in the U.S. creates a societal impact. In dollar terms, the societal impact can be indirect (lost wages, etc.) as well as direct (medical care, etc.). CHBRP did not identify data that displays the broad societal impact of infertility, specifically. However, research shows that, on an individual basis, treatment for infertility in the United States is very costly in terms of time and personal finances (Katz et al., 2011; Wu et al., 2013; Wu et al., 2014). To that end, see the *Benefit Coverage, Utilization, and Cost Impacts* section for estimates of cost impacts on payers, including enrollees, and the *Long-Term Impacts* section on economic loss for estimates on indirect costs to enrollees. Such figures represent a subset of the total societal impact related to infertility.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, AB 767 would modify the current infertility treatment mandate, which requires most group market DMHC-regulated plans and CDI-regulated policies to *offer* coverage for infertility treatment, excluding in vitro fertilization (IVF), as an optional rider. AB 767 would instead mandate that plans and policies, except for individual market plans and policies and Medi-Cal, *provide* coverage for infertility treatment, including IVF, and mature oocyte cryopreservation (OC). Additional information on infertility causes, diagnostic work-up, preventive options, and treatments is included in the *Background* section.

Research Approach and Methods

As presented in the *Background* section, infertility diagnosis and treatment encompasses a wide range of tests, treatments, and medications. It is not feasible for CHBRP to review the literature on the effectiveness of the numerous diagnostic and treatment options for all causes of infertility to which AB 767 applies within the 60-day timeframe allotted for this analysis. In light of the wide range of conditions that cause infertility, the types of treatments to which AB 767 would apply, and the fact that AB 767 addresses the provision of coverage of infertility benefits, the medical effectiveness review summarizes these findings from evidence:[25] (1) the impact of health insurance coverage (specifically *mandates to cover*) for infertility treatments and (2) the medical effectiveness of the two treatments newly mandated under the bill language (IVF and mature OC).

Studies of infertility treatments and impacts of infertility insurance coverage were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, and Business Source Complete, the Cumulative Index of Nursing and Allied Health Literature, and PsycINFO. Websites 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 (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network. The search was limited to abstracts of studies published in English.

The search related to the effectiveness and harms of IVF and planned OC ("planned oocyte cryopreservation") was limited to studies published from 2000 to present. Due to the amount of literature published related to IVF, CHBRP focused on previously published systematic reviews to inform the medical effectiveness analysis. In assessing harms related to IVF and planned OC, CHBRP relied primarily on previously published systematic reviews when possible and expanded the inclusion to well-designed trials and cohort studies for less common harms and complications. The search related to the impact of health insurance coverage for infertility treatment was limited to studies published from 2012 to present because CHBRP had previously conducted thorough literature searches on these topics in 2013 for AB 460.

Of the 480 articles found in the literature review, 227 were reviewed for potential inclusion in this report on AB 767, and a total of 29 studies were included in the medical effectiveness review for this report, as well as 8 studies that were included in the previous review for AB 460. The other articles were eliminated

[25] Much of the discussion below is focused on reviews of available literature. However, as noted on page 11 of the Medical Effectiveness analysis and research approach document (posted here), in the absence of "fully-applicable to the analysis" peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

because they did not focus on mandate coverage including IVF, did not report relevant outcomes, or were not reporting findings from 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.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature. Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

Key Questions

1. What is the effectiveness of IVF and planned OC as treatments for infertility?
2. What are the harms associated with IVF and planned OC?
3. What is the impact of health insurance coverage for infertility treatments on the use of these treatments and associated health outcomes?

Methodological Considerations

As mentioned previously, due to the amount of available literature, the medical effectiveness review relied on existing systematic reviews reporting the effectiveness of IVF. These reviews typically compared the effectiveness of IVF to either intrauterine insemination (IUI) or expectant management (conceiving without intervention). CHBRP's discussion of planned OC is limited to women seeking fertility preservation due to age-related reasons. The review only identified retrospective cohort studies examining the effectiveness of planned OC and none of these studies included an expectant management comparison; studies either compared planned OC among nononcologic vs. oncologic patients, cryopreserved vs. fresh embryos, or lacked a comparison group. This review also excludes any discussion of fertility preservation for iatrogenic infertility; a complete discussion of cryopreservation for that population is discussed in CHBRP's April 2019 analysis of SB 600.[26]

When assessing studies examining the impact of health insurance mandates on treatment utilization and outcomes, the medical effectiveness analysis was only interested in studies looking at mandates covering IVF; there is literature from AB 460 that discussed mandates broadly or without IVF coverage that CHBRP has omitted for this review. This analysis will consider studies published after 2013 in addition to CHBRP's previous findings, as ART is a rapidly developing field with clinical advancements expected to have occurred in the last 5 years.

Outcomes Assessed

To assess the effectiveness of IVF and planned OC, CHBRP assessed the impact on health outcomes including the number of embryos transferred, use of intracytoplasmic sperm injection (ICSI), pregnancy rates, live births, and rates of multiple births. The goal health outcome of IVF is pregnancy and then live birth. Lower pregnancy and birth rates can also be a marker of fewer embryos transferred. The number of embryos transferred is an important outcome because transferring more than one embryo per IVF cycle is done to increase the likelihood of pregnancy, however it also increases the risks of a multiple gestation pregnancy (twins, triplets, or more), increasing both maternal and fetal risks, including preterm birth.

[26] CHBRP's April 2019 analysis of SB 600 Fertility Preservation is available at: http://chbrp.org/completed_analyses/index.php

ICSI is an IVF procedure in which a single sperm cell is injected directly into the cytoplasm of an egg to fertilize the egg, compared to conventional IVF in which multiple sperm are placed in proximity to an egg to fertilize it. ICSI is medically indicated in cases of male-factor infertility when sperm are limited in number or motility. ICSI can be used for reasons other than male-factor infertility, such as to increase the likelihood of IVF success and when genetic screening of the embryo is performed if preferred by the fertility specialist. In studies on IVF use, ICSI rates can be a marker of an unnecessary, higher level intervention due to pressures for IVF to be successful.

To assess the harms of IVF and planned OC, CHBRP assessed the effects on maternal health outcomes, including ovarian hyperstimulation syndrome, ectopic pregnancies, cardiovascular complications, post-pregnancy cancer, and multiple gestation. CHBRP also assessed the effects on neonatal health outcomes, such as the rate of preterm or low-birthweight births and the incidence of cancer or cardiovascular disease, major/minor malformations, cerebral palsy, and infant death.

For studies of the impact of coverage for infertility treatments, CHBRP assessed effects on two types of outcomes: (1) use of infertility treatments, such as number of embryos transferred; and (2) health outcomes of infertility treatments, such as pregnancy rates, live birth rates, and rates of multiple births.

Study Findings[27]

CHBRP identified four systematic reviews comparing the effectiveness of IVF versus other infertility treatments and found that IVF is an effective treatment for infertility, resulting in increased pregnancy rates and live birth rates. CHBRP identified four retrospective cohort studies assessing the effectiveness of planned oocyte preservation that consistently found that planned OC is an effective treatment for infertility, resulting in pregnancies and live births.

CHBRP identified 17 studies (13 systematic reviews and four observational studies) that analyzed the potential harms and complications associated with IVF and planned OC. CHBRP found evidence that IVF is associated with certain maternal and fetal harms, including ovarian hyperstimulation syndrome and thromboembolism. There is also evidence that IVF can lead to multiple gestation and preterm delivery. However, it is important to note that multiple gestation is associated with higher numbers of embryos transferred per cycle, and that preterm delivery is associated with multiple gestation — these outcomes can be mitigated by single embryo transfers. CHRBP found evidence that IVF mandates are associated with lower numbers of embryos transferred per cycle. There is also evidence that IVF mandates lead to fewer births per cycle (due to the decreased number of embryos transferred per cycle), and a reduction in overall harms of IVF (i.e., lower rates of multiple gestation, preterm deliveries and low-birthweight births).

Effectiveness of IVF

CHBRP identified four systematic reviews including 55 unique (non-overlapping) studies comparing the effectiveness of IVF versus other infertility treatments (Humphries et al., 2016; Pandian et al., 2015; Siristatidis et al., 2015; Vitorino et al., 2011). A 2015 Cochrane Review compared the effectiveness of

[27] The following figures in this section summarize CHBRP's findings regarding the strength of the evidence for the effects of insurance coverage for, and effectiveness of, IVF and planned OC addressed by AB 767. For test, treatments, and services for which CHBRP concludes that there is clear and convincing, preponderance, limited, or inconclusive evidence, the placement of the highlighted box indicates the strength of the evidence. If CHBRP concludes that evidence is insufficient, a figure that states "Insufficient Evidence" will be presented.

various infertility treatments (IVF, expectant management, intrauterine insemination, and IUI plus a type of medication [e.g., gonadotropins/clomiphene/letrozole]) on live birth rates for patients with diverse causes of infertility including endometriosis and unexplained infertility (Pandian et al., 2015). A total of five randomized-controlled trials (RCTs) were included in the review, with 1,622 participants. Among the studies, a subset reported a higher live birth rate for women undergoing IVF, compared to women completing the expectant management treatment (n = 51; odds ratio [OR]=22.00 [95% CI 2.56-189.37]). In addition, the live birth rate was higher among IVF versus IUI patients (n = 156; OR=2.47 [95% CI 1.19-5.12]). The review also found there was no conclusive evidence between conducting IVF versus IUI + gonadotropins and IVF versus IUI + clomiphene. Regarding multiple pregnancies due to ovarian stimulation, there was no significant difference among women undergoing IVF verses IUI (OR: 0.63, 95% CI, 0.27-1.5).

As discussed previously, a patient's race/ethnicity could impact the success of infertility treatments. As observed via a systematic review by Humphries et al. (2016) assessing 24 peer-reviewed publications, Caucasian women were more likely to achieve a pregnancy after completing IVF treatments as compared to both Asian and African American women (36.2% vs. 31.4% and 24.4% respectively). Caucasian women were also more likely to achieve higher birth rates than Asian women (30.7% vs. 24%; OR=0.64 [95% CI, 0.51–0.80]) and African American women (30.7% vs. 16.9%; OR=0.50 [95% CI, 0.33–0.72]) (Humphries et al., 2016).

A 2011 systematic review synthesized 17 studies focusing on HIV serodiscordant couples (couples in which one is HIV-positive and the other HIV-negative) striving to achieve conception. A total of 738 IVF cycles were completed among 579 serodiscordant couples. The median cumulative pregnancy rate among IVF patients was 52.9% (range: 41%–67.35%). Additionally, the median number of transferred embryos was 2.9 (range: 2.5–3.5), and the fertilization rate was 71.5% (range: 50.1%–77.1%). Finally, it is important to note that no seroconversions were reported among the studies of HIV serodiscordant couples and/or any newborn infants (Vitorino et al., 2011).

A 2015 systematic review analyzed data from 11 studies, which include a total of 268 polycystic ovarian disorder (PCOS) patients, and 440 infertile, non-PCOS patients, undergoing IVF treatment. After undergoing treatment, women with PCOS were more likely than the non-PCOS patients to achieve pregnancy (OR=3.29 [95% CI, 1.42–7.62]). The birth rate and embryo transfer rate trended towards higher in the PCOS group but not significantly different between both groups undergoing IVF for infertility (Siristatidis et al., 2015).

Summary of findings regarding IVF effectiveness: There is a preponderance of evidence from four systematic reviews that IVF is an effective treatment for infertility, resulting in increased pregnancy rates and birth rates.

Figure 1. Effectiveness of IVF as a Treatment for Infertility

Effectiveness of Planned Oocyte Cryopreservation

CHBRP identified four retrospective cohort studies assessing the effectiveness of planned OC (Cobo et al., 2018; Cobo et al., 2016; Doyle et al., 2016; Garcia-Velasco et al., 2013). One of these studies was

conducted in the United Sates (Doyle et al., 2016), while the other three included women from infertility clinics in Spain (Cobo et al., 2018; Cobo et al., 2016; Garcia-Velasco et al., 2013).

Doyle et al. (2016) analyzed a retrospective cohort study of 875 women undergoing planned OC at a single center in the United States between August 2009 and January 2015. This cohort was comprised of women undergoing medically indicated IVF, with cryopreservation due to unavailability of sperm, to limit the number of embryos created, or elective preservation for non-medically indicated fertility preservation. The mean age of the women undergoing planned OC was 34.9 years. One-hundred seventeen patients returned to use their preserved oocytes (13.4%). The live birth rate per transfer cycle was 38.6% (Doyle et al., 2016).

Cobo et al. (2018)[28] examined a multisite, retrospective cohort of 5,289 patients undergoing planned OC due to age-related fertility decline between January 2007 and May 2018 at multiple infertility clinics in Spain (the cohort also included 1,073 patients undergoing fertility preservation prior to cancer treatment; their outcomes are not reported here). The mean patient age at cryopreservation was 37.2 years. In this cohort, 641 (12.1%) women returned to retrieve their preserved oocytes after an average of 2.1 years, resulting in 115 live births; an additional 47 live births were seen among 159 patients undergoing transfer of surplus cryopreserved embryos. The authors analyzed the live birth rate based on patient age at cryopreservation, and found that cryopreservation at 35 years or younger resulted in a significantly higher cumulative live birth rate per patient (68.8%) compared with women undergoing cryopreservation after age 35 (25.5%) (Cobo et al., 2018)

Cobo et al. (2016)[28] also analyzed a group of 1,468 Spanish women undergoing elective OC from January 2007 to April 2015. The majority of the women (n=1,382; 94%) were undergoing cryopreservation because of age-related fertility decline; the remaining women were undergoing cryopreservation due to non-cancer medical reasons (e.g., endometriosis). Mean age at cryopreservation was 37.2 years. The majority of women undergoing planned OC due to age-related reasons did so between ages 37 and 39 years (63%), whereas women with a non-cancer medical condition started at a younger age (33.1% between ages 31 and 35 years and 29.6% between ages 36 and 39 years). In the overall cohort, 137 (9.3%) women returned to use their preserved oocytes after an average storage period of 2.1 years. Significantly more women who underwent planned OC due to non-cancer medical reasons returned to use their preserved oocytes (19.8% vs. 8.7%; $p<0.05$). In the overall cohort, the ongoing pregnancy rate (defined as pregnancy $\geq$12 weeks with fetal heart beat) per patient was 27.0%; the rate among women who preserved due to age was slightly less than the overall rate (21.6%) and significantly lower than the rate among women who preserved due to non-cancer medical reasons (64.7%; $p<0.05$). In the overall cohort, there were 31 live births, including three sets of twins; 24 of these births occurred in the age-related cohort and seven in the non-cancer cohort (Cobo et al., 2016).

Garcia-Velasco et al. (2013)[28] also analyzed a Spanish cohort including 560 non-oncologic patients undergoing planned OC between March 2007 and June 2012; the majority of these patients were undergoing cryopreservation due to age-related reasons (n=505; 90.2%). This study also included 475 oncological patients; their data is not reported here. The mean age of women undergoing planned OC was 36.7 years. Twenty-six patients who preserved oocytes due to non-oncologic reasons returned to retrieve their cryopreserved oocytes (4.6%) after an average storage time of 1.7 years. The ongoing pregnancy rate per patient was 33.3% after cryotransfer. Five healthy babies have been born (one from a cryotransfer) (Garcia-Velasco et al., 2013).

[28] Cobo (2018), Cobo (2016), and Garcia-Velsaco (2013) all report on cohorts of women from the same multisite settings in Spain over similar recruitment periods. However, the publications do not indicate that these are overlapping cohorts and as such, CHBRP has treated them as three separate publications with unique cohorts.

Professional societies have differed on the ethics of age-related OC. In 2013, the American Society of Reproductive Medicine (ARSM) and the Society of Assisted Reproductive Technology (SART) released guidelines around OC, and noted that planned OC "should not be recommended in order to bypass age-related infertility decline due to the absence of data supporting safety, efficacy, ethics, emotional risks, and cost-effectiveness of egg freezing for that indication" (ASRM, 2013). The American College of Obstetricians and Gynecologists (ACOG) adopted the ARSM-SART guideline in 2014 (ACOG, 2014a). In 2018, the ASRM Ethics Committee released an opinion on planned OC for future reproductive potential, stating that planned OC is an ethically permissible procedure that serves women's legitimate interest in reproductive autonomy; because this is a newer procedure, the benefits and harms are not fully understood and this should be discussed with women (ASRM, 2018).

Summary of findings regarding planned OC: There is a preponderance of evidence from four studies that planned OC results in pregnancy and live births. However, due to the lack of studies with relevant comparator groups (e.g., expectant management or fertility treatments without planned OC), there is insufficient evidence to assess whether planned OC is more effective than other infertility treatments at the time of desired fertility.

Figure 2. Effectiveness of Planned Oocyte Cryopreservation for Fertility Preservation

Harms of Infertility Treatment

CHBRP identified 17 studies (13 systematic reviews and four observational studies) that analyzed the potential harms and complications associated with IVF and planned OC. Maternal harms include the incidence of ovarian hyperstimulation syndrome, ectopic pregnancy, cardiovascular complications, post-pregnancy cancer, and complications stemming from the increased incidence of pregnancy with multiples associated with IVF. Harms affecting the offspring of infertility treatment include preterm birth, low birthweight, pediatric cancer, congenital malformations, developmental disorders, and infant death.

Maternal harms

Ovarian hyperstimulation syndrome

Ovarian hyperstimulation syndrome (OHSS) occurs when the ovaries are hyperstimulated and enlarged due to due fertility treatment. Clinical features of OHSS range be mild (e.g., abdominal distention, diarrhea), moderate (same symptoms as mild, along with abdominal fluid build-up visible on ultrasound), severe (e.g., severe abdominal pain, rapid weight gain, syncope) or critical (e.g., acute renal failure, sepsis, thromboembolism). An older systematic review (including literature published between 1990 and 2002) found that the incidence of moderate OHSS ranges from 3% to 6% and severe/critical OHSS ranges from 0.1% to 2%; the incidence of mild OHSS is higher, ranging from 20% to 33% of IVF cycles (Delvigne and Rozenberg, 2002).

Ectopic pregnancy

A 2015 cohort study including 553,577 pregnancies reported to the National ART Surveillance System (NASS) between 2001 and 2011 included 9,480 ectopic pregnancies in ART pregnancies; of those 485 were heterotopic, meaning both extra-uterine (ectopic) and intrauterine pregnancy occurred simultaneously. The rate of ectopic pregnancy was higher with fresh, nondonor cycles (2.0%; 95% CI, 1.9–2.0) than with fresh, donor cycles (1.0%; 95% CI, 0.9–1.1). The rate of ectopic pregnancy increased with the number of embryos transferred; 1.7% (95% CI, 1.7–1.8) for one embryo compared to 2.5% (95% CI, 2.1–2.3) with four embryos. The authors concluded that the national rate of ectopic pregnancy in ART, 1.7% for a single embryo transfer, was similar to the general population rate, 2.0% (Perkins et al., 2015).

Cardiovascular complications

Three studies have found that IVF is associated with an increased risk of pulmonary and venous thromboembolism during pregnancy, and that this risk is highest in the first trimester and in pregnancies with multiples. A large cross-sectional study of women undergoing IVF in Sweden (n=24,498) individually matched with women with spontaneous pregnancies (n=116,960) found that the risk of venous thromboembolism was higher among women undergoing IVF (4.2 per 1,000 women) compared with spontaneous conceptions (2.5 per 1,000 women) (hazard ratio [HR]=1.77; 95% CI, 1.41–2.23) (Henriksson et al., 2013).

The study also found that the risk was particularly high during the first trimester, with 1.5 per 1,000 women undergoing IVF experiencing thromboembolism compared with 0.3 per 1,000 women with spontaneous conceptions (HR=4.22; 95% CI, 2.46–7.26). Similarly, the rate of pulmonary embolism was higher among women undergoing IVF (3.0 per 10,000 women) compared with spontaneous conception (0.40 per 10,000 women) (HR=6.97; 95% CI 2.21–21.96) (Henriksson et al., 2013). A large cohort study, also conducted in Sweden (n=964,532 deliveries) also found that the incidence of first-trimester venous thromboembolism was higher among IVF pregnancies (1.67 per 1,000 women) compared to non-IVF pregnancies (0.17 per 1,000 women) (OR=9.8; 95% CI, 6.7–14.3) (Rova et al., 2012). A cohort study of women undergoing IVF in Denmark (n=18,787) compared the incidence of venous thrombosis after IVF versus the incidence in spontaneous pregnancies. The incidence rate ratio (IRR) of venous thrombosis was higher among during pregnancies among those undergoing IVF (2.2 per 1,000 women) compared to a reference population (IRR=3.0; 95% CI, 2.1–4.3). This study also found that the rate of venous thrombosis was higher among multiple pregnancies compared to the reference group (0.6 per 1,000 women; IRR=4.4 [95% CI, 2.4–8.3]), but was not significantly higher compared to singleton IVF pregnancies (Hansen et al., 2014).

In contrast to thromboembolism, a meta-analysis of six observational studies of women who received fertility treatment (n=41,190; not limited to IVF) compared with those who did not (n=1,400,202) found no difference in the risk of cardiac events among women receiving fertility treatment (Dayan et al., 2017).

Post-pregnancy cancer

A 2013 meta-analysis by Li et al included eight cohort studies (n=764,455) and found no significant association between IVF treatment and overall cancer risk. The meta-analysis did not identify any significant association between IVF and risk for breast, ovarian, or cervical cancer (Li et al., 2013). A 2015 meta-analysis of six cohort studies (n=776,224) compared the incidence of uterine cancer among patients receiving fertility treatment (defined as using IVF with or without ovulation-induction medications). This analysis found no significant difference in the incidence of uterine cancer among the fertility treatment group (0.14%; 150/103,758) and the non-fertility treatment group (2.22%; 14,918/672,466), reporting an odds ratio of 0.78 (95% CI, 0.39–1.57) (Saso et al., 2015).

Multiple gestation

As noted previously, use of infertility treatments is associated with increased risk of multiple births. In 2016, the CDC estimated that twins accounted for about 3% of all live births in the general population and almost 19% of live births among persons undergoing ART; similarly, triplets and higher-order multiples accounted for 0.1% of lives births in the general population as compared with 0.6% of live births from ART (Martin et al., 2018). Maternal medical complications are more common in multiple gestation pregnancies, including hyperemesis gravidarum (severe morning sickness), gestational hypertension, pre-eclampsia and gestational diabetes (Finlayson et al., 2016). Infant complications arising from multiple gestation include preterm birth, fetal growth restriction, congenital anomalies, and malformations (Mandy, 2019).

Offspring harms

Preterm birth

Four systematic reviews reported data on preterm births among women undergoing infertility treatment (Hoorsan et al., 2017; McGovern et al., 2004; Qin et al., 2016). The total number of studies included in each review ranged from 15 to 30. For instance, Qin et al. (2016) reported a preterm birth rate of RR=1.08 (95% CI, 1.02-1.13) among twins conceived via ART (N = 5,944) compared to twins spontaneously conceived (N = 12,742). Horrsan et al. (2017) reported a preterm labor odds ratio of 1.79 (95% CI, 1.21–2.63), among 5,470,181 infants (315,402 cases and 5,154,779 controls).

Low birthweight

Two systematic reviews reported higher rates of low birthweight in offspring of women treated for infertility (Hoorsan et al., 2017; Qin et al., 2016). Horrsan et al. (2017) reported an odds ratio of 1.89 (95% CI, 1.36–2.62) among 5,470,181 infants (315,402 cases and 5,154,779 controls). Another review included an assessment of nine studies focusing on twins conceived via ART versus twins conceived spontaneously (Qin et al., 2016). A risk ratio of 1.09 (95% CI, 1.03–1.16) was reported when comparing the likelihood of a twin being born with a low birthweight among the two groups (ART group: N = 4,297 and SC group: N = 7,808).

Pediatric Cancer

The associated risk of cancer among children conceived via infertility treatments is under investigation as some studies suggest the risk is higher, while others suggest the risks are lower. For example, Wang et al. (2018) reviewed 29 studies (N= 327,884) and found that approximately 578 children who were born post-fertility treatments were diagnosed with cancer. The overall risk was 1.16 (95% CI, 1.01-1.32) (Wang et al., 2018). Another review assessed 11 studies (N = 38,815) and observed a lower cancer incidence (n=47) than expected (n=38) (standardized incidence ratio [SIR]=1.23 [95% CI, 0.93-1.37]) (Raimondi et al., 2005).

Congenital Malformations

Several congenital malformations appear to have higher rates among children conceived with ART. Hoorsan et al. (2017) assessed the risk of cardiovascular abnormalities among children conceived via ART (IVF or other ART fertility treatment) verses spontaneous conception with a meta-analysis of 30 articles. As previously described, a total of 5,470,181 infants were assessed (315,402 cases and 5,154,779 controls). Children born via ART had a higher chance of being diagnosed with a cardiac abnormality compared to SC infants (OR=1.43 [95% CI, 1.27 to 1.62]). Additionally, ART infants had a

higher chance of being diagnosed with a central nervous system abnormality compared to SC infants (OR=1.36 [95% CI, 1.10–1.70]). This meta-analysis also reported urogenital system abnormalities (OR=1.58 (95% CI, 1.28–1.94) and musculoskeletal disorders (OR=1.35; 95% CI, 1.12–1.64) were more common, but chromosomal abnormalities were not significantly higher among ART infants.

Qin et al. (2016) reviewed 14 studies that reported data on congenital malformations. Twins conceived via ART (N = 6,068) were more likely to be diagnosed with a malformation than twins conceived spontaneously (N = 13,220) (OR=1.26; 95% CI, 1.09–1.46;). Additionally, another review identified a similar finding across 46 studies (OR=1.37; 95% CI: 1.26–1.48) (Wen et al., 2012).

Cerebral palsy, autism spectrum disorder, and developmental delay

One systematic review reported data on cerebral palsy, autism spectrum disorder, and developmental delay. Hvidtjørn et al. (2009) conducted a meta-analysis among nine studies (N = 19,462) and observed children conceived with IVF were more likely to be diagnosed with cerebral palsy due to preterm delivery compared to those conceived spontaneously (OR=2.18 [95%CI, 1.71-2.77]). Among studies on autism spectrum disorder and 30 studies on developmental delay, they found inconsistent results (Hvidtjorn et al., 2009).

Infant death

One systematic review (Qin et al., 2016) observed perinatal mortality among 10 studies (ART group: N = 4,564; spontaneous conception group: N = 8,178) and determined the rate to be higher for twins conceived via ART compared to twins conceived spontaneously (RR=1.60 [95% CI, 1.20–2.13]; p-value: 0.01).

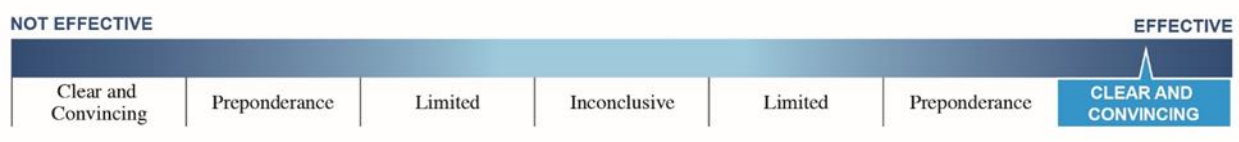
Childhood weight

Guo et al. (2017) examined body mass index among children born post-IVF treatment and found that they had a comparable BMI to spontaneously conceived children (-0.04 kg/m2; 95% CI, -0.28, 0.20) (Guo et al., 2017).

Summary of findings regarding the harms associated with infertility treatment: There is a preponderance of evidence that IVF is associated with certain maternal harms, including ovarian hyperstimulation syndrome and thromboembolism. There is also clear and convincing evidence that IVF is related to multiple gestation and preterm delivery, and associated harms. However, it is important to note that multiple gestation is associated with higher numbers of embryos transferred per cycle, and that preterm delivery is associated with multiple gestation. These outcomes can be mitigated by increases in single embryo transfers.

Figure 3. Maternal Harms of IVF and Planned Oocyte Cryopreservation

Figure 4. Harms of IVF and Planned Oocyte Cryopreservation due to Multiple Gestation and Preterm Delivery



Impact of Infertility Treatment Health Insurance Mandates including IVF Coverage

Bitler and Schmidt (2006, 2012) examined the impact of state-level insurance mandates for infertility coverage on the utilization of infertility treatments using pooled data from the 1982, 1988, 1995 and 2002 NSFG surveys. Their 2006 analysis found no evidence that state-level mandates impact utilization of infertility treatments for the overall population of women aged 15–44, or for examined subgroups (college-educated women, older women, white women). The only significant finding was an interaction between the presence of a state-level mandate, high education, and age 30 years or greater (marginal effect, 4.6 percentage points); the authors posit that expanding infertility treatment access may differentially impact highly educated older women (Bitler and Schmidt, 2006).

The 2012 study also found that any significant impact of state-level mandates on infertility treatment utilization was limited to highly educated older women (4.1 percentage point increase in probability of using infertility treatment), and that the effects of infertility insurance mandates was only significant for use of ovulation-inducing drugs (32% increase in use compared to baseline [without a mandate]) (Bitler and Schmidt, 2012). For IVF, the presence of a mandate resulted in a 0.4% decrease in utilization compared to baseline. The authors compared utilization in states with "mandates to cover" versus "mandates to offer" and found that both mandate types had similar effects on utilization of infertility treatments (Bitler and Schmidt, 2012).

Impact on IVF utilization

In the 2013 analysis of AB 460, CHBRP concluded that results from six studies (Banks et al., 2010; Henne and Bundorf, 2008; Jain et al., 2002; Martin et al., 2011; Navarro et al., 2008; Reynolds et al., 2003) were consistent in their findings that clinics in states with infertility treatment insurance mandates had an increase in the number of IVF cycles, lower numbers of embryos transferred per cycle, lower pregnancy rates and fewer births per cycle compared to states without mandates. This effect of infertility insurance may be specific to the type of treatment (IVF) where insurance coverage reduces financial pressure to achieve a pregnancy in the minimal number of IVF cycles, thus decreasing the pressure to transfer more embryos per cycle, which in turn reduces birth rates and multiple birth rates (Martin et al., 2011).

CHBRP identified three studies published since the AB 460 review examining the impact of state mandates including IVF treatment on IVF utilization (Boulet et al., 2015; Crawford et al., 2016; Dieke et al., 2018). With the exception of Crawford (2016), these studies were consistent in their findings that states with infertility treatment insurance mandates covering IVF had lower numbers of embryos transferred per cycle, more single embryo transfers, fewer cycles with $\geq$3 embryos transferred and less use of ICSI.

Dieke (2018) analyzed 2000–2015 data from the National ART Surveillance System (NASS), comparing states with an infertility mandate to cover IVF (n=8; AR, CT, HI, IL, MA, MD, NJ and RI) versus those that do not have a mandate, with an emphasis on the use of ICSI in mandate versus nonmandate states. This analysis found that IVF cycles in mandated states were more likely to involve <10 oocytes retrieved

(p<0.05) and more likely to be single embryo transfers (29.3% in mandate states vs. 22.3%; p<0.05). ICSI use was more common in nonmandate states than states with mandates (79.4% vs. 70.8%; p<0.05). For cycles without male-factor infertility, the increase in ICSI use was greater among nonmandate states (34.6% in 2000 to 73.9% in 2015) versus mandated states (39.5% to 63.5%); the percentage increase was approximately 7% for male-factor infertility in both mandate and nonmandate states.

Crawford (2016) analyzed 1996-2013 NASS data comparing IVF utilization premandate and postmandate implementation in two states (Connecticut and New Jersey) compared to four states without a mandate (Maine, New Hampshire, Pennsylvania, and Vermont). The New Jersey mandate was enacted in 2001, and Connecticut in 2005; the study generated a two-year pre- and post-implementation period for each state and compared IVF utilization between each state and the nonmandate states. This study found that IVF use in the mandated states was greater in the post-implementation period than in the nonmandate states. After mandate implementation in both New Jersey and Connecticut, there was a significant increase in the number of IVF cycles per 1,000 females aged 15-44 compared with the nonmandate states (interaction p<0.001). This analysis found that changes in IVF practice (ICSI use, mean number of embryos transferred, transfers of ≥2 embryos) across mandate periods were not significantly different for the states with mandates compared to those without. The authors posit that these IVF practice changes suggest changes in care patterns across the ART community, versus changes attributable only to the mandate.

Boulet (2015) linked 2007-2009 NASS data with vital records from Massachusetts (which has an infertility mandate including IVF), Michigan and Florida (neither of which had a mandate). This study found that more deliveries conceived by IVF occurred in the mandate state versus nonmandate states (2.9% of all deliveries vs. 0.8%). The analysis found lower average numbers of embryos transferred per cycle in the mandate state versus nonmandate states (mean, 2.2 versus 2.4; p<0.001), more elective single embryo transfers (8.6% of all transfers in the mandate state vs. 2.5%; p<0.001), fewer cycles involving ≥3 embryos transferred (23.1% vs. 33.6%; p<0.001), and a higher percentage of transfers resulting in a term, normal birthweight singleton (64.6% vs. 56.3%; p<0.001). The analysis also found less use of ICSI in mandate states versus nonmandate states (39.2% vs. 64.1%).

Interaction of Health Insurance Mandates for IVF and Age

CHBRP identified three studies examining the interaction of health insurance mandates covering IVF and age; two were discussed in AB 460 (Banks et al., 2010; Martin et al., 2011) and one study was identified as part of this review (Boulet et al., 2015). Banks (2010) found that although there was a consistent relationship between mandates and number of embryos transferred across all age groups, the impact of mandates on the number of births per transfer was only seen among the youngest (<35 years; p=0.01) and oldest (41-42 years; p=0.02) age groups (Banks et al., 2010). Martin (2011) found that younger age groups (<35 years) in mandate states were significantly more likely to have fewer embryos transferred compared to older age groups (Martin et al., 2011).

Boulet (2015) found that women younger than 35 years living in a nonmandate state were more likely to transfer ≥3 embryos per cycle compared to those living in a mandate state (adjusted RR 4.18 [95% CI, 2.74-6.36]), and correspondingly, deliveries resulting from the transfer of ≥3 embryos in the nonmandate state were higher (26.9% vs. 7.0% in mandate states). Women 35 years and older living in a mandate state were also more likely to transfer ≥3 embryos than those living in nonmandate states (RR, 1.46 [95% CI, 1.17-1.81]), but the difference in proportion of live births resulting from these transfers between mandate vs. nonmandate states was less pronounced (33.6% vs. 39.7% in nonmandate states) (Boulet et al., 2015).

Impact on IVF-Related Birth Outcomes

In the 2013 analysis of AB 460, CHBRP concluded that results from four studies were consistent in their findings that states with infertility treatment insurance mandates covering IVF had lower pregnancy rates, fewer births per cycle, lower rates of multiple births, and fewer adverse birth outcomes compared to states without mandates (Henne and Bundorf, 2008; Jain et al., 2002; Martin et al., 2011; Navarro et al., 2008).

CHBRP identified two studies published since the AB 460 review examining the impact of state mandates including IVF treatment on birth outcomes (Boulet et al., 2015; Crawford et al., 2016); these studies also found that IVF in states without mandates were more likely to result in more live births, multiple births, preterm deliveries and low-birthweight births.

Crawford (2016) found that there was no significant difference between Connecticut (mandate state) and the nonmandate states between premandate and postmandate implementation in the percentage of transfers resulting in live births, multiple births, preterm births or low-birthweight births. Compared with New Jersey (mandate state), the nonmandate states saw significantly larger increases in percentage of transfers resulting in live births (interaction p=0.049) as well as multiple births (interaction p=0.005) likely due to the higher (but not significantly different) rates of transfers involving >2 embryos in the nonmandate states; changes in preterm and low-birthweight births were not significant.

Boulet (2015) found that, compared to mandated states, IVF deliveries in nonmandate states were more likely to be twins (adjusted RR, 1.2 [95% CI, 1.12-1.29]) or higher order multiples (adjusted RR, 2.4 [95% CI, 1.81–3.28]), and were more likely to result in preterm deliveries (adjusted RR, 1.3 [95% CI, 1.20–1.42] or low-birthweight births (adjusted RR, 1.3 [95% CI, 1.17–1.40].

As mentioned previously, Martin and colleagues (2011) note that insurance coverage for IVF may reduce the financial pressure to achieve a pregnancy in the minimal number of IVF cycles, thus decreasing the pressure to transfer more embryos per cycle, which in turn reduces birth rates and multiple birth rates. Multiple births are considered an adverse outcome of IVF, leading to more complications and worse health outcomes, such as preterm birth or low birthweight.

Summary of findings regarding the impact of health insurance mandates including IVF coverage on utilization and related birth outcomes: There is a *preponderance of evidence* that infertility treatment health insurance mandates are associated with an increase in utilization of infertility treatments in general, as well as a preponderance of evidence that IVF insurance mandates are associated with a decrease in the number of embryos transferred per IVF cycle and a decrease in the proportion of cycles transferring ≥2 embryos, and that these decreases are more pronounced among younger women. There is also a preponderance of evidence that IVF mandates are associated with lower pregnancy rates (due to a decrease in embryos transferred), and a lower likelihood of other adverse birth outcomes, including rates of multiple births.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, AB 767 would require DMHC-regulated group health plans and CDI-regulated group policies to provide coverage for infertility treatments, including in vitro fertilization (IVF), and mature oocyte cryopreservation (OC). Individual plans and Medi-Cal are excluded from AB 767.

This section reports the potential incremental impacts of AB 767 on estimated baseline benefit coverage, utilization, and overall cost.

Approach and Assumptions

CHBRP's overarching approach to the cost analysis of AB 767 and accompanying key assumptions are described below.

Infertility Services

- CHBRP examined 2016 MarketScan® database and Milliman's proprietary 2016 Consolidated Health Cost Guidelines™ Sources Database (CHSD) for infertility services among enrollees with an infertility diagnosis in California as well as New Jersey, a state where an infertility mandate is already in place. Using estimates from the peer-reviewed literature on differences in utilization rates for infertility services in states with infertility coverage mandates in place versus those without coverage mandates, CHBRP estimated baseline utilization rates for enrollees in California in 2020.[29] New Jersey utilization rates were used to model postmandate utilization for California.[30] More detail on this is included in Appendix C.

- The claims data for diagnostic and treatment services for females aged 15–44 years with infertility diagnoses were categorized into the following broad groups for female enrollees:
  - Diagnostic Services
  - Medications (i.e., infertility treatment using only medication)
  - IUI
  - IVF
  - ICSI
  - As explained in the *Policy Context* section, GIFT and ZIFT were not included in this analysis.

- The claims data for male enrollees aged 18–60 years were grouped as the following:
  - Diagnostic Services
  - Treatment

- Postmandate utilization rates and distribution of services (e.g., percent receiving medication, IUI, IVF, ICSI) is assumed to shift in proportion to that observed in New Jersey plus an additional increase due to pent-up demand for these services. Pent-up demand is assumed to occur given the financial burden currently cited by couples hoping to use infertility services but are unable to

[29] Per content expert input, infertility diagnoses in claims data are reflective of the inability to become pregnant after 12 months or more of regular unprotected intercourse without conceiving, at which point a diagnostic evaluation is indicated, as defined by the American Society of Reproductive Medicine. Milliman's 2016 Consolidated Health Cost Guidelines (CHSD) were also used in the analysis of utilization.

[30] As discussed in Medical Effectiveness, utilization of infertility services is higher in states where an infertility mandate is in place compared to states without a mandate (Boulet et al., 2019; Crawford et al., 2016; Dieke et al., 2018).

because of cost barriers. It is assumed that utilization in the first and second year would be 10% greater than the NJ utilization rates as awareness around the infertility mandate would increase. Per literature on mandates in other states and internationally (Chambers et al., 2014), pent-up demand for infertility services dissipates over time and utilization reaches a steady state after a few years postmandate (Machado and Sanz-de-Galdeano, 2015).

- With CHBRP's content expert input, CHBRP assumes there is an acceptable number of infertility service providers and facilities in California to accommodate the increase in utilization of services postmandate as described above, thus CHBRP assumes no supply-side deficiencies that would hinder utilization increases.[31]

Planned Oocyte Cryopreservation

- AB 767 includes the coverage of mature OC; as described in the *Policy Context* section, CHBRP examines this as specifically mature OC for planned OC, as opposed to OC for iatrogenic infertility. No utilization data are available for planned OC in MarketScan claims data. There are no studies that estimate utilization of OC for non-iatrogenic or planned use, thus the approach to CHBRP's estimation of utilization change postmandate due to AB 767's coverage of mature OC included an estimate of potential increase in utilization per CHBRP's content expert. Table 1 estimates of utilization change do not include planned fertility preservation, however CHBRP offers an estimate of potential cost increase if a modest proportion of females of reproductive age opt to use the service in the *Baseline and Utilization* subsection below.

Pregnancy and Related Outcomes

- Rates of pregnancies, percent resulting in live birth, percent resulting in single birth, percent resulting in twin birth and percent resulting in higher order multiples as a result of the use of infertility services for the broad categories of IVF, IUI, medications, were obtained from the peer reviewed literature. The *Medical Effectiveness* section provides details on the pregnancy outcomes related to IVF. For the non-IVF infertility services, additional literature was sourced to obtain these estimates (Diamond et al., 2015; Hill et al., 2013; van der Poel et al., 2010).

- To capture the full cost of coverage of infertility services for each year, CHBRP included the cost of pregnancies and births resulting from infertility services in year 1 into year 1 cost estimates. Similarly, for the infertility services used in year 2, costs from resulting pregnancies and births are included in year 2 estimates.

- Literature based estimates of cost per pregnancy and live birth for singleton, twin, and multiple births take into account additional neonatal care costs associated with each type of birthweight, such as use of neonatal intensive care unit (NICU) services (Lemos et al., 2013).

[31] In 2015, there were 65 infertility clinics in California with 7,802 live birth deliveries; assisted reproductive technology procedures per 1 million women aged 15-44 years in California = 2,869. There are recent reports regarding California's role as a leading destination for infertility tourism and many clinics in the state handle a high volume of patients each year (Dunn J. How California became the world's fertility treatment destination. Vogue. March 13, 2019. Available at: https://www.vogue.com/article/california-worlds-fertility-treatment-destination).

Benefit Coverage and Unit Cost

- Infertility service coverage provided by carriers with regards to cost-sharing, number of cycles covered, and other limits to treatment at baseline is assumed to stay the same postmandate since AB 767 does not place limitations on how infertility services is to be covered by carriers.[32]

- Unit cost estimates are from 2016 MarketScan and 2016 CHSD for California. Medical costs are trended at an annual rate of 2% per the medical component of the Consumer Price Index and pharmacy costs are trended at an annual rate of 7.5% per Milliman's Health Cost Guidelines.

For further details on the underlying data sources and methods used in this analysis, please see Appendix C.

Baseline and Postmandate Benefit Coverage

Currently, 4.3% of enrollees with health insurance that would be subject to AB 767 in DMHC-regulated group plans or CDI-regulated group policies have coverage for infertility treatments, including IVF (see Table 1). All enrollees have coverage for female surgical treatments under major medical coverage so surgical treatments were not modeled in this analysis. No enrollees currently have coverage for mature OC as defined by AB 767. AB 767 does not apply to individual market or Medi-Cal enrollees.

Current coverage of infertility treatments and mature OC was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 68% of enrollees with private market health insurance that can be subject to state mandates.

Benefit coverage for relevant infertility services among enrollees in DMHC-regulated plans or CDI-regulated policies would increase to 100% based on the CHBRP assumption that all noncompliant plans and policies at baseline would become compliant postmandate.

Plans vary with regards to how infertility services are covered, such as imposing cost-sharing, age restrictions, restrictions on number of treatment cycles, or a cap on the dollar amount covered for services. Based on responses to the carrier survey, a portion of enrollees who currently have coverage for infertility services have cost sharing for infertility services that is the same as major medical services. For enrollees who have infertility coverage but do not have the same cost share as major medical services, CHBRP found in its carrier survey that coverage includes a 50% co-insurance for these services, including IVF, without an out of pocket maximum. Because the bill does not specify any limits on enrollee cost-sharing, for example specifying that fertility related out of pocket expenses not exceed a certain amount as for all other conditions, CHBRP assumes postmandate carriers would cover infertility services with the same restrictions in baseline.[33] CHBRP assumed the baseline percentage of enrollees with infertility coverage the same as major medical services would remain unchanged postmandate.

Enrollee cost sharing for pregnancies and births as a result of infertility services were assumed to have coverage the same as major medical services in the baseline and postmandate scenarios.

[32] AB 767 does not mandate the same copayments, deductibles, and limits are applied to infertility benefits as to other medical or surgical benefits. A separate copayment, coinsurance, deductible, dollar maximum, visit maximum or procedure maximum can thus be imposed on any infertility treatment as can limiting infertility coverage to a certain number of egg retrievals per lifetime for the covered person.
[33] Ibid

Baseline and Postmandate Utilization

CHBRP examined claims data for baseline estimates of utilization of infertility services among enrollees in California. There are approximately 53,000 users of female diagnostic tests at baseline and 14,000 users of medications for infertility (i.e., only medications and no other service). IUI baseline utilization is about 9,000 users annually. IVF services alone (i.e. without ICSI) is estimated to have about 2,000 users and ICSI, which is done with IVF, is about 2,000 users annually. For males, at baseline there are 25,000 users of diagnostic tests and 11,000 users of any male treatment. At baseline there are an estimated 7,000 pregnancies due to the use of infertility services and 6,000 live births from these pregnancies.

To estimate the degree to which utilization of infertility services might shift postmandate, CHBRP examined the literature to obtain estimates of utilization change in states where infertility mandates have already been implemented. As described in the *Medical Effectiveness* section, studies have noted significant increase in utilization of IVF in mandate states compared to nonmandate states, having used National ART Surveillance System (NASS) data to examine increase in IVF cycles (Boulet et al., 2019; Crawford et al., 2016; Dieke et al., 2018). However, these studies are limited to IVF treatment and do not include an examination of the change in other infertility services, such as diagnostic tests and IUI. Thus, CHBRP obtained utilization data on all infertility services from MarketScan for a state with an existing mandate to be able to obtain estimates of potential postmandate change for all infertility services as categorized above.

To identify the most appropriate mandate state to use in this analysis, CHBRP examined infertility legislation from the states whereby the state mandates included all types of infertility services (including explicit mention of ICSI), no specific cap on the dollar amount covered, and no cap on the number of cycles to determine which other states had mandates most close to the bill language laid out in AB 767. See Table in Appendix C for the full list of states with infertility mandates to cover IVF and limits placed by those mandates. Massachusetts and New Jersey were the two states identified in this process. While Delaware's infertility mandate is also flagged as similar to that of California's, it was enacted in 2018 and CHBRP's claims data are for 2016, therefore postmandate utilization could not be estimated with data from Delaware. CHBRP determined New Jersey's infertility mandate limits on age and egg retrievals are likely to be close to the types of limits carriers may issue if AB 767 were to pass since the bill does not specify any restrictions to placing such limits. Thus, claims data from New Jersey were used to generate utilization rates and these rates were applied to the California enrollee population to estimate postmandate utilization in California.

An additional increase due to pent-up demand for these services was considered. Pent-up demand is assumed to occur given the financial burden currently cited by couples hoping to use infertility services but are unable to because of cost barriers (Eisenberg et al., 2010). It is assumed that utilization in the first and second year would be 10% greater than the NJ utilization rates. Pent-up demand for infertility services likely dissipates over time and utilization reaches a steady state after a few years postmandate (Chambers et al., 2014; Machado and Sanz-de-Galdeano, 2015).

CHBRP did not find any source of data on baseline utilization for planned OC or likely changes postmandate. CHBRP estimates[34] that if 2% of women aged 25–37 years used planned OC services, the total expenditures would increase by $319,683,000 (premium increases for private employers for group insurance increase 0.79% and CalPERS HMO 0.82%). If a higher share of women aged 25–37 used planned OC (5%), total expenditures would increase by $799,197,000 (premium increases for private employers for group insurance increase 1.24% and CalPERS HMO 1.31%). This assumes the average cost for OC is $10,078.

[34] A utilization range of 2% to 5% was discussed and agreed upon between CHBRP and the content expert.

Baseline and Postmandate Per-Unit Cost

CHBRP estimated unit cost of infertility services for females and males using 2016 MarketScan and 2016 CHSD data (Table 1) for commercial lines of business in the state of California. Diagnostic services were estimated as an average cost per person receiving one or more diagnostic services. Male treatment cost per person was calculated similarly. Female infertility service costs were determined by assigning each woman with an infertility diagnosis to one of the four treatment categories (ICSI, IVF, IUI or medication only) or the no treatment category. All relevant costs associated with treatment for the calendar year were included in the average cost per user calculation. Mature OC was calculated as a case rate assuming 95% of women had a single cycle and 5% of women had 2 cycles. For additional detail regarding the specific services included in each of the rates, please see Appendix C.

CHBRP assumed literature based estimates of cost per pregnancy and live birth for singleton, twin, and multiple births that take into account additional neonatal care costs associated with each type of birthweight, such as use of neonatal intensive care unit (NICU) services (Lemos et al., 2013). The per unit cost of pregnancies that do not result in a live birth was developed from the 2019 Milliman Health Cost Guidelines and includes inpatient services for complications and pregnancies that do not result in a delivery due to miscarriage or abortion, maternity professional and maternity anesthesia charges. All medical services were trended to 2020 using 2% medical trend and 7.5% pharmacy trend.

CHBRP considered changes in per unit cost for infertility treatments. A recent study using claims data from 2011 examined the magnitude by which infertility treatment expenditures incurred by health carriers is higher in states with infertility mandates compared to states without mandates (Boulet et al., 2019). Authors found that infertility treatment – IUI, medications, and IVF – expenditures per enrollee were higher for women living in states with an infertility mandate compared to women in nonmandate states. Per correspondence with the author of the study, it is unclear if any unit cost change in the services might have occurred postmandate. Increases in expenditures by may be driven by increased number of infertility treatment visits and additional services for women in mandate states. Per CHBRP's content expert, it is unlikely that unit cost of infertility services would change in the short term postmandate (e.g. year 1 or year 2) and unclear how costs might change over the longer term. Thus, CHBRP estimates no unit cost change to infertility services in year 1 or 2 postmandate.

Baseline and Postmandate Expenditures

Table 5 and Table 6 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses). AB 767 would increase total net annual expenditures by $627,288,000 or 0.39% for enrollees with DMHC-regulated plans and CDI-regulated policies. This includes estimates for infertility services and associated pregnancies. It does not include additional expenditures as a result of fertility preservation services.

Premiums

Overall, premiums increase $537,778,000 postmandate as a result of AB 767. Changes in premiums would vary by market segment (see Table 5 and Table 6), with health insurance that would be subject to AB 767. The largest increases are among small group plans in both DMHC-regulated plans (0.68%) and CDI-regulated policies (0.53%). Among publicly funded DMHC-regulated CalPERS HMOs, the premium increase is 0.47%.

Enrollee Expenses

AB 767-related changes in enrollee expenses for covered benefits (deductibles, copays, etc.) and enrollee expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 5 and Table 6) with health insurance that would be subject to AB 767 expected to use infertility services during the year after enactment. CHBRP projects no change to copayments or coinsurance rates at baseline vs postmandate as AB 767 does not specify any limitations to how plans can apply coinsurance to infertility services. Because the increase in utilization of infertility services there would be an increase in enrollee cost sharing. The largest increases are for the small group plans for both DMHC-regulated and CDI-regulated plans and policies.

Out-of-Pocket Spending for Covered and Noncovered Expenses

CHBRP estimates the marginal impact of the bill on out-of-pocket spending for covered and noncovered expenses, defined as uncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (e.g., deductibles, copayments, and coinsurance). CHBRP estimates that enrollees with uncovered expenses at baseline would receive on the whole a $133,897,000 reduction in their out-of-pocket spending for covered and noncovered expenses associated with AB 767's coverage of infertility services (Table 1).

Potential Cost Offsets or Savings in the First 12 Months After Enactment

If infertility services are covered and the financial pressure of trying to have a child with the fewest number of cycles is alleviated, infertility mandates can have the effect of encouraging patients to use a greater number of single embryo transfers. As discussed in the *Medical Effectiveness* section, the peer reviewed literature suggests that while infertility mandates increase the utilization of infertility treatments overall, thus increasing the potential for multiple births associated with infertility treatments, this potential for more costly multiple births is actually offset by a decline in the use of multiple embryo transfers (and increase in single embryo transfers) as seen in states with infertility mandates (Banks et al., 2010; Boulet et al., 2019; Crawford et al., 2016; Dieke et al., 2018; Henne and Bundorf, 2008; Jain et al., 2002; Martin et al., 2011; Navarro et al., 2008; Reynolds et al., 2003). This suggests that while states with infertility treatment insurance mandates have an increase in the number of IVF cycles, there is an offset associated with the reduction in financial pressure to achieve a pregnancy in the minimal number of IVF cycles, thus decreasing the pressure to transfer more embryos per cycle, which thus reduces birth rates and multiple birth rates (Martin et al., 2011). The cost model is not able to directly calculate the potential cost savings stemming from fewer multiple births or fewer preterm deliveries. Note that in comparing pregnancy and birth outcomes (namely, percent twin and percent multiple births) at baseline from 2016 National ART Surveillance System data in California versus New Jersey, there are only small differences in the twin and multiple birth rates: in California, 41.2% of all IVF procedures result in pregnancy, 67.5% of which result in live birth, 12.4% are twin live birth, and 1.6% are multiple births. In New Jersey (mandate state), 41.7% of all IVF procedures result in pregnancy, 69.2% of which result in live birth, 11.4% are twin live birth, and 1.2% are higher multiple births.

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies would remain proportional to the increase in premiums. 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 portion of

premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

Potential Cost of Exceeding Essential Health Benefits

As explained in the *Policy Context* section, infertility services required to be covered by AB 767 are not included in California's EHB package. The state is required to defray the additional cost incurred by enrollees in qualified health plans (QHPs) for any state benefit mandate that exceeds the state's definition of essential health benefits (EHBs). Coverage for infertility services, as would be required if AB 767 were enacted, could trigger this requirement for the state to defray related costs.

CHBRP has considered means of projecting the potential cost to the state of enacting a benefit mandate that would exceed EHBs. As federal regulations are not yet final, CHBRP presents several scenarios regarding the cost to the state, should AB 767 be judged to exceed EHBs. Impacts would vary by market segment (and by market segment enrollment) (Table 4).

Table 4. Estimated State Responsibility for Portion of Mandate that Is in Excess of EHBs, California, 2020

	DMHC-Regulated		CDI-Regulated		
	Small Group	Individual	Small Group	Individual	TOTAL
Enrollee counts					
Total enrollees in plans/policies subject to state mandates	3,099,000	--	108,000	--	3,207,000
Number of enrollees in QHPs(a)	658,000	--	12,000	--	670,000
Premium cost of mandated benefit					
Estimated premium cost of mandated benefit (b)	$6.43	--	$7.10	--	$6.45
Marginal premium impact with offsets (c)	$6.43	--	$7.10	--	$6.45
Marginal premium impact considering baseline coverage (d)	$3.78	--	$3.53	--	$3.77
Estimated annual state responsibility for portion of mandate that is in excess of EHB					
Scenario 1 - Full estimated cost (e) = (a) x (b) x 12	$50,801,000	--	$1,023,000	--	$51,823,000
Scenario 2 - With cost offsets (f) = (a) x (c) x 12	$50,801,000	--	$1,023,000	--	$51,823,000
Scenario 3 - With baseline coverage offset (g) = (a) x (d) x 12	$29,830,000	--	$509,000	--	**$30,339,000**

Source: California Health Benefits Review Program, 2019.
Notes: (a) States are required to defray the costs of state-mandated benefits that are in excess of the EHB for QHPs. QHPs are a subset of the plans offered in the individual and small group markets. AB 767 only applies to small-group QHPs.
(b) Estimated full cost of the mandated benefit without offsets for reduction in costs for related benefits that are EHBs.

(c) Estimated marginal premium impact considering some of the increase in costs associated with a given benefit mandate may be offset by reductions in costs for related benefits that are EHBs.
(d) Estimated marginal premium impact of the proposed mandated benefit considering some QHPs may already cover the mandated benefit. It is yet to be determined whether the State is responsible for defraying the full cost of the mandated benefit in this circumstance.
Key: CDI=California Department of Insurance; DMHC=Department of Managed Health Care

Postmandate Changes in the Number of Uninsured Persons[35]

Because the change in average premiums does not exceed 1% for any market segment (Table 1, Table 5, and Table 6) for coverage of infertility treatments, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 767.

However, should 5% of female enrollees aged 25–37 use mature OC services as a form of fertility preservation, premiums would increase by more than 1% for enrollees in group and CalPERS HMO plans (premium increases for private employers for group insurance increase 1.24% and CalPERS HMO 1.31%). It is unclear how the increase in premiums translates into uninsurance since not all of the increase is transferred to the enrollee.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of AB 767.

How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

IVF generally is self-funded when there is no coverage and there may be some opportunity for enrollees without coverage to seek help via grant or loan programs through private organizations. There are no state-funded programs providing direct financial assistance to enrollees in California. In California, unreimbursed medical expenses are income tax deductible, following the federal deductibility threshold. CHBRP is unable to provide a quantifiable estimate of shifts from private grant and loan funding to health plans and programs postmandate.

[35] See also CHBRP's *Uninsured: Criteria and Methods for Estimating the Impact of Mandates on the Number of Individuals Who Become Uninsured in Response to Premium Increases (December 2015)*, available at http://chbrp.com/analysis_methodology/cost_impact_analysis.php.

Table 5. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2020

	DMHC-Regulated						CDI-Regulated			
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)*	*MCMC (65+) (c)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	10,565,000	3,099,000	2,184,000	523,000	6,796,000	795,000	318,000	108,000	102,000	24,490,000
Total enrollees in plans/policies subject to AB 767	10,565,000	3,099,000	0	523,000	0	0	318,000	108,000	0	16,899,000
Premiums										
Average portion of premium paid by employer	$555.35	$341.99	$0.00	$493.71	$268.13	$694.55	$710.92	$462.84	$0.00	$118,029,198,000
Average portion of premium paid by employee	$39.66	$205.44	$437.39	$94.04	$0.00	$0.00	$250.37	$202.64	$475.67	$26,521,718,000
Total premium	**$595.01**	**$547.43**	**$437.39**	**$587.76**	**$268.13**	**$694.55**	**$961.29**	**$665.48**	**$475.67**	**$144,550,916,000**
Enrollee expenses										
For covered benefits (deductibles, copays, etc.)	$46.18	$121.03	$115.38	$48.33	$0.00	$0.00	$162.44	$186.84	$168.51	$14,750,880,000
For noncovered benefits (e)	$0.61	$1.31	$0.00	$0.47	$0.00	$0.00	$0.98	$1.24	$0.00	$133,897,000
Total expenditures	**$641.80**	**$669.77**	**$552.77**	**$636.55**	**$268.13**	**$694.55**	**$1,124.71**	**$853.56**	**$644.18**	**$159,435,692,000**

Source: California Health Benefits Review Program, 2019.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.[36]

(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 would be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

[36] For more detail, see *Estimates of Sources of Health Insurance in California*, available at http://chbrp.com/analysis_methodology/cost_impact_analysis.php.

Table 6. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2020

	DMHC-Regulated						CDI-Regulated			
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)*	*MCMC (65+) (c)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	10,565,000	3,099,000	2,184,000	523,000	6,796,000	795,000	318,000	108,000	102,000	24,490,000
Total enrollees in plans/policies subject to AB 767	10,565,000	3,099,000	2,184,000	523,000	0	0	318,000	108,000	0	14,613,000
Premiums										
Average portion of premium paid by employer	$2.6831	$2.3264	$0.00	$2.3166	$0.00	$0.00	$2.5089	$2.4591	$0.00	$453,977,000
Average portion of premium paid by employee	$0.1916	$1.3976	$0.000	$0.4413	$0.00	$0.00	$0.8836	$1.0766	$0.00	$83,801,000
Total premium	$2.8747	$3.7240	$0.00	$2.7578	$0.00	$0.00	$3.3925	$3.5357	$0.00	**$537,778,000**
Enrollee expenses										
For covered benefits (deductibles, copays, etc.)	$1.0990	$1.8821	$0.00	$1.0896	$0.00	$0.00	$1.2635	$1.8763	$0.00	$223,409,000
For noncovered benefits (e)	-$0.6071	-$1.3082	$0.00	-$0.4650	$0.00	$0.00	-$0.9816	-$1.2411	$0.00	-$133,897,000
Total expenditures	$3.3665	$4.2979	$0.00	$3.3824	$0.00	$0.00	$3.6744	$4.1710	$0.00	**$627,290,000**
Percent change										
Premiums	0.4831%	0.6803%	0 %	0.4692%	0 %	0 %	0.3529%	0.5313%	0%	0.3720%
Total expenditures	0.5245%	0.6417%	0 %	0.5314%	0 %	0 %	0.3267%	0.4887%	0%	0.3934%

Source: California Health Benefits Review Program, 2019.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.[37]

(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 would be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

[37] For more detail, see *Estimates of Sources of Health Insurance in California*, available at http://chbrp.com/analysis_methodology/cost_impact_analysis.php.

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, AB 767 would modify the current infertility mandate, which requires health plans and policies to *offer* coverage for infertility services, excluding in vitro fertilization (IVF) coverage. In contrast, AB 767 would require group health plans and policies, excluding the individual market and Medi-Cal, to *provide* coverage for infertility treatments, including IVF, and mature oocyte cryopreservation (planned oocyte preservation).

The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate). This section estimates the short-term impact[38] of AB 767 on infertility treatment-relevant public health impacts (i.e., fertility outcomes, mental health outcomes, and quality of life), potential harms of treatment use, and potential impacts on disparities with respect to treatment use and outcomes. See *Long-Term Impacts* for a discussion of public health impacts regarding planned oocyte cryopreservation (OC), premature death, and economic loss.

Estimated Public Health Outcomes

Measurable public health outcomes relevant to AB 767 include mental health and quality of life, multiple gestation outcomes, and impact on barriers to infertility treatments.

As presented in the *Medical Effectiveness* section, there is a preponderance of evidence that state health insurance mandates for infertility treatments are associated with an increase in utilization of those treatments, including IVF. There is also a preponderance of evidence that IVF is an effective treatment for infertility and planned oocyte preservation is an effective step to preserve infertility and as a treatment for future infertility in conjunction with IVF.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, 4.3% of enrollees with health insurance subject to AB 767 have coverage for infertility treatments, including IVF, and no enrollees have coverage for planned OC at baseline. If enacted, CHBRP estimates that the proportion of enrollees with insurance coverage for infertility treatment, including IVF and planned OC, would increase to 100% postmandate. In addition, the number using diagnostic infertility services would increase from 78,000 to 85,000 and the number using infertility treatment services would increase from 38,000 enrollees to 55,000 enrollees in the first year postmandate. The additional 17,000 persons (1,000 males and 16,000 females) would newly use all forms of infertility treatment and demonstrate the greatest increases for IVF with ICSI use among females (350% increase) and general treatment for males (9% increase).

As presented in Table 1, CHBRP estimates that the number of pregnancies resulting from infertility treatments in the first year postmandate will increase the number of pregnancies by 6,000 (from 7,000 to 13,000) and the number of live births by 5,000 (from 6,000 to 11,000).These estimates are supported by a preponderance of evidence that infertility treatments, including IVF and planned oocyte preservation, are medically effective and that health insurance benefit mandates are effective in increasing utilization of treatments for infertility, including IVF.

[38] CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

Mental Health and Quality of Life Outcomes

Receiving an infertility diagnosis can be a cause of stress, distress, anxiety, and depression among both female and male partners (Greil et al., 2010; Zurlo et al., 2018) The stress attributable to infertility in females has been compared to that experienced by female cancer patients (Roudsari et al., 2007). In one study of heterosexual couples seeking infertility treatments, nearly one-third of females reported depression, with 13% reporting severe depressive symptoms (Nelson et al., 2008). Higher levels of psychological distress and diminished quality of life have been found among females who view their future happiness as contingent on becoming a parent (Greil et al., 2010), among Asian women in the United States (Greil et al., 2016), and among couples experiencing infertility for three years or longer (Zurlo et al., 2018).

CHBRP also reviewed literature regarding the psychosocial impacts of undergoing treatment for infertility. Milazzo et al. (2016) conducted a recent systematic review and meta-analysis of 21 studies including 7,258 women and 5,653 that evaluated depression and anxiety outcomes associated with ART failures (i.e., a pregnancy did not result after embryo transfer occurred). Results of the meta-analysis showed that infertility-associated depression and anxiety significantly increased for both men and women in the period directly following a failed ART treatment. Although both depression and anxiety slightly decreased in the 6 months following a failed ART cycle, higher levels of both conditions were observed compared to before the participants engaged in ART. Following a treatment failure, men and women both reported more adverse emotional adjustment outcomes, such as anger and low self-esteem, as compared with baseline and compared to persons who experienced treatment success. Overall women with treatment failures experienced a higher level of negative emotional outcomes as compared with men, including more guilt, anger, frustration, and powerlessness, as well as less happiness and confidence (Milazzo et al., 2016). According to one study, the average number of ART cycles needed before a pregnancy success was 3.4 (Katz et al., 2011), therefore it is likely that the incidence of psychosocial distress would increase among the women and men who would newly use ART as a result of this bill.

Although experiencing infertility and undergoing infertility treatments is associated with significant mental health and quality of life deficits, CHBRP identified evidence showing that achievement of a successful pregnancy through infertility treatment may alleviate the psychosocial burden of these experiences. One study measuring life satisfaction among women with infertility participating in the National Survey of Fertility Barriers found that women who successfully conceived a pregnancy with medical intervention reported significantly higher life satisfaction levels than women who did not have a successful treatment experience or who never sought treatment for their infertility (McCarthy and Chiu, 2011). In addition, results of a recent systematic review and meta-analysis evaluating depression and anxiety associated with ART outcomes among a cumulative 7,258 women and 5,653 men demonstrated that a successful ART treatment was associated with a statistically significant decrease in depression as compared with patient-reported depression levels prior to treatment. Moreover, persons who experienced treatment success exhibited lower levels of emotional distress and isolation and reported healthier marital relationships as compared with persons who experienced treatment failure with ART (Milazzo et al., 2016)

Although CHBRP found evidence that engaging in infertility treatments may result in short-term psychosocial harms, evidence-based literature also indicates that the inability to have wanted children is itself associated with stress, anxiety, depression, and quality of life deficits that are likely to decrease upon the achievement of a successful pregnancy through treatment. Therefore, it stands to reason that mental health and quality of life would improve for the additional 5,000 persons and couples who would have a live birth resulting from infertility treatments postmandate.

Although persons experiencing infertility and engaging in unsuccessful treatment may experience mental health and quality of life deficits, it is important to consider that the alternative to treatment is having no children or pursuing adoption which may not be acceptable or feasible for many enrollees with infertility.

Potential Harms from Multiple Births with Infertility Treatment

When data are available, CHBRP estimates the marginal change in relevant harms associated with interventions affected by the proposed mandate. In the case of AB 767 there is evidence to suggest that an increase in the use of infertility treatments could result in harm. Potential harms associated with the use of infertility treatments, include increased risk of adverse maternal and perinatal outcomes associated with multiple births.

As described in the *Medical Effectiveness* section some treatments for infertility, particularly IVF and ovulation stimulating medications, increase the risk of having multiple gestation pregnancies, which are associated with an increased risk of maternal and perinatal complications, including preeclampsia, preterm birth, and low birthweight (2017; Martin et al., 2018). Although these risks are not greater than those experienced by women with multiple gestation pregnancies conceived without ART, the incidence of twins and higher-order multiples is disproportionately greater among persons undergoing ART than among the general population (twins: 19% vs. 3%; triplets or more: 0.6% vs. 0.1%) (Martin et al., 2018).

CHBRP's literature search identified several studies suggesting that the high rate of multiple births with ART may be, in part, attributable to the high financial burden of uncovered treatment costs posed to the individual[39] (Banks et al., 2010; Kulkarni et al., 2017; Martin et al., 2011; Smith et al., 2011). Among a cohort of couples receiving care at infertility clinics in San Francisco, Smith et al. (2011) observed that higher income couples were significantly more likely to use more cycles of IVF over an 18-month period as compared with lower-income women, but did not experience significantly different live birth outcomes, suggesting that lower-income women may have been incentivized by high costs to transfer multiple embryos in order to increase the chance of conception with fewer cycles. Moreover, Martin et al. (2011) and Kulkarni et al. (2017) found that rates of multiple births and multiple embryo transfers were significantly lower among persons undergoing ART in states with insurance benefit mandates for ART; however, rates of multiple gestation pregnancies with ART in mandated states remained higher than the general population. This effect appears to be more pronounced among older women and may further vary based on the fertility beliefs and cultural attitudes towards infertility treatment of the recipients (Banks et al., 2010).

Comparing pregnancy and birth outcomes (namely, percent twin and percent multiple births) at baseline from 2016 National ART Surveillance System data, in California, 41.2% of all IVF procedures result in pregnancy, 67.5% of which result in live birth, 12.4% are twin live birth, and 1.6% are multiple births. In New Jersey (mandate state), 41.7% of all IVF procedures result in pregnancy, 69.2% of which result in live birth, 11.4% are twin live birth, and 1.2% are higher-order multiple births.

CHBRP estimates that, postmandate, AB 767 would increase utilization of IVF and ovulation-stimulating medications among enrollees with state-regulated insurance, which could result in an increase in the rate of multiple births and associated adverse maternal and fetal outcomes among the enrollees who would contribute to the additional 7,000 pregnancies projected to occur with infertility treatment in the first year postmandate. However, to the extent that insurance benefit mandates promote single embryo transfers during individual cycles of IVF by alleviating uncovered out-of-pocket costs, some of the potential risk for multiple births with IVF in California could be attenuated.

[39] The median cost of one cycle of IVF, including medications, in the United States is $19,234 (Wu et al., 2014).

Impact on Disparities[40]

Insurance benefit mandates that bring more state-regulated plans and policies to parity may change an existing disparity. As described in the *Background* section, disparities in infertility and infertility treatment use exist by race/ethnicity and gender identity/sexual orientation. Within the first year postmandate, CHBRP estimates AB 767 could create or exacerbate disparities in gender identity and sexual orientation and would have no impact on racial/ethnic disparities. (For discussion of potential impacts beyond the first 12 months of implementation see the *Long-Term Impacts* section.)

Impact on Racial or Ethnic Disparities

As presented in the *Background* section, infertility rates are highest among racial and ethnic minorities, yet utilization of infertility treatments is highest among non-Hispanic whites (Chandra et al., 2013; Craig et al., 2019; Janitz et al., 2018). Furthermore, studies have shown that black and Hispanic women wait longer to seek care for an infertility diagnosis as compared with white women (Chin et al., 2015). In addition, CHBRP found evidence suggesting that, as compared with white women, racial and ethnic minority groups experience less infertility treatment success, with respect to pregnancies and births, and are also more likely to experience multiple gestation pregnancies, which have been associated with increased risk of adverse maternal and perinatal outcomes (Humphries et al., 2016; McQueen et al., 2015; Quinn and Fujimoto, 2016).

The medical effectiveness review found a preponderance of evidence that insurance benefit mandates increase utilization of infertility treatments in general and for IVF, specifically. However, CHBRP's literature review found evidence suggesting that insurance benefit mandates may not impact the differential use and treatment outcomes observed among racial and ethnic minorities as compared with whites. In Massachusetts, a state with an insurance benefit mandate for infertility care, Jain et al. (2005) compared the racial and ethnic distribution of patients at a large infertility treatment clinic to the statewide distribution and found that Hispanics were disproportionately underrepresented, accounting for 6.8% of the state population but only 3.9% of infertility patients. Differential use by Hispanic populations was also observed in an equal-access military health setting, with Hispanics accounting for 9% of the Department of Defense, but only 4% of persons seeking infertility care in a military healthcare setting (Feinberg et al., 2007). More recently, Dieke et al. (2017) analyzed use of ART by all racial and ethnic groups reported in the 2014 National ART Surveillance System (NASS) database and stratified use rates by state insurance mandate status. Although ART utilization rates were significantly higher among all racial and ethnic groups in states with insurance benefit mandates, as compared with nonmandate states, the differences in rates by racial and ethnic groups persisted, with the lowest rates observed for Hispanic and non-Hispanic black women regardless of mandate status.

CHBRP identified two studies that describe the impact of insurance benefit mandates on racial and ethnic differences in treatment outcomes, such as multiple gestation pregnancies and miscarriages. In the first, Feinberg et al. (2006) compared treatment outcomes in a military population with insurance for infertility treatment and found that African American patients experienced a significantly higher miscarriage rate and lower live birth rate with ART as compared with non-Hispanic white patients. This result is consistent with the previously-described racial and ethnic disparities in ART outcomes among the general population (Humphries et al., 2016; McQueen et al., 2015). In the second study, Luke et al. (2016) observed that the rate of multiple gestation pregnancy and preterm births among singleton pregnancies did not differ for

[40] For details about CHBRP's methodological approach to analyzing disparities, see the *Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts* document here: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

Hispanic and non-Hispanic black populations using ART in states with insurance benefit mandates (i.e., Massachusetts) as compared with nonmandate states (i.e., Florida and Michigan).

These findings suggest that economic barriers are not the primary mediators of who does and does not access infertility care with respect to racial and ethnic groups. Rather, as described in the *Background* section, cultural and social factors, such as ethical reservations about medical intervention for conception or intercommunity stigma regarding infertility, may play a larger role.

Racial and ethnic disparities in the prevalence of infertility have been consistently documented; furthermore, disparities in use and outcomes of infertility treatments have also been described for racial and ethnic minorities. However, CHBRP found literature indicating that racial and ethnic disparities in infertility treatment use and outcomes persist in states with insurance benefit mandates for infertility care. Therefore, CHBRP estimates that AB 767 would have no impact on racial and ethnic disparities in infertility prevalence, treatment use, or outcomes.

Impact on Disparities by Marital Status or Sexual Orientation

As described in the *Background* section, an increasing number of single persons and same-sex couples are pursuing biological reproduction through infertility treatments; however, these populations face disproportionate barriers to infertility treatment as compared with opposite-sex couples.

Advocacy and professional groups have described access barriers to single persons and same-sex couples on the basis of definitional discrimination wherein infertility is often defined only among persons who have attempted to become pregnant through 12 months of regular intercourse with an opposite-sex partner. By definition, same-sex couples and single persons cannot meet this standard. CHBRP did not find any literature addressing the differential impact of more- or less-inclusive infertility definitions for coverage of infertility on disparities in marital status or sexual orientation. However, if passed, AB 767 would amend the current infertility treatment benefit mandate in California by removing the definitional clause defining infertility by the aforementioned clinical standard and would solely define infertility as “the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility.” This definition relies on the interpretation of a physician or surgeon, who would be free to recognize the lack of a biologically compatible partner as a cause of infertility. Moreover, this definition does not arbitrarily impose time-related barriers, which are often not meaningful to same-sex couples. If enacted, AB 767 would also preserve the current nondiscrimination clause that prohibits the denial of coverage for infertility treatments on the basis of marital status or sexual orientation.

Although AB 767 would mandate coverage for all infertility treatments, including IVF, it does not mandate coverage for the donor materials (i.e., sperm, embryos, gestational carriers) that all single persons and same-sex couples need in order to have a baby. This may create a financial-related disparity wherein same-sex couples retain higher out-of-pocket costs as compared with opposite-sex couples who may not need to utilize donor materials to conceive. For example, one study conducted among almost 400 women at eight reproductive endocrinology clinics in California found that the median cost for one cycle of standard IVF was $24,373 whereas the median cost of one cycle of IVF with donor eggs was $38,015, which, if AB 767 were enacted, would account for nearly an additional $14,000 in uncovered expenses (Katz et al., 2011). Analysis of the same cohort found that the median out-of-pocket cost for one round of artificial insemination with partner sperm was $2,623 which is about half of what the National LGBT Health Education Center estimates artificial insemination with donor sperm would cost ($5,000) (National LGBT Health Education Center, 2019; Wu et al., 2014). Estimates for infertility treatment using a gestational carrier range from range from $80,000 to $140,000 depending on medical and legal arrangements (National LGBT Health Education Center, 2019).

In a similar manner, lack of coverage for donor materials could potentially create a financial disparity between male and female same-sex couples and singles who are attempting to conceive as males need to utilize IVF with donor eggs and gestational carriers in order to conceive, which, as described above, is a more expensive process as compared to artificial insemination with donor sperm needed for female same-sex or single conception. Additionally, CHBRP assumes that, whereas most infertility treatments would have minimal cost-sharing burdens postmandate, IVF would likely be subject to the 50% cost-sharing policies observed in other states with health insurance benefit mandates. Subsequently, this differential financial burden could potentially lead to a disparity in utilization of infertility treatments.

AB 767 would remove language from current law that defines infertility between opposite-sex couples and expand the definition of infertility to any condition recognized by a physician or surgeon as a cause of infertility, thereby potentially removing one barrier to care. However, CHBRP did not identify any evidence-based literature regarding the potential impact of insurance mandates on infertility-related disparities among same-sex couples, nor did CHBRP find literature assessing the impact of definitional changes in law that may impact the way that same-sex couples access infertility care. Therefore, the impact on gender identity and sexual orientation disparities is unknown.

It should be noted that, in not mandating coverage for donor materials and gestational carriers, the implementation of AB 767 could exacerbate or create disparities between same-sex couples/single persons and opposite sex couples, or create a disparity between male and female same-sex couples or singles. However, the potential magnitude of this effect is unknown.

Impact on Socioeconomic Disparities

As described in the *Background* section, cost is one of the most significant barriers to treatment for infertility and is experienced as both high out-of-pocket spending and loss of wages from missed work due to treatment administration. Consequently, persons with high income demonstrate disproportionately greater use of treatments for infertility, are more likely to use higher-intensity (and higher cost) treatments, and seek treatment for infertility earlier as compared with persons who have low income.

If enacted, AB 767 would expand the definition of infertility and mandate coverage for all non-experimental infertility treatments, including IVF, for all state-regulated commercial group and CalPERS plans in California. These provisions, as described in the Medical Effectiveness and Cost sections, would result in a reduction of $133,897,000 in previously uncovered expenses associated with these treatments and a corresponding increase in utilization for all infertility diagnostics and treatments, primarily among persons with no or insufficient coverage at baseline. In this manner, cost-related treatment barriers may be attenuated thereby reducing income-associated disparities in infertility treatment use postmandate among enrollees impacted by AB 767. However, AB 767 does not limit the extent of cost-sharing for infertility treatments, which may temper the magnitude significantly if high co-insurance structures are applied as observed in other mandated states, like New Jersey (see the *Benefit Coverage, Cost, and Utilization* section for more information).

Although documented income-related disparities in infertility treatment use may be alleviated among enrollees with commercial group and CalPERS coverage, it should be noted that AB 767 does not apply to Medi-Cal and the individual market. By definition, Medi-Cal enrollees are low-income, as are a significant portion of enrollees in the individual market. Excluding these groups may result in the persistence of high out-of-pocket expense burdens on those with comparably small disposable incomes, thereby exacerbating infertility treatment use and outcome disparities between high- and low-income enrollees.

If enacted, AB 767 would reduce out-of-pocket spending by $133,897,000 among enrollees in commercial group and CalPERS plans without coverage for infertility treatments at baseline and, as a result, increase utilization of treatments among these enrollees in the first year postmandate. To the extent that the mandated coverage would attenuate cost-related barriers to infertility treatment access and use, disparities by income level would be reduced; however, it is unknown how the increase in utilization and would be distributed across income-levels, therefore the magnitude of this effect is unknown.

It should be noted that, in excluding Medi-Cal and commercial plans sold on the individual market, a significant portion of low-income persons in California would continue to face high out-of-pocket and uncovered costs for infertility treatment, which could potentially exacerbate income-related disparities in treatment use and infertility outcomes.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact[41] of AB 767, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization Impacts

As discussed above, in the short-term, the aggregate pregnancy and birth rate is expected to increase postmandate due to increased utilization of infertility services. In the longer term, it is possible that the coverage of infertility services results in encouraging couples to undergo infertility treatment earlier than they would normally and where pregnancy might be achieved naturally (Machado and Sanz-de-Galdeano, 2015). It is also possible that in the longer-term the coverage of infertility services might encourage delays in child bearing, thus shifting utilization to females on the upper end of the age spectrum where infertility services are still clinically appropriate.

Cost Impacts

A recent study using claims data from 2011 examined the magnitude by which infertility treatment expenditures incurred by health carriers is higher in states with infertility mandates compared to states without mandates (Boulet et al., 2019). Authors found that infertility treatment — IUI, medications, and IVF — expenditures per enrollee were higher for women living in states with an infertility mandate compared to women in nonmandate states. This could be driven by the increased number in infertility treatment visits and medication claims for these women in mandate states. Per correspondence with the author of the study, it is unclear if any unit cost change in the services might have occurred postmandate. It is unclear if costs of infertility services change when mandates are introduced. Per CHBRP's content expert, it is possible that over time as infertility services are covered, there may be pressure to clinics to accept lower reimbursement for services. It is also possible that clinics decide to move out of network with carriers if contract rates are not high enough. There are no studies examining market changes when infertility mandates have been introduced in other states.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments) while other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects (beyond 12-months postmandate) to the public's health that would be attributable to the mandate, including impacts on long-term health outcomes, disparities, the social determinants of health, premature death, and economic loss. In the case of AB 767, long-term health outcomes are presented for IVF, planned oocyte cryopreservation (OC), as well as impacts on premature death and economic loss.

[41] See also CHBRP's *Criteria and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

Long-Term Health Outcomes for Planned Oocyte Cryopreservation

CHBRP found one study reporting on live birth outcomes for women using planned OC. Cobo et al. (2018) report that over a 10-year period, 12.1% percent of women using planned OC retrieved frozen oocytes and 18% of these women had live births. In the case of AB 767, CHBRP estimates that an additional 31,700 females (2% of female enrollees aged 25–37) would utilize planned OC annually as a result of AB 767, and an estimated 3,806 females newly covered for planned OC in a given year would eventually retrieve the frozen eggs. Given that the live birth rate reported in the Cobo analysis is 18%, about 685 live births would occur in the original cohort of 1,586,000 newly covered females using planned fertility preservation.[42] Note that more than one ART cycle may be required to achieve the live birth.

For each cohort of females electing to undergo mature OC for the prevention of age-related infertility in a given year, CHBRP estimates the long-term marginal impact of AB 767 would yield about 685 more live births among these women over time.

Although AB 767 would decrease the financial burden of planned OC services in the short term, AB 767 would not cover future storage costs, which can range from $100 to $1,500 per year (average $300/year) (Mesen et al., 2015). These additional uncovered costs may have an impact on the demand for these services, but the magnitude of this effect is unknown.

Potential Harms Associated with Planned Oocyte Cryopreservation and IVF

Those who elect to undergo planned OC, and who later experience infertility, must use assisted reproductive technology (ART) to utilize the frozen oocytes and become pregnant.

CHBRP identified a single study assessing perinatal outcomes for children born from frozen oocytes. Cobo et al. (2014) reported that 1,027 babies were born from cryopreserved oocytes in 2014 with no observed increase in the rate of obstetric problems (e.g., gestational diabetes, preeclampsia, preterm birth) or perinatal deficits (e.g., low birthweight, congenital abnormalities, gestational age at birth) compared to babies born from ART procedures using fresh oocytes.

The American Society of Reproductive Medicine's Ethics Committee opinion on oocyte preservation states that uncertainties remain around the efficacy of planned oocyte preservation in reducing future infertility, and women must be informed that the benefits and harms are not fully understood. Planned OC does not guarantee future successful fertilization or pregnancy (2018). Moreover, whereas planned OC may allow women to successfully utilize IVF at older ages, it is possible that the burden of adverse maternal and perinatal adverse outcomes associated with advanced maternal age pregnancies would increase.

As in the medical effectiveness discussion of harms related to IVF, in the case of multiple embryo transfer and multiple gestation, which is more common after IVF than occurs spontaneously (19% vs 3% for twins and 0.6% vs 0.1% for higher order multiples), there is an increased risk of pre-term birth compared to singleton gestations and compared to non-IVF multiple gestations. Children born pre-term have a higher risk of developmental issues such as cerebral palsy that can lead to long-term health, education, and social support needs (Martin et al., 2018).

[42] Should 5% of female enrollees ages 25-37 used planned OC (79,300 enrollees), an estimated 9,516 women would retrieve the frozen oocytes, and an estimated 1,713 additional live births would occur in the original cohort of 1,586,000 newly covered females using planned fertility preservation.

Evidence-based literature indicates that fertility preservation poses no higher risk to the health outcomes of children conceived with cryopreserved transfers as compared with ART-conceived children from fresh transfers. Additionally, literature indicates that, although there are harms to utilizing ART for conception and pregnancy with or without planned oocyte preservation, these are small and the alternative is lack of fertility.

Impacts on Premature Death and Economic Loss

Premature death

Premature death is often defined as death occurring before the age of 75 years (Cox, 2006).[43] In California, it is estimated that there are nearly 102,000 premature deaths each year, accounting for about 1.9 million years of potential life lost (YPLL) (CDPH, 2011).

Females

A recent study examining long-term health outcomes in 78,000 women enrolled in the Prostate, Lung, Colorectal, and Ovarian (PLCO) cancer screening trial, found that women who reported an infertility diagnosis had a 10% increased risk of all-cause mortality and a 20% increased risk of cancer-related mortality after 13 years of follow-up as compared with women who never experienced infertility. The authors stated that it was not possible to ascertain whether the excess mortality among women with infertility was driven by the experience of infertility itself or whether it was the underlying conditions that caused infertility in individuals that contributed to premature death (Stentz et al., 2017). Therefore, it is unknown if treatment for infertility would reduce premature death.

Males

CHBRP identified one study that evaluated the risk of premature death associated with infertility in males. Among almost 12,000 men (average age evaluated for infertility at infertility clinics in California and Texas, Eisenberg et al. (2014) observed that men diagnosed with male-factor infertility due to two or more sperm defects (i.e., motility, concentration, volume, count) had 2.3 times the risk of early death compared to men with normal sperm over an average 7.7 years of follow-up. The average age at death observed among men in the California cohort was 44 years. As with women, the authors noted that infertility alone may be an indicator of underlying disease or diminished fitness that could lead to worse health outcomes later in life (Eisenberg et al., 2014). Therefore, it is unknown if treatment for infertility would reduce premature death.

Infertility is associated with increased risk of death in both females and males as compared with the fertile population, although it is unclear to what extent excess mortality risk is attributable to infertility itself or to the underlying health conditions that cause infertility; therefore, the impact of AB 767 on premature death among enrollees who are subject to the bill is unknown.

Economic loss

Economic loss associated with disease is generally presented in the literature as an estimation of the value of the YPLL in dollar amounts (i.e., valuation of a population's lost years of work over a lifetime). In

[43] 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). For more information about CHBRP's public health methodology, see http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

addition, morbidity associated with the disease or condition of interest can also result in lost productivity by causing a worker to miss days of work due to illness or acting as a caregiver for someone else who is ill.

CHBRP identified one study that estimated productivity loss among women and men undergoing treatment for infertility. Among a cohort of 318 couples seeking infertility care at eight US infertility practices who recorded diaries of the time spent pursuing infertility care over an 18-month period, the average amount of time spent on fertility care was 125 hours, which is equivalent to 15.6 work days. Overall, IVF was the most time-costly treatment, requiring an average of 162 hours to complete one cycle, followed by IUI (70 hours) and ovulation medications (25.7 hours). Among couples pursuing the treatments mandated by AB 767, provider visits accounted for the greatest time loss. Although health insurance coverage status for infertility treatment was recorded, it was not found to be significantly associated with any treatment-related time differences (Wu et al., 2013).

Among the 37,500 women who utilize mature oocyte preservation as a preventive therapy for infertility as mandated by AB 767, some of the time-cost of IVF would be offset if they choose to utilize their already frozen eggs. Although women who elect to freeze their eggs still need to undergo IVF to fertilize and implant the eggs, they would not duplicate the time investment required to retrieve oocytes during the infertility treatment process. Additionally, given that the previously harvested oocytes may be more likely to be viable due to the early age at which they were retrieved, women utilizing IVF after planned oocyte preservation may require fewer cycles, and therefore fewer productive hours missed, to achieve a successful pregnancy. It is possible that some of the women who engaged in planned oocyte preservation would have other underlying causes of infertility at the time of retrieval, but for those who can make use of their preserved oocytes, the time-cost associated with egg retrieval on the back end could be substantially reduced.

Infertility treatments are costly in terms of time to search for and undergo treatments. Although CHBRP estimates that AB 767 would decrease financial burden and increase utilization associated with these treatments, CHBRP concludes that AB 767 would not impact economic loss since the mandate does not alter the procedures or time-investment required to undergo infertility treatment. For the 31,700 (2%) to 79,300 (5%) women who would undergo planned OC, the time-cost of this treatment would be distributed over two time periods but would amount to the same cumulative burden.

APPENDIX A TEXT OF BILL ANALYZED

On February 20, 2019, the California Assembly Committee on Health requested that CHBRP analyze AB 767.

Below is the bill language, as it was introduced on February 19, 2019. Immediately following is the bill language as amended on April 9, 2019. CHBRP incorporated these amendments into the analysis.

ASSEMBLY BILL **No. 767**

Introduced by Assembly Member Wicks
(Principal coauthors: Assembly Members Burke and Low)
(Principal coauthor: Senator Stern)

February 19, 2019

An act to amend Sections 1248 and 1374.55 of the Health and Safety Code, and to amend Section 10119.6 of the Insurance Code, relating to healthcare coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 767, as introduced, Wicks. Healthcare coverage: infertility.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law imposes various requirements and restrictions on health care service plans and health insurers, including, among other things, a requirement that every group health care service plan contract or health insurance policy that is issued, amended, or renewed on or after January 1, 1990, offers coverage for the treatment of infertility, except in vitro fertilization, under those terms and conditions as may be agreed upon between the group subscriber or the group policyholder and the health care service plans or the health insurers. Existing law provides that any employer that is a religious organization or health care service plans and health insurers which are a subsidiary of an entity whose owner or corporate member is a religious organization shall not be required to offer coverage for forms of treatment of infertility in a manner inconsistent with the religious organization’s religious and ethical principles, as specified.

This bill would require every health care service plan contract or health insurance policy that is issued, amended, or renewed on or after January 1, 2020, to provide coverage for in vitro fertilization, as a treatment of infertility, and mature oocyte cryopreservation. The bill would delete the exemption for religiously affiliated employers, health care service plans, and health insurance policies, from the requirements relating to coverage for the treatment of infertility, thereby imposing these requirements on these employers, plans, and policies. The bill would also delete the requirement that a health care service plan contract and health insurance policy provide infertility treatment under agreed upon terms that are communicated to all group contractholders and prospective group contractholders. By expanding the duties of health care service plans, the bill would expand the scope of an existing crime, thereby imposing 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.

DIGEST KEY

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

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BILL TEXT

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

SECTION 1. Section 1248 of the Health and Safety Code is amended to read:

1248. For purposes of this chapter, the following definitions shall apply:

(a) “Division” means the Medical Board of California. All references in this chapter to the division, the Division of Licensing of the Medical Board of California, or the Division of Medical Quality shall be deemed to refer to the Medical Board of California pursuant to Section 2002 of the Business and Professions Code.

(b) (1) “Outpatient setting” means any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility, as defined in Section 1250, and where anesthesia, except local anesthesia or peripheral nerve blocks, or both, is used in compliance with the community standard of practice, in doses that, when administered have the probability of placing a patient at risk for loss of the patient’s life-preserving protective reflexes.

(2) "Outpatient setting" also means facilities that offer in vitro fertilization, as defined in *paragraph (2) of* subdivision ~~(b)~~ *(e)* of Section 1374.55.

(3) "Outpatient setting" does not include, among other settings, any setting where anxiolytics and analgesics are administered, when done so in compliance with the community standard of practice, in doses that do not have the probability of placing the patient at risk for loss of the patient's life-preserving protective reflexes.

(c) "Accreditation agency" means a public or private organization that is approved to issue certificates of accreditation to outpatient settings by the board pursuant to Sections 1248.15 and 1248.4.

SEC. 2. Section 1374.55 of the Health and Safety Code is amended to read:

1374.55 (a) On and after January 1, ~~1990,~~ *2020,* every health care service plan contract that is issued, amended, or renewed that covers hospital, medical, or surgical expenses on a group basis, where the plan is not a health maintenance organization as defined in Section 1373.10, shall ~~offer~~ *provide* coverage for the treatment of infertility, ~~except~~ *including* in vitro fertilization, ~~under those terms and conditions as may be agreed upon between the group subscriber and the plan. Every plan shall communicate the availability of that coverage to all group contractholders and to all prospective group contractholders with whom they are negotiating.~~ *and mature oocyte cryopreservation.*

~~(b)For purposes of this section, "infertility" means either (1) the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility, or (2) the inability to conceive a pregnancy or to carry a pregnancy to a live birth after a year or more of regular sexual relations without contraception. "Treatment for infertility" 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.~~

~~(c)~~

(b) On and after January 1, ~~1990,~~ *2020,* every health care service plan that is a health maintenance organization, as defined in Section 1373.10, and that issues, renews, or amends a health care service plan contract that provides group coverage for hospital, medical, or surgical expenses shall offer the coverage specified in subdivision (a), according to the terms and conditions that may be agreed upon between the group subscriber and the plan to group contractholders with at least 20 employees to whom the plan is offered. The plan shall communicate the availability of the coverage to those group contractholders and prospective group contractholders with whom the plan is negotiating.

~~(d)~~

(c) This section shall not be construed to deny or restrict in any way any existing right or benefit to coverage and treatment of infertility under an existing law, plan, or policy.
~~(e)This section shall not be construed to require any employer that is a religious organization to offer coverage for forms of treatment of infertility in a manner inconsistent with the religious organization's religious and ethical principles.~~

~~(f)(1)This section shall not be construed to require any plan, which is a subsidiary of an entity whose owner or corporate member is a religious organization, to offer coverage for treatment of infertility in a manner inconsistent with that religious organization's religious and ethical principles.~~

~~(2)For purposes of this subdivision, "subsidiary" of a specified corporation means a corporation more than 45 percent of the voting power of which is owned directly, or indirectly through one or more subsidiaries, by the specified corporation.~~

~~(g)~~

(d) Consistent with Section 1365.5, coverage for the treatment of infertility shall be offered and, if purchased, provided without discrimination on the basis of age, ancestry, color, disability, domestic partner status, gender, gender expression, gender identity, genetic information, marital status, national origin, race, religion, sex, or sexual orientation. Nothing in this subdivision shall be construed to interfere with the clinical judgment of a physician and surgeon.

(e) The following definitions shall apply for purposes of this section:

(1) "Infertility" means the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility.

(2) "In vitro fertilization" means the laboratory medical procedures involving the in vitro fertilization process.

(3) "Mature oocyte cryopreservation" means the procedures consistent with established medical practices, including laboratory medical procedures, involving ovulation induction, egg retrieval, and freezing of the egg.

(4) "Preventative fertility care treatment" means procedures consistent with established medical practices in the treatment of fertility care, which is rendered by a licensed physician and surgeon, to prevent the inability to conceive a child.

(5) "Treatment for infertility" means procedures consistent with established medical practices in the treatment of infertility by a licensed physician and surgeon, including, but not limited to, diagnosis, diagnostic tests, medication, surgery, gamete intrafallopian transfer, and in vitro fertilization.

SEC. 3. Section 10119.6 of the Insurance Code is amended to read:

10119.6 (a) On and after January 1, ~~1990,~~ *2020,* every insurer issuing, renewing, or amending a policy of disability insurance that covers hospital, medical, or surgical expenses on a group basis shall ~~offer~~ *provide* coverage of infertility treatment, ~~except~~ *including* in vitro fertilization, ~~under those terms and conditions as may be agreed upon between the group policyholder and the insurer. Every insurer shall communicate the availability of that coverage to all group policyholders and to all prospective group policyholders with whom they are negotiating.~~ *and mature oocyte cryopreservation.*

~~(b)For purposes of this section, "infertility" means either (1) the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility, or (2) the inability to conceive a pregnancy or to carry a pregnancy to a live birth after a year or more of regular sexual relations without contraception. "Treatment for infertility" 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.~~

~~(c)~~

(b) This section shall not be construed to deny or restrict in any way any existing right or benefit to coverage and treatment of infertility under an existing law, plan, or policy.

~~(d)This section shall not be construed to require any employer that is a religious organization to offer coverage for forms of treatment of infertility in a manner inconsistent with the religious organization's religious and ethical principles.~~

~~(e)(1)This section shall not be construed to require any insurer, which is a subsidiary of an entity whose owner or corporate member is a religious organization, to offer coverage for treatment of infertility in a manner inconsistent with that religious organization's religious and ethical principles.~~

~~(2)For purposes of this subdivision, "subsidiary" of a specified corporation means a corporation more than 45 percent of the voting power of which is owned directly, or indirectly through one or more subsidiaries, by the specified corporation.~~

~~(f)~~

(c) This section applies to every disability insurance policy that is issued, amended, or renewed to residents of this state regardless of the situs of the contract.

~~(g)~~

(d) Consistent with Section 10140, coverage for the treatment of infertility shall be offered and, if purchased, provided without discrimination on the basis of age, ancestry, color, disability, domestic partner status, gender, gender expression, gender identity, genetic information, marital status, national origin, race, religion, sex, or sexual orientation. Nothing in this subdivision shall be construed to interfere with the clinical judgment of a physician and surgeon.

(e) The following definitions shall apply for purposes of this section:

(1) "Infertility" means the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility.

(2) "In vitro fertilization" means the laboratory medical procedures involving the in vitro fertilization process.

(3) "Mature oocyte cryopreservation" means the procedures consistent with established medical practices, including laboratory medical procedures, involving ovulation induction, egg retrieval, and freezing of the egg.

(4) "Preventative fertility care treatment" means procedures consistent with established medical practices in the treatment of fertility care, which is rendered by a licensed physician and surgeon, to prevent the inability to conceive a child.

(5) "Treatment for infertility" means procedures consistent with established medical practices in the treatment of infertility by a licensed physician and surgeon, including, but not limited to, diagnosis, diagnostic tests, medication, surgery, gamete intrafallopian transfer, and in vitro fertilization.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

AMENDED IN ASSEMBLY APRIL 09, 2019

CALIFORNIA LEGISLATURE— 2019–2020 REGULAR SESSION

ASSEMBLY BILL No. 767

Introduced by Assembly Member Wicks
(Principal coauthors: Assembly Members Burke and Low)
(Principal coauthor: Senator Stern)

February 19, 2019

An act to amend ~~Sections 1248 and~~ *Section* 1374.55 of the Health and Safety Code, and to amend Section 10119.6 of the Insurance Code, relating to ~~healthcare~~ *health care* coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 767, as amended, Wicks. ~~Healthcare~~ *Health care* coverage: infertility.

Existing law, the Knox-Keene Health Care Service Plan Act of ~~1975,~~ *1975 (Knox-Keene Act),* provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law imposes various requirements and restrictions on health care service plans and health insurers, including, among other things, a requirement that every group health care service plan contract or health insurance policy that is issued, amended, or renewed on or after January 1, 1990, offers coverage for the treatment of infertility, except in vitro fertilization, under those terms and conditions as may be agreed upon between the group subscriber or the group policyholder and the health care service plans or the health insurers. *The Knox-Keene Act specifies that a health care service plan that is a health maintenance organization (HMO) is required to provide this coverage to a group contractholder with at least 20 employees.* Existing law provides that any employer that is a religious organization or health care service plans and health insurers which are a subsidiary of an entity whose owner or corporate member is a religious organization shall not be required to offer coverage for forms of treatment of infertility in a manner inconsistent with the religious organization's religious and ethical principles, as specified.

This bill would require ~~every~~ *all* health care service plan ~~contract~~ *contracts, including every HMO contract,* or health insurance policy that is issued, amended, or renewed on or after January 1, 2020, to provide coverage for in vitro fertilization, as a treatment of infertility, and mature oocyte cryopreservation. The bill would delete the exemption for religiously affiliated employers, health care service plans, and health insurance policies, from the requirements relating to coverage for the treatment of infertility, thereby imposing these requirements on these employers, plans, and policies. The bill would also delete the

requirement that a health care service plan contract and health insurance policy provide infertility treatment under agreed upon terms that are communicated to all group contractholders and prospective group contractholders. By expanding the duties of health care service plans, the bill would expand the scope of an existing crime, thereby imposing 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.

DIGEST KEY
Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

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BILL TEXT

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

~~SECTION 1.Section 1248 of the Health and Safety Code is amended to read:~~

~~1248.~~

~~For purposes of this chapter, the following definitions shall apply:~~

~~(a)"Division" means the Medical Board of California. All references in this chapter to the division, the Division of Licensing of the Medical Board of California, or the Division of Medical Quality shall be deemed to refer to the Medical Board of California pursuant to Section 2002 of the Business and Professions Code.~~

~~(b)(1)"Outpatient setting" means any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility, as defined in Section 1250, and where anesthesia, except local anesthesia or peripheral nerve blocks, or both, is used in compliance with the community standard of practice, in doses that, when administered have the probability of placing a patient at risk for loss of the patient's life-preserving protective reflexes.~~

~~(2)"Outpatient setting" also means facilities that offer in vitro fertilization, as defined in paragraph (2) of subdivision (e) of Section 1374.55.~~

~~(3)"Outpatient setting" does not include, among other settings, any setting where anxiolytics and analgesics are administered, when done so in compliance with the community standard of practice, in doses that do not have the probability of placing the patient at risk for loss of the patient's life-preserving protective reflexes.~~

~~(c)"Accreditation agency" means a public or private organization that is approved to issue certificates of accreditation to outpatient settings by the board pursuant to Sections 1248.15 and 1248.4.~~

~~SEC. 2.~~*SECTION 1.*

Section 1374.55 of the Health and Safety Code is amended to read:

1374.55.

(a) On and after January 1, 2020, every health care service plan contract that is issued, amended, or renewed that covers hospital, medical, or surgical expenses on a group ~~basis, where the plan is not a health maintenance organization as defined in Section 1373.10,~~ *basis* shall provide coverage for the treatment of infertility, including in vitro fertilization, and mature oocyte cryopreservation.

~~(b)On and after January 1, 2020, every health care service plan that is a health maintenance organization, as defined in Section 1373.10, and that issues, renews, or amends a health care service plan contract that provides group coverage for hospital, medical, or surgical expenses shall offer the coverage specified in subdivision (a), according to the terms and conditions that may be agreed upon between the group subscriber and the plan to group contractholders with at least 20 employees to whom the plan is offered. The plan shall communicate the availability of the coverage to those group contractholders and prospective group contractholders with whom the plan is negotiating.~~

~~(c)~~

(b) This section shall not be construed to deny or restrict in any way any existing right or benefit to coverage and treatment of infertility under an existing law, plan, or policy.

~~(d)~~

(c) Consistent with Section 1365.5, coverage for the treatment of infertility shall be ~~offered and, if purchased,~~ provided without discrimination on the basis of age, ancestry, color, disability, domestic partner status, gender, gender expression, gender identity, genetic information, marital status, national origin, race, religion, sex, or sexual orientation. Nothing in this subdivision shall be construed to interfere with the clinical judgment of a physician and surgeon.

~~(e)~~

(d) The following definitions shall apply for purposes of this section:

(1) "Infertility" means the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility.

(2) "In vitro fertilization" means the laboratory medical procedures involving the in vitro fertilization process.

(3) "Mature oocyte cryopreservation" means the procedures consistent with established medical practices, including laboratory medical procedures, involving ovulation induction, egg retrieval, and freezing of the egg.

~~(4)"Preventative fertility care treatment" means procedures consistent with established medical practices in the treatment of fertility care, which is rendered by a licensed physician and surgeon, to prevent the inability to conceive a child.~~

~~(5)~~

(4) "Treatment ~~for~~ *of* infertility" means procedures consistent with established medical practices in the treatment of infertility by a licensed physician and surgeon, including, but not limited to, diagnosis, diagnostic tests, medication, surgery, gamete intrafallopian transfer, and in vitro fertilization.

~~SEC. 3.~~*SEC. 2.*

Section 10119.6 of the Insurance Code is amended to read:

10119.6.

(a) On and after January 1, 2020, every insurer issuing, renewing, or amending a policy of disability insurance that covers hospital, medical, or surgical expenses on a group basis shall provide coverage of infertility treatment, including in vitro fertilization, and mature oocyte cryopreservation.

(b) This section shall not be construed to deny or restrict in any way any existing right or benefit to coverage and treatment of infertility under an existing law, plan, or policy.

(c) This section applies to every disability insurance policy that is issued, amended, or renewed to residents of this state regardless of the situs of the contract.

(d) Consistent with Section 10140, coverage ~~for the treatment~~ of infertility *treatment* shall be offered and, if purchased, provided without discrimination on the basis of age, ancestry, color, disability, domestic partner status, gender, gender expression, gender identity, genetic information, marital status, national origin, race, religion, sex, or sexual orientation. Nothing in this subdivision shall be construed to interfere with the clinical judgment of a physician and surgeon.

(e) The following definitions shall apply for purposes of this section:

(1) "Infertility" means the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility.

(2) "In vitro fertilization" means the laboratory medical procedures involving the in vitro fertilization process.

(3) "Mature oocyte cryopreservation" means the procedures consistent with established medical practices, including laboratory medical procedures, involving ovulation induction, egg retrieval, and freezing of the egg.

~~(4)"Preventative fertility care treatment" means procedures consistent with established medical practices in the treatment of fertility care, which is rendered by a licensed physician and surgeon, to prevent the inability to conceive a child.~~

~~(5)"Treatment for infertility"~~

(4) "Coverage of infertility treatment" means procedures consistent with established medical practices in the treatment of infertility by a licensed physician and surgeon, including, but not limited to, diagnosis, diagnostic tests, medication, surgery, gamete intrafallopian transfer, and in vitro fertilization.

~~SEC. 4.~~*SEC. 3.*

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

for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

APPENDIX B LITERATURE REVIEW METHODS

This appendix 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.

As presented in the *Background* section, infertility diagnosis and treatment encompasses a wide range of tests, treatments, and medications. It is not feasible for CHBRP to review the literature on the effectiveness of the numerous diagnostic and treatment options for all causes of infertility to which AB 767 applies within the 60-day timeframe allotted for this analysis. In light of the wide range of conditions that cause infertility and the types of treatments to which AB 767 would apply, and the fact that AB 767 addresses the provision of coverage of infertility benefits, the medical effectiveness review summarizes these findings from evidence:[44] (1) the impact of health insurance coverage (specifically *mandates to cover*) for infertility treatments and (2) the medical effectiveness of the two treatments newly mandated under the bill language (i.e., IVF and mature OC).

Studies of infertility treatments and impacts of infertility insurance coverage were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, Business Source Complete, the Cumulative Index of Nursing and Allied Health Literature, and PsycINFO. Websites 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 (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network. The search was limited to abstracts of studies published in English.

The search related to the effectiveness and harms of IVF and planned OC ("planned oocyte cryopreservation") was limited to studies published from 2000 to present. Due to the amount of literature published related to IVF, CHBRP focused on previously published systematic reviews to inform the medical effectiveness analysis. In assessing harms related to IVF and planned OC, CHBRP relied primarily on previously published systematic reviews when possible and expanded the inclusion to well-designed trials and cohort studies for less common harms and complications. The search related to the impact of health insurance coverage for infertility treatment was limited to studies published from 2012 to present because CHBRP had previously conducted thorough literature searches on these topics in 2013 for AB 460.

Of the 480 articles found in the literature review, 227 were reviewed for potential inclusion in this report on AB 767, and a total of 29 studies were included in the medical effectiveness review for this report, as well as eight studies that were included in the previous review for AB 460. The other articles were eliminated because they did not focus on mandate coverage including IVF, did not report relevant outcomes, or were not reporting findings from clinical research studies.

[44] Much of the discussion below is focused on reviews of available literature. However, as noted on page 11 of the Medical Effectiveness analysis and research approach document (posted here), in the absence of "fully-applicable to the analysis" peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach*.[45] 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;*
- *Limited evidence;*
- *Inconclusive evidence; and*
- *Insufficient evidence.*

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

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

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

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

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

[45] Available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

Search Terms (* indicates truncation of word stem)

The following Medical Subject Headings (MeSH) were used to search PubMed and Cochrane:

- Age Factors
- Autism Spectrum Disorder
- Autistic Disorder
- Birth Rate
- Cardiovascular Diseases
- Cerebral Palsy
- Cleft Palate
- Cost Benefit Analysis
- Cost of Illness
- Cost Savings
- Cryopreservation
- Depression
- Depressive Disorder
- Developmental Disabilities
- Down Syndrome
- Educational Status
- Ethnic Groups
- Embryo Transfer
- Fertilization in Vitro
- Fertilization in Vitro/adverse effects
- Fertility Preservation
- Gender Identity
- Health Care Costs
- Health Impact Assessment
- Health Services Accessibility
- Health Services Needs and Demand
- Health Status Disparities
- Healthcare Disparities
- Homosexuality, Female
- Homosexuality, Male
- Incidence
- Infant, Low Birth Weight
- Infertility/Therapy
- Insemination, Artificial
- Insurance, Health
- Insurance Coverage
- Live Birth
- Minority Health
- Neoplasms
- Oocytes
- Pregnancy Complications
- Pregnancy Outcome
- Pregnancy Rate
- Premature Birth
- Prevalence
- Quality of Life
- Race Factors
- Reproductive Medicine/Legislation and jurisprudence
- Reproductive Techniques, Assisted
- Risk Assessment
- Risk Factors
- Sexuality
- Social Determinants of Health
- Sperm Injections, Intracytoplasmic/adverse effects
- Stress, Psychological
- Transgendered Persons
- Treatment Outcome

The following keywords were used to search PubMed, Cochrane, Web of Science, EMBASE, Business Source Complete and Web sites:

- Access
- Age
- Anxiet*
- Artificial insemination
- Assisted reproductive technology
- Assistive reproductive technology
- Autism
- Autistic
- Barrier*
- Behavioral disorder*
- Birth
- Birth outcomes
- Birth rates
- Cancer*
- Cardiovascular disease*
- Cerebral palsy
- Childhood tumors
- Cleft palate
- Complications
- Cost*
- Cost offset
- Cost savings
- Cost effective*
- Cost utility
- Cryopreservation
- Death

- Depression
- Demand
- Demographic*
- Developmental disabilit*
- Discrimination*
- Disparit*
- Down's syndrome
- Economic loss
- Education
- Educational attainment
- Educational status
- Effects of insurance mandates
- Effective*
- Embryo transfer
- Ethnic*
- Ethnic disparities
- Fertilization in vitro
- Fertility preservation
- Financial burden
- Gender
- Harms
- Homosexual*
- Impact*
- In-vitro fertilization
- Income
- infertility
- Infertility insurance mandates
- Infertility therapy
- Infertility treatments
- Insurance coverage
- Insurance mandates
- Intracytoplasmic sperm injection
- Health outcomes
- Lesbian*
- Live birth rates
- Long term impact*
- Malformations
- Market
- Maternal fertility status
- Mature oocyte cryopreservation
- Mental retardation
- Miscarriage
- Morbidity
- Mortality
- Multiple birth rates
- Oocytes
- Out of pocket
- Outcome*
- Pregnancy
- Pregnancy complication*
- Pregnancy outcome*
- Pregnancy rate*
- Premature death
- Premium*
- Preventive fertility care treatment*
- Price elasticity
- Productivit*
- Psychological
- Quality of life
- Race
- Racial disparities
- Religion
- Religious
- Reproductive Medicine
- Reproductive technique*
- Risk*
- Risk factors
- Safety
- Same sex couples
- Sex differences
- Sexual orientation
- Social determinants
- Stigma
- Stress
- Transgender*
- Treatment outcomes
- Treatment utilization
- Uncovered cost*
- Utilisation
- Utilization

APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm, Milliman, Inc.[46]

Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses are available at CHBRP's website.[47]

This appendix describes analysis-specific data sources, estimation methods, caveats, and assumptions used in preparing this cost impact analysis.

Analysis-Specific Caveats and Assumptions

As explained in the *Policy Context* section, GIFT and ZIFT were not included in this analysis.

Identification of Infertility Cases

- CHBRP examined 2016 MarketScan® database and Milliman's proprietary 2016 Consolidated Health Cost Guidelines™ Sources Database (CHSD) for infertility services among enrollees with an infertility diagnosis in California as well as New Jersey, a state where an infertility mandate is already in place.
- The analysis of California's 2016 MarketScan and 2016 CHSD claims data for infertility services required categorizing claims to estimate annual utilization rates and cost per services. Only enrollees with 11 or more months of enrollment who had drug coverage were included in the analysis. The female reproductive age range is 15-44 years. The male reproductive age range is 18-60 years.
- Content expert input and guidance from recent research on the impact of state-level infertility mandates on health plan expenditures that also used MarketScan data (Boulet et al., 2019) were the basis for CHBRP's methodology on how to group claims codes into treatment categories.
- Infertility Diagnosis — For all diagnostic and treatment categories, the claims were first subset to only include claims for members with the following infertility ICD 10 diagnosis codes: N468, N469, N970, N971, N972, N978, N979, Z3141, Z3162, Z3181, Z3183, Z3184, and Z3189.
- Diagnostic Procedures - For the claims with the infertility diagnosis codes, the following Healthcare Common Procedure Coding System (HCPCS) codes were used to identify diagnostic services: 54500, 54505, 54800, 55200, 55300, 55550, 58340, 58345, 58350, 58540, 58560, 58700, 58740, 58752, 58770, 58920, 74740, 76831, 83001, 83002, 89300, 89310, 89320, 89321, 89322, 89330, 89331, G0027, S3655.

[46] CHBRP's authorizing statute, available at http://chbrp.com/CHBRP%20authorizing%20statute_2018_FINAL.pdf, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

[47] See method documents posted here, http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see *2019 Cost Analyses: Data Sources, Caveats, and Assumptions*.

- Male treatments were identified as claims with an infertility diagnosis code and the following HCPCS codes: 0357T, 58323, 58970, 58974, 58976, 89250, 89251, 89253, 89254, 89255, 89257, 89258, 89259, 89260, 89261, 89264, 89268, 89272, 89280, 89281, 89290, 89291, 89325, 89329, 89335, 89337, 89342, 89343, 89344, 89346, 89352, 89353, 89354, 89356, S4011, S4015, S4016, S4017, S4018, S4020, S4021, S4022, S4023, S4025, S4026, S4027, S4028, S4030, S4031, S4035, S4037, S4040, S4042, 76948, 55400, 55870
- To categorize female enrollees into the four treatment categories, ICSI, IVF, IUI and OI, CHBRP completed the following steps:
    - Step 1: Using the claims with the infertility diagnosis codes, assign female enrollees to a treatment category by the following hierarchy:
        - ICSI – Assisted oocyte fertilization HCPCS 89280 or 89281
        - IVF – Follicle puncture for oocyte retrieval HCPCS 58970 or Embryo transfer HCPCS 58974
        - IUI – Artificial insemination HCPCS 58321 or 58322, Sperm washing HCPCS 58323, Sperm isolation 89260, or IUI case rate S4035
    - Step 2: For members identified in one of the three groups in Step 1, all claims associated with that member that have an infertility diagnosis code are included in the enrollee's treatment costs.
    - Step 3: For the enrollees identified in step 1, the following prescription drugs were included: Anastrozole, Cetrorelix acetate, Chorionic gonadotropin, Chorionic gonadotropin alfa, recombinant, Clomiphene citrate, Follicle stimulating hormone/luteinizing hormone, Follitropin beta, Follitropin beta/ganirelix acetate, Follitropin alfa, Ganirelix acetate, Gonadorelin acetate, Gonadorelin hydrochloride, Histrelin acetate, Hydroxyprogesterone caproate, Letrozole, Lutropin alfa, Medroxyprogesterone acetate, Metformin hydrochloride, Norethindrone, Norethindrone acetate, Progesterone, Progesterone, micronized, Urofollitropin, Bravelle, Bromocriptine mesylate, Cabergoline, Cetrotide, Chorionic gonadotropin, Clomid, Clomiphene citrate, Dexamethasone, Femara, Follistim aq, Ganirelix acetate, Glucophage, Gonal-f, Gonal-f rff, Gonal-f rff pen, Menopur, Metformin hcl, Novarel, Ovidrel, Pregnyl w/diluent benzyl, Repronex, Synarel, Estrace, Testosterone gel, Testosterone patch, Omnitrope.
    - Step 4: For enrollees not categorized into one of the three treatment categories listed in step 1, they were included in the medication only treatment category if they had one of the following drugs: Cetrorelix acetate, Chorionic gonadotropin, Chorionic gonadotropin alfa, recombinant, Clomiphene citrate, Follicle stimulating hormone/luteinizing hormone, Follitropin beta, Follitropin beta/ganirelix acetate, Follitropin alfa, Ganirelix acetate, Gonadorelin acetate, Gonadorelin hydrochloride, Histrelin acetate, Letrozole, Progesterone, micronized, Urofollitropin, Bravelle, Clomid, Clomiphene citrate, Femara, Follistim aq, Ganirelix acetate, Gonal-f, Gonal-f rff, Gonal-f rff pen, Menopur, Novarel, Ovidrel, Pregnyl w/diluent benzyl, Repronex, Synarel. Women with progesterone only also needed to have estradiol to be included in the medication only treatment category.
    - Step 5: The enrollees as a percentage of the total reproductive population in each category were calculated and used as the baseline with coverage utilization assumptions. The CA cost per enrollee was used as the cost per user.

Baseline utilization – Infertility Services

- Percent (%) of people with infertility – Using the New Jersey data grouped by gender, the count of enrollees with a diagnostic code listed above as a percent of the total New Jersey enrollees in reproductive age range was assumed to be the utilization of diagnostic services for the baseline with coverage population.
- Percent (%) of reproductive people with infertility using services – The New Jersey utilization data grouped into the infertility treatment categories listed above was used as the baseline with coverage utilization assumption.
- MarketScan and CHSD data in California provides a snapshot of utilization of infertility services among those with some coverage of these services. Because infertility is largely not covered by insurance, a significant portion of utilization at baseline is driven by individuals who use services without coverage. Per CHBRP's content expert, approximately 80% of patients presenting at infertility clinic have coverage for diagnostic tests and about 40% have coverage for infertility treatment. To estimate the utilization stemming from enrollees who obtain services without coverage in California at baseline, CHBRP used estimates from the peer-reviewed literature applied to 2016 MarketScan data from New Jersey, where infertility treatment is covered via a state mandate. Evidence from the peer-reviewed literature that suggests utilization of IVF services in mandate states vs nonmandate states is 1:4 ratio (Chambers et al., 2014). CHBRP applied this ratio for IVF and ICSI to the New Jersey data to estimate utilization in California. A study from couples in Northern California, where the population is likely more affluent than the rest of the state, suggests that 58% of couples who are diagnosed with infertility but do not pursue treatment cite financial difficulty as the reason for not pursuing treatment (Eisenberg et al., 2010). Given non-IVF services are less costly to enrollees, IUI and medication utilization in California is assumed to be 20% less than that of New Jersey; and diagnostic testing for females and treatment for males is assumed to be 5% less than New Jersey. Because male diagnostic tests are inexpensive, utilization rates among enrollees represented in the claims database in New Jersey are assumed to be the same as that in California.
- To estimate the degree to which utilization of infertility services might shift postmandate, CHBRP identified various data sources. Examining utilization rates claims for states with an existing infertility mandate was determined to be a sound means of obtaining potential postmandate rates. Thus, CHBRP first examined infertility legislation from the states whereby the state mandates included all types of infertility services (including explicit mention of ICSI), no specific cap on the dollar amount covered, and no cap on the number of cycles to determine which other states had mandates most close to the bill language laid out in AB 767. See Table 7 below for the full list of states with infertility mandates to cover IVF and limits placed by those mandates. Massachusetts and New Jersey were the two states identified in this process. While Delaware's infertility mandate is also flagged as similar to that of California's, it was enacted in 2018 and CHBRP's claims data are for 2016, thus postmandate utilization could not be estimated with data from Delaware. CHBRP determined New Jersey's infertility mandate limits on age and egg retrievals are likely to be close to the types of limits carriers may issue if AB 767 were to pass since the bill does not specify any restrictions to placing such limits. Thus, 2016 MarketScan claims data from New Jersey were used to estimate postmandate utilization.

Table 7. States with Infertility Mandates to Cover IVF and Limits Placed by those Mandates

	Limit			
State Mandate	**Age**	**$ amount covered**	**# of IVF cycles**	**Egg retrieval**
Arkansas	-	$15,000 lifetime max	-	-
Connecticut	-	-	2 cycles max	-
Delaware	<45 years at time of female egg retrieval	-	-	6 egg retrievals max
Hawaii	-	-	1 cycle max	-
Illinois	-	-	Note, ISCI not included in mandate	4 egg retrievals; 2 more if live birth successful
Maryland	-	$100,000 max	-	-
Massachusetts	-	-	-	-
New Jersey	<45 years	-	-	4 egg retrievals max
Rhode Island	25-42 years	$100,000 max	-	-

Source: (NCSL, 2018)

Postmandate utilization – Infertility

- Percent (%) of people with infertility – Same as the baseline population.
- Percent (%) of reproductive people with infertility using services – The baseline with coverage utilization rates adjusted for 10% pent-up demand in both years 1 and 2.

Baseline Cost – Infertility Services

- Using the treatment categories outlined in the Identification of Infertility Cases section, the California average cost per identified user was calculated.
- Medical claims were trended using a 2.0% medical trend, the medical component of CPI, and a 7.5% pharmacy trend rate, from the 2019 Milliman Health Cost Guidelines.

Postmandate Cost – Infertility Services

- Postmandate costs of infertility services are assumed to be the same as baseline infertility service costs.

Pregnancies

- For each of the treatment categories, the % of users of the infertility services resulting in a pregnancy, the % of pregnancies resulting in a non-live birth, single birth, twins, or three or more babies was assumed as follows:

Table 8. Pregnancy related outcomes of infertility treatment, by treatment category

Type of Pregnancy/Birth	% Resulting in Pregnancy	% Not Live	% Live Single	% Twins	% Multi
Baseline					
Medication Only	25.4%	17.1%	75.0%	7.8%	0.1%
IVF	41.2%	18.4%	67.5%	13.8%	0.4%
ICSI	41.2%	18.4%	67.5%	13.8%	0.4%
IUI	15.2%	16.0%	81.1%	2.8%	0.1%
Postmandate					
Medication Only	25.4%	17.1%	75.0%	7.8%	0.1%
IVF	41.7%	18.2%	69.2%	12.2%	0.4%
ICSI	41.7%	18.2%	69.2%	12.2%	0.4%
IUI	15.2%	16.0%	81.1%	2.8%	0.1%

Source: California Health Benefits Review Program, 2019.

- The Medication only source was a blend of outcomes from the use of clomiphene and letrozole (Diamond et al., 2015).

- The IVF and ICSI source for the baseline population is California observed pregnancy rates and for the postmandate is New Jersey observed pregnancy rates from the National ART Surveillance, US, 2015. The postmandate rate has slightly more live births, more single births and fewer multi-births than the baseline population due to women getting more cycles with fewer embryos transferred as a result of cost.

- The IUI pregnancy rates are the 2017 national average for all pregnancies as provided by the CDC. Because these rates were only reported for live births, the values were adjusted for the percentage of non-life births from stillbirths and miscarriages, reported by the CDC and March of Dimes respectively.[48]

[48] CDC estimates 1% of pregnancies result in stillbirth (Macdorman et al., 2015) and March of Dimes estimates up to 15% of pregnancies result in miscarriage (https://www.marchofdimes.org/miscarriage.aspx)

- CHBRP assumed literature based estimates of cost per pregnancy and live birth for singleton, twin, and multiple births that take into account additional neonatal care costs associated with each type of birthweight, such as use of neonatal intensive care unit (NICU) services (Lemos et al., 2013). The per unit cost of pregnancies that do not result in a live birth was developed from the 2019 Milliman Health Cost Guidelines and includes inpatient services for complications and pregnancies that do not result in a delivery due to miscarriage or abortion, maternity professional and maternity anesthesia charges. All medical services were trended to 2020 using 2% medical trend and 7.5% pharmacy trend. The baseline and postmandate costs are assumed to be the same.

Fertility Preservation

- The case rate used for the cost of fertility preservation of mature oocytes is from the 2019 CHBRP analysis of SB 600. CHBRP's analysis of SB 600 is available at www.chbrp.org.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits AB 767 would mandate. 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 therefore 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 cost-sharing arrangements for description treatment or service. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

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 currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask 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.

However, CHBRP is aware of some large employers (i.e., Google and Facebook) that do provide coverage for the full range of infertility treatments in addition to planned oocyte cryopreservation (OC), suggesting there is a public demand for these services.

Second Year Impacts on Benefit Coverage, Utilization, and Cost

In order to develop Table 9, CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of AB 767 would have a substantially different impact on utilization of either the tests, treatments, or services for which coverage was directly addressed, the utilization of any indirectly affected utilization, or both. To generate this table, CHBRP reviewed the

literature and consulted content experts about the possibility of varied second year impacts and applied what was learned to a projection of a second year of implementation.

Table 9. AB 767 Impacts on Benefit Coverage, Utilization, and Cost, 2021

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
Benefit coverage				
Total enrollees with health insurance subject to state benefit mandates (a)	24,395,000	24,395,000	0	0%
Total enrollees with health insurance subject to AB 767	14,630,000	14,630,000	0	0%
Percentage of enrollees with coverage for infertility services, including IVF	4.3%	100%	96%	2247%
Number of enrollees with coverage for infertility services, including IVF	623,297	14,630,000	96%	2247%
Percentage of enrollees with coverage for mature oocyte cryopreservation as defined by AB 767	0%	100%	100%	100%
Number of enrollees with coverage for mature oocyte cryopreservation as defined by AB 767	0	14,630,000	100%	100%
Utilization and unit cost				
Female - Number of enrollees using:				
Diagnostic tests	52,000	58,000	5,000	12%
Medications only	14,000	17,000	3,000	21%
IVF	2,000	7,000	5,000	250%
ICSI-IVF	2,000	9,000	7,000	350%
IUI	9,000	10,000	1,000	11%
Male - Number of enrollees using:				
Diagnostic tests	24,000	27,000	3,000	13%
Treatment	11,000	12,000	1,000	9%
Average per unit cost				
Diagnostic tests	$467	$467	$0	0%
Medications only	$5,756	$5,756	$0	0%
IVF	$16,012	$16,012	$0	0%
ICSI-IVF	$30,027	$30,027	$0	0%
IUI	$6,900	$6,900	$0	0%
Male diagnostic tests	$83	$83	$0	0%
Male treatment	$652	$652	$0	0%
Pregnancy				
# of pregnancies due to infertility services (all types)	7,000	13,000	6,000	86%

# of live birth deliveries due to infertility services (single, twin, multiples)	6,000	11,000	5,000	83%
Average annual cost of pregnancy and delivery from infertility services (single, twin, multiples)	$37,000	$39,000	1,000	5%
Expenditures				
Premiums by payer				
Private employers for group insurance	$90,700,422,000	$91,148,774,000	$448,352,000	0.49%
CalPERS HMO employer expenditures (b) (c)	$3,234,903,000	$3,249,963,000	$15,060,000	0.47%
Medi-Cal Managed Care Plan expenditures	$29,186,401,000	$29,186,401,000	$0	0%
Enrollees with individually purchased insurance	$13,111,153,000	$13,111,153,000	$0	0%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (c)	$15,255,718,000	$15,339,320,000	$83,602,000	0.55%
Enrollee expenses				
For covered benefits (deductibles, copayments, etc.) (d)	$15,636,259,000	$15,864,108,000	$227,849,000	1.46%
For noncovered benefits (e)	$136,793,000	$0	$136,793,000	-100%
Total expenditures	$167,261,649,000	$167,899,719,000	$638,070,000	0.38%

Source: California Health Benefits Review Program, 2019.

Notes: For estimates of the impact of mature oocyte cryopreservation coverage, refer to the *Benefit, Cost, and Utilization* section.

(a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.[49]

(b) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care.

(d) Enrollee out-of-pocket expenses for covered benefits for IVF & ICSI services (not including associated pregnancies) is $44,110,547 at baseline and $172,904,155 postmandate, resulting in an increase of 292%; for all other infertility services, out-of-pocket expenses at baseline is $15,592,148,453 and $15,691,203,845 postmandate, a 0.64% increase.

(e) Includes only expenses 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 would be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organizations; ICSI = intracytoplasmic sperm injection; IUI = intrauterine insemination; IVF = in vitro fertilization

[49] For more detail, see *Estimates of Sources of Health Insurance in California*, available at http://chbrp.com/analysis_methodology/cost_impact_analysis.php.

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A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing researchers and analysts who are **Task Force Contributors** to CHBRP from UC that conduct 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 manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, **Milliman**, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

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 of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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*Karen Shore is an Independent Contractor with whom CHBRP works to support legislative analyses and other special projects on a contractual basis.

CHBRP is an independent program administered and housed by the University of California, Berkeley, in the Office of the Vice Chancellor for Research.

CHBRP gratefully acknowledges the efforts of the team contributing to this analysis:

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

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