California Health Benefits Review Program

Analysis of California Senate Bill (SB) 999 Contraceptives: Annual Supply

A Report to the 2015-2016 California State Legislature

March 28, 2016



Key Findings: Analysis of California Senate Bill (SB) 999 Contraceptives: Annual Supply

Summary to the 2015-2016 California State Legislature, May 2016



AT A GLANCE

Senate Bill SB 999 would require DMHC-regulated plans or CDIregulated policies to cover a 12-month supply of Food and Drug Administration (FDA) approved, self-administered hormonal contraceptives dispensed at one time to an enrollee, either as prescribed or at the enrollee's request.

- Enrollees covered. CHBRP estimates that in 2016, 25.2 million Californians have state-regulated coverage that would be subject to SB 999.
- Impact on expenditures. CHBRP estimates that total net annual expenditures would decrease by \$42,799,000 or 0.03% for enrollees with DMHC-regulated plans and CDI-regulated policies. Savings are attributed to prevented unintended pregnancies as a result of access to a longer supply of selfadministered hormonal contraceptives and fewer office visits.
- Essential Health Benefits. SB 999 does not constitute a new benefit but rather, alters the terms and conditions (i.e., supply dispensed) of an existing benefit (coverage for self-administered hormonal contraceptives). SB 999 does not exceed essential health benefits (EHBs).
- **Medical effectiveness.** There is a preponderance of evidence to indicate that dispensing oral contraceptives in larger quantities leads to a reduction in unintended pregnancy and related outcomes.
- **Benefit coverage.** CHBRP estimates that coverage for an annual supply of self-administered hormonal contraceptives (including oral contraceptive pill, patch, and ring) would increase from 0% to 100% of enrollees of DMHC-regulated plans and CDI-regulated policies.
- Utilization. Postmandate, CHBRP estimates that the number of active self-administered hormonal contraceptive prescriptions will remain the same, but more women will receive a 12-month supply at once. Office visits are expected to decrease.
- **Public Health.** As a result of SB 999, CHBRP estimates a decrease in unintended pregnancies of 15,000 (which includes 6,000 fewer live births, 2,000 fewer miscarriages, and 7,000 fewer abortions).
- Long-term impacts. CHBRP projects that SB 999 would result in a decrease in the rate of unintended pregnancies and abortions over the long term, resulting in a corresponding decrease in the risk of maternal mortality, adverse child health outcomes, behavioral problems in children, and negative psychological outcomes associated with unintended pregnancies for both mothers and children. Avoiding unintended pregnancies also helps women to delay childbearing and pursue additional education, spend additional time in their careers, and have increased earning power over the long term.

BILL SUMMARY

SB 999 (introduced January 2016) would require DMHCregulated plans or CDI-regulated policies issued, amended, renewed or delivered on or after January 1, 2017, to cover a 12-month supply of FDA-approved, selfadministered hormonal contraceptives dispensed at one time to an enrollee. This includes the oral contraceptive pill, the vaginal ring, and the contraceptive patch. A 12month supply may be dispensed either as prescribed or at the enrollee's request. Unless the prescribing provider specifies "no change to quantity" on the enrollee's prescription, the enrollee may request up to a 12-month supply from their pharmacy.

INCREMENTAL IMPACT OF SENATE BILL (SB) 999

Benefit Coverage, Utilization, and Cost

Coverage Impacts

Out of the 25.2 million enrollees in DMHC-regulated plans and CDI-regulated policies subject to state mandates, all would be subject to SB 999, as the bill does not exempt any group (Figure 1). However, Medi-Cal already has a policy in place that allows enrollees to receive a 12-month supply at one time of oral contraceptives (but not the ring or patch). Premandate, 27% of enrollees have coverage that is partially compliant with this proposed bill, and 0% of enrollees have coverage that is fully compliant with SB 999.

Based on 2013 and 2014 MarketScan claims data, 744,000 California women aged 15 to 44 years subject to SB 999 (3.2% of enrollees) have active prescriptions for self-administered hormonal contraceptives. In this group:

- 67% (500,000) receive their contraceptives in a 1month supply per refill;
- 32% (240,000) receive their contraceptives in a 3month supply per refill;



• 0.6% (5,000) receive their contraceptives in a 12month supply at one time.



Figure 1. Health Insurance in CA and SB 999

Utilization Impacts

Postmandate, CHBRP estimates that the number of active self-administered hormonal contraceptive prescriptions will remain the same as prior to the mandate. It is important to note that one prescription may be used to dispense several refills. For example, a prescription valid for one year may be used to dispense four 3-month supplies throughout the year or one 12-month supply at one time. A prescription for self-administered hormonal contraceptives is typically valid for one year.

Based on evidence from the research literature, CHBRP estimates that the enrollee population that has selfadministered hormonal contraceptive prescriptions would have them filled in the following distribution:

- 185,000 would choose to receive 1 month at a time;
- 275,000 would choose to receive 3 months at a time;
- 285,000 would choose to receive 12 months at one time.

Cost Impacts

CHBRP estimates that SB 999 would decrease total net annual expenditures by \$42,799,000 or 0.03% for enrollees with DMHC-regulated plans and CDI-regulated policies (see Table 1). This estimate includes anticipated savings in 2017 from reduced unintended pregnancies (subsequent reduced delivery, miscarriage, and abortion costs), and the reduced office visits in the first year postmandate.

The mandate is expected to impact premiums in the following ways:

- Privately funded DMHC-regulated plans: range from a decrease of \$0.08 PMPM in the smallgroup market to a decrease of \$0.11 PMPM in the large-group market for 2017;
- CDI-regulated policies: range from a decrease of \$0.08 PMPM in the small-group market to a decrease of \$0.13 PMPM in the individual and large-group markets in 2017;
- Publicly funded DMHC-regulated plans: CalPERS HMO premiums will decrease by \$0.26 PMPM. Medi-Cal managed care plans will not have any cost impacts.

Average enrollee out-of-pocket expenses would decrease for all insured populations, with the exception of Medi-Cal beneficiaries, who would have no change. The decreases range from \$0.15 PMPM in small-group markets (both DMHC-regulated plans and CDI-regulated policies) to \$0.32 PMPM for CaIPERS enrollees.

Public Health

Unintended Pregnancy

Obtaining a 12-month supply of self-administered hormonal contraceptives at one time reduces the potential for delays in refills between cycles. Consistent, continuous contraceptive use helps to prevent any extension of the usual hormone-free interval; extension of this interval results in an increased possibility of unintended pregnancy.

As a result of SB 999, CHBRP estimates that:

 Unintended pregnancies would decrease by 15,000 (which includes 6,000 fewer live births, 2,000 fewer miscarriages, and 7,000 fewer abortions).



The reduction in unintended pregnancies will also result in a reduction in negative health outcomes associated with unintended pregnancy, including delayed prenatal care, low birth weight, and preterm birth.

Risks and Harms of Increased Supply of Contraceptives Dispensed at One Time

There is no evidence to suggest that there would be any difference in health risks for women receiving a 1-month or 3-month supply versus a 12-month supply of selfadministered hormonal contraceptives other than the increased risk of unintended pregnancy among the women in the 1-month and 3-month groups as described elsewhere in this report. This analysis did not find evidence to indicate any potential health risks or harms of having a larger supply of self-administered hormonal contraceptives available to a patient.

Medical Effectiveness

There is clear and convincing evidence that selfadministered hormonal contraceptives are effective in preventing pregnancy. There is also clear and convincing evidence to suggest that unintended pregnancy leads to a decrease in prenatal care and breastfeeding.

However, fewer studies examine the effect of the amount of dispensed supply of self-administered hormonal contraceptives, the primary impact of SB 999. There is a preponderance of evidence from studies with moderate research designs that conclude that dispensing oral contraceptives in larger quantities leads to a reduction in unintended pregnancy and related outcomes. There was no known literature on the impact of dispensing patterns for vaginal ring and contraceptive patch.

Two studies were conducted examining data on women receiving oral contraceptive pills through the California Family PACT (Planning, Access, Care and Treatment) Program to compare pregnancy rates between women given a 12-month supply to those given a 1- or 3-month supply (Foster et al., 2011; Foster et al., 2006b).

The results indicated that women who were given a 12month supply had reduced rates of unintended pregnancy (1.2% of women who received a 12-month supply and 3.3% of women who received a 3-month supply) (Foster et al., 2011). There was an associated 30% decrease in the odds of having an unintended pregnancy, as well as a 46% decrease in the odds of an abortion when dispensing a 12-month supply compared to dispensing 1- or 3-month supplies (Foster et al., 2011).

Long-Term Impacts

Unintended Pregnancy and Abortion

The reductions in unintended pregnancies and resulting abortions estimated in year one postmandate are likely to persist over time. CHBRP estimates that passage of SB 999 may result in a decrease in the rate of unintended pregnancies and abortion in the long term, and thus substantial long-term cost reductions.

Maternal Mortality and Child Health Outcomes

In the long term, assuming that SB 999 increases utilization of a 12-month supply of self-administered hormonal contraceptives beyond the first year postmandate, there may be a decrease in the rate of unintended pregnancies, thereby decreasing the risk of maternal mortality. A decrease in the rate of unintended pregnancies would also decrease the risk of poor child health outcomes for children born from unintended pregnancies.

CONTEXT FOR BILL CONSIDERATION

Essential Health Benefits and the Affordable Care Act

SB 999's requirements regarding a 12-month supply of FDA-approved, self-administered hormonal contraceptives would not alter the benefit coverage requirements, only the permitted supply dispensed at one time. Therefore, SB 999 does not exceed EHBs, and would not trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in qualified health plans (QHPs) in Covered California.

A Report to the California State Legislature

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March 28, 2016

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REVISION HISTORY

Date	Description of Revisions
May 3, 2016	Table D-2 on page D-4, Appendix DIn Table D-2 (Outpatient Prescription Drug Coverage in the Large Group and PubliclyFunded Markets, 2017), CHBRP corrected two mislabeled rows. In the original report, therows for "No OPD Coverage" and "Other OPD Coverage" were mislabeled. The error iscorrected in this revised version.

ABOUT CHBRP

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



An analytic staff in the University of California's Office of the President supports a task force of faculty and research staff from several campuses of the University of California 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, and 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, as well as all CHBRP reports and publications are available at <u>www.chbrp.org</u>.

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SB 999 IMPACTS ON BENEFIT COVERAGE, UTILIZATION, AND COST

Table 1. SB 999 Impacts on Benefit Coverage, Utilization, and Cost in 2017

	Premandate	Postmandate	Increase/ Decrease	Change Postmandate
Benefit coverage				
Total enrollees with health insurance subject to state benefit mandates (a)	25,155,000	25,155,000	0	0%
Total enrollees with health insurance subject to SB 999	25,155,000	25,155,000	0	0%
Number of enrollees with health insurance fully compliant with SB 999	0	25,155,000	25,155,000	N/A
Percentage of enrollees with health insurance fully compliant with SB 999	0%	100%	100%	N/A
Number of enrollees with health insurance partially compliant with SB 999 ^(f)	6,891,000	0	-6,891,000	-100%
Percentage of enrollees with health insurance partially compliant with SB 999 ^(f)	27%	0%	-27%	-100%
Utilization and cost				
Total enrollees using 1- month supply of self- administered hormonal contraceptives	500,000	185,000	-315,000	-63%
Total enrollees using 3- month supply of self- administered hormonal contraceptives	240,000	275,000	35,000	15%
Total enrollees using 12 month supply of self- administered hormonal contraceptives	5,000	285,000	280,000	5603%
Total enrollees using self- administered hormonal contraceptives	744,000	744,000	0	0%
Count of unintended pregnancies resulting in a delivery	28,000	22,000	-6,000	-23%
Count of unintended pregnancies resulting in a miscarriage	9,000	7,000	-2,000	-23%
Count of unintended pregnancies resulting in an abortion	30,000	23,000	-7,000	-23%
Average cost per script (1-month supply)	\$62	\$62	\$0	0%

Average cost per script (3-month supply)	\$167	\$167	\$0	0%
Average cost per script (12-month supply)	\$749	\$749	\$0	0%
Average cost per office visit	\$101	\$101	\$0	0%
Average cost of delivery	\$15,364	\$15,364	\$0	0%
Average cost of miscarriage	\$4,249	\$4,249	\$0	0%
Average cost of abortion	\$2,357	\$2,357	\$0	0%
Expenditures				
Premium expenditures by p	<u>bayer</u>			
Private employers for group insurance	\$64,837,024,000	\$64,824,501,000	-\$12,5230,000	-0.02%
CalPERS HMO employer expenditures ^(d)	\$4,756,143,000	\$4,754,013,000	-\$2,130,000	-0.04%
Medi-Cal Managed Care Plan expenditures ^(e)	\$16,670,700,000	\$16,670,700,000	\$0	0.00%
Enrollees for individually purchased insurance	\$22,073,116,000	\$22,067,889,000	-\$5,227,000	-0.02%
Individually purchased – outside Exchange	\$10,875,864,000	\$10,873,498,000	-\$2,366,000	0.02%
Individually purchased – Covered California	\$11,197,252,000	\$11,194,391,000	-\$2,861,000	-0.03%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care ^{(a) (c)}	\$20,496,488,000	\$20,492,304,000	-\$4,184,000	-0.02%
Enrollee expenses				
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$16,248,327,000	\$16,229,592,000	-\$18,735,000	-0.12%
Enrollee expenses for noncovered benefits ^(e)	\$0	\$0	\$0	0.00%
Total expenditures	\$145,081,798,000	\$145,038,999,000	-\$42,799,000	-0.03%

Source: California Health Benefits Review Program, 2016.

Notes: (a) This population includes persons with privately funded (including Covered California) and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans) health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employer-sponsored health insurance.

(b) Enrollees with current coverage compliant with SB 999 are limited to Medi-Cal enrollees.

(c) Of the increase in CalPERS employer expenditures, about 56.7% or -\$919,000, would be state expenditures for CalPERS members who are state employees, state retirees, or their dependents. This percentage reflects the share of enrollees in CalPERS HMOs as of September 30, 2015. CHBRP assumes the same ratio in 2017.

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

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.
 (f) Health insurance that has no OPD benefit or has an OPD benefit not regulated by DMHC or CDI is considered compliant (see Appendix D).

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

POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)¹ conduct an evidence-based assessment of the medical, financial, and public health impacts of SB 999, Health insurance: contraceptives annual supply.

If enacted, SB 999 would affect the health insurance of approximately 25.2 million enrollees (65.2% of all Californians). This represents 100% of the 25.2 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law — health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would affect the health insurance of enrollees in DMHC-regulated plans, CDI-regulated policies, Medi-Cal enrollees in DMHC-regulated plans, and CalPERS.

Bill-Specific Analysis of SB 999, Health Insurance: Contraceptives: Annual Supply

Bill Language

SB 999 would require DMHC-regulated plans or CDI-regulated policies issued, amended, renewed, or delivered on or after January 1, 2017, to cover a 12-month supply of Food and Drug Administration (FDA) approved, self-administered hormonal contraceptives dispensed at one time to an enrollee, either as prescribed or at the enrollee's request. Unless a prescribing provider indicates "no change to quantity," an enrollee may request up to a 12-month supply of FDA-approved, self-administered hormonal contraceptives. SB 999 preserves existing language in state law that exempts certain religious employers from providing this coverage to their employees. The full text of SB 999 can be found in Appendix A.

Analytic Approach and Key Assumptions

SB 999 applies specifically to FDA-approved, self-administered hormonal contraceptives, which include oral contraceptives (also called the "pill"), the contraceptive ring, and the patch. Emergency contraceptives were not included in this analysis as self-administered hormonal contraceptives because they are classified by the FDA in a separate contraceptive category from hormonal contraceptives.² CHBRP examined contraceptive use for women aged 15 to 44 as this is the age range for "childbearing age" that is commonly used by the Centers for Disease Control and Prevention (Jones et al., 2012).

It is important to note the distinction between a prescription and a dispensed refill for self-administered hormonal contraceptives. One prescription may authorize several dispensed refills. For example, a prescription valid for one year may be used to dispense four 3-month supplies throughout the year or one 12-month supply at one time. Prescriptions for self-administered hormonal contraceptives are typically valid for one year.

For a full set of assumptions related to the cost and use estimates, please see Appendix C.

¹ CHBRP's authorizing statute is available at <u>www.chbrp.org/docs/authorizing_statute.pdf</u>.

² Categories are defined as permanent sterilization, long-acting reversible contraceptives, short-acting hormonal methods, barrier methods, and emergency contraception at http://www.fdo.gov/EcrCoppumper/Pu/udiopeg/EcrCop

Interaction with Existing Requirements

SB 999 may interact and align with the following state and federal mandates or provisions.

California law and regulations

In 2014, California passed the Contraceptive Coverage Equity Act (SB 1053), which amended California's existing coverage law.³ Current state law requires all DMHC-regulated plans and CDI-regulated policies to provide coverage for at least one form of contraception from each of the 18 FDA-approved contraception types (i.e., contraceptive drugs, devices, products, and voluntary sterilization), as well as contraceptive education and counseling. Plans and policies are required to cover at least one therapeutic equivalent of a prescribed contraceptive drug, device, or product. State law prohibits cost sharing for the aforementioned services in nongrandfathered⁴ group and individual health plans and policies.

SB 999 would not alter cost sharing for self-administered hormonal contraceptives, but would change the amount a pharmacist could dispense at one time (up to a 12-month supply at once), either as prescribed or at the enrollee's request.

Medi-Cal enrollees are eligible to receive up to a 12-month supply of oral contraceptives pills, but not the ring or patch.⁵ On February 5, 2016, the Department of Health Care Services released an All Plan Letter (APL) stating that Medi-Cal managed care plans "must pay for up to a 12-month supply of oral contraceptives, if such quantity is dispensed in an onsite clinic and billed by a qualified family planning provider, including out-of-plan providers."⁶ It appears that the letter was released to clarify the policy and coverage requirements.

California's Family Planning, Access, Care and Treatment (Family PACT) Program

The Office of Family Planning in the Department of Health Care Services administers the Family Planning, Access, Care and Treatment (Family PACT) program. Family PACT intends to provide comprehensive family planning services to California women and men with eligible income (under 200% of the federal poverty level) who have no other source of family planning services. Family PACT provides services at no cost to over 1.8 million people each year; 63% of whom are Latino, 86% of whom are women or teenaged girls, and 37% of whom accessed services in Los Angeles (Baker et al., 2013).

Family PACT allows eligible public and nonprofit clinics to dispense up to 13 "cycles" of oral contraceptive pills (Foster et al., 2006b). Only clinics with the ability to dispense drugs on site are permitted to dispense a 12-month supply of contraceptives.⁷

Similar requirements in other states

Currently, only Oregon and the District of Columbia have laws in effect that are similar to SB 999. In 2015, Oregon became the first state in the country to require that private insurers cover a 12-month

³ H&SC Section 1367.25 and IC Sections 10123.196, as enacted by AB 39 (1999).

⁴ A grandfathered health plan is defined as: "A group health plan that was created — or an individual health insurance policy that was purchased — on or before March 23, 2010. Grandfathered plans are exempted from many changes required under the Affordable Care Act. Plans or policies may lose their 'grandfathered' status if they make certain significant changes that reduce benefits or increase costs to consumers." More information on this definition can be found here: www.healthcare.gov/glossary/grandfathered-health-plan/.

⁵ Medi-Cal Provider Manual: Part 2, Obstetrics (OB): Family Planning.

⁶ California All Plan Letter 16-003 (2016).

⁷ Personal communication, DG Foster, University of California San Francisco, February 2016.

supply of contraceptives, including oral contraceptives, the patch, and the ring dispensed at one time.⁸ Following Oregon, the District of Columbia passed similar legislation.⁹ At the time of publication of this report, several other states have considered such legislation, including Alaska,¹⁰ New York,¹¹ Rhode Island,¹² Washington,¹³ and Wisconsin.¹⁴

Additionally, some state Medicaid programs and state family planning programs for low-income residents already require a 12-month supply of contraceptives to be dispensed at one time, including the Oregon Contraceptive Care (CCare) program.

Federal requirements

There are no federal requirements that CHBRP is aware of. There is some Congressional interest in providing an annual supply of contraceptives. In July 2015, 55 members of Congress co-signed a letter urging the Department of Health and Human Services to require health insurers to provide access to a 1year supply of birth control at a time without out-of-pocket costs.¹⁵

Affordable Care Act

Under the Affordable Care Act (ACA), California expanded the Medi-Cal program (Medicaid in California)¹⁶ and provided subsidized and nonsubsidized health insurance available through Covered California, the state's health insurance marketplace.¹⁷

A number of ACA provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how SB 999 may interact with requirements of the ACA, specifically the requirement for certain health insurance to cover essential health benefits (EHBs).¹⁸

Essential Health Benefits

State health insurance marketplaces, such as Covered California, are responsible for certifying and selling qualified health plans (QHPs) in the small-group and individual markets. Health insurance offered in Covered California is required to at least meet the minimum standard of benefits as defined by the ACA as essential health benefits (EHBs), and available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.^{19,20}

¹⁵ Members of U.S. Congress. (2015, July 2). [Letter to Sylvia Burwell]. Available at:

http://speier.house.gov/images/pdf/7-2-15 Congressional Letter to HHS re 12 mobc dispensing.compressed.pdf. ¹⁶ The Medi-Cal expansion is to 133% of the federal poverty level (FPL): 138% with a 5% income disregard.

¹⁷ The ACA requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces.

¹⁸ The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California - to cover 10 specified categories of EHBs. Resources on EHBs and other ACA impacts are available on the CHBRP website: http://www.chbrp.org/other publications/index.php.

¹⁹ The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options. CCIIO, Essential Health Benefits Bulletin. Available at: cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf. ²⁰ H&SC § 1367.005; IC § 10112.27.

⁸ Or. Rev. Stat. § 743A.066.

⁹ D.C. Act 21-91.

¹⁰ SB 156, 29th Leg (Alaska 2016).

¹¹ A.8135-B/S.6013-B, 2015 Reg Sess (N.Y. 2015)

¹² H5706, 2015 Reg Sess (R.I. 2015).

¹³ HB 2465, 2015-16 Reg Sess (Wash. 2016).

¹⁴ AB 932, 2015-16 Reg Sess (Wis. 2016).

States may require such QHPs to offer benefits that exceed EHBs.²¹ However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the QHP.^{22,23} On the other hand, "state rules related to provider types, cost-sharing, or reimbursement methods" would *not meet* the definition of state benefit mandates that could exceed EHBs.²⁴

SB 999 and EHBs

SB 999's requirements regarding 12-month supply of FDA-approved, self-administered hormonal contraceptives would not alter the benefit coverage requirements; only the permitted supply dispensed at one time. Therefore, SB 999 does not exceed EHBs, and therefore would not trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in qualified health plans (QHPs)²⁵ in Covered California.

²¹ ACA § 1311(d)(3).

²² State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

²³ 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 a 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.

²⁴ 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.

²⁵ In California, QHPs are nongrandfathered small-group and individual market DMHC-regulated plans and CDIregulated policies sold in Covered California, the state's health insurance marketplace.

BACKGROUND ON CONTRACEPTION

The National Survey of Family Growth (NSFG) estimates that in 2011-2013, 99% of sexually experienced women in the United States aged 15 to 44 years have ever used some form of contraception (Daniels and Mosher, 2013), and about 62% of these women are currently using some form of contraception (Daniels et al., 2015). Although the FDA categorizes contraceptives into five methods — permanent sterilization, long-acting reversible contraceptives (LARC), short-acting hormonal methods, barrier methods, and emergency contraception — SB 999 only impacts *self-administered hormonal contraceptives*, which includes oral contraceptives and the contraceptive ring or patch. Of the current users surveyed in the 2011-2013 NSFG, 28.5% are using some administered, hormonal contraceptives: 25.9% use oral contraceptives and 2.6% use the ring or patch (Daniels et al., 2015).

Contraception and the Risk of Unintended Pregnancy

Some sexually active women aged 15 to 44 years may be at risk of an unintended pregnancy, but consistent use of effective contraception greatly reduces the risk of unintended pregnancy. In the United States, 68% of women at risk of an unintended pregnancy use contraception correctly and consistently throughout any given year and account for only 5% of unintended pregnancies. In comparison, 18% of women at risk use contraception inconsistently or incorrectly throughout any given year and 14% do not use any contraception for one month or longer during the year; these women account for 41% and 54% of all unintended pregnancies (see Figure 2) (Guttmacher Institute, 2015).



Figure 2. Relationship between Contraceptive Use and Risk of Unintended Pregnancy

Source: Guttmacher Institute, 2015

Notes: (a) "Consistent use" refers to women without any gaps in use, who used their method consistently and correctly during all months when they were sexually active, including those who used a long-acting or permanent method.

(b) "Inconsistent use" refers to women who used a method in all months that they were sexally active, but missed taking some pills, or skipped use or incorrectly used their barrier method or condom during some acts of intercourse.(c) "Nonuse" refers to women who were sexually active, but did not use any method of contraception. "Long gaps in use" refers to women who did use a contraceptive during the year, but had gaps in use of one month or longer when they were sexually active.

Based on 2014 CHIS data, there are 5,860,000 women aged 15 to 44 who were sexually active in the past year (defined as one or more sexual partners). In California, nearly half (48%) of the over 818,700 pregnancies per year are unintended (393,000) (Kost, 2015). Assuming national contraception utilization rates are similar to those in California, the 18% of women using contraception inconsistently or incorrectly throughout any given year (approximately 1.05 million women) would potentially benefit from SB 999 by eliminating some barriers (adherence, consistent use) to effective contraception use.

For additional information about contraception, please refer to CHBRP's 2014 analysis of SB 1053 (Mitchell), which was signed by Governor Brown on September 25, 2014.²⁶ SB 1053 mandated that health plans and insurers cover FDA-approved contraceptive drugs, devices, products, and voluntary sterilization procedures in each contraceptive category outlined by the FDA, as well as contraceptive education and counseling (CHBRP, 2014).

Patterns of Contraceptive Use

As displayed in Table 2, across the United States, the utilization of self-administered hormonal contraceptives varies by several demographic categories, including age and race/ethnicity. Younger women (aged 15 to 24 years) are more likely to use a self-administered hormonal contraceptive (contraceptive pill, patch, or ring) than older women, whereas older women are more likely to choose a long-acting reversible method of contraception (e.g., IUD, implant) or sterilization (data not shown) (Daniels et al., 2015). While non-Hispanic black women have lower utilization of self-administered hormonal contraceptives compared to other races/ethnicities, overall they have the highest utilization of the contraceptive ring or patch. Self-administered hormonal contraceptive use increases with both education and income level.

As seen in Table 2, compared to women without a high school diploma (or GED), women with a bachelor's degree or higher are more likely to use the contraceptive pill, ring, or patch (5.4% vs. 34.9%, respectively). Similarly, women whose income is at or above 300% of the federal poverty level (FPL) are more likely to use these contraceptive methods compared to women whose income is 149% of the FPL or less (33.8% vs. 17.3%, respectively) (Table 2). Based on estimates from the 2008 California Women's Health Survey, the proportion of women above 200% FPL using self-administered hormonal contraceptives was higher than the proportion of women at or below 200% FPL (15.5% vs. 8.7%) (Chabot et al., 2012).

Social Determinants of Health and Disparities in Contraceptive Use and Unintended Pregnancies

Per statute, CHBRP now includes discussion of disparities under the broader umbrella of social determinants of health (SDoH).²⁷ SDoH includes factors outside of the traditional medical care system that influence health status and health outcomes. CHBRP will consider the full range of SDoH and related

²⁷ CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from Healthy People 2020, 2015; APHA, 2014). For more information about SDoH, see CHBRP's publication: *Incorporating Relevant Social Determinants of Health into CHBRP Benefit Mandate Analyses*, available at:

²⁶ CHBRP's 2014 analysis of SB 1053: <u>http://chbrp.ucop.edu/index.php?action=read&bill_id=155&doc_type=3</u>

http://www.chbrp.org/analysis_methodology/docs/Incorporating%20Relevant%20Social%20%20Determinants%20of %20Health%20in%20CHBRP%20Analyses%20Final%2003252016.pdf.

disparities²⁸ (e.g., income, education, or social construct around age, race/ethnicity, gender, and gender identity/sexual orientation) that are relevant to the bill and where evidence is available. In the case of SB 999, evidence shows that unintended pregnancies occur disproportionately among younger women, Hispanics, and non-Hispanic blacks, and that educational attainment and income are correlated with higher rates of unintended pregnancy. With the exception of younger women, all of these groups of women have lower utilization of self-administered hormonal contraceptives.

As seen in Table 2, unintended pregnancy rates are highest among women aged 15 to 24 years (61 per 1,000 women) and Hispanic or non-Hispanic black women (58 and 79 per 1,000 women, respectively). The rate of unintended pregnancy is inversely related to income. Poorer women (with incomes at or below 149% of the FPL) have significantly higher rates of unintended pregnancies compared to women between 150 and 200% FPL or at or above 300% FPL. Women who did not graduate high school or obtain their GED have much higher unintended pregnancy rates than women who graduated college.

Table 2. Percent Distribution of Self-Administered Hormonal Contraception Use and UnintendedPregnancy Rates Among Sexually Active Female Contraceptive Users Aged 15 to 44 Years, by Age,Race/Ethnicity, Education, and Income — United States, 2011-2013

Contraception Utilization								
Demographic Characteristic	Any self- administered hormonal contraceptive ^a (%)	Oral contraceptivesª (%)	Contraceptive ring or patch ^a (%)	Overall Unintended Pregnancy Rate, per 1,000 women per year				
All Women	28.5	25.9	2.6	45				
Age Group								
15-24	51.5	47.3	4.2	61				
25-34	28.1	25.0	3.1	54				
35-44	13.4	12.4	1.0	16				
Race/Ethnicity								
Hispanic	21.1	19.0	2.1	58				
White non- Hispanic	31.4	29.0	2.4	33				
Black non- Hispanic	20.1	17.0	3.1	79				

²⁸ Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: "Health disparities are potentially avoidable differences in health (or health risks that policy can influence) between groups of people who are more or less advantaged socially; these differences systematically place socially disadvantaged groups" at risk for worse health outcomes (Braveman, 2006)

Table 2. Percent Distribution of Self-Administered Hormonal Contraception Use and UnintendedPregnancy Rates Among Sexually Active Female Contraceptive Users Aged 15 to 44 Years, by Age,Race/Ethnicity, Education, and Income — United States, 2011-2013 (Cont'd)

Contraception Utilization								
Demographic Characteristic	Any self- administered hormonal contraceptive ^a (%)	Oral contraceptivesª (%)	Contraceptive ring or patch ^a (%)	Overall Unintended Pregnancy Rate, per 1,000 women per year				
Educational Attain	ment ^d							
No HS diploma or GED	5.4	5.4	*	73				
HS diploma or GED	14.9	12.7	2.2	59				
Some college, no bachelor's degree	26.1	22.7	3.4	46				
Bachelor's degree or higher	34.9	31.9	3.0	25				
Income Level ^d								
0-149% FPL	17.3	14.1	3.2	137				
150-299% FPL	25.7	23.0	2.7	85				
300% FPL or more	33.8	31.7	2.1	26				

Source: (Daniels et al., 2015; Finer and Zolna, 2014; Finer and Zolna, 2016)

Notes: (a) Utilization estimates were taken from Daniels et al., 2015

(b) Unintended pregnancy rates were taken from Finer and Zolna, 2016, with the exception of rates by income level, which was taken from Finer and Zolna, 2014.

(c) This is the unintended pregnancy rate among the overall study population. Published data that for selfadministered hormonal contraceptives only and by sub-group (pill, ring, patch) was not available.

(d) Restricted to women aged 20 to 44 years.

*Does not meet the authors' (Daniels et al.) standards of reliability or precision.

Key: FPL=federal poverty line; GED=General Educational Development test; HS=high school

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context*, SB 999 would mandate coverage of a 12-month supply of FDAapproved self-administered hormonal contraceptives dispensed at one time. The medical effectiveness review summarizes findings from the literature on the effectiveness of self-administered hormonal contraceptives in general as well as literature on the impact of dispensing oral contraceptives in quantities in excess of 90 days and up to 1 year. The FDA-approved self-administered hormonal contraceptives include oral contraceptives (pill, mini-pill, and extended/continuous use pill), contraceptive patch (Ortho Evra®), and vaginal contraceptive ring (NuvaRing®).²⁹ Although emergency contraceptives are also FDA-approved for use as a hormonal contraception, they are classified as a separate category of contraceptives by the FDA and are not recommended as a regular form of contraception. Therefore, they are not included in this analysis or literature review.

Research Approach and Methods

Studies of self-administered hormonal contraceptive effectiveness were identified through searches of relevant databases of peer-reviewed literature listed in Appendix B. The search was limited to abstracts of studies published in English. Due to the existence of a high-quality systematic review conducted in 2012 on the impact of dispensing quantity of oral contraceptives on health outcomes, the medical effectiveness search was limited to studies published from 2012 to the present. The cost and public health searches encompassed studies from 2006 to 2016. For medical efficacy of individual types of contraception, CHBRP relied on a systematic review and meta-analysis published in 2011 (Trussell, 2011). This approach is consistent with the approach CHBRP has taken in its analyses of previous topics with many different mandated benefits. Of the 141 articles identified in the literature review, 34 were reviewed for potential inclusion in this report on SB 999, and a total of 8 studies were included in the medical effectiveness review for this report. Only articles that directly addressed one of the four research questions below were included in this report. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B: Literature Review Methods.

This literature review will address the following hypothesized linkages as described in Figure 3:

- 1. Evidence on the impact of policies allowing for dispensing of a 12-month supply of contraceptives on dispensing patterns.
- 2. Impact of dispensing patterns on adherence to contraceptive regimens and pill wastage.
- 3. Impact of adherence to oral contraceptive regimens on unintended pregnancy rates.
- 4. Impact of unintended pregnancy on outcomes such as abortion rate, birth outcomes, infant morbidity and mortality, and child health status.

²⁹ The list of FDA-approved contraceptives can be found here (updated 12/02/2015): <u>http://www.fda.gov/ForConsumers/ByAudience/ForWomen/FreePublications/ucm313215.htm</u>

Figure 3. Hypothesized Linkages Between SB 999 and Improvement in Unintended Pregnancy Rates and Related Outcomes



Outcomes Assessed

In alignment with the hypothesized linkages above, this analysis looked at the following outcome measures: utilization of self-administered contraception, gap in oral contraceptive use, quantity of cycles dispensed, pill wastage, unintended pregnancy, abortion, use of prenatal care, breastfeeding, measures of infant wellness, and measures of maternal wellness.

Study Findings

Impact of Policies Allowing for Dispensing of a 12-Month Supply of Contraceptives on Dispensing Patterns

No literature was identified that reviewed the impact of policies allowing for a 12-month supply of contraceptives on dispensing patterns. One study conducted in California found that among a group of 28,000 women receiving oral contraceptives from clinics that can dispense a 12-month supply at no cost to the patient, 11% were dispensed pills in a 1-month supply, 27% were dispensed in a 3-month supply, 7% were dispensed in a 6-month supply, 4% were dispensed in a 10-month supply, 34% were dispensed in a 12-month supply, and 17% were dispensed in other quantities (Foster et al., 2011). As there was only one study identified that looked at this topic, CHBRP concludes that there is insufficient evidence to determine the impact of policies allowing for dispensing of 12-month supply of self-administered oral contraceptives on dispensing patterns.

Impact of dispensing Patterns on Adherence to Oral Contraceptive Regimens and Other Outcomes

The literature review did not find any articles that looked at the impact of quantity dispensed of the contraceptive patch or vaginal ring and related health outcomes. Therefore, the literature discussed in this section reports on the impact of quantity dispensed on oral contraceptives only. A systematic review conducted in 2012 identified four articles that addressed the number of oral contraceptive pill packs dispensed at a time and the resulting health outcomes. One of these studies was conducted in Jamaica looking at dispensing patterns of four cycles or less, and was therefore not included in the results below. It is important to note that the greatest risk of unintended pregnancy among self-administered hormonal contraceptive users occurs when the 7-day hormone-free interval is extended (Guilbert et al., 2008). Therefore, women who run out of pills and extend their hormone-free interval are at greater risk of unintended pregnancy compared to women who miss a pill in the middle of the cycle.

Outcome	Frequency of Continuous Pill usage	Frequency of Pregnancy Tests	Pregnancy Rate	Frequency of Pill Wastage	Abortions
Foster et al., 2006b	43% (13 cycles); 22% (3 cycles); 20% (1 cycle)	25% (13 cycles); 46% (3 cycles); 45% (1 cycle)		6.5% (13 cycles); 2.0% (3 cycles); 2.4% (1 cycle)	
Foster et al., 2011	40% (13 cycles); 25% (3 cycles); 21% (1 cycle)		 1.2% (13 cycles); 3.3% (3 cycles); 2.9% (1 cycle) 30% reduction in the odds of unintended pregnancy (12 cycles vs. 1 or 3) 		46% reduction in odds of an abortion when dispensing a 1-year supply
White and Westhoff, 2011	51% (7 cycles); 35% (3 clcyes)		9,0%(7 cycles); 9.9% (3 cycles)	1.88 packs/person unused (7 cycles) 0.49 packs/person unused (3 cycles)	

 Table 3. Outcomes Associated with Number of Oral Contraceptives Distributed at One Time

Sources: Foster et al., 2006b; Foster et al., 2011; White and Westhoff, 2011.

Studies comparing 12 months of dispensed oral contraceptives to shorter-term dispensing

Two studies were conducted examining data on women receiving oral contraceptive pills through the California Family PACT (Planning, Access, Care and Treatment) Program to compare pregnancy rates between women given a 12-month supply to those given a 1- or 3-month supply (Foster et al., 2011; Foster et al., 2006b). Pregnancy rates and dispensed quantity of oral contraceptives were connected by contraceptive dispensing claims in Family PACT and pregnancy events in Medi-Cal. The results indicated that women who were given a 12-month supply had a reduced risk of unintended pregnancy (1.2% of women who received a 12-month supply and 3.3% of women who received a 3-month supply) (Foster et al., 2011). There was an associated 30% decrease in the odds of having an unintended pregnancy, as well as a 46% decrease in the odds of an abortion when dispensing a 12-month supply compared to dispensing 1- or 3-month supplies (Foster et al., 2011). In addition, one study found increased expenditures for women receiving the 3-month and 1-month cycle compared to women who received 13 cycles at the initial visit (\$99 more for the 3 cycles and \$44 more for women who received only 1 cycle) (Foster et al., 2006b). These expenditures included pregnancy tests and clinician encounters. Women given the 12-month supply were also more likely to have received Pap and Chlamydia tests and less likely than women given the 1-month and 3-month supply to have taken a pregnancy test (Foster et al., 2006b). It is important to note that the Family PACT population used in the Foster et al. (2006b and 2011) analyses may not match that of the full insured population subject to SB 999 in terms of demographics and access to contraception.

Studies comparing dispensed quantities fewer than 12 months

White and Westhoff (2011) used a randomized trial with female participants starting oral contraceptive pills (OCP) at an urban family planning clinic. A significant proportion of the study population was Hispanic, urban, and poor. Participants were randomized to receive 3 or 7 cycles (except participants younger than 18 or uninsured who received their entire supply at initial visit), with the main outcome measure being 6-month OCP continuation within each group. The results of the trial showed that women who were given 7 cycles had higher 6-month continuation rates (51% compared to 35%). Women given 7 cycles were provided less medical surveillance, without experiencing increased adverse health events (White and Westhoff, 2011). In addition, the pill wastage was higher in the 7-cycle group compared to the 3-cycle group (1.88 vs. 0.49 unused pill packs per person).

Figure 4. Summary of Findings related to the effect of dispensing patterns of oral contraceptives on adherence and pregnancy outcomes

Treatment				Conclusion				
Evidence on the effect of dispensing patterns of oral contraceptives on adherence and pregnancy outcomes.			ng es.	There is a preponderance of evidence from studies with moderate research designs that conclude that dispensing oral contraceptives in larger quantities leads to a reduction in unintended pregnancy and related outcomes.				
Not Effective						•		Effective
Clear and Convincing	High Prepor	Moderate derance of Evic	Low dence	Ambiguous	Low Prepor	Moderate derance of Evi	High idence	Clear and Convincing

Source: California Health Benefits Review Program.

Impact of Adherence to Oral Contraceptive Regimens on Unintended Pregnancy Rates

A systematic review found nine studies that examined pregnancy rates among women of reproductive age neither breastfeeding (given the reduced chance of becoming pregnant) 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 is close to 45% (Finer and Zolna, 2016). 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 for self-administered hormonal contraceptives are 0.3% for perfect use and 9% for typical use (see Table 4), it is reasonable to conclude that using any of the contraceptives listed below is more effective than not using any contraception in preventing unintended pregnancies. "Typical Use" provides rates adjusted for such factors as non-adherence, improper dosage,

not following device or medication instructions properly, improper implantation or administration, and sporadic or non-usage during all cases of intercourse. "Perfect Use" assumes a failure only due to the device or medication itself and not failure to use as prescribed. As shown in Table 4, the most heavily utilized self-administered hormonal contraceptive was oral contraceptives, followed by the patch, and then the vaginal ring.

Table 4. FDA Approval Date, Utilization, and Percentage of Women Experiencing an Unintended

 Pregnancy During the First Year of Use of Contraception, United States

Contraceptive Method	% of women 15- 44 who have ever used contraceptives (2006-2010) ^(a)	% of women with unintended pregnancy Typical Use	% of women with unintended pregnancy Perfect Use
Hormonal methods			
Oral contraceptives	81.9%	9%	0.3%
Contraceptive patch	10.4%	9%	0.3%
Vaginal contraceptive ring	6.3%	9%	0.3%

Source: Utilization rates were taken from Daniels et al., 2013. Medical effectiveness was taken from Trussell, 2011.

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

Effectiveness of self-administered hormonal contraceptives

Hormonal methods prevent pregnancy by interfering with ovulation and possible fertilization of the egg. The FDA-approved contraceptives in this method category are oral contraceptives (the pill, mini-pill, and extended/continuous use pill), contraceptive patches, and the vaginal contraceptive ring.

Oral contraceptives

Oral contraceptives include the pill, mini-pill, and extended/continuous use pill. The pill and the extended/continuous use pill are known as "combined pills" and both contain the hormones estrogen and progestin, which stop the ovaries from releasing eggs. They also thicken the cervical mucus, which keeps sperm from getting to the egg.

The mini-pill is also known as the progestin-only pill, and uses a single hormone, progestin. Progestin keeps the sperm from getting to the egg as the main prevention effect, and exhibits a secondary and less frequent effect of stopping the ovaries from releasing eggs.

All pill types require a prescription that specifies the daily ingestion of a pill at the same time of day every day, whether or not an individual is having sex. Effectiveness of oral contraceptives is compromised if pills are delayed or missed or if there is simultaneous use with some other medications such as certain anti-epilepsy drugs.

As calculated by Trussell (2011), "typical" use of a combined pill or progestin-only pill as contraception resulted in an unintended pregnancy rate of 9%. This is much higher than the rate of unintended

pregnancy for "perfect" use of the combined pill or progestin-only pill (0.3%). Imperfect use is generally due to not faithfully taking the pill every day at the same time.

Contraceptive patch

The contraceptive patch is a prescription-only skin patch that can be worn on the lower abdomen, buttocks, upper arm, or back. It contains two hormones (estrogen and progestin) that stop the ovaries from releasing eggs. It also thickens the cervical mucus, which keeps sperm from getting to the egg. The patch is worn for a three-week period. During the fourth week no patch is worn, thus triggering a menstrual period. As calculated by Trussell (2011), "typical" use of the contraceptive patch as contraception resulted in an unintended pregnancy rate of 9%. This is much higher than the rate of unintended pregnancy for "perfect" use of the contraceptive patch (0.3%). Imperfect use is generally due to nonadherence to the dosing schedule.

Vaginal contraceptive ring

The vaginal contraceptive ring is a flexible ring that is about 2 inches in diameter. It releases two hormones (estrogen and progestin) that stop the ovaries from releasing eggs. It also thickens the cervical mucus, which keeps sperm from getting to the egg. The ring is inserted into the vagina for 3 weeks and then taken out for 1 week. The menstrual period should start during the ring-free week. A prescription is required. As calculated by Trussell (2011), "typical" use of the vaginal contraceptive ring as contraception resulted in an unintended pregnancy rate of 9%. This is much higher than the rate of unintended pregnancy for "perfect" use of the vaginal contraceptive ring (0.3%). Imperfect use is generally due to (a) nonadherence to the dosing schedule, or (b) improper placement or the ring slipping out. If the ring slips out, another form of birth control is recommended until the ring has been in place for 7 consecutive days.

Figure 5. Summary of Findings related to effectiveness of self-administered hormonal contraception

Treatment				Conclusion				
Evidence about effectiveness of self- administered hormonal contraception			There is clear and hormonal contract	l convinci eption is e	ng evidenc effective in	e that s preven	self-administered ting pregnancy.	
Not Effective								Effective
Clear and Convincing	High	Moderate	Low	Ambiguous	Low	Moderate	High	Clear and Convincing

Preponderance of Evidence

Source: California Health Benefits Review Program.

Preponderance of Evidence

Impact of unintended pregnancy on maternal and child health outcomes

Unintended pregnancies are associated with a range of adverse maternal and child health outcomes. A review by Gipson et al. (2008) found that studies consistently show women with unintended pregnancies are more likely to delay prenatal care and have fewer prenatal care visits. Children born from unintended pregnancies are also less likely to be breastfed or are breastfed for a shorter period of time. Multiple studies found behavioral outcomes associated with unintended pregnancies, such as parenting difficulties, physical abuse, and violence (Gipson et al., 2008). Unintended pregnancies also experience negative psychological outcomes more often as studies show they have a significantly higher risk of maternal depression compared to women with intended pregnancies (Gipson et al., 2008). According to the Guttmacher Institute and the United Nations Population Fund, 22 million induced abortions, 1.4 million

infant deaths and 142,000 maternal deaths could all be prevented if the estimated 52 million unintended pregnancies that occur worldwide annually were avoided (Singh et al., 2003).

Figure 6. Summar	y of Findings	related to e	vidence abou	t the im	pact of	unintended	pregnancy
	3-						

Treatment				Conclusion						
Evidence about impact of unintended pregnancy				There is clear and convincing evidence to suggest that unintended pregnancy leads to a decrease in prenatal care and breastfeeding. Studies with weaker research designs suggest that there may also be an impact on maternal depression and childrearing.						
Not Effective								Effective		
Clear and Convincing	High Prepor	Moderate Inderance of Evic	Low lence	Ambiguous	Low Prepon	Moderate Iderance of Evi	High idence	Clear and Convincing		

Source: California Health Benefits Review Program.

Potential Harms Associated with Allowing for Dispensing of a 12-Month Supply of Self-Administered Hormonal Contraceptives

Although some increased health risks have been identified with the use of self-administered hormonal contraceptives, these increased risks occur when comparing women on self-administered hormonal contraceptives to women not using contraceptives.³⁰ There is no evidence to suggest that there would be any difference in health risks for women receiving a 1-month or 3-month supply versus a 12-month supply of self-administered hormonal contraceptives other than the increased risk of unintended pregnancy among the women in the 1-month and 3-month group as described elsewhere in this report. This analysis did not find evidence to indicate any potential health risks or harms of having a larger supply of self-administered hormonal contraceptives available to a patient.

Pill wastage is the main non-health harm associated with SB 999. It is estimated that pill wastage will increase nearly threefold as a result of SB 999. The cost implications of this are discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section.

³⁰ For an in-depth description on benefits and risks of contraceptive use (not limited to self-administered hormonal contraceptives), please see CHBRP report, "Analysis of Senate Bill 1053: Health Care Coverage: Contraceptives."

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

SB 999 would require DMHC-regulated health plans and CDI-regulated policies to cover a 12-month supply of self-administered hormonal contraceptives at one time. Please see the *Background on Contraception* and *Medical Effectiveness* sections for a full description of the contraceptive methods covered in this analysis. Consistent with the research literature and common medical practice, CHBRP examines the impact of SB 999 for women aged 15 to 44 years, as this is the population most likely to take self-administered hormonal contraceptives for the purposes of avoiding unintended pregnancy. While self-administered hormonal contraceptives may be used for purposes other than contraception as might be medically determined, CHBRP estimates are based on these usages in the group aged 15 to 44 years. Additionally, SB 999 does apply to DMHC-regulated plans and CDI-regulated policies that do not have an outpatient drug benefit. However, this is a very small population (less than 2%) in the insured markets. CHBRP assumes that there will be no differential change in utilization among this population compared to enrollees in plans with a prescription drug benefit.

This section reports the potential incremental impact of SB 999 on estimated baseline benefit coverage, utilization, and overall cost. For further details on the underlying data sources and methods, please see Appendix C.

Benefit Coverage

Premandate (Baseline) Benefit Coverage

Currently, 27% of enrollees subject to SB 999 have partially mandate-compliant coverage for selfadministered hormonal contraceptives (see Table 1). This represents the 6.89 million enrollees who have coverage for a 12-month dispensation of self-administered hormonal contraceptives through the Medi-Cal program, as the Medi-Cal managed care plans cover only 12-month supply for the pill, and even this coverage has not yet been fully implemented among all plans. There were no enrollees in private DMHCregulated plans or CDI-regulated policies that had even partially compliant coverage for 12-month supply of self-administered hormonal contraceptives. There are also no enrollees with current coverage that is fully compliant with SB 999.

Current coverage of 12-month cycle supply of self-administered hormonal contraceptives was determined by a survey of the seven largest providers of health insurance in California. Responses to this survey represent:

- 94% of enrollees in the privately funded market subject to state mandates, including
 - o 95% of enrollees in DMHC-regulated plans; and
 - o 86% of enrollees in CDI-regulated policies.

Postmandate Benefit Coverage

Postmandate, 100% of enrollees in DMHC-regulated plans and CDI-regulated policies would have mandate-compliant coverage for receiving up to 12 months of self-administered hormonal contraceptives at one time (see Table 1).

Utilization

Premandate (Baseline) Utilization

CHBRP uses the 2013 and 2014 MarketScan claims data to establish baseline use of self-administered hormonal contraceptives (see Appendix C for full description of methods). CHBRP estimates that 744,000 women aged 15 to 44 (3.2% of all enrollees) currently have active prescriptions for self-administered hormonal contraceptives (see Table 1). Of that group, 500,000 (67%) currently receive their self-administered hormonal contraceptives with a 1-month supply per prescription refill. An additional 240,000 (32%) currently receive their self-administered hormonal contraceptive prescriptions with 3 months supply at a time. Finally, 5,000 (0.6%) enrollees received 12 months of their self-administered hormonal contraceptives at one time.

Currently, the distribution of self-administered hormonal contraceptives in the insured population leads to 67,000 unintended pregnancies (Table 1). Using the latest data available to estimate the results of these unintended pregnancies (Kost, 2015), CHBRP estimates that 28,000 result in live births, 9,000 result in miscarriages, and 30,000 result in abortions.

Postmandate Utilization

Postmandate, CHBRP estimates that the total number of active self-administered hormonal contraceptive prescriptions (customarily prescribed for 12 months, with either monthly or tri-monthly refills) will remain the same as prior to the mandate (744,000). This provides the most conservative estimate of the first year postmandate impact (see the Long-Term Impacts of Contraceptives for a discussion of potential increases in utilization past the first year). CHBRP further assumes that the postmandate self-administered hormonal contraceptive prescriptions would be filled as follows: 15% would receive 1 month at a time, 38% would receive 3 months, and 47% would receive 12 months (see Table 1 and Table 5 for figures and Appendix C for full method). This projection is based on the most recent research available for the distribution of how many cycles of self-administered hormonal contraceptives enrollees choose to receive at clinics when the option of 12-month supply is available (Foster et al., 2011) and additional consultation with the lead author of the study.³¹ This also represents the most conservative estimate of how many enrollees will choose a 12-month supply, as the segments of enrollees who had prescriptions for 2 or 4 to 11 months were proportionally distributed among the 1-, 3- and 12-month populations.

This projected postmandate distribution of the utilization of 12-month supply of self-administered hormonal contraceptives applies to enrollees in privately-funded DMHC-regulated plans and CDI-regulated policies, as well as enrollees in CaIPERS. Enrollees in Medi-CaI managed care programs are not projected to change their utilization of self-administered hormonal contraceptives. The final distribution of utilization rates for the 12-month supply of self-administered hormonal contraceptives (see Table 1) represents a weighted combination of all enrollees.

³¹ E-mail correspondence with Diana Greene Foster, March 3, 2016.

Number of Cycles Dispensed	% of women aged 15-44, Premandate	% of women aged 15-44, Postmandate	Change, in Percentage Points
1 Month (1 cycle)	67%	15%	- 52
3 Months (3 cycles)	32%	38%	6
12 Months (12-13 cycles)	0.6%	47%	46
Total	100%	100%	

Table 5. Distribution of Number of Cycles of Self-Administered Hormonal Contraceptives Dispensed at

 One Time, Pre- and Postmandate Under SB 999

Source: CHBRP Cost and Coverage Model, 2016; Foster et al., 2011.

This increase in covered number of self-administered hormonal contraceptives cycles dispensed at one time will also increase the average number of cycles used per enrollee. Based on a comprehensive study of the implementation of covering a 12-month supply of self-administered hormonal contraceptives in California's Family PACT program (Foster et al., 2006b), CHBRP assumed that enrollees who switch from receiving their self-administered hormonal contraceptives 1 month at a time to 12 months at a time would increase their average number of cycles used from 4 to 12. Similarly, enrollees who switch from receiving their self-administered hormonal contraceptives in a 3-month supply to a 12-month supply would increase their average number of cycles used from 9 to 12 (See Appendix C for a full methods discussion). These rates of pill usage are based on the findings of Foster et al. (2006b) that women receiving 12 months of self-administered hormonal contraceptives used on average 14 cycles for the total length of time that they were using this form of contraception.

Postmandate, the change in the percentage of enrollees receiving larger number of cycles at one time will have an effect on the number of unintended pregnancies (see Table 1). As shown in the *Medical Effectiveness* section, self-administered hormonal contraceptives are highly effective at reducing unintended pregnancies. Applying the 30% reduction in the odds of unintended pregnancy seen in empirical data from Foster et al. (2011), CHBRP estimates that postmandate, there will be a total of 52,000 unintended pregnancies among the 744,000 enrollees who use self-administered hormonal contraceptives. This represents a total reduction in unintended pregnancies of 15,000. That equates to 6,000 fewer live births, 2,000 fewer miscarriages, and 7,000 fewer abortions (Kost, 2015).

Impact on access and health treatment/service availability

CHBRP estimates that there will be an increase in access to self-administered hormonal contraceptives for women who switch to get their prescriptions dispensed as a 12-month supply from lower frequencies, and that the current supply of self-administered hormonal contraceptives will be able to meet this demand. CHBRP also assumes that there will be no change postmandate in the service availability of obtaining self-administered hormonal contraceptives, meaning that there will be no shortage of self-administered hormonal contraceptives caused by SB 999.

Per-Unit Cost

Premandate (Baseline) and Postmandate Per-Unit Cost

Based on MarketScan data, CHBRP estimates that the average per-unit cost of a 1-month supply of selfadministered hormonal contraceptives is \$62, the average cost of a 3-month supply is \$167, and the average cost of a 12-month supply is \$749 (see Table 1). Postmandate, CHBRP estimates that there will be no change in these average per-unit costs.

Premiums and Expenditures

Premandate (Baseline) Premiums and Expenditures

Table 6 presents per member per month (PMPM) premandate estimates for premiums and expenditures by market segment for DMHC-regulated plans and CDI-regulated policies.

PMPM by market segment for DMHC-regulated plans and CDI-regulated policies, respectively, is as follows:

- Large group: \$553.67 and \$662.37.
- Small group: \$470.64 and \$585.28.
- Individual market: \$423.95 and \$365.22.

Total current annual expenditures for all DMHC-regulated plans and CDI-regulated policies is \$145,081,797,000.

Postmandate Expenditures

Changes in total expenditures

SB 999 would decrease total net annual expenditures by \$42,799,000 or 0.03% for enrollees with DMHCregulated plans and CDI-regulated policies (see Table 1). This represents the anticipated savings in 2017 due to the avoidance of unintended pregnancies (leading to reduced delivery, miscarriage, and abortion costs) and the reduced number of office visits in the first year postmandate. The decrease in total expenditures is due to a \$24,063,000 decrease in total health insurance premiums paid by employers and enrollees, along with a decrease in enrollee out-of-pocket expenditures (\$18,735,000), for an overall net decrease of \$42,799,000.

Postmandate premium expenditures and PMPM amounts per category of payer

Decreases in insurance premiums as a result of SB 999 would vary by market segment (see Table 7). Note that the total population in Table 7, reflects the full 25,155,000 enrollees in DMHC-regulated plans and CDI-regulated policies subject to SB 999.

In DMHC-regulated plans, CHBRP estimates that premium changes would range from a decrease of \$0.08 PMPM in the small-group market to a decrease of \$0.11 PMPM in the large-group market for 2017 (see Table 7). In CDI-regulated policies, estimated premium changes range from a decrease of \$0.08

PMPM in the small-group market to a decrease of \$0.13 PMPM in the individual and large-group markets in 2017.

Among publicly funded DMHC-regulated health plans, CHBRP estimates that CalPERS HMO premiums will decrease by \$0.26 PMPM (Table 7). CHBRP estimates that the Medi-Cal managed care plans will not have any cost impacts.

Average enrollee out-of-pocket expenses would decrease for all insured populations, with the exception of Medi-Cal beneficiaries, who would have no change. The decreases range from \$0.15 PMPM in small-group markets (both DMHC-regulated plans and CDI-regulated policies) to \$0.32 PMPM (Table 7) for CalPERS enrollees. These decreases are due to fewer copays associated with fewer visits to the pharmacy or physician for refills, and reduced expenses due to avoidance of unintended pregnancies, which result in fewer delivery, miscarriage, or abortion costs.

Potential cost offsets or savings in the first 12 months after enactment

Research has shown that moving from a 1-month or 3-month supply of self-administered hormonal contraceptives to a 12-month supply dispensed at one time reduces the odds of having an unintended pregnancy by 30% (see *Medical Effectiveness* section; Foster et al., 2006b). As mentioned in the postmandate utilization section above, CHBRP estimates that 15,000 total unintended pregnancies will be averted following the enactment of SB 999 (Table 1). Of these unintended pregnancies, 45% would have resulted in abortions, 42% would have been live births, and 13% would have resulted in fetal loss (Kost, 2015). The average cost of an abortion in the insured population is \$2,357, the average cost of a live birth is \$15,364, and the average cost for an office visit for a miscarriage is \$4,249 for \$122,346,000 in avoided costs. These estimated savings are spread throughout the enrollee population, offsetting the cost increases due to higher number of total months of self-administered hormonal contraceptives supplied with the increased coverage, and the potential wastage due to those increases (see Appendix C for full discussion of how the offsets interact).

Postmandate administrative expenses and other expenses

Generally, CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies will 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.

Related Considerations for Policymakers

Cost of Exceeding Essential Health Benefits

Coverage for a 12-month dispensed supply of self-administered hormonal contraceptives under SB 999 are only requirements on the terms and conditions for existing benefits, and so would not trigger the requirement to cover mandates that exceed EHBs, and the state would not need to defray the costs.

Postmandate Changes in Uninsured and Public Program Enrollment

Changes in the number of uninsured persons³²

CHBRP estimates premium decreases for each market segment. In general, premium increases of less than 1% would not have a measurable impact on the number of persons who are uninsured. CHBRP does not anticipate loss of health insurance, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of health insurance, changes in employer contribution rates, changes in take-up of health insurance by employees, or purchase of individual market policies, due to the small size of the increase in premiums after the mandate.

Changes in public program enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs or on utilization of covered benefits in the publicly funded insurance market.

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

Self-administered hormonal contraceptives have been shown to be highly effective at preventing unintended pregnancy (see *Medical Effectiveness* section). Lacking coverage for receiving a full 12-month supply at one time places a burden on the enrollee in refilling their prescription, which has been shown to both increase the unintended pregnancy rate and the abortion rate (Foster et al., 2006b; Foster et al., 2011). Jick et al. (2009) and Trussell (2011) found that the three self-administered hormonal contraceptive methods (ring, pill, and patch) had equal effectiveness rates of preventing pregnancy. Foster et al. (2006a) also found that Family PACT paid on average \$99 more per enrollee for women who receive a 1-month self-administered hormonal contraceptive supply at a time, and \$44 more per enrollee among those receiving 3-month supplies at time, compared to enrollees who received a full 12-month supply dispensed at one time. It follows that current lack of 12-month supply of self-administered hormonal contraceptives has increased the unintended pregnancy rate as well as the abortion rate among the insured population of California, shifting costs to enrollees for out-of-pocket expenses such as copays and purchase of pregnancy tests, and increasing premiums for maternity benefit costs among enrollees in DMHC-regulated plans and CDI-regulated policies.

³² See also CHBRP's *Criteria and Methods for Estimating the Impact of Mandates on the Number of Uninsured*, available at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php

Table 6. Baseline (Premandate) Per Member Per Month Premiums and Total	al Expenditures by Market Segment, California, 2016
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	DMHC-Regulated						C			
	Private (t	ely Funded P by Market) ^(a)	lans	Pub	licly Funded P	lans	Privat (tely Funded F by Market) ^(a)	Plans	
	Large Group	Small Group	Individual	CalPERS HMOs ^(b)	MCMC (Under 65) ^(c)	MCMC (65+) ^(c)	Large Group	Small Group	Individual	Total
Enrollee counts										
Total enrollees in plans/policies subject to state	0 128 000	2 805 000	2 840 000	861.000	6 221 000	561.000	300.000	721.000	579.000	25 155 000
	9,130,000	2,003,000	3,040,000	001,000	0,331,000	301,000		731,000	579,000	
plans/policies subject to SB 999	9,138,000	2,805,000	3,840,000	861,000	6,331,000	561,000	309,000	731,000	579,000	25,155,000
Premium Costs										
Average portion of premium paid by employer	\$444.39	\$309.74	\$0.00	\$460.33	\$180.00	\$445.00	\$523.71	\$426.22	\$0.00	\$86,263,866,000
Average portion of premium paid by employee	\$109.27	\$160.90	\$423.95	\$115.08	\$0.00	\$0.00	\$138.66	\$159.06	\$365.22	\$42,569,604,000
Total premium	\$553.67	\$470.64	\$423.95	\$575.41	\$180.00	\$445.00	\$662.37	\$585.28	\$365.22	\$128,833,470,000
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$44.43	\$93.55	\$112.36	\$31.43	\$0.00	\$0.00	\$111.69	\$177.13	\$108.98	\$16,248,327,000
Enrollee expenses for benefits not covered ^(e)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
Total expenditures	\$598.10	\$564.19	\$536.30	\$606.84	\$180.00	\$445.00	\$774.06	\$762.41	\$474.20	\$145,081,797,000

Source: California Health Benefits Review Program, 2016

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

(b) As of September 30, 2015, 57%, or 462,580 CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2017.

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

(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CaIPERS HMOs, Medi-CaI 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 currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: 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 7. Postmandate Impacts of the Mandate on Per Member Per Month Premiums and Total	al Expenditures b	y Market Segment,	California, 2017
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	DMHC-Regulated							CDI-Regulated			
	Privately Funded Plans (by Market) ^(a)			Publ	Publicly Funded Plans			Privately Funded Plans (by Market) ^(a)			
	Large Group	Small Group	Individual	CalPERS HMOs ^(b)	MCMC (Under 65) ^(c)	MCMC (65+) ^(c)	Large Group	Small Group	Individual	Total	
Enrollee counts											
Total enrollees in plans/policies subject to state mandates ^(d)	9,138,000	2,805,000	3,840,000	861,000	6,331,000	561,000	309,000	731,000	579,000	25,155,000	
Total enrollees in plans/policies subject to SB 999	9,138,000	2,805,000	3,840,000	861,000	6,331,000	561,000	309,000	731,000	579,000	25,155,000	
Premium Costs					· · · ·						
Average portion of premium paid by employer	-\$0.09	-\$0.05	\$0.00	-\$0.21	\$0.00	\$0.00	-\$0.09	-\$0.06	\$0.00	-\$14,653,000	
Average portion of premium paid by employee	-\$0.02	-\$0.03	-\$0.09	-\$0.05	\$0.00	\$0.00	-\$0.02	-\$0.02	-\$0.13	-\$9,411,000	
Total premium	-\$0.11	-\$0.08	-\$0.09	-\$0.26	\$0.00	\$0.00	-\$0.12	-\$0.08	-\$0.13	-\$24,063,000	
Enrollee expenses											
Enrollee expenses for covered benefits (deductibles, copays, etc.)	-\$0.09	-\$0.07	-\$0.09	-\$0.06	\$0.00	\$0.00	-\$0.07	-\$0.07	-\$0.11	-\$18,735,000	
Enrollee expenses for benefits not covered ^(e)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0	
Total expenditures	-\$0.20	-\$0.15	-\$0.18	-\$0.32	\$0.00	\$0.00	-\$0.19	-\$0.15	-\$0.24	-\$42,799,000	
Postmandate Percent Change											
Insured premiums	-0.0202%	-0.0175%	-0.0222%	-0.0448%	0.0000%	0.0000%	-0.0179%	-0.0140%	-0.0353%	-0.0187%	
Total expenditures	-0.0340%	-0.0270%	-0.0341%	-0.0532%	0.0000%	0.0000%	-0.0239%	-0.0196%	-0.0497%	-0.0295%	

Source: California Health Benefits Review Program, 2016.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, inside and outside the exchange.

(b) As of September 30, 2013, 57.5%, or 462,580 CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2017.

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

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

Key: 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.
PUBLIC HEALTH IMPACTS

The public health impact analysis includes estimates on mandate-relevant health outcomes, potential treatment harms, social determinants of health (including potential disparities), financial burden, premature death, and economic loss in the short and long term. This section estimates the short-term impact³³ of SB 999 on health outcomes (unintended pregnancies, abortions, and prenatal and perinatal outcomes) harms, financial burden, social determinants of health, and disparities. See the *Long-Term Impacts of Contraceptives* section for discussion of the impact of SB 999 on outcomes related to unintended pregnancy beyond the first 12 months of the bill implementation.

As discussed in the *Background on Contraception* section, although approximately two-thirds of sexually active women aged 15 to 44 years in the United States use any type of contraception, they may still be at risk of an unintended pregnancy due to method failure, inconsistent use, or incorrect use. Of all women at risk of an unintended pregnancy, the majority (68%) use contraception consistently and only account for 5% of all unintended pregnancies, whereas 18% of women use contraception inconsistently or incorrectly and 14% do not use contraception at all or with long gaps (one month or longer) in use and account for the remaining 95% of unintended pregnancies (with inconsistent use accounting for 41% and nonuse/long gaps in use accounting for 54%) (Guttmacher Institute, 2015). In California, 42% of unintended pregnancies result in a birth, 45% end in an abortion, and 13% end in fetal loss (Kost, 2015).

As presented in the *Medical Effectiveness* section (page 19), there are three types of FDA-approved selfadministered hormonal contraceptives: oral contraceptives, the contraceptive patch, and the vaginal contraceptive ring. The medical effectiveness review found a preponderance of evidence that providing higher quantities dispensed of oral contraceptives is associated with a reduction in the odds of unintended pregnancy and abortion and increased frequency of continuous pill usage. The medical effectiveness review did not find any literature assessing the impact of quantity dispensed of the contraceptive patch or ring on health outcomes.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section (page 26), CHBRP estimates that 27% of enrollees (6.9 million enrollees) had partially mandate-compliant coverage for a 12-month supply of self-administered hormonal contraceptives premandate, and an estimated 25.2 million enrollees would gain mandate-compliant coverage postmandate. Of the 6.9 million enrollees with premandate coverage, CHBRP estimates that only 5,000 enrollees were using a 12-month supply of self-administered hormonal contraceptives. Postmandate, CHBRP estimates that the number of enrollees using self-administered hormonal contraceptives would remain the same, but that 285,000 enrollees (47%) would shift to using a 12-month supply of self-administered hormonal contraceptives.

Estimated Public Health Outcomes

Impact on Continuous Contraceptive Use

Studies have found that women cite numerous barriers to consistent use of contraceptives, including an inability to refill their hormonal contraceptive prescription in a timely manner. A 2011 nationally representative survey of women at risk of an unintended pregnancy found that 29% of women who ever had a prescription for hormonal contraception had trouble obtaining or refilling their prescription; 18% of women reported running out of their hormonal birth control entirely without being able to obtain a new supply; and 4% cited difficulty accessing a pharmacy, including inconvenient pharmacy hours, as a

³³ CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

specific barrier (Grindlay and Grossman, 2015). Obtaining a 12-month supply reduces the potential for delays in refills between cycles of self-administered hormonal contraception. Consistent, continuous contraceptive use is important because it helps to prevent any extension of the usual hormone-free interval, or the time between the last active pill, ring, or patch of a woman's cycle and the first pill, ring, or patch of the next cycle. A systematic review by Zapata et al. (2013) found that extending the pill-free interval for low- or very-low-dose oral contraceptives beyond the usual 7 days to between 8 and 14 days resulted in increased likelihood of ovulation, hence increasing the possibility of unintended pregnancy (Zapata et al., 2013).

As presented in the *Medical Effectiveness* section, research has found that increasing the number of oral contraceptives dispensed at one time was associated with reduction in interruptions in pill usage. To the extent that SB 999 reduces interruptions in use of self-administered hormonal contraception, it may reduce the likelihood of unintended pregnancies.

Impact on Unintended Pregnancy and Abortion

Based on self-administered hormonal contraceptives effectiveness rates discussed in the *Medical Effectiveness* section and projected increases in utilization discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP is able to estimate the number of unintended pregnancies and abortions averted by the projected increases in self-administered hormonal contraceptive utilization. As presented in *the Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP estimates that among the 744,000 enrollees using self-administered hormonal contraceptives, 280,000 enrollees will shift to using a 12-month prescription postmandate (resulting in 285,000 total enrollees using a 12-month supply). Among the 285,000 enrollees using a 12-month prescription for self-administered hormonal contraceptives, CHBRP estimates that SB 999 will result in 15,000 averted unintended pregnancies (Table 8). Based on estimates by Kost (2015) that 45% of unintended pregnancies in California end in abortion and 13% result in miscarriage, CHBRP estimates that 7,000 abortions and 2,000 miscarriages would be averted due to decreases in unintended pregnancies resulting from SB 999. For detailed methodology, please refer to Appendix C.

	% Womon with	Premandate		Postmandate	
	Unintended Pregnancies	Utilization	Estimated Unintended Pregnancies	Utilization	Estimated Unintended Pregnancies
1 Month self- administered hormonal contraceptives	9% ^(a)	500,000	45,000	185,000	17,000
3 Months self- administered hormonal contraceptives	9% ^(a)	240,000	22,000	275,000	25,000
12 Months self- administered hormonal contraceptives	3.6% ^(b)	5,000	<1,000	285,000	10,000
Total Unintended Pregnancies			67,000		52,000
Averted uninte				15,000	
A				7,000	
Avert				2,000	

Table 8. Estimated Numbers of Unintended Pregnancies, Premandate and Postmandate

Source: Medical effectiveness is based on Trussell, 2011 and Foster, 2011; number of additional users is based on CHBRP 2016 cost model.

(a) Estimated pregnancies occurring using 1-month or 3-month prescriptions of self-administered hormonal contraceptives assumes typical use of these methods (see *Medical Effectiveness* section).

(b) Estimated rate is based on Foster (2011), who found a 30% reduction in the odds of unintended pregnancy when using a 12-month prescription of oral contraceptives.CHBRP assumes this 30% reduction in the odds of an unintended pregnancy would apply to all types of self-administered hormonal contraceptives.

(c) Estimates of averted abortions and fetal loss are based on estimates from Kost (2015).

Health outcomes associated with unintended pregnancy

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 women with intended pregnancies, women 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 birth weight 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 (Cheng et al, 2009; Gipson et al., 2008). 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 women to these inherent

risks more often (compared to intended pregnancies). 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 found 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.

As described in the *Medical Effectiveness* section, there is clear and convincing evidence that selfadministered hormonal contraceptives are effective at reducing the risk of unintended pregnancies and a preponderance of evidence from two California-based studies that dispensing a 12-month supply of selfadministered hormonal contraceptives further reduces the risk of unintended pregnancy. As described in the *Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP projects that SB 999 would increase the utilization of 12-month dispensed prescriptions for self-administered hormonal contraceptives by 280,000 enrollees. As a result of this increase in utilization, it is expected that, in the first year postmandate, there will be a reduction in the number of unintended pregnancies overall (15,000 averted) and those ending in abortion (7,000 averted), as well as a reduction in negative health outcomes associated with unintended pregnancy. Although use of contraception can reduce maternal mortality rates, CHBRP found no evidence specific to the impact on self-administered hormonal contraceptive methods on reducing maternal mortality; thus, the impact of SB 999 on maternal mortality is unknown.

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, self-administered contraceptive use is associated with an increased risk of cardiovascular diease, including myocardial infarction and stroke, and weight gain (Trussel and Guthrie, 2011). However, these health risks exist when comparing women on self-administered hormonal contraceptives to women not on these forms of contraceptives. This increased risk is not expected to occur between women currently on continuous self-administered hormonal contraceptives compared to those with less continuous use of these contraceptives due to differences in the quantities dispensed.

In the case of SB 999, there is evidence to suggest that the use of self-administered hormonal contraceptives could result in harm; however, any harm must be weighed against the health benefits of contraceptive use. CHBRP projects that SB 999 would increase utilization of 12 months of self-administered hormonal contraceptives by 280,000 enrollees (see *Benefit Coverage, Utilization, and Cost Impacts* section). These enrollees may be at higher risk of cardiovascular disease and potential side effects from hormonal contraceptive use such as headaches and weight gain. However, the evidence (as presented in the *Medical Effectiveness* section) shows that the benefits of self-administered hormonal contraceptive use outweigh the harms.

Social Determinants of Health and Disparities

CHBRP defines social determinants of health (SDoH) as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (e.g., economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from Healthy People 2020, 2015; APHA, 2014). These factors generally occur prior to or outside of the health care system and are highly correlated with downstream subsequent impacts of affected individuals, such as avoidable illnesses and premature death. However, the relationship between SDOH and health status/outcomes is complex; periodically, health outcomes can

influence SDoH.³⁴ CHBRP will consider the full range of SDoH (e.g., income, education, or social construct around age, race/ethnicity, gender, and gender identity/sexual orientation) that are relevant to this bill and where evidence is available.

The aforementioned social determinants of health, in conjunction with other factors (e.g., genetics, sex), may contribute to health disparities³⁵ as measured by race/ethnicity, age, and income. Insurance benefit mandates that bring all state-regulated plans and policies to parity may change an existing disparity. CHBRP has access to data about enrollee age and gender, but the lack of data on the racial/ethnic composition and income distribution *within specific insurance markets* prohibits CHBRP from estimating a baseline composition. However, using existing data about two large groups (Medi-Cal and privately funded enrollees,³⁶ we are able to provide qualitative, directional statements about mandate impacts on income disparities (as measured by above and below 138% FPL), and racial/ethnic disparities, in addition to age and gender.

In this section, CHBRP will discuss the social determinants of health and disparities that impact a woman's risk of unintended pregnancy (e.g., socioeconomic status, racial/ethnic, or age disparities) and whether SB 999's mandate of coverage for 12 months of self-administered hormonal contraceptives would mitigate the effects of those social determinants. In the *Long-Term Impacts of Contraceptives* section, CHBRP will discuss the impacts of having an unintended pregnancy on a woman's social determinants of health, including educational attainment and earning potential.

Age

As presented in the *Background on Contraception* section, there are disparities by age in unintended pregnancy rates. Rates of unintended pregnancy are highest among younger women aged 15 to 24 years (108 per 1,000 women), compared to women aged 25 to 34 years (62 per 1,000 women) and women aged 35 to 44 (19 per 1,000 women). Similarly, utilization of self-administered hormonal contraceptives is highest among younger women: 51.5% among women aged 15 to 24 years compared to 13.4% among women aged 35 to 44.

Disparities in the rate of unintended pregnancies exist by age group; furthermore, evidence indicates that the highest utilization of self-administered hormonal contraceptives occurs amongst younger women, who also have the highest unintended pregnancy rate. Therefore, SB 999 will likely reduce unintended pregnancies at a higher rate among younger women, resulting in a possible reduction of this disparity; however, the magnitude is unknown because CHBRP is unable to estimate the differential uptake of self-administered hormonal contraceptives by age group.

³⁴ For more information about SDoH see CHBRP's publication: *Incorporating Relevant Social Determinants of Health into CHBRP Benefit Mandate Analyses,* available at:

http://www.chbrp.org/analysis_methodology/docs/Incorporating%20Relevant%20Social%20%20Determinants%20of %20Health%20in%20CHBRP%20Analyses%20Final%2003252016.pdf.

³⁵ Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: "Health disparities are potentially avoidable differences in health (or health risks that policy can influence) between

groups of people who are more or less advantaged socially; these differences systematically place socially disadvantaged groups" at risk for worse health outcomes (Braveman, 2006).

³⁶ See also CHBRP's Incorporating Relevant Social Determinants of Health Into CHBRP Benefit Mandate Analyses, available at

http://www.chbrp.org/analysis_methodology/docs/Incorporating%20Relevant%20Social%20%20Determinants%20of %20Health%20in%20CHBRP%20Analyses%20Final%2003252016.pdf.

Socioeconomic Status

Evidence presented in the *Background on Contraception* section indicates that factors such as educational attainment and income impact unintended pregnancy rates. Rates of unintended pregnancy are considerably higher among women without a high school diploma and with incomes at or below 149% of the federal poverty line (FPL). These disparities may be driven in part by differences in contraceptive use by socioeconomic status. As noted in the *Background on Contraception* section, women without a high school diploma were less likely to use any self-administered hormonal contraceptives compared to women with at least a Bachelor's degree (5.4% vs. 34.9%), as were women with incomes at or below 149% FPL compared to women at or above 300% FPL (17.3% vs. 33.8%).

Socioeconomic disparities in the rate of unintended pregnancies exist; however, the literature indicates that women with higher incomes and more education are more likely to use the self-administered hormonal contraceptive methods covered by SB 999. Therefore, SB 999 will likely reduce unintended pregnancies at a higher rate among women at a higher socioeconomic status, and the impact of the mandate on women at the highest risk of unintended pregnancy may be lower; however, the magnitude is unknown because CHBRP is unable to estimate the differential uptake of self-administered hormonal contraceptives by socioeconomic status.

Race/Ethnicity

As presented in the *Background on Contraception* section, racial/ethnic disparities exist in unintended pregnancy rates. Rates of unintended pregnancy are among non-Hispanic blacks (92 per 1,000 women) and Hispanics (79 per 1,000 women) are twice that of non-Hispanic whites (38 per 1,000 women). These disparities may be driven in part by differences in contraceptive use by race and ethnicity. As noted in the *Background on Contraception* section, Hispanic and non-Hispanic black women are less likely to use self-administered hormonal contraceptives than non-Hispanic white women (21.1% and 20.1% compared to 31.4%). However, Hispanics and non-Hispanic blacks are more likely than non-Hispanic whites to use other methods of contraception, such as female sterilization (32.9% and 36.8% vs. 21.4%), contraceptive implant (1.9% and 2.1% vs. 0.9%) and the injectable (4.7% and 10.0% vs. 3.1%) (Daniels et al., 2015).

Racial/ethnic disparities in the rate of unintended pregnancies exist; however, the literature indicates that non-Hispanic white women are more likely to use the self-administered hormonal contraceptive methods covered by SB 999. Therefore, SB 999 will likely reduce unintended pregnancies at a higher rate among non-Hispanic white women, and the impact of the mandate on women at the highest risk of unintended pregnancy may be lower; however, the magnitude is unknown because CHBRP is unable to estimate the differential uptake of self-administered hormonal contraceptives by race/ethnicity.

Estimated Impact on Financial Burden

When possible, CHBRP estimates the marginal impact of mandates on financial burden, defined as uncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (e.g., deductibles, copayments, and co-insurance). SB 999 would shift some contraceptive costs from enrollees to health plans and insurers through reduced cost sharing. The *Benefit Coverage, Utilization, and Cost Impacts* section estimates a decrease in enrollee out-of-pocket expenditures for previously covered benefits by \$18.7 million due to shifting some contraceptive costs from enrollees to health plans and insurers through reduced cost sharing for services other than prescriptions for self-administered hormonal contraceptives. Therefore, the additional enrollees with uncovered expenses premandate would receive a reduction in their financial burden associated with contraceptive use. CHBRP estimates are based on claims data and

may underestimate the cost savings for enrollees due to carriers' ability to negotiate discounted rates that are unavailable to patients and their families.

CHBRP estimates that SB 999 would modify coverage and reduce the financial burden by approximately \$18.7 million in the first year, postmandate, for enrollees who would be mandate-eligible for a 12-month prescription of self-administered hormonal contraceptives.

LONG-TERM IMPACTS OF CONTRACEPTIVES

In this section, CHBRP estimates the long-term impact³⁷ of SB 999, defined as impacts occurring beyond the first 12 months of 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.

In the long term, the number of Californians enrolled in DMHC-regulated plans or CDI-regulated policies subject to SB 999 would increase, as the number of women aged 15 to 44 years in California increases.

Long-Term Utilization and Cost Impacts

Utilization Impacts

As seen in the *Public Health Impacts* section, women often cite availability and ease of access as a reason to not use self-administered hormonal contraceptives. It is likely that the increased access to a 12-month supply of self-administered hormonal contraceptives will encourage a greater proportion of women over time to use this effective method of birth control, as the barriers to obtaining a consistent supply will be reduced. Providers will also likely encourage their patients to choose to receive the full 12-month supply of self-administered hormonal contraceptives at one time, so that the prescription will have maximum effectiveness. The potential long-term utilization rates of self-administered hormonal contraceptives is likely to therefore increase over time, meaning that the number of prescriptions for self-administered hormonal contraceptives will increase.

Additionally, SB 493 (enacted in October 2013) will be implemented soon, and will also likely increase the number of enrollees who receive 12 months of self-administered hormonal contraceptives. This bill allows for pharmacists to dispense self-administered hormonal contraceptives without a prescription, although the number of cycles allowed to be dispensed at one time has yet to be determined by regulators. Should SB 999 be enacted, there may be pressure to allow pharmacists to also dispense 12 months of self-administered hormonal contraceptives without a prescription, under their authority from SB 493. This potential interaction would increase the use of self-administered hormonal contraceptives over time.

Cost Impacts

In the 12 months following enactment, CHBRP estimates that the enactment of SB 999 will reduce both the rate of unintended pregnancy and the abortion rate. In later years, CHBRP anticipates that these trends will continue, generating additional cost savings over time. Additionally, there will be cost savings associated with reduced complications from potential adverse postpartum outcomes, such as depression or caesarean operation recovery. As utilization of receiving a 12-month supply of self-administered hormonal contraceptives increases (see above), this will lead to an even larger reduction in the overall population's unintended pregnancy rate, as a greater proportion of women take-up self-administered hormonal contraceptives for their birth control method. While CHBRP estimates approximately \$47.8 million in savings from reductions in unintended pregnancies (leading to reductions in live births,

³⁷ See also CHBRP's *Critereia and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

miscarriages, and abortions), these savings would increase in the long run with greater reductions in unintended pregnancies.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments) while other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects of a proposed mandate (beyond CHBRP's 12-month analytic timeframe) to capture possible impacts to the public's health that would be attributable to the mandate, including impacts on premature death and economic loss.

As discussed in the *Public Health Impacts* section, SB 999 would increase the number of enrollees who receive 12-months supply of self-administered hormonal contraceptives at one time by 280,000 in the first year postmandate (see *Benefit Coverage, Utilization, and Cost Impacts* section), leading to a reduction in the number of unintended pregnancies overall, those ending in abortion, and negative health outcomes associated with unintended pregnancy in the first year postmandate.

SB 999 also has the potential to impact public health outcomes beyond the first 12 months of bill implementation. This section will qualitatively discuss the potential long-term impacts of SB 999 on the incidence of unintended pregnancy and abortion, maternal and child health and behavioral outcomes, harms, social determinants of health, and disparities. The discussion on possible impacts on health, behavioral, and socioeconomic outcomes will be based primarily on reviews of the literature conducted by (Gipson et al., 2008; Logan et al., 2007; 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 women 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, such as the social determinants of health of the mother. Overall, studies of the longterm impacts of unintended pregnancy provide relatively weak evidence on the weight of the impacts due to unintendedness alone.

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 999 will result in 15,000 averted unintended pregnancies; among those averted pregnancies, there would be 7,000 averted abortions. These reductions in unintended pregnancies and resulting abortions are likely to persist over time. As mentioned above, CHBRP assumes that increased access to a 12-month supply of self-administered hormonal contraceptives may encourage more women to use these methods over less effective contraceptive methods (e.g., barrier methods) and that providers may encourage a 12-month supply so that the prescription will have maximum effectiveness.

Assuming that SB 999 increases utilization of a 12-month supply of self-administered hormonal contraceptives beyond the first year postmandate, there may be a decrease in the rate of unintended pregnancies and abortions occurring 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 women with intended pregnancies, women with unintended pregnancies are more likely to delay initiating prenatal care, more likely to have a low-birth-weight baby, and less likely to breast feed (Cheng et al., 2009; Gipson et al., 2008; Shah et al., 2011). Reviews of the literature have 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 (Gipson et al., 2008; Logan et al., 2007; Sonfield et al., 2013). Some qualitative research indicates that women 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 999 increases utilization of a 12-month supply of self-administered hormonal 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 (Logan et al., 2007). Additionally, compared to children who were born from intended pregnancies, 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 in early adulthood, and are more likely be depressed or receive mental health services in adulthood (Sonfield et al., 2013).

In the long term, assuming that SB 999 increases utilization of a 12-month supply of self-administered hormonal 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 those aged 15 to 17 years, 91% of pregnancies are unintended) are more likely to lag behind their peers at age two 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 999 increases utilization of a 12-month supply of self-administered hormonal contraceptives beyond the first year postmandate, there may be a decrease in the rate of unintended pregnancies, and thereby decreasing the risk of poor mother-child relationships and behavioral problems.

Impacts on the Social Determinants of Health and Disparities

Socioeconomic Status

As discussed in the *Public Health Impacts* section, unintended pregnancy rates are highest among women without a high school diploma and with incomes at or below 149% of the federal poverty line (FPL); however, utilization of self-administered hormonal contraceptives is lowest among these women.

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 those aged 15 to 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 women's professional pursuits and time spent in the labor force by allowing them 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 men and women. Thus, women with an average age of 30 and who were childless earned about 90% of the hourly wages earned by men in that age group, but younger women who were mothers earned 73% as much as similarly aged men.

In the long term, to the extent that SB 999 increases utilization of a 12-month supply of self-administered hormonal contraceptives beyond the first year postmandate, there may be a reduction in the rate of unintended pregnancies, thereby allowing women to delay childbearing and pursue additional education, spend additional time in their careers, and have increased earning power. However, there is likely to be less of an impact among socioeconomically disadvantaged women who are at the highest risk of unintended pregnancies, due to their lower self-administered hormonal contraceptives use and other social determinants of health influencing their health outcomes.

Age and Racial/Ethnic Disparities

As discussed in the *Public Health Impacts* section, there are age and racial/ethnic disparities in unintended pregnancy rates. Younger women (aged 15 to 24 years) have the highest rates of unintended pregnancies compared to women aged 25 to 44 years, as well as the highest rate of self-administered hormonal contraceptives use. In contrast, Hispanics and non-Hispanic blacks have the highest rates of unintended pregnancies, yet utilization of self-administered hormonal contraceptives is lowest among this group, as compared to non-Hispanic whites.

In the long term, to the extent that SB 999 increases utilization of a 12-month supply of self-administered hormonal contraceptives beyond the first year postmadate, there may be a reduction in the rate of unintended pregnancies among younger women. However, there is likely to be less of an impact among Hispanic and non-Hispanic black women who are at the highest risk of unintended pregnancies, due to

their lower self-administered hormonal contraceptives use and other social determinants of health influencing their health outcomes.

Impacts on Premature Death

Premature death is often defined as death before the age of 75 years (Cox, 2006). The overall impact of premature death due to a particular disease can be measured in years of potential life lost prior to age 75 and summed for the population (generally referred to as "YPLL") (Cox, 2006; Gardner and Sanborn, 1990). In California, it is estimated that there are nearly 102,000 premature deaths each year, accounting for more than two million YPLL (CDPH, 2013; Cox, 2006). In order to measure the impact of premature mortality across the population impacted by a proposed mandate, CHBRP first collects baseline mortality rates. Next, the literature is examined to determine whether the proposed mandated benefit impacts mortality and whether YPLL have been established for the given condition. Some diseases and conditions do not result in death, and therefore a mortality outcome is not relevant.

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

Premature Death

Pregnancy always carries inherent risks, including maternal mortality, and unintended pregnancies expose women to these inherent risks more often. Based on estimated maternal mortality ratios from the World Health Organization (WHO), researchers estimated that nearly 61% of maternal deaths in the United States were averted by contraceptive use and that if unmet demand for contraception was met, an estimated 76% of maternal deaths could be averted by contraceptive use (Ahmed et al., 2012). However, CHBRP found no literature specifying averted maternal deaths based on self-administered hormonal contraceptives use alone.

Although use of contraception can reduce maternal mortality rates, CHBRP found no evidence specific to the impact on self-administered hormonal contraceptive methods on reducing maternal mortality; thus, the impact of SB 999 on maternal mortality is unknown.

APPENDIX A TEXT OF SENATE BILL 999

On January 28, 2016, the California Senate Committee on Health requested that CHBRP analyze SB 999.

SENATE BILL

No. 999

Introduced by Senator Pavley

(Principal coauthor: Senator Hertzberg)

(Principal coauthors: Assembly Members Atkins, Gomez, and Gonzalez)

(Coauthors: Senators Allen, Hall, Hill, Jackson, Leyva, and Wieckowski)

(Coauthors: Assembly Members Burke, Cristina Garcia, Levine, McCarty, and Williams)

February 10, 2016

An act to amend Section 4064.5 of the Business and Professions Code, to amend Section 1367.25 of the Health and Safety Code, and to amend Section 10123.196 of the Insurance Code, relating to contraceptives.

LEGISLATIVE COUNSEL'S DIGEST

SB 999, as introduced, Pavley. Health insurance: contraceptives: annual supply.

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 also provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2016, to provide coverage for women for all prescribed and FDA-approved female contraceptive drugs, devices, and products, as well as voluntary sterilization procedures, contraceptive education and counseling, and related followup services.

This bill would require a health care service plan or a health insurance policy issued, amended, or renewed on or after January 1, 2017, to cover a 12-month supply of FDA-approved, self-administered hormonal contraceptives dispensed at one time by a prescriber, pharmacy, or onsite at a location licensed or authorized to dispense drugs or supplies. 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.

Existing law authorizes a pharmacist to dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial

quantity of less than a 90-day supply followed by periodic refills of that amount if the patient has met specified requirements, including having completed an initial 30-day supply of the drug. Existing law prohibits a pharmacist from dispensing a greater supply of a dangerous drug if the prescriber indicates "no change to quantity" on the prescription.

This bill would authorize a pharmacist to dispense prescribed, FDA-approved, self-administered hormonal contraceptives either as prescribed or, at the patient's request, in a 12-month supply, unless the prescriber specifically indicates no change to quantity.

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

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

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. (a) The Legislature hereby finds all of the following:

(1) California has a long history of, and commitment to, expanding access to services that aim to reduce the risk of unintended pregnancies and improving reproductive health outcomes.

(2) California's Family Planning, Access, Care, and Treatment (PACT) program, created in 1999, is viewed nationally as the "gold standard" of publicly funded programs providing access to reproductive health care. The program has long recognized the value and importance of providing women with a year's supply of birth control.

(3) The Affordable Care Act (ACA) and subsequent federal regulations made contraceptive coverage a national policy by requiring most private health insurance plans to provide coverage for a broad range of preventive services without cost-sharing, including FDA-approved prescription contraceptives.

(4) Since the passage of the ACA, many states have passed laws strengthening or expanding this federal contraceptive coverage requirement. In 2014, California passed the Contraceptive Coverage Equity Act of 2014, which requires plans to cover all prescribed FDA-approved contraceptives for women without cost-sharing, and requires plans to cover at least one therapeutic equivalent of a prescribed contraceptive drug, device, or product.

(5) Numerous studies support what California has determined for decades in the Family PACT program: dispensing a 12-month supply of birth control at one time has numerous benefits, including, but not limited to, reducing a woman's odds of having an unintended pregnancy by 30 percent, increasing contraception continuation rates, and decreasing costs per client to insurers by reducing the number of pregnancy tests and pregnancies.

(6) Access to contraception is a key element in shaping women's health and well-being. Nearly all women have used contraceptives at some point in their lives, and 62 percent are currently using at least one method.

(7) Several states have mirrored the year-supply requirement for contraceptive coverage in their publicly funded family planning or Medicaid programs, recognizing the health benefits of reducing barriers to continuous and effective use of contraception. Recently, Oregon and Washington D.C. have gone further to require private health care service plans and health insurance policies to also cover a 12-month supply of contraceptives. With California's history of leadership in establishing public policies that increase access to contraceptives, adopting a similar requirement is a natural progression of our state's commitment to reducing unintended pregnancy.

(b) It is therefore the intent of the Legislature to expand on California's existing contraceptive coverage policy by requiring all health care service plans and health insurance policies, including both commercial and Medi-Cal managed care plans, to cover a 12-month supply of a prescribed FDA-approved contraceptive, such as the ring, the patch, and oral contraceptives.

SEC. 2. Section 4064.5 of the Business and Professions Code is amended to read:

4064.5. (a) A pharmacist may dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of that amount if all of the following requirements are satisfied:

(1) The patient has completed an initial 30-day supply of the dangerous drug.

(2) The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills.

(3) The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary.

(4) The pharmacist is exercising his or her professional judgment.

(b) For purposes of this section, if the prescription continues the same medication as previously dispensed in a 90-day supply, the initial 30-day supply under paragraph (1) of subdivision (a) is not required.

(c) A pharmacist dispensing an increased supply of a dangerous drug pursuant to this section shall notify the prescriber of the increase in the quantity of dosage units dispensed.

(d) In no case shall a pharmacist dispense a greater supply of a dangerous drug pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "No change to quantity," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "No change to quantity," provided that the prescriber personally initials the box or checkmark. To indicate that an increased supply shall not be dispensed pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "No change to quantity," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "No change to quantity." In either instance, it shall not be required that the prescriber.

(e) This section shall not apply to psychotropic medication or

psychotropic drugs as described in subdivision (d) of Section 369.5 of the Welfare and Institutions Code.

(f) Except for the provisions of subdivision (d), this section does not apply to a prescription for FDA-approved, self-administered hormonal contraceptives approved by the FDA. A prescription for FDA-approved, self-administered hormonal contraceptives shall be dispensed either as provided on the prescription or, at the patient's request, up to a 12-month supply.

(f)

(g) Nothing in this section shall be construed to require a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including, but not limited to, a state program or state employer, to provide coverage for a dangerous drug in a manner inconsistent with a beneficiary's plan benefit.

SEC. 3. 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, through December 31, 2015, inclusive, and an individual health care service plan contract that is amended, renewed, or delivered on or after January 1, 2000, through 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 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:

(A) Except as provided in subparagraphs (B) and (C) of paragraph (2), all FDA-approved contraceptive drugs, devices, and other products for women, including all FDA-approved contraceptive drugs, devices, and products available over the counter, as prescribed by the enrollee's provider.

(B) Voluntary sterilization procedures.

(C) Patient education and counseling on contraception.

(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 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. 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.

(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 prescribed contraceptive drug, device, or product without cost sharing. Any 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 impose any restrictions or delays on the coverage required under this subdivision.

(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, "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.

(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 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.

(d) (1) Every health care service plan contract that is issued, amended, renewed, or delivered on or after January 1, 2017, shall cover a 12-month supply of FDA-approved, self-administered hormonal contraceptives dispensed by a prescriber or pharmacy at one time to an enrollee.

(2) If a 12-month supply of FDA-approved, self-administered hormonal contraceptives is dispensed onsite at a location licensed or otherwise authorized to dispense drugs or supplies, the health care service plan shall cover the 12-month supply.

(d)

(e) This section shall not be construed to exclude coverage for contraceptive supplies as prescribed by a provider, acting within his or her 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.

(e)

(*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.

(f)

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

(g)

(*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.

SEC. 4. 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:

(A) Except as provided in subparagraphs (B) and (C) of paragraph (2), all FDA-approved contraceptive drugs, devices, and other products for women, including all FDA-approved contraceptive drugs, devices, and products available over the counter, as prescribed by the insured's provider.

(B) Voluntary sterilization procedures.

(C) Patient education and counseling on contraception.

(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 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.

(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.

(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 prescribed contraceptive drug, device, or product without cost sharing. Any 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 impose any restrictions or delays on the coverage required under this subdivision.

(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.

(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.

line 31 (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 shall provide written notice to any prospective employee once an offer of employment has been made, and prior to that person commencing that employment, listing the contraceptive health care services the employer refuses to cover for religious reasons.

(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 a 12-month supply of FDA-approved, self-administered hormonal contraceptives dispensed by a prescriber or pharmacy at one time to an insured.

(2) If a 12-month supply of FDA-approved, self-administered hormonal contraceptives is dispensed onsite at a location licensed or otherwise authorized to dispense drugs or supplies, the insurer shall cover the 12-month supply.

(f)

(g) This section shall not be construed to exclude coverage for contraceptive supplies as prescribed by a provider, acting within his or her 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.

(g)

(*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.

(h)

(*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.

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

APPENDIX B LITERATURE REVIEW METHODS

Appendix B describes methods used in the medical effectiveness literature review for SB 999. SB 999 would mandate coverage of a 12-month supply of Food and Drug Administration (FDA) approved self administered hormonal contraceptives dispensed at one time. The medical effectiveness review summarizes findings from the literature on the effectiveness of self-administered hormonal contraceptives in general as well as literature on the impact of dispensing oral contraceptives in quantities in excess of 90 days and up to 1 year using a systematic review of literature published through 2012 and individual studies published after 2012. In addition, literature on the effectiveness of individual self-administered hormonal contraceptives and contraception overall was taken from a previous CHBRP report on the subject, SB 1053, published in 2014 (CHBRP, 2014).

The FDA-approved hormonal contraceptives include: oral contraceptives (pill, mini-pill, and extended/continuous use pill), contraceptive patch (Ortho Evra®), vaginal contraceptive ring (NuvaRing®), and contraceptive injections (Depo-Provera®; Depo-Subq Provera®).³⁸ Of these, all but the contraceptive injections are self-administered and will be covered in this analysis. Although Emergency Contraceptives are also FDA-approved for use as hormonal contraception, they are classified as a separate category of contraceptives by the FDA and are not recommended as a regular form of contraception. Therefore, they are not included in this analysis or literature review.

Studies of hormonal contraceptive effectiveness were identified through searches of relevant databases of peer-reviewed literature listed below. The search was limited to abstracts of studies published in English. Due to the existence of a high-quality systematic review conducted in 2012 on the impact of dispensing quantity of oral contraceptives on health outcomes, the medical effectiveness search was limited to studies published from 2012 to the present. The cost and public health searches encompassed studies from 2006 to 2016. For medical efficacy of individual types of contraception, CHBRP relied on a systematic review and meta analysis published in 2011 (Trussell, 2011). This approach is consistent with the approach CHBRP has taken in its analysis of previous topics with many different mandated benefits. Of the 141 articles identified in the literature review, 34 were reviewed for potential inclusion in this report on SB 999, and a total of 8 studies were included in the medical effectiveness review for this report.

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*.³⁹ To grade the evidence for each outcome measured, the team uses a grading system with the following categories:

- Research design;
- Statistical significance;

³⁸ The list of FDA-approved contraceptives can be found here (updated 12/02/2015): http://www.fda.gov/ForConsumers/ByAudience/ForWomen/FreePublications/ucm313215.htm

³⁹ Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

- Direction of effect;
- Size of effect; and
- Generalizability of findings.

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

- Clear and convincing evidence;
- Preponderance of evidence;
- Ambiguous/conflicting evidence; and
- Insufficient evidence.

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

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective. This can be further subdivided into preponderance of evidence from high-quality studies and preponderance of evidence from low-quality studies.

Search Terms

The search terms used to locate studies relevant to SB 999 were as follows:

Major MeSH terms used to search PubMed

Contraceptives, Oral, Hormonal Cost of Illness Costs and Cost Analysis [EXP] Healthcare Disparities Medication Adherence Pregnancy, Unplanned Sex Characteristics [EXP] Socioeconomic Factors [EXP]

Vital Statistics [EXP]Keywords used to search PubMed, Cochrane Library, EconLit, Web of

Science, and relevant websites:

12 Month supply Contraceptive patch* Cost or Costs Dispens* Effectiveness Incidence Lost Productivity Marketing Morbidity Pack* Poverty Prevalence Price elasticity Pricing Race Racial disparities Socioeconomic Transdermal patch* Vaginal ring*

* = Truncation

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

This appendix describes data sources, estimation methodology, as well as general and mandate-specific caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP website at: www.chbrp.org/analysis methodology/cost impact analysis.php.

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as contracted actuarial firms, Milliman, Inc, and Pricewaterhouse Coopers (PwC).⁴⁰

Data Sources

This subsection discusses the variety of data sources CHBRP uses. Key sources and data items are listed below, in Table .

Data Source	Items
California Department of Health Care Services (DHCS) administrative data for the Medi-Cal program, data available as of end of December 2014	Distribution of enrollees by managed care or FFS distribution by age: 0–17; 18–64; 65+ Medi-Cal Managed Care premiums
California Department of Managed Health Care (DMHC) data from the interactive website "Health Plan Financial Summary Report," August–October, 2015	Distribution of DMHC-regulated plans by market segment*
California Department of Insurance (CDI) Statistical Analysis Division data; data as of December 31, 2015	Distribution of CDI-regulated policies by market segment

Table C-1. Data for 2017 Projections

⁴⁰ CHBRP's authorizing statute, availabe at <u>www.chbrp.org/docs/authorizing_statute.pdf</u>, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

Data Source	Items		
California Health Benefits Review Program (CHBRP) Annual Enrollment and Premium Survey of California's largest (by enrollment) health care service plans and health insurers; data as of September 30, 2015; responders' data represent approximately 97% of persons not associated with CalPERS or Medi-Cal with health insurance subject to state mandates(full-service (nonspecialty) DMHC-regulated plan enrollees and of full-service (nonspecialty) CDI-regulated policy enrollees).	 Enrollment by: Size of firm (2–50 as small group and 51+ as large group) DHMC vs. CDI regulated Grandfathered vs. nongrandfathered Premiums for individual policies by: DMHC vs. CDI regulated Grandfathered vs. nongrandfathered 		
California Employer Health Benefits Survey, 2014 (conducted by NORC and funded by CHCF)	 Enrollment by HMO/POS, PPO/indemnity self- insured, fully insured, Premiums (not self-insured) by: Size of firm (3–25 as small group and 25+ as large group) Family vs. single HMO/POS vs. PPO/indemnity vs. HDHP employer vs. employer premium share 		
California Health Interview Survey (CHIS)	Uninsured, age: 65+ Medi-Cal (non-Medicare), age: 65+ Other public, age: 65+ Employer-sponsored insurance, age: 65+		
California Public Employees' Retirement System (CalPERS) data, enrollment as of October 1, 2015	CalPERS HMO and PPO enrollment • Age: 0–17; 18–64; 65+ • HMO premiums		
California Simulation of Insurance Markets (CalSIM) (projections for 2017)	Uninsured, age: 0–17; 18–64 Medi-Cal (non-Medicare) (a), age: 0–17; 18–64 Other public (b), age: 0–64 Individual market, age: 0–17; 18–64 Small group, age: 0–17; 18–64 Large group, age: 0–17; 18–64		
Centers for Medicare and Medicaid (CMS) administrative data for the Medicare program, annually (if available) as of end of September	HMO vs. FFS distribution for those 65+ (noninstitutionalized)		
Milliman estimate	Medical trend influencing annual premium increases		

Notes: (*) CHBRP assumes DMHC-regulated PPO group enrollees and POS enrollees are in the large-group segment.

Key: CDI=California Department of Insurance; CHCF=California HealthCare Foundation; CHIS=California Health Interview Survey; CMS=Centers for Medicare & Medicaid Services; DHCS=Department of Health Care Services; DMHC=Department of Managed Health Care; FFS=fee-for-service; HMO=health maintenance organization; NORC=National Opinion Research Center; POS=point of service; PPO=preferred provider organization. Further discussion of external and internal data follows.

Internal data

- CHBRP's Annual Enrollment and Premium Survey collects data from the six largest providers of health insurance in California (including Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, and Kaiser Foundation Health Plan,) to obtain estimates of enrollment not associated with CalPERS or Medi-Cal by purchaser (i.e., large and small group and individual), state regulator (DMHC or CDI), grandfathered and nongrandfathered status, and average premiums. CalSIM and market trends were applied to project 2017 health insurance enrollment in DMHC-regulated plans and CDI-regulated policies.
- CHBRP's other surveys of the largest plans/insurers collect information on benefit coverage relevant to proposed benefit mandates CHBRP has been asked to analyze. In each report, CHBRP indicates the proportion of enrollees — statewide and by market segment — represented by responses to CHBRP's bill-specific coverage surveys. The proportions are derived from data provided by CDI and DMHC.

External sources

- California Department of Health Care Services (DHCS) data are used to estimate enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System plans), which may be subject to state benefit mandates, as well as enrollment in Medi-Cal Fee For Service (FFS), which is not. The data are available at: www.dhcs.ca.gov/dataandstats/statistics/Pages/Monthly_Trend_Report.aspx.
- California Employer Health Benefits Survey data are used to make a number of estimates, including: premiums for employment-based enrollment in DMHC-regulated health care service plans (primarily health maintenance organizations [HMOs] and point of service [POS] plans) and premiums for employment-based enrollment in CDI-regulated health insurance policies regulated by the (primarily preferred provider organizations [PPOs]). Premiums for fee-for-service (FFS) policies are no longer available due to scarcity of these policies in California. This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. More information on the CHCF/NORC data is available at: www.chcf.org/publications/2014/01/employer-health-benefits.
- California Health Interview Survey (CHIS) data are used to estimate the number of Californians aged 65 and older, and the number of Californians dually eligible for both Medi-Cal and Medicare coverage. CHIS data are also used to determine the number of Californians with incomes below 400% of the federal poverty level. CHIS is a continuous survey that provides detailed information on demographics, health insurance coverage, health status, and access to care. More information on CHIS is available at: www.chis.ucla.edu.
- California Public Employees Retirement System (CalPERS) data are used to estimate premiums and enrollment in DMHC-regulated plans, which may be subject to state benefit mandates, as well as enrollment in CalPERS' self-insured plans, which is not. CalPERS does not currently offer enrollment in CDI-regulated policies. Data are provided for DMHC-regulated plans enrolling non-Medicare beneficiaries. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOC) documents publicly available at: <u>www.calpers.ca.gov</u>. California Simulation of Insurance Markets (CalSIM) estimates are used to project health insurance status of Californians aged 64 and under. CalSIM is a microsimulation model that projects the effects of

the Affordable Care Act on firms and individuals. More information on CalSIM is available at: http://healthpolicy.ucla.edu/programs/health-economics/projects/CalSIM/Pages/default.aspx.

- To estimate the premium impact of certain mandates, PwC's projections may derive from its proprietary comprehensive pricing model, which provides benchmark data and pricing capabilities for commercial health plans. The pricing model factors in health plan features such as deductibles, copays, out-of-pocket maximums, covered services, and degree of healthcare management. The pricing model uses normative data and benefit details to arrive at estimates of allowed and net benefit costs. The normative benchmarking utilization metrics within the pricing model are developed from a database of commercial (under 65) health plan experience representing approximately 20 million annual lives.
- The MarketScan databases, which reflect the health care claims experience of employees and dependents covered by the health benefit programs of large employers, are used to estimate utilization and unit cost. These claims data are collected from insurance companies, Blue Cross Blue Shield plans, and third-party administrators. These data represent the medical experience of insured employees and their dependents for active employees, early retirees, individuals with COBRA continuation coverage, and Medicare-eligible retirees with employer-provided Medicare Supplemental plans. No Medicaid or Workers Compensation data are included.
- Ingenix MDR Charge Payment System, which includes information about professional fees paid for health care services, based upon claims from commercial insurance companies, HMOs, and self-insured health plans.

Projecting 2017

This subsection discusses adjustments made to CHBRP's Cost and Coverage Model to project 2017, the period when mandates proposed in 2016 would, if enacted, generally take effect. It is important to emphasize that CHBRP's analysis of specific mandate bills typically addresses the <u>incremental</u> effects of a mandate — specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, *holding all other factors constant*. CHBRP's estimates of these incremental effects are presented in the *Benefit Coverage, Utilization, and Cost Impacts* section of this report.

Baseline premium rate development methodology

The key components of the baseline model for utilization and expenditures are estimates of the per member per month (PMPM) values for each of the following:

- Insurance premiums PMPM;
- Gross claims costs PMPM;
- Member cost sharing PMPM; and
- Health care costs paid by the health plan or insurer.

For each market segment, we first obtained an estimate of the insurance premium PMPM by taking the 2015 reported premium from the abovementioned data sources and trending that value to 2017. CHBRP uses trend rates published in PwC's "Behind the Numbers" health care trend report to estimate the health care costs for each market segment in 2017.

The large-group market segments for each regulator (CDI and DMHC) are split into grandfathered and nongrandfathered status. For the small-group and individual markets, further splits are made to indicate association with Covered California, the state's health insurance marketplace. Doing so allows CHBRP to

separately calculate the impact of ACA and of specific mandates, both of which may apply differently among these subgroups. The premium rate data received from the CHCF/NORC California Employer Health Benefits survey did not split the premiums based on grandfathered or exchange status. However, CHBRP's Annual Enrollment and Premium (AEP) survey asked California's largest health care service plans and health insurers to provide their average premium rates separately for grandfathered and nongrandfathered plans. The ratios from the CHBRP survey data were then applied to the CHCH/NORC aggregate premium rates for large and small group, to estimate premium rates for grandfathered and nongrandfathered plans that were consistent with the NORC results. For the individual market, the premium rates received from CHBRP's AEP survey were used directly.

The remaining three values were then estimated by the following formulas:

- Health care costs paid by the health plan = insurance premiums PMPM × (1 profit/administration load);
- Gross claims costs PMPM = health care costs paid by the health plan ÷ percentage paid by health plan; and
- Member cost sharing PMPM = gross claims costs × (1 percentage paid by health plan).

In the above formulas, the quantity "profit/administration load" is the assumed percentage of a typical premium that is allocated to the health plan/insurer's administration and profit. These values vary by insurance category, and under the ACA, are limited by the minimum medical loss ratio requirement. CHBRP estimated these values based on actuarial expertise at PwC, and their associated expertise in health care.

In the above formulas, the quantity "percentage paid by health plan" is the assumed percentage of gross health care costs that are paid by the health plan, as opposed to the amount paid by member cost sharing (deductibles, copays, etc.). In ACA terminology, this quantity is known as the plan's "actuarial value." These values vary by insurance category. For each insurance category, estimated the member cost sharing for the average or typical plan in that category is based on the actuarial value of the plan. For "metal tier" plans, the average cost share is calculated as 100% minus the plan actuarial value. For non-"metal tier" plans, Milliman estimated the actuarial value using the Milliman Health Cost Guidelines to estimate the percentage of gross health care costs that are paid by the carrier.

General Caveats and Assumptions

This subsection discusses the general caveats and assumptions relevant to all CHBRP reports. The projected costs are estimates of costs that would result if a certain set of assumptions were exactly realized. Actual costs will differ from these estimates for a wide variety of reasons, including:

- Prevalence of mandated benefits before and after the mandate may be different from CHBRP assumptions.
- Utilization of mandated benefits (and, therefore, the services covered by the benefit) before and after the mandate may be different from CHBRP assumptions.
- Random fluctuations in the utilization and cost of health care services may occur.

Additional assumptions that underlie the cost estimates presented in this report are:

- Cost impacts are shown only for plans and policies subject to state benefit mandate laws.
- Cost impacts are only for the first year after enactment of the proposed mandate.

- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of the premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for 1 year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts, please see: www.chbrp.org/analysis_methodology/docs/longterm_impacts08.pdf.

There are other variables that may affect costs, but which CHBRP did not consider in the estimates presented in this report. Such variables include, but are not limited to:

- Population shifts by type of health insurance: If a mandate increases health insurance costs, some employer groups and individuals may elect to drop their health insurance. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefits: To help offset the premium increase resulting from a mandate, deductibles or copayments may be increased. Such changes would have a direct impact on the distribution of costs between health plans/insurers and enrollees, and may also result in utilization reductions (i.e., high levels of cost sharing result in lower utilization of health care services). CHBRP did not include the effects of such potential benefit changes in its analysis.
- Adverse selection: Theoretically, persons or employer groups who had previously foregone health insurance may elect, postmandate, to enroll in a health plan or policy because they perceive that it is now to their economic benefit to do so.
- Medical management: Health plans/insurers may react to the mandate by tightening medical management of the mandated benefit. This would tend to dampen the CHBRP cost estimates. The dampening would be more pronounced on the plan/policy types that previously had the least effective medical management (i.e., PPO plans).
- Geographic and delivery systems variation: Variation exists in existing utilization and costs, and in the impact of the mandate, by geographic area and by delivery system models. Even within the health insurance plan/policy types CHBRP modeled (HMO, including HMO and POS plans, and non-HMO, including PPO and FFS policies), there are likely variations in utilization and costs. Utilization also differs within California due to differences in the health status of the local population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between providers and health plans/insurers. Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, CHBRP has estimated the impact on a statewide level.
- Compliance with the mandate: For estimating the postmandate impacts, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the benefit coverage requirements of the bill. Therefore, the typical postmandate coverage rates for persons enrolled in health insurance plans/policies subject to the mandate are assumed to be 100%.

Analysis Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions relevant to the analysis of SB 999.

CHBRP assumes that users for self-administered hormonal contraceptives are aged 15 to 44. CHBRP also assumes the effects of the mandate in SB 999 will not cause an increase in number of users; only shifts in the supply of cycles dispensed at once. To calculate the shift in utilization in self-administered hormonal contraceptives, CHBRP applied ratios from Foster et al. (2011), proportionally distributing the populations of users of self-administered hormonal contraceptives who received a number other than 1, 3, or 12 cycles. A limitation of this method is that the Family PACT population used in the Foster et al. (2011) analysis may not match that of the full insured population in terms of demographics, as Family PACT users are more likely to face additional access barriers. These additional barriers would have a dampening effect on those enrollees choosing to access 12 month self-administered hormonal contraceptives, indicating that this distribution should be considered a floor for the potential impact of SB 999. The full insured population, with greater economic and family planning stability, may in fact choose to get 12 months supply of self-administered hormonal contraceptives at a higher rate than the distribution suggested by Foster et al.'s (2001) work.

CHBRP included the following projection of the final distribution of self-administered hormonal contraceptive users in the estimates:

- 15% will receive a 1-month supply.
- 38% will receive a 3-month supply.
- 47% will receive a 12-month supply.
- On average, 1-month users receive a total of 4 months' supply in a year.
- On average, 3-month users receive a total of 9 months' supply in a year.

Additionally, CHBRP assumes that office visits to obtain prescriptions will likely decrease due to users receiving a 12-month supply of self-administered hormonal contraceptives. Based on Foster et al. (2011), CHBRP assumes that enrollees receiving 12 months of self-administered hormonal contraceptives at once will have on average 2.1 office visits per year, while those with fewer number of cycles will have 3 office visits per year.

CHBRP assumes that the mandate will have no impact on per-unit costs for any type of selfadministered hormonal contraceptive. In the Truven MarketScan database, reliable data was not available for per-unit cost for a 12-month supply of self-administered hormonal contraceptives because 12 month supply of self-administered hormonal contraceptives were not widely covered in the submitted data. Therefore, 12-month costs were estimated based on the costs of 1-month and 3-month supplies of self-administered hormonal contraceptives extrapolated to an average 12-month supply per-unit cost.

- In estimating the reduced medical expenditures due to a reduction of unintended pregnancies during the first year, CHBRP applies ratios from the research literature (Foster et al., 2011; Kost, 2015; Trussel, 2011) and makes the following assumptions: 9% of women using self-administered hormonal contraceptives have unintended pregnancies under the current coverage.
- Postmandate, there will be a reduction in the odds of having an unintended pregnancy of 30%.
- Of the self-administered hormonal contraceptive users that will have an unintended pregnancy:

- o an estimated 42% will result in a delivery,
- o an estimated 13% will have miscarriages, and
- o an estimated 45% will have an abortion.

Based on Truven MarketScan data, the average cost of deliveries is \$15,364, the average cost of a miscarriage is \$4,249, and the average cost of an abortion is \$2,357. The average unit cost of office visit is based on all CPT codes for new patient and existing patients. CHRBP did not include estimates of the potential averted health costs of children after birth in this analysis, including maternal post-partum depression. CHBRP also did not quantify the potential medical expenditures due to averted sexually transmitted diseases. Additionally, utilization for Medi-Cal is assumed to be the same pre- and postmandate because enrollees are currently eligible to receive up to a 12-month supply of self-administered hormonal contraceptives in the pill form.

The estimated cost impacts of the mandates include the equation, Δ NrC, where:

 ΔN = change in number of enrollees using the benefit r = utilization rate per contraceptive user C = cost per unit for number of scripts for self-administered hormonal contraceptives, office visits, and pregnancies.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits SB 999 would mandate. Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- Considers the bargaining history of organized labor; and
- Compares the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include contraceptive supply dispensed in their health insurance negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

CalPERS fully-insured HMOs provide benefit coverage for self-administered hormonal contraceptives that is similar to what is is available through group health insurance plans and policies that would be subject to the mandate. CalPERS self-insured plans provide coverage for outpatient prescription drugs through CVS Health. All prescriptions, including self-administered hormonal contraceptives, are limited to a 30-day supply at a non-CVS retail pharmacy and a 90-day supply through CVS retail pharmacy or mail order.

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.
APPENDIX D OUTPATIENT PRESCRIPTION DRUG BENEFITS AND STATE-LEVEL MANDATES

As noted in Table , for 2017, CHBRP estimates that approximately 1.8% of enrollees in plans regulated by the California Department of Managed Health Care (DMHC) or policies regulated by the California Department of Insurance (CDI) have no coverage for outpatient prescription drugs (OPDs) and 3.1% of these enrollees have OPD coverage that is not regulated by DMHC or CDI.

Table D-1. Outpatient Prescription Drug Coverage, 2017

	Enrollees in DMHC-Regulated Plans and in CDI-Regulated Policies
Enrollee Counts	
Total enrollees in plans/policies subject to state Mandates (a)	25,155,000
Outpatient Precription Drug (OPD) Coverage	
DMHC- or CDI-regulated brand name and generic OPD coverage	94.3%
DMHC- or CDI-regulated generic only coverage	0.8%
No OPD coverage	1.8%
Other OPD coverage	3.1%

Source: California Health Benefits Review Program, 2016.

Notes: (a) 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.

Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; HMO=Health Maintenance Organization; OPD=Ouptpatient Prescription Drug.

Additional detail about the presence and absence of OPD coverage in various market segments is presented below, in Tables 11 and 12.

Relevant State and Federal Law

A number of overlapping state and federal laws require broad OPD coverage or coverage for particular drugs, but the requirements are not applicable to all forms of health insurance.

- Some (but not all) small-group and individual market health care service plans and health insurance policies are required to provide coverage for OPDs as part of coverage for essential health benefits.⁴¹
- Some (but not all) large-group, small-group, and individual market health care service plans and health insurance policies are required to provide coverage for particular drugs as part of preventive services, but not for all OPDs.⁴²

Some state-level mandates, applicable to some or all plans and policies regulated by DMHC or CDI, require coverage for particular drugs. For example, there is a mandate that requires coverage for insulin and prescription drugs for the treatment of diabetes but does not require coverage for drugs that treat diabetes-related conditions.⁴³ However, this mix of laws does not require that all enrollees in plans and policies regulated by DMHC or CDI have an OPD benefit.

Presence or Absence of Coverage for Outpatient Prescription Drugs and Related Regulation

Coverage of OPDs was estimated through surveys and queries. For enrollees in the privately funded markets regulated by DMHC and CDI, coverage was determined by responses to a survey of the six largest providers of health insurance in California. Responses to this survey represent 97% of enrollees in these markets. The California Public Employees' Retirment System (CalPERS) was queried regarding coverage among DMHC regulated plan enrollees associated with CalPERS. The California Department fo Health Care Services (DHCS) was queried about covereage among Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

From this information, CHBRP concluded that most enrollees have coverage for OPDs through their DMHC-regulated plan or CDI-regulated policy. These enrollee's OPD coverage is generally accessed through the enrollee's "pharmacy benefit," and generally used when acquiring drugs at an outpatient pharmacy or mail order service. When OPD coverage is handled through a subcontracting pharmacy benefit management (PBM) organization, the plan or policy, licensed by DMHC or CDI, requires the subcontracting PBM to comply with relevant state-level health insurance benefit mandates.

As coverage for OPDs is not universally required, some enrollees in DMHC-regulated plans and CDIregulated policies have no OPD coverage. Although these enrollee's health insurance cover prescription drugs delivered during a hospital (or other facility) admission and some prescription drugs that are dispensed through a clinician's office, these enrollees' health insurance would not generally help them acquire drugs intended for outpatient use. As noted above, there are some drug specific exceptions, such as insulin, but coverage would be limited to those specific outpatient drugs.

In terms of alternate regulation, some enrollees who have no OPD benefit through their DMHC-regulated plan or CDI-regulated policy still do have an OPD benefit — but have it through another source, one that is not regulated by DMHC or CDI. Such a circumstance can occur if, for example, an employer arranges for a large group plan to exclude coverage for OPDs and then contracts separately with a PBM to administer an OPD benefit. In this example, the PBM is not a subcontractor to a plan or insurer; it is

⁴¹ California Health & Safety Code: 1367.005, 1367.006, 1367.0065; California Insurance Code: 10112.27, 10112.28, 10112.285; Federal Affordable Care Act of 2010: Section 1301, 1302, and Section 1201 modifying Section 2707 of the PHSA

⁴² California Health & Safety Code: 1367.002; California Insurance Code: 10112.2; Federal Affordable Care Act of 2010: Section 1001 modifying Section 2713 of the PHSA

¹³ California Health & Safety Code: 1367.51 and California Insurance Code: 10176.61

directly contracting with the employer. If the contracting PBM is not licensed by either DMHC or CDI, it is not subject to state-level health insurance benefit mandates.

Table D-2: Outpatient Prescription Drug Coverage in the Large Group and Publicly Funded Markets, 2017

]	CDI-Regulated Policies					
	Privately Funded Large Group			Put	licly Funded Pl MCMC	Privately Funded Large Group		
	Grand-fathered	Non-Grand- fathered		CalPERS HMOs (a)	(Under 65) (b)	<i>MCMC</i> (65+) (<i>b</i>)	Grandfathered	Non-Grand- fathered
Enrollee Counts								
Total enrollees in plans/policies subject to state Mandates (c)	2,362,000	6,776,000		861,000	6,331,000	561,000	27,000	282,000
Outpatient Prescription Drug (OPD) Coverage								
DMHC or CDI regulated brand name and generic OPD coverage	94.1%	89.0%		74.4%	100.0%	100.0%	85.0%	94.1%
DMHC or CDI regulated generic only coverage								
No OPD coverage	5.4%	3.2%						2.1%
Other OPD coverage	0.5%	7.8%		25.6%			15.0%	3.8%

Source: California Health Benefits Review Program, 2016.

Notes: (a) As of September 30, 2015, 58% of CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2017.

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

(c) 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.

(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CaIPERS HMOs, Medi-CaI 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.

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; OPD = Ouptpatient Prescription Drug.

Table D-3: Outpatient Prescription Drug Coverage in the Small Group and Individual Markets, 2017

	DMHC-Regulated Plans							CDI-Regulated Policies							
	Privately Funded Small Group			Privately Funded Individual				Privately Funded Small Group			Privately Funded Individual				
	Grand- fathered	Non- Grand- fathered		Grand- fathered	Non-Grand- fathered Outside Market- place (a)	Non- Grand- fathered Covered California		Grand- fathered	Non- Grand- fathered		Grand- fathered	Non-Grand- fathered Outside Market- place (a)	Non- Grand- fathered Covered California		
Enrollee Counts															
Total enrollees in plans/policies subject to state Mandates (b)	440,000	2,365,000		324,000	1,359,000	2,157,000		9,000	722,000		437,000	137,000	5,000		
Outpatient Prescription Drug (OPD) Coverage															
DMHC or CDI regulated brand name and generic OPD coverage	99.9%	99.8%		92.4%	100.0%	100.0%		100.0%	100.0%		38.7%	100.0%	100.0%		
DMHC or CDI regulated generic only coverage											47.8%				
No OPD coverage	0.1%	0.2%		7.6%	0.0%	0.0%		0.0%	0.0%		13.5%	0.0%	0.0%		
Other OPD coverage															

Source: California Health Benefits Review Program, 2016.

Notes: (a) The Affordable Care Act of 2014 (ACA) requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces. In California, the marketplace is called "Covered California."

(b) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CaIPERS HMOs, Medi-CaI 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.

(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).

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; OPD = Ouptpatient Prescription Drug

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CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

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 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, PricewaterhouseCoopers, 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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A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP Faculty Task Force comprises rotating representatives from six University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis.

CHBRP staff coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature.

CHBRP is also grateful for the valuable assistance of its National Advisory Council, who provide expert reviews of draft analyses and offer general guidance on the program. CHBRP is administered by the UC Health at the University of California, Office of the President, led by John D. Stobo, MD, Executive Vice President.

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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