# California Health Benefits Review Program

Analysis of California Assembly Bill 2029 Health Care Coverage: Treatment for Infertility

A Report to the 2021–2022 California State Legislature

April 16, 2022



# Key Findings Analysis of California Assembly Bill 2029 Health Care Coverage: Treatment for Infertility

Summary to the 2021–2022 California State Legislature, April 16, 2022



# **SUMMARY**

The version of California Assembly Bill 2029 analyzed by CHBRP would require coverage for fertility services to diagnose and treat infertility; cost sharing must be similar in structure as for other benefits.

In 2023, of the 22.8 million Californians enrolled in state-regulated health insurance, 14.8 million of them would have insurance subject to AB 2029. Enrollees in Medi-Cal managed care plans regulated by the Department of Managed Health Care (DMHC) have coverage that is exempt, as do employees of religious employers.

**Benefit Coverage:** At baseline, 23% of enrollees with health insurance that would be subject to AB 2029 have coverage for fertility services that includes in vitro fertilization (IVF). CHBRP found 0% of enrollees have fully compliant health insurance that includes coverage for fertility services *and* cost sharing for covered fertility services (i.e., deductible, copayment, or coinsurance) that is **not** different from those imposed on other benefits. Postmandate, fully compliant benefit coverage for a new state benefit mandate that appears to exceed the definition of Essential Health Benefits (EHBs) in California.

**Medical Effectiveness:** CHBRP finds there is *clear and convincing evidence* that IVF is an effective treatment for infertility and a *preponderance of evidence* that IVF is associated with certain maternal and offspring harms. CHBRP also finds *clear and convincing evidence* that mandates for fertility services are associated with increased utilization of infertility treatments, a decrease in the number of embryos transferred per cycle, and a lower likelihood of adverse birth outcomes, including rates of multiple births.

**Cost and Health Impacts<sup>1</sup>:** In 2023, AB 2029 would increase total net annual expenditures by \$714,800,000 or 0.48% for enrollees with plans regulated by DMHC and policies regulated by the

The largest premium increases are among DMHCregulated small-group plans (1.1%), DMHCregulated individual plans (1.0%), and CDI-regulated individual plans (1.1%). Increases in premiums stems from both increases of (1) utilization of fertility services and (2) resulting pregnancies and births. About 74% of increase in premiums is attributable to the increase in fertility services and about 26% is attributable to increases in pregnancy related services. The increase in utilization of fertility services would lead to an estimated additional 6,000 live birth deliveries postmandate (a 55% increase from baseline), of which 3.4% are twin deliveries and 0.2% are 3+ multiple births.

Mental health and quality of life would improve for the additional 6,000 persons and couples who would have live birth deliveries resulting from infertility treatments postmandate, in both the short and long term.

Because the rate of multiple gestation pregnancies would decrease due to the requirement of singleembryo transfers unless indicated, and by decreasing the financial barrier to IVF that has previously encouraged multiple embryos transferred in a single IVF cycle, there would be a resulting decrease in the harms associated with multiple gestation pregnancies for enrollees accessing IVF treatments.

Disparities related to income, relationship status, sexual orientation and gender identity are expected to decrease but not reach complete parity for those with insurance subject to the mandate. Cost sharing for IVF could remain a financial barrier to utilization. As Medi-Cal is excluded, disparities for those with Medi-Cal compared to those with commercial insurance subject to the mandate would increase, worsening income and racial/ethnicity disparities.

and other aspects of health make stability of impacts less certain as time goes by.

California Department of Insurance (CDI). This is due to a \$957,449,000 (0.72%) increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, an increase of \$44,921,000 in enrollee cost sharing for covered benefits, and a decrease of \$287,570,000 in enrollee expenses for noncovered benefits.

<sup>&</sup>lt;sup>1</sup> Similar cost and health impacts could be expected for the following year, though possible changes in medical science



# CONTEXT

Infertility is the inability to have a child and is a complex condition that can take many forms.<sup>2</sup> 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 experience difficulty having another), either of which may be related to the inability to become pregnant or successfully carry a pregnancy to term. Infertility can have many causes including medical conditions, as the result of medical treatments (such as for cancer), or because it is not possible for the individual or couple to become pregnant without intervention (such as for single persons or same-sex couples).

In 2019, 2.1% of all births in the United States resulted from using assisted reproductive technology. Advances in infertility treatments and in vitro fertilization (IVF) have made single-embryo transfers the preferred method for the majority of women seeking pregnancy through IVF, especially for women under 38 years of age.

# **BILL SUMMARY**

AB 2029 would require commercial and CaIPERS health plans and policies to provide "coverage for the diagnosis and treatment of infertility and fertility services." Health plans and policies must include the notice of coverage in the plan's evidence of coverage (EOC) materials. DMHC-regulated Medi-Cal managed care plans are not subject to AB 2029.

AB 2029 also:

- Specifies that coverage includes up to four completed oocyte retrievals and unlimited embryo transfers;
- Expands the definition of infertility to include persons unable to reproduce either as an individual or with their partner without medical intervention;
- Limits cost sharing (deductible, copayment, coinsurance) to the same structure as for other benefits; and
- Prohibits other coverage limitations that are different from those of other benefits.

For this analysis, CHBRP assumes:

• All nonexperimental infertility treatments would need to be covered for a plan to be in compliance with AB 2029. These services include diagnosis, medications, surgery, artificial

<sup>2</sup> Refer to CHBRP's full report for full citations and references.

insemination (such as intrauterine insemination [IUI]), IVF, and IVF with intracytoplasmic sperm injection (ICSI).

Figure A notes how many Californians have health insurance that would be subject to AB 2029.



Source: California Health Benefits Review Program, 2022.

# **IMPACTS**

# **Benefit Coverage, Utilization, and Cost**

Due to changes in bill language, baseline population estimates within CHBRP's cost and coverage model, and CHBRP's analytic approach, the utilization and expenditures in the analysis of AB 2029 cannot be compared to the utilization and expenditure estimates in CHBRP's analyses of AB 767 conducted in 2019 or AB 2871 conducted in 2020.

#### **Benefit Coverage**

At baseline, 23% of enrollees with health insurance that would be subject to AB 2029 have fertility coverage that includes IVF. CHBRP found 0% enrollees have health insurance that includes fertility coverage *and* cost sharing for covered fertility services (i.e., deductible, copayment, or coinsurance) that is **not** different from



those imposed on other benefits. Coverage by type of procedure varies substantially. While the majority of enrollees (76%) have coverage for female and male diagnostic tests, about 42% have coverage for female medication prescriptions for infertility and 23% have coverage for IVF and ICSI.

Postmandate, benefit coverage for fertility services would increase to 100% for all enrollees with health insurance subject to AB 2029.

#### Utilization

IVF utilization at baseline is approximately 1 procedure per 1,000 enrollees and 1 procedure per 1,000 enrollees for ICSI. CHBRP's IVF utilization data are defined by services per 1,000 enrollees, rather than by users, thus CHBRP is unable to identify users of more than 4 oocyte retrievals. However, literature suggests that most users of IVF complete fewer than four cycles of IVF.

With regards to other fertility services, the highest utilization is of diagnostic tests and medication prescriptions for infertility. For females at baseline there are 31 diagnostic tests per 1,000 enrollees and 24 prescriptions for infertility medications per 1,000. For males, there are about 13 diagnostic tests, treatments, and medications per 1,000 enrollees. IUI is used at a rate of about 2 procedures per 1,000 enrollees. Some enrollees may use multiple services. For example, enrollees who use IVF also use prescription medications and may also receive diagnostic tests. CHBRP is not able to identify this overlap in utilization.

Of services provided at baseline, approximately 60% of IVF and ICSI services are not covered, in contrast to 24% to 26% of diagnostic tests for females and males.

In addition to the shift of fertility benefits from not covered to covered, additional utilization would occur among enrollees who were previously not using fertility services. Postmandate, CHBRP estimates IVF utilization rises to about 2 procedures per 1,000 with a similar increase for ICSI. For both ICSI and IVF, these changes reflect an 80% increase in utilization postmandate. The increases in utilization postmandate for all other services are lower than the increases estimated for IVF and fall in the range of a 3% to 19% increase, which is expected not only because coverage for these services at baseline is greater but also because with the availability of IVF as a covered service postmandate, utilization would shift towards IVF.

#### Expenditures

AB 2029 would increase total net annual expenditures by \$714,800,000 or 0.48% for enrollees with DMHC-

regulated plans and CDI-regulated policies. This is due to a \$957,449,000 (0.72%) increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, an increase of \$44,921,000 in enrollee cost sharing for covered benefits, and a decrease of \$287,570,000 in enrollee expenses for noncovered benefits.

The largest premium increases are among DMHC-regulated small-group plans (1.1%), DMHC-regulated individual plans (1.0%), and CDI-regulated individual policies (1.1%).

It is important to note that the increase in premiums stem from both increases in utilization of (1) fertility services as mandated by AB 2029 and (2) pregnancies and births for which AB 2029 does not change coverage. About 74% of increase in premiums is attributable to the increase in fertility services and about 26% is attributable to increases in pregnancy-related services.

#### Figure B. Expenditure Impacts of AB 2029



Source: California Health Benefits Review Program, 2022.

#### Enrollee expenses

Impacts on enrollee out-of-pocket expenses can be classified in the following way:

- For the enrollees who do not have fertility coverage at baseline and are using fertility services paid for entirely out of their own pocket, enrollee out-of-pocket expenses for these noncovered benefits decrease postmandate given these enrollees would be covered when using fertility services postmandate.
- For enrollees who have coverage for fertility services at baseline but have cost sharing that is more than for other benefits (e.g., 50% coinsurance and no annual out-of-pocket maximum), postmandate these enrollees would experience reduced out-of-pocket expenses.



• For enrollees who do not have coverage for fertility services at baseline and are not using these services due to cost barriers, postmandate out-of-pocket expenses would increase given their new utilization.

Postmandate, average cost sharing per service for covered benefits would mostly decrease, because cost sharing would be limited to the same structure as for other benefits. The majority of enrollees with coverage for infertility treatments at baseline have cost sharing that is higher than that for other benefits, such as a 50% coinsurance. As a result, average cost sharing for IVF, ICSI, and IUI procedures would decrease by 73% to 74% postmandate, from \$7,350 to \$1,940 for IVF, \$740 to \$190 for ICSI, and \$260 to \$70 for IUI.

However, at the per member per month (PMPM) level, cost sharing for covered benefits in the form of deductibles, coinsurance, and copayments would mostly increase given greater utilization of fertility services and due to the change in noncovered services becoming covered postmandate (Figure B). The enrollee expenses for noncovered benefits decreases, offsetting all increases in cost sharing for covered benefits (Figure B). Changes range between a reduction of \$0.52 PMPM for large-group DMHC-regulated plans and an increase of \$1.99 for CDI-regulated individual market policies.

#### **Pregnancy-Related Offsets**

CHBRP estimates an increase in 7,000 pregnancies due to the increase in fertility services postmandate, a 54% increase from baseline. This results in an additional 6,000 live birth deliveries due to increases in utilization of fertility services postmandate (a 55% increase from baseline), of which 3.4% are twin deliveries and 0.2% are 3+ multiple births. This reflects the lower rate for multiple births (i.e., more than twins) for enrollees with coverage for fertility services.

The average cost of pregnancies and deliveries from fertility services would decrease by \$1,000, which is a 3% reduction from baseline, because of the reduction in higher-cost twin/multiples deliveries.

#### Medi-Cal

Beneficiaries in DMHC-regulated Medi-Cal managed care plans do not have coverage subject to AB 2029. Therefore, there is no impact for these beneficiaries.

## CalPERS

Among publicly funded DMHC-regulated CaIPERS HMOs, the premium increase is 0.86% (\$50,650,000). PMPM, total premiums would increase by \$5.77. Enrollees using fertility services would experience a reduction in expenses for noncovered benefits of \$1.30 PMPM.

#### **Covered California – Individually Purchased**

Premiums for enrollees in individual plans purchased through Covered California would increase by \$185,158,000 or 1.05%. PMPM, premiums would increase by \$7.13 (DMHC-regulated plans) or \$6.55 (CDI-regulated policies) and expenses for noncovered benefits would decrease by \$2.77 (DMHC-regulated plans) or \$2.72 (CDI-regulated policies).

#### Number of Uninsured in California

The change in average premiums exceeds 1% for DMHC-regulated small-group and individual plans and for CDI-regulated individual plans; however, when split into premiums stemming from fertility services versus pregnancies and births, the average change in premiums from fertility services is below 1%. CHBRP expects potential premium increases might be applied by health plans and policies in different years subsequent to the mandate, thus premium increases would likely be spread out. It is unclear how these increases in premiums could translates into uninsurance postmandate since not all of the increase is transferred to the enrollee.

# **Medical Effectiveness**

The medical effectiveness review summarizes the following findings from evidence: (1) the medical effectiveness and harms of IVF (i.e., the treatment newly mandated) and (2) the impact of health insurance mandates requiring coverage for fertility treatments on health outcomes. CHBRP finds there is:

- *Clear and convincing*<sup>3</sup> evidence that IVF is an effective treatment for infertility, resulting in increased pregnancy rates and birth rates.
- A preponderance of evidence<sup>4</sup> that certain harms are increased among children conceived via IVF, including preterm birth, low birthweight, certain congenital malformations, and infant

<sup>&</sup>lt;sup>3</sup> *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.

<sup>&</sup>lt;sup>4</sup> *Preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.



death. However, it is important to note that risk for some harms is higher for multiple gestation pregnancies; these outcomes can be mitigated by single-embryo transfers.

- Clear and convincing evidence that infertility treatment health insurance mandates are associated with an increase in utilization of infertility treatments.
- Clear and convincing 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.
- Clear and convincing evidence that IVF mandates are associated with lower pregnancy rates resulting from IVF postmandate compared to baseline (due to a decrease in embryos transferred), and a lower likelihood of other adverse birth outcomes, including rates of multiple births.

# **Public Health**

#### Mental Health and Quality of Life

CHBRP found evidence that mental health and quality of life would improve for the additional 6,000 persons and couples who would have live birth deliveries resulting from infertility treatments postmandate. CHBRP also found evidence that engaging in infertility treatments may result in short-term psychosocial harms; evidencebased literature also indicates that the inability to have wanted children is associated with stress, anxiety, depression, and quality-of-life deficits that decreases upon the achievement of a successful pregnancy through treatment.

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 attempting 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**

CHBRP estimates that AB 2029 would decrease the rate of multiple gestation pregnancies such that for enrollees without coverage for IVF, 6.7% are twin births and 0.3% are multiple births (i.e., more than twins) versus for enrollees with IVF coverage 4.5% are twin births and 0.2% are multiple births. By limiting IVF to single-embryo transfers and by decreasing the financial barrier to IVF that has previously encouraged multiple embryos transferred in a single IVF cycle, there would be a decrease in harms associated with multiple gestation pregnancies for enrollees accessing IVF treatments.

For enrollees who experience multiple gestation pregnancies, the risks associated with IVF and infertility treatments remain unchanged. However, the benefits of IVF may outweigh the risks for persons who desire a child.

#### **Impact on Disparities**

There is evidence that state health insurance mandates for fertility services increase utilization of infertility treatments for Black and Hispanic women; however, the disparity between White women and Black and Hispanic women persist despite increased access to IVF through health insurance coverage for infertility treatments. Therefore, CHBRP projects that by covering infertility treatments for all commercially insured enrollees, AB 2029 would result in increased IVF utilization by persons of all races/ethnicities but would have no impact on the disparity in IVF utilization between White persons and persons of other racial backgrounds among persons with commercial insurance. However, AB 2029 excludes Medi-Cal beneficiaries enrolled in DMHC-regulated plans for mandated coverage for infertility treatments, including IVF. In excluding Medi-Cal, a significant portion of Black and Hispanic persons and low-income persons in California would continue to face high out-of-pocket and uncovered costs for infertility treatment, which could potentially exacerbate racial/ethnic and income-related disparities in infertility treatment use and infertility outcomes.

Additionally, CHBRP projects that AB 2029's more inclusive definition of infertility would increase access to infertility care for single persons and same-sex couples and would reduce disparities in infertility treatment by gender identity and sexual orientation. It should be noted that the implementation of AB 2029 would not eliminate all financial disparities in infertility treatment between same-sex couples/single persons and opposite-sex couples, as there could still be a disparity between male and female same-sex couples or single persons compared to couples who do not need donor materials, surrogates or gestational carriers.

To the extent that the mandated coverage would reduce 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 would be distributed across income-levels and how different cost-sharing requirements impact persons of varying income levels, therefore the reduction in income-



related disparities in access to fertility treatments is unknown.

## **Long-Term Impacts**

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

Insurance coverage for IVF is associated with fewer medically unnecessary multiple-embryo transfers and ongoing insurance coverage would be associated with a sustained reduction in multiple-embryo transfer. Therefore, in future years as in the first year postmandate, fewer multiple-embryo transfers would be associated with fewer multiple gestation pregnancies, fewer multiple births, and fewer maternal and offspring harms that are associated with multiple gestation pregnancies and multiple deliveries. Some of these maternal and offspring harms could have long-term health impacts and these would then be avoided.

For couples who experience infertility, AB 2029 could prevent long-term negative mental health outcomes associated with infertility and not being able to have a desired child to the extent that AB 2029 allows access to IVF that was previously inaccessible due to financial barriers and that assisted reproductive technology (ART) treatments are successful and result in live birth.

# **Essential Health Benefits and the Affordable Care Act**

AB 2029 would require coverage for a new state benefit mandate that appears to exceed the definition of Essential Health Benefits (EHBs) in California. 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 EHBs. Coverage for infertility treatment required by mandate (not resulting pregnancies and births), as would be required if AB 2029 were enacted, could trigger this requirement and so require the state to defray related costs.

Total estimates for the state range between \$224,739,000 (\$3.93 PMPM) and \$235,557,000 (\$4.12 PMPM).

# A Report to the California State Legislature

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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 <u>www.chbrp.org.</u>

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Table 1. Impacts of AB 2029 on Benefit Coverage,	Utilization, and Cost, 2023
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Baseline	Postmandate	Increase/ Decrease	Percentage Change
22,810,000	22,810,000	22,810,000	22,810,000
14,776,000	14,776,000	0%	0%
23%	100%	77%	336%
			336%
0	14,776,000	14,776,000	
enrollees)	<u> </u>		
-	22	1.0	80%
		-	80%
			6%
-		-	3%
			19%
13.0	13.0	0	0%
<u>.</u>			
\$14 700	\$14 700	\$0	0%
			0%
			0%
·		\$0	0%
\$480	\$590	\$110	23%
\$84	\$84	\$0	0%
or enrollees with cov	erage (c)		
\$7,350	\$1,940	-\$5,410	-74%
\$740	\$190	-\$550	-74%
\$260	\$70	-\$190	-73%
	<b>\$</b> 22	¢10	100%
\$10	\$20	\$10	100 /0
\$10 \$260	\$20 \$80	-\$180	-69%
	Baseline 22,810,000 14,776,000 23% 3,389,928 0% 0 enrollees) 1.2 0.9 2.0 31.8 24.0 13.0 \$1,480 \$14,700 \$1,480 \$510 \$1,480 \$510 \$110 \$480 \$510 \$110 \$480 \$510 \$110 \$480 \$510 \$14,700 \$1,480 \$510 \$1,480 \$14,700 \$1,480 \$510 \$1,480 \$510 \$1,480 \$140 \$100 \$1,480 \$100 \$1,480 \$100 \$1,480 \$100 \$1,480 \$100	Baseline         Postmandate           22,810,000         22,810,000           14,776,000         14,776,000           23%         100%           3,389,928         14,776,000           0%         100%           0%         100%           1.2         2.2           0.9         1.7           2.0         2.2           31.8         32.6           24.0         28.6           13.0         13.0           \$14,700         \$14,700           \$14,80         \$14,80           \$14,80         \$510           \$14,00         \$14,80           \$14,00         \$14,90           \$14,700         \$14,700           \$14,700         \$14,700           \$14,80         \$14,80           \$14,700         \$14,700           \$14,80         \$1,480           \$510         \$510           \$14,80         \$1,480           \$14,80         \$1,480           \$14,80         \$1,480           \$14,80         \$1,480           \$14,700         \$14,700           \$14,80         \$1,480           \$10         \$110<	22,810,000         22,810,000         22,810,000           14,776,000         14,776,000         0%           23%         100%         77%           3,389,928         14,776,000         11,386,072           0%         100%         100%           0%         100%         100%           0%         100%         100%           11,386,072         100%         100%           0%         100%         100%           10         14,776,000         14,776,000           11,2         2.2         1.0           0.9         1.7         0.8           2.0         2.2         0.1           31.8         32.6         0.9           24.0         28.6         4.6           13.0         13.0         0           \$14,700         \$14,700         \$0           \$14,80         \$1,480         \$0           \$14,80         \$1,480         \$0           \$14,80         \$1,480         \$0           \$14,480         \$1,480         \$0           \$14,80         \$1,480         \$0           \$110         \$10         \$0           \$480

Birth outcomes				
Estimated number of pregnancies due to fertility services	13,000	20,000	7,000	54%
Estimated number of live birth deliveries due to infertility	11,000	17,000	6,000	55%
Average 1st year cost of pregnancies and deliveries from fertility services	\$37,000	\$36,000	-\$1,000	-3%
Expenditures				
Premiums (expenditures) by payer				
Private employers for group insurance	\$52,967,575,000	\$53,414,746,000	\$447,171,000	0.84%
CalPERS HMO employer expenditures (d)	\$5,895,476,000	\$5,946,126,000	\$50,650,000	0.86%
Medi-Cal Managed Care Plan expenditures	\$25,989,411,000	\$25,989,411,000	\$0	0%
Enrollee premiums (expenditures)				
Enrollees with individually purchased insurance	\$24,029,788,000	\$24,278,757,000	\$248,969,000	1.04%
Individually purchased – outside Exchange	\$6,324,312,000	\$6,388,123,000	\$63,811,000	1.01%
Individually purchased – Covered California	\$17,705,476,000	\$17,890,634,000	\$185,158,000	1.05%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi- Cal Managed Care (e)	\$24,504,936,000	\$24,715,595,000	\$210,659,000	0.86%
Enrollee out-of-pocket expenses				
Cost sharing for covered benefits (deductibles, copayments, etc.)	\$15,807,011,000	\$15,851,932,000	\$44,921,000	0.28%
Expenses for noncovered benefits (f)	\$287,570,000	\$0	-\$287,570,000	-100%
Total expenditures	\$149,481,767,000	\$150,196,567,000	\$714,800,000	0.48%

Source: California Health Benefits Review Program, 2022.

*Notes:* (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.<sup>5</sup>

(b) Because medications are used during IVF as well as other services, the increase in IVF leads to an increase utilization of more expensive fertility medications. Due to the change in the mix of services and the increase in the number of medications for IVF, the average cost per service increases.

(c) Postmandate, average cost sharing for all covered services decreases, except for female diagnostic services due to the interplay between plan design and the presence of coinsurance for enrollees who would be newly covered (i.e., the presence of coinsurance in the plans that offer new coverage postmandate increases cost sharing). CHBRP does not assume that the cost of individual services would change as a result of AB 2029. CHBRP assumes the mix of services would change, which results in a change in the average cost per service.

(d) Of the increase in CalPERS employer expenditures, about 51.7%, or \$26,186,000 would be state expenditures for CalPERS members who are state employees or their dependents. About one in four (24.8%) of these enrollees has a pharmacy benefit not subject to DMHC. CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(e) 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.

(f) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. 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.

<sup>&</sup>lt;sup>5</sup> For more detail, see CHBRP's *Estimates of Sources of Health Insurance in California for 2023*, a resource available at <u>http://chbrp.org/other\_publications/index.php</u>.

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

# **POLICY CONTEXT**

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)<sup>6</sup> conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 2029, Treatment of Infertility. AB 2029 was amended on April 6<sup>th</sup> and the Assembly Committee on Health requested CHBRP incorporate these amendments into the analysis of AB 2029.

# **Bill-Specific Analysis of AB 2029, Treatment of Infertility**

#### Bill Language, as Amended on April 6, 2022

AB 2029 would require commercial and CalPERS health plans and policies to *provide* "coverage for the diagnosis and treatment of infertility and fertility services." Health plans and policies must include the notice of coverage in the plan's evidence of coverage (EOC) materials. Medi-Cal managed care plans and the health insurance of employees of religious employers are not subject to AB 2029. The full text of AB 2029 can be found in Appendix A.

Current law requires most group health plans and policies to *offer<sup>7</sup>* coverage for the treatment of infertility, excluding in vitro fertilization (IVF).

#### Definition of infertility

Current law<sup>8</sup> 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 2029 amends the definition of infertility to state infertility means "a disease or condition characterized by any of the following:

- A licensed physician's findings, based on a patient's medical, sexual, and reproductive history, age, physical findings, diagnostic testing, or any combination of those factors. This definition shall not prevent testing and diagnosis of infertility prior to the 12-month or 6-month period to establish infertility in paragraph (3);
- (2) A person's inability to reproduce either as an individual or with their partner without medical intervention; or
- (3) The failure to establish a pregnancy or carry a pregnancy to live birth after regular, unprotected sexual intercourse. For the purposes of this section, 'regular, unprotected sexual intercourse' means no more than 12 months of unprotected sexual intercourse for a person under 35 years of age or no more than 6 months of unprotected sexual intercourse for a person 35 years of age or

<sup>&</sup>lt;sup>6</sup> CHBRP's authorizing statute is available at <u>www.chbrp.org/about\_chbrp/faqs/index.php</u>.

<sup>&</sup>lt;sup>7</sup> "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.

<sup>&</sup>lt;sup>8</sup> H&SC Section 1374.55 and IC Section 10119.6.

older. Pregnancy resulting in miscarriage does not restart the 12-month or 6-month time period to qualify as having infertility."

#### 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 2029 does not include a definition of "treatment for infertility."

However, AB 2029 does specify that coverage for the diagnosis and treatment of infertility and fertility services includes four completed oocyte retrievals with unlimited embryo transfers in accordance with the guidelines of the American Society for Reproductive Medicine (ASRM), using single-embryo transfer when recommended and medically appropriate.

#### Terms and conditions

AB 2029 places the following restrictions on coverage for fertility services.

- Any exclusion, limitation, or other restriction on coverage for fertility medications that are different from those imposed on other prescription medications.
- Any exclusion, limitation, or other restriction on coverage for any fertility services based on a
  covered individual's participation in fertility services provided by or to a third party. Third party is
  defined as "an oocyte, sperm or embryo donor, a gestational carrier or surrogate that enables
  intended recipient(s) to become a parent(s)."
- Any deductible, copayment, or coinsurance for fertility services that is different from those imposed on other benefits.
- A benefit maximum, waiting period, or any other limitation for fertility services that is different from those imposed on other benefits.

#### Discrimination clause

The current mandate to offer includes a nondiscrimination clause that states coverage for the treatment of infertility and fertility services shall be "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 subdivision shall not be construed to interfere with the clinical judgment of a physician and surgeon." This clause remains generally unchanged in AB 2029.

#### Religious exemption

Current California 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 2029 includes an exemption for religious employers, as defined by current law.

#### **Relevant Populations**

If enacted, AB 2029 would apply to the health insurance of approximately 14,776,000 enrollees (38% of all Californians). This represents 64% of the 22,810,000 million Californians who will have health

insurance regulated by the state that may be subject to any state health benefit mandate law, which includes health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would apply to the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies, exempting DMHC-regulated Medi-Cal managed care plans.

#### **Religious exemption**

As with California's current mandate to offer fertility coverage, religious employers as defined by current law are exempt from AB 2029. Religious employers are those whose primary purpose is the inculcation of religious values and that meet other specifications.<sup>9</sup>

CHBRP is unable to estimate the number of enrollees in plans or policies purchased by religious employers, although the number is likely small. Should some or all employers/plan sponsors exercise the religious exemption and exclude coverage, the projected impacts in CHBRP's may be reduced.

# **Analytic Approach and Key Assumptions**

CHBRP previously analyzed similar bill language, AB 767 Infertility in 2019 and AB 2781 Treatment of Infertility in 2020. Where applicable, this analysis builds off of those previous analyses.

#### **Definition of Infertility for Analysis of AB 2029**

There are multiple definitions of infertility (see Appendix D), including those provided by existing law, AB 2029, insurers' medical policies, national surveys, and clinical societies.

When using "infertility" throughout this report, CHBRP refers to AB 2029's definition of infertility, unless otherwise specified.<sup>10</sup>

By broadening the definition of infertility, AB 2029 encompasses a wider population eligible to be diagnosed with infertility. This definition recognizes infertility in enrollees regardless of their conception-related intentions and for whom timeframe restrictions are not meaningful, such as single persons, same-sex couples, transgender persons, and persons who are medically or surgically sterile for noncontraceptive reasons. 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. CHBRP assumes AB 2029's definition of infertility would encompass single women, single men, same-sex couples, and transgender persons, enabling them to receive coverage for infertility treatments.

#### **Treatment for Infertility**

CHBRP assumes all nonexperimental infertility treatments would need to be covered for a plan to be in compliance with AB 2029. These services include diagnosis, medications, surgery, artificial insemination (such as intrauterine insemination [IUI]), IVF, and IVF with intracytoplasmic sperm injection (ICSI). Genetic testing of embryos would only be covered if necessary for the diagnosis and treatment of

<sup>&</sup>lt;sup>9</sup> Religious employers eligible for exemptions include an entity (1) whose purpose is the inculcation of religious values, (2) that primarily employs persons who share the entity's religious tenets, (3) that primarily serves persons who share the entity's religious tenets, (3) that primarily serves persons who share the entity's religious tenets, and (4) that is a nonprofit organization. These qualifications mirror those for a religious employer eligible for exemption in prior federal rules. A religious employer that invokes the exemption must provide written notice to prospective plan enrollees and must list the health care services that the employer will not cover for religious reasons.

<sup>&</sup>lt;sup>10</sup> 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 due to data sources are described and cited when necessary.

infertility per ASRM guidance. More information about nonexperimental infertility treatments is included in the *Background on Infertility* section.

CHBRP assumes AB 2029 does not require storage of frozen materials unless included as part of the infertility treatment (such as between the oocyte retrieval/fertilization and the first successful embryo transfer).

Gamete intrafallopian transfer (GIFT) and zygote intrafallopian transfer (ZIFT) have mostly been replaced by IVF. Therefore, CHBRP does not incorporate utilization of GIFT and ZIFT into the cost impact projections.

#### **Changes to Terms and Conditions**

#### Fertility medications

CHBRP assumes that should a health plan or policy place limitations on other prescription medications, such as limits on quantity distributed at one time, the number of yearly prescriptions, lifetime limits, or other such restrictions, plans and policies could place similar limits on fertility medications.

#### Fertility services provided by or to a third party

AB 2029 specifies that coverage for fertility services cannot be restricted based on a covered individual's participation in fertility services provided by or to a third party, as defined.

It is unclear whether AB 2029 would require coverage for biologic donor materials, gestational carriers or surrogacy services, or medical costs for the utilization of gestational carriers or surrogates. Should regulators interpret AB 2029 to require coverage for these services, additional expenditures would be expected.

- One interpretation is that, should an enrollee use "third party assisted reproduction" and engage a gestational carrier or surrogate to carry the pregnancy, fertility services provided to the enrollee (such as oocyte retrieval and fertilization of the oocyte) would be covered, while the services provided to the surrogate would not be covered (embryo transfer). Additionally, if an enrollee uses biologic material from a donor, any services performed for the enrollee (such an embryo transfer) would be covered.
- Another interpretation is that AB 2029 would require coverage for medical services provided to a
  third party if the enrollee's fertility treatment requires either biological donor materials or the use
  of a gestational carrier or surrogate. In this interpretation, CHBRP assumes only medical services
  related to third-party services would be covered (e.g., procuring a donated oocyte, embryo
  transfer to the gestational carrier); additional service fees paid to surrogates or gestational
  carriers, or for biologic donor materials would not be covered.

Due to the lack of clarity in the AB 2029 amended language for this section, CHBRP has modeled the first interpretation of bill language, and discusses the second qualitatively throughout.

Enrollees who are single, in same-sex relationships, or are transgender, may need to use these options, in addition to some enrollees who are in opposite-sex relationships. It is unclear whether not covering donor materials, surrogacy/gestational carrier services, or storage of biologic materials would be discriminatory based on AB 2029's definition of infertility and the discrimination clause.

#### Cost sharing

AB 2029 specifies the cost sharing (deductibles, coinsurance, copayments) cannot be different from those of other benefits. Currently, many fertility benefits are provided through a rider, a separate policy purchased by employers for their employees. These riders often include different cost-sharing policies,

including a 50% coinsurance. Additionally, because these fertility benefits are purchased in addition to "major medical" benefits,<sup>11</sup> they do not count towards the deductible and annual out-of-pocket maximums.

AB 2029 would require that cost sharing is the same as major medical. This means that fertility services would apply to the deductible and annual out-of-pocket maximums, thereby not only limiting enrollee costs at the time of service, but enrollee expenses would also be subject to an overall out-of-pocket maximum. This would cap an enrollee's total annual out-of-pocket costs for fertility services and other health care services obtained within the same plan year.

#### Benefit maximums, waiting periods, or other limitations

AB 2029 additionally specifies that the benefit maximums, waiting periods, or other limitations cannot be different from other benefits. The Affordable Care Act (ACA; see more below) prohibits lifetime or annual benefit maximums for services that are considered essential health benefits (EHBs) for most health plans and policies.<sup>12</sup> Infertility riders may include a benefit maximum of a certain number of oocyte retrievals or embryo transfers, or will cap expenses at a certain dollar amount. These limits would be prohibited except as specified by the bill language (limit of four oocyte retrievals).

#### **Other Key Assumptions**

AB 2029 would not require coverage for fertility preservation services, for example, used when a woman freezes embryos or oocytes for potential future use as a way to increase the chances of having a successful pregnancy at a later time or when a person freezes sperm or oocytes prior to medical treatment that could lead to infertility (such as for cancer or gender-affirming care).

AB 2029 does not include an upper age bound for the coverage for fertility services. CHBRP assumes if medically appropriate, services for enrollees older than 44 years would be covered (reproductive age range is typically defined as ages 15 to 44 years for women with no upper age limit for men). More information about reproductive capability by age is included in the *Background* section.

Due to changes in the bill language and baseline population estimates within CHBRP's cost and coverage model, the utilization and expenditures in the analysis of AB 2029 cannot be compared to the utilization and expenditure estimates in CHBRP's analyses of AB 767 conducted in 2019 or AB 2871 conducted in 2020.

## **Interaction With Existing State and Federal 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 treatments, 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

<sup>&</sup>lt;sup>11</sup> "Major medical" benefits are typically classified as hospital, surgical, and ambulatory medical services.

<sup>&</sup>lt;sup>12</sup> <u>https://www.hhs.gov/healthcare/about-the-aca/benefit-limits/index.html</u>

at an additional cost (e.g., a rider). "Mandate to cover" means that all health insurance subject to the law must cover the benefit.

CHBRP reviewed the state's DMHC Independent Medical Review (IMR) determinations for inclusion of fertility services to treat infertility for years 2018 to March 2022. Six health plan decisions were upheld in instances where enrollees requested coverage for infertility treatments, either due to insufficient medical evidence or advanced maternal age and the likelihood of success. Four health plan decisions were upheld because the enrollee did not meet the medical definition of infertility. Another four health plan decisions were overturned because reviewers determined there was medical evidence to support the requested services to diagnose or treat infertility.

Governor Newsom signed SB 600<sup>13</sup> in 2019, which states standard fertility preservation services for persons at risk of experiencing iatrogenic infertility (infertility caused by medical treatments, such as chemotherapy) are a basic health care service, such as semen and oocyte retrieval and potentially storage for the materials. SB 600 does not require coverage for services to treat infertility, should an enrollee experience iatrogenic infertility, and decide to use the preserved reproductive materials. Coverage for the treatment for iatrogenic infertility would fall under AB 2029.

For an overview of existing California law compared with AB 2029, please see Appendix D.

#### Similar requirements in other states

Currently, 17 states have laws that require insurance companies to *cover* infertility treatments and two states — California and Texas — have laws that require insurance companies to *offer* coverage for infertility treatments (Figure 1) (KFF, 2020).

Among the 19 states with infertility treatment mandates, eight states have fertility mandates that do not include coverage for IVF (California, Louisiana, Montana, New Hampshire, Ohio, Texas, Utah, and West Virginia). Eleven states include requirements for complete IVF coverage; nine of these states have comprehensive IVF coverage (Connecticut<sup>14</sup>, Colorado, Delaware<sup>15</sup>, Illinois<sup>16</sup>, Maryland<sup>17</sup>, Massachusetts, New Jersey<sup>18</sup>, New York<sup>19</sup>, and Rhode Island<sup>20</sup>), and two states include specific limits on the coverage for IVF (Arkansas caps benefits at \$15,000 per lifetime; Hawaii covers one cycle of IVF).

Additionally, New Hampshire's 2020 law includes coverage for medical expenses for third-party services, including medical costs related to procuring biologic donor materials (semen or oocyte) and some medical costs related to surrogacy (costs



*Source:* California Health Benefits Review Program, 2022. Adapted from Peipert, 2022.

<sup>&</sup>lt;sup>13</sup> H&SC 1374.551.

<sup>&</sup>lt;sup>14</sup> Limit of 4 cycles of ovulation induction.

<sup>&</sup>lt;sup>15</sup> Limit of fewer than 6 oocyte retrievals.

<sup>&</sup>lt;sup>16</sup> Limit to 6 oocyte retrievals.

<sup>&</sup>lt;sup>17</sup> Limit to 3 cycles of IVF and lifetime maximum of \$100,000.

<sup>&</sup>lt;sup>18</sup> Limit of 4 oocyte retrievals per lifetime.

<sup>&</sup>lt;sup>19</sup> Limit of 3 cycles of IVF.

<sup>&</sup>lt;sup>20</sup> Lifetime limit of \$100,000.

associated with fertilization).<sup>21</sup> The law does not include coverage for the embryo transfer into the surrogate or any nonmedical expenses.

Other examples of unique state laws are Louisiana, which prohibits 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.

Ten states have introduced infertility mandate legislation or legislation modifying existing infertility mandates in 2022: Illinois, Maryland, Minnesota, New Jersey, Oregon, Pennsylvania, Virginia, Washington, West Virginia, and Wisconsin (RESOLVE, 2022). Noticeable differences in legislation include: New Jersey's introduced bill would require coverage for intrauterine insemination, in addition to the existing infertility mandate; Pennsylvania's introduced bill would require coverage for fertility services without cost-sharing, including gestational carriers; and four state bills include mentions of third-party language, similar to language included in the introduced version of AB 2029 (Illinois, Virginia, Washington, and Wisconsin).

California previously introduced similar legislation to AB 2029 in 2021, AB 797, in addition to bills previously analyzed by CHBRP and mentioned above.

#### **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 2029 may interact with requirements of the ACA as presently exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).22,23

#### Prohibition on Annual and Lifetime Limits

The ACA prohibits annual and lifetime dollar limits on most covered benefits for most plans and policies.<sup>24</sup> Grandfathered individual health plans and policies are exempt from the annual benefit limits requirement. Benefits that are not considered EHBs are not subject to the prohibition of annual and lifetime limits.

<sup>&</sup>lt;sup>21</sup> New Hampshire Surrogacy Law, http://nhsurrogacy.com/new-hampshire-health-insurance-surrogacy/.

<sup>&</sup>lt;sup>22</sup> 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. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other\_publications/index.php.

<sup>&</sup>lt;sup>23</sup> Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law. <sup>24</sup> <u>https://www.hhs.gov/healthcare/about-the-aca/benefit-limits/index.html</u>

#### **Essential Health Benefits**

In California, nongrandfathered<sup>25</sup> individual and small-group health insurance is generally required to cover EHBs.<sup>26</sup> In 2023, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs.<sup>27</sup>

States may require state-regulated health insurance to offer benefits that exceed EHBs.<sup>28,29,30</sup> Should California do so, the state could be required to defray the cost of additionally mandated benefits for enrollees in health plans or policies purchased through Covered California, the state's health insurance marketplace. However, state benefit mandates specifying provider types, cost sharing, or other details of existing benefit coverage would not meet the definition of state benefit mandates that could exceed EHBs<sup>31</sup> and CHBRP is unaware of any state mandate passed into law that has been determined to exceed EHBs.

#### AB 2029 could be interpreted to exceed the EHBs for the following reasons:

- AB 2029 would apply to small-group and individual market qualified health plans (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.
- 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." AB 2029 would appear to meet this federal definition.

As outlined above, AB 2029 would require coverage for a new state benefit mandate that appears to exceed the definition of EHBs in California. Additional information about the potential costs of exceeding EHBs is included in the *Benefit Coverage, Utilization, and Cost Impacts* section.

As mentioned above, Colorado recently passed a fertility mandate that would apply to QHPs. The legislature introduced a bill in 2022 that would only implement the provisions of the bill that impact QHPs if the federal government determines the fertility mandate does not exceed EHBs.<sup>32</sup>

<sup>&</sup>lt;sup>25</sup> A grandfathered health plan is "a group health plan that was created – or an individual health insurance policy that was purchased – on or before March 23, 2010. Plans or policies may lose their 'grandfathered' status if they make certain significant changes that reduce benefits or increase costs to consumers." Accessed at: www.healthcare.gov/glossary/grandfathered-health-plan.

<sup>&</sup>lt;sup>26</sup> For more detail, see CHBRP's issue brief, *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits*, available at <u>https://chbrp.org/other\_publications/index.php</u>.

<sup>&</sup>lt;sup>27</sup> See CHBRP's resource, *Estimates of Sources of Health Insurance in California* and CHBRP's issue brief *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits: An Update and Overview of New Federal Regulations*, both available at <u>https://chbrp.org/other\_publications/index.php</u>.
<sup>28</sup> ACA Section 1311(d)(3).

<sup>&</sup>lt;sup>28</sup> ACA Section 1311(d)(3).

<sup>&</sup>lt;sup>29</sup> 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: <a href="http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf">www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf</a>.

<sup>&</sup>lt;sup>30</sup> 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.

<sup>&</sup>lt;sup>31</sup> 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.

<sup>&</sup>lt;sup>32</sup> https://leg.colorado.gov/bills/hb22-1008

# **BACKGROUND ON INFERTILITY**

Infertility is the inability to have a child and is a complex condition that can take many forms. 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 experience difficulty having another), either of which may be related to the inability to become pregnant or successfully carry a pregnancy to term. Infertility can have many causes including medical conditions, as the result of medical treatments (such as for cancer), or because it is not possible for the individual or couple to become pregnant without intervention (such as for single persons or same-sex couples). 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 United States — may experience infertility treatment success using donor materials (ACOG, 2014). 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.<sup>33</sup>

# **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).<sup>34</sup>

As defined by the NSFG:

*-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).

*-Impaired fecundity is the difficulty conceiving or carrying a pregnancy to term once pregnant* among women of any relationship status or sexual orientation within a 3-year period.

<sup>&</sup>lt;sup>33</sup> Men produce sperm throughout their lives, and it is thought there is no maximum age at which it is not possible for a male to father a child.

<sup>&</sup>lt;sup>34</sup> The NSFG consists of nationally representative data gathered from in-person interviews with males and females aged 15–44 years for cycles 2006–2015 and 15–49 years for cycles 2015-2019, administered by trained interviewers. Only one person per household was interviewed.

As AB 2029 is broadly inclusive of all persons experiencing infertility, regardless of timeframe, marital status, or cause, and this definition aligns more closely with the NSFG's definition of impaired fecundity.<sup>35</sup> Below, CHBRP presents prevalence of both infertility and impaired fecundity.

#### Females

Results of the 2015–2019 cycles of the NSFG (Table 2) indicate that almost 14% of all women aged 15 to 49 years with no live births in the United States have impaired fecundity (primary impaired fecundity) and 19% of all married women with no live births are infertile (primary infertility) (NSFG, 2021). Among women who have had a birth and later experience infertility (secondary infertility), 6% of married or cohabitating women who had one or more previous births are now infertile, and 13% of women aged 15 to 44 years who had one or more previous births now have impaired fecundity (secondary impaired fecundity) (NSFG, 2021).

Table 2. Prevalence of Infertility and Impaired Fecundity Among Women Aged 15–49 Years by Age
Group and Parity, National Survey of Family Growth Cycles 2015–2019

	Infertility Among Women Co- Habitating with Opposite Sex Partners, (within a year) % (a)		Impaired Fecundity Among Women of Any Relationship Status (within 3 years), % (b)		
	Primary (0 births)	Secondary (1 + births)	Primary (0 births)	Secondary (1 + births)	
Overall	19.4	6.0	13.8	13.1	
Age group, years					
15–29	12.6	5.1	9.2	12.0	
30–39	22.1	5.7	22.2	12.2	
40-49	26.8	6.5	33.4	14.5	

Source: National Survey of Family Growth (NSFG, 2021).

Note: Estimates of infertility may reflect the fertility status of a respondent's partner as well their own.

(a) Includes married women; infertility includes women who are not surgically sterile and have at least 12 consecutive months of unprotected sexual intercourse without becoming pregnant.

(b) Includes women of all marital statuses; includes women who are not surgically sterile, and for whom it is difficult to get pregnant or carry a pregnancy to term once pregnant, within a 3-year period.

#### 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 to 44 years,<sup>36</sup> 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 2015–2019 NSFG were not yet available; however, 9.4% of men aged 15 to 44 years reported some type of impaired fertility in the

<sup>&</sup>lt;sup>35</sup> Persons who are surgically sterile for *noncontraceptive* 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.

<sup>&</sup>lt;sup>36</sup> 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.

2006–2011 NSFG; of those, a little over half (5.2%) of men were subfertile<sup>37</sup> and just under half (4.2%) were nonsurgically sterile (Chandra et al., 2013). The Assisted Reproductive Technology (ART) Fertility Clinic and National Summary Report (2019) shows that 27.5% of ART usage is due to male factor infertility (CDC, 2019b).

# **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). Infertility can be congenital or arise during a person's lifetime including due to cancer treatment or gender-affirming care. See Appendix D for the causes of infertility among females, males, transgender, and nonbinary persons.

Treatments for infertility can target the cause of infertility, and many treatments, including IVF, are options for a number of different causes of infertility.

#### **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, 6 months of unprotected intercourse for women over 35 years of age, and for any women 40 years of age and older (ASRM, 2021). 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, 2021). After semen analysis, males maybe be additionally evaluated using endocrine evaluation, post-ejaculation urinalysis, or ultrasonography of the scrotum or genital tract to identify structural abnormalities (Schlegel et al., 2020).

In the 2006–2010 cycle of the NSFG, 7.3% of women and 5.3% of men aged 25 to 44 years reported that either they or their partners had ever undergone tests to diagnose infertility (Chandra et al., 2014; NSFG, 2017b). In 2015–2019, 5.6% of women aged 15 to 49 years reported infertility tests for man or woman (NSFG, 2021).

<sup>&</sup>lt;sup>37</sup> "Subfertility generally describes any form of reduced fertility with prolonged time of unwanted non-conception". (Gnoth et al., 2005).

#### **Treatments for Infertility**

There are a number of treatment options consistent with established medical practice for women and men seeking medical help to achieve a pregnancy (ASRM, 2020; CDC, 2019a).

Common treatments for infertility:

• **Medical advice:** 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.

#### **Common Infertility Treatment Acronyms**

- ART: assisted reproductive technology ASRM: American Society for Reproductive Medicine ICI: intracervical insemination ICSI: intracytoplasmic sperm injection IUI: intrauterine insemination IVF: in vitro fertilization PGT: preimplantation genetic testing
- **Medications:** In general, medications are used to time or stimulate the release of oocytes (ovulation) or stimulate greater egg production in instances of abnormal ovarian function where ovulation is reduced. They can also be used in some cases of male factor infertility. Medications are often used in combination with intrauterine insemination (IUI). There are also medications that are used as part of IVF (described below).
- Artificial insemination: IUI is the most common form of artificial insemination and the deliberate introduction of semen into the uterus. 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 female same-sex couples wishing to conceive. Intracervical insemination (ICI) 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 technology (ART): ART is defined as any procedure in which both the oocyte (egg) and sperm are handled.
  - In vitro fertilization (IVF): This is the most common form of ART. IVF is a multicomponent process in which a woman is given medication injection to induce oocyte maturation; mature eggs (oocytes) are retrieved from the ovaries and then combined (fertilized) with sperm in a culture dish in a laboratory. The resulting embryo or embryos are then transferred into the uterus while fresh or can be frozen for later use (cryopreservation). The uterus can be prepared for embryo transfer with medications or the woman's natural hormones, as medically needed. One cycle of IVF consists of oocyte retrieval, oocyte fertilization, and embryo implantation. If viable oocytes or embryos are available from previous cycles and were frozen for later use (cryopreservation), implantation (or fertilization and then implantation) alone may be used.
    - Optional genetic testing can occur with IVF (preimplantation genetic testing [PGT<sup>38</sup>]) and is often not covered by insurance. However, IVF can be used without genetic testing.
  - 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.
    - Optional genetic testing (PGT) can occur with ICSI and is often not covered by insurance. However, ICSI can be used without genetic testing.

<sup>&</sup>lt;sup>38</sup> If genetic testing is not done pre-implantation, genetic screening or testing can be done on the pregnancy once pregnancy is established and then is often covered under pregnancy health benefits.

Less common treatments for infertility:

#### • Uncommon forms of ART:

- Zygote intrafallopian tube transfer (ZIFT) and gamete intrafallopian tube transfer (GIFT).
- Surgery: With the advent of IVF, surgery is becoming a less common infertility treatment option.
  - 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 specifically for infertility purposes (rather than other medical reasons): Surgery to remove fibroids from the uterus that could interfere with fertility.
  - Endometriosis excision or ablation specifically for infertility purposes (rather than other medical reasons): 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.

#### Single-embryo transfer

Advances in infertility treatments and IVF have made single-embryo transfers the preferred method for the majority of women seeking pregnancy through IVF, especially for women under 38 years of age. Historically, multiple-embryo transfers were valued, but embryological advances during the last 10 years have led to increased selection of quality embryos and better maternal and infant outcomes for single births (Dahan and Tannus, 2020). The ASRM guidelines indicate that infertility treatment plans should be individualized to each patient's unique circumstances, but single-embryo transfer is recommended especially for women aged 37 years or younger, when the use of an euploid<sup>39</sup> embryo is available, and for gestational carriers to reduce the risks associated with multiple gestation pregnancies. Circumstances where more than one embryo may be transferred in a single transfer procedure include older females (patients aged 38–40 years: up to two blastocytes or three untested cleavage-stage embryos; patients aged 41–42 years: up to three blastocytes or four untested cleavage-stage embryos), patients who don't meet favorable prognosis criteria<sup>40</sup>, and favorable patients who fail to conceive after multiple cycles with high-quality embryos (Ethics Committee of the American Society for Reproductive Medicine, 2021c).

Single-embryo transfers are not only associated with better maternal and infant health outcomes compared to multiple-embryo transfers (see Potential Harms From Multiple Births With Infertility Treatment in the Public Health section for outcomes associated with multiple births), but the costs associated with single-embryo transfers are less compared to multiple-embryo transfers. Evidence shows that hospital costs (maternal delivery, hospitalization, initial neonatal admission) associated with births from double-embryo transfers are 2.5 times greater than for births that follow single-embryo transfer (Carpinello et al., 2016a). Additionally, the incremental cost of each baby gained from a double-embryo transfer or greater than three embryo transfers is significantly greater than the cost of one IVF cycle in the United States (Carpinello et al., 2016a).

#### Utilization of treatments

In 2019, 2.1% of all births in the United States resulted from using ART (CDC, 2022). In the 2015–2019 cycle of the NSFG, 12% of women aged 15 to 49 years reported that they had received any type of service to diagnose or treat infertility (NSFG, 2021). Among the same cohort of women, 8.9% used

<sup>&</sup>lt;sup>39</sup> Euploid is the normal number of chromosomes for a species.

<sup>&</sup>lt;sup>40</sup> Favorable prognosis as described by ASRM is "young age, expectation of one or more high-quality embryos available for cryopreservation, euploid embryos, and previous live birth after an IVF cycle" (Ethics Committee of the American Society for Reproductive Medicine, 2021c).

medical help to achieve pregnancy, 6.7% received advice, 5.6% reported infertility tests on woman or man, 4% reported using ovulation drugs, 0.7% had surgery for treatment of blocked fallopian tubes, 1.7% had artificial insemination, 0.5% had ever used any form of ART, and 5.2% had any medical help to prevent miscarriage (NSFG, 2021).

#### Effectiveness of ART treatments

IVF has become the most effective treatment for all causes of infertility, but it is the most invasive and expensive compared to other infertility treatments (ASRM, 2020). Recommendations for unexplained infertility include ovulation-stimulation with oral medications in combination with IUI as first-line therapy with birth rates of 24% to 31% (ASRM, 2020). When this method is unsuccessful after three to four cycles, ART including IVF is recommended with single-embryo transfer preferred when patients meet favorable prognosis (Ethics Committee of the American Society for Reproductive Medicine, 2021c) (see Single Embryo Transfer above). The effectiveness of ART varies by age of the woman. Women over the age of 40 years on average require more oocyte retrievals per live-birth and have lower birth rates after embryo transfer compared to younger women (Table 3). According to one study, the average number of ART cycles needed before a pregnancy success was 3.4 (Katz et al., 2011).

# Table 3. Cumulative Success Rates for ART Intended and Actual Egg (Oocyte) Retrievals Among Patients Using Their Own Eggs in the United States, 2019

	Age of Patient			
All patients (with or without prior ART cycles)	<35	35-37	38-40	>40
Average number of intended retrievals per live-birth delivery (a)(c)	1.9	2.6	4.1	12.6
Percentage of intended retrievals results in live-birth deliveries (a)(c)	52.7%	38.0%	24.4%	7.9%
Percentage of actual retrievals resulting in live-birth deliveries (b)(c)	55.7%	41.5%	27.6%	9.5%
Percentage of embryo transfers resulting in live-birth deliveries (c)	49.7%	44.8%	39.6%	22.6%

Source: CDC, 2019b.

Notes: CDC data from fertility clinics in the United States that report and verify data on the ART cycles started, carried out, and the outcomes of the cycles in their clinics.

(a) "Intended retrievals" is when an ART cycle begins with an attempt to retrieve oocytes.

(b) "Actual retrievals" is when one or more oocytes is successfully retrieved.

(c) Live-birth deliveries include singleton and multiple gestation pregnancies; however, the vast majority are singleton deliveries. *Key:* ART = assisted reproductive technology.

#### Third-Party Reproduction: Donor Materials, Surrogacy, and Gestational Carriers

Egg (oocyte) or sperm donation are necessary when an individual or couple cannot produce their own viable egg or sperm or cannot conceive after attempted infertility treatments using their own egg and sperm. The indications for egg donation for women include advanced reproductive age, diminished ovarian reserve, poor oocyte or embryo quality in prior attempts at IVF, hypothalamic hypogonadism, and the possibility of passing genetic defects (ASRM, 2013b; Dunne, 2020); same-sex male couples or single men would also require egg donation. Sperm donation is necessary when men have no sperm or poor semen analysis, ejaculatory dysfunction, male factor infertility, sexually transmissible infection that cannot be eradicated, female partner is Rh-negative and severely Rh-isoimmunized and male partner is Rh-positive, or there is possibility of passing genetic defects (ASRM, 2013b). Same-sex female couples or single women would also require sperm donation. Transgender and nonbinary persons might also need third-party reproduction depending on their individual reproductive needs. There are additional costs associated when using egg or sperm donation including the payment to the donor for the donation service

and medical procedures, costs for the oocyte retrieval procedure (for egg donation), testing/screening of the eggs or sperm, storage of the egg or sperm, and procedures to produce pregnancy such as with IUI and IVF.

Embryos can also be donated. In ART, embryos are often cryopreserved for later transfer and in some cases, more embryos are cryopreserved than end up being needed by the person or couple who had them cryopreserved. In this case, the embryos may be donated to other persons or couples. Donated embryos can be used when a couple or person cannot produce a viable embryo with their own or donated eggs, sperm, or both, or the cost of these is prohibitive (Finger et al., 2010). There may be associated costs with the thawing, transfer procedure, cycle coordination and documentation, and infectious disease screening and testing of donors and the individual receiving the embryo, but no costs associated with the embryo itself as this is deemed unethical (ASRM, 2013b). (See section on *Marital Status and Sexual Orientation Disparities*.)

In some cases, gestational carriers or surrogacy may be needed to carry a pregnancy to term, for example due to medical conditions that make pregnancy unsafe or for a male-male couple; either donated eggs, sperm, or embryos can be used or the egg and sperm of the couple desiring the child, if viable (Dunne, 2020). Gestational carriers are women who carry the pregnancy of a genetically unrelated fetus through IVF using the intended parent(s)' egg or sperm or donated egg or sperm and IVF (CDC, 2016). Traditional surrogacy is when the woman both carries the pregnancy and donates the egg with either donated or intended parent's sperm utilizing IUI or IVF (Ethics Committee of the American Society for Reproductive Medicine, 2021a; Greenfeld and Seli, 2016). Costs associated with gestational carriers or surrogacy include any costs associated with donated materials (eggs, sperm, or embryos), IVF to create an embryo to implant (if needed), the implantation or insemination procedure, and the gestational carrier's or surrogate's fee and travel fees.

#### Prevalence and effectiveness of third-party donation for IVF

In the United States from 2004 to 2013, 16.1% of all IVF cycles used any kind of third-party donation (oocyte donation, sperm donation, embryo donation, or gestational carrier) with oocyte donation (10.4%) the most common third-party donation method followed by sperm donation (2.7%), gestational carrier (0.9%), and embryo donation (0.6%). Approximately 1.5% of third-party IVF donations utilized multiple third-party methods (Kushnir et al., 2017). Third-party donation is most common among women over age 40 years and White women (Kushnir et al., 2017). In the United States from 2004 to 2013, third-party IVF accounted for 20.4% of all live IVF births,, and the live birth rate for third-party IVF increased from 37.7% in 2004 to 40.5% in 2013 compared to autologous<sup>41</sup> IVF (27% in 2004 to 32% in 2013) (Kushnir et al., 2017).

# Treatment Considerations for Same-Sex Couples, Single Persons, and Transgender and Nonbinary Persons

#### Same-sex couples and single persons

For two women in a relationship or single women, donor sperm will be needed, and if home insemination is not a feasible option, then ICI (in a clinical setting), IUI, or IVF will be needed. There are costs associated with obtaining donor sperm and the procedures for insemination. For two men in a relationship or men who are single, donor eggs and a gestational carrier with IVF or traditional surrogacy with IUI or IVF will be needed (Ethics Committee of the American Society for Reproductive Medicine, 2021a; Greenfeld and Seli, 2016). Costs associated with these treatments are described above.

<sup>&</sup>lt;sup>41</sup> Autologous IVF is when the oocyte is obtained from the women who will carry the pregnancy and fertilized with partner sperm.

#### Transgender and nonbinary persons

ART for transgender and nonbinary persons does not differ from fertility services provided to nontransgender persons (Ethics Committee of the American Society for Reproductive Medicine, 2021d). Many transgender and nonbinary persons want to have children and may need to access fertility services and/or use of third-party donor materials to have a child. Some transgender and nonbinary persons might have completed sperm, oocyte, or embryo cryopreservation prior to gender-affirming medication or surgical care and have these materials available for use with fertility treatments (Ethics Committee of the American Society for Reproductive Medicine, 2021d).

## **Treatment-Associated Financial Burden**

The cost associated with infertility treatments, especially IVF, is the most significant barrier for couples or persons accessing fertility services (Ethics Committee of the American Society for Reproductive Medicine, 2021b; Duffy et al., 2021), regardless of race/ethnicity or insurance status (Insogna et al., 2020).

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 with the use of frozen embryo transfers. 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). 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). A recent study in the United States showed that patients and families requested \$52 million in fertility-related funds via crowdfunding over the last 8 years, which suggests an unmet financial burden associated with fertility expenses (Lai et al., 2021).

For current, California-specific estimates of treatment costs, demand, and utilization, please see Table 1 and the *Benefit Coverage, Utilization, and Cost Impacts* section. For more information on financial barriers to treatment, see the *Socioeconomic Status* section within the *Disparities* section below.

# **Disparities<sup>42</sup> and Social Determinants of Health<sup>43</sup> 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, socioeconomic status, insurance status and SDOH.

<sup>&</sup>lt;sup>42</sup> 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).

<sup>&</sup>lt;sup>43</sup> 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 Office of Disease Prevention and Health Promotion, 2019; CDC, 2014). See CHBRP's SDoH white paper for further information: http://chbrp.com/analysis\_methodology/public\_health\_impact\_analysis.php.

#### **Disparities**

#### Race or ethnicity

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; Ebeh and Jahanfar, 2021; Kelley 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 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, 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. However, Hispanic women were significantly more likely to seek medical advice or infertility testing compared to non-Hispanic women (Janitz et al., 2019). Research indicates that Hispanic women are underrepresented among the population of women receiving ART, have longer wait times for treatment, have concerns of stigma, are less likely to receive treatment, and may have worse outcomes with IVF than White women (Komorowski and Jain, 2022). 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). In a study by Almquist et al. (2021), non-Hispanic Black women had higher rates of insurance coverage but were more likely to discontinue fertility services after an unsuccessful IVF cycle and less likely to have a live birth compared to White women.

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. 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 Potential Harms from Multiple Births with Infertility Treatment 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 women from minority racial/ethnicity groups may contribute to the previously discussed disparity in treatment outcomes, but these cannot explain the full magnitude of the difference (Humphries et al., 2016; Insogna and Ginsburg, 2018).

#### Relationship status, sexual orientation, or gender identity

As described previously, single persons, same-sex couples, and many transgender and nonbinary persons 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, 2017a). 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 with donor oocytes and surrogates (Carpinello et al., 2016b; Grover et al., 2013). Despite these increases, advocates and professional groups, such as the ASRM,

recognize that single persons, same-sex couples, and transgender and nonbinary persons face disproportionate barriers to infertility treatment as compared with opposite-sex couples.

Single persons, same-sex couples, and transgender and nonbinary persons are sometimes subject to definitional barriers that mediate their utilization of infertility treatments. Single persons, same-sex couples, and transgender and nonbinary 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, 2008; National LGBT Health Education Center, 2019).

Single persons, same-sex couples, and many transgender and nonbinary persons need to use third-party reproduction, which poses an additional cost burden beyond the previously discussed expense of standard infertility treatments. 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 or 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).

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

#### Socioeconomic status

Research shows that women who utilized fertility services the least have lower income, have less education, are non-U.S. citizens, are uninsured, and use the emergency room as their primary healthcare resource; women who report higher education and household incomes are more likely to utilize fertility services (Greil et al., 2011; Kelley et al, 2019). Among women in California, lower income and educational levels are significantly associated with longer durations of untreated infertility (Ho et al., 2017) and women with college education have almost twice the odds of achieving a pregnancy as compared with women without a degree (Smith et al., 2011).

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

#### Insurance status

Chandra et al. (2014) found that a lack of resources such as income and health insurance were a critical predictor of utilization of fertility services. Women without insurance coverage for services to treat infertility, such as IVF, are three times more likely to end treatment after one cycle compared with women with insurance (Bedrick et al, 2019). Research that has examined the barrier of not having health insurance coverage for infertility treatments has found that this barrier is significantly higher for Hispanic and Black women compared to non-Hispanic White women (Missmer et al., 2011). In addition, there is some evidence that patients without insurance coverage for fertility services are not offered clinically appropriate treatments and receive substandard care (Insogna and Ginsburg, 2018).

#### **Social Determinants of Health**

Social determinants of health (SDOH) include factors outside of the traditional medical care system that influence health status and health outcomes. With respect to AB 2029, CHBRP found literature regarding the impact of cultural beliefs and discrimination on the prevalence of infertility treatment use and outcomes.

#### Cultural and religious beliefs

Compared with White women, Black 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 (Missmer et al., 2011). Moreover, 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 (Greil et al., 2011).

Community-related social stigma may also be a reason racial and ethnic minority populations seek out infertility treatments less often than non-Hispanic White women. Black and Hispanic women report infertility-related stigma more frequently than White and Asian women and are less likely to seek treatment as a result of encouragement from a partner or family member (Greil et al., 2011). Similarly, Black women are up to four 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 are seven 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 (Missmer et al., 2011).

#### **Societal Impact of Infertility in the United States**

As described previously, infertility is a common condition and the presence of infertility in the United States creates a societal impact. In dollar terms, the societal impact can be indirect (lost wages, etc.) as well as direct (medical care, etc.). 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, 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. CHBRP did not identify data that displays the broad societal impact of infertility, specifically.

#### **Demand for Fertility Treatment in the United States**

In the United States, experts estimated in 2009 that only 24% of ART needs were being met and 1.5% of births in the United States resulted from ART compared to an average of 3% in Europe (Chambers et al., 2009; Daar et al., 2015).

Infertility may be a life crisis for couples or persons who desire a wanted child. Expert opinion states "No patient 'chooses' to require fertility services; anyone who could build a family at no cost without medical involvement would do so..." (Kawwass et al., 2021). Many couples who experience infertility desire children, but the financial burden associated with infertility, specifically IVF, creates prohibitive barriers to having children (see Treatment-Associated Financial Burden above). People seeking fertility services must make decisions about the amount of money they are willing to spend and when to stop seeking infertility treatments after failed interventions as there are many uncertainties related to whether health insurance will cover fertility services and the if the ART treatments will result in pregnancy and live birth (Klitzman, 2017).

Adoption is another option for couples seeking to have a family, but adoption is also associated with complex, time-consuming legal processes, high costs that vary state to state, and uncertainty that it will result in a child in the family (Gumus and Lee, 2012). Many people must repeatedly reconsider whether to keep seeking infertility treatment, adopt, or not have a child (Klitzman, 2017).

There is a growing viewpoint that infertility is a medical condition and the desire to raise children is a biologic right; these sentiments have contributed to state mandates requiring coverage for fertility services and health insurance coverage for fertility services (Kawwass et al., 2021). However, there is evidence of significant gaps in access to fertility care especially for single persons, transgender persons, and women and men in same-sex relationships even in states with mandated health insurance coverage for infertility treatments has been shown to reduce unnecessary procedures and promote single-embryo transfers, which are associated with improved maternal and infant outcomes (Kawwass et al., 2021). (See the *Public Health* section for further discussion of the impact of state-mandated health insurance coverage for infertility treatments and disparities.)

# **MEDICAL EFFECTIVENESS**

As discussed in the *Policy Context* section, AB 2029 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 2029 would instead mandate that plans and policies *provide* coverage for infertility treatment and specifies coverage for four completed oocyte retrievals with unlimited embryo transfer procedures in accordance with the guidelines of the American Society for Reproductive Medicine (ASRM), using single-embryo transfer when recommended and medically appropriate. Additional information on infertility causes, diagnostic work-up, and treatment options is included in the *Background* section.

# **Research Approach and Methods**

As presented in the *Background* section, infertility diagnosis and treatments encompass a wide range of tests, procedures, 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 2029 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 2029 would apply, that fertility treatments offered in accordance to ASRM guidelines have established effectiveness, and the fact that AB 2029 addresses the coverage for fertility benefits, this CHBRP medical effectiveness review summarizes the following findings from evidence: (1) the medical effectiveness of IVF (i.e., the treatment newly mandated) and (2) the impact of health insurance mandates to cover infertility treatments on health outcomes. A similar literature review was performed for CHBRP's analysis of AB 767 Infertility in 2019 and summarized again for AB 2781 in 2020. This report summarizes the findings from the previous CHBRP reviews plus literature published since 2019 regarding the impact of IVF insurance mandates.

Studies of infertility treatments and impacts of fertility 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 American Society for Reproductive Medicine (ASRM) was search for professional guidelines and committee opinion reports. The search was limited to abstracts of studies published in English.

CHBRP reviewed 41 articles identified in the literature review related to the impact of IVF insurance mandates for potential inclusion in this analysis of AB 2029. A total of four studies were included in the medical effectiveness report for this report, as well as 24 studies included in the previous review for AB 767. The other articles were eliminated because they did not focus on mandated 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 as treatment for infertility?
- 2. What are the harms associated with IVF?

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 on the effectiveness of IVF, the medical effectiveness review relied on existing systematic reviews reporting the effectiveness of IVF that were included in the 2019 CHRBP analysis of AB 767. These reviews typically compared the effectiveness of IVF to either intrauterine insemination (IUI) or expectant management (conceiving without intervention). This review also excludes any discussion of fertility preservation for iatrogenic infertility; a complete discussion of fertility preservation for that population is discussed in CHBRP's April 2019 analysis of SB 600.<sup>44</sup> This analysis contains a limited assessment on the effectiveness of third-party reproduction (the use of donor oocytes, donor sperm, gestational carriers, or surrogacy) as the assessments for IVF effectiveness and harms were completed for a prior analysis (AB 767) and studies of IVF effectiveness in general include patients who may have received third-party reproduction IVF. Additionally, this analysis incorporates into the findings on IVF effectiveness evidence from the literature on IVF mandate effectiveness and updates findings on IVF harms where literature reviewed for AB 767 was more than 10 years old, given changes in ART approaches over the past decade.

When assessing studies examining the impact of health insurance mandates on treatment utilization and outcomes, the medical effectiveness analysis was interested in studies looking at mandates covering IVF because AB 2029 would expand the requirements of fertility services to include IVF. This review will summarize the findings from the previous CHBRP analysis on AB 767 regarding the impact of health insurance mandates as well as summarize new findings from the updated literature search.

## **Outcomes Assessed**

To assess the effectiveness of IVF, CHBRP summarized findings from a prior analysis of AB 767, which 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. 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 and is also used to increase the likelihood of IVF success for unexplained infertility. 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, CHBRP summarized findings from a prior analysis of AB 767, which assessed the effects on maternal health outcomes, including ovarian hyperstimulation syndrome, ectopic pregnancies, cardiovascular complications, and multiple gestation pregnancies. CHBRP also assessed the effects on neonatal health outcomes, such as the rate of preterm or low-birthweight births and the incidence of major/minor malformations, cerebral palsy, and infant death.

For studies of the impact of insurance coverage for infertility treatments, CHBRP assessed effects on two types of outcomes: (1) use of infertility treatments, such as number of completed oocyte retrievals or the number of embryos transferred; and (2) health outcomes of infertility treatments such as pregnancy rates, live birth rates, rates of multiple births, and adverse health outcomes. Please refer to the *Public Health Impacts* section for a discussion of the impact of IVF on quality of life.

<sup>&</sup>lt;sup>44</sup> CHBRP's April 2019 analysis of SB 600 Fertility Preservation is available at: <u>http://chbrp.org/completed\_analyses/index.php</u>
#### **Pregnancy Rates, Birth Rates and Embryo Transfers**

The goal health outcome of IVF is pregnancy and then live birth. Lower pregnancy and birth rates per IVF cycle can occur when a single-embryo is transferred per cycle such that these lower rates can be markers of fewer embryos transferred. The number of embryos transferred per cycle is an important measure because transferring more than one embryo per IVF cycle — done to increase the likelihood of pregnancy — increases the risks of multiple gestation pregnancies (twins, triplets, or more). Multiple-embryo transfers should only be done for specific medical purposes (Practice Committee of the American Society for Reproductive Medicine, 2017). Multiple births are considered an adverse outcome of IVF, leading to more complications and worse health outcomes, such as preterm birth or low birthweight.

## Study Findings<sup>45</sup>

#### **Findings from Previous Analyses**

#### Effectiveness of IVF

CHBRP's previous analysis of AB 767 identified four systematic reviews including 55 unique (nonoverlapping) 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). These reviews all concluded that IVF is an effective treatment for infertility, resulting in increased pregnancy rates and live birth rates.

A 2015 Cochrane Review including five randomized controlled trials (RCTs) compared the effectiveness of various infertility treatments on live birth rates for patients with diverse causes of infertility including endometriosis and unexplained infertility (Pandian et al., 2015). 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% confidence interval (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]). 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. A systematic review by Humphries et al. (2016) assessing 24 observational studies found that Asian and African American women were less likely to achieve a pregnancy after completing IVF treatments as compared to White women (31.4% and 24.4% vs. 36.2%, respectively). Asian women and African American women were also less likely to have live births than White women: 24% vs. 30.7% (OR, 0.64; [95% CI, 0.51–0.80]) and 16.9% vs. 30.7% (OR, 0.50 [95% CI, 0.33–0.72]), respectively (Humphries et al., 2016).

A 2011 systematic review synthesized 17 studies (including eight open trials) focusing on HIV serodiscordant couples (couples in which one is HIV-positive and the other HIV-negative) striving to achieve conception. 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%) (Vitorino et al., 2011).

A 2015 systematic review analyzed data from 11 observational studies, which included patients with polycystic ovarian disorder (PCOS) and infertile, non-PCOS patients undergoing IVF treatment. After undergoing treatment, women with PCOS were more likely than the non-PCOS patients to achieve

<sup>&</sup>lt;sup>45</sup> 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 addressed by AB 2029. 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.

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).

For additional details regarding these systematic reviews, please refer to CHBRP's 2019 analyses of AB 767.

#### Additional findings from IVF mandate literature

Multiple studies compare infertility outcomes between states with infertility treatment mandates and those without. These studies found IVF treatments, regardless of insurance mandate coverage, resulted in live births for 33% to 57% of participants (Bedrick et al. 2019; Crawford et al., 2016; Peipert et al., 2022; Reynolds et al., 2003; Zagadailov et al., 2020). Although these studies compared birth rates between persons in mandate compared to nonmandate states without a no-treatment control group, by definition, all persons in the studies who were receiving IVF had infertility — the inability to conceive without medical intervention. Therefore, the pregnancy and live birth rates described in these studies can be understood to represent the effectiveness of IVF compared to no treatment.

#### *Third-party reproduction (donor oocytes, donor sperm, gestational carriers, surrogates)*

Third-party IVF is used when IVF will not be, or has not been, successful without donor material or gestational carriers (or surrogates). As such, successful IVF using third-party reproduction represents improved effectiveness beyond autologous (non-third-party) IVF. As discussed in the *Background* section, a study utilizing the Society of Assisted Reproductive Technologies Clinic Outcome Reporting System data, a U.S. national registry, found that 16.1% of all IVF cycles from 2004 to 2013 used any kind of third-party donation. Oocyte donation was used in 10.4% of cycles, sperm donation in 2.7% of cycles, gestational carriers in 0.9% of cycles, embryo donation in 0.6% of cycles, and more than one third-party reproduction type was used in 1.5% of cycles (Kushnir et al., 2017). Third-party IVF cycle volume increased from 2004 to 2013 at a higher rate than autologous (non-third-party) IVF cycle volume, 53% compared to 24% (Kushnir et al., 2017). The live birth rate for IVF after third-party reproduction is higher than the live birth rate for autologous IVF and has increased from 2004 to 2013, from 37.7% to 40.5% live birth rate among third-party IVF cycles and from 27% to 32% live birth rate among autologous cycles (Kushnir et al., 2017).

**Summary of findings regarding IVF effectiveness:** There is *clear and convincing evidence* that IVF, without or with third-party reproduction, is an effective treatment for infertility, resulting in increased pregnancy rates and live birth rates compared to no fertility treatment.

#### Figure 2. Effectiveness of IVF as a Treatment for Infertility

EFFECTIVE						EFFEC
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	CLEAR AND CONVINCING

#### Harms of fertility treatment

CHBRP's previous review of AB 767 identified 17 studies (13 systematic reviews and four observational studies) that analyzed the potential harms and complications associated with IVF. These harms are briefly summarized below. For additional details regarding these studies and findings, please refer to CHBRP's previous review AB 767.

#### Maternal harms of IVF

- Ovarian hyperstimulation syndrome: Ovarian hyperstimulation syndrome (OHSS) occurs when the ovaries are hyper stimulated and enlarged due to fertility treatment. Earlier studies estimated that OHSS occurs in 20% to 30% of ART cycles (Delvigne and Rozenberg, 2002); however, newer approaches to IVF and preventative strategies (e.g., use of gonadotropin releasing hormone-antagonist IVF cycles) have decreased hospital admissions for OHSS from 2 per 10,000 women hospitalized in 2005 to 1.2 per 10,000 women hospitalized in 2014 (Rotshenker-Olshinka et al., 2020).
- Ectopic pregnancy: A 2015 cohort study based on data reported to the National ART Surveillance System between 2001 and 2011 found that 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., 2016).
- **Cardiovascular complications:** Three studies have reported an increased risk of pulmonary (HR, 6.97% [95% CI, 2.21 21.96]) and venous thromboembolism (HR, range 1.77–4.22) during pregnancy for women using IVF, and that this risk is highest in the first trimester and in pregnancies with multiples (Hansen et al., 2014; Henriksson et al., 2013, Rova et al., 2012). However, 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).
- **Multiple gestation pregnancies:** As noted previously (see Outcomes Assessed discussion above), use of infertility treatments is associated with increased risk of multiple births. Multiple births are most common when multiple embryos are transferred during a single transfer. 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 pregnancies include preterm birth, fetal growth restriction, congenital anomalies, and malformations (Mandy, 2019).

#### Offspring harms of IVF

- **Preterm birth:** Three systematic reviews found an increased risk of preterm births among women undergoing infertility treatment (Hoorsan et al., 2017; McGovern et al., 2004; Qin et al., 2016). Qin et al. (2016) reported a preterm birth rate risk ratio (RR) of 1.08 (95% CI, 1.02–1.13) among twins conceived via ART compared to twins spontaneously conceived. Hoorsan et al. (2017) reported a preterm labor OR of 1.79 (95% CI, 1.21–2.63), among infants conceived by ART (including both singleton and multiples). McGovern et al. (2004) reported a preterm birth relative risk of 1.98 (95% CI, 1.77–2.22) in singleton pregnancies conceived by ART compared to spontaneously conceived pregnancies.
- 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). Hoorsan et al. (2017) reported an odds ratio of 1.89 (95% CI, 1.36–2.62) among infants conceived by ART versus infants spontaneously conceived. Qin et al. (2016) found that the likelihood of a twin being born with a low birthweight was higher among twins conceived via ART versus twins conceived spontaneously (RR, 1.09 [95% CI, 1.03–1.16]).
- Congenital malformations: Several congenital malformations appear to have higher rates among children conceived with ART. A systematic review of 30 articles found that children born via ART had a higher chance of being diagnosed with a cardiac abnormality compared to infants conceived spontaneously (OR, 1.43 [95% CI, 1.27–1.62]). The review also found that ART infants had a higher chance of being diagnosed with a central nervous system abnormality (OR, 1.36 [95% CI, 1.10–1.70], urogenital system abnormalities (OR, 1.58 [95% CI, 1.28–1.94]) and musculoskeletal disorders (OR, 1.35 [95% CI, 1.12–1.64]) compared to infants conceived

spontaneously. The review did not find that chromosomal abnormalities were significantly higher among ART infants (Hoorsan et al., 2017). Two other systematic review found that twins conceived via ART were more likely to be diagnosed with a malformation than twins conceived spontaneously (OR, 1.26–1.37) (Qin et al., 2016; Wen et al., 2012)

Infant death: One systematic review found that the rate of perinatal mortality was higher for twins conceived via ART compared to twins conceived spontaneously (RR, 1.60 [95% CI, 1.20–2.13]; p-value = 0.01) (Qin et al., 2016).

**Summary of findings regarding the maternal harms associated with infertility treatment:** CHBRP's prior analysis of AB 767 concluded that there is a *preponderance of evidence* that IVF is associated with certain maternal harms, including thromboembolism. There is also a *preponderance of evidence* that IVF is related to multiple gestation pregnancies and preterm delivery, and associated harms. However, it is important to note that multiple gestation pregnancies is associated with higher numbers of embryos transferred per cycle, and that preterm delivery is associated with multiple gestation pregnancies. These outcomes can be mitigated by increases in single-embryo transfers.

**Summary of findings regarding the offspring harms associated with infertility treatment:** CHBRP's prior analysis of AB 767 concluded that there is a *preponderance of evidence* that certain harms are increased among children conceived via IVF, including preterm birth, low birthweight, certain congenital malformations, cerebral palsy, and infant death. However, it is important to note that risk for some harms is higher for multiple gestation pregnancies; these outcomes can be mitigated by single-embryo transfers.

#### Figure 3. Maternal Harms of IVF



#### Figure 4. Harms of IVF due to Multiple Gestation Pregnancy and Preterm Delivery

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Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	CONVINCIN

#### Figure 5. Offspring Harms of IVF

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					Λ	
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	PREPONDERANCE	Clear and Convincing

#### Findings from Updated Medical Effectiveness Analysis

#### Impact on IVF utilization and IVF-related birth outcomes

CHBRP's previous review of AB 767 included nine studies examining the impact of state mandates including IVF treatment on IVF utilization (Banks et al., 2010; Boulet et al., 2015; 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) With the exception of Crawford et al. (2016), these studies 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, more single-embryo transfers, fewer cycles with  $\geq$ 3 embryos transferred and less use of ICSI, lower pregnancy rates, fewer births per cycle, lower rates of multiple births, and fewer adverse birth outcomes compared to states without mandates.

In contrast to these studies, Crawford et al. (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 in the first 2 years postmandate, 2001—2003, 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. There were no significant differences in birth rates or multiple birth rates in Connecticut postmandate (2005–2007). During this time, multiple-embryo transfers during IVF was becoming less common in mandate and nonmandate states. The authors conclude the lack of difference in birth rates and embryos transferred between mandate and nonmandate states could have been due to mandate religious and small-employer exceptions, continued financial barriers due to cost sharing, and ART cycle limitations (limits: two ART cycles in Connecticut, four egg retrievals and all associated ART in New Jersey). Additional details about these studies can be found in the 2019 analysis of AB 767.

The updated literature search for AB 2029 identified four new studies examining the relationship between insurance mandates, IVF utilization and related birth outcomes. Bedrick et al. (2019) compared IVF outcomes for 669 women undergoing treatment at one academic medical center serving populations living in a state with an IVF treatment mandate (Illinois) and a state without (Missouri). Women without IVF insurance coverage were more likely to discontinue treatment after an unsuccessful first cycle compared to women with insurance coverage (OR, 3.12 [95% CI, 2.22-4.40]). Dupree et al. (2019) examined claims data from October 2012 through January 2017 for 18,282 women enrolled in a selfinsured plan at a large public university, which began providing insurance coverage for IVF for women aged 42 years and younger in 2015. Coverage for IVF increased IVF utilization (defined as oocyte retrievals per 10,000 women) from 34.3 cycles per 10,000 women before 2015 to 92.6 cycles after 2015. A review of IVF cycles reported by the 2018 Centers for Disease Control ART Fertility Clinic Success Rate Report found that IVF utilization in states with comprehensive mandates (requiring insurance providers to cover the cost of IVF) was 132% higher than states with noncomprehensive coverage or no mandated coverage 6.23 cycles vs. 2.68 cycles per 1,000 women, respectively. This study also found that states with comprehensive mandates had higher birth rates, lower rates of multiple births, and significantly lower mean number of embryos per transfer (Peipert et al., 2022). A retrospective cohort study based on National Assisted Reproductive Surveillance System (NASS) data from 2000 through 2016 found that states with ART insurance mandates had lower rates of ICSI utilization, lower rates pregnancy rates, higher live birth rates, more elective single-embryo transfer, and lower rates of twin births compared to states without ART insurance mandates (Zagadailov et al., 2020).

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.

#### Interaction of Health Insurance Mandates for IVF and Age

In the previous review of AB 767, CHBRP identified three studies examining the interaction of health insurance mandates covering IVF and age (Banks et al., 2010; Boulet et al., 2015; Martin et al., 2011). Banks et al. (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 et al. (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 et al. (2015) found that women younger than 35 years living in a nonmandate state were more likely to transfer  $\geq$ 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  $\geq$ 3 embryos in the nonmandate state were higher (26.9% vs. 7.0% in mandate states).

The updated literature search for AB 2029 identified two new studies examining the relationship between insurance mandates and IVF utilization. Dupree et al. (2019) found that IVF utilization increased post-insurance mandate for all age groups, but this increase was significantly higher for women aged 30 to 34 years (increase of 97.8 cycles per 10,000 women) and women aged 35 to 42 years (increase of 76.8 cycles per 10,000 women) compared to women aged 22 to 29 years (increase of 7.0 cycles per 10,000 women). Piepert et al. (2022) found that comprehensive mandates significantly increased live births per cycle compared to women aged 37 years and younger and significantly decreased the mean number of embryos transferred per procedure for the same younger age group.

Summary of findings regarding the impact of health insurance mandates including IVF coverage on utilization and related birth outcomes: There is *clear and convincing evidence* that infertility treatment health insurance mandates are associated with an increase in utilization of infertility treatments. There is *clear and convincing 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 *clear and convincing evidence* that IVF mandates are associated with lower pregnancy rates resulting from IVF (due to a decrease in embryos transferred), and a lower likelihood of other adverse birth outcomes, including rates of multiple births.

Figure 6. Effectiveness of IVF Insurance Mandates to Increase Utilization, to Decrease Number of Embryos per Transfer, and to Lower Birth Rates and Harms Associated with IVF including Multiple Births

<b>FEFECTIVE</b>						EFFECT
						٨
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	CLEAR AND CONVINCING

# **Summary of Medical Effectiveness Findings**

The medical effectiveness review for AB 2029 finds:

- There is *clear and convincing evidence* that IVF is an effective treatment for infertility, resulting in increased pregnancy rates and birth rates.
- CHBRP's prior analysis of AB 767 concluded that there is a preponderance of evidence that IVF is associated with certain maternal harms, including thromboembolism. There is also a preponderance of evidence that IVF is related to multiple gestation pregnancies and preterm delivery, and associated harms. However, it is important to note that multiple gestation pregnancy is associated with higher numbers of embryos transferred per cycle, and that preterm delivery is associated with multiple gestation pregnancy. These outcomes can be mitigated by increases in single-embryo transfers.
- CHBRP's prior analysis of AB 767 concluded that there is a preponderance of evidence that certain harms are increased among children conceived via IVF, including preterm birth, low birthweight, certain congenital malformations, cerebral palsy, and infant death. However, it is

important to note that risk for some harms is higher for multiple gestation pregnancies; these outcomes can be mitigated by single-embryo transfers.

- There is *clear and convincing evidence* that infertility treatment health insurance mandates are associated with an increase in utilization of infertility treatments.
- There is clear and convincing 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 *clear and convincing evidence* that IVF mandates are associated with lower pregnancy rates resulting from IVF (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 2029 would require commercial and CaIPERS health plans and health policies regulated by DMHC or CDI to provide coverage for "the diagnosis and treatment of infertility and fertility services." AB 2029 also prohibits plans and policies from applying a deductible, copayment, or coinsurance for fertility services that is different from those imposed on other benefits. DMHC-regulated Medi-Cal managed care plans are exempt from AB 2029

If enacted, AB 2029 would apply to the health insurance of approximately 14,776,000 enrollees. This represents about 65% of the 22.8 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law, which includes health insurance regulated by DMHC or CDI.

This section reports the potential incremental impacts of AB 2029 on estimated baseline benefit coverage, utilization, and overall cost.

#### **Analytic Approach and Key Assumptions**

The *Policy Context* section explains the overarching analytic approach and key assumptions of CHBRP's analysis of AB 2029. As stated there, CHBRP previously analyzed similar bill language — AB 2781 in 2020 and AB 767 in 2019 — and much of the work produced for those bill analyses is still relevant to the analysis of AB 2029.

To provide new fiscal impacts for AB 2029, CHBRP first conducted a review of the literature published in 2020 to 2022 to identify new sources of information that could inform the analytic approach and assumptions for its analysis of cost impacts. From this literature search, CHBRP identified a key source of literature (Peipert et al., 2022), a retrospective cohort study of in vitro fertilization (IVF) cycles from over 450 clinics in the United States from data reported by the CDC's Assisted Reproductive Technology (ART) Fertility Clinic Success Rates Report. Authors of this study estimated IVF utilization and birth outcome differences between states with a mandate to cover fertility services in place compared to those without such mandates. With this updated literature and input from CHBRP's content expert, CHBRP shifted its modeling approach for the analysis of AB 2029 to using the CDC's 2019 ART Surveillance data. The use of CDC's ART data for IVF utilization estimates departs from the use of claims data in the analyses of AB 767 and AB 2781, wherein estimates of utilization change came from the examination of shifts in fertility services used in New Jersey, a state where a fertility mandate existed. For the analysis of AB 2029, CHBRP opted to use CDC's ART data from California to obtain the most recent data on IVF and intracytoplasmic sperm injection (ICSI) and live birth rate delivery estimates of single and multiple births in 2019, and apply a postmandate utilization change assumption using results from Peipert and colleagues' (2022) work on the difference in IVF use in mandate states versus nonmandate states (described in more detail below and in Appendix C).

Since CDC's ART data do not include data on other fertility services such as diagnostic tests, infertility medications, and intrauterine insemination (IUI), as CHBRP included in its previous analyses, CHBRP used Miliman's proprietary 2019 Consolidated Health Cost Guidelines<sup>™</sup> Sources Database (CHSD) data on utilization in California for all other fertility services besides IVF and ICSI (i.e., diagnostic tests, medications, IUI, and other treatment services). Estimated postmandate changes were based on assumptions gathered from the literature and content expert input and are described in greater detail in Appendix C. All costs per service, including costs for pregnancies and birth outcomes, were obtained from the 2019 CHSD dataset for California, trended to 2023.

The analysis of cost impact were developed using following **key considerations**, **assumptions**, **and methods**:

#### Benefit coverage

• CHBRP found benefit coverage for fertility services at baseline in this analysis of AB 2029 (approximately 23% of enrollees at baseline have coverage for fertility services) was higher compared to previous analyses of AB 767 and AB 2781 (approximately 4%). CHBRP assumed this difference reflects an increasing trend in employers offering fertility coverage to employees. This assumption is based on evidence found by Mercer's National Survey of Employer-Sponsored Health Plans' Survey on Fertility Benefits, in which fertility coverage offered to employees by employers of all sizes nationally is rising (Mercer, 2021), as well as responses to CHBRP's survey of health insurance carriers in California.

#### Fertility services utilization

- Data from 2019 CDC ART were used to estimate utilization; CHBRP applied trend assumptions to estimate utilization in 2023 (see more detail in Appendix C).
- CHBRP assumes utilization data from states with and without coverage mandates reflects the
  utilization differential between enrollees with and without coverage. CHBRP assumed the IVF
  utilization rate per 1,000 for the population with coverage for fertility services is 2.3 times the IVF
  utilization rate for the population without coverage based on Peipert et al. (2022), which examined
  utilization data from states with mandates for fertility services compared to those without such
  mandates. CHBRP assumes IVF utilization in the first year postmandate arrives at a steady state
  as seen in mandate states examined by Peipert et al (2022).
- Rates of IVF procedures per 1,000 enrollees for enrollees with and without coverage for IVF were
  multiplied by the percentage of IVF cycles that include ICSI (2019 CDC ART data) to estimate the
  rate of ICSI for enrollees with and without coverage.
- For all other fertility services other than IVF and ICSI, which were based on CHSD data, coverage assumptions for each service from CHBRP's carrier survey were applied to the CHSD data to estimate utilization rates of fertility services for enrollees with coverage. Assumptions regarding the utilization differentials for covered and noncovered enrollees are detailed in Appendix C.
- IVF and ICSI procedures per 1,000 rates were trended from 2019 to 2023 using an 0.2% annual utilization trend developed by comparing the 2019 and 2018 CDC State Specific Assisted Reproductive Technology Surveillance Reports. An additional one-time 30% increase was included in the 2023 estimate to account for increase in utilization of IVF observed after the conclusion of lock-down period of the COVID-19 pandemic; this estimated increase was based on actuarial judgement using evidence from post-pandemic increase in infertility and ART service use found in Zhou et al. (2021). The IUI and medication utilization rates were also trended from 2019 to 2023 and include an additional one-time increase as detailed in Appendix C.
- Based on content expert input, CHBRP assumed there is an acceptable number of fertility 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.

#### Pregnancy and live births

• To capture the full cost of coverage for fertility services for each year, CHBRP assumed the cost of pregnancies and births resulting from fertility services in year 1 are incurred in year 1.

#### Fertility services provided by or to a third party

• In this analysis of fiscal impacts, CHBRP assumes AB 2029 coverage for fertility services provided by or to a third party means when an enrollee uses third party assisted reproduction and engages a gestational carrier or surrogate to carry the pregnancy, fertility services provided to the enrollee (such as oocyte retrieval and fertilization of the oocyte) would be covered, while the

services provided to the surrogate or gestational carrier would not be covered (embryo transfer). Additionally, if an enrollee uses biologic material from a donor, any services performed for the enrollee (such an embryo transfer) would be covered. An alternate interpretation of AB 2029 is that services performed to obtain donor biologic material and transfer of an embryo to a surrogate and related services to the carrier would be covered. Under this interpretation, overall expenditure estimates postmandate would be higher than those presented here, however CHBRP is unable to estimate the degree to which expenditures would be greater.

• CHBRP is unable to estimate potential differential impacts of the bill on utilization postmandate among single persons, same-sex couples, and transgender and nonbinary persons who may require donor materials, surrogacy, or gestational carriers. The aforementioned CDC ART surveillance data and claims data reflect use of fertility services among all persons regardless of their background, relationship status, sexual orientation or gender-identity. The *Public Health* section offers a qualitative discussion of the potential of AB 2029 in impacting disparities in use of fertility services by relationship, sexual orientation, or gender identity.

For details on the underlying data sources, methods, and a list of all assumptions used in this analysis, please see Appendix C.

Due to changes in bill language, baseline population estimates within CHBRP's cost and coverage model, and CHBRP's analytic approach, the utilization and expenditures in the analysis of AB 2029 cannot be compared to the utilization and expenditure estimates in CHBRP's analyses of AB 767 conducted in 2019 or AB 2871 conducted in 2020.

## **Baseline and Postmandate Benefit Coverage**

At baseline, 23% of enrollees with health insurance that would be subject to AB 2029 have fertility coverage that includes IVF. CHBRP found 0% enrollees have health insurance that includes fertility coverage *and* cost sharing for covered fertility services (i.e., deductible, copayment, or coinsurance) that is **not** different from those imposed on other benefits.

Given all enrollees have coverage for female surgical treatments under major medical coverage, surgical treatments were not modeled in this analysis. Coverage by type of procedure varies substantially. While the majority of enrollees (76%) have coverage for female and male diagnostic tests, about 44% have coverage for female medication prescriptions for infertility and 23% have coverage for IVF and ICSI.

Benefit coverage for relevant fertility services among enrollees in commercial and CalPERS DMHCregulated 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.

### **Baseline and Postmandate Utilization**

CHBRP examined claims data for baseline estimates of utilization of fertility services among enrollees in California. (See Key Assumptions discussed above for more details on CHBRP's approach; Table 1.)

IVF utilization at baseline is approximately 1 procedure per 1,000 enrollees and 1 procedure per 1,000 enrollees for ICSI. CHBRP's IVF utilization data are defined by services per 1,000 enrollees, rather than by users, thus CHBRP is unable to identify users of more than four oocyte retrievals (limit as defined by AB 2029, see *Policy Context* section). However, literature suggests that most users of IVF complete fewer than four cycles of IVF and thus would complete fewer than four oocyte retrieval procedures (Katz et al, 2011; see *Background* section for more). With regards to other fertility services, the highest utilization is from diagnostic tests and medication prescriptions for infertility. For females at baseline there are 32 diagnostic tests per 1,000 enrollees and 24 prescriptions for infertility medications per 1,000. For males, there are about 13 diagnostic tests, treatments, and medications per 1,000 enrollees. IUI is used at a rate

of about 2 procedures per 1,000 enrollees. Some enrollees may use multiple services. For example, enrollees who use IVF also use prescription medications and may also receive diagnostic tests. CHBRP is not able to identify this overlap in utilization.

CHBRP examined utilization of services received at baseline by benefit coverage (Figure 7). Use of services at baseline varies by type of infertility service. For example, about 60% of services received at baseline for IVF and ICSI are not covered at baseline, which is in contrast to about 24% to 26% of diagnostic tests for females and males used at baseline without coverage. All services not covered at baseline would become covered postmandate.

In addition to the shift of fertility benefits from not covered to covered, additional utilization will occur among enrollees who were previously not using fertility services. Applying the assumed postmandate increases described in the Key Assumptions section above and in more detail in Appendix C, CHBRP estimates IVF utilization rises to about 2 procedures per 1,000 with a similar increase for ICSI. For both ICSI and IVF, these changes reflect an 80% relative increase in utilization postmandate. The increases in utilization postmandate for all other services are lower than the increases estimated for IVF and fall in the range of a 3% to 19% increase (Table 1), which is expected not only because coverage for these services at baseline is greater but also because with the availability of IVF coverage postmandate utilization likely shifts towards IVF given greater clinical effectiveness.



Figure 7. Services Received at Baseline by Benefit Coverage, 2023

Source: California Health Benefits Review Program, 2022.

Key: ICSI = with intracytoplasmic sperm injection; IUI = intrauterine insemination; IVF = in vitro fertilization

## **Baseline and Postmandate Per-Unit Cost**

Costs of fertility services range from a low of \$84 (male diagnostic tests, treatments, medications) for males and \$110 (female diagnostic tests) to \$14,700 (IVF) for females. ICSI procures (\$1,480) are an add-on cost to the IVF procedure. CHBRP estimates that no changes in average costs per are expected postmandate as there are no provisions in the bill that would create any upward or downward pressure on the unit costs for any of the services. Note in Table 1 that the change in average cost per service for female medications postmandate is due solely to the mix of services that would occur postmandate (i.e., medications for IVF treatment), which results in a change in the average cost per service. Because medications are used during IVF as well as other services, the increase in IVF leads to an increase utilization of more expensive fertility medications. Due to the change in the mix of services and the increase in the number of medications for IVF, the average cost per service would increase.

# **Baseline and Postmandate Expenditures**

Table 5 and Table 6 present baseline and postmandate expenditures by market segment for DMHCregulated 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 2029 would increase total net annual expenditures by \$714,800,000 or 0.48% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a \$957,449,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, an increase of \$44,921,000 in enrollee cost sharing for covered benefits, and a decrease of \$287,570,000 in enrollee expenses for noncovered benefits (Table 6).

#### Premiums

Overall, premiums would increase \$957,449,000 postmandate as a result of AB 2029. Changes in premiums as a result of AB 2029 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 5, and Table 6), with health insurance that would be subject to AB 2029. The largest increases are among DMHC-regulated small-group plans (1.1%), DMHC-regulated individual market plans (1.0%), and CDI-regulated individual policies (1.1%). Among publicly funded DMHC-regulated CaIPERS HMOs, the premium increase is 0.86%. These increases in premiums in per member per month (PMPM) dollars range between an increase of \$4.50 PMPM (DMHC-regulated large-group plans) to \$7.13 PMPM (DMHCregulated individual market plans).

Premiums for enrollees in individual plans purchased through Covered California would increase by \$185,158,000 or 1.05% (Table 1). PMPM, premiums would increase by \$7.13 (DMHCregulated plans) or \$6.55 (CDI-regulated policies) and expenses for noncovered benefits would decrease by \$2.77 (DMHCregulated plans) or \$2.72 (CDI-regulated policies) (Table 6).

It is important to note that the increase in premiums stem from both increases in utilization of (1) fertility services and (2) pregnancies and births. About 74% of increase in premiums is Figure 8. Commercial and CalPERS Employer and Enrollee Premium Expenditure Impacts, by Service Category (Fertility Services and Pregnancy Related Services), 2023



*Source*: California Health Benefits Review Program, 2022.

attributable to the increase in fertility services and about 26% is attributable to increases in pregnancyrelated services (Figure 8).

#### **Enrollee Expenses**

AB 2029–related changes in cost sharing for covered benefits (deductibles, copays, etc.) and out-ofpocket expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 5, and Table 6) with health insurance that would be subject to AB 2029 expected to use the relevant fertility services during the year after enactment.

As discussed in the *Policy Context* section, AB 2029 specifies cost sharing (deductibles, coinsurance, copayments) cannot be different from those of major medical. Baseline benefit coverage for fertility services is mostly provided as an insurance rider, which may have a 50% coinsurance and wherein fertility service expenses do not count towards the deductible and annual out-of-pocket maximums. As AB 2029 would require cost sharing is the same as major medical, fertility services would apply to the deductible and annual out-of-pocket maximums postmandate.

Impacts for enrollees using fertility services on enrollee expenses can be classified in the following way:

- For the enrollees who do not have fertility coverage at baseline and are using fertility services paid for entirely out of their own pocket, out-of-pocket expenses for these noncovered benefits decrease postmandate given these enrollees would be covered when using fertility services postmandate. Expenses of noncovered services at baseline are discussed in greater detail below and shown in Figure 9.
- For enrollees who have coverage for fertility services at baseline but have cost sharing that is more than major medical (e.g., 50% coinsurance and no annual out-of-pocket maximum), postmandate these enrollees would experience reduced out-of-pocket expenses.
- For enrollees who do not have coverage for fertility services at baseline and are not using these services due to cost barriers, postmandate out-of-pocket expenses would increase given their new utilization.

As described above, enrollees without coverage at baseline using fertility services are reflected in expenditures for noncovered benefits at baseline (\$287,570,000 in Table 1). Figure 9 shows the breakdown of these expenditures wherein IVF represents over half of the expenditures at baseline. Postmandate, the classification of these expenditures would shift to being covered.



Figure 9. Total Expenditures of Noncovered Services at Baseline by Service Category, 2023

Source: California Health Benefits Review Program, 2023.

Key: ICSI = with intracytoplasmic sperm injection; IUI = intrauterine insemination; IVF = in vitro fertilization

Postmandate, average cost sharing per service for covered benefits would mostly decrease, because cost sharing is limited to the same structure as for other benefits (Table 1). The majority of enrollees with coverage for infertility treatments at baseline have cost sharing that is higher than that for other benefits, such as a 50% coinsurance. As a result, average cost sharing for IVF, ICSI, and IUI procedures would decrease by 73% to 74% postmandate, from \$7,350 to \$1,940 for IVF, \$740 to \$190 for ICSI, and \$260 to \$70 for IUI.

However, at the PMPM level, cost sharing for covered benefits in the form of deductibles and copayments would mostly increase given greater utilization of fertility services and due to the change in noncovered services becoming covered postmandate. The enrollee expenses for noncovered benefits decreases, offsetting all increases in cost sharing for covered benefits.

CHBRP finds the largest increases in enrollee cost sharing for covered benefits would be for enrollees in DMHC-regulated individual (\$1.56 PMPM) and small-group plans (\$1.34 PMPM) and CDI-regulated individual and small-group policies (\$1.99 PMPM and \$1.71 PMPM, respectively), given these enrollees are most likely to not have fertility coverage at baseline (Table 6). The smallest increase would be for CaIPERS HMOs (\$0.05 PMPM). There would be a reduction in cost sharing for covered benefits for large-group DMHC-regulated plans (-\$0.52 PMPM).

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

As discussed in the *Medical Effectiveness* section, the peer reviewed literature suggests that while fertility 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 fertility mandates (Bedrick et al., 2022; Boulet et al., 2019; Martin et al., 2011; Peipert et al., 2022; Zagadailov et al., 2020) 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; Peipert et al, 2022).

As with utilization of fertility services, postmandate impact on births depends on the type of coverage at baseline (i.e., no coverage but using fertility services paid for entirely out of pocket, no coverage and not using fertility services due to cost barrier, or have coverage but with cost sharing higher than major medical). For enrollees who do not have coverage at baseline and are not using fertility services at baseline, when they are covered postmandate and become users of fertility services they would experience new live birth deliveries.

CHBRP estimates an increase in 7,000 pregnancies due to fertility services postmandate, a 54% increase from baseline (Table 1). CHBRP estimates an additional 6,000 live birth deliveries due to fertility services postmandate (a 55% increase from baseline), of which 3.4% would be twin deliveries and 0.2% would be 3+ multiple births. This reflects the lower rate for multiple births (i.e., more than twins) for enrollees with coverage for IVF; at baseline, the rate of multiple births for enrollees with IVF coverage is 10%, which is lower than the rate of multiple births for noncovered enrollees of 14%, based on results from Peipert et al. (2022). CHBRP estimates at baseline, 5.6% of births are twins and 0.3% are multiples (i.e., more than twins). Postmandate, 4.8% births would be twins and 0.2% multiples.

The average cost of pregnancies and deliveries from fertility services would be expected to decrease by \$1,000, which is a 3% reduction from baseline, because of the reduction in higher-cost twin/multiples deliveries.

#### **Postmandate Administrative Expenses and Other Expenses**

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDIregulated 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, fertility treatments covered by AB 2029 are not included in California's essential health benefit (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 EHBs. Coverage for infertility treatment required by mandate (not resulting pregnancy and births), as would be required if AB 2029 were enacted, could trigger this requirement and so require 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 in Table 4 several scenarios regarding the cost to the state, should AB 2029 be judged to exceed EHBs. In one scenario looking at the estimated premium cost of mandated benefits not considering baseline coverage, impacts by market segment (and by market segment enrollment) range between \$3.41 PMPM for CDI-regulated small-group policies and \$4.39 PMPM for DMHC-regulated individual plans, and the estimated annual state responsibility for the portion that is in excess of EHBs ranges from \$1.8 million (CDI small group) to \$141 million (DMHC individual). When the marginal premium impact considers baseline coverage, impacts by market segment (and by market segment enrollment) range between \$3.26 PMPM for CDI-regulated small-group policies and \$4.12 PMPM for DMHC-regulated individual market plans with the estimated annual state responsibility for the portion that is in excess of EHBs ranges from \$1.7 million (CDI small group) to \$133 million (DMHC individual).

	DMHC-Regulated		CDI-Re		
	Small Group	Individual	Small Group	Individual	Total
Enrollee counts					
Total enrollees in plans/policies subject to state mandates	2,125,000	2,758,000	44,000	166,000	5,093,000
Number of enrollees in QHPs (a)	1,960,000	2,681,000	44,000	85,000	4,770,000
Premium cost of mandated benefit					
Estimated premium cost of mandated benefit (b)	\$3.76	\$4.39	\$3.41	\$3.83	\$4.12
Marginal premium impact considering baseline coverage (c)	\$3.68	\$4.12	\$3.26	\$3.83	\$3.93
Estimated annual state responsibility for portion of mandate that is in excess of EHB	0.00	Ψτ. ΤΖ	ψ0.20	<u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u></u>	<b>40.00</b>
Scenario 1: Full estimated $cost = (a) x (b) x 12$	\$88,503,000	\$141,343,000	\$1,802,000	\$3,908,000	\$235,557,000
Scenario 2: With baseline coverage offset = (a) x (c) x 12	\$86,496,000	\$132,612,000	\$1,722,000	\$3,908,000	\$224,739,000

# Table 4. Estimated State-Responsibility for Portion of Mandate that Is in Excess of EHBs, California, 2023

Source: California Health Benefits Review Program, 2022.

*Notes*: (a) States are required to defray the costs of state-mandated benefits that are in excess of EHBs for QHPs. QHPs are a subset of the plans offered in the individual and small group markets.

(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 of the proposed mandated benefit considering some QHPs may already cover the mandated benefit.

(d) 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; EHBs = essential health benefits; QHPs = qualified health plans.

#### **Postmandate Changes in the Number of Uninsured Persons**

The change in average premiums would exceed 1% for DMHC-regulated small-group and individual plans and for CDI-regulated individual policies (Table 6); however, when split into premiums stemming from fertility services versus pregnancies and births, the average change in premiums from fertility services would be below 1%. CHBRP expects potential premium increases might be applied by health plans and policies in different years subsequent to the mandate, thus premium increases would likely be spread out. It is unclear how these increases in premiums could translates into uninsurance postmandate 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 2029.

#### 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.

#### Summary of benefit coverage, utilization, and cost impacts:

Benefit coverage for fertility services increases from 23% at baseline to 100% postmandate. No enrollees have baseline benefit coverage that is compliant with AB 2029's cost-sharing provision.

Many enrollees using fertility services at baseline either pay for the services fully out of pocket because the services are not covered or pay cost sharing that is different from "major medical." Postmandate, these enrollees experience a reduction in out-of-pocket expenses for fertility services.

Utilization of fertility services increases postmandate for enrollees who did not have coverage at baseline and become newly covered postmandate. Postmandate, CHBRP estimates IVF utilization rises to about 2 procedures per 1,000 with a similar increase for ISCI. For both ICSI and IVF, these changes reflect an 80% increase in utilization postmandate.

With increases in utilization of fertility services and resulting pregnancies and births, there would be an increase in enrollee expenditures reflected in the increase in per member per month enrollee expenditures.

For the enrollee, how cost sharing shifts depends on their baseline benefit coverage and utilization that shifts postmandate, for example:

• For the enrollees who do not have coverage at baseline and use fertility services paid for entirely out of their own pocket, there would be a **decrease** in enrollee out-of-pocket expenses for these

noncovered benefits postmandate. Cost sharing for covered fertility services postmandate would be less than out-of-pocket expenses at baseline.

- For enrollees who have coverage at baseline and use fertility services but have cost sharing that is more than major medical (e.g., 50% coinsurance and no annual out-of-pocket maximum), there would be a **decrease** in enrollee out-of-pocket expenses for fertility services postmandate.
- For enrollees who do not have coverage at baseline and are not using these services due to cost barriers, there would be an **increase** in enrollee out-of-pocket expenses given their new utilization of fertility services; they would also experience new expenses for new pregnancies and births postmandate.

			DMHC	-Regulated				CDI-Regula	ited	
	-	ommercial I (by Market)		Pul	olicly Funded	Plans	C	ommercial P (by Market)		
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)(f)	MCMC (65+) (c)(f)	Large Group	Small Group	Individual	Total
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Total enrollees in plans/policies subject to AB 2029	8,317,000	2,125,000	2,758,000	881,000	0	0	485,000	44,000	166,000	14,776,000
Premiums									-	
Average portion of premium paid by employer	\$407.24	\$369.14	\$0	\$557.65	\$238.69	\$521.94	\$465.60	\$379.33	\$0	\$84,852,462,000
Average portion of premium paid by employee	\$166.59	\$204.69	\$691.58	\$113.48	\$0	\$0	\$228.48	\$246.41	\$572.88	\$48,534,724,000
Total premium	\$573.83	\$573.83	\$691.58	\$671.13	\$238.69	\$521.94	\$694.08	\$625.74	\$572.88	\$133,387,186,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	\$48.46	\$124.44	\$175.87	\$58.77	\$0	\$0	\$146.18	\$200.65	\$200.15	\$15,807,011,000
Expenses for noncovered benefits (e)	\$1.02	\$2.44	\$2.77	\$1.30	\$0	\$0	\$2.02	\$2.34	\$2.72	\$287,570,000
Total expenditures	\$623.30	\$700.71	\$870.22	\$731.19	\$238.69	\$521.94	\$842.28	\$828.73	\$775.74	\$149,481,767,000

Table 5. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2023

Source: California Health Benefits Review Program, 2022.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace). (b) Approximately 51.7% 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.

(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 covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

(f) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. *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.

			DMHC-	Regulated	-	-		CDI-Regula	ated	
	С	Commercial P (by Market)		Pub	olicly Funded	Plans	C	ommercial P (by Market		
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)(f)	MCMC (65+) (c)(f)	Large Group	Small Group	Individual	Total
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Total enrollees in plans/policies subject to AB 2029	8,317,000	2,125,000	2,758,000	881,000	0	0	485,000	44,000	166,000	14,776,000
Premiums										
Average portion of premium paid by employer	\$3.20	\$4.10	\$0.00	\$4.79	\$0.00	\$0.00	\$3.73	\$3.47	\$0.00	\$497,820,000
Average portion of premium paid by employee	\$1.31	\$2.28	\$7.13	\$0.97	\$0.00	\$0.00	\$1.83	\$2.25	\$6.55	\$459,628,000
Total premium	\$4.50	\$6.38	\$7.13	\$5.77	\$0.00	\$0.00	\$5.56	\$5.72	\$6.55	\$957,449,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	-\$0.52	\$1.34	\$1.56	\$0.05	\$0.00	\$0.00	\$0.97	\$1.71	\$1.99	\$44,920,000
Expenses for noncovered benefits (e)	-\$1.02	-\$2.44	-\$2.77	-\$1.30	\$0.00	\$0.00	-\$2.02	-\$2.34	-\$2.72	-\$287,570,000
Total expenditures	\$2.96	\$5.28	\$5.92	\$4.52	\$0.00	\$0.00	\$4.51	\$5.09	\$5.82	\$714,799,000
Percent change										
Premiums	0.78%	1.11%	1.03%	0.86%	0.00%	0.00%	0.80%	0.91%	1.14%	0.72%
Total expenditures	0.48%	0.75%	0.68%	0.62%	0.00%	0.00%	0.54%	0.61%	0.75%	0.48%

#### Table 6. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2023

Source: California Health Benefits Review Program, 2022. Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Approximately 51.7% 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.

(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 covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

(f) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

*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

# **PUBLIC HEALTH IMPACTS**

As discussed in the *Policy Context* section, AB 2029 would modify the current fertility mandate, which requires health plans and policies to *offer* coverage for fertility services, excluding in vitro fertilization (IVF) coverage, to require all DMHC-regulated health plans and CDI-regulated policies, excluding Medi-Cal, to *provide* coverage for infertility treatments, including IVF with a limit of four oocyte retrievals.

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<sup>46</sup> of AB 2029 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.

## **Estimated Public Health Outcomes**

Measurable public health outcomes relevant to AB 2029 include mental health and quality of life, multiple gestation pregnancy outcomes, and impact on barriers to infertility treatments.

As presented in the *Medical Effectiveness* section, there is *clear and convincing evidence* that infertility treatment health insurance mandates are associated with an increase in utilization of infertility treatments and lower likelihood of adverse birth outcomes, including rates of multiple births; there is also *clear and convincing evidence* that IVF is an effective treatment for infertility, and state health insurance mandates for *infertility treatments* are associated with a decrease in the number of embryos transferred per IVF cycles.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, 23% of enrollees with health insurance subject to AB 2029 have coverage for infertility treatments, including IVF, at baseline. If enacted, CHBRP estimates that the proportion of enrollees with insurance coverage for infertility treatment, including IVF, would increase to 100% postmandate. In addition, utilization of IVF and intracytoplasmic sperm injection (ICSI) procedures would increase by 80% relative to baseline (1.1% absolute IVF utilization increase); utilization for other fertility services such as diagnostic tests and medications would also increase, albeit to a smaller degree, in the range of a 3% to 19% increase in the first year postmandate. These increases in fertility services utilization translate into an increase of 7,000 pregnancies due to fertility services postmandate (a 54% increase in pregnancies) and an increase in of 6,000 live birth deliveries due to fertility services postmandate (a 55% increase in live birth deliveries).

As presented in Table 1, among those with health insurance subject to AB 2029, CHBRP estimates an increase in pregnancies resulting from increased utilization of infertility treatments in the first year postmandate by 7,000 (from 13,000 to 20,000) and an increase in live birth deliveries by 6,000 (from 11,000 to 17,000) due to 14,500 ART procedures (from 18,200 to 32,700). These estimates are supported by *clear and convincing evidence* that infertility treatments, including IVF, are medically effective at leading to live birth compared to no infertility treatment, and *clear and convincing evidence* that health insurance benefit mandates are effective in increasing utilization of treatments for infertility, including IVF. Although AB 2029 would greatly reduce financial barriers to IVF utilization for covered enrollees, cost sharing could still represent a significant financial barrier for some enrollees.

#### Mental Health and Quality of Life Outcomes

Receiving an infertility diagnosis can be a cause of stress, distress, anxiety, and depression among both females and males (Ethics Committee of the American Society for Reproductive Medicine, 2021b; Greil et al., 2010; Nelson et al, 2008; Zurlo et al., 2018). The stress attributable to infertility in females has been

<sup>&</sup>lt;sup>46</sup> CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

compared to that experienced by female cancer patients (Roudsari et al., 2007). 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 3 years or longer (Zurlo et al., 2018). Men and women experience anxiety and lower fertility-specific quality of life in the time before starting infertility treatment (Cusatis et al., 2019).

CHBRP also reviewed literature regarding the psychosocial impacts of undergoing treatment for infertility. Milazzo et al. (2016) showed that infertility-associated depression and anxiety significantly increased for both men and women in the period directly following a failed ART treatment. 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). For insured women who end infertility treatments, psychological stress is the most common burden reported followed by out-of-pocket costs and loss of insurance (Domar et al., 2018).

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. 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, 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).

CHBRP found evidence that mental health and quality of life would improve for the additional 6,000 persons and couples who would have live birth deliveries resulting from infertility treatments postmandate. CHBRP also 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 associated with stress, anxiety, depression, and quality-of-life deficits that decreases upon the achievement of a successful pregnancy through treatment.

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 attempting 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 Fertility 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 2029, 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 and harms associated with offspring conceived with ART.

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 (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). Offspring harms associated with IVF include preterm birth, low birthweight, congenital malformations (central

nervous system abnormality, urogenital system abnormalities, musculoskeletal disorders), and infant death, and these risks are highest among multiple gestation pregnancies (Qin et al., 2016).

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<sup>47</sup> (Banks et al., 2010; Kulkarni et al., 2017; Martin et al., 2011; Smith et al., 2011). 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 differences in rates of pregnancies, suggesting that lower-income women may have been incentivized by high costs to transfer multiple embryos during a single transfer procedure 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).

Evidence shows that state mandates for fertility service coverage reduce the number of embryos transferred and IVF-associated multiple births (Banks et al., 2010; Boulet et al., 2015; Crawford et al., 2016). A recent study found that in states with mandates that provide comprehensive<sup>48</sup> coverage for fertility services, significantly fewer embryos were transferred per transfer procedure compared to states with noncomprehensive coverage for fertility services. Furthermore, in states with comprehensive coverage for fertility services, multiple births per pregnancy were significantly lower compared to states with noncomprehensive fertility service coverage (Peipert et al., 2022).

AB 2029 states that coverage for IVF includes four oocyte retrievals with unlimited embryo transfers and should use single-embryo transfers when recommended and medically appropriate per the ASRM guidelines. (See Single Embryo Transfer in *Background* section for discussion of ASRM guidelines for single-embryo transfers.)

CHBRP estimates that AB 2029 would decrease the rate of multiple gestation pregnancies from baseline levels for enrollees without IVF coverage for 6.7% twin births and 0.3% multiple births (i.e., more than twins) among all IVF births to postmandate estimates for enrollees with IVF coverage for 4.5% twin births and 0.2% multiple births postmandate among IVF births by limiting IVF to single-embryo transfers and by decreasing the financial barrier to IVF that has previously encouraged multiple embryos transferred in a single IVF cycle, and thus decrease the harms associated with multiple gestation pregnancies for enrollees accessing IVF treatments.

For enrollees who experience multiple gestation pregnancies, the risks associated with IVF and infertility treatments remain unchanged. However, the benefits of IVF may outweigh the risks for persons who desire a child.

# Impact on Disparities for Commercial and CalPERS Enrollees<sup>49</sup>

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

http://chbrp.com/analysis\_methodology/public\_health\_impact\_analysis.php.

<sup>&</sup>lt;sup>47</sup> The median cost of one cycle of IVF, including medications, in the United States is \$19,234 (Wu et al., 2014).
<sup>48</sup> States included in the comprehensive coverage category had insurance mandates for fertility services that included coverage for IVF compared to noncomprehensive states where coverage did not include IVF, excluded certain segments of the insurance market, limited treatment cycles, require 5 years of infertility, or had lifetime caps (Peipert et al., 2022).

<sup>&</sup>lt;sup>49</sup> For details about CHBRP's methodological approach to analyzing disparities, see the *Benefit Mandate Structure* and Unequal Racial/Ethnic Health Impacts document here:

use exist by race/ethnicity, marital status and sexual orientation, and socioeconomic status. Within the first year postmandate, among enrollees with commercial insurance, CHBRP estimates AB 2029 could decrease marital status and sexual orientation disparities and could reduce racial/ethnic disparities. Disparities would increase for persons with Medi-Cal as Medi-Cal is excluded by this bill. (See Benefit Mandate Structure and Unequal Racial/Ethnic and Socioeconomic Impacts for discussion of disparities for Medi-Cal. For a 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, disparities exist for racial and ethnic women related to infertility treatment access and outcomes.

The medical effectiveness review found a *preponderance of evidence* that insurance benefit mandates increase utilization of infertility treatments in general and for IVF, specifically. 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 of IVF use by racial and ethnic groups persisted, with the lowest rates observed for Hispanic and non-Hispanic Black women regardless of mandate status. The authors of this review conclude that the disparity may be due to out-of-pocket costs or cultural factors such as infertility stigma or fear disappointing a partner (Dieke et al., 2017).

CHBRP identified two studies that describe the impact of insurance benefit mandates on racial and ethnic differences in fertility treatment outcomes, such as multiple gestation pregnancies and miscarriages. Feinberg et al. (2006) compared treatment outcomes in a military population with insurance for infertility treatment and found that Black 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). Luke et al. (2016) observed that the rates of both preterm births among singleton pregnancies and multiple gestation pregnancy did not differ for 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).

There is evidence that state health insurance mandates for fertility services increase utilization of infertility treatments for Black and Hispanic women; however, the disparity between White women and Black and Hispanic women persists despite increased access to IVF through health insurance coverage for infertility treatments.

Therefore, CHBRP projects that by covering infertility treatments for all commercially insured enrollees, AB 2029 would result in increased IVF utilization by persons of all races/ethnicities; however, there would be no impact on the disparity in IVF utilization between White persons and persons of other racial backgrounds among persons with commercial insurance.

#### Impact on Disparities by Relationship Status, Sexual Orientation, or Gender Identity

As described in the *Background* section, an increasing number of single persons, same-sex couples, and transgender and nonbinary persons 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, same-sex couples, and transgender and nonbinary persons 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, single persons, same-sex couples, and many transgender and nonbinary persons cannot meet this standard. CHBRP did not find any literature addressing the differential impact of more- or less-inclusive infertility definitions for coverage for fertility on disparities in relationship status, sexual orientation, or gender identity. However, if passed, AB 2029 would amend the current infertility treatment benefit mandate in California by removing the definitional clause defining infertility by the aforementioned clinical standard and would include the following definition of infertility: "person's inability to reproduce either as an individual or with their partner without medical intervention." If enacted, AB 2029 would also preserve the current nondiscrimination clause that prohibits the denial of coverage for infertility treatments on the basis of relationship status, sexual orientation, or gender identity.

Single persons, same-sex couples, and many transgender and nonbinary persons will require donor materials and possibly gestational carriers or surrogates in addition to IVF to achieve pregnancy. To the extent that AB 2029 mandates coverage for both IVF and medical costs associated with the use of donor materials and IVF procedures for gestational carriers or surrogates, there would be a reduction in the substantial financial barriers for persons who need third-party reproduction. Coverage for medical costs for third-party reproduction would reduce financial disparities between those who do not require donor material for fertility and those that do. However, cost sharing would still be required and so persons requiring these more costly medical services would have a greater cost-sharing burden. Additionally, AB 2029 would not cover the fee to purchase donor oocytes or sperm or the service fee for a gestational carrier or surrogate. This may continue part of a financial disparity wherein persons who need third-party reproduction retain higher out-of-pocket costs as compared with - persons who may not need to utilize donor materials or gestational carriers or surrogates to conceive. For example, one study 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 2029 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 \$80,000 to \$140,000 depending on medical and legal arrangements (National LGBT Health Education Center, 2019).

AB 2029 would remove language from current law that defines infertility between opposite-sex couples and expand the definition of infertility to include an individual or couple with an inability to reproduce, thereby potentially removing one barrier to care. CHBRP projects that this more inclusive definition of infertility would increase access to fertility care for single persons, same-sex couples, and transgender and nonbinary persons and would reduce disparities in infertility treatment by relationship status, sexual orientation, or gender identity.

It should be noted that, by allowing cost sharing (albeit greatly reducing out-of-pocket costs as compared with baseline), the implementation of AB 2029 would not eliminate all financial disparities in fertility treatment between those who do not require third-party reproduction and those that do.

#### **Impact on Socioeconomic Disparities**

As described in the *Background* section, cost is one of the most significant barriers to treatment for infertility. 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.

AB 2029, as described in the *Medical Effectiveness* and *Cost* sections, would result in a reduction of \$287,570,000 in previously uncovered expenses associated with infertility 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 would be reduced, thereby reducing income-associated disparities in infertility treatment use postmandate among

enrollees impacted by AB 2029. However, AB 2029 does require cost sharing consistent with cost sharing for major medical care these requirements may vary across different plans and policies and offer different out-of-pocket maximums, deductibles, and cost-sharing amounts. It is unknown to the extent that different enrollees are impacted by cost-sharing requirements; therefore, the cost sharing associated with AB 2029 may still be a financial barrier for enrollees with newly covered infertility treatments including IVF. One study on IVF utilization after insurance mandate found utilization was highest among high-income women, and the authors concluded that the 20% cost sharing may have discouraged use for some women (Dupree et al., 2019). Incurring one large health care–associated payment can be especially burdensome for lower resource persons, and research shows that most adults are not prepared for a financial disruption of \$400 or greater (Chen et al., 2021; Federal Reserve, 2020).

Although documented income-related disparities in infertility treatment use may be alleviated among enrollees with commercial insurance policies and plans, it should be noted that AB 2029 does not apply to Medi-Cal. By definition, Medi-Cal enrollees are low-income, as are a significant portion of enrollees in the individual market. Excluding this group 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 (Ethics Committee of the American Society for Reproductive Medicine, 2021b).

AB 2029 would increase utilization of infertility treatments among enrollees with mandated coverage and as a result and would reduce out-of-pocket spending for fertility treatments by \$287,570,000 among enrollees. To the extent that the mandated coverage would reduce 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 would be distributed across income levels and how different cost-sharing requirements impact persons of varying income levels; therefore, the reduction in income-related disparities in access to fertility treatments is unknown.

# **Benefit Mandate Structure and Unequal Racial/Ethnic and Socioeconomic Impacts**

AB 2029 would require compliance from the health insurance of enrollees in CDI-regulated policies and other enrollees in DMHC-regulated plans but would not be applicable to the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans. As previously discussed, disparities related to infertility treatments exist for racial/ethnic groups and low-income persons and **excluding Medi-Cal beneficiaries** from coverage for infertility treatments and services may increase the existing disparities.

People from minority racial/ethnic groups including people who are Hispanic, Black, and Asian represent around 80% of Medi-Cal enrollees in DMHC-regulated plans compared to 55% of commercial enrollees. However, while these racial/ethnic groups are overrepresented in the Medi-Cal population relative to their share of California's population, there are more people from minority racial/ethnic groups among commercial enrollees (around 8 million) than there are among Medi-Cal beneficiaries enrolled in DMHC-regulated plans (around 5 million).<sup>50</sup> By not extending coverage for infertility treatments including IVF to the Medi-Cal population, which covers a higher proportion of Hispanic and Black persons than other races/ethnicities, AB 2029 has the potential to further increase disparities in access to infertility treatments by race/ethnicity. See the *Background* section for further discussion of barriers and factors that impact IVF utilization and disparities.

Although some documented income-related disparities in infertility treatment use may be alleviated among enrollees with commercial insurance policies and plans, as AB 2029 does not apply to Medi-Cal and, by definition, Medi-Cal enrollees are low-income, excluding this group will result in the persistence of

<sup>&</sup>lt;sup>50</sup> See the CHBRP report *Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts*, available at: https://files4.1.revize.com/chbrpnew/Benefit%20Mandate%20Structure%20and%20Race%20and%20Ethnicity%20.p df

high out-of-pocket expense burdens for these persons. This has the potential to exacerbate infertility treatment use and outcome disparities between Medi-Cal and commercial insurance enrollees.

AB 2029 excludes Medi-Cal beneficiaries enrolled in DMHC-regulated plans for mandated coverage for infertility treatment, including IVF. CHBRP identified existing disparities in infertility treatments for Black and Hispanic persons compared to White persons and for low-income persons. In excluding Medi-Cal, a significant portion of Black and Hispanic persons and low-income persons in California would continue to face high out-of-pocket and uncovered costs for infertility treatment, which could potentially exacerbate racial/ethnic and income-related disparities in infertility treatment use and infertility outcomes.

# LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of AB 2029, 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.

For AB 2029, many of the health outcomes discussed in the *Medical Effectiveness* and the *Public Health* sections would occur after the first 12 months due to the time required for in vitro fertilization (IVF) treatment and pregnancy. Additionally, some persons undergoing IVF will repeat the process in the future for an additional child. The process from identifying infertility; undergoing infertility diagnostic testing; deciding to pursue IVF; beginning hormone treatment for IVF; oocyte retrieval or procuring donated oocytes, sperm preparation, or procuring donated sperm; creating the embryo; genetic testing if needed; and embryo transfer can take from several months to more than a year. If the process does not successfully lead to pregnancy and birth, it would need to be repeated. For IVF that results in successful pregnancy, the typical pregnancy duration is 10 months. Therefore, the majority of the impact of AB 2029 would occur after the first 12 months. This includes the same impacts seen in the first 12 months that occur after 12 months for persons who do not complete IVF or pregnancy within 12 months, for persons who complete IVF again for an additional pregnancy in later years, and for persons who newly access IVF treatment in future years. It also includes additional impacts that would occur years after IVF treatments done within the first 12 months or in later years.

# Long-Term Utilization and Cost Impacts

#### **Utilization Impacts**

As discussed above, in the short-term, the aggregate pregnancy and birth rate would be expected to increase postmandate due to increased utilization of fertility services. In the longer term, it is possible that the coverage for fertility services would result in encouraging couples to undergo infertility treatment earlier than they would normally and where pregnancy might be achieved naturally given more time (Machado and Sanz-de-Galdeano, 2015). It is also possible that in the longer term, coverage for fertility services might encourage delays in childbearing or encourage higher use among older enrollees, thus shifting utilization to females on the upper end of the age spectrum where fertility services are still clinically appropriate. In the study by Peipert et al. (2022), there was significantly higher utilization among the oldest age group (42 years and older; 4.38 cycles per 1,000) in states with comprehensive fertility mandates (2.67 cycles per 1,000). This older age group in mandate states had significantly higher live birth rates per cycle (4%) compared to nonmandate states (2%) (Peipert et al, 2022).

#### **Cost Impacts**

A study using claims data from 2011 found per member per month expenditures for infertility treatment were three times higher for those living in states with a mandate compared with states without a mandate (Boulet et al., 2019). Per correspondence with the author of the study, it is unclear if any unit cost change in the services might have occurred postmandate, thus it is unclear if costs of fertility services change when mandates are introduced. Per CHBRP's content expert, it is possible that over time as fertility services are covered, there may be pressure on 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 fertility 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 2029, long-term health outcomes associated with insurance coverage for IVF include pregnancy outcomes over time and long-term mental health outcomes after IVF.

#### **Reduced Harms Associated with Multiple Births**

Insurance coverage for IVF is associated with fewer medically unnecessary multiple-embryo transfers and ongoing insurance coverage will be associated with a sustained reduction in multiple-embryo transfers. Therefore, in future years as in the first year postmandate, fewer multiple-embryo transfers would be associated with fewer multiple gestation pregnancies, fewer multiple births, and fewer maternal and offspring harms that are associated with multiple gestation pregnancies and multiple deliveries. Some of these maternal and offspring harms could have long-term health impacts and these would then be avoided.

#### Long Term Parental Mental Health

Research shows that successful assisted reproductive technology (ART) treatment is associated with improved mental health outcomes for women impacted by infertility. A study that looked at female mental health outcomes 20 to 23 years after IVF attempts found that fewer women who had biologic children reported depression symptoms compared to women who do not have children (Vikstrom et al., 2015). For couples who experience infertility, AB 2029 could prevent long-term negative mental health outcomes associated with infertility and not being able to have a desired child to the extent that AB 2029 allows access to IVF that was previously inaccessible due to financial barriers and that ART treatments are successful and result in live birth.

# APPENDIX A TEXT OF BILL ANALYZED

On February 16, 2022, the California Assembly Committee on Health requested that CHBRP analyze AB 2029.

#### **ASSEMBLY BILL**

NO. 2029

#### Introduced by Assembly Member Wicks

#### February 14, 2022 Amended April 6, 2022

An act to repeal and add Section 1374.55 of the Health and Safety Code, and to repeal and add Section 10119.6 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2029, as introduced, Wicks. Health care coverage: treatment for 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, offer coverage for the treatment of infertility, except in vitro fertilization. Existing law provides that any employer that is a religious organization, or a health care service plan or health insurer that is 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 a health care service plan contract or health insurance policy that is issued, amended, or renewed on or after January 1, 2023, to provide coverage for the diagnosis and treatment of infertility and fertility services. The bill would revise the definition of infertility, and would remove the exclusion of in vitro fertilization from coverage. The bill would delete the exemption for religiously affiliated employers, health care service plans, and health insurance policies, health care service plans and health insurers 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 a 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. With respect to a health care service plan contracts

or any entity that enters into a contract with the State Department of Health Care Services for the delivery of health care services pursuant to specified provisions. The bill would prohibit a health care service plan that is a health maintenance organization or health insurer from placing different conditions or coverage limitations on fertility medications or services, or the diagnosis and treatment of infertility and fertility services, than would apply to other conditions, as specified. Because the violation of these provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program.

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

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

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

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

**SECTION 1.** Section 1374.55 of the Health and Safety Code is repealed.

**SEC. 2.** Section 1374.55 is added to the Health and Safety Code, to read:

**1374.55.** (a) A health care service plan contract that covers hospital, medical, or surgical expenses that is issued, amended, or renewed on or after January 1, 2023, shall provide coverage for the diagnosis and treatment of infertility and fertility services. The coverage required by this subdivision includes four completed oocyte retrievals with unlimited embryo transfers in accordance with the guidelines of the American Society for Reproductive Medicine (ASRM), using single embryo transfer when recommended and medically appropriate. Every health care service plan shall include notice of the coverage specified in the plan's evidence of coverage.

(b) For purposes of this section, "infertility" means a disease, condition, or status characterized by any of the following:

(1) A licensed physician's findings, based on a patient's medical, sexual, and reproductive history, age, physical findings, diagnostic testing, or any combination of those factors. This definition shall not prevent testing and diagnosis of infertility prior to the 12-month or 6-month period to establish infertility in paragraph (3).

(2) A person's inability to reproduce either as an individual or with their partner without medical intervention.

(3) The failure to establish a pregnancy or to carry a pregnancy to live birth after regular, unprotected sexual intercourse. For purposes of this section, "regular, unprotected sexual intercourse" means no more than 12 months of unprotected sexual intercourse for a person under

35 years of age or no more than 6 months of unprotected sexual intercourse for a person 35 years of age or older. Pregnancy resulting in miscarriage does not restart the 12-month or 6-month time period to qualify as having infertility.

(c)On and after January 1, 2023, every health care service plan that is a health maintenance organization, as defined in Section 1373.10, and that issues, amends, or renews, a health care service plan contract that provides coverage for hospital, medical, or surgical expenses shall provide the coverage specified in subdivision (a). The plan shall include the notice of the coverage specified in the plan's evidence of coverage. The plan may not include any of the following:

#### (c) The contract may not include any of the following:

(1) Any exclusion, limitation, or other restriction on coverage of fertility medications that are different from those imposed on other prescription medications.

(2)Any exclusion, limitation, or other restriction on coverage of any fertility services based on a covered individual's participation in fertility services provided by or to a third party.

(2) Any exclusion or denial of coverage of any fertility services based on a covered individual's participation in fertility services provided by or to a third party. For purposes of this section, "third party" includes an oocyte, sperm, or embryo donor, gestational carrier, or surrogate that enables an intended recipient to become a parent.

(3) Any deductible, copayment, coinsurance, benefit maximum, waiting period, or any other limitation on coverage for the diagnosis and treatment of infertility, except as provided in subdivision (a) that are different from those imposed upon benefits for services not related to infertility.

(d) This section does not in any way deny or restrict any existing right or benefit to coverage and treatment of infertility or fertility services under an existing law, plan, or policy.

(e) Consistent with Section 1365.5, coverage for the treatment of infertility and fertility services shall be 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 subdivision shall not be construed to interfere with the clinical judgment of a physician and surgeon.

(f) This section does not apply to Medi-Cal managed care health care service plan contracts or any entity that enters into a contract with the State Department of Health Care Services for the delivery of health care services pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), Chapter 8.75 (commencing with Section 14591), or Chapter 8.9 (commencing with Section 14700) of Part 3 of Division 9 of the Welfare and Institutions Code.

(g) This section shall not apply to a religious employer, as defined in paragraph (1) of subdivision (c) of Section 1367.25.

SEC. 3. Section 10119.6 of the Insurance Code is repealed.

#### SEC. 4.Section 101196 is added to the Insurance Code, to read:

#### <del>101196. (a)A</del>

#### SEC. 4. Section 10119.6 is added to the Insurance Code, to read:

**10119.6.** (*a*) *A* policy of disability insurance that covers hospital, medical, or surgical expenses that is issued, amended, or renewed on or after January 1, 2023, shall provide coverage for the diagnosis and treatment of infertility and fertility services. The coverage required by this subdivision includes four completed oocyte retrievals with unlimited embryo transfers in accordance with the guidelines of the American Society for Reproductive Medicine (ASRM), using single embryo transfer when recommended and medically appropriate. Every insurer shall include notice of the coverage specified in the insurer's evidence of coverage.

(b) For purposes of this section, "infertility" means a disease, condition, or status characterized by any of the following:

(1) A licensed physician's findings, based on a patient's medical, sexual, and reproductive history, age, physical findings, diagnostic testing, or any combination of those factors. This definition shall not prevent testing and diagnosis prior to the 12-month or 6-month period to establish infertility in paragraph (3).

(2) A person's inability to reproduce either as an individual or with their partner without medical intervention.

(3) The failure to establish a pregnancy or to carry a pregnancy to live birth after regular, unprotected sexual intercourse. For purposes of this section "regular, unprotected sexual intercourse" means no more than 12 months of unprotected sexual intercourse for a person under 35 years of age or no more than 6 months of unprotected sexual intercourse for a person 35 years of age or older. Pregnancy resulting in miscarriage does not restart the 12-month or 6-month time period to qualify as having infertility.

(c) The policy may not include any of the following:

(1) Any exclusion, limitation, or other restriction on coverage of fertility medications that are different from those imposed on other prescription medications.

(2) Any exclusion or denial of coverage of any fertility services based on a covered individual's participation in fertility services provided by or to a third party. For purposes of this section, "third party" includes an oocyte, sperm or embryo donor, gestational carrier, or surrogate that enables an intended recipient to become a parent.

(3) Any deductible, copayment, coinsurance, benefit maximum, waiting period, or any other limitation on coverage for the diagnosis and treatment of infertility, except as provided in

subdivision (a) that are different from those imposed upon benefits for services not related to infertility.

#### <del>(e)</del>

(*d*) This section does not in any way deny or restrict any existing right or benefit to coverage and treatment of infertility or fertility services under an existing law, plan, or policy.

#### <del>(d)</del>

(e) 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.

#### <del>(e)</del>

(f) Consistent with Section 10140, coverage for the treatment of infertility and fertility services shall be 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 subdivision shall not be construed to interfere with the clinical judgment of a physician and surgeon.

(g) This section shall not apply to a religious employer, as defined in paragraph (1) of subdivision

#### (e) of Section 10123.196.

**SEC. 5**. 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 literature review conducted for this report. A discussion of CHBRP's system for medical effectiveness grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

Studies of infertility treatments and impacts of fertility 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 American Society for Reproductive Medicine (ASRM) was search for professional guidelines and committee opinion reports. The search was limited to abstracts of studies published in English.

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

## **Medical Effectiveness Review**

CHBRP reviewed 41 articles identified in the literature review related to the impact of IVF insurance mandates for potential inclusion in this analysis of AB 2029. A total of four studies were included in the medical effectiveness report for this report, as well as 24 studies included in the previous review for AB 767. The other articles were eliminated because they did not focus on mandated coverage including IVF, did not report relevant outcomes, or were not reporting findings from clinical research studies.

## **Medical Effectiveness 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*.<sup>51</sup> 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;

<sup>&</sup>lt;sup>51</sup> Available at: <u>http://chbrp.com/analysis\_methodology/medical\_effectiveness\_analysis.php</u>.
- Inconclusive evidence; and
- Insufficient evidence.

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the <u>large majority</u> 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 <u>majority</u> 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.

### **Search Terms (\* indicates truncation of word stem)**

**Birth Injuries Birth Rate Cost Analysis Cost Benefit Analysis** Cost of Illness Cost Savings Dystocia Embryo Transfer **Epidemiologic Studies** Ethnicity Fetal Death Gender Identity Gender Identity Health Care Costs Health Disparity, Minority and Vulnerable Populations Health Impact Assessment Health Inequities Health Services Accessibility Health Services Administration Healthcare Disparities Incidence Infertility Insemination, Artificial Insurance Coverage Insurance Coverage Insurance, Health Intracytoplasmic Sperm Injection

Maternal Age Minority Health **Oocyte Donation** Oocytes Pregnancy Pregnancy Complications Pregnancy Outcome **Pregnancy Rate** Pregnant Women Prevalence Procedures and Techniques Utilization Quality of Life **Race Factors** Racial Groups Reproductive History **Reproductive Medicine** Reproductive Techniques, Assisted Sex Factors Sexual and Gender Minorities Sexuality Single Person Social Determinants of Health Sperm Injections, Intracytoplasmic Stress, Psychological Surrogate Mothers Transgendered Persons Treatment Outcome Utilization Review

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

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc, the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.<sup>52</sup> 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.<sup>53</sup>

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

## **Analysis-Specific Data Sources**

Current coverage for infertility for commercial enrollees was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represented 86% of commercial enrollees with health insurance that can be subject to state benefit mandates. In addition, CalPERS and DHCS were queried regarding related benefit coverage.

For this analysis, CHBRP relied on Current Procedural Terminology (CPT<sup>®</sup>) codes to identify services related to AB 2029. CPT copyright 2022 American Medical Association. All rights reserved. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. CPT is a registered trademark of the American Medical Association.

## **Analysis-Specific Caveats and Assumptions**

The analytic approach and key assumptions are determined by the subject matter and language of the bill being analyzed by CHBRP. As a result, analytic approaches may differ between topically similar analyses, and therefore the approach and findings may not be directly comparable. Prior CHBRP analyses of fertility service bills were developed focusing on the annual cost of all fertility services for users of fertility services. The analysis of AB 2029 was developed using the cost and utilization of each fertility service. The methodology and results of AB 2029 cost analysis are not comparable to results of prior infertility bills.

### Methodology and Assumptions for Baseline Benefit Coverage

- The population subject to the mandated offering includes persons covered by DMHC-regulated commercial insurance plans, CDI-regulated policies, and CaIPERS plans subject to the requirements of the Knox-Keene Health Care Service Plan Act.
- CHBRP surveyed the carriers to determine the percentage of the population with coverage for fertility services. For carriers who did not respond to the 2022 survey, the response from the 2020 survey for AB 2781 or 2019 AB 767 was assumed.

 <sup>&</sup>lt;sup>52</sup> CHBRP's authorizing statute, available at <u>https://chbrp.org/about\_chbrp/index.php</u>, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
 <sup>53</sup> See method documents posted at <u>http://chbrp.com/analysis\_methodology/cost\_impact\_analysis.php</u>; in particular, see 2022 Cost Analyses: Data Sources, Caveats, and Assumptions.

### Methodology and Assumptions for Baseline Utilization

### In vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI)

- CHBRP estimated the number of IVF procedures per 1,000 commercially insured enrollees that occurred in 2019 based on the total number of IVF procedures and transfers performed in California for California residents according to the State Specific Assisted Reproductive Technology Surveillance 2019 Data Brief published by the CDC, assuming all IVF procedures were performed on CalPERS, self-insured, and fully insured enrollees. The number of transfers and cycles were grossed up to account for only 98% of clinics reporting data (i.e., the reported data is assumed to account for 98% of IVF procedures). CHBRP assumes the transfers reported by the CDC were full cycles including retrievals and transfers, and the difference between the total number of procedures performed and reported transfers are retrieval-only cycles.
- The total rate of IVF procedures per 1,000 enrollees was then refined into estimated rates for enrollees with and without coverage for IVF. This allocation assumed 0% of CaIPERS (2022 and 2020 CHBRP carrier surveys), 24% of fully insured (2022 and 2020 CHBRP carrier surveys), and 37% of self-funded employers (KFF, 2020) had coverage for IVF.
- CHBRP assumed the population with coverage utilizes IVF at a rate per 1,000 equal to 2.3 times the IVF utilization rate per 1,000 for the population without coverage (Peipert et al., 2022). The underlying analysis used to determine the utilization differential between enrollees with and without coverage compares utilization data from states with and without coverage mandates. Some enrollees in the states without coverage mandates may already have coverage for fertility services while enrollees in states with coverage mandates may not be state-regulated and are not required to offer coverage. Using the utilization differential between data from states with and without coverage mandates as a proxy for the utilization differential between enrollees with and without coverage mandates as a proxy for the utilization differential between enrollees with and without coverage mandates as a result of AB 2029.
- The IVF procedures per 1,000 rates for enrollees with and without coverage for IVF were then multiplied by the percentage of cycles IVF cycles that include ICSI, 76.6%, (2019 CDC Assisted Reproductive Technology Fertility Clinic and National Summary Report) to determine the rate of ICSI for enrollees with and without coverage.
- The IVF and ICSI procedures per 1,000 rates were then trended from 2019 to 2023 using a 0.2% annual utilization trend developed by comparing the 2019 and 2018 CDC State-Specific Assisted Reproductive Technology Surveillance Reports. An additional one-time 30% increase was included in the 2023 estimate to account for the recent sustained increase in utilization of IVF observed after the conclusion of the lock-down period of the COVID-19 pandemic (Zhou et al., 2021).

### Other fertility services

- Fertility services were identified in Milliman's proprietary 2019 Consolidated Health Cost Guidelines™ Sources Database (CHSD). This database only captures services that are covered by insurance.
- Content expert input and guidance from recent research on the impact of state-level infertility mandates on health plan expenditures that 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, Z3181, Z3183, Z3189, Z31441, Z3149, Z317, Z319, N4601, N46021, N46022, N46023, N46024, N46025, N46029, N4611, N46121, N46122, N46123, N46124, N46125, N46129.
  - Diagnostic procedures For the claims with the infertility diagnosis codes, the following CPT <sup>54</sup>/Healthcare Common Procedure Coding System (HCPCS) codes were used to identify diagnostic services: 54500, 54505, 54800, 55200, 55300, 55550, 58340, 58345,

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58350, 58540, 58560, 58700, 58740, 58752, 58770, 58920, 74740, 76831, 83001, 83002, 89300, 89310, 89320, 89321, 89322, 89325, 89329, 89330, 89331, G0027, S3655, Q0115. Only services provided to females ages 18-44 and males ages 18-60 were included in the analysis.

- Male treatments were identified as claims with an infertility diagnosis code and the following CPT/HCPCS codes: 0357T, 55400, 58323, 55870, 58970, 58974, 58976, 89250, 89251, 89253, 89254, 89255, 89257, 89258, 89259, 89260, 89261, 89264, 89268, 89272, 89280, 89281, 89290, 89291, 89335, 89337, 89342, 89343, 89344, 89346, 89352, 89353, 89354, 89356, 89398, S4011, S4015, S4016, S4017, S4018, S4020, S4021, S4022, S4023, S4025, S4026, S4027, S4028, S4030, S4031, S4035, S4037, S4040, S4042, 76948. Only services provided to males ages 18-60 were included in the analysis.
- Intrauterine insemination (IUI) was identified with the following CPT<sup>55</sup> codes: 58321, 58322. All services that occurred during the IUI visit were included in the cost per service.
- Medications For enrollees with an infertility diagnosis, the following prescription drugs are included: Anastrozole, Bravelle, Bromocriptine mesylate, Cabergoline, Cetrorelix acetate, Cetrotide, Chorionic gonadotropin, Chorionic gonadotropin alfa, Clomid, Clomiphene citrate, Dexamethasone, Estrace, Femara, Follicle stimulating hormone/luteinizing hormone, Follistim aq, Follitropin beta, Follitropin beta/ganirelix acetate, Follitropin alfa, Ganirelix acetate, Glucophage, Gonadorelin acetate, Gonadorelin hydrochloride, Gonal-f, Gonal-f rff, Gonal-f rff pen, Histrelin acetate, Hydroxyprogesterone caproate, Letrozole, Lutropin alfa, Medroxyprogesterone acetate, Menopur, Metformin hcl, Metformin hydrochloride, micronized, Norethindrone, Norethindrone acetate, Novarel, Omnitrope, Ovidrel, Pregnyl w/diluent benzyl, Progesterone, recombinant, Repronex, Synarel, Testosterone gel, Testosterone patch, and Urofollitropin. Only scripts provided to females aged 18 to 44 years and males aged 18 to 60 years are included in the analysis.
- Because CHSD only includes claims for covered fertility services and membership for enrollees with and without coverage, CHBRP divided the utilization rates from the data by the percentage with coverage for each service from the carrier surveys to determine the utilization rate of services for enrollees with coverage.
- IUI and female diagnostic testing utilization among enrollees without coverage in California were assumed to be 10% less than that of enrollees with coverage. Male diagnostic tests, treatments, and medication utilization rates among enrollees without coverage are assumed to be the same as those with coverage. The coverage rate differentials are based on the observed utilization rate change for the state of Delaware before (2018) and after (2019) a similar mandate to cover fertility services went into effect.
- Female medication utilization among enrollees without coverage in California was assumed to be 20% less than that of enrollees with coverage. This value was derived by applying the IVF utilization differential for those with and without coverage to the medication utilization of enrollees who utilized IVF. CHBRP assumed all other female medication utilization would not change.
- The IUI and medication utilization rates were trended from 2019 to 2023 using a 1.3% utilization trend (Zhou et al., 2021). An additional one-time 22% increase was included to account for the recent sustained increase in utilization of infertility care observed after the lock-down period of the COVID-19 pandemic (Zhou et al., 2021).

### Methodology and Assumptions for Baseline Cost

- CHBRP calculated the average cost per service using Milliman's proprietary 2019 Consolidated Health Cost Guidelines™ Sources Database (CHSD).
  - The average costs per IVF full cycle and retrieval only were calculated as the sum of the average allowed costs of services underlying bundled rates for complete IVF and IVF

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cancelled prior to transfer according to the Aetna infertility code mapping tool. CHBRP assumed the visits were distributed among CPT codes 99213-99215. To each case CHBRP added one unit of CPT<sup>3</sup> 00840 for anesthesia and one unit of CPT 99215 as an initial consult.

- The average cost per ICSI was calculated as the average allowed cost per procedure for CPT<sup>56</sup> 89280 and 89281.
- Average costs per script of female medication were developed separately for enrollees who utilized and did not utilize IVF. The average cost per script of females who utilize IVF is over four times the average cost per script of females who did not utilize IVF. The average costs per script were multiplied by the script utilization rates per 1,000 for those who utilized and those who did not utilize IVF to determine the average cost per service at baseline for those with and without coverage for IVF. For lines of business where the percentage with coverage for medications exceeded the percentage with coverage for IVF at baseline, CHBRP assumed the proportion with coverage for IVF also has coverage for medications.
- For all other services, the average cost per service was calculated using the logic used to determine the baseline utilization.
- The average costs per medical service were trended from 2019 to 2023 using a 4% annual trend. Average costs per script for medications were trended from 2019 to 2023 using a 3.5% annual trend. These trends are based on trends from the 2021 Milliman Health Cost Guidelines.

### Methodology and Assumptions for Baseline Cost Sharing

- CHBRP assumed the cost sharing for diagnostic services for enrollees with coverage is the same as major medical cost sharing because diagnostic services for covered persons are covered under the medical plan. Enrollee cost share is equal to one minus the line of business paid-to-allowed ratio multiplied by the diagnostic services cost.
- All other services are assumed to have a 50% coinsurance without an out-of-pocket maximum.
- Services provided to enrollees without coverage are assumed to be paid by the enrollee in full.

#### Methodology and Assumptions for Postmandate Utilization

 CHBRP assumed the utilization rate for enrollees with coverage postmandate is equal to the utilization rate for enrollees with coverage at baseline. CHBRP did not make a utilization adjustment for the difference in cost share at baseline versus what is required postmandate since the underlying experience used to determine the utilization rates likely reflects different enrollee cost sharing.

#### Methodology and Assumptions for Postmandate Cost

 CHBRP assumed the average cost per service would not change as a result of AB 2029. CHBRP assumed an increase in IVF coverage would cause a shift to more expensive medications, resulting in a higher average cost per script.

#### Methodology and Assumptions for Postmandate Cost Sharing

CHBRP assumed the average cost sharing for enrollees in DMHC regulated plans is the same as
cost sharing for other services covered under major medical policies. Enrollee cost share is equal
to one minus the line of business paid-to-allowed ratio multiplied by the average cost per service.
The cost sharing for each service is capped at the average out-of-pocket maximum by line of
business. Because some enrollees may receive more than one service, the accumulation of
these services may cause the enrollee to exceed the out-of-pocket maximum at a faster rate than
implied by this analysis. This analysis does not account for the interaction between the services
and could overstate the cost sharing, thereby understating premium impact.

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### Methodology and Assumptions Related to Pregnancies

- CHBRP assumed 46% of IVF procedures result in pregnancy (CDC, 2019b). Of those pregnancies, 16.8% result in miscarriages, 76.8% are single deliveries, and 6.4% are higher-order deliveries (CDC, 2019b). Triplets and higher-order infants conceived using ART occur at a rate 4 times the rate of all infants. Triplets and higher-order infants occur at a rate of 0.08% (Osterman et al, 2021), implying 6.1% of IVF deliveries are twin deliveries and 0.3% are higher order.
- The IVF multiple-birth rate for states without a comprehensive mandate for coverage for fertility services is 1.4 times the multiple-birth rate of states with a comprehensive mandate (Peipert et al., 2022). Using this statistic and the IVF coverage rates from the carrier surveys, CHBRP assumed that 78.4% of deliveries are single, 4.5% are twins, and 0.2% are multiple-birth for enrollees with coverage for IVF. For those without coverage, CHBRP assumed that 76.2% of deliveries are single, 6.7% are twin deliveries, and 0.3% are multiple birth.
- CHBRP assumed about 15% of IUI procedures result in pregnancy (Starosta et al., 2020). CHBRP assumes about 12% of pregnancies result in a miscarriage (March of Dimes. 2022). CHBRP assumed the delivery distribution is like the overall population, where 84.7% are single, 2.7% are twin and 0.1% are multi-birth deliveries (Osterman et al., 2021).
- The 2022 cost-per-pregnancy assumptions from CHBRP's analysis for AB 2781 are trended to 2023 using a 6.5% outpatient annual trend for miscarriages and 4.0% inpatient annual trend for live births.

Major medical cost sharing, as described in the prior section, is assumed for pregnancies at baseline and post mandate.

## **Determining Public Demand for the Proposed Mandate**

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 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 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 (e.g., Google and Facebook) that do provide coverage for the full range of fertility treatments, suggesting there is a public demand for these services (KFF, 2020; Mercer, 2021).

# Second-Year Impacts on Benefit Coverage, Utilization, and Cost

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of AB 2029 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. CHBRP reviewed the literature and consulted content experts about the possibility of varied second-year impacts and determined the second year's impacts of AB 2029 would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures would be due to population changes between the first year postmandate and the second year postmandate.

# APPENDIX D ADDITIONAL BACKGROUND INFORMATION ON INFERTILITY

# **Definitions of Infertility**

There are multiple definitions of infertility:

- The current fertility treatment mandate includes a definition of infertility;
- AB 2029'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.<sup>57</sup>

**Current fertility treatment mandate.** California's current fertility treatment mandate to offer 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."

**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 opposite-sex 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 (ASRM). 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 (NSFG)**. 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.

**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).

# **Common Causes of Infertility**

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

<sup>&</sup>lt;sup>57</sup> There are likely further definitions of infertility beyond those listed here. These definitions are addressed in this report because they directly relate to AB 2029 and/or the data and literature discussed in the report.

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 aged 30 to 35 years 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.
- **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.

Less common causes of infertility are:

- Infertility among transgender people: People who are transgender and undergo gender confirmation surgery or hormonal therapy could become infertile.
- **latrogenic infertility:** Medically induced infertility caused by a medical intervention used to treat a primary disease or condition. latrogenic infertility is typically caused by cancer treatments, such as radiation and chemotherapy (gonadotoxic treatments) or surgical removal of reproductive organs. Less frequently, fertility is compromised by treatments for autoimmune disorders such as systemic lupus erythematosus or rheumatoid arthritis or Crohn's disease (Bermas and

Sammaritano, 2015; Lawrenz et al., 2011). Autoimmune conditions sometimes require gonadotoxic or surgical treatments (Bermas and Sammaritano, 2015); persons with gender and sex diversity such as those who are transgender may also undergo gonadotoxic treatments.

### **Existing California Law Compared with AB 2029**

As discussed in the *Policy Context* section, AB 2029 modifies the existing mandate to offer services to treat infertility and interacts with other existing California Law. Table 7 provides a high-level comparison of existing California law with AB 2029.

#### Table 7. Existing California Law Compared With AB 2029

	Existing California Laws	Changes due to AB 2029
Coverage requirement for services to treat infertility	Group plans/policies required to <i>offer</i> (excludes HMOs and religious employers)	Mandate to <i>cover</i> (excludes religious employers); applies to individual, small group, and large groups plans/policies.
Definition of infertility	Narrow	Broad
Treatments of infertility	Specifies, excludes IVF	No definition, but does specify that coverage must include four completed oocyte retrievals and unlimited embryo transfers
Fertility preservation	Covered in instances of potential iatrogenic infertility	No change
Cost sharing	Not specified	Limited to same as "major medical"
Other limits	Not specified	Limited to same as "major medical"
Third-party services	Not specified	Potentially included

Source: California Health Benefits Review Program, 2022.

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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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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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