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Analysis of California Senate Bill 523 Health Care Coverage: Contraceptives

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Analysis of California Senate Bill 523 Health Care Coverage: Contraceptives

A Report to the 2021–2022 California State Legislature

April 18, 2021



Key Findings

Analysis of California Senate Bill 523 Health Care Coverage: Contraceptives

Summary to the 2021–2022 California State Legislature, April 18, 2021



SUMMARY

The version of California Senate Bill (SB) 523 analyzed by CHBRP (amended March 16, 2021) would require health plans and policies, including Medi-Cal managed care plans, to expand coverage for contraception to include all U.S. Food and Drug Administration (FDA)-approved contraceptives for men and women, male sterilization procedures, and certain clinical services. The bill also removes the requirement for a prescription to obtain coverage of FDA-approved over-the-counter (OTC) contraceptives. SB 523 requires coverage without cost sharing or out-of-pocket (OOP) expenses for these additional benefits and explicitly prohibits health plans and policies from imposing medical management techniques to access coverage.

In 2022, of the 21.9 million Californians enrolled in state-regulated health insurance, 13.9 million of them would have insurance potentially impacted by SB 523.

Benefit Coverage: CHBRP estimates at baseline 0% of enrollees have coverage of nonprescription OTC contraceptives, and 100% have coverage with some cost sharing, depending on the plan or policy, for vasectomies and related clinical services. At baseline, CHBRP estimates 18,755 commercial enrollees use nonprescription OTC female barrier contraceptives; 106,492 enrollees use emergency contraceptives (EC); 2,080,696 enrollees use nonprescription OTC male barrier contraceptives; and 14,204 enrollees obtain vasectomies and related clinical services per year. SB 523 may exceed the definition of EHBs in California.

Medical Effectiveness: There is *insufficient evidence* to determine how insurance coverage for contraceptives affected by SB 523 and also how utilization management policies impact contraceptive utilization. There is *clear and convincing evidence* that using any of the contraceptives impacted by SB 523 is more effective than not using any contraception in preventing unintended pregnancies, and that condoms are effective in preventing the

transmission of sexually transmitted infections (STIs)/HIV.

Cost and Health Impacts¹: In 2022, CHBRP estimates SB 523 would result in an increase of approximately 4% in utilization of nonprescription OTC contraceptives and of 1.77% for vasectomies and related clinical services. This would result in a \$182,077,000 (-0.14%) decrease in annual expenditures (-0.14%) (includes any likely costs associated with unintended pregnancies and STIs due to increased utilization of contraception, as well as applicable reductions in benefit-related expenses for enrollees).

SB 523 would result in a reduction in negative health outcomes associated with unintended pregnancy. CHBRP is unable to estimate a quantitative impact on STI rates. However, it stands to reason that some new utilizers of condoms may be at lower risk of acquiring or transmitting an STI and be at lower risk for infection-related adverse health outcomes.

CONTEXT

The Affordable Care Act (ACA) requires that nongrandfathered group and individual health insurance plans and policies cover women's preventive care benefits, including the full range of 18 FDA-approved contraceptive methods for women. These benefits, which include OTC contraceptive methods, must be covered without cost sharing if prescribed by a health care provider. California codified this mandate into state law in 2014.²

Contraceptives can be provided in a variety of settings: in a health care provider setting, pharmacy setting, and a retail OTC setting. Each of these settings offers a number of FDA-approved contraceptives. Contraceptives provided through a health care provider are generally contraceptives that need to be inserted or fitted, or include surgical methods of sterilization. Contraceptives provided in a pharmacy setting are those requiring a prescription either from a health care provider or pharmacist. OTC contraceptives are available in a

¹ Similar cost and health impacts could be expected for the following year, though possible changes in medical science

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

² Refer to CHBRP's full report for full citations and references.

retail setting and do not require a health care provider or pharmacist to access.

BILL SUMMARY

SB 523 requires health plans and policies to expand coverage for contraception to include all FDA-approved contraceptives for men and women, male sterilization procedures, and certain clinical services. The bill also removes the requirement for a prescription to obtain coverage of FDA-approved OTC contraceptives. SB 523 requires coverage without cost sharing or OOP expenses for these additional benefits and explicitly prohibits health plans and policies from imposing medical management techniques to access coverage. Specifically, SB 523 does the following:

- Prohibits a health plan or policy from requiring a prescription in order to obtain coverage for FDA-approved OTC contraceptive drugs, devices, and products.
- Requires health plans and policies to provide point-of-sale coverage, without cost sharing or medical management restrictions, for all FDA-approved OTC contraceptive drugs, devices, and products obtained at in-network pharmacies.
- Requires health plans and policies to reimburse enrollees for OOP expenses for OTC birth control methods purchased at any out-of-network pharmacy in California, without medical management restrictions.
- Requires coverage of clinical services related to the provision or use of contraceptives, including consultations, examinations, procedures, ultrasound, anesthesia, patient education, and counseling.
- Allows health plans and policies to limit how often an enrollee may obtain all covered contraceptives and the quantity that they may receive.
- Prohibits health plans and policies from imposing prior authorization, step therapy, or other utilization control techniques on coverage for contraceptive drugs, devices, and products, except as otherwise authorized (see previous bullet).
- Clarifies the definition of medical inadvisability to allow for considerations such as severity of side effects, reversibility of the contraceptive, and ability to adhere to the method. Requires health plans/policies to defer to the judgment of the attending provider in the determination of medical inadvisability of a contraceptive and provide coverage for an alternative prescribed

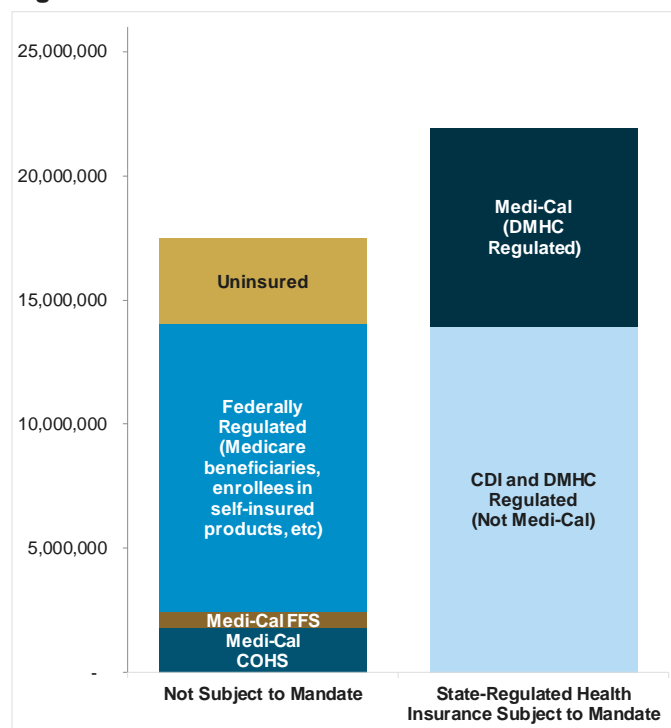
contraceptive, when applicable, without cost sharing.

- Requires religious employers who invoke the religious exemption for contraceptive coverage to inform prospective enrollees/insureds prior to enrollment of all contraceptive coverage that is not available through the plan/policy due to religious reasons.

SB 523 impacts coverage, costs, and related terms and conditions for six contraceptive types, including condoms (male and female), contraceptive sponges, spermicide, levonorgestrel (emergency contraception), and vasectomy.

Figure A notes how many Californians have health insurance that would be subject to SB 523. For beneficiaries under Medi-Cal managed care plans, all contraception that is impacted by the bill is fully covered without cost sharing either under the Medi-Cal program or the California Family Planning, Access, Care, and Treatment (Family PACT) Program, or CHBRP assumes would be covered under the pharmacy benefit and therefore “carved out” of care provided by Medi-Cal managed care plans.

Figure A. Health Insurance in CA and SB 523



Source: California Health Benefits Review Program, 2021.

IMPACTS

Benefit Coverage, Utilization, and Cost

Benefit Coverage

CHBRP estimates at baseline 0% of enrollees have coverage of nonprescribed OTC contraceptives, and 100% have coverage for vasectomies and related clinical services. Among commercial/CalPERS enrollees, vasectomies and related clinical services have an average of \$341 in cost sharing; this is an average across all enrollees, including enrollees in preferred provider organization (PPO) and HMO plans.

Utilization

CHBRP estimates that postmandate, there would be a cost shift and increase in utilization of nonprescription OTC contraceptives and vasectomies and related clinical services due to the elimination of cost sharing for vasectomies and OOP costs for nonprescription OTC contraceptives proposed under SB 523. CHBRP estimated utilization would increase by 4.8% for nonprescription OTC contraceptives and 2.1% for vasectomies due to these reductions in costs.

CHBRP anticipates SB 523 would have no impact on Medi-Cal coverage or expenditures. CHBRP estimates that, among commercial enrollees:

- At baseline, 18,755 individuals use nonprescription OTC female barrier contraceptives (e.g., sponge, female condom, spermicide). Postmandate, 19,513 individuals would use female nonprescription OTC contraceptives, an increase of 4.05%.
- At baseline, 106,492 individuals use emergency contraceptives. Postmandate, 110,794 individuals would use emergency contraceptives, an increase of 4.04%.
- At baseline, a total of 2,080,696 enrollees use nonprescription OTC male barrier contraceptives (i.e., male condoms). Postmandate, 2,164,864 individuals would use male condoms, an increase of 4.05%.
- At baseline, a total of 14,204 individuals obtain vasectomies and related clinical services. Postmandate, an additional 252 enrollees would obtain vasectomies and related clinical services for a total of 14,455 enrollees, an increase of 1.77%.

Expenditures

CHBRP assumes that increased use of nonprescription OTC contraceptives and vasectomies would result in a reduced number of unintended pregnancies. Due to insufficient evidence available to estimate the effectiveness of insurance coverage of nonprescription OTC contraceptives, CHBRP is unable to estimate changes in STIs as a result of SB 523.

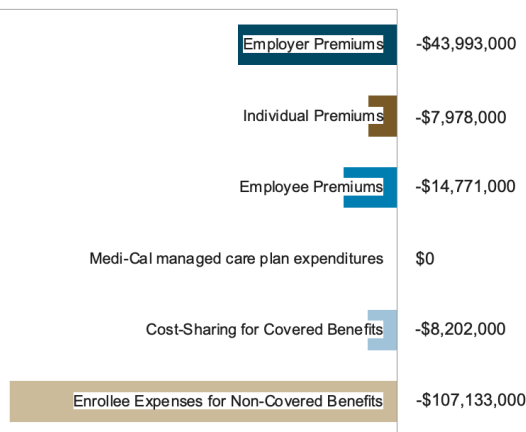
According to the CHBRP Cost and Coverage Model, there would be an estimated 12,293 averted unintended pregnancies in the first year postmandate, a reduction of 11.56% from baseline. These pregnancy outcomes at baseline result in an average of \$13,951 per averted unintended pregnancy, accounting for labor and delivery charges, medical costs associated with stillbirths or miscarriages, and costs for abortion services.

At baseline, CHBRP estimates that there are 4,173 commercial enrollees undergoing tubal ligation procedures. CHBRP assumes that for every 100 vasectomies, there would be 93.5 fewer tubal ligations, assuming the sexual partner has health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). Given the postmandate induced coverage of vasectomies, CHBRP estimates a 5.64% reduction in tubal ligations, resulting in an estimated cost offset of \$19,014 per unit for female sterilization procedures and related clinical services.

Due to cost offsets from a reduction in unintended pregnancies and female sterilization procedures postmandate, CHBRP estimates that SB 523 would decrease total premiums by about \$66,743,000 across DMHC- and CDI-regulated plans and policies. The greatest change in premiums would be for large-group plans in the DMHC-regulated market (a decrease of \$0.44 per member per month).

SB 523 would decrease total net annual expenditures by \$182,077,000 (0.14%) for enrollees with plans regulated by the DMHC and policies regulated by the CDI. This is due to a \$66,743,000 decrease in total health insurance premiums paid by employers and enrollees for newly covered benefits and a decrease of \$8,202,000 in enrollee expenses for covered benefits and \$107,133,000 in enrollee expenses for noncovered benefits.

Figure B. Expenditure Impacts of SB 523



Source: California Health Benefits Review Program, 2021.

Medi-Cal

CHBRP assumes that all OTC contraceptives would be available under the pharmacy benefit. As of a to-be-determined date, all items covered under the pharmacy benefit for Medi-Cal managed care plans are paid for on a fee-for-service basis and are “carved out” of care provided by Medi-Cal managed care plans. Vasectomies are already covered without cost sharing under Medi-Cal. Therefore, SB 523 would result in no impact to the coverage provided to Medi-Cal managed care plan beneficiaries or related premiums.

CalPERS

Among CalPERS HMO plans, there is an estimated decrease of \$0.44 in per member per month premiums.

Number of Uninsured in California

Because the change in average premiums does not exceed 1% for any market segment, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 523.

Medical Effectiveness

CHBRP investigated findings from evidence on (1) effectiveness of contraceptive methods at preventing unplanned pregnancies and transmission of STIs, (2) the impact of point-of-sale coverage and reimbursement on utilization of nonprescription OTC contraceptives, (3) the impact of utilization management on contraceptive utilization, and (4) potential side effects of nonprescription OTC contraceptive utilization.

³ *Clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of

Over the course of a year, sexually active women not using contraceptives have an 85% chance of becoming pregnant, with a 46% unintended pregnancy rate among women discontinuing previous contraceptive use. CHBRP found *clear and convincing evidence*³ that using any of the contraceptives impacted by SB 523 is more effective than not using any contraception in preventing unintended pregnancies.

CHBRP also found there is:

- *Clear and convincing evidence* that condoms are effective at preventing transmission of STIs/HIV based on a systematic review of 14 studies. There is also *clear and convincing evidence* based on a systematic review of five randomized controlled trials (RCTs) that spermicide is not effective in preventing transmission of STIs/HIV.
- *Insufficient evidence* to determine how insurance coverage for contraceptives affected by SB 523 (i.e., nonprescription OTC contraceptives and vasectomy) impacts contraceptive utilization.
- *Insufficient evidence* on the impact of utilization management policies on contraceptive utilization.

Public Health

In the first year postmandate, there would be a reduction in the number of unintended pregnancies overall (12,293 averted), as well as a reduction in negative health outcomes associated with unintended pregnancy.

CHBRP projects that SB 523 would increase utilization of male condoms by approximately 84,169 enrollees but is unable to estimate a quantitative impact on STI rates due to increased access to male condoms; however, it stands to reason that some of the 84,169 enrollees (and their partners) may be at lower risk of acquiring or transmitting an STI and be at lower risk for infection-related adverse health outcomes. In addition, there are broad benefits of contraceptive use and the estimated additional 89,481 enrollees using nonprescription OTC contraceptives or vasectomy would benefit from these noncontraceptive health and family planning benefits.

In the first year postmandate, to the extent that SB 523 reduces disparities that are due to coverage differences or ameliorates barriers due to OOP costs (but not due to preferences about specific contraceptive coverage) CHBRP estimates a reduction in disparities related to race/ethnicity, age, and social determinants of health

studies are of high quality and consistently find that the treatment is either effective or not effective.

(SDoH) in contraceptive use and unintended pregnancy; however, the magnitude is unknown.

Long-Term Impacts

CHBRP estimates annual utilization of induced nonprescription OTC contraceptives and vasectomies after the initial 12 months from the enactment of SB 523 would likely stay similar to utilization estimates during the first 12 months postmandate. Utilization changes may occur if new nonprescription OTC medications or procedures change the landscape for enrollees, or social marketing programs influence enrollee behavior; however, CHBRP is unable to predict these types of changes. Similarly, health care utilization due to improved reproductive health services may change in the long term.

Assuming that SB 523 increases utilization of contraceptives beyond the first year postmandate, there may be a decrease in the rate of unintended

pregnancies, abortions, and STI transmissions in the long-term. As such, there may also be a decrease in the adverse health outcomes associated with conditions. In addition, the potential decrease in the rate of unintended pregnancies may allow females to delay childbearing and pursue additional education, spend additional time in their careers, and have increased earning power.

Essential Health Benefits and the Affordable Care Act

Coverage for contraceptives is currently required as part of EHBs in California. However, existing law only requires coverage of female contraception. Thus, coverage of male contraception, as mandated by SB 523, would require coverage for a new benefit that may exceed EHBs in California.

A Report to the California State Legislature

Analysis of California Senate Bill 523 Health Care Coverage: Contraceptives

April 18, 2021

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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 www.chbrp.org.

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Table 1. SB 523 Impacts on Benefit Coverage, Utilization, and Cost, 2022

	Baseline (2022)	Postmandate Year 1 (2022)	Increase/Decrease	Change Postmandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	21,945,000	21,945,000	0	0.00%
Total enrollees with health insurance subject to SB 523 (b)	21,945,000	21,945,000	0	0.00%
Total enrollees potentially impacted by SB 523 (c)	13,940,000	13,940,000	0	0.00%
Total percentage of enrollees potentially impacted by SB 523	64%	64%	0%	0.00%
Total percentage of enrollees with coverage for nonprescription over-the-counter contraceptives	0%	100%	100%	0.00%
Total percentage of enrollees with coverage for vasectomies	100%	100%	0%	0.00%
Utilization and Cost				
Number of enrollees utilizing nonprescription over-the-counter contraceptives (d)				
Female barrier	18,755	19,513	759	4.05%
Emergency contraceptives (levonorgestrel)	106,492	110,794	4,301	4.04%
Male barrier	2,080,696	2,164,864	84,169	4.05%
Average annual cost of nonprescription over-the-counter contraceptives				
Female barrier	\$129	\$129	\$0	0.00%
Emergency contraceptives (levonorgestrel)	\$36	\$36	\$0	0.00%
Male barrier	\$48	\$48	\$0	0.00%
Average annual enrollee cost sharing and out-of-pocket costs for covered and noncovered nonprescription over-the-counter contraceptives (e)				
Female barrier	\$129	\$19	-\$110	-84.91%
Emergency contraceptives (levonorgestrel)	\$36	\$3	-\$33	-90.79%
Male barrier	\$48	\$7	-\$41	-84.89%
Average cost and utilization of vasectomies				
Number of enrollees utilizing vasectomies	14,204	14,455	252	1.77%
Average cost of vasectomies	\$1,456	\$1,456	\$0	0.00%
Average enrollee cost sharing of vasectomies (e)	\$341	\$61	-\$281	-82.28%
Number of enrollees with services that may be avoided as a result of SB 523				
Estimated number of enrollees with unintended pregnancies (f)	106,306	94,012	(12,293)	-11.56%
Estimated number of enrollees using female sterilization (g)	4,173	3,938	(235)	-5.64%

Average cost of services that may be avoided as a result of SB523				
Unintended pregnancies	\$13,951	\$13,951	\$0	0.00%
Female sterilization	\$19,014	\$19,014	\$0	0.00%
Average enrollee cost sharing of services that may be avoided as a result of SB 523				
Unintended pregnancies	\$1,561	\$1,544	-\$17	-1.12%
Female sterilization	\$153	\$162	\$9	5.97%
Expenditures				
<i>Premium (expenditures) by payer</i>				
Private employers for group insurance	\$55,032,803,000	\$54,992,804,000	-\$39,999,000	-0.07%
CalPERS HMO employer expenditures (h) (i)	\$5,765,017,000	\$5,761,023,000	-\$3,994,000	-0.07%
Medi-Cal Managed Care Plan expenditures	\$24,150,529,000	\$24,150,529,000	\$0	0.00%
<i>Enrollee premiums (expenditures)</i>				
Enrollees for individually purchased insurance	\$15,847,507,000	\$15,839,529,000	-\$7,978,000	-0.05%
Individually purchased – outside exchange	\$4,890,852,000	\$4,889,427,000	-\$1,425,000	-0.03%
Individually purchased – Covered California	\$10,956,655,000	\$10,950,102,000	-\$6,553,000	-0.06%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (i)	\$20,753,446,000	\$20,738,675,000	-\$14,771,000	-0.07%
<i>Enrollee out-of-pocket expenses</i>				
Cost sharing for covered benefits (deductibles, copayments, etc.)	\$13,168,032,000	\$13,159,830,000	-\$8,202,000	-0.06%
Expenses for noncovered benefits (j)	\$107,133,000	\$0	-\$107,133,000	-100.00%
Total Expenditures	\$134,824,467,000	\$134,642,390,000	-\$182,077,000	-0.14%

Source: California Health Benefits Review Program, 2021.

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.

(b) Enrollee count represents enrollees with medical benefit coverage subject to SB 523. Not all enrollees with medical benefit coverage also have pharmacy benefit coverage subject to SB 523. Of these enrollees, 59.2% have DMHC- or CDI-regulated pharmacy coverage.

(c) CHBRP assumes that nonprescription OTC contraceptives would be covered under the pharmacy benefit and therefore “carved out” of coverage for Medi-Cal managed care plans, and that vasectomies are fully covered without cost sharing under Medi-Cal or the California Family Planning, Access, Care, and Treatment (Family PACT) Program. As such, DMHC Medi-Cal enrollees are not impacted by SB 523. Not all enrollees with medical benefit coverage also have pharmacy benefit coverage subject to SB 523. Of these enrollees, 93.2% have DMHC- or CDI-regulated pharmacy coverage.

(d) Female barrier includes female condoms, contraceptive sponges, and spermicides. Emergency contraceptives include all over-the-counter emergency contraceptives. Ulipristal acetate (e.g., Ella®) is excluded because it is prescription only. Male barrier includes male condoms.

(e) Grandfathered and HSA-qualified plans have cost sharing postmandate.

(f) Unintended pregnancies include abortions, miscarriages, stillbirths, and deliveries.

(g) CHBRP assumed every 100 vasectomies would result in a reduction of 93.5 female sterilizations. Female sterilizations include tubal ligations.

(h) Of the decrease in CalPERS employer expenditures, about 54.1%, or -\$2,161,000 would be state expenditures for CalPERS members who are state employees or their dependents. About one in four (24.4%) of these enrollees has a pharmacy benefit not subject to DMHC. CHBRP has projected no over-the-counter contraceptive impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(i) 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.

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

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

POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)⁴ conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 523, Health Care Coverage: Contraceptives. SB 523 includes a health insurance benefit mandate in sections 4 and 5, amending Health and Safety Code Section 1367.25 and Insurance Code Section 10123.196, respectively. This report analyzes the impacts of these two sections per CHBRP's authorizing statute.

Bill-Specific Analysis of SB 523, Health Care Coverage: Contraceptives

Bill Language

SB 523 requires health plans and policies to expand coverage for contraception to include all U.S. Food and Drug Administration (FDA)-approved contraceptives for men and women, male sterilization procedures, and certain clinical services. The bill also removes the requirement for a prescription to obtain coverage of FDA-approved over-the-counter (OTC) contraceptives. SB 523 requires coverage without cost sharing or out-of-pocket (OOP) expenses for these additional benefits and explicitly prohibits health plans and policies from imposing medical management techniques to access coverage. Specifically, SB 523 does the following:

- Prohibits a health plan or policy from requiring a prescription in order to obtain coverage for FDA-approved OTC contraceptive drugs, devices, and products.
- Requires health plans and policies to provide point-of-sale coverage, without cost sharing or medical management restrictions, for all FDA-approved OTC contraceptive drugs, devices, and products obtained at in-network pharmacies.
- Requires health plans and policies to reimburse enrollees for OOP expenses for OTC birth control methods purchased at any out-of-network pharmacy in California, without medical management restrictions.
- Requires coverage of clinical services related to the provision or use of contraceptives, including consultations, examinations, procedures, ultrasound, anesthesia, patient education, and counseling.
- Allows health plans and policies to limit how often an enrollee may obtain all covered contraceptives and the quantity that they may receive.
- Prohibits health plans and policies from imposing prior authorization, step therapy, or other utilization control techniques on coverage for contraceptive drugs, devices, and products, except as otherwise authorized (see previous bullet).
- Clarifies the definition of medical inadvisability to allow for considerations such as severity of side effects, reversibility of the contraceptive, and ability to adhere to the method. Requires health plans/policies to defer to the judgment of the attending provider in the determination of medical inadvisability of a contraceptive and provide coverage for an alternative prescribed contraceptive, when applicable, without cost sharing.
- Requires religious employers who invoke the religious exemption for contraceptive coverage to inform prospective enrollees/insureds prior to enrollment of all contraceptive coverage that is not available through the plan/policy due to religious reasons.

The full text of SB 523 can be found in Appendix A.

⁴ CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.

Relevant Populations

If enacted, SB 523 would apply to the health insurance of approximately 21.9 million enrollees (55.7% of all Californians). This represents 100% of 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.

For beneficiaries under Medi-Cal managed care plans, all contraception that is impacted by the bill (see Table 2) is fully covered without cost sharing either under the Medi-Cal program or the California Family Planning, Access, Care, and Treatment (Family PACT) Program, or CHBRP assumes would be covered under the pharmacy benefit and therefore “carved out” of care provided by Medi-Cal managed care plans. See the *Benefit Coverage, Utilization, and Cost Impacts, Analytical Approach and Key Assumptions*, and California Policy Landscape sections for additional information. As such, SB 523 would have no impact on coverage or costs of contraception under Medi-Cal managed care plans.

Analytic Approach and Key Assumptions

CHBRP previously analyzed similar bill language, SB 1053 in 2014 and SB 999 in 2016. Where applicable, this analysis builds off those previous analyses.

SB 523 impacts coverage, costs, and related terms and conditions for six contraceptive types, including condoms (male and female), sponges, spermicides, levonorgestrel (emergency contraception [EC]), and vasectomy.

CHBRP uses the following terms throughout the report:

- “Point-of-sale coverage.” The coverage the enrollee receives at the time of receipt of the benefit, or in the case of SB 523, the contraceptive (e.g., male condom, female condom, etc.).
- “Nonprescription OTC contraceptives.” Refers to FDA-approved contraceptives that do not require a prescription to access, including male and female condoms, contraceptive sponge, spermicide, and levonorgestrel (i.e., EC such as Plan B[®]; Plan B One-Step[®], Next Choice, and Next Choice One Step). Ulipristal acetate (e.g., Ella[®]) is not included in this definition because it always requires a prescription.
- “Cost sharing.” Includes copayments, coinsurance, and deductibles charged to enrollees for covered benefits. It does not include premiums. See the Cost Sharing and Utilization Management section below for additional information.
- “Out-of-pocket expenses.” Costs to enrollees for noncovered benefits. These costs do not include those defined as cost sharing. See the Cost Sharing and Utilization Management section below for additional information.
- “Utilization management.” All utilization control techniques and medical management, such as prior authorization and step therapy. See the Cost Sharing and Utilization Management section below for additional information.
- “Women” and “Pregnant women.” CHBRP uses the terms “women” and “pregnant women” but recognizes that some individuals identify as male or nonbinary and may also have female reproductive organs.
- “Men.” CHBRP uses the term “men,” but recognizes that some individuals identify as female or nonbinary and may also have male reproductive organs.

CHBRP makes the following assumptions for the purposes of this analysis:

- CHBRP assumes that all OTC contraceptives would be available under the pharmacy benefit. As of a to-be-determined date,⁵ all items covered under the pharmacy benefit for Medi-Cal managed care plans are paid for on a fee-for-service basis and are “carved out” of care provided by Medi-Cal managed care plans. Therefore, SB 523 would result in no impact to the coverage provided to Medi-Cal managed care plan beneficiaries. More information about pharmacy benefit coverage among Californians with state-regulated health insurance is available in CHBRP’s resource *Estimates of Pharmacy Benefit Coverage in California for 2022*.⁶
- CHBRP assumes that if SB 523 is enacted, plans and policies would only cover contraceptives for the enrollee and not the enrollee’s partner or any other individual covered under the plan/policy. For example, CHBRP assumes that women would have coverage for female condoms, spermicides, and sponges, but would not have coverage for male condoms.
- Existing law prohibits health plans and policies from imposing restrictions or delays on contraceptive coverage. See California Policy Landscape for additional information. CHBRP assumes that the provisions of SB 523 relating to utilization management would have no impact on utilization of covered contraceptives that would continue to only be available with a prescription upon enactment of SB 523, and surgical procedures that are already covered under existing law.

CHBRP is unable to estimate any effects from the provisions of SB 523 relating to religious employers.

Interaction With Existing Federal and State Requirements

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

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 SB 523 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).^{7,8}

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

Federally selected preventive services

The ACA requires that nongrandfathered group and individual health insurance plans and policies cover certain preventive services without cost sharing when delivered by in-network providers and as soon as

⁵ The implementation originally scheduled for April 1, 2021, was delayed due to contracting issues, not due to a change in approach. CHBRP assumes implementation will occur by January 1, 2022.

⁶ Available on CHBRP’s website under “Resources”: www.chbrp.org/other_publications/index.php

⁷ The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to qualified health plans 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.

⁸ 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.

12 months after a recommendation appears in the Health Resources and Services Administration (HRSA)-supported health plan coverage guidelines for women's preventive services.⁹

Women's preventive care benefits under the HRSA guidelines include the full range of FDA-approved female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes, as prescribed by a health care provider. The guidelines also recommend coverage for patient education and counseling for women of reproductive capacity, if prescribed by a health care provider. There are currently 18 FDA-approved contraceptive methods for women, including: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives — combined pill, (8) oral contraceptives — progestin only, (9) oral contraceptives — extended or continuous use, (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms, (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, (17) EC (levonorgestrel), and (18) EC (ulipristal acetate).¹⁰ Health plans and policies must cover at least one form of contraception in each of these methods without cost sharing.¹¹ It should be noted that some of these contraceptives are available OTC, including female condoms, spermicides, and contraceptive sponges; however, they are only required to be covered if prescribed by a health care provider.

There is no federal mandate to cover male-controlled contraceptive methods, including male condoms and sterilization procedures (vasectomies).

Health plans and policies may use reasonable medical management techniques on contraception coverage to control costs and promote efficient delivery of care, including the imposition of cost sharing. For example, plans and policies may discourage brand-name pharmacy items over generic ones through cost sharing. However, plans and policies must accommodate any individual for whom a particular drug (generic or brand name) would be medically inappropriate, as determined by the individual's health care provider, by having a mechanism for waiving cost sharing for the physician-recommended product based on medical necessity.^{11,12}

Essential Health Benefits

Nongrandfathered plans and policies sold in the individual and small-group markets are required to meet a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.^{13,14} CHBRP estimates that approximately 4 million Californians (10%) have insurance coverage subject to EHBs in 2021.¹⁵

States may require plans and policies to offer benefits that exceed EHBs.¹⁶ However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either

⁹ More information is available on CHBRP's website under "Resources":

www.chbrp.org/other_publications/index.php.

¹⁰ HRSA, Women's Preventive Services Guidelines. Available at: <https://www.hrsa.gov/womens-guidelines-2016/index.html#general%20notices>. Accessed March 28, 2021.

¹¹ CMS, Affordable Care Act Implementation FAQs - Set 12. Available at:

https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12. Accessed, March 28, 2021.

¹² HRSA, FAQs about Affordable Care Act Implementation. Available at: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf. Accessed March 28, 2021.

¹³ CCIIO, Information on Essential Health Benefits (EHB) Benchmark Plans. Available at:

<https://www.cms.gov/cciio/resources/data-resources/ehb.html>.

¹⁴ H&SC Section 1367.005; IC Section 10112.27.

¹⁵ CHBRP, *Estimates of Sources of Health Insurance in California in 2021*. Available at:

www.chbrp.org/other_publications/index.php.

¹⁶ ACA Section 1311(d)(3).

by paying the purchaser directly or by paying the qualified health plan (QHP).^{17,18} Health plans and policies sold outside of the health insurance marketplaces are not subject to this requirement to defray the costs. State rules related to provider types, cost sharing, or reimbursement methods would not meet the definition of state benefit mandates that could exceed EHBs.¹⁹

Coverage for contraceptives is currently required as part of EHBs in California.²⁰ However, existing law only requires coverage of female contraception. Thus, coverage of male contraception, as mandated by SB 523, would require coverage for a new benefit that may exceed EHBs in California.²¹ This would appear to trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in qualified health plans in Covered California, the state’s health insurance marketplace. For an estimate of the cost of exceeding EHBs, see the *Benefit Coverage, Utilization, and Cost Impacts* section of this report.

California Policy Landscape

California law and regulations

In California, contraceptives are furnished or available in different locations including health care provider settings, pharmacy settings, and retail OTC settings. Table 2 displays all FDA-approved contraceptive methods and the locations in which they are furnished or dispensed in California.

Table 2. Furnisher and Setting for FDA-Approved Contraception Methods in California.

Furnisher – Setting	Type of Contraceptive	Contraceptive Method	X If Impacted by SB 523
Health Care Provider – Office or Clinic	Diaphragm	Barrier	
	Cervical cap	Barrier	
	Contraceptive patch (Ortho Evra®)	Hormonal	
	Oral contraceptives (pill; mini-pill; extended/continuous use pill)	Hormonal	
	Vaginal contraceptive ring (NuvaRing®)	Hormonal	
	Contraceptive injection (Depo-Provera®, Depo-SubQ Provera®)	Hormonal	
	Copper intrauterine device (IUD) (ParaGard®)	Implanted Device	
	Levonorgestrel-releasing IUD (Mirena®)	Implanted Device	

¹⁷ 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: <https://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf>.

¹⁸ 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.

¹⁹ 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.

²⁰ Centers for Medicare & Medicaid Services. California EHB Benchmark Plan. Accessed April 2021. Available at: <https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/Updated-California-Benchmark-Summary.pdf>

²¹ Communication with the Department of Managed Health Care, April 2021.

	Low dose levonorgestrel-releasing IUD (Skyla®)	Implanted Device	
	Etonogestrel contraceptive implant (Implanon®, Nexplanon®)	Implanted Device	
	Sterilization implant for women (hysteroscopic sterilization implant) (Essure®)	Permanent	
	Sterilization surgery for men (vasectomy)	Permanent	X
	Sterilization surgery for women (laparoscopic surgical sterilization, or tubal ligation)	Permanent	
Pharmacist – Pharmacy	Levonorgestrel (Plan B®, Plan B One Step®, Next Choice, Next Choice One Step)	Emergency	X
	Ulipristal acetate (Ella®)	Emergency	
	Contraceptive patch (Ortho Evra®)	Hormonal	
	Contraceptive injection (Depo-Provera®, Depo-SubQ Provera®)	Hormonal	
	Oral contraceptives (pill; mini-pill; extended/continuous use pill)	Hormonal	
	Vaginal contraceptive ring (NuvaRing®)	Hormonal	
Self – Retail Over-the-Counter (e.g., pharmacy, convenience store)	Male Condom	Barrier	X
	Female condom	Barrier	X
	Sponge	Barrier	X
	Spermicide	Barrier	X
	Levonorgestrel (Plan B®, Plan B One Step®, Next Choice, Next Choice One Step)	Emergency	X

Source: California Health Benefits Review Program, 2021.

Coverage and costs

California’s Contraceptive Coverage Equity Act of 2014 (Act)²² codified ACA mandates regarding contraceptive coverage for women into state law. The Act requires commercial health plans and policies and Medi-Cal managed care plans to provide coverage for all prescribed FDA-approved contraceptive drugs, devices, and products for women. Plans and policies must cover, without cost sharing, at least one form of contraception within each FDA-approved method. Generally, health plans and policies are not required to cover brand-name contraceptives if they cover an FDA-approved generic therapeutic equivalent. However, if the generic therapeutic equivalent is not available, the plan or policy must cover the brand-name contraceptive without cost sharing. California law currently does not require coverage for OTC contraception without a prescription, thus enrollees must pay the full cost of nonprescription OTC contraceptives out of pocket.

Existing law also requires coverage for voluntary sterilization, contraceptive education, counseling and related follow-up care for women. Male sterilization is not required to be covered under California law; however, the vast majority of California’s largest health insurance providers do provide coverage. Medi-Cal also provides full coverage for male sterilization without cost sharing. See the *Benefit Coverage*,

²² California Legislative Information (2014). SB 1053 Health care coverage: contraceptives.

Utilization, and Cost Impacts section for additional information. As it is a covered benefit for many plans and policies, male sterilization (vasectomies) may have some cost sharing associated with it, depending on the type of coverage.

Religious employers whose primary purpose is the inculcation of religious values and that meet other specifications may be exempt from the state mandate.²³

In 2016, California passed SB 999, which requires health plans and policies to cover a 12-month supply of self-administered hormonal contraceptives to women when dispensed at one time, without cost sharing. SB 999 also authorizes pharmacists to furnish such contraceptives under specified conditions.²⁴

To narrow the gap between insured and uninsured women and men in California, the Department of Health Care Services (DHCS) developed the Family PACT program²⁵. Family PACT provides publicly funded coverage for comprehensive clinical family planning services for any person with a family income at or below 200% of the federal poverty level, regardless of age or immigration status. The program serves approximately 1.1 million residents. Individuals who have other health coverage, including Medi-Cal fee-for-service and managed care, can be eligible for Family PACT benefits. Coverage includes family planning–related services and male and female sterilization; all FDA-approved contraceptive drugs (i.e., prescription and OTC), devices, and supplies; and health education and counseling services.²⁶ See the Federally Selected Preventive Services section above for a full list of FDA-approved contraception.

Utilization management

Existing California law generally prohibits health plans and insurers from imposing restrictions or delays on coverage for contraceptive drugs, devices, and products.²⁷ SB 523 specifies that these restrictions or delays include prior authorization, step therapy, and other utilization control techniques.

Current law also prohibits health plans and policies from imposing utilization controls or other forms of medical management in limiting the supply of FDA-approved self-administered hormonal contraceptives that may be dispensed to an enrollee. SB 523 would expand this prohibition on medical management to include coverage for FDA-approved OTC contraceptives, with one exception to authorize plans and policies to limit the quantity and frequency at which an enrollee can obtain the contraceptives.

Some contraceptive drugs, devices, or products may be deemed medically inadvisable for a patient by their health care provider. In these circumstances, existing law allows health plans and policies to impose utilization management procedures on coverage of an alternative contraceptive. “Utilization management procedures” is not defined under current law; however, the term generally refers to prior authorization, step therapy, and other utilization management techniques. SB 523 would prohibit health plans and policies from allowing such practices in these situations.

Patient confidentiality

Health plans/insurers are required to honor enrollee requests for confidential communications relating to receipt of sensitive services. Health care providers are authorized by law to make arrangements with a

²³ Religious employers eligible for exemptions include an entity: (a) whose purpose is the inculcation of religious values, (b) that primarily employs persons who share the entity’s religious tenets, (c) that primarily serves persons who share the entity’s religious tenets, d) 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.

²⁴ Title 16 California Code of Regulations § 1746.1

²⁵ DHCS Letter “Family PACT Program Overview.” Updated August 2020. (<https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/fpact/fam.pdf>).

²⁶ WIC 14132.

²⁷ HSC 1367.25(b)(3); INS 10123.196(b)(3).

patient for payment of OOP expenses and communicate that arrangement with the health plan/insurer.²⁸ As reproductive health care services, including contraceptive use, are sensitive in nature, enrollees may request confidentiality from health plans/insurers so that these procedures are not shown in the explanation of benefits (EOB). Health plans/insurers use EOBs in part to prevent fraud. They are sent to policyholders and typically show the actions taken by any individual covered under the plan/policy and all related costs. While SB 523 addresses cost sharing and coverage of contraceptives and related services, the provisions do not impact existing law related to patient confidentiality for sensitive services. Thus, patient confidentiality is not specifically addressed in this report. CHBRP did, however, consider patient confidentiality when estimating induced demand.

Similar requirements in other states

Sixteen states and the District of Columbia (DC) codified into state law the provisions of the ACA mandate that prohibit cost sharing for contraceptives.²⁹ Nine states and DC prohibit insurance plans from imposing restrictions and delays, or the use of medical management techniques that restrict access to contraceptives. See Table 3 for a list of states that currently require contraceptive coverage similar to that mandated by SB 523.

Similar state legislation has been introduced this year in Alaska, Hawaii, Kentucky, Minnesota, Rhode Island, Utah, and West Virginia. Some states would also include provisions similar to those mandated under California's SB 999 of 2016 and SB 1053 of 2014. At the federal level, H.R. 239 of 2021 prohibits the Department of Veteran Affairs from requiring veterans to pay for any contraceptive item that is required to be covered by health plans without cost sharing.³⁰

Table 3. State Coverage and Requirements for Contraceptive Methods

	OTC Methods		Male Sterilization	Cost Sharing Prohibition	Prohibition on Restrictions/Delays or Medical Management
	Male	Female			
California		X		X	X
Connecticut	X	X		X	
Delaware		X		X	X
DC	X	X		X	X
Illinois		X	X	X	X
Maine				X	
Maryland		X (only EC)	X	X	
Massachusetts		X		X	
Nevada		X (only EC)		X	X
New Hampshire				X	
New Jersey		X (no condoms)	X	X	
New Mexico	X	X	X	X	X
New York	X	X	X	X	X
Oregon		X (no condoms)	X	X	X

²⁸ CIV 56.107; INS 791.29.

²⁹ Insurance Coverage of Contraceptives. Guttmacher Institute Report available at <https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives#>. Accessed March 18, 2021.

³⁰ Legislative search through PoliticoPro, conducted between March 15, 2021, and March 29, 2021.

Vermont			X	X	X
Virginia				X	
Washington	X	X	X	X	X
Total	4 + DC	12 + DC	8	16 + DC	9 + DC

Source: California Health Benefits Review Program, 2021 and Guttmacher, 2021.

Key: DC = District of Columbia; EC = emergency contraception; OTC = over the counter.

Cost Sharing and Utilization Management

This section provides an overview of the cost-sharing and utilization management structures used for health insurance benefits, including prescription drugs.

Cost Sharing

Payment for use of covered benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee using the covered test, treatment, or service. Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium expenses³¹). Some health insurance benefit designs incorporate higher enrollee cost sharing in order to lower premiums. Reductions in allowed copayments, coinsurance, and/or deductibles can shift the cost to premium expenses or to higher cost sharing for other covered benefits.³² Annual OOP maximums for covered benefits limit annual enrollee cost sharing (medical and pharmacy benefits). After an enrollee has reached this limit through payment of coinsurance, copayments, and/or deductibles, insurance pays 100% of the covered services. The enrollee remains responsible for the full cost of any tests, treatments, or services that are not covered benefits.

Utilization Management

Utilization management policies, also known as utilization control techniques or medical management, are used by health plans and insurers to control costs, ensure medication compatibility, and manage safety. Examples include benefit coverage requirements related to prior authorization, step therapy, formularies, quantity limits, and limits related to the age or sex of the enrollee (such as prescription-only infant formula or prostate cancer screening for men). Prior authorization typically requires providers to establish eligibility and submit documentation demonstrating medical need to the plan/insurer for approval of coverage before either medical services are provided or a prescription is filled in order to qualify for payment. Health plans/insurers may also impose prior authorization requirements on nonpreferred medications in an effort to promote the use of preferred medications that they can procure at lower prices. Health plans/insurers may use step therapy protocols to apply clinical guidelines established by professional societies and other recognized organizations to treatment plans. They require an enrollee to try and fail one or more medications prior to receiving coverage for the initially prescribed medication.

³¹ Premiums are paid by most enrollees, regardless of their use of any tests, treatments, or services. Some enrollees may not pay premiums because their employers cover the full premium, they receive premium subsidies through Covered California, or receive benefits through Medi-Cal.

³² Plans and policies sold within Covered California are required by federal law to meet specified actuarial values. The actuarial value is required to fall within specified ranges and dictates the average percent of health care costs a plan or policy covers. If a required reduction in cost sharing impacts the actuarial value, some number of these plans or policies might have to alter other cost-sharing components of the plan and/or premiums in order to keep the overall benefit design within the required actuarial value limits.

BACKGROUND ON CONTRACEPTIVES

Contraceptive Methods

As discussed in the *Policy Context* section, SB 523 requires health plans and policies to expand coverage for contraception to include all U.S. Food and Drug Administration (FDA)-approved over-the-counter (OTC) contraceptives for men and women, male sterilization procedures, and certain clinical services. SB 523 impacts coverage, costs, and related terms and conditions for six contraceptive types, including condoms (male and female), sponges, spermicides, levonorgestrel (emergency contraceptives [EC]), and vasectomy.

Condoms (Male and Female)

The male condom is a thin film sheath of latex or polyurethane placed over the penis. The female condom (also known as an internal condom) is a thin, lubricated pouch that is put into the vagina.

Contraceptive Sponge and Spermicide

The sponge with spermicide is a disk-shaped polyurethane device containing spermicide. It is inserted into the vagina before sex and protects against pregnancy for up to 24 hours. The sponge must be left in place for at least six hours after having sex. It must be removed and disposed of within 30 hours after insertion.

Spermicide may also be inserted directly into the vagina in foam, cream, jelly, film, or tablet form. It must be inserted between 5 and 90 minutes prior to having sex. It typically must be left in place at least 6 to 8 hours after sex.

Levonorgestrel

Levonorgestrel is a second-generation synthetic progestogen used in EC such as Plan B® and Plan B One-Step®, Next Choice, and Next Choice One Step. Some forms of levonorgestrel require a prescription or have age restrictions while others do not. The pill(s) should be taken as soon as possible, but at least within 72 hours after having unprotected sex. Although FDA-approved use is only up to 72 hours, clinically it is used up to 120 hours after unprotected intercourse.

Vasectomy

Vasectomy is a permanent sterilization surgery for men usually done under local anesthesia. Sometimes it is possible to reverse the operation, but not always, and the reversal surgery is generally more complex than the sterilization surgery. The surgery blocks the vas deferens (the tubes that carry sperm from the testes to other glands) so that semen no longer contains sperm. It usually takes about three months to clear sperm out of the system. Until testing confirms the semen is sperm free, the possibility of pregnancy remains, and another form of birth control is recommended in the interim. Health care providers typically meet with patients prior to the procedure to ensure it is the best form of birth control for the individual.

Contraception Utilization

According to the most recent data available from the National Survey of Family Growth (NSFG, 2017–2019), among women aged 15 to 49 years currently using contraception, 8.4% use male condoms and 5.6% use male sterilization. The most commonly used methods — female sterilization (18.0%), oral contraceptive pills (14.0%), long-acting reversible contraception (i.e., intrauterine devices and contraceptive implant, 10.4%) are not covered by SB 523 (Daniels and Abma, 2020).

2015–2019 NSFG data shows that 22% of women aged 15 to 49 years who have ever had sexual intercourse have ever used EC. Older data (NSFG, 2006–2010) found that most females used EC once (59%) or twice (24%), whereas 17% used it three or more times. Nearly one-quarter of all sexually experienced females aged 20 to 24 years have ever used EC, compared to 16% of females aged 25 to 29 years, 14% of those aged 15 to 19 years, and 5% of those aged 30 to 44 years (Daniels et al., 2013).

Dual-Method Utilization

No one contraceptive method is highly effective at preventing both unintended pregnancy and protecting against transmission of sexually transmitted infections (STI) and human immunodeficiency virus (HIV). Condoms are the only method that protect against STIs and HIV, yet condoms are less effective than other methods at preventing pregnancy. Dual-method utilization can effectively prevent both unintended pregnancy and STIs by combining consistent use of both male condoms and a method effective at preventing pregnancy, such as implanted devices, hormonal methods, or sterilization.

In the United States, an estimated 10% of women aged 15 to 44 years who had intercourse in the past 3 months used condoms in combination with other methods. Dual-method condom use is highest among women aged 15 to 19 years (32.3%) and decreases with age. A 2010 study estimated use of both condoms and highly effective methods such as IUDs, injections, and oral contraceptives could prevent approximately 80% of unintended pregnancies and abortions (Pazol, 2010). However, protection against unintended pregnancy and STIs requires that dual-method utilization be consistent and sustained. Qualitative research with participants in a randomized controlled trial to increase dual-method use found that while one-third of participants initiated dual-method use over a two-year period, more than three-quarters of those participants initiating did not maintain consistent and sustained dual-method use (Peipert et al., 2011).

Contraceptive Access and Barriers

As noted above, SB 523 requires health plans and policies to expand coverage for contraception to include all U.S. FDA-approved OTC contraceptives. OTC contraceptives may be obtained at pharmacy counters, clinics such as Planned Parenthood, or other retail locations. Table 4 outlines the primary location where the 1,867,000 currently insured adult respondents to the 2016 California Health Interview Survey (CHIS) received their birth control.

Table 4. Main Location Where Insured Adults Received Birth Control (CHIS, 2016)

Main Location Where Insured Adults Received Birth Control	Percent of Adult Respondents (%)
Private doctor office or HMO facility	54.9%
Hospital or hospital clinic	13.5%
Planned Parenthood	11.5%
County health department, family planning clinic, or community clinic	5.7%*
Other clinic or some other place (a)	14.4%

Source: California Health Interview Survey (2016).

Notes: *Statistically unstable.

(a) Includes school or school-based clinic, employer or company clinic, Indian health service, and pharmacy.

Individual-level barriers to contraceptive use include low perception of risk of pregnancy, HIV, and/or STIs (Brown et al., 2011; Condelli, 1986); embarrassment associated with purchasing or obtaining contraceptives (Reeves et al., 2016); religious beliefs (Brewster et al., 1998; Hill et al., 2014); and low health literacy (Frost et al., 2007).

Biggs et al. (2012) surveyed 536 females obtaining services at U.S. family planning clinics who had unprotected intercourse in the past 3 months and found that nearly half (49%) cited barriers in accessing birth control services. Of these women, 9% cited birth control cost or insurance coverage as the specific access barrier. Additionally, 11% could not get an appointment for birth control when needed, 7% could not get to a clinic, 3% did not want to go to a clinic or see a doctor, and 3% did not know where to get birth control method. These are all barriers that could be at least partially ameliorated by expanding access to OTC contraceptive methods.

Previous research has identified several barriers specific to condom use. Cohen et al. (1999) explored the impact of price on condom use when a program distributing free condoms was replaced with a program providing low-cost condoms (25 cents). Pre- and post-surveys found that the increase in cost resulted in fewer participants obtaining condoms (57% to 30%) and fewer using condoms during their most recent sexual encounter (77% to 64%). Pharmacies in areas with high prevalence of HIV/STIs often lock condoms to prevent theft. One study found that in 82% of pharmacy sites in one neighborhood with a high prevalence of HIV/STIs, assistance was required to access the condoms (Rizkalla et al., 2010). The female condom is often difficult to find in pharmacies and expensive, which affects utilization (Hoffman et al., 2004).

Among females using EC, the reason for use was nearly evenly divided between fear of birth control method failure (45%) and unprotected sex (Daniels et al., 2013). Older (aged 30–34 years) females and non-Hispanic Whites were more likely to cite fear of method failure whereas younger (aged 20–29 years) females, Hispanics, and non-Hispanic Black people were more likely to use EC due to unprotected sex (Daniels et al., 2013).

Health Outcomes Associated with Contraception

Unintended Pregnancy

Although utilization of contraception is high (65% of all U.S. women aged 15–49 years), there is still a large proportion of women at risk of an unintended pregnancy, defined as a pregnancy that is mistimed, unplanned, or unwanted at the time of conception (CDC, 2019). NSFG data (2015–2017) indicates that approximately 37% of births among women aged 15 to 49 years old in the prior five years were unintended (NCHS, 2019). Nationally, researchers estimated that 42% of unintended pregnancies ended in abortion (excluding miscarriages) and 58% ended in birth in 2011 (Finer and Zolna, 2016). In California in 2010, researchers estimated that 45% of unintended pregnancies ended in abortion, 42% ended in a birth, and 13% ended in fetal loss (Guttmacher Institute, 2016). Unintended pregnancy is also associated with a number of negative health outcomes for the mother and child, such as delays in initiating prenatal care, decreased likelihood of breastfeeding, negative maternal mental health outcomes, adolescent behavioral issues, and reduced educational attainment and economic stability (Gipson et al., 2008; Logan et al., 2007; Sonfield et al., 2013).

Sexually Transmitted Infections

As noted above, condoms are the only method that protects against STIs. Recent NSFG data suggests the utilization rate of male condoms is 8.4% but utilization of all female barrier condoms is low — data from 2006 to 2010 indicates that 0.3% of U.S. females aged 15 to 44 years use female barrier methods (Jones et al., 2012).

Based on 2018 CDC reporting surveillance data, California ranks among the top states for high rates of chlamydia (13th), gonorrhea (14th), adult syphilis (3rd), and congenital syphilis (5th) among all states, with more than 327,000 combined cases in 2018 (CDPH, 2018; CDC, 2018). In addition, there are an estimated 5,000 new cases of HIV and 35,000 new cases of hepatitis C each year in California. At any point in time, it is estimated that millions of Californians are infected with other STIs such as HPV (11 million), genital herpes simplex (2.5 million), and trichomoniasis (330,000). For additional information on

sexually transmitted infections and diseases (STDs), please see CHBRP's analysis of SB 306: STD Testing (CHBRP, 2021a).

Disparities³³ and Social Determinants of Health³⁴ Related to Contraception

Per statute, CHBRP includes discussion of disparities and social determinants of health (SDoH) as it relates to contraception use, unintended pregnancies, and STIs. Disparities are noticeable and preventable differences between groups of people.

Disparities

Gender

According to the NSFG, sterilization is more common among females compared to males. Data from NSFG 2011–2013 indicate that 15.5% of females and 5.1% of males were sterilized (Daniels et al., 2015).

Race or ethnicity

In the United States, there is significant variation in contraceptive method utilization across racial/ethnic groups. A report by Jones et al. (2012) found that Asians are more likely to use condoms compared to other racial/ethnic groups and non-Hispanic Whites are more likely to undergo vasectomies. Among U.S. females, use of EC is highest among non-Hispanic White and Hispanic females (11%, respectively) compared to non-Hispanic Black females (8%) (Daniels et al., 2013). According to 2003 CHIS data, use of EC is highest among African American females (5.6%), followed by Latinas, Asians, and American Indian/Alaska Natives with similar utilization (4.9%, 4.4%, 4.5%, respectively), whereas non-Latina White and Pacific Islander females had the lowest utilization of EC (3.2% and 1.1%, respectively) (Baldwin et al., 2008). In 2011, the NSFG estimated the unintended pregnancy rate was highest among non-Hispanic Black and Hispanic women (79 per 1,000 females and 58 per 1,000 females) compared to non-Hispanic White women (33 per 1,000 women) (Finer and Zolna, 2016). In the same year, the percentage of unintended pregnancies ending in abortion were highest among non-Hispanic Black women (50%) and Hispanic women (40%) compared to White women (36%) (Finer and Zolna, 2016).

In a qualitative study exploring attitudes around male sterilization, Shih et al. (2013b) found that males and females from all racial/ethnic groups with positive views of sterilization cited desires to care for their existing family and sharing contraceptive responsibilities. Males and females from all racial/ethnic groups cited negative connotations about sterilization and concern for loss of manhood as reasons for not choosing male sterilization. White males and females identified positive social support for male sterilization, whereas Black and Latino males and females cited lack of social support and social acceptance around male sterilization. In addition, males and females from all racial/ethnic groups cited misconceptions about the sterilization procedure and long-term impact on sexual function, and Black and Latino males and females had misconceptions about the reversibility of male sterilization, such as the belief that female sterilization was something that could be “reversed or undone” because “it’s easy to just untie them” (with regard to tubal ligation) whereas vasectomy was an irreversible procedure. Shih et al. (2013b) found that contraceptive counseling for couples does not routinely include men or the option of vasectomy.

³³ 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).

³⁴ 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: (CDC, 2014c; Healthy People 2020, 2019). See CHBRP's SDoH white paper for further information: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

Age

NSFG data (2011–2013) indicates that use of condoms is highest among females aged 15 to 24 years (21.4%) and decreases with age (9.4% among females aged 35 to 44 years). In contrast, use of male sterilization increases with age (3.8% among those aged 25 to 34 years vs 17.9% among those aged 35 to 44 years) (Daniels et al., 2015). Data from the 2006–2010 NSFG found that 23% of females aged 20 to 24 years have ever used EC, compared to 16% of females aged 25 to 29 years and 14% of females aged 15 to 19 years (Daniels et al., 2013).

The unintended pregnancy rate is lowest among the youngest and oldest age groups (41 per 1,000 females aged 15 to 19 years and 16 per 1,000 females aged 35 years and older) and peaks among females aged 20 to 24 years (81 per 1,000 females). In 2011, the percentage of unintended pregnancies ending in abortion did not vary substantially between age groups (Finer and Zolna, 2016).

Social Determinants of Health (SDoH)

SDoH include factors outside of the traditional medical care system that influence health status and outcomes (e.g., income, education, geography, etc.). For the majority of contraceptive methods, utilization increases with educational attainment (Daniels and Abma, 2020). This trend is also seen among U.S. females using EC. NSFG data (2006–2010) found that 12% of females with a Bachelor's degree or higher have used EC compared to 6% of females with less than a high school education (Daniels et al., 2013). Disparities in contraceptive use also exist by type of insurance coverage and poverty level. Vasectomy rates are higher among males with private insurance (14.4% compared to 5.0% with public insurance or 3.8% without insurance) and use increases with income but peaks (22.3%) at 300% to 399% federal poverty level (FPL). Condom use increases slightly with income (from 14.9% [0-149% FPL] to 17.7% [400% or more FPL]) and is slightly higher among individuals with private insurance (16.3%) or without insurance (19.6%) compared to those with public insurance (12.0%) (Jones et al., 2012).

The rate of unintended pregnancy is inversely related to improved socioeconomic status. Poorer females (with incomes less than 199% of the FPL) have significantly higher rates of unintended pregnancy compared to females with incomes 200% and above. Females who did not graduate high school have much higher unintended pregnancy rates than females who graduated college (Finer and Zolna, 2016).

Societal Impact of Unintended Pregnancy

Unintended pregnancies result in direct and indirect economic and societal costs. According to Trussell et al. (2013), the 3.1 million unintended pregnancies occurring annually in the United States result in approximately \$4.6 billion in annual medical costs. Based on national and state-level data, Sonfield and Kost (2013) estimated that in 2008, there were 1.1 million publicly funded, unintended births nationally and 152,600 in California, paid for by public programs such as Medicaid, the Children's Health Insurance Program, and the Indian Health Service. Nationally, these births accounted for slightly more than half (53%) of all publicly funded births and nearly two-thirds (65%) of all births resulting from unintended pregnancies. In California, these births accounted for nearly 56% of all publicly funded births and 62% of all births resulting from unintended pregnancies. Sonfield and Kost (2013) also estimated the total government expenditures for publicly funded births based on prior methodology (Frost et al., 2010); these costs include the costs of prenatal care, delivery, postpartum care, and medical care for the infant for one year. Based on previous research estimating that public investment in family planning services, such as contraceptives, results in \$12.7 billion (in 2010 dollars) in annual gross savings (by reducing unintended pregnancies and ensuing births), Sonfield and Kost (2013) estimated that in the absence of family planning services, annual public costs of births from unintended pregnancies would exceed \$25 billion.

Please note, the societal impact discussed here is relevant to a broader population than that impacted by SB 523. See the *Benefit Coverage, Utilization, and Cost Impacts* section for estimates of direct cost impacts for the specific population impacted by SB 523.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, SB 523 requires health plans and policies to expand coverage for contraception to include all U.S. Food and Drug Administration (FDA)-approved over-the-counter (OTC) contraceptives for men and women, male sterilization procedures, and certain clinical services. SB 523 requires coverage without cost sharing or out-of-pocket (OOP) expenses for these additional benefits and explicitly prohibits health plans and policies from imposing utilization management policies to access coverage. Additional information on contraceptive methods is included in the *Background on Contraceptives* section. The medical effectiveness review summarizes findings from evidence³⁵ on (1) effectiveness of contraceptive methods at preventing unplanned pregnancies and transmission of sexually transmitted infections (STIs), (2) the impact of point-of-sale coverage and reimbursement on utilization of nonprescription OTC contraceptives, (3) the impact of utilization management on contraceptive utilization, and (4) potential side effects of nonprescription OTC contraceptive utilization.

Research Approach and Methods

Relevant studies were identified through searches of PubMed, the Cochrane Library, Embase, and Cumulative Index of Nursing and Allied Health Literature. The search was limited to abstracts of studies published in English. The initial search was limited to studies published from 2010 to present. In addition, for research questions that returned a small number of articles, searching was done from 2000 to present. Of the 372 articles found in the literature review, 27 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not focus on the specified contraceptives, were focused on a specific population, or reported on interventions that were not related to the provisions specified in SB 523. 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.³⁶ 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 contraceptive methods impacted by SB 523 in preventing unplanned pregnancy?
2. What is the effectiveness of contraceptive methods impacted by SB 523 in preventing transmission of HIV and STIs?
3. What is the impact of OOP costs on utilization of contraceptive methods impacted by SB 523?
4. What is the impact of utilization management policies on utilization of contraceptive methods impacted by SB 523?
5. What are the harms related to utilization of contraceptive methods impacted by SB 523?

³⁵ Much of the discussion in this section is focused on reviews of available literature. However, as noted in the section on Implementing the Hierarchy of Evidence on page 11 of the *Medical Effectiveness Analysis and Research Approach* document (posted at http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php), in the absence of fully applicable to the analysis peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

³⁶ Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. For more information on CHBRP's use of grey literature, visit http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

Outcomes Assessed

For studies of the impact of SB 523, CHBRP assessed effects on three outcomes: (1) use of contraception, (2) unintended pregnancy rates, and (3) STI/HIV transmission. CHBRP's decision to analyze these outcomes reflects the causal pathway by which coverage for contraceptive services could affect unintended pregnancy rates and STIs/HIV. The unintended pregnancy rate is based on a combination of factors such as type of contraceptive used, the efficacy of the contraceptive used, and the difficulty of using the contraceptive correctly and consistently. The literature reports on both the effectiveness (typical use of a contraceptive) and efficacy (theoretical perfect use of contraceptives). A comparison of the effectiveness and efficacy for each contraceptive reviewed is presented in Table 5.

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of contraceptive benefits as defined by SB 523. Each section is accompanied by a corresponding figure. The title of the figure indicates the test, treatment, or service for which evidence is summarized. The statement in the box above the figure presents CHBRP's conclusion regarding the strength of evidence about the effect of a particular test, treatment, or service based on a specific relevant outcome and the number of studies on which CHBRP's conclusion is based. Definitions of CHBRP's grading scale terms is included in the box below, and more information is included in Appendix B.

The following terms are used to characterize the body of evidence regarding an outcome:

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.

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

Limited evidence indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.

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.

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.

More information is available in Appendix B.

Contraceptive Effectiveness at Preventing Unplanned Pregnancy

A systematic review found nine studies that examined pregnancy rates among women of reproductive age neither breastfeeding nor using contraception (Trussell, 2011). This review found that over the course of a year, these women had between a 78.1% and 94.0% — or a weighted average of 85% — chance of becoming pregnant. Other research suggests that the rate of unintended pregnancy among women discontinuing contraceptive use is closer to 46% (Vaughan et al., 2008). These are the baseline rates from which to compare effectiveness of each of the contraceptives discussed below.

Most of the research related to contraceptive methods is not classified as high quality as defined by CHBRP methodology (see Appendix B for description). This is due, in part, to the prevailing opinion that it is not ethical to randomize women who do not want to get pregnant into groups using a placebo contraceptive. Therefore, the comparison between a selected contraceptive and no contraceptive has to be estimated indirectly using published data on pregnancy rates among women using no contraception. Given that the unintended pregnancy rates range from 0.05% to 28% depending on the specific type of contraceptive (see Table 5), it is reasonable to conclude that using any of the contraceptives listed below are more effective than not using any contraception in preventing unintended pregnancies.

Table 5 provides the unintended pregnancy rates for both the “typical” use of a contraceptive and the “perfect” use. Typical use provides rates adjusted for such factors as nonadherence, improper dosage, not following device or medication instructions properly, improper implantation or administration, and sporadic or nonuse during all cases of intercourse. Perfect usage assumes a theoretically perfect use, with failure only due to the device or medication itself.

Table 5 shows both the contraceptives that would be newly covered under SB 523 in addition to the contraceptives already covered at baseline. This is in part to give context to the medical effectiveness rates for the contraceptives that would be newly covered under SB 523.

Table 5. Summary of Evidence of Medical Effectiveness of Contraception

Contraceptive Method (Setting)	% of females aged 15–44 years who have ever relied on method (2006-2010) (a)	% of women with unintended pregnancy	% of women with unintended pregnancy	Impacted by SB 523 (h)
		Typical Use	Perfect Use	
Clinical Setting				
Diaphragm w/spermicide	3.1%	12%	6%	No
Cervical cap w/spermicide	<0.8%(b)	18%	10-13%	No
Contraceptive injections	23.2%	6%	0.2%	No
Copper IUD (ParaGard®)	7.7%(c)	0.8%	0.6%	No
Levonorgestrel-releasing IUD (Mirena®)	7.7% (c)	0.2%	0.2%	No
Etonogestrel contraceptive implant (Implanon®, Nexplanon®) (d)	1.9%	0.05%	0.05%	No
Surgical sterilization for men (vasectomy)	13.3%	0.15%	0.10%	Yes
Laparoscopic surgical sterilization for women	19.5%	0.5%	0.5%	No
Pharmacy (with Prescription)				
Oral contraceptives	81.9%	9%	0.3%	No
Contraceptive patch	10.4%	9%	0.3%	No
Vaginal contraceptive ring	6.3%	9%	0.3%	No
Emergency contraceptives: ulipristal acetate (Ella®)	(e)	1.8%	Not Reported	No
Over the Counter (OTC)				
Male condom	93.4%	18%	2%	Yes
Female condom	1.7%	21%	5%	Yes

Sponge	4.3%	Parous women (f): 24% Nulliparous women: 12%	Parous women: 20% Nulliparous women: 9%	Yes
Spermicide	3.4-6.8%	28%	18%	Yes
Emergency contraceptives: Levonorgestrel (Plan B®; Plan B One-Step®, Next Choice, Next Choice One Step)	(g)	2.6%	Not Reported	Yes

Source: Utilization rates were taken from Daniels et al., 2013b. Medical effectiveness was taken from Trussell, 2011, except for EC (Glasier et al., 2010), cervical cap (Trussell et al., 1993), and Essure (Smith, 2010).

Notes: (a) Asked of women who had ever had sexual intercourse.

(b) Utilization figure includes cervical cap and other methods.

(c) Use of IUD was not broken out by copper and hormonal types. Overall, ever-use rate for IUDs was 7.7%.

(d) Norplant® was the first FDA approved implantable contraceptive device in 1990 but was later removed from the market. Implanon® was the first FDA approved implantable contraceptive device that is still in use today. The utilization rate is for Norplant® or Implanon® while the effectiveness data is for Implanon®.

(e) Use of EC was not broken out by type. Overall, ever-use rate for EC was 10.8%.

(f) Parous: women who have previously given birth; nulliparous: women who have never given birth.

(g) This type of contraception was not asked about on the National Family Growth Survey because it is a newer type of contraception.

(h) As discussed in the *Policy Context*, CHBRP assumes that the provisions of SB 523 relating to utilization management would have no impact on utilization of those contraceptives that are only available with a prescription, regardless of coverage, and surgical procedures that are already covered under existing law.

Key: IUD = intrauterine device.

There are six contraceptive methods that are impacted by SB 523:

Male condom

As calculated by Trussell (2011), typical use of the male condom has an unintended pregnancy rate of 18%. This is much higher than the rate of unintended pregnancy for perfect use of male condom (2%) due to (a) not always using the condom during intercourse, or (b) not using the condom properly.

Female condom

As calculated by Trussell (2011), “typical” use of the female condom resulted in an unintended pregnancy rate of 21%. This is much higher than the rate of unintended pregnancy for “perfect” use of the female condom (5%). Imperfect use is generally due to not always using the female condom during intercourse or not properly following the instructions.

Sponge

The effectiveness of the sponge differs for women who have previously given birth (parous women) and those who have never given birth (nulliparous). As calculated by Trussell (2011), for typical usage, parous women have a 24% chance of experiencing an unintended pregnancy within the first year of use, and nulliparous women experience half of that rate at 12%. For perfect usage, a similar relative difference is also observed, at 20% for parous women and 9% for nulliparous women. Imperfect use is generally due to not always using the sponge, and not following the instructions with regard to placement, insertion, and removal time windows.

Spermicide alone

As calculated in Trussell (2011), the unintended pregnancy rate for typical use of spermicide alone is 28% compared to 18% under perfect use. A Cochrane systematic review of 14 clinical trials analyzing the effectiveness of spermicide used alone as the primary method of birth control revealed that dosage was related to effectiveness, with the probability of pregnancy at six months 22% for a lower dose gel, and 14% for a higher dose gel (Grimes et al., 2013). However, behavior of the user was found to be more important than the characteristics of the spermicide products in determining the probability of pregnancy (Grimes et al., 2013).

Levonorgestrel (emergency contraceptive)

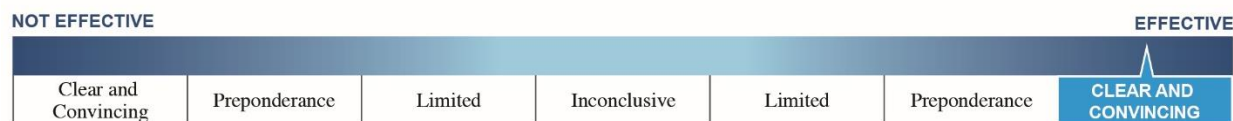
According to Glasier et al. (2010) the results of an analysis comparing emergency contraceptives (EC) showed that among women taking levonorgestrel within 72 hours of unprotected sex, 2.6% of women became pregnant. Comparing this to the 5.4% of women expected to get pregnant in absence of EC, the use of levonorgestrel within 72 hours reduces expected pregnancy rates by 52% (p=0.001) (Glasier et al., 2010).

Vasectomy (sterilization surgery for men)

Typical- and perfect-use rates provided by Trussell (2011) were 0.15% and 0.10%, respectively, and are described as “arbitrary” estimates that reflect the lack of quality research and underreporting of surgical failure in the literature for these procedures. In this case, the difference between typical and perfect use rates reflects an estimate of the effect of unprotected intercourse during the period before the individual is certified as sperm free. Additionally, sometimes the vas deferens is not completely blocked by the procedure, or it may grow back together.

Summary of findings regarding contraceptives: There is *clear and convincing evidence* that contraception impacted by SB 523 is effective at preventing unintended pregnancy based on a systematic review of nine studies.

Figure 1. Effectiveness of Contraceptives on Preventing Unintended Pregnancy



Contraceptive Effectiveness at Preventing STI Transmission

The CDC’s clinical prevention guidance for the prevention and control of STIs/HIV includes the following recommendations: (1) STI/HIV risk assessment by health care providers, (2) provision of STI/HIV prevention counseling by health care providers, (3) counseling related to abstinence and reduction of number of sexual partners, and (4) consistent utilization of male and female condoms (CDC, 2015).

Most of the research related to effectiveness of contraceptive methods in preventing STI/HIV transmission is not classified as high quality as defined by CHBRP methodology. This is due to the fact that it is not ethical to randomize people who may be exposed to STIs/HIV to use no method of protection during sexual activity. Therefore, the studies that are conducted mostly involve studies of serodiscordant sexual partners — i.e., sexual partners where one has an HIV infection and the other does not — and allows for self-selection into using protection or not. The medical effectiveness of nonprescription OTC contraceptive methods to prevent STI/HIV transmission is discussed below.

Male condom

One Cochrane review summarized the effectiveness of male condom use on transmission of HIV among heterosexual partners (Weller et al., 2002). This meta-analysis found 14 studies that examined risk of HIV transmission between serodiscordant male and female partners. The study found that HIV transmission was decreased by 80% for sexual partners who regularly used condoms compared to those sexual partners who never used condoms. Smith et al. (2015) found that the adjusted estimated effectiveness of condom use among men who have sex with men (MSM) with HIV-positive partners was approximately 70%.

The types of research studies related to the impact of condom use to reduce STI/HIV transmission is not classified as “high quality” as defined by CHBRP methodology (see Appendix B for description). It is not possible to conduct a randomized controlled trial (RCT) due to ethical considerations of randomizing HIV serodiscordant partners who do not want to transmit HIV to a placebo group. Therefore, the comparison between a selected contraceptive and no contraceptive has to be estimated indirectly using published data on transmission rates among couples using no condoms. Given that the use of condoms reduced HIV transmission rates by 80% and 70% among heterosexual partners and MSM, respectively, it is reasonable to conclude that using a condom is more effective than not using a condom in preventing STI/HIV prevention.

Female condom

A systematic review of the effectiveness of the female condom in protecting against STI/HIV transmission summarized the findings of five RCTs (Vijayakumar et al., 2006). They concluded based on this research that there was limited but convincing evidence that female condoms are effective in decreasing STI incidence in women, but also recommended further research to improve the evidence base.

In an updated systematic review and meta-analysis conducted on the effectiveness of female condoms in preventing HIV/STIs, Wiyeh et al. (2020) included 15 studies of 6,291 women. This systematic review found that the use of female condoms in addition to male condoms was more effective in preventing STIs (e.g., chlamydia and gonorrhea) compared to use of male condoms alone (Wiyeh et al., 2020). Furthermore, Wiyeh et al. (2020) concluded with limited evidence that the use of female condoms in addition to male condoms may be of similar effectiveness when compared to use of male condoms alone in preventing HIV transmission.

Spermicide alone

One Cochrane review investigated the impact of spermicide on transmission of HIV (Wilkinson et al., 2003). This review of five RCTs found that the overall risk of infection with HIV in women from men was not significantly associated with use of spermicide. In addition, there was some evidence that the use of spermicide increased genital lesions, which could potentially increase transmission of HIV. In a systematic review of five trials, Obiero et al. (2012) found no evidence of a significant effect in the use of spermicide to reduce the risk of HIV infection among women. Similar to Wilkinson and colleagues (2003), Obiero et al. (2012) found that the use of spermicide significantly increased the risk of genital lesions.

There was insufficient evidence related to the impact of other contraceptive methods impacted by SB 523 (i.e., contraceptive sponge, EC [levonorgestrel], and vasectomy) on STIs/HIV.

Summary of findings regarding contraceptives impacted by SB 523: There is *clear and convincing evidence* that condoms are effective at preventing transmission of STIs/HIV based on three systematic reviews of 29 studies (Figure 2). There is also *clear and convincing evidence* based on a systematic review of five RCTs that spermicide is not effective in preventing transmission of STIs/HIV (Figure 3). There is *insufficient evidence* related to the impact of other contraceptives impacted by SB 523 (i.e., contraceptive sponge, EC [levonorgestrel], and vasectomy) on STIs/HIV (Figure 4).

Figure 2. Effectiveness of Condoms on Prevention of STI/HIV Transmission

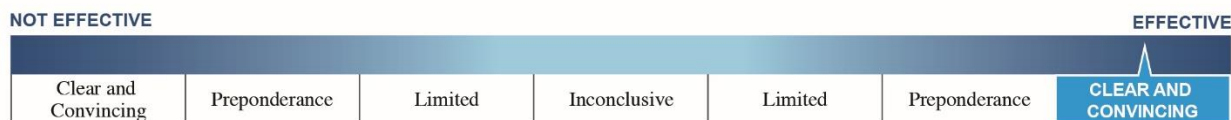


Figure 3. Effectiveness of Spermicide on Prevention of STI/HIV Transmission

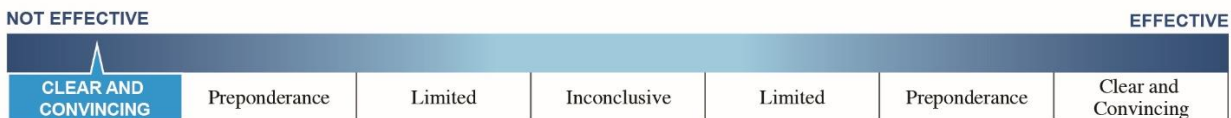


Figure 4. Effectiveness of the Contraceptive Sponge, EC, and Vasectomy on Prevention of STI/HIV Transmission



Impact of Out-of-Pocket Costs on Utilization of Contraceptives

The literature on the impact of OOP costs on utilization of contraceptives has exclusively focused on contraceptives that were provided in the context of covered insurance benefits. Therefore, there is no literature that directly examines the impact of insurance coverage or cost sharing on utilization of nonprescription OTC contraceptives. There is some literature that examines the impact of health promotion programs that provide condoms as part of the program. This literature is not directly comparable to covering condoms through health insurance in that these health promotion programs typically included other aspects such as counseling and outreach that would impact condom utilization. Although there is no literature that directly addresses the impact of insurance coverage for OTC contraceptives without a prescription, a brief summary of the literature related to the impact of insurance coverage on other contraceptives is provided below for context.

Insurance coverage for OTC contraceptives

CHBRP identified four studies that examined the impact of state-level contraceptive coverage mandates on utilization of contraception. Atkins and Bradford (2014) found that state-level contraceptive coverage mandates led to an increase in contraceptive utilization by 5%. Johnston and Adams (2017) estimated that state-level contraceptive coverage mandates reduced the unintended birth rate by 1.58 percentage points, and Dills and Grecu (2017) found that contraceptive coverage mandates were associated with a 4% decrease in births among young Hispanic women and single mothers. Trudeau and colleagues (2018) performed analyses that suggested the impact of contraceptive coverage mandates were driven in part by the implementation of the young adult dependent coverage component of the Affordable Care Act (ACA).

One review identified five studies looking at the impact of the ACA's provision to eliminate cost sharing for prescription contraceptive coverage on contraceptive insurance claims (Lee et al., 2020). Two of the identified studies reported an overall increase in claims for contraception among enrollees in employer-sponsored plans (Becker et al., 2018; Carlin et al., 2016). Three other studies examined the impact of the ACA on utilization of long-acting reversible contraceptives (LARC). Two of the studies found either no increase in use or a small increase in use but did not take into account baseline cost sharing (Pace et al., 2013; Snyder et al., 2018). The third study found that after taking into account baseline cost sharing for LARC, utilization did significantly increase once cost sharing was removed (Dalton et al., 2018).

Summary of findings regarding the impact of OOP costs on utilization of contraceptives covered by SB 523: There is *insufficient evidence* to determine whether decreasing OOP costs through insurance coverage for contraceptives affected by SB 523 impacts utilization.

Figure 5. The Impact of Insurance Coverage for OTC Contraceptives on Contraceptive Use

NOT EFFECTIVE		INSUFFICIENT EVIDENCE				EFFECTIVE	
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing	

Utilization Management for Contraceptive Coverage

As discussed in the *Policy Context* section, utilization management policies are used by health plans and insurers to control how patients access treatments and services. This can include techniques such as prior authorization, step therapy, and requiring a prescription for OTC products. No literature was identified that evaluated the impact of prior authorization or step-therapy requirements on the utilization of contraceptives. In addition, no literature was identified that evaluated the impact of requiring prescriptions for contraceptives available OTC in the United States. Overall, no studies were identified in this review that directly addressed the utilization management provisions as specified in SB 523.

Summary of findings regarding the impact of contraception utilization management policies on utilization: There is *insufficient evidence* to determine whether utilization management policies impact contraceptive utilization.

Figure 6. The Impact of Utilization Management Policies on Contraceptive Use

NOT EFFECTIVE		INSUFFICIENT EVIDENCE				EFFECTIVE	
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing	

Health Risks, Side Effects, and Noncontraceptive Benefits of Contraception

Contraceptives pose very few risks to users and in general are considered safer for women than pregnancy (Trussell and Guthrie, 2007). The major health risks associated with contraceptive use including cardiovascular disease and cancer have been studied primarily with hormonal contraceptives in women. This review of health risks, side effects, and noncontraceptive benefits of contraception is limited to contraceptives impacted by SB 523.

Over-the-counter contraceptives

- **Condoms:** The main danger related to the use of condoms are related to a potential allergic reaction to latex (Trussell and Guthrie, 2007). Additional side effects for men also include decreased sensitivity during intercourse (Trussell and Guthrie, 2007). Condoms also can protect against STIs including HIV and provide other noncontraceptive benefits such as delaying premature ejaculation for men (Trussell and Guthrie, 2007).
- **Contraceptive sponge:** Use may increase risks of vaginal and urinary tract infections and toxic shock syndrome. Women may also report side effects such as pelvic discomfort, vaginal irritation, and allergic reactions (Trussell and Guthrie, 2007).
- **Spermicide:** Use may increase vaginal and urinary tract infections and possible increase in susceptibility to HIV/AIDS if exposed (Trussell and Guthrie, 2007). Additional side effects include vaginal irritation and allergic reactions.

- **Levonorgestrel (EC):** A Cochrane review of 47 articles conducted a meta-analysis on safety and side effects of OTC EC (Leelakanok and Methaneethron, 2020). The authors concluded that most common side effects were not serious. Common side effects included alteration of menstrual flow (46.8%); bleeding (31%); short, light menstrual flow (26.2%); spotting (23.5%); and early menstruation (18.5%). Neurological side effects included headache (12.4%) and dizziness (10.8%). Gastrointestinal side effects included nausea (15%) and lower abdominal pain (11.4%), vomiting (8.5%), and diarrhea (4.4%).

Vasectomy

Risks of surgical contraceptive methods include pain or infection at surgical site. Postoperative complications for sterilization procedures, such as vasectomy, are rare and minor in nature (Adams and Wald, 2009). It is estimated that overall, 15% of vasectomies resulted in post-surgery pain, with higher rates (24%) reported among those with a scalpel vasectomy compared to those having a vasectomy using non-scalpel techniques (7%) (Auyeung et al., 2020). Post-vasectomy pain syndrome (i.e., chronic pain that lasts for at least 3 months that interferes with daily activities) was reported in 5% of cases (Auyeung et al., 2020). In the case of vasectomy, perioperative bleeding occurs in about 2.4% of no-scalpel vasectomies and 4% of incisional vasectomies (Cook et al., 2007). As with any surgical procedure, infection is also a risk with 0.7% (non-scalpel) to 4% (incisional) of cases resulting in a postoperative infection (Cook et al., 2007). In addition, although vasectomies may be reversed, there is no guarantee that the reversal of a vasectomy will be successful; therefore, it is only recommended for males who are certain that they do not want to have any more children. The evidence related to the impact of vasectomy on prostate cancer is mixed. While there is some evidence that men undergoing vasectomy do not have higher rates of prostate cancer than men who had not undergone the procedure, a 2020 38-year cohort study of 26,238 men with prostate cancer found that vasectomy increased risk of prostate cancer by 1.15 (Holt et al., 2008; Husby et al., 2020).

Summary of Findings

- Over the course of a year, sexually active women not using contraceptives have an 85% chance of becoming pregnant, with a 46% unintended pregnancy rate among women discontinuing previous contraceptive use. There is *clear and convincing evidence* that using any of the contraceptives impacted by SB 523 is more effective than not using any contraception in preventing unintended pregnancies.
- There is *clear and convincing evidence* that condoms are effective at preventing transmission of STIs/HIV. There is also *clear and convincing evidence* that spermicide is not effective in preventing transmission of STIs/HIV. There is *insufficient evidence* related to the effectiveness of other contraceptive methods covered by SB 523 (i.e., contraceptive sponge, EC [levonorgestrel], and vasectomy) in preventing transmission of STIs/HIV.
- There is *insufficient evidence* to determine how insurance coverage for contraceptives affected by SB 523 (i.e., nonprescription OTC contraceptives and vasectomy) impacts contraceptive utilization.
- There is *insufficient evidence* to determine how utilization management policies impact contraceptive utilization.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, SB 523 requires DMHC-regulated plans and CDI-regulated policies to expand coverage for contraception to include all U.S. Food and Drug Administration (FDA)-approved over-the-counter (OTC) contraceptives for men and women, male sterilization procedures, and certain clinical services. The bill also eliminates the requirement for a prescription to obtain coverage of FDA-approved OTC contraceptives. SB 523 requires coverage without cost sharing or out-of-pocket (OOP) expenses for these additional benefits and explicitly prohibits health plans and policies from imposing utilization management policies to access coverage.

In addition to commercial enrollees, more than 50% of enrollees associated with the California Public Enrollees' Retirement System (CalPERS) and more than 70% of Medi-Cal beneficiaries are enrolled in DMHC-regulated plans.³⁷ SB 523 would impact these CalPERS enrollees benefit coverage as 100% of these enrollees do not have coverage of nonprescription OTC contraception at baseline. SB 523 also prohibits cost sharing for vasectomies and associated clinical services. As noted in the *Policy Context* section, SB 523 would not impact Medi-Cal beneficiaries' benefit coverage of vasectomies, because these enrollees do not have cost sharing or utilization management requirements for vasectomy services.

This section reports the potential incremental impacts of SB 523 on estimated baseline benefit coverage, utilization, and overall cost. For a complete list of all products and services included, see the *Medical Effectiveness* section. As contraceptives are used for the prevention of sexually transmitted infections (STIs) and unintended pregnancies, CHBRP has estimated the potential reductions in the incidence of these conditions and their associated costs. Additionally, CHBRP estimated potential reductions in female sterilization procedures due to an increase in vasectomies. For further details on the underlying data sources and methods used in this analysis, please see Appendix C.

CHBRP has made a number of analytic assumptions, including:

- As discussed in the *Background on Contraceptives, Public Health Impacts, and Medical Effectiveness* sections, prescription and OTC contraceptive use is influenced by a variety of factors including availability, accessibility, and acceptability of the different methods (Blankenship et al., 2000; CDC, 2015; Charania et al., 2011; Frost and Darroch, 2008). CHBRP assumes that SB 523 would not lead to changes in supply of OTC contraceptives or availability of medical services associated with use of contraceptives covered by this bill.
- CHBRP assumes that individuals would have to purchase nonprescription OTC contraceptives at the pharmacy counter to obtain point-of-sale coverage. If individuals purchase nonprescription OTC contraceptives at the retail counter or at other retail locations (e.g., grocery stores or convenience stores), CHBRP assumes that they would have to submit a claim for the coverage of these products, which would dampen use of this benefit.
- SB 523 allows plans to establish frequency and quantity limits for coverage of contraceptive methods. CHBRP did not make assumptions about these limits; the CHBRP Cost and Coverage Model relies on assumptions and calculations regarding expected utilization of each type of contraceptive method.
- As mentioned in the *Background and Public Health Impacts* sections, CHBRP assumes that this bill removes cost barriers but does not address significant barriers to contraceptive use such as patient confidentiality, attitudes and knowledge, social norms, or preferences related to the use of nonprescription OTC contraceptives. For example, adolescents and young adults — the highest users of barrier contraceptives (Foster et al., 2004) — may choose not to use insurance coverage to obtain contraception due to confidentiality concerns.
- Some men and women who faced cost barriers and did not obtain nonprescription OTC contraceptives at baseline would successfully obtain nonprescription OTC contraceptives

³⁷ For more detail, see CHBRP's *Estimates of Sources of Health Insurance in California for 2021*, a resource available at http://chbrp.org/other_publications/index.php.

postmandate due to the removal of OOP costs. There are no data in the literature on price elasticity for nonprescription OTC contraceptives. CHBRP therefore assumes that utilization of nonprescription OTC contraceptives would increase by 4.8% among all enrollees in commercial plans and policies who had OOP costs at baseline, similar to the increase in the use of prescription methods (e.g., diaphragm, ring, patch, prescription EC, and hormonal contraceptives) after the implementation of the ACA (Becker et al., 2018) (see Appendix C for a full explanation). CHBRP assumes that utilization would increase by 4.8% for all nonprescription OTC contraceptive categories for individuals in all income categories.

- Some men who faced cost-sharing barriers and did not obtain covered vasectomies at baseline would successfully obtain vasectomies postmandate due to the removal of cost sharing. There are no data on the price elasticity for vasectomies. CHBRP assumes that utilization of vasectomies would increase by 2.1% based on the price elasticity for similar nonemergency healthcare services (see Appendix C for a full explanation).
- CHBRP assumes that plans and policies would only cover nonprescription OTC contraceptives for the enrollee and not for the enrollees' partner. Thus, CHBRP assumes that plans would cover male condoms only for men and that female condoms, spermicide, levonorgestrel (EC), and the sponge would only be covered for women.
- CHBRP assumes that all Medi-Cal beneficiaries would receive pharmacy coverage through Medi-Cal Rx (DHCS, 2021b). CHBRP assumes that the bill would not change nonprescription OTC contraceptive coverage for Medi-Cal beneficiaries because Medi-Cal Rx is "carved out" and would thus not be subject to the mandate.
- SB 523 does not affect coverage for vasectomies, but rather impacts cost sharing for existing coverage. In approaching this issue, CHBRP is unable to estimate the specific amount of cost sharing for individual enrollees among DMHC-regulated plans and CDI-regulated policies. However, in CHBRP's survey of the largest providers of health insurance in California, health plans and policies reported that enrollees who currently have coverage for vasectomies also have cost sharing. To estimate the impact of eliminating cost sharing, CHBRP applied an average estimated rate of cost sharing adjusted for plan design based on existing medical claims data for vasectomies and related clinical services (see Appendix C for full details).
- For vasectomies, CHBRP assumes utilization of health care services in 2022 would be roughly equivalent to utilization in 2018,³⁸ with adjustments made to account for changes in enrollment and population. CHBRP does not make additional assumptions to adjust for changes in utilization due to COVID-19 because recent 2020 claims data indicates utilization in aggregate has mostly returned to prepandemic levels. However, CHBRP acknowledges utilization has not rebounded for some services and for some groups of enrollees (i.e., visits for younger children had not returned to prepandemic baseline as of October 2020) (Mehrota et al., 2020). Additionally, there are other unknown factors that may impact utilization as a result of COVID-19, such as the potential impacts of deferred care and long-term impacts from COVID-19 infections.
- CHBRP assumes that health savings account (HSA) and grandfathered plans would still have cost sharing for nonprescription OTC contraceptives and vasectomies postmandate. Approximately 892,000 or 4.1% of enrollees are enrolled in an HSA-qualified plan.

Baseline and Postmandate Benefit Coverage

SB 523 would apply to 100% of the 21,945,000 enrollees in DMHC- and CDI-regulated plans and policies (Table 1). Of these enrollees, CHBRP estimates that 64%, or 13,940,000, would be impacted by SB 523. Baseline coverage of prescription and nonprescription OTC contraceptives and vasectomies was determined by a 2014 survey of the largest (by enrollment) providers of health insurance in California (CHBRP, 2014) and from 2019 claims data. CHBRP assumes that coverage of these services has not changed since 2014.

³⁸ CHBRP uses Milliman's 2018 Consolidated Health Cost Guidelines Sources Database (CHSD) and 2018 MarketScan Commercial Claims and Encounters Database (MarketScan) to estimate utilization in 2022.

At baseline, among commercial/CalPERS enrollees (see Table 1):

- 0% have coverage of nonprescription OTC contraceptives.
- 100% have coverage of vasectomies and related clinical services with an average of \$341 in cost sharing; this is an average across all enrollees, including enrollees in preferred provider organization (PPO) and HMO plans.

At baseline, among Medi-Cal beneficiaries (see Table 1):

- 0% have coverage of nonprescription OTC contraceptives.
- 100% have coverage of male vasectomies with no cost sharing.

Postmandate, commercial enrollees — except for those in HSA and grandfathered plans — would see an elimination of OOP costs for nonprescription OTC contraceptives. Commercial enrollees in HSA and grandfathered plans would not see a reduction in OOP costs postmandate for nonprescription OTC contraceptives. Thus, on average, CHBRP estimates that enrollee OOP costs would decrease by 84.91% for female barrier contraceptives, 90.79% for EC, and 84.89% for male barrier contraceptives (Table 1). Similarly, while commercial enrollees in non-HSA and nongrandfathered plans would see an elimination of cost sharing for vasectomies postmandate, commercial enrollees in HSA and grandfathered plans would not see reductions in cost sharing postmandate for vasectomies. Thus, CHBRP estimates that, on average, enrollee cost sharing for vasectomies would decrease by 82.28% (Table 1).

CHBRP estimates that Medi-Cal beneficiaries would not see reductions in OOP costs for nonprescription OTC contraceptives postmandate. As vasectomies are already covered without cost sharing in Medi-Cal, CHBRP estimates no change in cost sharing postmandate for Medi-Cal beneficiaries.

Baseline and Postmandate Utilization

As nonprescription OTC contraceptives are currently not covered by commercial and CalPERS markets, CHBRP used national and California-based surveys to estimate baseline utilization (see Appendix C for a full explanation). CHBRP assumes SB 523 would lead to an overall increase of nonprescription OTC contraceptive use driven by reducing OOP costs for commercial and CalPERS enrollees. As noted earlier, CHBRP assumes no increases in utilization for Medi-Cal beneficiaries.

Female Barrier Contraceptives

At baseline, CHBRP estimates that 18,755 commercial enrollees used nonprescription female barrier contraceptives (e.g., sponge, female condom, and spermicide). Postmandate, there would be a cost shift and a small overall increase in utilization due to the elimination of OOP costs. To estimate changes in utilization postmandate, CHBRP estimated that utilization would increase by 4.8% postmandate among individuals who experience reductions in OOP (see the full explanation in Appendix C). CHBRP estimates that postmandate, 19,513 individuals would use female nonprescription OTC contraceptives, an increase of 4.05%. Previous studies have found that as coverage of contraceptives increases, individuals shift from less to more effective methods (Carlin et al., 2016), thus CHBRP assumes that individuals using these contraceptive methods would not switch from more effective contraceptives (e.g., hormonal contraceptives, long-acting reversible contraceptives) to female barrier methods.

Emergency Contraceptives (levonorgestrel)

CHBRP estimates that 106,492 individuals used EC at baseline. CHBRP used the same estimate of increased utilization postmandate (4.8%) as above and estimates that 110,794 individuals would use EC postmandate, an increase of 4.04%.

Male Condoms

At baseline, a total of 2,080,696 enrollees used male condoms. Postmandate, there would be a cost shift and a small overall increase in utilization due to the elimination of OOP costs for male condoms. CHBRP used the same estimate of increased utilization (4.8%) as above and estimates that 2,164,864 individuals would use male condoms postmandate, an increase of 4.05%.

Vasectomies

At baseline, 14,204 individuals obtained vasectomies and used related clinical services. Postmandate, there would be an overall increase in utilization due to the elimination of cost sharing for vasectomies and related clinical services. To estimate changes in utilization postmandate, CHBRP estimated that utilization would increase by 2.1% (see the full explanation in Appendix C). This induced utilization would result in a total of 252 enrollees who have any induced use of vasectomies for a total of 14,455 enrollees who would obtain vasectomies postmandate, an increase of 1.77%. CHBRP assumes that vasectomies and female sterilization (tubal ligation) are used by partners who opt to stop having children, and that for every 100 vasectomies, there are 93.5 fewer female tubal ligations (Landry and Ward, 1997).

Vasectomies and related clinical services are already covered without cost sharing for Medi-Cal beneficiaries, thus CHBRP does not estimate any increases in induced postmandate utilization for this population.

Baseline and Postmandate Costs

CHBRP assumes that unit costs of nonprescription OTC contraceptives and vasectomies and related services do not change postmandate. As nonprescription OTC contraceptives are not covered at baseline, CHBRP based estimates of the costs of these products on average prices at Walmart and retail pharmacies such as CVS and estimated annual use using national and state survey data (see Appendix C for estimated annual costs per OTC contraceptive type).

For nonprescription OTC contraceptives, CHBRP assumed an average annual cost of \$129 for female barrier contraceptives, \$36 for EC, and \$48 for male condoms.

Using relevant codes from the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), CHBRP extracted data from Milliman's 2019 Consolidated Health Cost Guidelines™ Sources Database Plus (CHSD) to develop baseline estimates of utilization and costs of vasectomies and related clinical services (see Appendix C for full list of codes).

At baseline, according to the Milliman claims database, vasectomies and related clinical services have an average total cost of \$1,456 (Table 1); these totals include any costs from related clinical services performed 30 days before and after the vasectomy. Baseline cost sharing for vasectomies and related clinical services is, on average, \$341 for commercial enrollees — an average across all plans (HMOs and PPOs). Commercial enrollees in non-HSA and nongrandfathered plans would see an elimination of cost sharing postmandate, but enrollees in HSA and grandfathered plans would still experience cost sharing. Thus, on average, CHBRP estimates that postmandate enrollee cost sharing would be \$61.

Baseline and Postmandate Expenditures

Table 7 and Table 8 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies according to the CHBRP Cost and Coverage Model. 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). As noted in the *Policy Context* section, the “carve out” of outpatient prescription drugs results in no impact to the

coverage provided to Medi-Cal managed care plan beneficiaries and thus no changes in premiums or total expenditures. Vasectomies are already covered without cost sharing for Medi-Cal managed care plans, so SB 523 also results in no changes to premiums or expenses.

SB 523 would decrease total net annual expenditures by \$182,077,000 or by 0.14% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a \$66,743,000 decrease in total health insurance premiums paid by employers and enrollees for newly covered benefits and a decrease of \$8,202,000 in enrollee expenses for covered benefits and \$107,133,000 in enrollee expenses for noncovered benefits.

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

CHBRP assumes that increased use of nonprescription OTC contraceptives and vasectomies will result in a reduced number of unintended pregnancies. As the *Medical Effectiveness* section notes, although nonprescription OTC barrier contraceptives have the potential to reduce STIs, given the other barriers to utilization of these contraceptives and insufficient evidence available to estimate the effectiveness of insurance coverage of nonprescription OTC contraceptives, CHBRP is unable to estimate changes in STIs as a result of SB 523. A 2017 systematic review of condom distribution program identified a single study with an intervention with some similarity to SB 523, which found that programs that only reduce cost barriers but do not address other barriers to contraceptive use (knowledge, attitudes, preferences, beliefs, and social norms) did not find a reduction in STIs (Malekinejad et al., 2017). Others have also noted the absence of evidence associated with interventions similar to SB 523 (Shrestha et al., 2016).

According to the CHBRP Cost and Coverage Model, there would be an estimated 12,293 averted unintended pregnancies postmandate (refer to Appendix C for methodology), a reduction of 11.56% from baseline (Table 1). These pregnancy outcomes at baseline result in an average of \$13,951 per averted unintended pregnancy, accounting for labor and delivery charges, medical costs associated with stillbirths or miscarriages, and costs for abortion services. Prenatal care is not included in these average costs.

At baseline, CHBRP estimates that there are 4,173 commercial enrollees undergoing tubal ligation procedures. According to the CHBRP Cost and Coverage Model, there would be an estimated 3,938 tubal ligation procedures and associated service reduced postmandate given the induced utilization of vasectomies, a 5.64% reduction (Table 1). These female sterilization procedures and related clinical services cost approximately \$19,014 per unit.

Premiums

Baseline PMPM premiums in DMHC-regulated commercial plans range from \$555.38 in the small-group market to \$624.47 in the individual market (see Table 7). Baseline PMPM premiums in DMHC-regulated publicly funded plans range from \$226.61 in the Medi-Cal managed care market to \$637.27 in the CalPERS HMO market. In CDI-regulated commercial plans, baseline PMPM premiums range from \$545.57 in the individual market to \$717.35 in the large-group market.

Due to cost offsets from a reduction of unintended pregnancies and female sterilization procedures postmandate, CHBRP estimates that the mandate would decrease total premiums by about \$66,743,000 (see Table 8). Changes in premiums as a result of SB 523 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 7, and Table 8), with health insurance that would be subject to SB 523.

The greatest change in premiums as a result of SB 523 is for commercial large-group plans in the DMHC-regulated market (0.08% decrease) (see Table 8). Among publicly funded DMHC-regulated health plans, there are no projected changes in premiums. Among CalPERS HMO plans, there is an estimated decrease of \$0.44 in PMPM premiums.

Enrollee Expenses

SB 523–related changes in cost sharing for covered benefits (deductibles, copays, etc.) and OOP expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 7, and Table 8) with health insurance that would be subject to SB 523 expected to use nonprescription OTC contraceptives and vasectomies and related clinical services during the first 12 months after enactment. In addition, grandfathered and HSA plans will still have cost sharing and OOP costs for covered and noncovered nonprescription OTC contraceptives and vasectomies. SB 523 would reduce cost sharing for covered benefits by 0.06% (Table 1). This is due to a reduction in cost sharing for vasectomies and nonprescription OTC contraceptives, and reductions in expenditures related to unintended pregnancies. For enrollees in non-HSA and nongrandfathered plans, SB 523 would reduce OOP costs for noncovered benefits (i.e., nonprescription OTC contraceptives) by 100%.

Table 6 presents average enrollee OOP expenses impacted by SB 523. Among commercial/CalPERS/Medi-Cal HMO enrollees who have existing benefit coverage of vasectomies, the percent of enrollees who would be impacted by SB 523 is 0.1% for large-group, small-group, individual, and CalPERS HMO markets. As noted earlier, vasectomies are covered without cost sharing at baseline for Medi-Cal beneficiaries, so Medi-Cal beneficiaries would have no change in OOP expenses.

Due to new coverage of nonprescription OTC contraceptives and a reduction of cost sharing for vasectomies as a result of SB 523, CHBRP also estimates that total OOP expenses for enrollees would decrease by type of contraceptive:

- **Nonprescription OTC female barrier contraceptives:** The percent of enrollees that would be newly covered ranges from 0.1% in large-group and CalPERS HMOs to 0.2% in small-group and individual plans. The range in the annual OOP expenses for female barrier methods would be \$107 in large-group plans to \$129 in CalPERS HMOs.
- **Nonprescription OTC emergency contraceptives:** The percent of enrollees that would be newly covered ranges from 0.6% in CalPERS HMOs to 0.9% in small-group plans. The range in OOP expenses for nonprescription OTC EC would be \$32 in small-group and individual plans to \$36 in CalPERS HMOs.
- **Nonprescription OTC male barrier contraceptives:** The percent of enrollees that would be newly covered ranges from 12.3% in CalPERS HMOs to 18.0% in individual plans. The range in OOP expenses would be \$40 in large-group plans to \$48 in CalPERS HMOs.
- **Vasectomy:** CHBRP assumed 100% premandate coverage of vasectomies, so the percent of enrollees that would be newly covered is 0. While enrollees in non-HSA and nongrandfathered plans will have no cost sharing postmandate, enrollees in HSA and grandfathered plans will see cost sharing postmandate.

CHBRP estimates are based on claims data and may underestimate the cost savings for enrollees due to plans and policies’ ability to negotiate discounted rates that are unavailable to patients and their families.

Table 6. Average Enrollee Out-of-Pocket Expenses Impact of SB 523

	Large Group	Small Group	Individual	CalPERS HMO	Medi-Cal HMO
Enrollees with Baseline Coverage					
% of enrollees with out-of-pocket expenses impact due to SB 523 (a)					
Female barrier	0.0%	0.0%	0.0%	0.0%	0.0%
Female – emergency contraceptives	0.0%	0.0%	0.0%	0.0%	0.0%
Male barrier	0.0%	0.0%	0.0%	0.0%	0.0%
Vasectomy	0.1%	0.1%	0.1%	0.1%	0.0%

Average annual out-of-pocket expenses impact for enrollees					
Female barrier	\$0	\$0	\$0	\$0	\$0
Female – emergency contraceptives	\$0	\$0	\$0	\$0	\$0
Male barrier	\$0	\$0	\$0	\$0	\$0
Vasectomy	\$218	\$368	\$422	\$275	\$0
Enrollees Newly Covered					
% of enrollees with out-of-pocket expenses impact due to SB 523 (a)					
Female barrier	0.1%	0.2%	0.2%	0.1%	0.0%
Female – emergency contraceptives	0.8%	0.9%	0.8%	0.6%	0.0%
Male barrier	14.9%	17.0%	18.0%	12.3%	0.0%
Vasectomy	0.0%	0.0%	0.0%	0.0%	0.0%
Average annual out-of-pocket expenses impact for enrollees					
Female barrier	\$107	\$110	\$115	\$129	\$0
Female – emergency contraceptives	\$33	\$32	\$32	\$36	\$0
Male barrier	\$40	\$41	\$42	\$48	\$0
Vasectomy	\$0	\$0	\$0	\$0	\$0

Source: California Health Benefits Review Program, 2021.

Notes: Average enrollee expenses includes cost-sharing (e.g., copays, deductibles) for covered benefits and out-of-pocket expenses for noncovered benefits.

(a) Not including impacts on premiums.

(b) Benefit coverage for Medi-Cal beneficiaries does not generally include any cost sharing.

It should be noted that Table 6 shows the average enrollee annual impact in the form of cost-sharing savings. These numbers reflect population averages and would vary significantly for individual enrollees. Sources of variation include the specific OTC contraceptives utilized by the enrollee, yearly limits placed by plans, and the cost sharing applicable to their specific plan or policy. An enrollee may experience a mandate impact significantly higher or lower than those included in Table 6. Moreover, as noted earlier, enrollees in HSA and grandfathered plans would still experience cost sharing and OOP costs postmandate.

Postmandate Administrative Expenses and Other Expenses

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

Other Considerations for Policymakers

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

Potential Cost of Exceeding Essential Health Benefits

As explained in the *Policy Context* section, nonprescription OTC male contraceptives and vasectomies are not included in California’s EHB package. The state is required to defray the additional cost incurred by enrollees in qualified health plans (QHPs) for any state benefit mandate that exceeds the state’s definition of essential health benefits (EHBs). Coverage for nonprescription OTC contraceptives and

vasectomies required by mandate, as would be required if SB 523 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 9 several scenarios regarding the cost to the state, should SB 523 be judged to exceed EHBs. Impacts would vary by market segment (and by market segment enrollment). In scenario 1, the full estimated cost would likely range between \$395,000 in the CDI-regulated individual market and \$20,072,000 in the DMHC-regulated individual market. In scenario 2, with the full estimated cost with cost offsets, the impacts would vary from -\$7,867,000 in the DMHC-regulated individual market to -\$125,000 in the CDI-regulated individual market. In scenario 3, with baseline coverage offset, the impacts would range from \$395,000 in the CDI-regulated small-group market and \$20,072,000 in the DMHC-regulated individual market.

Postmandate Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 7, and Table 8, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 523.

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 SB 523.

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

In general, CHBRP assumes that enrollees who do not have benefit coverage pay for treatments/services directly (e.g., self-pay). However, in some cases, those noncovered benefits may be provided by public programs or by other, alternative sources. Below, are examples of programs that currently distribute nonprescription OTC and prescription contraceptives to California residents:

- Student health clinics (Wang et al., 2018), community clinics (CDC, 2015), and family services clinics currently provide OTC and prescription contraceptives to many individuals without cost. For example, the San Francisco AIDS Foundation provides millions of condoms and other OTC contraceptives and HIV and STI testing resources to individuals in the County of San Francisco (CDC, 2015). Similarly, LA Condom, a program from the County of Los Angeles Department of Public Health, distributes free condoms via urgent care facilities, community clinics, homeless shelters, and community centers (Los Angeles County Department of Public Health, 2020). The Condom Access Program provides free condoms for individuals aged 12 to 19 years in California (Teensource.org, 2021).
- As described in the *Policy Context* section, the Family PACT program provides comprehensive family planning services to eligible low-income residents. In 2016 to 2017, barrier methods and emergency contraceptives comprised the highest proportion of contraceptive methods reimbursed by Family PACT for females at 38.1%. Over 300,000 Family PACT clients were dispensed barrier methods and about 170,000 clients received emergency contraceptives in 2016 to 2017 (DHCS, 2017). Approximately 100,000 male clients received a barrier method in 2016 to 2017, and 900 clients received a vasectomy (DHCS, 2017).

Table 7. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2022

	DMHC-Regulated						CDI-Regulated			TOTAL
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (c)	Large Group	Small Group	Individual	
Enrollee Counts										
Total enrollees in plans/policies subject to state mandates (d)	8,405,000	2,086,000	1,989,000	889,000	7,218,000	787,000	384,000	43,000	144,000	21,945,000
Total enrollees in plans/policies subject to SB 523	8,405,000	2,086,000	1,989,000	889,000	7,218,000	787,000	384,000	43,000	144,000	21,945,000
Premium Costs										
Average portion of premium paid by employer	\$426.28	\$374.49	\$0.00	\$540.40	\$226.61	\$478.87	\$530.80	\$421.81	\$0.00	\$84,948,349,000
Average portion of premium paid by enrollee	\$141.02	\$180.89	\$624.47	\$96.86	\$0.00	\$0.00	\$186.55	\$212.07	\$545.57	\$36,600,954,000
Total Premium	\$567.30	\$555.38	\$624.47	\$637.27	\$226.61	\$478.87	\$717.35	\$633.88	\$545.57	\$121,549,303,000
Enrollee Expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	\$43.61	\$121.70	\$173.51	\$50.75	\$0.00	\$0.00	\$134.75	\$197.13	\$184.11	\$13,168,032,000
Expenses for noncovered benefits (e)	\$0.61	\$0.70	\$0.75	\$0.50	\$0.00	\$0.00	\$0.63	\$0.71	\$0.56	\$107,133,000
Total Expenditures	\$611.52	\$677.77	\$798.73	\$688.52	\$226.61	\$478.87	\$852.73	\$831.72	\$730.23	\$134,824,467,000

Source: California Health Benefits Review Program, 2021.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, both on Covered California and outside the exchange.

(b) As of January 2021, 54.1% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2022.

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

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

(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.

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

Table 8. Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2022

	DMHC-Regulated						CDI-Regulated			TOTAL
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (c)	Large Group	Small Group	Individual	
Enrollee Counts										
Total enrollees in plans/policies subject to state mandates (d)	8,405,000	2,086,000	1,989,000	889,000	7,218,000	787,000	384,000	43,000	144,000	21,945,000
Total enrollees in plans/policies subject to SB 523	8,405,000	2,086,000	1,989,000	889,000	0	0	384,000	43,000	144,000	13,940,000
Premium Costs										
Average portion of premium paid by employer	-\$0.3332	-\$0.2060	\$0.0000	-\$0.3744	\$0.0000	\$0.0000	-\$0.2493	-\$0.1666	\$0.0000	-\$43,992,000
Average portion of premium paid by enrollee	-\$0.1102	-\$0.0995	-\$0.3253	-\$0.0671	\$0.0000	\$0.0000	-\$0.0876	-\$0.0838	-\$0.1246	-\$22,750,000
Total Premium	-\$0.4434	-\$0.3055	-\$0.3253	-\$0.4415	\$0.0000	\$0.0000	-\$0.3369	-\$0.2503	-\$0.1246	-\$66,743,000
Enrollee Expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	\$0.0255	-\$0.1703	-\$0.2451	-\$0.0819	\$0.0000	\$0.0000	\$0.0732	-\$0.1973	-\$0.0128	-\$8,202,000
Expenses for noncovered benefits (e)	-\$0.6147	-\$0.6989	-\$0.7548	-\$0.5048	\$0.0000	\$0.0000	-\$0.6313	-\$0.7097	-\$0.5560	\$107,133,000
Total Expenditures	-\$1.0327	-\$1.1747	-\$1.3252	-\$1.0282	\$0.0000	\$0.0000	-\$0.8950	-\$1.1573	-\$0.6934	\$182,077,000
Postmandate Percent Change										
Percent change insured premiums	-0.0782%	-0.0550%	-0.0521%	-0.0693%	0.0000%	0.0000%	-0.0470%	-0.0395%	-0.0228%	-0.0549%
Percent Change total expenditures	-0.1689%	-0.1733%	-0.1659%	-0.1493%	0.0000%	0.0000%	-0.1050%	-0.1392%	-0.0950%	-0.1350%

Source: California Health Benefits Review Program, 2021.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, both on Covered California and outside the exchange.

(b) As of January 2021, 54.1% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2022.

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

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

(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.

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

Table 9. Estimated State Responsibility for Portion of Mandate That Is in Excess of EHBs, California, 2022

	DMHC-Regulated		CDI-Regulated		TOTAL
	Small Group	Individual	Small Group	Individual	
Enrollee Counts					
Total enrollees in plans/policies subject to state mandates	2,086,000	1,989,000	43,000	144,000	4,262,000
Number of enrollees in QHPs (a)	1,909,000	1,924,000	43,000	75,000	3,951,000
Premium Cost of Mandated Benefit					
Estimated premium cost of mandated benefit (b)	\$0.77	\$0.87	\$0.77	\$0.47	\$0.81
Marginal premium impact with offsets (c)	-\$0.31	-\$0.34	-\$0.26	-\$0.14	-\$0.32
Marginal premium impact considering baseline coverage (d)	\$0.77	\$0.87	\$0.77	\$0.47	\$0.81
Estimated Annual State Responsibility for Portion of Mandate That Is in Excess of EHBs					
Scenario 1 — Full estimated cost (e) = (a) x (b) x 12	\$17,669,000	\$20,072,000	\$395,000	\$419,000	\$38,555,000
Scenario 2 — With cost offsets (f) = (a) x (c) x 12	-\$7,191,000	-\$7,867,000	-\$137,000	-\$125,000	-\$15,320,000
Scenario 3 — With baseline coverage offset (g) = (a) x (d) x 12	\$17,669,000	\$20,072,000	\$395,000	\$419,000	\$38,555,000

Source: California Health Benefits Review Program, 2021.

Notes: (a) States are required to defray the costs of state-mandated benefits that are in excess of the 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 considering some of the increase in costs associated with a given benefit mandate may be offset by reductions in costs for related benefits that are EHBs.

(d) Estimated marginal premium impact of the proposed mandated benefit considering some QHPs may already cover the mandated benefit. It is yet to be determined whether the state is responsible for defraying the full cost of the mandated benefit in this circumstance.

Key: CDI = California Department of Insurance; DMHC = Department of Managed Health Care; EHBs = essential health benefits; QHPs = qualified health plans.

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, SB 523 requires DMHC-regulated plans and CDI-regulated policies to expand coverage for contraception to include all U.S. Food and Drug Administration (FDA)-approved over-the-counter (OTC) contraceptives for men and women, male sterilization procedures, and certain clinical services. The bill also eliminates the requirement for a prescription to obtain coverage of FDA-approved OTC contraceptives. SB 523 requires coverage without cost sharing or out-of-pocket (OOP) expenses for these additional benefits and explicitly prohibits health plans and policies from imposing utilization management policies to access coverage.

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 impact³⁹ of SB 523 on unintended pregnancies, sexually transmitted infections (STIs), and other health outcomes. See *Long-Term Impacts* for discussion of the impact of SB 523 on outcomes beyond the first 12 months of bill implementation.

Estimated Public Health Outcomes

As discussed in previous sections, SB 523 impacts coverage related to nonprescription OTC and male-specific contraception; thus, the public health impact analysis focused exclusively on these contraceptive methods (i.e., male condom, female condom, contraceptive sponge, spermicide, levonorgestrel [EC], and vasectomy).

Unintended Pregnancy

As discussed in the *Background on Contraceptives* section, although approximately two-thirds of sexually active heterosexual females aged 15 to 44 years in the United States use contraception, they may still be at risk of an unintended pregnancy due to method failure, inconsistent use, or incorrect use. As presented in *Medical Effectiveness*, there is clear and convincing evidence that contraception is effective at preventing unintended pregnancy. Among the 89,481 enrollees using contraceptives postmandate, CHBRP projects that 12,293 unintended pregnancies would be averted, and 5,532 abortions would be averted (see *Benefit Coverage, Utilization, and Cost* section). For detailed methodology, please refer to Appendix C.

Related health outcomes

Unintended pregnancies and births (which can be categorized as either “mistimed” or “unwanted”) are associated with a range of adverse prenatal and postpartum outcomes. A review by Gipson et al. (2008) found that research consistently shows that compared to females with intended pregnancies, females with unintended pregnancies are more likely to delay initiating prenatal care and have fewer prenatal care visits. A systematic review by Shah et al. (2011) found that the odds of low birthweight and preterm birth were higher among unintended pregnancies compared to intended pregnancies (adjusted odds ratio [OR] =1.60 and 1.33, respectively). In postpartum, Gipson et al. (2008) found that research consistently shows that compared to children born from intended pregnancies, children born from unintended pregnancies are less likely to be breastfed or are more likely to be breastfed for a shorter duration. One study analyzing Pregnancy Risk Assessment Monitoring System (PRAMS) data in Maryland found that after controlling for sociodemographic factors, unhealthy behaviors such as cigarette and alcohol use during pregnancy were more likely to be associated with an unwanted pregnancy than with intended or mistimed pregnancies (Cheng et al., 2009).

Unintended pregnancies can also lead to adverse maternal health outcomes. There are inherent risks of pregnancy, including maternal mortality, and unintended pregnancies expose females to these inherent

³⁹ CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

risks more often. Based on estimated maternal mortality ratios from the World Health Organization (WHO), Ahmed et al. (2012) estimated the effect of contraceptive use on maternal mortality and estimated that nearly 61% of maternal deaths in the United States could be averted by contraceptive use and that if unmet demand for contraception was satisfied, an estimated 76% of maternal deaths could be averted by contraceptive use. Additionally, a recent meta-analysis of 30 studies involving 65,454 participants found that unintended pregnancy is significantly associated with the risk of developing postpartum depression (Qiu et al., 2020).

As described in the *Medical Effectiveness* section, there is *clear and convincing evidence* that contraception is effective at preventing unintended pregnancy, but the effectiveness varies by method. In the *Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP projects that SB 523 would increase utilization of barrier methods, levonorgestrel (EC) and vasectomies by 89,481 enrollees. As a result of this increase in utilization, CHBRP estimates that, in the first year postmandate, there would be a reduction in the number of unintended pregnancies overall (12,293 averted) and those ending in abortion (5,532 averted), as well as a reduction in negative health outcomes associated with unintended pregnancy.

Sexually Transmitted Infections (STIs)

As discussed in the *Background* section, the incidence of STIs such as chlamydia, gonorrhea, and syphilis are high in California (CDC, 2018; CDPH, 2018). STIs can lead to adverse health outcomes, including pelvic inflammatory disease, which can lead to pain and difficulty or inability to become pregnant among females, and in rare cases can lead to sterility in males (CDC, 2014a; CDC, 2014b).

As presented in the *Medical Effectiveness* section, there is *clear and convincing evidence* that condoms are effective at preventing transmission of STIs/HIV. Female condoms are the only female barrier method that protects against STIs (ACOG, 2018) yet utilization of female barrier methods is low — data from 2006 to 2010 indicated that only 0.3% of U.S. females aged 15 to 44 years use female barrier methods (Jones et al., 2012). CHBRP projects an increase in enrollees utilizing barrier methods postmandate (see the *Benefit Coverage, Utilization, and Cost Impacts* section), but is unable to estimate an associated change in STI rates. A 2017 systematic review of condom distribution programs found that programs that only reduce cost barriers but do not address other barriers to condom use (knowledge, attitudes, preferences, beliefs, and social norms) did not result in a reduction in STIs (Malekinejad et al., 2017).

CHBRP projects that SB 523 would increase utilization of female and male condoms by approximately 759 and 84,169 enrollees, respectively, but CHBRP is unable to estimate a quantitative impact on STI rates due to increased access to condoms. However, it stands to reason that some of the new utilizers of condoms (and their partners) may be at lower risk of acquiring or transmitting an STI and be at lower risk for infection-related adverse health outcomes.

Noncontraceptive Health Benefits

There are broad benefits of contraceptive use, beyond preventing unintended pregnancies. Contraceptive use allows females to plan for pregnancy and achieve desired birth spacing, which is associated with improved maternal health outcomes and decreases poor fetal health outcomes, such as prematurity and low birthweight. This ability to avert an unintended pregnancy by delaying and spacing childbearing positively impacts a woman's income and economic stability, societal advancement, family stability, mental health, and happiness (Guttmacher Institute, 2013). Frost and Lindberg (2013) surveyed over 2,000 females receiving services at U.S. family planning clinics and found that females strongly believed that using birth control allowed them to take better care of themselves or their family. More than half of females surveyed strongly believed that using birth control allowed them to support themselves financially, stay in school or finish their education, and get or keep their job or have a career. As mentioned in the *Background* section, condoms are the only method that protects against STIs, including HIV (Trussell and Guthrie, 2011).

There are broad benefits of contraceptive use and the estimated additional 89,481 enrollees using nonprescription OTC contraceptives or vasectomy would benefit from these noncontraceptive health and family planning benefits.

Potential Harms From Contraceptives

When data are available, CHBRP estimates the marginal change in relevant harms associated with interventions affected by the proposed mandate. As discussed in the *Medical Effectiveness* section, contraceptives pose very few risks to users and are in general considered safer for women than pregnancy (Trussell and Guthrie, 2007). However, there is evidence to suggest that an increase in the use of contraception methods impacted by SB 523 could result in some side effects and harm. Female and male barrier method users may be at risk for potential side effects such as allergic reactions, urinary tract infections, pelvic discomfort, and vaginal irritation or infection. Women using EC may experience side effects such as changes in menstrual flow, headaches, dizziness, and gastrointestinal symptoms. Males obtaining vasectomies may be at increased risk of possible postoperative complications; however, these risks are rare.

As discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section, the projected increase in vasectomy utilization postmandate would result in a decrease in female sterilization procedures (235 enrollees). In the absence of undergoing female sterilization, these enrollees would avoid risks (although rare) associated with surgical contraceptive methods such as pain, infection, or postoperative complications (Adams and Wald, 2009; Cook et al., 2007).

In the case of SB 523, there is evidence to suggest that an increase in the use of nonprescription OTC contraceptives and vasectomy could result in side effects or harm; however, any harm must be weighed against the health benefits of contraceptive use. As reported in *Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP projects a decrease in female sterilization procedures due to SB 523; as such, these enrollees would avoid risks associated with female surgical contraceptive methods.

Impact on Disparities⁴⁰

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 contraception use and unintended pregnancies exist by gender, race/ethnicity, age, and social determinants of health.

Impact on Gender Disparities

As documented in the *Background* section, National Survey of Family Growth (NSFG) respondents are more likely to cite female sterilization as their current contraceptive method compared to male sterilization. As described in the *Benefit Coverage, Utilization, and Cost* section, CHBRP projects that SB 523 would result in an additional 252 enrollees seeking male sterilization procedures and 235 female sterilization procedures would be avoided.

There are gender disparities in the utilization of sterilization (see *Background* section) and evidence indicates that sterilization for males and females is medically effective. CHBRP estimates that SB 523 would result in 252 additional male sterilization procedures and 235 fewer female sterilization procedures.

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

Impact on Racial or Ethnic Disparities

As presented in the *Background* section, numerous racial/ethnic disparities exist in contraceptive utilization, unintended pregnancy rates, and abortion rates. The *Background* section also discusses differences in attitudes and preferences around contraceptive method choice between racial/ethnic groups. Non-Hispanic Black and Hispanic women experience higher rates of unintended pregnancies than White women, and a larger percentage of unintended pregnancies among these women end in abortion.

Racial/ethnic disparities in the utilization of contraceptives exist, as do disparities in unintended pregnancy (see *Background* section). As discussed in the *Benefit Coverage, Utilization, and Cost* section, CHBRP projects an overall increase in utilization of barrier methods, nonprescription EC, and vasectomies due to SB 523, but is unable to provide a quantitative estimate of the mandate's possible impact on racial/ethnic disparities. To the extent that SB 523 reduces disparities that are due to coverage differences or ameliorates barriers due to OOP costs (but not due to preferences about specific contraceptive coverage), CHBRP estimates a reduction in racial/ethnic disparities in contraceptive use and unintended pregnancy in the first year, postmandate; however, the magnitude is unknown.

Impact on Age Disparities

As presented in the *Background* section, use of condoms is highest among younger age groups whereas use of sterilization increases with age and use of EC is highest among females aged 20 to 24 years (Daniels et al., 2015; Daniels et al., 2013). The percentage of pregnancies that were unintended is inversely related to age, the unintended pregnancy rate peaks among females aged 20 to 24 years but the percentage of pregnancies ending in abortion does not vary substantially between age groups (Finer and Zolna, 2016).

Age disparities in the utilization of contraceptives exist, as do disparities in unintended pregnancy (see *Background* section). As discussed in the *Benefit Coverage, Utilization, and Cost* section, CHBRP projects an overall increase in utilization of barrier methods, nonprescription EC, and vasectomies due to SB 523, but is unable to provide a quantitative estimate of the mandate's possible impact on age disparities. To the extent that SB 523 reduces disparities that are due to coverage differences or ameliorates barriers due to OOP costs (but not due to preferences about specific contraceptive coverage), CHBRP estimates a reduction in disparities in contraceptive use and unintended pregnancy in the first year, postmandate; however, the magnitude is unknown.

Social Determinants of Health (SDoH)

As presented in the *Background* section, the utilization of most contraceptives (including EC) increases with education attainment and generally increases with higher income and enrollment in private insurance (Daniels and Abma, 2020; Daniels et al., 2013; Jones et al., 2012). The rate of unintended pregnancy is inversely related to improved socioeconomic status (Finer and Zolna, 2016).

Disparities in the utilization of contraceptives and unintended pregnancy exist based on educational attainment and income (see *Background* section). As discussed in the *Benefit Coverage, Utilization, and Cost* section, CHBRP projects an overall increase in utilization of barrier methods, nonprescription EC, and vasectomies due to SB 523, but is unable to provide a quantitative estimate of the mandate's possible impact on disparities related to educational attainment and income. To the extent that SB 523 reduces disparities that are due to coverage differences or ameliorates barriers due to OOP costs (but not due to preferences about specific contraceptive coverage), CHBRP estimates a reduction in disparities in contraceptive use and unintended pregnancy in the first year, postmandate; however, the magnitude is unknown.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of SB 523, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

CHBRP estimates annual utilization of nonprescription over-the-counter (OTC) contraceptives and vasectomies beyond the initial 12 months from the enactment of SB 523 would likely stay similar to utilization estimates during the first 12 months postmandate. Utilization changes may occur if additional nonprescription OTC medications or procedures change the landscape for enrollees; however, CHBRP is unable to predict these types of changes.

Similarly, health care utilization due to improved reproductive health services may change in the long term. Additionally, increased knowledge of the benefit and future social marketing programs could affect use of barrier contraceptives — particularly male condoms — and could affect sexually transmitted infection (STI) rates. A cost-effectiveness study of condom distribution programs in England, which included education and support in addition to condom distribution, was estimated to reduce 5,123 new STIs per year (Sadler, 2017). These programs, which addressed a variety of barriers to male condom use, were estimated to have an incremental cost of £17,411 per quality-adjusted life year compared to no program. Another study in the Netherlands examining the cost-effectiveness of condom distribution programs in bars and saunas frequented by men who have sex with men found that annual incidence of gonorrhea decreased by 5.73% and 7.62% for HIV (Bom, 2019). This program found that for every €1 spent on condom distribution, €5.51 was saved. However, in contrast to the mandate under SB 523, which requires that individuals obtain condoms at an in-network pharmacy for point-of-sale coverage, this condom distribution program promoted free condoms at places where sexual encounters might be initiated, reducing an important barrier to use. As noted earlier, SB 523 addresses only the cost barrier to contraceptive use, thus other interventions may be needed to impact long-term utilization and costs.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments), whereas 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 social determinants of health, premature death, and economic loss.

SB 523 has the potential to impact public health outcomes beyond the first 12 months postmandate. This section provides a qualitative discussion of the potential long-term impacts on the incidence of unintended pregnancy and abortion, maternal and child health and behavioral outcomes, socioeconomic outcomes, harms, and gender and racial/ethnic disparities. The discussion on possible impacts on health, behavioral, and socioeconomic outcomes will be based primarily on reviews of the literature conducted by Logan et al. (2007), Gipson et al. (2008), and Sonfield et al. (2013). Studies assessing the relationship between pregnancy intention and outcomes are subject to methodological limitations if the analysis does not address the confounding influences of family background and individual characteristics. As explained in Logan et al. (2007), "In studies that do not adequately account for pre-existing characteristics of the mother, associations may be incorrectly attributed to pregnancy intentions when, in fact, they are actually due to characteristics of the mother (such as low socioeconomic status) that make the females more likely to have an unintended birth and more likely to have poorer outcomes for the children or themselves." Relatively few studies reviewed for this section on long-term impacts used strong designs to account for

confounding factors. Overall, studies of the long-term impacts of unintended pregnancy provide relatively weak evidence on the weight of the impacts due to unintendedness alone.

Incidence of Unintended Pregnancy and Abortion

Based on estimates of contraceptive effectiveness rates discussed in the *Medical Effectiveness* section and projected increases in utilization discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section, in the first year postmandate, CHBRP estimates that SB 523 would result in 12,293 averted unintended pregnancies; among those averted pregnancies, there would be 5,532 averted abortions. In the long-term, due to eliminated cost sharing and OTC access, SB 523 may encourage enrollees to continue utilizing effective contraceptive methods and avoid unintended pregnancies, particularly among those at highest risk, such as younger females.

Assuming that SB 523 increases utilization of contraceptives beyond the first year postmandate, there may be a decrease in the rate of unintended pregnancies and abortions in the long term.

Incidence of Sexually Transmitted Infections

As discussed in the *Medical Effectiveness* and *Benefit Coverage, Utilization, and Cost Impacts* sections, CHBRP concludes that condoms are effective at preventing transmission of STIs/HIV and projects an increase in condom use postmandate but is unable to estimate an associated change in STI rates.

Assuming SB 523 increases condom utilization beyond the first year postmandate, it stands to reason that there may be a decrease in STI transmissions and associated adverse health outcomes in the long term.

Health and Behavioral Outcomes

Physical and mental health (mother)

As discussed in the *Public Health Impacts* section, research shows that compared to females with intended pregnancies, females with unintended pregnancies are more likely to delay initiating prenatal care, more likely to have a low-birthweight baby, and less likely to breastfeed (Cheng et al., 2009; Gipson et al., 2008; Shah et al., 2010). Pregnancy always carries inherent risks, including maternal mortality, and unintended pregnancies expose females to these inherent risks more often. Based on estimated maternal mortality ratios from the WHO, Ahmed et al. (2012) estimated the effect of contraceptive use on maternal mortality. Ahmed et al. (2012) estimated that nearly 61% of maternal deaths in the United States were averted by contraceptive use and that if unmet demand for contraception was satisfied, an estimated 76% of maternal deaths could be averted by contraceptive use.

Reviews of the literature by Logan et al. (2007), Gipson et al. (2008), and Sonfield et al. (2013) found that studies show an association between unintendedness and lower levels of psychological well-being during pregnancy and after birth, risk of depression and anxiety, and lower levels of happiness. Some qualitative research indicates that females with an unintended birth often receive support from their families, friends, and community, which may reduce the overall negative psychological impact of the unintended pregnancy.

In the long term, assuming that SB 523 increases utilization of contraceptives beyond the first year postmandate, there may be a decrease in the rate of unintended pregnancies, thereby decreasing the risk of maternal mortality and averting negative psychological outcomes associated with unintended pregnancies.

Physical and mental health (child)

Reviews of the literature by Logan et al. (2007) and Sonfield et al. (2013) found that studies show an association between unintendedness and physical and mental health of the child. Poor physical outcomes include reporting less than excellent health, being overweight, and being too active or not active enough. Additionally, compared to children who were wanted, children born from an unintended pregnancy are more likely to suffer from lower levels of psychological wellbeing in both childhood and adulthood, be less well adapted as children, have lower self-esteem as in early adulthood, and are more likely to be depressed or receive mental health services in adulthood.

In the long term, assuming that SB 523 increases utilization of contraceptives beyond the first year postmandate, there may be a decrease in the rate of unintended pregnancies, thereby decreasing risk of poor child health outcomes and averting negative psychological outcomes associated with children born from unintended pregnancies.

Behavioral outcomes

The reviews from Logan et al. (2007), Gipson et al. (2008) and Sonfield et al. (2013) found that studies show an association between unintendedness and some behavioral outcomes, such as attachment security and delinquency. For example, some studies have found that compared to children born from unintended pregnancies, children born from intended pregnancies were more likely to have strong attachment security with their mother and had mothers that spent more leisure time with them (such as reading or singing to them), whereas mothers who had an unintended pregnancy were more likely to spank or physically abuse their children and spend less leisure time with them. The review by Logan et al. (2007) found some evidence that suggests that adolescents born from unintended pregnancies report higher levels of delinquency, particularly among males and those born to mothers who were 20 years or older at the birth. Unintendedness does not seem to be associated with behavioral issues at younger or older ages (Logan et al., 2007). In addition, children born to teen mothers (among females aged 15–17 years, 91% of pregnancies are unintended) are more likely to lag behind their peers at age 2 in terms of behavioral and cognitive development and more prone to risky behaviors later in life, such as fighting and smoking (Sonfield et al., 2013).

In the long term, assuming that SB 523 increases utilization of contraceptives beyond the first year postmandate, there may be a decrease in the rate of unintended pregnancies, thereby decreasing the risk of poor mother-child relationships and behavioral problems.

Potential Harms From Contraceptives

When data are available, CHBRP estimates the marginal change in relevant harms associated with interventions affected by the proposed mandate. In the case of SB 523, there is evidence to suggest that an increase in the use of nonprescription OTC contraceptives and vasectomy could result in side effects or harm; however, any harm must be weighed against the health benefits of contraceptive use. CHBRP projects that SB 523 would increase utilization of female and male barrier contraceptives (condoms, contraceptive sponge, spermicide) by 84,928 enrollees (see Table 1). These enrollees may be at risk for potential side effects such as allergic reactions, urinary tract infections, pelvic discomfort, and vaginal irritation or infection. The 4,301 enrollees using nonprescription EC may experience side effects such as changes in menstrual flow, headaches, dizziness, and gastrointestinal symptoms. The 252 enrollees obtaining vasectomies may be at increased risk of possible postoperative complications; however, these risks are rare.

As discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section, the projected increase in vasectomy utilization postmandate would result in a decrease in female sterilization procedures (235 enrollees). In the absence of undergoing female sterilization, these enrollees would avoid risks (although

rare) associated with surgical contraceptive methods such as pain, infection, or postoperative complications (Adams and Wald, 2009; Cook et al., 2007).

In the case of SB 523, there is evidence to suggest that an increase in the use of nonprescription OTC contraceptives and vasectomy could result in side effects or harm; however, any harm must be weighed against the health benefits of contraceptive use. In the long term, assuming that SB 523 increases utilization of nonprescription OTC contraceptives and vasectomies beyond the first year postmandate, some enrollees may be at risk for contraceptive-related side effects. Additionally, assuming that SB 523 increases utilization of vasectomies, females would experience a decrease in risks associated with female surgical contraceptive methods.

Impacts on Disparities and the Social Determinants of Health⁴¹

As documented in the *Background on Contraceptives* section, there are numerous disparities in contraceptive utilization and unintended pregnancy rates by age, gender, race/ethnicity, and socioeconomic status.

There are disparities in the utilization of contraceptives and in unintended pregnancy rates (see *Background* section). In the long term, assuming that SB 523 increases utilization of contraceptives beyond the first year postmandate, there may be a reduction in disparities that are due to coverage differences or out-of-pocket (OOP) costs (but not to preferences about specific contraceptive methods) and in disparities in unintended pregnancy rates; however, the magnitude is unknown.

The review by Sonfield et al. (2013) found that access to contraception, reduced unintended pregnancy, and ability to delay childbearing has positive impacts on socioeconomic outcomes such as educational attainment and workforce participation. The review concludes that teenagers who have an unintended pregnancy (among females aged 15–17 years, 91% of pregnancies are unintended) are less likely to obtain any college education or degree and have fewer years of formal education overall compared to their peers who delayed childbearing. The review also found strong evidence that access to contraceptives can positively impact female's professional pursuits and time spent in the labor force by allowing females to delay and time childbearing to align with their professional opportunities. The evidence indicates that access to contraceptives and delayed childbearing may reduce the income gap between males and females. Thus, females with an average age of 30 years and who were childless earned about 90% of the hourly wages earned by men in that age group, but younger females who were mothers earned 73% as much as similarly aged men.

In the long term, assuming that SB 523 increases utilization of contraceptives beyond the first year postmandate, there may be a decrease in the rate of unintended pregnancies, thereby allowing females to delay childbearing and pursue additional education, spend additional time in their careers, and have increased earning power.

⁴¹ For more information about SDoH, see CHBRP's publication *Incorporating Relevant Social Determinants of Health Into CHBRP Benefit Mandate Analyses* at http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

APPENDIX A TEXT OF BILL ANALYZED

On February 17, 2021, the California Senate Committee on Health requested that CHBRP analyze SB 523. On March 16, 2021, SB 523 was amended, and the California Senate Committee on Health requested that CHBRP analyze the version of SB 523 amended on that date.

AMENDED IN SENATE MARCH 16, 2021

CALIFORNIA LEGISLATURE— 2021–2022 REGULAR SESSION

SENATE BILL

NO. 523

Introduced by Senator Leyva

February 17, 2021

An act to add Section 22856 to the Government Code, to amend Section 1367.25 of the Health and Safety Code, to amend Section 10123.196 of the Insurance Code, and to add Section 10509.5 to the Public Contract Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 523, as amended, Leyva. Health care coverage: contraceptives.

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 establishes health care coverage requirements for contraceptives, including, but not limited to, requiring a health care service plan, including a Medi-Cal managed care plan, or a health insurance policy issued, amended, renewed, or delivered on or after January 1, 2017, to cover up to a 12-month supply of federal Food and Drug Administration approved, self-administered hormonal contraceptives when dispensed at one time for an enrollee or insured by a provider or pharmacist, or at a location licensed or authorized to dispense drugs or supplies.

This bill, the Contraceptive Equity Act of 2021, would make various changes to expand coverage of contraceptives by a health care service plan contract or health insurance policy issued, amended, renewed, or delivered on and after January 1, 2022, including requiring a health care service plan or health insurer to provide point-of-sale coverage for over-the-counter FDA-approved contraceptive drugs, devices, and products at in-network pharmacies without cost-sharing or medical management restrictions and to reimburse enrollees and insureds for out-of-pocket costs for over-the-counter birth control methods purchased at any out-of-network pharmacy in California, without medical management restrictions. The bill would also require coverage for clinical services related to the provision or use of contraception, as specified. The bill would revise provisions applicable when a covered, therapeutic equivalent of a drug, device, or product is deemed medically inadvisable by deferring to the attending provider, as specified.

~~With respect to religious employers, this bill would authorize an enrollee or insured to submit a request to the health care service plan or health insurer if the employer elects not to purchase coverage for contraceptive methods, as required by existing law. The bill would require the applicable department to reimburse a religious employer for the contraceptive care and related products provided to the employee, as specified. The bill would prohibit the employer~~ *The bill would prohibit a religious employer, as defined, that requests and is provided a health care service plan contract or health insurance policy without coverage for FDA-approved contraceptive methods that are contrary to the religious employer's religious tenets, from discriminating or retaliating against the employee for independently obtaining contraceptives outside of the employer's plan or policy under this authorization.*

This bill would prohibit the Board of Public Relations of the Public Employees' Retirement System and the University of California from approving or renewing a health benefit plan that does not comply with the contraceptive coverage requirements of the bill and existing law described above, on and after January 1, 2022.

Because a willful violation of the bill's requirements 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.

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

As Amends the Law Today

***SECTION 1.** This act shall be known, and may be cited, as the Contraceptive Equity Act of 2021.*

***SEC. 2.** The Legislature finds and declares all of the following:*

(a) California has a long history of expanding timely access to birth control to prevent unintended pregnancy. Thanks to a combination of innovative policies and programs enacted statewide, unintended pregnancy rates are at a 30-year low.

(b) Despite the progress made, health disparities in reproductive health outcomes persist among Black, Indigenous and People of Color, including disproportionate unintended pregnancy, infant and maternal mortality, and (STD) rates. The legislature must take action to ensure that all Californians have equitable access to preventive contraceptive care.

(c) The federal Patient Protection and Affordable Care Act (Public Law 111-148) included a mandate that most health insurance plans cover contraception without out-of-pocket costs for patients.

(d) California's Contraceptive Coverage Equity Act of 2014 and the Annual Supply of Contraceptives Act of 2016, built on this federal policy and existing state law to be the first state

in the country to require coverage of birth control methods approved by the federal Food and Drug Administration for women without cost-sharing or restrictions and a 12-month supply of self-administered birth control dispensed at one time for individuals enrolled in health insurance plans and policies regulated by the Keene Health Care Service Act of 1975.

(e) Since 2014, several other states have expanded on California’s model legislation to create more equitable contraceptive coverage and access by requiring most health insurance plans and policies to cover voluntary sterilization services and all birth control methods available over-the-counter without a prescription for all beneficiaries, regardless of gender.

(f) A report by the Guttmacher Institute shows that vasectomy is among the most effective – and cost-effective contraceptive methods available.

(g) Trump-era attacks on birth control access have underscored the need to codify the expansion of contraceptive coverage for as many Californians as possible under state law.

(h) The COVID-19 public health emergency has also further illuminated the structural inequities that disproportionately affect youth, low-income people and communities of color in accessing birth control services. A report by the Guttmacher Institute revealed that 29 percent of White women, 38 percent of Black women and 45 percent of Latinas now face difficulties accessing birth control as a result of the pandemic.

(i) The COVID-19 pandemic has exacerbated rates of sexually transmitted diseases STDs in California and across the country that were already skyrocketing to epidemic proportions prior to the public health emergency. Condoms are the only birth control method that also reduce STD transmission rates.

(j) The Legislature intends to reduce sexual and reproductive health disparities and ensure greater health equity by providing a pathway for more Californians to get the contraceptive care they want, when they need it – without inequitable delays or cost barriers. This includes a pathway to no-cost coverage for Californians whose employer-based health insurance plan may exclude contraceptive care under existing California law.

(k) The Legislature intends for the relevant California departments and agencies to work in concert to ensure compliance with these provisions.

SEC. 3. *Section 22856 is added to the Government Code, to read:*

22856. *Notwithstanding any other law, commencing January 1, 2022, the board shall not approve a health benefit plan contract for employees that does not comply with the contraceptive coverage requirements of Section 1367.25 of the Health and Safety Code, Section 10123.196 of the Insurance Code, and Senate Bill No. 999 (Ch. 499, Stats. 2016).*

SEC. 4. Section 1367.25 of the Health and Safety Code is amended to read:

1367.25. (a) A group health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, renewed, or delivered on or after January 1, 2000, to December 31, 2015, inclusive, and an individual health care service plan contract that is amended,

renewed, or delivered on or after January 1, 2000, to December 31, 2015, inclusive, except for a specialized health care service plan contract, shall provide coverage for the following, under general terms and conditions applicable to all benefits:

(1) A health care service plan contract that provides coverage for outpatient prescription drug benefits shall include coverage for a variety of federal Food and Drug Administration (FDA)-approved prescription contraceptive methods designated by the plan. In the event the patient's participating provider, acting within ~~his or her~~ *the provider's* scope of practice, determines that none of the methods designated by the plan is medically appropriate for the patient's medical or personal history, the plan shall also provide coverage for another FDA-approved, medically appropriate prescription contraceptive method prescribed by the patient's provider.

(2) Benefits for an enrollee under this subdivision shall be the same for an enrollee's covered spouse and covered nonspouse dependents.

(b) (1) A health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, renewed, or delivered on or after January 1, 2016, shall provide coverage for all of the following services and contraceptive methods for ~~women~~ *all subscribers and enrollees*:

(A) Except as provided in subparagraphs (B) and (C) of paragraph (2), all FDA-approved contraceptive drugs, devices, and other ~~products for women~~, *products*, including all FDA-approved contraceptive drugs, devices, and products available over the ~~counter, as prescribed by the enrollee's provider~~, *counter without a prescription, as follows*:

(i) A health care service plan shall not require a prescription to trigger coverage of over-the-counter FDA-approved contraceptive drugs, devices, and products.

(ii) A health care service plan is required to provide point-of-sale coverage for over-the-counter FDA-approved contraceptive drugs, devices, and products at in-network pharmacies without cost-sharing or medical management restrictions and reimburse enrollees for out-of-pocket costs for over-the-counter birth control methods purchased at any out-of-network pharmacy in California without medical management restrictions.

(iii) A health care service plan may limit the frequency and define quantities with which the coverage required under this subparagraph is provided.

(B) Voluntary sterilization procedures.

(C) ~~Patient education and counseling on contraception~~. *Clinical services related to the provision or use of contraception, including consultations, examinations, procedures, ultrasound, anesthesia, patient education, and counseling.*

(D) Followup services related to the drugs, devices, products, and procedures covered under this subdivision, including, but not limited to, management of side effects, counseling for continued adherence, and device insertion and removal.

(2) (A) ~~Except for a grandfathered health plan, a health~~ *A health* care service plan subject to this subdivision shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to this ~~subdivision.~~ *subdivision, except for a grandfathered health plan or a qualifying health plan for a health savings account. For a qualifying health plan for a health savings account, the carrier shall establish the plan's cost-sharing for the coverage required pursuant to this subdivision at the minimum level necessary to preserve the enrollee's ability to claim tax-exempt contributions and withdrawals from the enrollee's health savings account under Internal Revenue Service laws and regulations.* Cost sharing shall not be imposed on any Medi-Cal beneficiary.

(B) If the FDA has approved one or more therapeutic equivalents of a contraceptive drug, device, or product, a health care service plan is not required to cover all of those therapeutically equivalent versions in accordance with this subdivision, as long as at least one is covered without cost sharing in accordance with this subdivision. *If there is no therapeutically equivalent generic substitute available in the market, a health care service plan is required to provide coverage without cost sharing for the original, brand name contraceptive.*

(C) If a covered therapeutic equivalent of a drug, device, or product is ~~not available, or is~~ deemed medically inadvisable by the enrollee's provider, a health care service plan shall ~~provide coverage, subject to a plan's utilization management procedures, for the~~ *defer to the determination and judgment of the attending provider and provide coverage for the alternative* prescribed contraceptive drug, device, *product,* or ~~product without cost sharing.~~ *Any request* *service without imposing any cost-sharing requirements. Medical inadvisability may include considerations such as severity of side effects, differences in permanence or reversibility of contraceptives and ability to adhere to the appropriate use of the drug or item, as determined by the attending provider. The department shall promulgate regulations establishing an easily accessible, transparent, and sufficiently expedient process that is not unduly burdensome, including timeframes, for an enrollee, an enrollee's designee, or an enrollee's provider to request coverage of an alternative prescribed contraceptive. A request* by a contracting provider shall be responded to by the health care service plan in compliance with the Knox-Keene Health Care Service Plan Act of 1975, as set forth in this chapter and, as applicable, with the plan's Medi-Cal managed care contract.

(3) Except as otherwise authorized under this section, a health care service plan shall not *infringe upon an enrollee's choice of contraceptive drug, device, or product and shall not* impose any restrictions or delays on the coverage required under this ~~subdivision.~~ *subdivision, including prior authorization, step therapy, or other utilization control techniques.*

(4) Benefits for an enrollee under this subdivision shall be the same for an enrollee's covered spouse and covered nonspouse dependents.

(5) For purposes of ~~paragraphs (2) and (3) of this subdivision, and subdivision (d), this~~ *subdivision,* "health care service plan" shall include Medi-Cal managed care plans that contract with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000) and Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code.

(c) Notwithstanding any other provision of this section, a religious employer may request a health care service plan contract without coverage for FDA-approved contraceptive methods that are contrary to the religious employer's religious tenets. If so requested, a health care service plan contract shall be provided without coverage for contraceptive methods. *The exclusion from coverage under this provision shall not apply to a contraceptive drug, device, procedure, or other product that is used for purposes other than contraception.*

(1) For purposes of this section, a "religious employer" is an entity for which each of the following is true:

(A) The inculcation of religious values is the purpose of the entity.

(B) The entity primarily employs persons who share the religious tenets of the entity.

(C) The entity serves primarily persons who share the religious tenets of the entity.

(D) The entity is a nonprofit organization as described in Section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

(2) Every religious employer that invokes the exemption provided under this ~~section~~ *subdivision* shall provide written notice to prospective enrollees prior to enrollment with the plan, listing the contraceptive health care services the employer refuses to cover for religious reasons.

(3) A religious employer that invokes the exemption under this subdivision may not discriminate, fire, or enforce other workplace punishment against an employee based on the employee's decision to independently obtain contraceptive coverage, care, or prescriptions outside of the employer-based plan.

(d) (1) Every health care service plan contract that is issued, amended, renewed, or delivered on or after January 1, 2017, shall cover up to a 12-month supply of FDA-approved, self-administered hormonal contraceptives when dispensed or furnished at one time for an enrollee by a provider, pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies.

(2) ~~Nothing in this~~ *This* subdivision shall *not* be construed to require a health care service plan contract to cover contraceptives provided by an out-of-network provider, pharmacy, or location licensed or otherwise authorized to dispense drugs or supplies, except as may be otherwise authorized by state or federal law or by the plan's policies governing out-of-network coverage.

(3) ~~Nothing in this~~ *This* subdivision shall *not* be construed to require a provider to prescribe, furnish, or dispense 12 months of self-administered hormonal contraceptives at one time.

(4) A health care service plan subject to this subdivision, in the absence of clinical contraindications, shall not impose utilization controls or other forms of medical management limiting the supply of FDA-approved, self-administered hormonal contraceptives that may be dispensed or furnished by a provider or pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies to an amount that is less than a 12-month supply.

(e) This section shall not be construed to exclude coverage for contraceptive supplies as prescribed by a provider, acting within ~~his or her~~ *the provider's* scope of practice, for reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause, or for contraception that is necessary to preserve the life or health of an enrollee.

(f) This section shall not be construed to deny or restrict ~~in any way~~ the department's authority to ensure plan compliance with this chapter when a plan provides coverage for contraceptive drugs, devices, and products.

(g) This section shall not be construed to require an individual or group health care service plan contract to cover experimental or investigational treatments.

(h) For purposes of this section, the following definitions apply:

(1) "Grandfathered health plan" has the meaning set forth in Section 1251 of PPACA.

(2) "PPACA" means the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), and any rules, regulations, or guidance issued thereunder.

(3) With respect to health care service plan contracts issued, amended, or renewed on or after January 1, 2016, "provider" means an individual who is certified or licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, or an initiative act referred to in that division, or Division 2.5 (commencing with Section 1797) of this code.

(i) The changes made to this section by the act that added this subdivision apply only to a health care service plan contract that is issued, amended, renewed, or delivered on or after January 1, 2022.

SEC 5. Section 10123.196 of the Insurance Code is amended to read:

10123.196. (a) An individual or group policy of disability insurance issued, amended, renewed, or delivered on or after January 1, 2000, through December 31, 2015, inclusive, that provides coverage for hospital, medical, or surgical expenses, shall provide coverage for the following, under the same terms and conditions as applicable to all benefits:

(1) A disability insurance policy that provides coverage for outpatient prescription drug benefits shall include coverage for a variety of federal Food and Drug Administration (FDA)-approved prescription contraceptive methods, as designated by the insurer. If an insured's health care provider determines that none of the methods designated by the disability insurer is medically appropriate for the insured's medical or personal history, the insurer shall, in the alternative, provide coverage for some other FDA-approved prescription contraceptive method prescribed by the patient's health care provider.

(2) Coverage with respect to an insured under this subdivision shall be identical for an insured's covered spouse and covered nonspouse dependents.

(b) (1) A group or individual policy of disability insurance, except for a specialized health insurance policy, that is issued, amended, renewed, or delivered on or after January 1, 2016, shall provide coverage for all of the following services and contraceptive methods for ~~women:~~ *all policyholders and insureds:*

(A) Except as provided in subparagraphs (B) and (C) of paragraph (2), all FDA-approved, contraceptive drugs, devices, and other ~~products for women,~~ *products,* including all FDA-approved, contraceptive drugs, devices, and products available over the ~~counter, as prescribed by the insured's provider.~~ *counter without a prescription, as follows:*

(i) A health insurer shall not require a prescription to trigger coverage of over-the-counter FDA-approved contraceptive drugs, devices, and products.

(ii) A health insurer is required to provide point-of-sale coverage for over-the-counter FDA-approved contraceptive drugs, devices, and products at in-network pharmacies without cost-sharing or medical management restrictions and reimburse insureds for out-of-pocket costs for over-the-counter birth control methods purchased at any out-of-network pharmacy in California without medical management restrictions.

(iii) A health care insurer may limit the frequency and define quantities with which the coverage required under this subparagraph is provided.

(B) Voluntary sterilization procedures.

(C) ~~Patient education and counseling on contraception.~~ *Clinical services related to the provision or use of contraception, including consultations, examinations, procedures, ultrasound, anesthesia, patient education, and counseling.*

(D) Followup services related to the drugs, devices, products, and procedures covered under this subdivision, including, but not limited to, management of side effects, counseling for continued adherence, and device insertion and removal.

(2) (A) ~~Except for a grandfathered health plan, a~~ A disability insurer subject to this subdivision shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to this ~~subdivision.~~ *subdivision, except for a grandfathered health plan or a qualifying health plan for a health savings account. For a qualifying health plan for a health savings account, the carrier shall establish the plan's cost-sharing for the coverage required pursuant to this subdivision at the minimum level necessary to preserve the insured's ability to claim tax exempt contributions and withdrawals from the insured's health savings account under Internal Revenue Service laws and regulations.*

(B) If the FDA has approved one or more therapeutic equivalents of a contraceptive drug, device, or product, a disability insurer is not required to cover all of those therapeutically equivalent versions in accordance with this subdivision, as long as at least one is covered without cost sharing in accordance with this subdivision. *If there is no therapeutically equivalent generic substitute available in the market, a health care service plan is required to provide coverage without cost sharing for the original, brand name contraceptive.*

(C) If a covered therapeutic equivalent of a drug, device, or product is ~~not available, or is~~ deemed medically inadvisable by the insured's provider, a disability insurer shall ~~provide coverage, subject to an insurer's utilization management procedures, for the~~ *defer to the determination and judgment of the attending provider and provide coverage for the alternative* prescribed contraceptive drug, device, *product*, or ~~product without cost sharing. Any request~~ *service without imposing any cost-sharing requirements. Medical inadvisability may include considerations such as severity of side effects, differences in permanence or reversibility of contraceptives and ability to adhere to the appropriate use of the drug or item, as determined by the attending provider. The department shall promulgate regulations establishing an easily accessible, transparent, and sufficiently expedient process that is not unduly burdensome, including timeframes, for an insured, an insured's designee or an insured's provider to request coverage of an alternative prescribed contraceptive. A request* by a contracting provider shall be responded to by the disability insurer in compliance with Section 10123.191.

(3) Except as otherwise authorized under this section, an insurer shall not *infringe upon an insured's choice of contraceptive drug, device, or product and shall not* impose any restrictions or delays on the coverage required under this ~~subdivision. subdivision, including prior authorization, step therapy, or other utilization control techniques.~~

(4) Coverage with respect to an insured under this subdivision shall be identical for an insured's covered spouse and covered nonspouse dependents.

(c) This section shall not be construed to deny or restrict in any way any existing right or benefit provided under law or by contract. *The exclusion from coverage under this provision shall not apply to a contraceptive drug, device, procedure, or other product that is used for purposes other than contraception.*

(d) This section shall not be construed to require an individual or group disability insurance policy to cover experimental or investigational treatments.

(e) Notwithstanding any other provision of this section, a religious employer may request a disability insurance policy without coverage for contraceptive methods that are contrary to the religious employer's religious tenets. If so requested, a disability insurance policy shall be provided without coverage for contraceptive methods.

(1) For purposes of this section, a "religious employer" is an entity for which each of the following is true:

(A) The inculcation of religious values is the purpose of the entity.

(B) The entity primarily employs persons who share the religious tenets of the entity.

(C) The entity serves primarily persons who share the religious tenets of the entity.

(D) The entity is a nonprofit organization pursuant to Section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

(2) Every religious employer that invokes the exemption provided under this ~~section subdivision~~ shall provide written notice to ~~any prospective employee once an offer of employment has been made, and prior to that person commencing that employment,~~ *prospective insureds prior to obtaining coverage under the policy*, listing the contraceptive health care services the employer refuses to cover for religious reasons.

(3) A religious employer that invokes the exemption under this subdivision may not discriminate, fire, or enforce other workplace punishment against an employee based on the employee's decision to independently obtain contraceptive coverage, care, or prescriptions outside of the employer-based policy.

(f) (1) A group or individual policy of disability insurance, except for a specialized health insurance policy, that is issued, amended, renewed, or delivered on or after January 1, 2017, shall cover up to a 12-month supply of FDA-approved, self-administered hormonal contraceptives when dispensed or furnished at one time for an insured by a provider, pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies.

(2) ~~Nothing in this~~ *This* subdivision shall *not* be construed to require a policy to cover contraceptives provided by an out-of-network provider, pharmacy, or location licensed or otherwise authorized to dispense drugs or supplies, except as may be otherwise authorized by state or federal law or by the insurer's policies governing out-of-network coverage.

(3) ~~Nothing in this~~ *This* subdivision shall *not* be construed to require a provider to prescribe, furnish, or dispense 12 months of self-administered hormonal contraceptives at one time.

(4) A health insurer subject to this subdivision, in the absence of clinical contraindications, shall not impose utilization controls or other forms of medical management limiting the supply of FDA-approved, self-administered hormonal contraceptives that may be dispensed or furnished by a provider or pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies to an amount that is less than a 12-month supply.

(g) This section shall not be construed to exclude coverage for contraceptive supplies as prescribed by a provider, acting within ~~his or her~~ *the provider's* scope of practice, for reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause, or for contraception that is necessary to preserve the life or health of an insured.

(h) This section only applies to disability insurance policies or contracts that are defined as health benefit plans pursuant to subdivision (a) of Section 10198.6, except that for accident only, specified disease, or hospital indemnity coverage, coverage for benefits under this section applies to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy or contract. This section shall not be construed as imposing a new benefit mandate on accident only, specified disease, or hospital indemnity insurance.

(i) For purposes of this section, the following definitions apply:

(1) "Grandfathered health plan" has the meaning set forth in Section 1251 of PPACA.

(2) “PPACA” means the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), and any rules, regulations, or guidance issued thereunder.

(3) With respect to policies of disability insurance issued, amended, or renewed on or after January 1, 2016, “health care provider” means an individual who is certified or licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, or an initiative act referred to in that division, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

(j) The changes made to this section by the act that added this subdivision apply only to a health insurance policy that is issued, amended, renewed, or delivered on or after January 1, 2022.

SEC. 6. Section 10509.5 is added to the Public Contract Code, to read:

***10509.5.** Notwithstanding any other law, commencing January 1, 2022, the University of California shall not approve a health benefit plan contract for employees that does not comply with the contraceptive coverage requirements of Section 1367.25 of the Health and Safety Code, Section 10123.196 of the Insurance Code, and Senate Bill No. 999 (Ch. 499, Stats. 2016).*

SEC. 7. 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.

Relevant studies were identified through searches of PubMed, the Cochrane Library, Embase, and Cumulative Index of Nursing and Allied Health Literature. The search was limited to abstracts of studies published in English. The initial search was limited to studies published from 2010 to present. In addition, for research questions that returned a small number of articles, searching was done from 2000 to present.

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

Of the 372 articles found in the literature review, 16 were reviewed for potential inclusion in this report on SB 523 and a total of 27 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not focus on the specified contraceptives, were focused on a specific population, or reported on interventions that were not related to the provisions specified in SB 523.

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*.⁴² To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and
- Generalizability of findings.

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

- *Clear and convincing evidence*;
- *Preponderance of evidence*;
- *Limited evidence*;
- *Inconclusive evidence*; and
- *Insufficient evidence*.

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

⁴² Available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

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

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

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

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

Search Terms

Abortion	Nonprescription Drug*
Abortion, Induced	Non-Prescription Drug*
Annual Cost*	OTC
Birth Control	Over-the-Counter Drug*
California	Pharmacies
College Student*	Point of Sale
Condoms	Postcoitus Contraceptive Agent*
Contraception	Pregnancy, Unwanted
Contraceptive Agents	Prior Authorization
Contraceptive Devices	Religion
Contraceptives	Sexually Transmitted Disease*
Cost	Sexually Transmitted Infection*
Cost Effectiveness	Spermatocidal Agents
Economics	STDS
Expenditure*	Step Therapy
Fail First Protocols	Transgender Men
Family Planning	Transgender Persons
Family Planning Services	Transmission*
Female Contraceptive Device*	Unit Cost*
Health Care Cost*	United States
HIV Infections	University Student*
Human Immunodeficiency Virus Infection*	Unplanned Pregnancy
LARC	Utilization Management
Long Acting Reversible Contraception	(* = Truncation of word stem)
Male Contraceptive Agent*	
Male Contraceptive Device*	

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.⁴³ 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.⁴⁴

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 of vasectomies for commercial enrollees was determined by a 2014 survey of the largest (by enrollment) providers of health insurance in California for the 2014 CHBRP analysis of SB 1053. Responses to this survey represent 92% of commercial enrollees with health insurance that can be subject to state benefit mandates. In addition, CalPERS, DHCS, and the four largest (by enrollment) DMHC-regulated plans enrolling Medi-Cal beneficiaries were queried regarding related benefit coverage. A 2021 survey of the largest (by enrollment) providers of health insurance in California was used to determine the number of HSA-qualified plans. Responses to this survey represent 89% of commercial enrollees with health insurance that can be subject to state benefit mandates.

Analysis-Specific Caveats and Assumptions

Assumptions for Baseline Benefit Coverage

- The population subject to the mandated offering includes individuals covered by DMHC-regulated commercial insurance plans, CDI-regulated policies, CalPERS HMO plans, and DMHC-regulated Medi-Cal managed care.
- CHBRP assumed 100% of the population subject to mandated offerings have coverage at baseline for vasectomies. In 2014, CHBRP conducted a health plan survey of coverage of vasectomies, which indicated over 99% of enrollees have vasectomy coverage.
- CHBRP assumed 0% of the population subject to the mandated offerings have coverage at baseline for nonprescription over-the-counter (OTC) contraceptives.
- CHBRP assumed the coverage for nonprescription OTC contraceptives would be processed through the pharmacy benefit. Therefore, only enrollees with DMHC-regulated or CDI-regulated pharmacy coverage are included in CHBRP's nonprescription OTC contraceptive cost impact analysis. Of the 21,945,000 enrollees, approximately 12,991,000, or 59.2%, have pharmacy coverage. The majority of people with DMHC-regulated medical only coverage are the Medi-Cal enrollees.
- CHBRP conducted a health plan survey to determine the percentage of enrollees that are enrolled in HSA qualified plans by regulator, line of business, and deductible or metal tier. Approximately 892,000, or 4.1%, of enrollees are enrolled in an HSA-qualified plan.

⁴³ CHBRP's authorizing statute, available at https://chbrp.org/about_chbrp/index.php, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

⁴⁴ See method documents posted at http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see *2021 Cost Analyses: Data Sources, Caveats, and Assumptions*.

Assumptions for Baseline Benefit Utilization

- CHBRP assumed that plans would only allow women to be able to purchase female barrier contraceptives including spermicidal foam, female condoms, and the birth control sponge, or emergency contraceptives. CHBRP assumed that plans would only allow men to purchase male condoms. CHBRP assumed 49.4% of the commercial population is female and 52.6% of the Medi-Cal population are female. These estimates are based on the 2020 California Census and Milliman’s Consolidated Health Cost Guidelines Sources Database (“CHSD”), respectively.
- CHBRP assumed women aged 15 to 54 years and men aged 15 to 64 years use contraceptives, using the same estimates as SB 1053 (CHBRP, 2014).
- CHBRP used a California-based survey to estimate the percentage of California women who are at risk of unintended pregnancy using reversible contraceptive methods and the percentage distribution of primary contraceptive method for California women to determine the female barrier method utilization per 1,000 women in the entire population (not just those at risk of pregnancy) (Foster et al., 2004). The contraceptive sponge utilization was not included in the source data so CHBRP assumed the same utilization as female condoms. CHBRP trended the utilization to 2022 using an 0.15% annual utilization trend based on the report *Condom Use During Sexual Intercourse Among Women and Men Aged 15–44 in the United States: 2011–2015 National Survey of Family Growth* report (Copen, 2017). The estimated number of women aged 0 to 17 years using barrier methods is 0.6 per 1,000 and the estimated number of women aged 18 to 64 years using barrier methods is 3.75 per 1,000 at baseline.
- CHBRP used a California-based survey to estimate the percentage of California women who are at risk of unintended pregnancy and the percentage of women who have used emergency contraceptives in the past year from Baldwin et al. (2008) to determine the utilization of emergency contraceptives per 1,000 women in the entire population (not just those at risk of pregnancy) (Baldwin et al., 2008). CHBRP trended the utilization to 2022 using a 2.0% annual utilization trend based on the Kaiser Family Foundation factsheet on emergency contraceptives (KFF, 2018). The estimated number of women aged 0 to 17 years using emergency contraceptives is 16.2 per 1,000 and the estimated number of women aged 18 to 64 years using emergency contraceptives is 17.0 per 1,000 at baseline.
- To determine the utilization of male barrier methods, CHBRP split the population by sexual partner preference and age group using the following assumptions:
 - The percentage of teenage males aged 15 to 17 years who are sexually active from the CDC data brief on *Sexual Activity, Contraceptive Use and Childbearing Teenagers Aged 15–19 in the United States* is 47% (Martinez and Abma, 2015).
 - Based on the 2019 California census, male teenagers aged 15 to 17 years are 17% of the male 0 to 17 population. This results in 8% of the male population aged 0 to 17 years are sexually active.
 - The percentage of males aged 18 to 44 years who are sexually active from the *Trends in Frequency of Sexual Activity and Number of Sexual Partners Among Adults Aged 18 to 44 Years in the US, 2000-2018* is 84%. CHBRP assumed 84% of the entire population aged 18 to 64 is sexually active (Ueda et al., 2020).
 - According to National Health Statistics data brief (Copen, 2017), among heterosexual teens who are sexually active, 93.1% use condoms. The survey only provided responses for adults up to age 44. Assuming males aged 45 to 64 years utilize condoms at the same rate as males aged 35 to 44 years, the percentage of heterosexual sexually active male adults aged 18 to 64 years who use condoms is 44.0%.
 - According to the American Community Survey 94.3% of males are heterosexual (Grey et al., 2016).
 - CHBRP estimates 56% of men who have sex with men population use condoms based on a study by on Pines et al. (2016).
 - Combining the utilization listed above using an annual trend of 1.2% based on a data brief from the 2011–2015 National Survey of Family Growth, the projected 2022 condom users per

1,000 are 72.1 for males aged 0 to 17 years and 373.4 for males aged 18 to 64 years (Copen, 2017).

- The utilization per 1,000 of vasectomies is from Milliman's 2019 CHSD. The data was limited to California commercial and Medi-Cal enrollees. It is trended to 2022 using a 1.3% trend. Commercial utilization is 2.7 users per 1,000 and Medi-Cal utilization is 0.3 users per 1,000.

Assumptions for Baseline Cost

- CHBRP assumed the costs per year of spermicide, female condoms, and the contraceptive sponge are \$45, \$900, and \$120, respectively. This is based on unit cost estimates from CVS and Walmart, assuming sexual intercourse 30 times per year. These values are trended to 2022 using the Consumer Price Index for All Urban Consumers (CPI-U) for the period of July 2019 to July 2020 of 1.0%.
- The average cost for emergency contraceptives is based on the 2019 CHSD for drugs classified under Medi-Span major subclass "Emergency Contraceptives" with Ella removed because Ella is a prescription-only emergency contraceptive. The data was limited to California commercial enrollees. Emergency contraceptives are also trended to 2022 using a 1.0% trend. The estimated 2022 cost of emergency contraceptives is \$36.
- CHBRP assumed the cost per year of male condoms is \$48. This is based on unit cost estimate of \$1 per condom from CVS and Walmart. CHBRP estimated that males have sex approximately 43 times per year (Ueda et al., 2020). This assumes those who reported having sex once or twice a year had sex twice a year, those who reported they have sex 1 to 3 times per month have sex twice per month, and those who reported having sex weekly have sex 1.5 times per week. Because condoms come in packages of 12, CHBRP assumed four packages per year at \$48. These values are trended to 2022 using the Consumer Price Index for All Urban Consumers (CPI-U) for the period of July 2019 to July 2020 of 1.0%.
- The average cost for vasectomies is based on Milliman's 2019 CHSD. The data was limited to California commercial and Medi-Cal enrollees. To determine the cost of vasectomies and related visits, CHBRP included all services that occurred the day of the vasectomy (HCPCS code 55250) and all services with an ICD-10 diagnosis code Z9852 or visits to a urologist that occurred 30 days before or after the vasectomy. The commercial average cost per person was trended to 2022 using an annual blended office and outpatient trend of 5.8%.

Assumptions for Baseline Cost Sharing

- CHBRP assumed all nonprescription OTC contraceptives are not covered benefits. Enrollees pay 100% of the cost of these services.
- For commercial vasectomies, CHBRP developed the cost share using the paid-to-allowed ratios for vasectomies and related services from Milliman's CHSD database. To adjust for average plan benefit differentials by line of business, factors were calculated by comparing paid-to-allowed ratios of each line of business to the overall paid-to-allowed ratios of the California commercial population in the CHSD database. The vasectomies and related services paid-to-allowed ratios were multiplied by the line of business factors to calculate line of business-specific vasectomies and related services paid-to-allowed ratios. One minus the line of business-adjusted paid-to-allowed ratio was applied multiplicatively to the cost of the vasectomies and related services.
- For Medi-Cal vasectomies, CHBRP assumed the cost sharing is \$0.

Assumptions for Postmandate Utilization

- For enrollees in commercial non-HSA qualified and nongrandfathered plans, CHBRP assumed the utilization for female barrier, emergency contraceptives, and male barrier methods would increase 4.8% postmandate. This utilization increase is based on an analysis of the impact of the Affordable Care Act on utilization of short-term contraceptives (Becker, 2018).

- For enrollees in commercial non-HSA qualified and nongrandfathered plans, CHBRP assumed vasectomy utilization would increase 2.1% based on Milliman’s Health Cost Guidelines’ induced utilization factors.
- For enrollees in commercial HSA-qualified and grandfathered plans, CHBRP assumed no increase in the utilization of any services impacted by SB 523.
- For Medi-Cal enrollees, CHBRP did not assume a change in vasectomy utilization.

Assumptions for Postmandate Cost

- CHBRP did not assume costs would increase as a result of SB 523.

Assumptions for Postmandate Cost Sharing

- For enrollees in commercial non-HSA qualified and nongrandfathered plans, CHBRP assumed the cost sharing for female barrier, emergency contraceptives, male barrier, and vasectomies would be \$0.
- For enrollees in commercial grandfathered plans, CHBRP assumed emergency contraceptives would be covered at the average generic cost share of \$11, from the Kaiser Family Foundation 2019 Employer Health Benefit Survey (KFF, 2019). CHBRP assumed the cost share would be equal to the noncovered services or cost sharing at baseline.
- For enrollees in commercial HSA-qualified plans, CHBRP assumed the cost share would be equal to the cost of noncovered services or cost sharing at baseline.

Assumptions for Postmandate Cost Offsets

Baseline

- According to the Guttmacher Institute, the unintended pregnancy rate per 1,000 women aged 15 to 44 years is 50. Of these unintended pregnancies, 64.3% are publicly funded (Guttmacher Institute, 2016). Using the distribution of enrollees by insurance type, CHBRP determined the unintended pregnancy rate per 1,000 is 7.2 for females aged 17 and under and 18.5 for females aged 18 to 64 years.
- According to Guttmacher Institute, 45% of unintended pregnancies end in abortion, 13% of unintended pregnancies end in miscarriage, and 42% of unintended pregnancies end in labor and delivery (Guttmacher Institute, 2016). CHBRP applied this distribution of services to the number of offsetting unintended pregnancies.
- The assumed cost of abortions came from CHBRP’s analysis of SB 245 (CHBRP, 2021b).
- CHBRP used Milliman’s 2019 CHSD to determine the cost of live births include vaginal and C-section deliveries, which include the professional and facility costs. The cost and frequency of this pregnancy outcome is determine using the following MS DRGs: 765, 766, 767, 768, 774, 775, 783, 784, 785, 786, 787, 788, 796, 797, 798, 805, 806. The cost per service was trended to 2022 using an annual trend of 6.0% for commercial and 1.7% for Medi-Cal.
- Miscarriages and stillbirth cost were determined using data from the 2019 CHSD matching the following ICD-10 diagnosis codes: O021, O030, O031, O032, O0330, O0331, O0332, O0333, O0334, O0335, O0336, O0337, O0338, O0339, O034, O035, O036, O037, O0380, O0381, O0382, O0383, O0384, O0385, O0386, O0387, O0388, O0389, O039, Z377, Z371, P95, Z374, or Z373. The cost per service was trended to 2022 using an annual trend of 6.0% for commercial and 1.7% for Medi-Cal.
- For abortions, CHBRP assumed the same cost sharing as CHBRP’s analysis of SB 245 (CHBRP, 2021b).
- For commercial miscarriages and deliveries, CHBRP assumed cost sharing based on the actuarial values of the underlying plans.

Female sterilization

- CHBRP used Milliman's 2019 CHSD to determine the cost and utilization of tubal ligation using the following HCPCS: 58600, 58605, 58611, 58615, 58670, 58671. CHBRP included all services incurred that day. Cost was trended to 2022 using a 7.0% annual trend. Utilization was trended to 2022 using a 1.0% trend.
- CHBRP assumed cost sharing for tubal ligation is \$0 for enrollees in nongrandfathered plans because female sterilization is covered at \$0 cost share under the ACA. For enrollees in grandfathered plans, CHBRP assumed cost sharing based on the actuarial values of the underlying plans.

Unintended pregnancies

- CHBRP assumed unintended pregnancy and female sterilization rates would decline as a result of increased contraceptive and vasectomy utilization. CHBRP was unable to estimate the changes in sexually transmitted infection rates due to an absence of evidence regarding mandates or programs such as SB 523.
- CHBRP calculated the unintended pregnancies postmandate as unintended pregnancies at baseline minus the reduction in unintended pregnancies as a result of SB 523.
- CHBRP assumed that at baseline, new users of barrier methods use the rhythm method, withdrawal, or no contraceptives. Using the failure rates and utilization rates according to a study by Wollum et al (2020), the combined failure rate of these methods 33%. The failure rate of condoms (which CHBRP also assumed for female barrier methods because not enough information is available) is 18%. Taking into account the men having sex with men population, this results in a 153 unintended pregnancy reduction per 1,000 new users of female barrier methods and 144 unintended pregnancy reduction per 1,000 new users of male barrier methods.
- According to Wollum et al. (2020) the failure rate of all non-EC weighted by utilization is 14.4%. According to this study, when all users were able to receive OTC emergency contraceptives at no out-of-pocket cost, the rate of unintended pregnancies decreased 8.0%. This results in a reduction of 115 unintended pregnancies per 1,000 users of emergency contraceptives.
- CHBRP applied the same distribution of abortions, miscarriages, and deliveries as assumed at baseline.
- CHBRP assumed the same cost of abortions, miscarriages, and deliveries as baseline.
- For abortions, CHBRP assumed the same cost sharing as CHBRP's analysis of SB 245 of 2021 (CHBRP, 2021b).
- For commercial miscarriages and deliveries, CHBRP assumed cost sharing based on the actuarial values of the underlying plans.
- The cost sharing for avoided unintended pregnancies is different from baseline cost sharing because the avoided unintended pregnancies are only from enrollees in nongrandfathered or non-HSA qualified plans.

Postmandate: Female sterilization

- CHBRP calculated female sterilization postmandate as female sterilization at baseline minus the reduction in female sterilization as a result of SB 523.
- CHBRP assumed that 93.5% of new users of vasectomies would result in a reduction of one tubal ligation. This is based on a literature review (Shih et al., 2013a; Shih et al., 2013b) and determining that in most cases, couples are deciding between a male or female sterilization and that 93.5% of men getting vasectomies are married or cohabitating at time of sterilization (Eckhaut, 2015).
- CHBRP assumed the same cost of tubal ligations as baseline.

- CHBRP assumed that because only enrollee in nongrandfathered plans are impacted by this bill, cost sharing for tubal ligation is \$0 because female sterilization is covered at \$0 cost share under the ACA.

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 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.

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 SB 523 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 impacts of SB 523 would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures are due to population changes between the first year postmandate and the second year postmandate.

APPENDIX D INFORMATION SUBMITTED BY OUTSIDE PARTIES

In accordance with the California Health Benefits Review Program (CHBRP) policy to analyze information submitted by outside parties during the first 2 weeks of the CHBRP review, the following parties chose to submit information.

The following information was submitted by Essential Access Health in March 2021.

- Foster DG, Biggs MA, Phillips KA, Grindlay K, Grossman D. Potential public sector cost-savings from over-the-counter access to oral contraceptives. *Contraception*. 2015;91(5): 373-379.
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Submitted information is available upon request. For information on the processes for submitting information to CHBRP for review and consideration please visit: www.chbrp.org/requests.html

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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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