

California Health Benefits Review Program

Analysis of Assembly Bill 1917: Outpatient Prescription Drugs: Cost Sharing

A Report to the 2013–2014 California Legislature

April 25, 2014



Analysis of California Assembly Bill (AB) 1917: Outpatient Prescription Drugs: Cost Sharing

SUMMARY TO THE 2013–14 CALIFORNIA LEGISLATURE • APRIL 25, 2014



AT A GLANCE

AB 1917 (as introduced February 25, 2014) would require nongrandfathered plans and policies, except for cost sharing reduction products (CSRs) sold in Covered California, to limit cost sharing for an outpatient prescription drug to no more than 1/24 of the annual out-of-pocket maximum mandated by the ACA (1/24 of \$6,350 in 2014), or \$265. For enrollees in high deductible health plans (HDHPs), this limit would only apply once the enrollee met their annual deductible. For enrollees in CSRs in Covered California, AB 1917 would require that cost sharing for all covered benefits in a month be limited to 1/24 of the annual out-of-pocket maximum of those products.

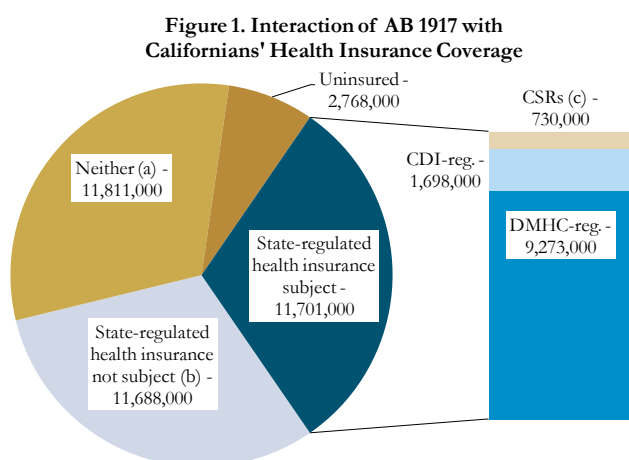
- **Enrollees covered.** CHBRP estimates that in 2015, 11.7 million of 23.4 million Californians with state-regulated health insurance would have coverage that would be subject to AB 1917. Medi-Cal Managed Care Plans are not subject to AB 1917 nor are grandfathered plans and policies.
 - **CSRs.** Enrollees eligible for cost sharing reductions under the ACA have incomes between 100% and 250% of the federal poverty level (FPL) and are enrolled in a silver metal-level qualified health plan (QHP) in Covered California. These products have reduced cost sharing, including a lower annual out-of-pocket maximum. CHBRP estimates there will be 730,000 enrollees in CSRs in California in 2015. The monthly cost-sharing limit on all covered benefits required by AB 1917 would change the benefit design of these products, bringing them out of compliance with Affordable Care Act (ACA) requirements. Therefore, CHBRP cannot estimate the impact of AB 1917 on benefit coverage, utilization, cost, and public health for CSRs.
- **Impact on expenditures.** AB 1917 would increase expenditures in California by an estimated \$106.1 million in the nongrandfathered group and individual market (excluding CSRs).
 - **Premiums.** Increases in per member per month (PMPM) premiums are estimated to range from an average of 0.047% (for DMHC-regulated large-group plans) to an average of 0.661% (for CDI-regulated individual market policies).
 - **Enrollee out-of-pocket expenses.** AB 1917 would shift costs from enrollees to health plans and insurers. Enrollee out-of-pocket expenses would be reduced by an estimated \$21.8 million.
- **Medical effectiveness.** Overall, there is strong evidence that persons who face higher cost sharing reduce use of both essential and nonessential services. For prescription drugs, there is evidence that as cost sharing increases for prescription drugs, including specialty prescription drugs, usage decreases.
- **Benefit coverage.** AB 1917 would apply to all outpatient prescription drugs; however, the mandate is estimated to have the greatest impact on high cost and/or specialty drugs. All enrollees subject to AB 1917 have coverage for outpatient prescription drugs, as broadly defined by AB 1917, and all have some form of cost sharing for these prescription drugs.
- **Utilization.** The limit on cost sharing would increase utilization of high cost and/or specialty drugs, both by enrollees using these prescription drugs premandate as well as by new users who will be using these drugs due to the lower cost sharing levels postmandate. Utilization would increase 2%, and there would be an estimated 947 new users (premandate, 45,410; postmandate, 46,357).
- **Public health.** CHBRP projects no measurable public health impact due to the small percentage of enrollees (0.42%) utilizing high cost and/or specialty prescription drugs with cost sharing that would be lowered as a result of AB 1917. However, CHBRP recognizes that on a case-by-case basis, AB 1917 may yield important health and quality of life improvements and could significantly impact disease progression and outcomes.
- **Essential Health Benefits (EHBs).** State rules related to cost sharing do not meet the definition of state benefit mandates that could exceed EHBs; therefore, AB 1917 would not exceed EHBs and would not require the state to defray the costs of this mandate for enrollees in QHPs.

BILL SUMMARY

AB 1917 would require:

- For a single covered outpatient prescription drug for a supply of up to 30 days, cost sharing cannot exceed 1/24 of the annual out-of-pocket maximum established by the ACA (1/24 of \$6,350 in 2014), or \$265.
- For plans and policies that meet the definition of a high deductible health plan (HDHP), this requirement would only apply once the deductible for the year has been met.
- For enrollees eligible for cost sharing reductions under the ACA, cost sharing in a single month cannot exceed 1/24 of the annual out-of-pocket maximum of the cost sharing reduction product.

State-regulated nongrandfathered group and individual market health insurance is subject to AB 1917. However, Medi-Cal Managed Care Plans are not subject to AB 1917. Therefore, the mandate would affect the health insurance of approximately 11.7 million enrollees (31% of all Californians). See Figure 1.



Source: California Health Benefit Review Program, 2014.

Notes: (a) Neither = Federally regulated health insurance, such as Medicare, veterans, or self-insured plans. (b) State-regulated health insurance not subject = grandfathered plans and policies; Medi-Cal Managed Care Plans. (c) CSRs = cost sharing reduction products sold in Covered California.

CHBRP KEY FINDINGS: INCREMENTAL IMPACT OF AB 1917

Cost Sharing Reduction Products

Enrollees eligible for cost sharing reductions under the ACA are those with incomes between 100% and 250% of the federal poverty level (FPL) who enroll in a silver metal-level qualified health plan (QHP) sold in Covered California. These products have reduced cost sharing, including a lower annual out-of-pocket maximum. These products are referred to as “CSRs” (cost sharing reduction products). CHBRP estimates there will be 730,000 enrollees in CSRs in California in 2015 (see Figure 1).

AB 1917 would place a monthly out-of-pocket limit on cost sharing for all covered benefits for enrollees in

CSRs. This would halve the annual out-of-pocket maximum for these products, increasing their actuarial value – the portion of costs the health insurance carrier pays for covered benefits – bringing the products out of ACA compliance. It is not possible to meet both the requirements of AB 1917 and the requirements of the ACA; therefore, CHBRP cannot estimate the benefit coverage, utilization, cost, and public health impacts for CSRs.

Benefit Coverage, Utilization and Cost

The number of enrollees subject to AB 1917 and included in this analysis is approximately 10,971,000 (excluding enrollees in CSRs). AB 1917 would apply to all outpatient prescription drugs; however, the mandate is estimated to have the greatest impact on high cost and/or specialty drugs.

Benefit coverage: AB 1917 defines an outpatient prescription drug broadly, including all covered prescription drugs self-administered, administered by a licensed health care professional in an outpatient setting, or administered in a non-inpatient clinical setting. All enrollees subject to AB 1917 have coverage for outpatient prescription drugs, as defined by AB 1917, and all have some form of cost sharing for these prescription drugs. AB 1917 mandates changes in cost sharing and does not mandate coverage of specific treatments and services; therefore, CHBRP does not estimate changes in benefit coverage due to AB 1917.

Benefit utilization: The cost sharing limit on outpatient prescription drugs would increase the number of enrollees utilizing these high cost and/or specialty prescription drugs as well as increase the number of prescription drug claims. Premandate, CHBRP estimates 45,410 enrollees would have a prescription drug claim with cost sharing greater than \$265 (1/24 of the annual out-of-pocket maximum), whereas postmandate, an estimated 46,357 enrollees would have a claim with cost sharing that would have exceeded the limit of \$265 premandate. This is an increase of 947 enrollees who will begin using these drugs due to the lower cost sharing levels postmandate. The average number of prescription drug claims in a year for these enrollees would increase 2%.

The reduction in cost sharing for outpatient prescription drugs would result in enrollees facing additional cost sharing for other covered health care services before they reach their annual out-of-pocket maximum. This would decrease these enrollees use of other health care services by an estimated 0.31%.

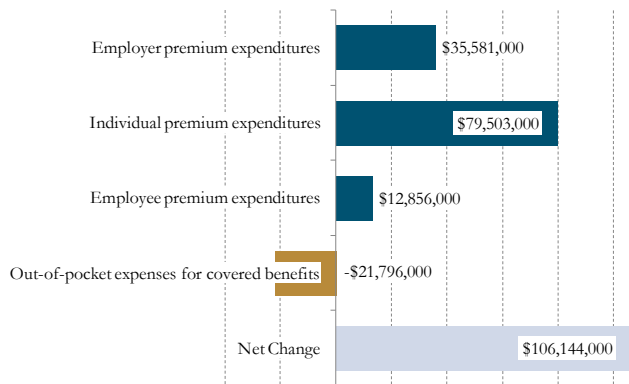
Benefit costs: See Figure 2 for a summary of changes in expenditures postmandate. In addition:

- The average cost sharing per outpatient prescription drug claim premandate is \$325. Average cost sharing

per claim postmandate will be reduced to \$189, a reduction of \$136 (42%).¹

- CalPERS total premiums are estimated to increase by \$7,581,000, or 0.18%.
- Increases in per member per month (PMPM) premiums are estimated to range from an average of 0.047% (for DMHC-regulated large-group plans) to an average of 0.661% (for CDI-regulated individual market policies) in the affected market segments.

Figure 2. Changes in Total and Aggregate Expenditures by Category Postmandate, AB 1917



Medical Effectiveness

Overall, there is strong evidence that persons who face higher cost sharing reduce use of both essential and nonessential services.

Prescription drug cost sharing: There is strong evidence that persons who face higher cost sharing for a prescription drug are less likely to maintain meaningful levels of prescription drug adherence than persons who face lower cost sharing. Furthermore, there is evidence that poorer adherence to prescription drug therapy for chronic conditions is associated with higher rates of hospitalization and emergency department visits and poorer health outcomes.

Specialty prescription drugs: There is a evidence that the effect of cost sharing on use of specialty drugs is similar to the effects for all kinds of prescription drugs — as cost sharing increases, usage decreases. However, there is some evidence that the effect of cost sharing may differ depending on the specific disease and specific specialty drug.

Public Health

Health impacts: CHBRP projects no measurable public health impact due to the small number of enrollees (46,357 of 10.97 million, 0.42%) with a reduction in cost sharing for prescriptions that would have exceeded the \$265 limit premandate. CHBRP

¹ The postmandate amount is lower than the limit of \$265 set by AB 1917 because some enrollees would reach their annual out-of-pocket maximum; these enrollees would have no cost sharing after reaching their annual out-of-pocket maximum.

recognizes that on a case-by-case basis, AB 1917 may yield important health and quality of life improvements for some persons.

Financial burden: To the extent that AB 1917 removes a cost barrier for some enrollees who would then initiate therapy earlier and maintain adherence, the health impact on disease progression and outcomes could be significant on a case-by-case basis.

Long-Term Impacts

Utilization and cost impacts: In the long-term, AB 1917 is likely to accelerate the use of high-cost prescription drugs due to reduced cost sharing and development of new high-cost specialty drugs. AB 1917 is likely to increase overall health expenditures most likely leading to increases in premiums.

Public health impacts: To the extent that cost barriers for high-cost and/or specialty prescription drugs are reduced, there are potentially beneficial long-term health impacts for people with chronic conditions such as multiple sclerosis and rheumatoid arthritis. However, CHBRP is unable to quantify the long-term public health impact of AB 1917 due to uncertainty in the market's response to the downward cost pressure of mandated reductions in enrollee cost sharing and the upward pressure of the increasing number and cost of specialty drugs.

Essential Health Benefits and the Affordable Care Act

AB 1917 modifies the cost sharing for outpatient prescription drugs, and, for enrollees in CSRs, for all covered benefits. As state rules related to cost sharing do not meet the definition of state benefit mandates that could exceed essential health benefits (EHBs), AB 1917 would not exceed EHBs and would not require the state to defray the costs of this mandate for enrollees in QHPs.

CONTEXT FOR BILL CONSIDERATION: COST SHARING AND SPECIALTY PRESCRIPTION DRUGS

What is cost sharing?: Payment for covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Specifically, the *patient* cost-share is the portion that enrollees are responsible for paying out-of-pocket directly to the provider for the health care service or treatment (including prescription drugs) covered by the plan or policy. Common cost-sharing mechanisms include: *deductibles* — a fixed dollar amount (lump sum for one or more services) an enrollee is required to pay out-of-pocket within a given time period (e.g., a year) before the health plan or insurer begins to pay, in part or in whole, for covered benefits; *copayments* — a flat dollar amount for a covered benefit; and *coinsurance* — a percentage of cost for a covered benefit. An *annual out-of-pocket maximum* is a limit on the

enrollee's total cost-sharing (copayments, coinsurance, and deductibles) obligations in a one-year period.

Cost sharing and outpatient prescription drugs:

Prescription drug benefits are a specific type of covered benefit usually subject to cost sharing as part of the medical benefit or a separate outpatient prescription drug benefit. The separate drug benefit designs can be characterized by the number of tiers (up to four) into which drug classes and specific medications are assigned. Each tier has a distinct cost-sharing level and/or form; the lower tiers are less costly to both the enrollee and to the health plan or insurer. Some payers use a four-tier system that includes life-style drugs and specialty drugs in the fourth tier; typically, these are the most costly drugs. The four-tier design frequently results in greater enrollee out-of-pocket expenses, thus the discussion of tiers is particularly relevant to the analysis of AB 1917.

Specialty prescription drugs: There is no standard industry definition of specialty prescription drugs, but it is generally recognized by many payers as prescription drugs with an average minimum monthly cost of \$1,150. Other criteria may include prescription drugs that treat a rare disease, require special handling, or have a limited distribution network.

Most of the conditions targeted by these specialty drugs tend to be chronic and progressive in nature and can impact quality of life, along with morbidity and mortality. Examples include growth hormone disorders, rheumatoid arthritis, asthma, multiple sclerosis, hepatitis C, hemophilia, cancer, and lupus.

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Additional free copies of this and other CHBRP bill analyses and publications may be obtained by visiting the CHBRP website at: www.chbrp.org.



The California Health Benefits Review Program (CHBRP) was established in 2002 to provide the California Legislature independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates and repeals per its authorizing statute.¹ The program was reauthorized in 2006 and again in 2009. CHBRP's authorizing statute defines legislation proposing to mandate or proposing to repeal an existing health insurance benefit as a proposal that would mandate or repeal a requirement that a health care service plan or health insurer: (1) permit covered enrollees to obtain health care treatment or services from a particular type of health care provider; (2) offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition; (3) offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service; and/or (4) specify terms (limits, timeframes, copayments, deductibles, coinsurance, etc.) for any of the other categories.

An analytic staff in the University of California's Office of the President supports a task force of faculty and staff from several campuses of the University of California to complete each analysis within a 60-day period, usually before the Legislature begins formal consideration of a mandate or repeal bill. A certified, independent actuary helps estimate the financial impacts. A strict conflict-of-interest policy ensures that the analyses are undertaken without financial or other interests that could bias the results. A National Advisory Council, drawn from experts from outside the state of California, provides balanced representation among groups with an interest in health insurance benefit mandates or repeals to review draft analyses to ensure their quality before they are submitted to the Legislature. Each report summarizes scientific evidence relevant to the proposed mandate, or proposed mandate repeal, but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work through an annual assessment on health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available on the CHBRP website, www.chbrp.org.

¹ Available at: www.chbrp.org/documents/authorizing_statute.pdf.

PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 1917. In response to a request from the California Assembly Committee on Health on February 25, 2014, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute, which established CHBRP to provide independent and impartial analysis of proposed health insurance benefit mandates and repeals.

Edward Yelin, PhD, and Margaret Fix, MPH, of the University of California, San Francisco, prepared the medical effectiveness analysis. Stephen L. Clancy, MLS, AHIP, of the University of California, Irvine, conducted the literature search. Dominique Ritley, MPH, and Ronald Fong, MD, MPH, of the University of California, Davis, prepared the public health impact analysis. Nadereh Pourat, PhD, and AJ Scheitler, MEd, PhD, of the University of California, Los Angeles, prepared the cost impact analysis. Susan Pantely, FSA, MAAA, and Dan Henry, ASA, MAAA, of Milliman, provided actuarial analysis. Debbie Stern, Rxperts, provided technical assistance with the literature review and expert input on the analytic approach. Laura Grossmann, MPH, of CHBRP staff prepared the *Introduction* and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Theodore Ganiats, MD, of the University of California, San Diego, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

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All CHBRP bill analyses and other publications and resources are available on the CHBRP website, www.chbrp.org.

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 1917

The California Assembly Committee on Health requested on February 25, 2014, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 1917: Outpatient prescription drugs: cost sharing. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.²

State benefit mandates apply to a subset of health insurance in California, those regulated by one of California's two health insurance regulators:³ the California Department of Managed Health Care (DMHC)⁴ and the California Department of Insurance (CDI).⁵ In 2015, CHBRP estimates that approximately 23.4 million Californians (60%) will have health insurance that may be subject to any state health benefit mandate law or law effecting the terms and conditions of coverage.⁶ Of the rest of the state's population, a portion will be uninsured (and therefore will have no health insurance subject to any benefit mandate), and another portion will have health insurance subject to other state laws or only to federal laws.

Nongrandfathered group and individual market DMHC-regulated plans and CDI-regulated policies are subject to AB 1917.⁷ However, Medi-Cal Managed Care is not subject to AB 1917. The regulator, DMHC, and the purchaser, the California Department of Health Care Services, have indicated that by referencing "group" plans, AB 1917 would not require compliance from plans enrolling Medi-Cal beneficiaries into Medi-Cal Managed Care.^{8,9} Therefore, the mandate would affect the health insurance of approximately 11.7 million enrollees (31% of all Californians).

² Available at: www.chbrp.org/docs/authorizing_statute.pdf.

³ California has a bifurcated system of regulation for health insurance. The Department of Managed Health Care (DMHC) regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers, which offer benefit coverage to their enrollees through health insurance policies.

⁴ DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code (H&SC) Section 1340.

⁵ CDI licenses "disability insurers." Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code (IC) Section 106(b) or Section 10198.6(a).

⁶ CHBRP's estimates are available at: www.chbrp.org/other_publications/index.php.

⁷ 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 ACA. Plans or policies may lose their 'grandfathered' status if they make certain significant changes that reduce benefits or increase costs to consumers" (www.healthcare.gov/glossary/grandfathered-health-plan/). Grandfathered plans and policies are not subject to AB 1917; only nongrandfathered plans and policies are subject to AB 1917.

⁸ Personal communication, S. Lowenstein, DMHC, January 2014.

⁹ Personal communication, C. Robinson, Department of Health Care Services, citing Sec. 2791 of the federal Public Health Service Act, January 2014.

Specialized health care service plans and specialized health insurance policies are also subject to AB 1917.¹⁰ Enrollees in these plans and policies are not included in the above estimates of enrollees subject to AB 1917.

Developing Estimates for 2015 and the Effects of the Affordable Care Act

The Affordable Care Act (ACA)¹¹ is substantially affecting health insurance and its regulatory environment in California. It is important to note that CHBRP's analysis of proposed benefit mandate bills typically address the incremental effects of the proposed bills — 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 this report. In order to accommodate continuing changes in health insurance enrollment, CHBRP is relying on projections from the California Simulation of Insurance Markets (CalSIM) model¹² to help estimate baseline enrollment for 2015. From this projected baseline, CHBRP estimates the incremental impact of proposed benefit mandates that could be in effect after January 2015.

Bill-Specific Analysis of AB 1917

AB 1917 would require that:

- For a single covered outpatient prescription drug for a supply of up to 30 days, cost sharing cannot exceed 1/24 of the annual out-of-pocket maximum established by the ACA and codified in California statute.¹³
 - For DMHC-regulated plans and CDI-regulated policies that meet the definition of a high deductible health plan (HDHP), this requirement would only apply once the deductible for the year has been met.
- For enrollees eligible for cost sharing reductions under the ACA, cost sharing in a single month not exceed 1/24 of the annual out-of-pocket maximum of the cost sharing reduction product.

Cost sharing reductions: Enrollees eligible for cost sharing reductions under the ACA are enrollees with incomes between 100% and 250% of the federal poverty level (FPL) who enroll in a silver metal-level¹⁴ QHP in Covered California.¹⁵ These products have reduced cost sharing,

¹⁰ Specialized health care service plans and specialized health insurance policies include chiropractic-only, vision-only, dental-only, and behavioral health-only insurance plans and policies.

¹¹ The federal “Patient Protection and Affordable Care Act” (P.L.111-148) and the “Health Care and Education Reconciliation Act” (P.L. 111-152) were enacted in March 2010. Together, these laws are referred to as the Affordable Care Act (ACA).

¹² CalSIM was developed jointly and is operated by the University of California, Los Angeles Center for Health Policy Research and the University of California, Berkeley Center for Labor Research. The model estimates the impact of provisions in the ACA on employer decisions to offer, and individual decisions to obtain, health insurance.

¹³ ACA Section 1302(c); H&SC Section 1367.006; and IC Section 19112.28.

¹⁴ Section 1302(d) of the ACA requires coverage within specified levels of coverage, or “precious metal” levels: bronze; silver; gold; and platinum. These precious metal levels correspond to an actuarial value for the plan or policy based on the cost-sharing features, not the benefits covered. The actuarial levels are as follows: 60% actuarial

including a lower annual out-of-pocket maximum. This report refers to these products as “CSRs” (cost sharing reduction products).

Cost sharing: Cost sharing would include copayments, coinsurance, and deductibles.

Prescription drug coverage: AB 1917 *does not* require DMHC-regulated plans or CDI-regulated policies to cover outpatient prescription drugs, nor does it require coverage of specific drugs or require changes be made to drug formularies. AB 1917 *does* use a broad definition of outpatient prescription drugs, which includes all covered prescription drugs self-administered, administered by a licensed health care professional in an outpatient setting, or administered in a non-inpatient clinical setting.

The cost-sharing limits required by AB 1917

Limit on outpatient prescription drugs. The ACA requires an annual out-of-pocket maximum for all nongrandfathered group and individual market plans and policies.^{16,17} The annual out-of-pocket maximum for 2015 has not been set yet; therefore, this report reflects estimates based on the annual out-of-pocket maximum in effect in 2014. In 2014, the annual out-of-pocket maximum is \$6,350 for self-only coverage and \$12,700 for family coverage.

For enrollees in nongrandfathered group and individual market plans and policies, excluding enrollees in CSRs, AB 1917 would require cost sharing for a single covered outpatient prescription drug for up to a 30-day supply not exceed \$265 (1/24 of the annual out-of-pocket maximum of \$6,350).¹⁸

Limit for enrollees in CSRs. AB 1917 would require enrollees in CSRs in Covered California “...not be required to pay in a single month more than 1/24 of the annual out-of-pocket limit for the cost sharing reduction product.” This provision of AB 1917:

1. References the annual out-of-pocket maximum for CSRs that, as a result of the reduced cost sharing for these products, is lower than the annual out-of-pocket maximum allowed for other nongrandfathered plans and policies under the ACA; and

value for bronze-level plans; 70% actuarial value for silver-level plans; 80% actuarial value for gold-level plans; and 90% actuarial value for platinum-level plans.

¹⁵ ACA Section 1402.

¹⁶ ACA Section 1302(c). ACA Section 1302(c) references Section 223(c)(2)(A)(ii) of the Internal Revenue Code of 1986, which defines maximum annual out-of-pocket expenses for high deductible health plans (HDHPs). Section 223(c)(2)(A)(ii) sets a baseline maximum annual out-of-pocket expense for HDHPs of \$5,000 for self-only coverage and \$10,000 for family coverage, but these dollar amounts are altered annually by a cost-of-living adjustment [Section 223(g) of the Internal Revenue Code]. Further, as established in Section 1302(c) of the ACA, for plan and policy years beginning after 2014, the limitation is that just described increased by a premium adjustment percentage, which is defined as “the percentage (if any) by which the average per capita premium for health insurance coverage in the United States for the preceding calendar year (as estimated by the Secretary no later than October 1 of such preceding calendar year) exceeds such average per capita premium for 2013 (as determined by the Secretary).”

¹⁷ The annual out-of-pocket maximum is inclusive of copayments, coinsurance, deductibles, and any other form of cost sharing, but not premiums. Cost sharing is generally understood to not include premiums, and premium payments would not accrue towards the annual out-of-pocket maximum.

¹⁸ This report assumes that, because a prescription drug is prescribed for one enrollee, the cost sharing limit is 1/24 of the annual out-of-pocket maximum for self-only coverage, not family coverage.

2. Limits what is paid in a month to 1/24 of the annual out-of-pocket maximum for all covered benefits, not just for an outpatient prescription drug.¹⁹

AB 1917's monthly limit on cost sharing for enrollees in CSRs would halve the annual out-of-pocket maximum for these products (see Table a). This would change the actuarial value of the products — the portion of costs the health insurance carrier pays for covered benefits — increasing the percentage of costs for which the health insurance carrier is responsible and decreasing the percentage of costs for which the enrollee is responsible.

The ACA sets the actuarial values of CSR products.²⁰ The halving of the annual out-of-pocket maximum for CSRs would increase the actuarial value of the products, bringing them out of compliance with the actuarial value requirements set by the ACA.

Table a summarizes the provisions of AB 1917 and the cost-sharing limits AB 1917 would require.

¹⁹ The language for this provision of the bill uses the term “pay” rather than “cost sharing.” However, as only cost sharing (e.g., copayments, coinsurance, deductibles) accrue to an enrollee’s annual out-of-pocket maximum, CHBRP assumes that it is cost sharing that is being limited and that the monthly cost of premiums are not included in the monthly limit of AB 1917.

²⁰ ACA Section 1402(c)(2).

Table a. AB 1917's Three Provisions and the Cost Sharing Limits

Product (a)	AB 1917 Provision	Cost Sharing Limit by Provision
Non-HDHP	Cost sharing cannot exceed 1/24 of the annual OOP max for a <i>single outpatient prescription drug</i> for up to a 30-day supply	<ul style="list-style-type: none"> • Annual OOP max (2014) = \$6,350 (self-only) (b) • 1/24 of annual OOP max = \$265 limit for an outpatient prescription drug for up to a 30-day supply
HDHP	<u>After an enrollee's deductible is met</u> , cost sharing cannot exceed 1/24 of the annual OOP max for a <i>single outpatient prescription drug</i> for up to a 30-day supply	<ul style="list-style-type: none"> • Annual OOP max (2014) = \$6,350 (self-only) (b) • 1/24 of annual OOP max = \$265 limit for an outpatient prescription drug for up to a 30-day supply, <u>after deductible is met</u>
CSRs (c)	Cost sharing in a single month cannot exceed 1/24 of the annual OOP max for a CSR product in Covered California <i>for all covered benefits</i>	<p>Enrollees with incomes between 100% and 200% FPL:</p> <ul style="list-style-type: none"> • Annual OOP max (2014) = \$2,250 self-only/\$4,500 family • 1/24 of annual OOP max = \$93.75 self-only/\$187.50 family monthly cost-sharing limit • AB 1917 halves the ACA annual OOP max — \$1,125 self-only/\$2,250 family — <u>bringing the products out of compliance with the actuarial value requirements set by the ACA</u> (d) <hr/> <p>Enrollees with incomes between 200% and 250% FPL:</p> <ul style="list-style-type: none"> • Annual OOP max (2014) = \$5,200 self-only/\$10,400 family • 1/24 of annual OOP max = \$216.67 self-only/\$433.33 family monthly cost-sharing limit • AB 1917 halves the ACA annual OOP max — \$2,600 self-only/\$5,200 family — <u>bringing the products out of compliance with the actuarial value requirements set by the ACA</u> (d)

Source: California Health Benefits Review Program, 2014.

Notes: (a) These are all nongrandfathered plans and policies; only nongrandfathered group and individual market plans and policies are subject to AB 1917.

(b) As a single prescription drug is prescribed for one enrollee, CHBRP assumes the cost-sharing limit is 1/24 of the annual out-of-pocket maximum for self-only coverage, not family coverage.

(c) A CSR product is a silver metal-level qualified health plan sold in Covered California to enrollees with incomes between 100% and 250% FPL. These products have reduced cost sharing, including a lower annual out-of-pocket maximum.

(d) AB 1917 would limit the amount an enrollee could pay in a month for all covered benefits to 1/24 of the annual out-of-pocket maximum. This halves the products' annual out-of-pocket maximum. For example, \$93.75 × 12 months = \$1,125, which is half of the set annual out-of-pocket maximum of \$2,250.

Key: CSRs=cost sharing reduction products; FPL=federal poverty level; HDHP=high deductible health plan; max=maximum; OOP=out-of-pocket.

Outpatient prescription drugs

AB 1917 defines outpatient prescription drugs as any covered outpatient prescription drug not administered in an inpatient setting, and would therefore include prescription drugs covered under both the outpatient prescription drug benefit and the medical benefit (e.g., injectable

drugs). The definition of outpatient prescription drugs in AB 1917 is broader than that currently defined in the California Code of Regulations and used by both DMHC and CDI.²¹ Were AB 1917 to be enacted, plans and policies in both regulated markets would be subject to the broader definition included in AB 1917 when meeting the requirements of the mandate.

Analytic Approach and Key Assumptions

AB 1917 would affect the terms and conditions of coverage; it does not mandate coverage of specific treatments or services. Therefore, CHBRP's analysis regarding medical effectiveness, cost, and public health impacts have all been adjusted to address the cost sharing requirements relevant to this bill.

CSRs

AB 1917 would limit the amount an enrollee could pay out-of-pocket in a month for all covered benefits to 1/24 of the annual out-of-pocket maximum of the CSR product, thus halving the yearly annual out-of-pocket maximum (see Table a). This would increase the actuarial value of the product, bringing it out of compliance with the actuarial value requirements set by the ACA.

Were AB 1917 to be enacted, CSRs would need to comply both with the cost sharing requirements of AB 1917 and with the actuarial value requirements of the ACA. Federal regulations require that first the annual out-of-pocket maximum is adjusted to meet actuarial value requirements.²² However, the annual out-of-pocket maximums for CSRs are set by CMS (see the annual out-of-pocket maximums in Table a) and thus cannot be adjusted upwards to bring the products into compliance with the actuarial value requirements.

It is not possible to meet both the requirements of AB 1917 and the requirements of the ACA. AB 1917 renders the CSR products out of ACA compliance; therefore, the impact of AB 1917 on benefit coverage, utilization, cost, and public health for CSRs cannot be estimated.

Specialized health care service plans and specialized health insurance policies

AB 1917 would apply to specialized health care service plans and policies (specialized health plans and policies). Specialized health plans and policies include chiropractic-only, vision-only, dental-only, and behavioral health-only plans and policies. Often these types of plans and policies are exempted from benefit mandates. Prescription drug coverage in some specialized health plans and policies may be minimal, whereas others, such as behavioral-health only plans and policies, may have more extensive coverage of prescriptions drugs for which enrollee cost sharing could exceed the limit AB 1917 would place on a covered outpatient prescription drug. The scope of enrollee coverage and outpatient prescription drug coverage in specialized health plans and policies in 2015 is not known to CHBRP; therefore, the benefit coverage, utilization, cost, and public health impacts on these products is not analyzed.

²¹ The California Code of Regulations defines outpatient prescription drugs as “self-administered drugs approved by the FDA for sale to the public through retail or mail-order pharmacies that require prescriptions and are not provided for use on an inpatient basis.” California Code of Regulations, Section 1300.67.24(a)(1).

²² Department of Health and Human Services. Actuarial Value and Cost-Sharing Reductions Bulletin. February 24, 2012. Available at: www.pnhp.org/news/2012/february/cms-on-actuarial-value-and-cost-sharing-reductions.

Interaction With Other California Requirements

Affordable Care Act requirements codified in California statute

Nongrandfathered small-group and individual market plans and policies are required to cover essential health benefits (EHBs); 1 of the 10 categories of EHBs is prescription drugs.²³ In addition, as previously discussed, the ACA places an annual out-of-pocket maximum on EHBs for all nongrandfathered group and individual market plans and policies,²⁴ and enrollees with incomes between 100% and 250% FPL in silver metal-level QHPs in Covered California (e.g., CSRs) receive cost sharing reductions.²⁵

Orally administered anticancer medications

In 2013, AB 219 (Perea) Health care coverage: cancer treatment was enacted, taking effect in 2015.²⁶ AB 219 will limit cost sharing for prescribed, orally administered anticancer medications to no more than \$200 for up to a 30-day supply. This report assumes, as a result of the passage of AB 219, that cost sharing for these prescription drugs would not be impacted by the provisions of AB 1917.

Additional DMHC and CDI prescription drug coverage requirements

In addition to AB 219, DMHC-regulated plans are subject to specific limitations regarding prescription drug cost sharing,²⁷ including:

- Copayments, deductibles, and other limitations cannot render the benefit illusory.²⁸
- The copayment cannot exceed the retail price of the drug.
- A copayment or coinsurance shall not exceed 50% of the “cost to the plan.”²⁹
- If a plan uses coinsurance, it must either: (1) have a maximum dollar amount cap on the coinsurance that will be charged for a single prescription; (2) have the coinsurance apply towards an annual out-of-pocket maximum for the plan; or (3) have the coinsurance apply towards an annual out-of-pocket maximum for the prescription drug benefit.

CDI limits expenses paid by the insured, requiring all policies to be economically sound.³⁰ Individual policies must provide “real economic value” to the insured.³¹

²³ ACA Section 1302; H&SC Section 1367.005; and IC Section 10112.27.

²⁴ ACA Section 1302(c); H&SC Section 1367.006; and IC Section 10112.28.

²⁵ ACA Section 1402.

²⁶ H&SC Section 1367.656; IC Section 10123.206.

²⁷ California Code of Regulations, Section 1300.67.24.

²⁸ H&SC Section 1367; California Code of Regulations Title 28, Section 1300.67.4.

²⁹ The “cost to the plan” means the actual cost incurred by the plan or its contracting pharmacy benefit manager.

³⁰ IC Section 10291.5(a)(1).

³¹ IC Section 10291.5(b)(7)(A) and 10270.95.

Requirements in Other States

Some states have recently passed or are considering legislation aimed at addressing the high cost sharing some enrollees may have for prescription drugs. Most recently, Delaware enacted legislation that required copayments or coinsurance on a specialty tier drug not exceed \$100 per month for up to a 30-day supply of any single drug nor exceed, in the aggregate for specialty tier covered drugs, \$200 per month per enrollee. In Virginia, a bill was introduced at the end of last year (2013) that would require copayments or coinsurance not exceed \$150 per month for a prescription drug covered in a specialty drug tier for to a 30-day supply of any single drug. In addition, in Indiana, a bill was introduced this year (2014) that would, among other requirements, not allow copayments or coinsurance to exceed \$200 for a 1-month supply of a single prescription drug or \$500 for a 1-month supply of more than one prescription drug.

Background on Cost Sharing and Specialty Prescription Drugs

CHBRP presents the following background information about two concepts important to the analysis of AB 1917: cost sharing and the role of specialty prescription drugs. This information is general in nature and provides context for the consideration of this bill.

What Is Cost Sharing?

Payment for covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Specifically, the *patient* cost-share is the portion that enrollees are responsible for paying out-of-pocket directly to the provider for the health care service or treatment (including prescription drugs) covered by the plan or policy. Noncovered services or treatments are always paid in full by the enrollee.

Common cost-sharing mechanisms include: *deductibles* — a fixed dollar amount (lump sum for one or more services) an enrollee is required to pay out-of-pocket within a given time period (e.g., a year) before the health plan or insurer begins to pay, in part or in whole, for covered health care services; *copayments* — a flat dollar amount for a covered benefit; and *coinsurance* — a percentage of cost for a covered benefit. An *annual out-of-pocket maximum* is a limit on the enrollee's total cost-sharing (copayments, coinsurance, and deductibles) obligations in a 1-year period. Once the annual limit is met, the enrollee pays no more cost sharing for the year. Premium payments are not considered part of cost sharing.

Cost sharing and outpatient prescription drug benefits

Prescription drug benefits are a specific type of covered benefit usually subject to cost sharing as part of the medical benefit or a separate outpatient prescription drug benefit. The separate drug benefit designs can be characterized by the number of tiers (up to four) into which drug classes and specific medications are assigned. Each tier has a distinct cost-sharing level and/or form; the lower tiers are less costly to both the enrollee and to the health plan or insurer. Some payers use a three- or four-tier system, which includes life-style drugs and specialty drugs in the fourth tier; typically, these are the most costly drugs. *The four-tier design frequently results in greater enrollee out-of-pocket expenses, thus the discussion of tiers is particularly relevant to the analysis of AB 1917, which would limit cost sharing for an outpatient prescription drug to \$265 (1/24 of the annual out-of-pocket maximum) for up to a 30-day supply.*

Specialty Prescription Drugs

There is no standard industry definition of specialty prescription drugs, but it is generally recognized by many payers as prescription drugs with an average minimum monthly cost of \$1,150. Other criteria may include prescription drugs that treat a rare disease, require special handling, or have a limited distribution network.

The number and cost of specialty prescription drugs continues to increase and payers are managing these high-cost drugs with different cost-sharing methods. For example, a 2011 national survey reported that 49% of plans place specialty drugs in tier 4 and 51% distribute specialty drugs among tiers 2 and 3 depending on their preferred status. Of the commercial plan respondents, 25% reported an average copayment of \$120 and 72% reported an average coinsurance of 22% for specialty drugs. Specialty drug copayments among all tiers ranged from \$10 to \$250 per prescription and coinsurance ranged from 10% to 50%.

Most of the conditions targeted by these specialty drugs tend to be chronic and progressive in nature and can impact quality of life, along with morbidity and mortality. Examples include growth hormone disorders, rheumatoid arthritis, asthma, multiple sclerosis, hepatitis C, hemophilia, cancer, and lupus.

Medical Effectiveness

CHBRP's medical effectiveness analysis for AB 1917 focuses on the impact of cost sharing on use of prescription drugs and, for those below specific income levels, on use of all health care services, including prescription drugs. CHBRP chose this analytic approach because AB 1917 would not increase the number of Californians who have health insurance coverage for prescription drugs in general, or, for those enrolled in CSRs in Covered California, for all health care services. Instead, AB 1917 would affect the terms and conditions of cost sharing for prescription drug coverage and all health care services. The analysis does not address the effectiveness of specific treatments because AB 1917 would not mandate coverage for any specific treatments, but instead, as indicated, would affect the terms and conditions of coverage.

CHBRP could find no studies of cost sharing that analyzed cost-sharing provisions as specific as those outlined in AB 1917. Instead, CHBRP presents reviews of literature whose findings approximate those in AB 1917. For the first provision, we review studies of the effect of cost sharing on prescription drug use, including specialty drugs; for the second, we review studies of the impact of cost sharing on prescription drugs use among those in HDHPs; and for the third, we review the impact of cost sharing on use of all health care services by low-income enrollees.

The only randomized controlled trial, the RAND Health Insurance Experiment (HIE), was conducted in the 1970s. That study established that cost sharing affects utilization, that the poor and elderly are more affected by cost sharing, and that use of essential and nonessential services are both affected by cost sharing. As discussed further, the results of more recent studies which were not randomized trials are broadly consistent with the results of the RAND HIE.

Study Findings

There is a preponderance of evidence from studies with strong research designs that persons who face higher cost sharing reduce use of both essential and nonessential health care services

Prescription drug cost sharing

- A large number of studies have been published on the effects of cost sharing on the use of prescription drugs by persons with health insurance.
- Studies of the effects of cost sharing on the population to which AB 1917 applies indicate:
 - There is a preponderance of evidence from studies with strong research designs that persons who face higher cost sharing for a prescription drug are less likely to maintain meaningful levels of adherence than persons who face lower cost sharing.
 - There is a preponderance of evidence from studies with moderate research designs that poorer adherence to prescription drug therapy for chronic conditions is associated with higher rates of hospitalization and emergency department visits and poorer health outcomes.
 - There is a preponderance of evidence from studies with moderate research designs that the effect of cost sharing on use of specialty drugs is similar to the effects for all kinds of prescription drugs, that is, as cost sharing increases, usage decreases. However, there is some evidence that the effect of cost sharing may differ depending on the specific disease and specific specialty drug.

Prescription drug cost sharing and high deductible health plans

- Most of the recent literature on the impact of deductibles has addressed HDHPs. Studies of HDHPs have compared persons in these plans to persons enrolled in health maintenance organizations or preferred provider organizations (PPOs).
- Studies of HDHPs in which prescription drugs were subject to the deductible had the following findings:
 - There is ambiguous evidence that persons enrolled in HDHPs were as likely to fill any prescriptions as persons enrolled in PPOs because CHBRP found only one well-designed study.
 - There is ambiguous evidence regarding effects of HDHPs on the number of prescriptions filled because findings vary widely across studies.
 - The preponderance of evidence from two studies with strong designs suggests that persons enrolled in HDHPs are more likely than persons enrolled in PPOs to discontinue use of some classes of prescription drugs for chronic conditions.
 - The preponderance of evidence from two studies with strong designs suggests that persons enrolled in HDHPs are less likely than persons enrolled in PPOs to be adherent to daily prescription drug therapy for some chronic conditions.

Cost sharing among low-income persons

- There is a preponderance of evidence from the RAND HIE and many subsequent observational studies that cost sharing has stronger effects on use of health care services by low-income persons than high-income persons. However, a recent well-done observational study of this issue in Massachusetts after its health reform indicates otherwise.

Benefit Coverage, Utilization, and Cost Impacts

Key Assumptions

CHBRP estimates the impact of AB 1917 on cost sharing for outpatient prescription drugs, but excludes enrollees in CSRs from those estimates. CHBRP does not estimate the impact of limiting cost sharing for all covered benefits for enrollees in CSRs. This exclusion is because the AB 1917 limit on cost sharing for these products would effectively reduce the annual out-of-pocket maximums, increasing the actuarial value of these products. If AB 1917 is enacted, the resulting change would render these products out of compliance with actuarial value requirements set by the ACA.

AB 1917 would apply to all outpatient prescription drugs; however, the mandate is estimated to have the greatest impact on high cost and/or specialty drugs, which most frequently have coinsurance requirements that could exceed the cost-sharing limit of AB 1917. CHBRP assumes that a reduction in cost sharing would lead to an increase in use of these prescription drugs (a price elasticity of 0.1 for private insurers). For CalPERS plans, an increase in use of infertility drugs was estimated (a price elasticity of 0.34).

A reduction in cost sharing for prescription drugs would lead to fewer enrollees reaching their annual out-of-pocket maximums. These enrollees would continue to have cost sharing for other covered health care services. CHBRP assumes a decline in use of other health care services for these enrollees due to the increase in cost sharing.

CHBRP assumes that 88% of large- and small-group plans and policies have a maximum dollar amount cap on cost sharing for a prescription drug that is set lower than \$265 (1/24 of the annual out-of-pocket maximum) for a 30-day supply; 12% do not have a prescription drug cap on cost sharing and could have cost sharing that would exceed the limit AB 1917 would require. In the absence of specific data on plans and policies in the individual market, CHBRP assumes that these plans and policies do not have maximum dollar amount caps on cost sharing for a prescription drug.

Table 1 summarizes the estimated benefit coverage, utilization, and cost impacts of AB 1917.

Coverage Impacts

CHBRP estimates 23,389,000 enrollees are insured in DMHC-regulated plans and CDI-regulated policies in California in 2015, 11,701,000 of which (50%) are subject to AB 1917. Of these enrollees, an estimated 730,000 are enrolled in CSRs in Covered California and are excluded

from the following analysis. Therefore, the number of enrollees subject to AB 1917 and included in this analysis is approximately 10,971,000.

- All enrollees subject to AB 1917 have coverage for outpatient prescription drugs, as defined by AB 1917, and all have some form of cost sharing for these drugs. The number of enrollees with coverage for outpatient prescription drugs will remain the same postmandate.
- Premandate, about 45,410 (0.41%) enrollees are estimated to have a prescription drug claim in a year with cost sharing that would exceed 1/24 of the annual out-of-pocket maximum (\$265) for a 30-day supply.

Utilization Impacts

- If AB 1917 is enacted, cost sharing for prescription drugs cannot exceed 1/24 of the annual out-of-pocket maximum for a 30-day supply, or \$265. Postmandate, an estimated 46,357 enrollees will have a prescription drug claim in a year with cost sharing that would have exceeded \$265 premandate, but no longer would. This is an increase of 947 (2.09%) enrollees who will begin using these drugs due to the lower cost sharing levels postmandate.
- The cost-sharing limit required by AB 1917 will also lead to an increase in the number of prescription drug claims with cost sharing that would have exceeded \$265 for up to a 30-day supply premandate. The increase in filled prescription drugs is from 6.09 premandate to 6.25 postmandate (2.72%).
- The average cost sharing per prescription drug claim premandate is \$324.83. Average cost sharing per prescription drug claim postmandate will be reduced to \$188.92, a reduction of \$135.91 (41.84%).³²
- Enrollees who have reduced cost sharing for prescription drugs due to AB 1917 would continue to have cost sharing for other covered health care services before they reach their annual out-of-pocket maximum. Subsequently, these enrollees would decrease their use of other health care services by an estimated 0.31%. The average cost sharing pre claim for other health care services would increase from \$15.82 to \$17.56 (10.97%).

Cost Impacts

- AB 1917 would increase total net expenditures in 2015 by \$106,114,000, or 0.08%, in the nongrandfathered group and individual market.
- Total premiums for private employers are estimated to increase by \$28,000,000, or 0.05%.

³² The postmandate amount is lower than the limit of \$265 set by AB 1917 because some enrollees would reach their annual out-of-pocket maximum; these enrollees have no cost sharing after reaching their annual out-of-pocket maximum.

- Total premiums for those with individually purchased insurance are estimated to increase by \$79,503,000, or 0.47%.
- CalPERS total premiums are estimated to increase by \$7,581,000, or 0.18%.
- AB 1917 would reduce enrollee out-of-pocket expenses (cost sharing) by an estimated \$21,796,000, or 0.17%.
- Total premiums for enrollees with group and CalPERS coverage are estimated to increase by \$12,856,000, or 0.06%.

Public Health Impacts

- *Health impacts:* CHBRP estimates that 46,357 enrollees, including 947 new users, would fill an additional 13,184³³ high-cost prescription drugs were AB 1917 enacted. However, CHBRP projects no measurable public health impact due to the small number of enrollees (46,357 of 10.97 million, 0.42%) with a reduction in cost sharing for prescriptions that would have exceeded the \$265/prescription limit premandate. CHBRP recognizes that on a case-by-case basis, AB 1917 may yield important health and quality of life improvements for some persons.
- *Financial burden:* In the first year postmandate, CHBRP estimates that AB 1917 would reduce out-of-pocket expenses by \$21.8 million for 46,357 of the 10.97 million enrollees whose cost sharing would no longer exceed the AB 1917 limit of \$265/prescription. This translates to a 42% reduction (\$132/prescription) in the average cost sharing for an enrollee's high-cost prescription drug. To the extent that AB 1917 removes a cost barrier for some enrollees who would then initiate therapy earlier and maintain adherence, the health impact on disease progression and outcomes could be significant on a case-by-case basis.
- *Disparities:* Although there are gender and racial/ethnic disparities in prevalence of certain diseases and conditions, and evidence that, in general, lower cost sharing can improve adherence, CHBRP estimates AB 1917 would have no measureable impact on disparities due to the small number of enrollees with prescriptions that would no longer exceed the cost-sharing limit of \$265/prescription. This magnitude is too small to measure a change in disparities within the California population.

Long-Term Impacts

Cost and Utilization

- In the long-term, AB 1917 is likely to accelerate the use of high-cost prescription drugs due to reduced cost sharing and development of new high-cost specialty drugs.
- AB 1917 is likely to increase overall health expenditures with use of existing and new high-cost prescription drugs. Increases in these expenditures will most likely lead to increases in premiums.

³³ Calculated as pre-/postmandate enrollees (avg. number of prescriptions): $46,357(6.25) - 45,410(6.09) = 13,184$.

Public Health

- *Health impacts:* To the extent that more people have access to high-cost and/or specialty prescription drugs due to reduced cost sharing, there is the potential for beneficial long-term health impacts for those with chronic conditions such as multiple sclerosis and rheumatoid arthritis. However, CHBRP is unable to estimate the long-term public health impact of AB 1917 due to uncertainty in the market's response to the downward cost pressure of mandated reductions in enrollee cost sharing and the upward pressure of the increasing number and cost of specialty drugs.
- *Premature mortality:* AB 1917 may decrease premature death resulting from a variety of conditions treated with high-cost, life-saving, or life-sustaining prescription drugs, but there is a lack of evidence to inform estimates of the marginal effect on all the possible health outcomes of the 46,357 enrollees who would change behavior due to the reduced cost sharing. Therefore, the magnitude of AB 1917's prescription drug cost-sharing limit on premature death is unknown.
- *Economic loss:* Although AB 1917 may affect economic loss resulting from a variety of conditions treated with high-cost prescription drugs, there is a lack of evidence to inform changes in future utilization. Therefore, the impact of AB 1917's prescription drug cost-sharing limit on economic loss is unknown.

Interaction With Essential Health Benefits

AB 1917 modifies the cost sharing for outpatient prescription drugs, and for enrollees in CSRs, for all covered benefits. As state rules related to cost sharing do not meet the definition of state benefit mandates that could exceed EHBs, AB 1917 would not exceed EHBs and would not require the state to defray the costs of this mandate for enrollees in QHPs.

Table 1. AB 1917's Impacts on Benefit Coverage, Utilization, and Cost, 2015

	Premandate	Postmandate	Increase/ Decrease	Change Postmandate
Benefit coverage				
Total enrollees with health insurance subject to state benefit mandates (a)	23,389,000	23,389,000	—	0.00%
Total enrollees with health insurance subject to AB 1917	11,701,000	11,701,000	—	0.00%
Total enrollees with health insurance subject to AB 1917 enrolled in CSRs in Covered California and <u>excluded</u> from the following analysis	730,000	730,000	—	0.00%
Total enrollees with health insurance subject to AB 1917 and included in the following analysis	10,971,000	10,971,000	—	0.00%
Utilization and cost				
Number of enrollees with high cost/specialty prescription drug claims greater than the AB 1917 limit on cost sharing	45,410	0	-45,410	100%
Number of enrollees with prescription drug claims impacted by the AB 1917 limit on cost sharing	45,410	46,357	947	2.09%
Percent of enrollees with prescription drug claims impacted by the AB 1917 limit on cost sharing	0.41%	0.42%	0.01%	2.09%
Average number of prescription drug claims impacted by the AB 1917 limit on cost sharing	6.09	6.25	0.17	2.72%
Average cost sharing per prescription drugs claim impacted by the AB 1917 limit on cost sharing	\$324.83	\$188.92	-\$135.91	-41.84%
Average number of other medical services received by enrollees with at least one prescription drug claim impacted by the AB 1917 limit on cost sharing	147.98	147.52	(0.46)	-0.31%
Average per-claim cost sharing of other medical services exceeding AB 1917 limit on cost sharing	\$15.82	\$17.56	\$1.74	10.97%
Expenditures (b)				
<i>Premium expenditures by payer</i>				
Private employers for group insurance	\$54,590,722,000	\$54,618,722,000	\$28,000,000	0.05%

Table 1. AB 1917's Impacts on Benefit Coverage, Utilization, and Cost, 2015 (Cont'd)

	Premandate	Postmandate	Increase/ Decrease	Change Postmandate
Expenditures (b) (Cont'd)				
CalPERS HMO employer expenditures (c)	\$4,297,494,000	\$4,305,075,000	\$7,581,000	0.18%
Medi-Cal Managed Care Plan expenditures	\$17,504,711,000	\$17,504,711,000	\$0	0.00%
Enrollees for individually purchased insurance	\$16,930,080,000	\$17,009,583,000	\$79,503,000	0.47%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (a) (d)	\$22,232,708,000	\$22,245,564,000	\$12,856,000	0.06%
<i>Enrollee expenses</i>				
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$12,867,143,000	\$12,845,347,000	-\$21,796,000	-0.17%
Total expenditures	\$128,422,858,000	\$128,529,002,000	\$106,144,000	0.08%

Source: California Health Benefits Review Program, 2014.

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

(b) Expenditures do not include estimates for Covered California enrollees in CSRs.

(c) Of the increase in CalPERS employer expenditures, about 57% or \$4,321,000 would be state expenditures for CalPERS members who are state employees or their dependents.

(d) Premium expenditures by enrollees include employee contributions to employer-sponsored health insurance and enrollee contributions for publicly purchased insurance.

Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; CSRs=cost sharing reduction products; DMHC=Department of Managed Health.

INTRODUCTION

The California Assembly Committee on Health requested on February 25, 2014, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 1917: Outpatient prescription drugs: cost sharing. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program’s authorizing statute.³⁴

State benefit mandates apply to a subset of health insurance in California, those regulated by one of California’s two health insurance regulators:³⁵ the California Department of Managed Health Care (DMHC)³⁶ and the California Department of Insurance (CDI).³⁷ In 2015, CHBRP estimates that approximately 23.4 million Californians (60%) will have health insurance that may be subject to any state health benefit mandate law or law effecting the terms and conditions of coverage.³⁸ Of the rest of the state’s population, a portion will be uninsured (and therefore will have no health insurance subject to any benefit mandate), and another portion will have health insurance subject to other state laws or only to federal laws.

Nongrandfathered group and individual market DMHC-regulated plans and CDI-regulated policies are subject to AB 1917.³⁹ However, Medi-Cal Managed Care is not subject to AB 1917. The regulator, DMHC, and the purchaser, the California Department of Health Care Services, have indicated that by referencing “group” plans, AB 1917 would not require compliance from plans enrolling Medi-Cal beneficiaries into Medi-Cal Managed Care.^{40,41} Therefore, the mandate would affect the health insurance of approximately 11.7 million enrollees (31% of all Californians).

³⁴ Available at: www.chbrp.org/docs/authorizing_statute.pdf.

³⁵ California has a bifurcated system of regulation for health insurance. The Department of Managed Health Care (DMHC) regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers, which offer benefit coverage to their enrollees through health insurance policies.

³⁶ DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code (H&SC) Section 1340.

³⁷ CDI licenses “disability insurers.” Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code (IC) Section 106(b) or Section 10198.6(a).

³⁸ CHBRP’s estimates are available at: www.chbrp.org/other_publications/index.php.

³⁹ 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 ACA. Plans or policies may lose their ‘grandfathered’ status if they make certain significant changes that reduce benefits or increase costs to consumers” (www.healthcare.gov/glossary/grandfathered-health-plan/). Grandfathered plans and policies are not subject to AB 1917; only nongrandfathered plans and policies are subject to AB 1917.

⁴⁰ Personal communication, S. Lowenstein, DMHC, January 2014.

⁴¹ Personal communication, C. Robinson, Department of Health Care Services, citing Sec. 2791 of the federal Public Health Service Act, January 2014.

Specialized health care service plans and specialized health insurance policies are also subject to AB 1917.⁴² Enrollees in these plans and policies are not included in the above estimates of enrollees subject to AB 1917.

Developing Estimates for 2015 and the Effects of the Affordable Care Act

The Affordable Care Act (ACA)⁴³ is substantially affecting health insurance and its regulatory environment in California. As of January 2014, an expansion of the Medi-Cal program, California's Medicaid program,⁴⁴ and the availability of subsidized and unsubsidized health insurance purchased through Covered California,⁴⁵ the state's newly established state health insurance marketplace, are significantly increasing the number of people with health insurance in California, and across the United States.

State health insurance marketplaces, such as Covered California, are responsible for certifying and selling qualified health plans (QHPs) in the small-group and individual markets. QHPs sold through Covered California are DMHC-regulated plans or CDI-regulated policies, and as such will be subject to California state benefit mandates.

It is important to note that CHBRP's analysis of proposed benefit mandate bills typically address the incremental effects of the proposed bills — 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 this report. In order to accommodate continuing changes in health insurance enrollment, CHBRP is relying on projections from the California Simulation of Insurance Markets (CalSIM) model⁴⁶ to help estimate baseline enrollment for 2015. From this projected baseline, CHBRP estimates the incremental impact of proposed benefit mandates that could be in effect after January 2015. CHBRP's methods for estimating baseline 2015 enrollment from CalSIM projections are provided in further detail in Appendix D.

Bill-Specific Analysis of AB 1917

Bill Language and Analysis

The full text of AB 1917 can be found in Appendix A.

⁴² Specialized health care service plans and specialized health insurance policies include chiropractic-only, vision-only, dental-only, or behavioral health-only insurance plans and policies.

⁴³ The federal "Patient Protection and Affordable Care Act" (P.L. 111-148) and the "Health Care and Education Reconciliation Act" (P.L. 111-152) were enacted in March 2010. Together, these laws are referred to as the Affordable Care Act (ACA).

⁴⁴ The Medicaid expansion is to 133% of the federal poverty level (FPL) — 138% with a 5% income disregard.

⁴⁵ The California Health Benefits Exchange Authorizing Statute is available here:

www.healthexchange.ca.gov/Documents/California%20Codes%20Governing%20the%20Health%20Benefit%20Exchange.pdf.

⁴⁶ CalSIM was developed jointly and is operated by the University of California, Los Angeles Center for Health Policy Research and the University of California, Berkeley Center for Labor Research. The model estimates the impact of provisions in the ACA on employer decisions to offer, and individual decisions to obtain, health insurance.

AB 1917 would require that:

- For a single covered outpatient prescription drug for a supply of up to 30 days, cost sharing cannot exceed 1/24 of the annual out-of-pocket maximum established by the ACA and codified in California statute.⁴⁷
 - For DMHC-regulated plans and CDI-regulated policies that meet the definition of a high deductible health plan (HDHP), this requirement would only apply once the deductible for the year has been met.
- For enrollees eligible for cost sharing reductions under the ACA, cost sharing in a single month not exceed 1/24 of the annual out-of-pocket maximum of the cost sharing reduction product.

Cost sharing reductions: Enrollees eligible for cost sharing reductions under the ACA are enrollees with incomes between 100% and 250% of the federal poverty level (FPL) who enroll in a silver metal-level⁴⁸ QHP in Covered California.⁴⁹ These products have reduced cost sharing, including a lower annual out-of-pocket maximum. This report refers to these products as “CSRs” (cost sharing reduction products).

Cost sharing: Cost sharing would include copayments, coinsurance, and deductibles. See the section *Background on Prescription Drug Cost Sharing and Specialty Prescription Drugs* for a description of copayments, coinsurance, and deductibles, as well as annual out-of-pocket maximums.

Prescription drug coverage: AB 1917 *does not* require DMHC-regulated plans or CDI-regulated policies to cover outpatient prescription drugs, nor does it require coverage of specific drugs or require changes be made to drug formularies. AB 1917 *does* use a broad definition of outpatient prescription drugs, which includes all covered prescription drugs self-administered, administered by a licensed health care professional in an outpatient setting, or administered in a non-inpatient clinical setting.

The cost-sharing limits required by AB 1917

Limit on outpatient prescription drugs. The ACA requires an annual out-of-pocket maximum for all nongrandfathered group and individual market plans and policies.^{50,51} The annual out-of-

⁴⁷ ACA Section 1302(c); H&SC Section 1367.006; and IC Section 19112.28.

⁴⁸ Section 1302(d) of the ACA requires coverage within specified levels of coverage, or “precious metal” levels: bronze, silver, gold, and platinum. These precious metal levels correspond to an actuarial value for the plan or policy based on the cost sharing features, not the benefits covered. The actuarial levels are as follows: 60% actuarial value for bronze-level plans; 70% actuarial value for silver-level plans; 80% actuarial value for gold-level plans; and 90% actuarial value for platinum-level plans.

⁴⁹ ACA Section 1402.

⁵⁰ ACA Section 1302(c). ACA Section 1302(c) references Section 223(c)(2)(A)(ii) of the Internal Revenue Code of 1986, which defines maximum annual out-of-pocket expenses for high deductible health plans (HDHPs). Section 223(c)(2)(A)(ii) sets a baseline maximum annual out-of-pocket expense for HDHPs of \$5,000 for self-only coverage and \$10,000 for family coverage, but these dollar amounts are altered annually by a cost-of-living adjustment [Section 223(g) of the Internal Revenue Code]. Further, as established by Section 1302(c) of the ACA, for plan and policy years beginning after 2014, the limitation is that just described, increased by a premium adjustment

pocket maximum for 2015, when AB 1917 would go into effect, has not been set yet; therefore, this report reflects estimates based on the annual out-of-pocket maximum in effect in 2014. In 2014, the annual out-of-pocket maximum is \$6,350 for self-only coverage and \$12,700 for family coverage.

For enrollees in nongrandfathered group and individual market plans and policies, excluding enrollees in CSRs, AB 1917 would require cost sharing for a single covered outpatient prescription drug for up to a 30-day supply not exceed \$265 (1/24 of the annual out-of-pocket maximum of \$6,350).

Because a prescription drug is prescribed for one enrollee, CHBRP assumes the cost-sharing limit is 1/24 of the annual out-of-pocket maximum for self-only coverage, not family coverage.

Limit for enrollees in CSRs. AB 1917 would require enrollees in CSRs “...*not be required to pay in a single month more than 1/24 of the annual out-of-pocket limit for the cost sharing reduction product.*” This provision of AB 1917:

1. References the annual out-of-pocket maximum for CSRs that, as a result of the reduced cost sharing for these products, is lower than the annual out-of-pocket maximum allowed for other nongrandfathered plans and policies under the ACA; and
2. Limits what is paid in a month to 1/24 of the annual out-of-pocket maximum for all covered benefits, not just for an outpatient prescription drug.

AB 1917’s monthly limit on cost sharing for enrollees in CSRs would halve the annual out-of-pocket maximum for these products (see Table 2). This would change the actuarial value of the products — the portion of costs the health insurance carrier pays for covered benefits — increasing the percentage of costs for which the health insurance carrier is responsible and decreasing the percentage of costs for which the enrollee is responsible.

The ACA sets the actuarial values of CSR products.⁵² The halving of the annual out-of-pocket maximum for CSRs would increase the actuarial value of the products, bringing them out of compliance with the actuarial value requirements set by the ACA.

percentage, which is defined as “the percentage (if any) by which the average per capita premium for health insurance coverage in the United States for the preceding calendar year (as estimated by the Secretary no later than October 1 of such preceding calendar year) exceeds such average per capita premium for 2013 (as determined by the Secretary).”

⁵¹ The annual out-of-pocket maximum is inclusive of copayments, coinsurance, deductibles, and any other form of cost sharing, but not premiums. Cost sharing is generally understood to not include premiums, and premium payments would not accrue towards the annual out-of-pocket maximum. See the section *Background on Prescription Drug Cost Sharing* for a description of how the annual out-of-pocket maximum interacts with other cost sharing mechanisms.

⁵² As set by the ACA, silver metal level QHPs general have an actuarial value of 70% – the health insurance carrier pays 70% of expected costs for covered benefits. For CSRs, the cost sharing reductions increase the actuarial value of the products. The increase in actuarial value for CSRs, as set by the ACA, is as follows: for enrollees between 100%–150% FPL, the health insurance carrier pays 94% of expected costs for covered benefits; for enrollees between 150%–200% FPL, the health insurance carrier pays 87% of expected costs for covered benefits; and for

Table 2 summarizes the provisions of AB 1917 and the cost-sharing limits AB 1917 would require.

Table 2. AB 1917's Three Provisions and the Cost-Sharing Limits

Product (a)	AB 1917 Provision	Cost Sharing Limit by Provision
Non-HDHP	Cost sharing cannot exceed 1/24 of the annual OOP max for a <i>single outpatient prescription drug</i> for up to a 30-day supply	<ul style="list-style-type: none"> • Annual OOP max (2014) = \$6,350 (self-only) (b) • 1/24 of annual OOP max = \$265 limit for an outpatient prescription drug for up to a 30-day supply
HDHP	<u>After an enrollee's deductible is met</u> , cost sharing cannot exceed 1/24 of the annual OOP max for a <i>single outpatient prescription drug</i> for up to a 30-day supply	<ul style="list-style-type: none"> • Annual OOP max (2014) = \$6,350 (self-only) (b) • 1/24 of annual OOP max = \$265 limit for an outpatient prescription drug for up to a 30-day supply, <u>after deductible is met</u>
CSRs (c)	Cost sharing in a single month cannot exceed 1/24 of the annual OOP max for a CSR product in Covered California <i>for all covered benefits</i>	<p>Enrollees with incomes between 100% and 200% FPL:</p> <ul style="list-style-type: none"> • Annual OOP max (2014) = \$2,250 self-only/\$4,500 family • 1/24 of annual OOP max = \$93.75 self-only/\$187.50 family monthly cost-sharing limit • AB 1917 halves the ACA annual OOP max — \$1,125 self-only/\$2,250 family — <u>bringing the products out of compliance with the actuarial value requirements set by the ACA</u> (d) <hr/> <p>Enrollees with incomes between 200% and 250% FPL:</p> <ul style="list-style-type: none"> • Annual OOP max (2014) = \$5,200 self-only/\$10,400 family • 1/24 of annual OOP max = \$216.67 self-only/\$433.33 family monthly cost-sharing limit • AB 1917 halves the ACA annual OOP max — \$2,600 self-only/\$5,200 family — <u>bringing the products out of compliance with the actuarial value requirements set by the ACA</u> (d)

Source: California Health Benefits Review Program, 2014.

Notes: (a) These are all nongrandfathered plans and policies; only nongrandfathered group and individual market plans and policies are subject to AB 1917.

(b) As a single prescription drug is prescribed for one enrollee, CHBRP assumes the cost-sharing limit is 1/24 of the annual out-of-pocket maximum for self-only coverage, not family coverage.

(c) A CSR product is a silver metal-level qualified health plan sold in Covered California to enrollees with incomes between 100% and 250% FPL. These products have reduced cost sharing, including a lower annual out-of-pocket maximum.

(d) AB 1917 would limit the amount an enrollee could pay in a month for all covered benefits to 1/24 of the annual out-of-pocket maximum. This halves the products' annual out-of-pocket maximum. For example, $\$93.75 \times 12$ months = \$1,125, which is half of the set annual out-of-pocket maximum of \$2,250.

enrollees between 200%–250% FPL, the health insurance carrier pays 73% of expected costs for covered benefits. [ACA Section 1402(c)(2)]

Key: CSRs=cost sharing reduction products; FPL=federal poverty level; HDHP=high deductible health plan; max=maximum; OOP=out-of-pocket.

Outpatient prescription drugs

AB 1917 would include any covered outpatient prescription drug not administered in an inpatient setting, and would therefore include prescription drugs covered under both the outpatient prescription drug benefit and the medical benefit. Most often, prescription drugs covered under the outpatient prescription drug benefit are self-administered and obtained through a retail or mail-order pharmacy. Prescription drugs covered under a medical benefit, such as chemotherapy and other injectable drugs, are often administered by a health professional in a doctor's office, clinic, or other outpatient setting.

The definition of outpatient prescription drugs in AB 1917 is broader than that currently defined in the California Code of Regulations and used by both DMHC and CDI. The California Code of Regulations defines outpatient prescription drugs as “self-administered drugs approved by the FDA for sale to the public through retail or mail-order pharmacies that require prescriptions and are not provided for use on an inpatient basis.”⁵³ “Self-administered” means those drugs that need not be administered in a clinical setting or by a licensed health care provider. Were AB 1917 to be enacted, DMHC-regulated plans and CDI-regulated policies would be subject to the broader definition included in AB 1917 when meeting the requirements of the mandate.

AB 1917: examples

Table 3 shows an example of how AB 1917 could affect cost sharing for a hypothetical specialty prescription drug covered under a plan's or policy's medical benefit. The examples in Table 3 show the effect for all three insured groups identified by AB 1917: non-HDHP plan or policy; HDHP plan or policy; and CSRs.

⁵³ California Code of Regulations, Section 1300.67.24(a)(1).

Table 3. Examples of the Impact of AB 1917 on Cost Sharing for a Specialty Drug Covered Under a Plan’s or Policy’s Medical Benefit That Costs \$3,000 per Prescription for up to a 30-Day Supply

Product (a)	Individual Medical Deductible	Coinsurance on Specialty Drugs (b)	Self-Only Annual OOP Maximum	Premandate	Postmandate	Change After Mandate
Non-HDHP	\$2,000	20%	\$6,350	<u>With medical deductible 100% unmet</u> \$2,000 deductible + 20% of remaining balance of \$1,000 = \$2,200 enrollee pays out-of-pocket	<u>With medical deductible 100% unmet</u> 1/24 of annual OOP limit of \$6,350 = \$265 enrollee pays out-of-pocket	Enrollee pays \$1,935 less
				<u>After medical deductible met</u> 20% of \$3,000 = \$600 enrollee pays out-of-pocket	<u>After medical deductible</u> 1/24 of annual OOP limit of \$6,350 = \$265 enrollee pays out-of-pocket	Enrollee pays \$335 less
HDHP	\$4,500 (overall deductible)	40%	\$6,350	<u>With overall deductible 100% unmet</u> \$3,000 enrollee pays out-of-pocket	<u>With overall deductible 100% unmet</u> \$3,000 enrollee pays out-of-pocket	No change
				<u>After overall deductible met</u> 40% of \$3,000 = \$1,200 enrollee pays out-of-pocket	<u>After overall deductible met</u> 1/24 of annual OOP limit of \$6,350 = \$265 enrollee pays out-of-pocket	Enrollee pays \$935 less
CSR	\$500	15%	\$2,250	<u>With medical deductible 100% unmet</u> \$500 + 15% of remaining balance of \$2,500 = \$875 enrollee pays out-of-pocket	<u>With medical deductible 100% unmet (c)</u> 1/24 of annual OOP limit of \$2,250 = \$93.75 enrollee pays out-of-pocket	Enrollee pays \$781.25 less
				<u>After medical deductible met</u> 15% of \$3,000 = \$450 enrollee pays out-of-pocket	<u>After medical deductible met (c)</u> 1/24 of annual OOP limit of \$2,250 = \$93.75 enrollee pays out-of-pocket	Enrollee pays \$356.25 less

Source: California Health Benefits Review Program, 2014.

Note: (a) The products used in this example are based on the standard benefit designs of individual market plans and policies in Covered California. These are just examples as there is broad range of plan and policy designs that would have varying levels of coinsurance charged for a specialty prescription drug.

(b) These examples assume a specialty drug administered in an outpatient setting that is subject to coinsurance separate from the cost sharing required for the office, clinic, or other outpatient setting visit. Some plans and policies require additional cost sharing on specialty drugs administered in an outpatient setting and others do not; these examples assume the former.

(c) For the CSRs, the limit an enrollee can spend in a month is for all covered benefits. This example assumes that there is not any other cost sharing an enrollee has yet spent in a month. If an enrollee paid cost sharing for covered benefits prior to this prescription drug, the enrollee would only pay out-of-pocket the amount needed to meet the monthly limit of \$93.75.

Key: CSR=cost sharing reduction product; HDHP = high deductible health plan; OOP = out-of-pocket.

Analytic Approach and Key Assumptions

AB 1917 would affect the terms and conditions of coverage; it does not mandate coverage of specific treatments or services. Therefore, CHBRP's analysis regarding medical effectiveness, cost, and public health impacts have all been adjusted to address the cost sharing requirements relevant to this bill.

CSRs

AB 1917 would require enrollees in CSRs “...not be required to pay in a single month more than 1/24 of the annual out-of-pocket limit for the cost sharing reduction product.” The following assumptions and approach are pertinent to CHBRP's analysis of this provision of the bill.

1. All covered benefits: The language for this provision of the bill does not specify outpatient prescription drugs, but instead specifies the limit an enrollee could pay in a month. Therefore, this provision would apply to cost sharing in a month for all covered benefits.

2. Definition of cost sharing: The language for this provision of the bill uses the term “pay” rather than “cost sharing.” However, as only cost sharing (e.g., copayments, coinsurance, deductibles) accrue to an enrollee's annual out-of-pocket maximum, CHBRP assumes that it is cost sharing that is being limited and that the monthly cost of premiums are not included in the monthly limit of AB 1917.

3. Actuarial value: AB 1917 would limit the amount an enrollee could pay out-of-pocket in a month for all covered benefits to 1/24 of the annual out-of-pocket maximum for the CSR product, thus halving the yearly annual out-of-pocket maximum (see Table 2). This would increase the actuarial value of the product, bringing it out of compliance with the actuarial values set by the ACA.

Were AB 1917 to be enacted, the CSR products would need to comply both with the cost sharing requirements of AB 1917 and with the actuarial value requirements of the ACA. Federal regulations require that first the annual out-of-pocket maximum is adjusted to meet actuarial value requirements.⁵⁴ However, the annual out-of-pocket maximums for CSRs are set by CMS (see the annual out-of-pocket maximums in Table 2) and thus cannot be adjusted upwards to bring the plans into compliance with the actuarial value requirements.

It is not possible to meet both the requirements of AB 1917 and the requirements of the ACA. AB 1917 renders the CSR products out of ACA compliance; therefore, the impact of AB 1917 on benefit coverage, utilization, cost, and public health for CSRs cannot be estimated.⁵⁵

The *Medical Effectiveness* section of this report provides a summary of the literature on the impact of cost sharing on low-income enrollees' use of covered benefits. The *Benefit Coverage*,

⁵⁴ Department of Health and Human Services. Actuarial Value and Cost-Sharing Reductions Bulletin. February 24, 2012. Available at: www.pnhp.org/news/2012/february/cms-on-actuarial-value-and-cost-sharing-reductions.

⁵⁵ Table 3 provided an example of how the limit required by AB 1917 for CSRs would affect enrollee cost sharing for a hypothetical specialty prescription drug. However, it was only theoretically, as the impact of AB 1917 on CSRs cannot be estimated.

Utilization, and Cost Impacts section of this report and Table 1 provide estimates of the number of enrollees in CSRs in 2015.

Specialized health care service plans and specialized health insurance policies

AB 1917 would apply to specialized health care service plans and specialized health insurance policies (specialized health plans and policies). Specialized health plans and policies include chiropractic-only, vision-only, dental-only, and behavioral health-only plans and policies. Often these types of plans and policies are exempted from benefit mandates.

As with full-service DMHC-regulated plans and CDI-regulated policies that provide coverage for hospital, medical or surgical benefits (the focus of this report), specialized health plans and policies are regulated by DMHC and CDI. Enrollees in specialized health plans and policies would overlap with enrollees in full-service plans and policies. Enrollees in full-service plans and policies could have coverage through a specialized health plan or policy for vision or dental, for example, which are services generally not covered through a full-service plan or policy. In addition, enrollees in specialized health plans and policies could be in more than one; for example, an enrollee could be enrolled in both a dental-only specialized health plan or policy as well as in a vision-only plan or policy. Enrollment in specialized health plans and policies varies in scope depending on the type of coverage provided. In the fourth quarter of 2013 for DMHC-regulated specialized health plans, more than 300,000 enrollees were in chiropractic-only plans, about 5 million enrollees were in behavioral health-only plans, and over 7 million enrollees were in vision-only plans.

The extent of outpatient prescription drug coverage under these specialized health plans and policies is not known to CHBRP. Although prescription drug coverage in some specialized health plans and policies may be minimal, other plans and policies, such as behavioral health-only plans and policies, may have more extensive coverage of prescription drugs for which enrollee cost sharing could exceed the limit AB 1917 would place on a covered outpatient prescription drug. As the scope of enrollee coverage and outpatient prescription drug coverage in specialized health plans and policies in 2015 is not known to CHBRP, these plans and policies are not further analyzed and are not included in the *Benefit Coverage, Utilization, and Cost Impacts* and the *Public Health Impacts* sections of this report.

Interaction With Other California Requirements

Affordable Care Act requirements codified in California law

Essential health benefits. Nongrandfathered small-group and individual market plans and policies are required to cover essential health benefits (EHBs). One of the 10 categories of EHBs is prescription drugs.⁵⁶

Annual out-of-pocket maximum. As discussed, the ACA places an annual out-of-pocket maximum on EHBs for all nongrandfathered group and individual market plans and policies.⁵⁷

⁵⁶ ACA Section 1302; H&SC Section 1367.005; and IC Section 10112.27.

⁵⁷ ACA Section 1302(c); H&SC Section 1367.006; and IC Section 10112.28.

Cost sharing reductions. As discussed, enrollees with incomes between 100% and 250% FPL in silver metal-level QHPs in Covered California receive cost sharing reductions that increase the actuarial value of the plans.⁵⁸

Preventive services coverage requirement. The ACA requires coverage of specified preventive services without cost sharing, which includes coverage of select prescription drugs.⁵⁹ For prescription drugs required to be covered under the preventive services requirement of the ACA, no cost sharing is required so AB 1917 would have no impact for these prescription drugs.

Orally administered anticancer medications

In 2013, AB 219 (Perea) Health care coverage: cancer treatment was enacted, taking effect in 2015.⁶⁰ AB 219 will limit cost sharing for prescribed, orally administered anticancer medications to no more than \$200 for up to a 30-day supply. Many orally administered anticancer medications are high cost and, prior to AB 219, would have potentially exceeded the cost-sharing limit of AB 1917.⁶¹ Because of the passage of AB 219, this report assumes AB 1917 would have no impact on cost sharing for orally administered anticancer medications.

Additional DMHC and CDI prescription drug coverage requirements

DMHC-regulated plans are subject to specific limitations regarding prescription drug cost sharing.⁶² Copayments, deductibles, and other limitations cannot render the benefit illusory.⁶³ Further cost sharing requirements on outpatient prescription drugs include:

- The copayment cannot exceed the retail price of the drug.
- A copayment or coinsurance shall not exceed 50% of the “cost to the plan.”⁶⁴
- If a plan uses coinsurance, it must either: (1) have a maximum dollar amount cap on the coinsurance that will be charged for a single prescription; (2) have the coinsurance apply towards an annual out-of-pocket maximum for the product; or (3) have the coinsurance apply towards an annual out-of-pocket maximum for the prescription drug benefit.

CDI limits expenses paid by the insured, requiring all policies to be economically sound.⁶⁵ Individual policies must provide “real economic value” to the insured.⁶⁶

Other requirements that might interact with AB 1917 are listed below, with the corresponding Health and Safety Code (H&SC) and Insurance Code (IC) footnoted, where applicable:

⁵⁸ ACA Section 1402.

⁵⁹ ACA Section 1001 modifying Section 2713 of the Public Health Service Act (PHSA); H&SC Section 1367.002; and IC Section 10112.2.

⁶⁰ H&SC Section 1367.656; IC Section 10123.206.

⁶¹ See CHBRP’s report on AB 219 for further information, available at: www.chbrp.org/completed_analyses/index.php.

⁶² California Code of Regulations, Section 1300.67.24.

⁶³ H&SC Section 1367; California Code of Regulations Title 28, Section 1300.67.4.

⁶⁴ The “cost to the plan” means the actual cost incurred by the plan or its contracting pharmacy benefit manager.

⁶⁵ Insurance Code Section, 10291.5(a)(1).

⁶⁶ IC Section 10291.5(b)(7)(A) and 10270.95.

- Off-label use:⁶⁷ Mandate to cover “off-label” uses of FDA-approved drugs — uses other than the specific FDA-approved use — in life-threatening situations and, in cases of chronic and seriously debilitating conditions, when a set of specified provisions regarding evidence are met.
- Coverage of previously covered drugs; medically appropriate alternatives:⁶⁸ Mandate to cover prescription drugs if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan’s prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee’s medical condition.
- Authorization for nonformulary prescription drugs:⁶⁹ Mandate to review coverage for nonformulary drugs. Nonformulary prescription drugs are permitted to have differential cost sharing as long as it complies with regulations governing the limitations on cost sharing for prescription drug benefits.⁷⁰

Requirements in Other States

Some states have recently passed or are considering legislation aimed at addressing the high cost sharing some enrollees may have for prescription drugs.

- In 2010, New York enacted legislation that placed restrictions on cost sharing for prescription drugs, aligning with the ACA.
- In 2012, Maine enacted legislation that places a maximum dollar amount cap on prescription drugs subject to coinsurance.
- In 2013, Delaware enacted legislation that required copayments or coinsurance on a specialty tier drug to not exceed \$100 per month for up to a 30-day supply of any single drug nor exceed, in the aggregate for specialty tier covered drugs, \$200 per month per enrollee.
- In Virginia, a bill was introduced at the end of last year (2013) that would require copayments or coinsurance for a drug covered in a specialty drug tier to not exceed \$150 per month for each specialty drug up to a 30-day supply of any single drug.
- In Indiana, a bill was introduced this year (2014) that would, among other requirements, not allow copayments or coinsurance to exceed \$200 for a 1-month supply of a single prescription drug or \$500 for a 1-month supply of more than one prescription drug.

CHBRP is not aware of specific legislation in another state placing the restriction of no more than 1/24 of the annual out-of-pocket maximum on a single prescription drug for up to a 30-day supply.

⁶⁷ H&SC Section 1367.21 and IC Section 10123.195.

⁶⁸ H&SC Section 1367.22.

⁶⁹ H&SC Section 1367.24.

⁷⁰ H&SC Section 1367.24.

Interaction With the Affordable Care Act

A number of ACA provisions have the potential to or do interact with state benefit mandates. Many aspects of how AB 1917 would interact with the ACA have been discussed. Below is an analysis of how AB 1917 may interact with the requirement for certain health insurance to cover EHBs.⁷¹

Essential Health Benefits

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.⁷² California has selected the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan as its benchmark plan.^{73,74}

The ACA allows a state to require that a QHP offered in a health insurance marketplace, such as Covered California, offer benefits that exceed EHBs.⁷⁵ 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.⁷⁶ However, as laid out in the Final Rule on EHBs HHS released in February 2013,⁷⁷ state benefit mandates enacted on or before December 31, 2011, would be included in a state’s EHBs for 2014 and 2015, 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. State benefit mandates that could exceed EHBs would “be specific to the care, treatment, and services that a state requires issuers to offer to its enrollees,” whereas “state rules related to provider types, cost sharing, or reimbursement methods” would not meet the definition of state benefit mandates that could exceed EHBs. A state’s health insurance marketplace would

⁷¹ Resources on EHBs and other ACA impacts are available on the CHBRP website:

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

⁷² The 10 specified categories of essential health benefits (EHBs) are: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. [ACA Section 1302(b)].

⁷³ 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: http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf. Accessed December 16, 2011.

⁷⁴ H&SC Section 1367.005; IC Section 10112.27.

⁷⁵ ACA Section 1311(d)(3).

⁷⁶ State benefit mandates enacted on or before December 31, 2011, may be included in a state’s EHBs for 2014 and 2015, 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.

⁷⁷ Department of Health and Human Services. 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. 12843. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

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.⁷⁸

AB 1917 and essential health benefits

AB 1917 modifies the cost sharing for outpatient prescription drugs, and, for enrollees in CSRs, for all covered benefits. Because state rules related to cost sharing do not meet the definition of state benefit mandates that could exceed EHBs, AB 1917 would not exceed EHBs and would not require the state to defray the costs of this mandate for enrollees in QHPs.

⁷⁸ Essential Health Benefits. Final Rule.

BACKGROUND ON COST SHARING AND SPECIALTY PRESCRIPTION DRUGS

CHBRP presents the following background information about two concepts important to the analysis of AB 1917: cost sharing and the role of specialty prescription drugs. This information is general in nature and provides context for the consideration of this bill.

What Is Cost Sharing?

Payment for covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Specifically, the *patient* cost-share is the portion that enrollees are responsible for paying out-of-pocket directly to the provider for the health care service or treatment (including prescription drugs) covered by the plan or policy. Noncovered services or treatments are always paid in full by the enrollee, heretofore referred to as “noncovered expenses.” Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium payments). CHBRP refers to these as enrollee out-of-pocket expenses.⁷⁹ Health plans and insurers use many different combinations of cost-sharing mechanisms to help assure medically necessary treatment and control costs.

Common Cost-Sharing Mechanisms

The following steps describe a common interaction of a set of cost-sharing mechanisms. The steps indicated here correspond to Figure 1 below. CHBRP notes that there are numerous cost-sharing combinations, and this example will not apply to all situations.

- **Step 1: Deductibles**

Deductibles are a fixed dollar amount (lump sum for one or more services) an enrollee is required to pay out-of-pocket within a given time period (e.g., a year) before the health plan or insurer begins to pay, in part or in whole, for covered health care services. A plan or policy can have more than one deductible, for example, a general deductible that applies to a specified set of covered medical benefits and another deductible that applies to prescription drugs or hospital admissions. Deductibles can range from \$200 for an outpatient pharmacy benefit to \$2,500 or more for a family medical benefit. Not all plans and policies have deductibles.

- **Step 2: Copayments and/or coinsurance**

Copayments and coinsurance are activated after the deductible has been met, if a plan/policy has a deductible.

Copayment is a form of cost sharing in which an enrollee pays a predetermined, flat dollar amount out-of-pocket at the time of receiving a health care service or when paying for a prescription, such as a \$5 copayment for a generic prescription drug. Copayments

⁷⁹ See CHBRP’s Glossary of Key Terms available at: www.chbrp.org/analysis_methodology/glossary_key_terms.php.

can vary across covered benefits, and a plan or policy may not require any copayments or may only require copayments for some covered benefits.

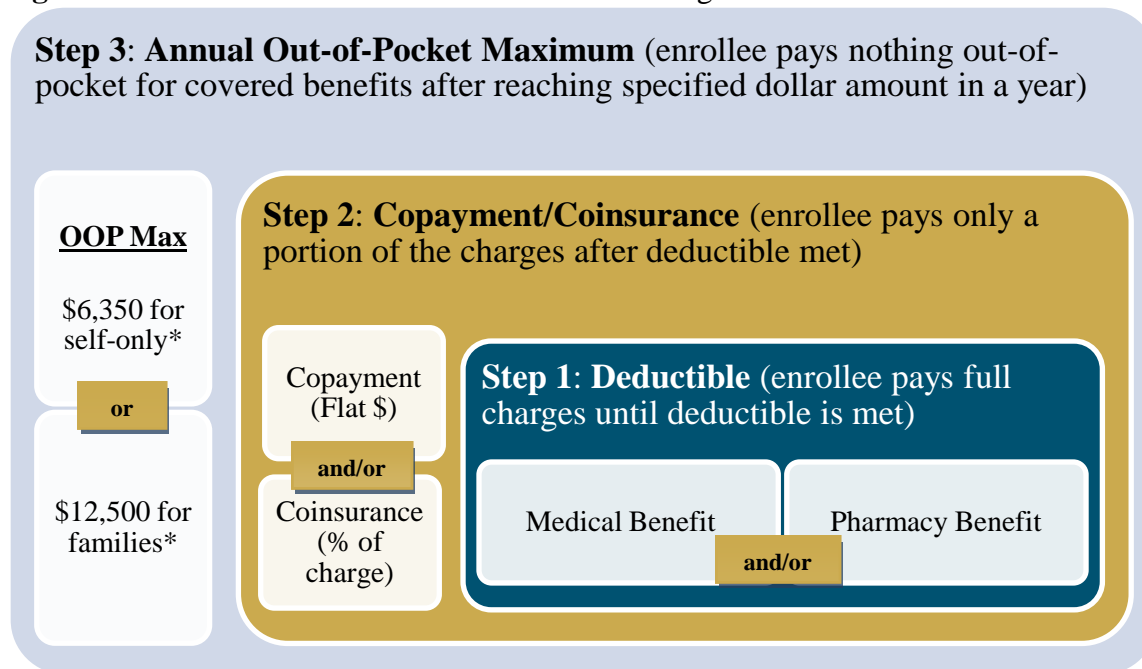
Coinsurance is the percentage of covered health care costs for which an enrollee is responsible, such as 25% of a hospitalization charge. As with copayments, coinsurance percentages can vary across covered benefits, and a plan or policy may not require any coinsurance or may only require coinsurance for some covered benefits.

It is not unusual for a prescription drug benefit plan to use copayments and coinsurance. For example, many times, generics are subject to a copayment, whereas specialty drugs are subject to a coinsurance.

- **Step 3: Annual out-of-pocket maximums**

Annual out-of-pocket maximums are limits on the enrollee’s cost-sharing (copayments, coinsurance, and deductibles) obligations in a 1-year period. Health care services that are not covered by the health plan or insurer would not be included in the maximum; enrollees are responsible for the full charges associated with noncovered services.

Figure 1. Overview of the Intersection of Cost-Sharing Mechanisms Used in Health Insurance



Source: California Health Benefits Review Program, 2014.

Note: * The annual out-of-pocket amounts in this figure are the maximum amounts allowed in 2014; some plans and policies may have lower annual out-of-pocket maximums.

Key: OOP Max=annual out-of-pocket maximum.

Cost Sharing and Outpatient Prescription Drug Benefits

Prescription drug benefits are a specific type of covered benefit usually subject to cost sharing. Outpatient prescription drug coverage can fall within the medical benefit and/or a designated outpatient prescription drug benefit. The designs are complex and vary widely within and between plans and policies. For example, a drug benefit design may require coinsurance on a

prescription drug, but cap the amount paid per 30- or 90-day supply. A health plan or insurer may have lower cost-sharing rates for prescriptions filled at a mail-order pharmacy service instead of a retail pharmacy, or at preferred versus nonpreferred pharmacies. Self-administered injectable drugs may be covered under the medical benefit by some health plans or insurers, and the prescription drug benefit by others. In addition, a health plan or insurer may require copayments for generic or preferred drugs and coinsurance on nonpreferred or specialty drugs (see discussion of prescription drug tiers below).

Outpatient prescription drug tier structures

In general, outpatient prescription drug benefit designs can be characterized by the number of tiers into which the drugs are divided, each tier having a distinct cost-sharing level and/or form. The prescription drugs in the lower tiers are less costly to both the enrollee and to the health plan or insurer. Some health plans or insurers use a four-tier system that generally includes life-style drugs and specialty drugs; typically, these are the most costly drugs. The four-tier design frequently results in greater enrollee out-of-pocket expenses, thus this discussion is particularly relevant to the analysis of AB 1917, which would limit cost sharing to no more than 1/24 of the annual out-of-pocket maximum (\$265).

- One-tier designs have the same cost sharing regardless of drug type.
- Two-tier designs generally have one payment for (1) *generic*⁸⁰ drugs and another for (2) *brand-name* drugs.
- Three-tier designs generally have one payment for (1) generics, and two different payments for brand-name drugs, dividing them into (2) *preferred*,⁸¹ with lower cost sharing, and (3) *nonpreferred*,⁸² with higher cost sharing.
- Four-tier designs generally have the three tiers above, plus a fourth and/or fifth cost-sharing level for specific drugs, such as “lifestyle” drugs (e.g., infertility, erectile dysfunction, weight loss), specialty drugs, or others for which a plan may want to impose differential cost sharing (see Table 5 for examples) (CHCF, 2014; KFF/HRET, 2013).

Overall, it appears that insured Californians have less exposure to high levels of cost sharing for prescription drugs than their counterparts in other states. Table 4 shows the prevalence of different prescription drug benefit structures among employer-sponsored health insurance in California and nationally. The size of workers in tier 4 cost-sharing structures has increased in California from 2% in 2005 to 7% in 2013. Nationally, there was a statistically significant increase in the percent of workers shifting to a four-tier structure between 2005 and 2013 (7% to 23%, respectively) (CHCF, 2014). The majority of the prescription drugs with cost sharing that could exceed the \$265 limit would fall into tier 4.

⁸⁰ A *generic* drug is no longer covered by patent protection and thus may be produced and/or distributed by multiple drug companies.

⁸¹ A *preferred* drug is one included on a formulary or preferred drug list; for example, a brand-name drug without a generic substitute.

⁸² A *nonpreferred* drug is one not included on a formulary or preferred drug list; for example, a brand-name drug with a generic substitute.

Table 4. Distribution of the Types of Prescription Drug Benefit Structures for Health Insurance Products in California and Nationally, 2013

Tiered Prescription Drug Design	California	Unites States
1 Tier	9%	5%
2 Tier	22%	10%
3 Tier	59%	59%
4 Tier	7%	23%
Other	3%	4%

Source: CHCF, 2014.

Average copayment/coinsurance by tier level in California

The California Employer Health Benefits Survey found that the average copayment among California workers in 2013 was \$10.04 for generics, \$25.41 for preferred, and \$41.85 for nonpreferred drugs (CHCF, 2014), meaning that a preferred drug has, on average, 60% the copayment of a nonpreferred drug for California enrollees with an employer-sponsored plan. A national survey found that fourth-tier drug copayments averaged \$80 in 2013, and the average coinsurance was 32% (KFF/HRET, 2013). The national survey also reported that workers in a four-tier system were divided fairly evenly between cost-sharing type, 48% coinsurance and 39% copayment, regardless of plan type (KFF/HRET, 2013).

What Are Specialty Prescription Drugs?

There is no standard industry definition of specialty prescription drugs, but a 2011 national survey of 102 commercial and Medicare/Medicaid plans found that 84% of payers identify cost as this category’s primary characteristic, with an average minimum monthly cost of \$1,154. Other criteria for defining a specialty prescription drug include treating a rare disease, requiring special handling, or having a limited distribution network (EMD Serono, 2012).

The number and cost of specialty prescription drugs continues to increase and payers are managing these high-cost drugs with different cost-sharing methods. For example, in the aforementioned survey, 49% of plans place specialty drugs in tier 4, and 51% distribute specialty drugs among tiers 2 and 3 depending on their preferred status. Of the commercial plan respondents, 25% reported an average copayment of \$120, and 72% reported an average coinsurance of 22% for specialty drugs. Specialty drug copayments among all tiers ranged from \$10 to \$250 per prescription, and coinsurance ranged from 10% to 50%. About 40% of plans used a coinsurance benefit design rather than copayments. In 2011, 71% of plans with coinsurance had a maximum dollar amount cap on cost sharing for a prescription drug with an average cap of \$218 (EMD Serono, 2012).

Examples of Conditions Treated With Specialty Prescription Drugs

The high-cost prescription drugs most likely impacted by AB 1917's limit fall into multiple classes of specialty and biologic drugs used to treat a range of conditions. The EMD Serono survey reported that more than 70% of plan respondents agreed on a list of the top 25 therapy categories classified as specialty drugs (EMD Serono, 2012). Most of the conditions targeted by these specialty drugs tend to be chronic and progressive in nature and can affect quality of life, along with morbidity and mortality. Examples include growth hormone disorders, rheumatoid arthritis, asthma, multiple sclerosis, hepatitis C, hemophilia, cancer, and lupus. Most require chronic medication treatment that can transition to an increased number of medications with disease progression.

Table 5 provides the California prevalence rates of a sample of conditions that might require specialty prescription drugs. Epidemiologists consistently are challenged with estimating prevalence rates for relatively uncommon conditions; CHBRP reports the most recent rates estimated or reported in the literature or by registry (e.g., HIV/AIDS, Hepatitis C, and organ transplants).

Table 5. Examples of Prevalence Rates in California or United States of Conditions Likely to Require Specialty Prescription Drugs for Treatment

Disease or Condition (a)	Prevalence	Data Year	Notes	Average Length of Treatment
Hepatitis C (b)	33,190 reported cases (88.3/100,000) (California)	2011	Est. 3.2 million living with chronic hepatitis C in U.S.; most acute and chronic infections are not reported	12–48 weeks, depending on drug
HIV/AIDS (c)	120,480 living cases (California)	2013	87% male; 43% white; 33% Hispanic; 64% age 30–49 yrs	Ongoing for chronic condition
Infertility (d)	204,000 women 15–44 yrs (California)	2012	Represents 3.8% of infertile CA women using ovulation drugs	Duration of attempts to become pregnant
Multiple sclerosis (e)	85/100,000 (U.S.)	1989–1994	2–3× more common in women; onset between age 20 and 50 yrs	Ongoing for chronic condition
Organ transplant (f)	3,491 (California)	2013	Overall CA patient survival rates range: at 1 yr, 78% to 97% and at 5 yr, 51% to 90% depending on organ	Ongoing following transplant
Rheumatoid arthritis (g)	1.3 million (U.S.)	2005	3× more common in women; onset age 30+ yrs	Ongoing for chronic condition
Systemic lupus erythematosus (h)	107/100,000 (U.S.)	2000	Majority are female; women of color at 2–3× increased risk; onset averages 15–44 yrs	Ongoing for chronic condition

Source: California Health Benefits Review Program, 2014.

Note: (a) California codified a cost-sharing limit of \$200 for oral chemotherapy drugs in 2013; therefore, cancers treated with these prescription drugs are not included in this table because their cost falls below the AB 1917 limit. (H&SC Section 1367.656; IC Section 10123.206).

(b) CDC, 2014; and CDPH, 2013b.

(c) CDPH, Office of AIDS, HIV/AIDS Surveillance Section (CDPH, 2013a).

(d) CHBRP estimates California infertility cases using 2011–2012 CHIS population (insured, California women age 15–44 years) (CHIS, 2011) and weighted utilization of ovulation drugs cited by Chandra et al., 2005.

(e) Noonan et al., 2002. No multiple sclerosis (MS) registry exists, and estimates of prevalence do vary by latitude. Another source reported about 250,000–350,000 U.S. residents are diagnosed with MS ("Multiple Sclerosis: Hope Through Research," NINDS. Publication No. 12-75. June 2012. Available at:

www.ninds.nih.gov/disorders/multiple_sclerosis/detail_multiple_sclerosis.htm).

(f) Health Resources and Services Administration, Organ Procurement and Transplant Network. <http://optn.transplant.hrsa.gov/data/default.asp>.

(g) Helmick et al., 2008; and Arthritis Foundation: Who Gets RA? (2014).

(h) Chakravarty et al., 2007.

MEDICAL EFFECTIVENESS

CHBRP's medical effectiveness analysis for AB 1917 focuses on the impact of cost sharing on use of prescription drugs and, for those below specific income levels, on use of all covered benefits, including prescription drugs. CHBRP chose this analytic approach because AB 1917 would not increase the number of Californians who have insurance coverage for prescription drugs in general, or for those enrolled in cost sharing reduction products (CSRs) in Covered California, coverage for all covered benefits. Instead, AB 1917 would affect the terms and conditions of cost sharing for prescription drug coverage and all covered benefits. The analysis does not address the effectiveness of specific treatments because AB 1917 would not mandate coverage for any specific treatments, but instead, as indicated, would affect the terms and conditions of coverage.

There are three specific provisions in AB 1917 affecting cost sharing. First, AB 1917 would limit cost sharing for outpatient prescription drugs to no more than 1/24 of the annual out-of-pocket maximum for a supply of up to 30 days for all nongrandfathered plans and policies (excluding CSRs). Second, this cost-sharing limit would only apply to high deductible health plans (HDHPs) once the deductible is met. And third, for enrollees in CSRs, AB 1917 would limit cost sharing per month for all covered benefits to no more than 1/24 of the annual out-of-pocket maximum.

Research Approach and Methods

CHBRP presents reviews of literature whose findings approximate those in AB 1917. For the first provision, we review studies of the effect of cost sharing on prescription drug use, including specialty drugs; for the second, we review studies of the impact of cost sharing on prescription drugs use among those in HDHPs; and for the third, we review the impact of cost sharing on use of all health care by low-income enrollees.

Studies of the effects of cost sharing on use of health care services were identified through searches of the Cochrane Library, EconLit, Google Scholar, PubMed, and Web of Science. The search was limited to abstracts of peer-reviewed research studies that were published in English, conducted in the United States, and published from 2010 to present. For studies published prior to 2010, CHBRP relied on a literature search conducted in 2010 for its analysis of AB 310 and in 2011 for its analysis of AB 1800, bills that also concerned the effects of cost sharing.

The review focused on studies conducted in the United States because findings from studies of cost sharing in countries with different types of health care systems may not be generalizable to the US in general and to California in particular. The majority of our analysis relies on three systematic reviews and additional smaller studies on cost sharing.

A total of 18 studies were included in the medical effectiveness review. 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 and Appendix C: Description of Studies on Medical Effectiveness of Cost Sharing.

Methodological Considerations

The most authoritative study on the impact of cost sharing on use of health care services is the RAND Health Insurance Experiment (HIE), a multisite randomized controlled trial (RCT) conducted in the 1970s (Newhouse, 1993). Health insurance in the United States has changed considerably since that time, as has the treatment of many diseases and conditions. A prime example of one such change is the development of specialty drugs, which can cost as much as \$20,000 a year or more. Although the RAND HIE remains the definitive study of the impact of cost sharing, the results may not be as applicable to the current situation as such a study would be if done more recently.

However, newer studies of the impact of cost sharing on use of health care services have not randomized subjects. The lack of randomization means that differences in use of health care services between persons facing higher and lower cost sharing may be due at least in part to factors other than cost sharing. These factors include health behaviors of beneficiaries (e.g., smoking, physical inactivity), severity of illness, income, education, and health care expenses of other family members. The best nonrandomized studies of cost sharing for prescription drugs and cost sharing for all forms of health care services have used rigorous methods to take such factors into account in their analyses. The best studies also examine the effects of changes in people's cost sharing that are beyond their control, such as an employer's decision to replace one type of health plan with another. Others examine changes in cost sharing options within existing health plan offerings, and compare persons who experience a change in cost-sharing to similar persons who do not experience the change (Remler and Greene, 2009; Swartz, 2010).

Most studies use only copayments as a means to assess the impact of cost sharing. However, cost sharing is discussed in different ways in a few studies. In a systematic review, Goldman et al. (2007) groups cost sharing to include any kind of prescription drug plan cost-containment measures, including copayments, tiering, or coinsurance (65 studies), pharmacy benefit caps or monthly prescription limits (11 studies), formulary restrictions (41 studies), and reference pricing (16 studies). Gibson et al. (2010b) created an index based on the average cost-sharing amount (i.e., copayment, coinsurance) per prescription (standardized to a 30-day supply) for brand and generic drugs in each antidiabetic medication to make comparisons. In another study, prescription cost sharing refers to out-of-pocket medication expenses (copayments, coinsurance, and deductibles) that are paid by a participant within an insurance plan (Johnston et al., 2012).

Outcomes Assessed

For the assessment of the impact of cost sharing, CHBRP first presents an overview of studies of the effect of cost sharing. This is followed by a review of studies of the effects of cost sharing on use of prescription drugs with a separate focus on specialty drugs, the subject of the first and second provisions of AB 1917, and on use of all covered services among those eligible for CSRs in Covered California, the subject of the third provision.

Studies of the impact of cost sharing on use of prescription drugs have measured use in a variety of ways. Some studies have examined the probability of filling any prescriptions or the number of prescriptions filled. Other studies have focused on cost sharing for prescription drugs for

chronic conditions that are taken on a daily basis. Some of these studies have evaluated the impact of differences in cost sharing on continuation or discontinuation of drug therapy, a measure of adherence. Others have used information on days of supply to calculate a *medication possession ratio*, a ratio of days of supply to the total number of days between prescription refills in the study period. Persons with a medication ratio above 0.8 are deemed to be adherent to daily drug therapy (e.g., had a sufficient supply of medication dispensed to enable them to take medication on 80% of days in the time period studied). Other studies also use treatment persistence, defined as the duration of time the patient remains on therapy, measured using refill patterns between expected refill dates.

Studies of the impact of cost sharing on all covered benefits by income level have focused on whether impacts on access to and utilization of health care services are greater for those below specific income levels.

CHBRP also identified and reviewed studies that directly examined the impact of cost sharing on health outcomes.

Study Findings

Cost Sharing in General

The RAND HIE found that persons enrolled in fee-for-service health insurance plans that had higher levels of cost sharing were less likely to be hospitalized, had fewer outpatient visits, and filled fewer prescriptions than persons with more generous coverage. Differences in use across cost-sharing levels were similar for all kinds of treatments studied, suggesting that persons did not distinguish between essential and nonessential treatments. Although the RAND HIE found no evidence of adverse effects of cost sharing among persons with average health, there was some evidence that higher cost sharing was associated with poorer health outcomes for low-income persons who were in poor health (Newhouse, 1993).

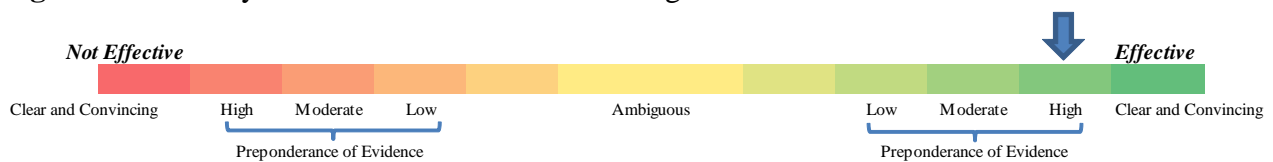
The RAND HIE experiment highlighted the fundamental role of cost sharing on health care utilization: increased cost sharing leads to lower utilization of services. The estimates of the size of this impact (price elasticity) may no longer be applicable today due to the substantial changes in health care and in the health care delivery system. However, the fundamental role of cost sharing on service use remains undisputed to date. Recent studies on the impact of cost sharing on use of high-cost and/or specialty prescription drugs indicate that the effect of cost sharing (the price elasticity) may be lower for some drugs and conditions (e.g., cancer) and higher for others (e.g., rheumatoid arthritis, infertility) (Dusetzina et al., 2014; Ito et al., 2013; Johnston et al., 2012; Kim et al., 2011). The impact of cost sharing can also be affected by the availability of lower-cost substitutes for prescription drugs.

A number of additional studies of the effects of cost sharing have been published since the RAND HIE. Findings from studies of the effects of cost sharing are largely consistent with findings from the RAND HIE (Austvoll-Dahlgren et al., 2008; Baicker and Goldman, 2011; Eaddy et al., 2012; Goldman et al., 2007; Remler and Greene, 2009; Simoens and Sinnaeve, 2013; Sinnott et al., 2013; Swartz, 2010).

The vast majority of studies examine changes in copayments. Persons whose health insurance requires copayments are responsible for the copayment every time a treatment subject to the copayment is provided. By contrast, persons who have a deductible must pay the full cost of treatments subject to the deductible until they reach their deductible. How persons respond to deductibles may differ depending on whether they anticipate meeting their deductible. Persons who do not anticipate that their out-of-pocket costs will exceed their deductible may be less likely to obtain care than persons who face only a copayment. Conversely, cost sharing may not have much of an effect on the use of treatments by persons who expect to exceed their deductible because they know that they will obtain more extensive coverage at that point.

Annual out-of-pocket maximums are limits on the total out-of-pocket expenses (excluding premium payments) associated with covered benefits that an enrollee is responsible for during a plan or policy year, above which health plans or insurers are responsible for all expenses for covered services. These maximums only affect persons whose out-of-pocket expenses exceed the maximum. These persons may be systematically different from the broader population of persons affected by copayments.

Figure 2. Summary of Evidence About Cost Sharing in General



There is a preponderance of evidence from studies of cost sharing for health care services with strong research designs that persons who face higher cost sharing use fewer services than persons with lower cost sharing, and that this effect occurs for both essential and nonessential treatments.

Prescription Drug Cost Sharing in General

CHBRP found no studies that compared the effect of cost sharing that did not exceed 1/24 of the annual out-of-pocket maximum with having higher cost sharing for prescription drugs and other covered benefits. There is insufficient evidence with respect to the impact on the use of prescription drugs of the provision of AB 1917 that would limit cost sharing for a covered outpatient prescription for a supply of up to 30 days to no more than 1/24 of the annual out-of-pocket maximum.

Because CHBRP found no studies on the specific provision in AB 1917, the literature on the effect of cost sharing on use of prescription drugs in general was reviewed. Simoens and Sinnaeve reviewed literature about whether there is an association between copayment and statin adherence and found that the literature supported a statistically significant negative association between copayment and statin adherence, that is, as copayments increased, adherence with statin regimens decreased. Outcomes were measured by probability of filling any prescriptions, the number of prescriptions filled, the medication possession ratio, and the proportion of days covered (Simoens and Sinnaeve, 2014).

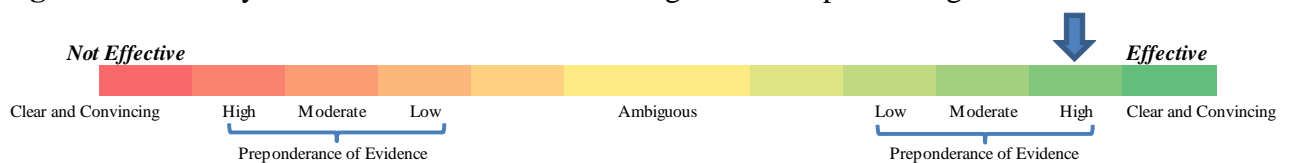
Another literature review, which included data from commercially insured populations, found that 85% of the studies reported, at a statistically significant level, that increased cost sharing was associated with a decrease in adherence.

Eight additional studies showed that increased levels of copayments lead to decreased adherence. (Campbell et al., 2011; Domino et al., 2011; Gibson et al., 2010b; Hoadley et al., 2012; Pesa et al., 2012; Patterson et al., 2011; Sacks et al., 2013; Wong et al., 2013). The study by Gibson et al. (2010b) included any form of cost sharing, including copayments and coinsurance.

Adherence to prescriptions drugs and health outcomes

Of the articles included in the review that investigated the relationship between adherence and outcomes, the majority noted that increased adherence was associated with a statistically significant improvement in outcomes (Eaddy et al., 2012). Poor adherence to prescription drug therapy for chronic conditions reduces the effectiveness of treatment (WHO, 2003). Persons whose chronic conditions are not well controlled have poorer health outcomes and often have more emergency department visits and hospitalizations. A systematic review of studies of adherence to prescription drug therapy for diabetes, high cholesterol, and high blood pressure found that 30 of 41 studies that assessed the impact of adherence on clinical outcomes reported that worse adherence was associated with worse outcomes (Cramer et al., 2008). Outcomes assessed included blood pressure control, heart attack, stroke, and mortality. More recent studies have examined effects on hospitalizations and emergency department visits. One study found that poorer adherence to statins (a medication used to lower cholesterol) is associated with a higher probability of hospitalization (Aubert et al., 2010). Another found that poorer adherence to medications to control blood pressure increased the odds of having an emergency department visit and being hospitalized (Pittman et al., 2010).

Figure 3. Summary of Evidence About Cost Sharing for Prescription Drugs



There is a preponderance of evidence from studies with strong designs that as cost sharing increases, adherence to drug regimens decreases. A majority of studies indicate that increased adherence is associated with improved outcomes.

Effects of cost sharing on use of specialty drugs

CHBRP identified four studies that examined the effects of cost sharing on use of specialty drugs.

The first of these studies analyzed the association between combination antiretroviral therapy (cART) prescription drug cost sharing and adherence⁸³ to initial cART in commercially insured patients with HIV. In the study, prescription drug cost sharing refers to the combination of

⁸³ Persons with a medication ratio above 0.8 are deemed to be adherent to daily drug therapy (e.g., had a sufficient supply of medication dispensed to enable them to take medication on 80% of days in the time period studied).

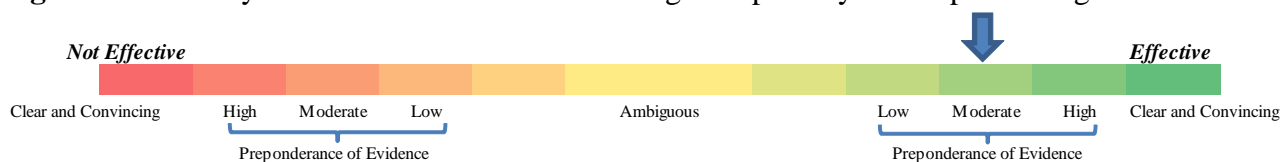
copayments, coinsurance, and deductibles. The authors found that increasing cost-sharing amounts were associated with significantly lower odds of reaching the clinically meaningful adherence thresholds of at least 78% adherence. Mean adherence ranged from 97.2% in patients with low cost-sharing levels (\$0 to \$20 per 30-day cART supply) to 94.0% in patients with high cost-sharing levels (from \$84 to \$3,832 per 30-day cART supply) (Johnston et al., 2012).

Another study looked at cancer treatment among adults with chronic myeloid leukemia who initiated imatinib, a tyrosine kinase inhibitor (TKI). TKIs are considered by some to be the most successful class of targeted therapies developed in cancer for improving survival (Experts in Chronic Myeloid Leukemia, 2013). The authors found that there was a 70% increase in the risk of discontinuing TKIs among patients with higher copayment requirements. Similarly, patients with higher copayments were 42% more likely to be nonadherent. Monthly copayments for imatinib averaged \$108; and ranged from \$0 to \$4,792 (Dusetzina et al., 2014). Another study consistent with these findings also showed that lower cost sharing contributes to a small improvement in quality of life (Ito et al., 2013).

Other studies have shown mixed responses to changes in cost sharing. Researchers looked at long-term users of multiple types of specialty drugs, including anti-inflammatory, immunosuppressant, cancer, and multiple sclerosis medications. For multiple sclerosis drugs, anti-inflammatory drugs, and cancer drugs, when cost sharing was increased patients, did not show a statistically significant change in adherence compared to patients whose copayments stayed the same. However, there was a small, but statistically significant, decrease in adherence for immunosuppressants. The researchers also found that the increased copayments were associated with lower persistence⁸⁴ for immunosuppressants and anti-inflammatory agents. Higher copayments were not associated with a statistically significant change in persistence for cancer or multiple sclerosis agents (Kim et al., 2011).

Several studies suggest that consumer sensitivity to cost sharing depends on a drug’s therapeutic class and that increased cost sharing may decrease “nonessential” drug use more than “essential” drug use (Goldman et al., 2007).

Figure 4. Summary of Evidence About Cost Sharing for Specialty Prescription Drugs



There is a preponderance of evidence from studies with moderate research designs that the effect of cost sharing on use of specialty drugs is similar to the effects for all kinds of prescription drugs, that is, as cost sharing increases, usage decreases. However, there is some evidence that the effect of cost sharing may differ depending on the specific disease and specific specialty drug.

⁸⁴ Treatment persistence, defined as the duration of time the patient remains on therapy, is measured using refill patterns between expected refill dates.

Prescription Drug Cost Sharing for High Deductible Health Plans

CHBRP found no studies that compared the effect of having cost sharing that did not exceed 1/24 of the annual out-of-pocket maximum after the annual deductible has been met with not having such a limit on cost sharing among persons in high deductible health plans (HDHPs).

Although no studies about the specific provision of AB 1917 affecting persons in HDHPs were found, the literature provides some insights into how deductibles affect use of prescription drugs and adherence to recommended drug therapy in such plans and policies.

Effects on filling prescriptions

One study compared samples of persons matched on demographic and health characteristics (the method is called “propensity score matching”) and who were enrolled in multiple HDHPs and preferred provider organizations (PPOs). The study examined the effect of switching from a PPO to a HDHP on the probability of filling any prescriptions. The authors found that persons who enrolled in HDHPs were more likely to fill at least one prescription per year (Waters et al., 2011). An important limitation of this study is that it did not distinguish persons who voluntarily switched from a PPO to a HDHP from persons who were compelled to switch because their employers replaced a PPO with a HDHP and offered no other health insurance options to their employees. Persons who voluntarily switch to a HDHP may be systematically different from persons whose employers make the choice for them (Lo Sasso et al., 2010).

Findings from studies that have assessed the effects of HDHPs on the number of prescriptions filled are ambiguous. The aforementioned study by Waters and colleagues (2011) reported that switching from a PPO to a HDHP was associated with an increase in the number of prescriptions filled. This finding was observed for both essential and nonessential prescription drugs and did not change when the sample was limited to persons who had high expenditures for prescription drugs at baseline or who were predicted to have high expenditures for all health care services during the study period. By contrast, a study that compared persons who received coverage through an employer that replaced two PPO plans with two HDHP plans to persons who were continuously enrolled in a PPO found that the number of prescriptions filled per year decreased among persons whose coverage switched from a PPO to a HDHP (Nair et al., 2009). A cross-sectional study that compared persons enrolled in HDHPs to persons enrolled in PPOs reached the same conclusion (Wilson et al., 2008). However, Parente and colleagues’ (2004) study of persons employed by a single large employer found the opposite effect, that switching from a health maintenance organization (HMO) or PPO to a HDHP was associated with a small increase in the number of prescriptions filled. A study that compared persons who received coverage through two medium-sized employers found no difference in the number of prescriptions filled between persons whose coverage switched from a PPO to a HDHP and persons who were continuously enrolled in a PPO (Borah et al., 2011).

There is ambiguous evidence from studies evaluating the effect of HDHPs on the number of prescriptions filled.

There is insufficient evidence on the effect of HDHPs on filling at least one prescription to draw firm conclusions.

Adherence to prescription drug therapy

Studies of the effects of HDHPs on adherence to prescription drug therapy have focused on persons with chronic conditions. These studies have measured adherence to prescription drug therapy in several different ways. The two most common measures are: (1) rates of discontinuation of prescription drug therapy; and (2) adherence to daily drug therapy for chronic conditions for which there is evidence that daily treatment is effective, such as asthma, high blood pressure, and high cholesterol.

One study (Chen et al., 2010b) compared adherence for eight therapeutic classes of chronic disease medications between persons who received coverage through employers that replaced a PPO with a HDHP and persons who received coverage through employers that continuously offered a PPO. They found no difference in the percentage of persons filling at least one prescription for a drug in any of the eight classes but found that persons whose employers replaced a PPO with a HDHP had fewer days with continuous supplies of drugs for treatment of epilepsy and high cholesterol, and that the difference was statistically significant. A study that examined persons who received coverage through a single employer reported that persons who voluntarily switched from a PPO to a HDHP were more likely than persons who were continuously enrolled in a PPO to discontinue drug therapy for high blood pressure or high cholesterol; this difference was also statistically significant (Greene et al., 2008).

Two studies compared adherence to daily drug therapy for chronic conditions. Chen and colleagues (Chen et al., 2010b) found that persons whose employers replaced a PPO with a HDHP had lower odds than persons continuously enrolled in PPOs of having a medication possession ratio of above 0.8 for daily medications used to treat asthma, cardiac conditions, and high cholesterol. Nair and colleagues (2009) reported that persons whose employer replaced a PPO with a HDHP were less likely than persons continuously enrolled in PPOs to have a medication possession ratio above 0.8 overall and for daily medications for asthma, diabetes, gastroesophageal reflux disease, high blood pressure, and high cholesterol.

One study of persons who received coverage through a single firm measured adherence by asking persons whether they had taken a lower dose of a prescription drug than recommended by their physician. The authors found that persons who voluntarily switched from a PPO to a HDHP were less likely than persons who were continuously enrolled in a PPO to take the recommended dose of a prescription drug (Dixon et al., 2008).

The consistent reductions in adherence to drug therapy for high cholesterol across these three studies may reflect the nature of this condition. High cholesterol does not have any symptoms. A person may have high cholesterol for many years before the condition causes heart disease or a heart attack. By contrast, some of the other chronic conditions studied, such as depression and rheumatoid arthritis, have symptoms that can have substantial effects on a person's ability to engage in work or leisure activities. Persons may be more sensitive to cost sharing for prescription drugs for asymptomatic conditions than for symptomatic conditions.

CHBRP found no studies that compared the effect of cost sharing that did not exceed 1/24 of the annual out-of-pocket maximum after the mandated annual deductible has been met with having no limit on cost sharing for prescription drugs and other covered benefits.

However, there is a preponderance of evidence from studies with strong designs that enrollment in a HDHP is associated with poorer adherence to drug therapy for certain chronic conditions, particularly high cholesterol.

There is ambiguous evidence with respect to the effect of HDHPs on the number of prescriptions filled.

Effect of Cost Sharing Among Low-Income Persons

Prescription drugs

Most of the literature on cost sharing among low-income persons has focused on prescription drug utilization. A meta-analysis of seven studies showed an 11% increased odds of nonadherence to prescription drugs in publicly insured populations when copayments for prescription drugs are required. Medication classes that appeared more than once in the meta-analysis included those for hypertension, hyperlipidemia, and diabetes, all of which are regarded as being essential (Sinnott et al., 2013).

Another study examined the relationship between changes in drug copayments and adherence with medications for the treatment of diabetes mellitus and congestive heart failure (CHF). Patients in low-income areas were more sensitive to copayment changes than patients in high-income areas. The relationship between income and price sensitivity was particularly strong for CHF patients. Above the lowest income category, price responsiveness to copayment rates was not consistently related to income (Chernew et al., 2008). Another study sought to assess the association of copayment status with statin adherence, stratified by socioeconomic status, in a veteran population (Kazerooni et al., 2013). The authors estimated socioeconomic status by using zip code median household income and measured statin adherence by medication possession ratio (MPR) and levels of low-density lipoprotein cholesterol (LDL) <100 mg/dL. Patients in lower and middle-income areas with copayments had significant decreases in adherence compared with those without copayments. They also had lower odds of attaining preferred levels of LDL cholesterol. These effects were not observed among persons in higher income areas. Results of the current study were consistent with the Chernew study (Chernew et al., 2008).

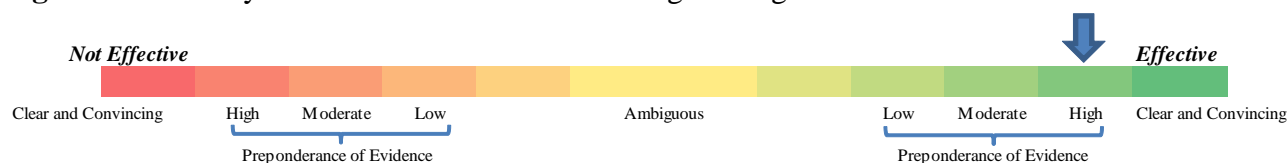
All covered benefits

The RAND HIE examined many medical outcome measures in various subgroups of enrollees. Although there was no compelling evidence that higher cost sharing led to worse health outcomes for the population as a whole, low-income participants who were in poor health appeared more vulnerable to adverse outcomes from higher cost sharing (Baicker and Goldman, 2011; Newhouse, 1993).

A more recent study evaluating the impact of cost sharing after implementation of Massachusetts' health reform found that for all medical services among those eligible for

subsidized premiums for private insurance or Medicaid, a 10% increase in prices faced by patients would reduce overall utilization by 1% to 2%. Those who were chronically ill, and especially those with diabetes, high cholesterol, and asthma, showed a lower price elasticity of demand (Chandra et al., 2014).

Figure 5. Summary of Evidence About Cost Sharing Among Low-Income Persons



A preponderance of evidence from the RAND HIE and subsequent observational studies with strong designs is that cost sharing has stronger effects on use of health care services, including prescription drugs, by low-income persons than high-income persons. However, a recent well-done observational study of this issue in Massachusetts after its health reform indicates otherwise.

Summary of Findings

There is a preponderance of evidence from studies with strong research designs that persons who face higher cost sharing reduce use of both essential and nonessential health care services.

Prescription Drug Cost Sharing

- A large number of studies have been published on the effects of cost sharing on the use of prescription drugs by persons with health insurance.
- Studies of the effects of cost sharing on the population to which AB 1917 applies indicate:
 - There is a preponderance of evidence from studies with strong research designs that persons who face higher cost sharing for a prescription drug are less likely to maintain meaningful levels of adherence than persons who face lower cost sharing.
 - There is a preponderance of evidence from studies with moderate research designs that poorer adherence to prescription drugs therapy for chronic conditions is associated with higher rates of hospitalization and emergency department visits and poorer health outcomes.
 - There is a preponderance of evidence from studies with moderate research designs that the effect of cost sharing on use of specialty drugs is similar to the effects for all kinds of prescription drugs, that is, as cost sharing increases, usage decreases. However, there is some evidence that the effect of cost sharing may differ depending on the specific disease and specific specialty drug.

Prescription Drug Cost Sharing and High Deductible Health Plans

- Most of the recent literature on the impact of deductibles has addressed HDHPs. Studies of HDHPs have compared persons in these plans to persons enrolled in HMOs or PPOs.
- Studies of HDHPs in which prescription drugs were subject to the deductible had the following findings:
 - There is ambiguous evidence that persons enrolled in HDHPs were as likely to fill any prescriptions as persons enrolled in PPOs because CHBRP found only one well-designed study.
 - There is ambiguous evidence regarding effects of HDHPs on the number of prescriptions filled because findings vary widely across studies.
 - The preponderance of evidence from two studies with strong designs suggests that persons enrolled in HDHPs are more likely than persons enrolled in PPOs to discontinue use of some classes of prescription drugs for chronic conditions.
 - The preponderance of evidence from two studies with strong designs suggests that persons enrolled in HDHPs are less likely than persons enrolled in PPOs to be adherent to daily prescription drug therapy for some chronic conditions.

Cost Sharing Among Low-Income Persons

- There is a preponderance of evidence from the RAND HIE and many subsequent observational studies that cost sharing has stronger effects on use of health care services by low-income persons than high-income persons. However, a recent well-done observational study of this issue in Massachusetts after its health reform indicates otherwise.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

AB 1917 applies to nongrandfathered group and individual market DMHC-regulated plans and CDI-regulated policies in California. This includes enrollees in Covered California plans and policies, including enrollees in cost sharing reduction products (CSRs), and enrollees in DMHC-regulated CalPERS plans. Medi-Cal Managed Care Plans are not subject to AB 1917. CHBRP estimates that there are 23,389,000 enrollees in DMHC-regulated plans and CDI-regulated policies in California in 2015, with 11,701,000 enrollees in nongrandfathered group and individual market plans and policies that would be subject to AB 1917.

AB 1917 would limit cost sharing for outpatient prescription drugs to no more than 1/24 of the annual out-of-pocket maximum for a supply of up to 30 days for all nongrandfathered group and individual market DMHC-regulated plans and CDI-regulated policies, excluding CSRs. This cost-sharing limitation would only apply to high deductible health plans (HDHPs) once the deductible is met. For enrollees in CSRs in Covered California, AB 1917 would limit cost sharing per month for all covered benefits to no more than 1/24 of the annual out-of-pocket maximum of the CSR product. Of the 11,701,000 enrollees in nongrandfathered group and individual market plans and policies subject to AB 1917, an estimated 730,000 enrollees are in CSRs in Covered California.

The cost impact of AB 1917 is based on the following key assumptions.

- AB 1917 does not mandate coverage of specific treatments and services or mandate changes to EHBs. The analysis assumes there are no changes in benefit design (such as changes to deductibles, copayments, or coinsurance) other than that cost sharing for an outpatient prescription drug cannot exceed 1/24 of the annual out-of-pocket maximum for a single prescription for a supply of up to 30 days, or that cost sharing per month for all covered benefits cannot exceed 1/24 of the annual out-of-pocket maximum of a CSR product. Alternative compliance approaches would lead to different impacts.
- CHBRP does not estimate the impact of the cost-sharing limit AB 1917 would require for CSRs. This is because the AB 1917 cost-sharing limit for these products would increase their actuarial value. This increase in actuarial value would render these products out of compliance with actuarial value requirements set by the ACA. CHBRP is not able to make these products align with both the requirements of AB 1917 and the actuarial value requirements of the ACA. These issues are discussed in the *Introduction* section of this report.
- AB 1917 does not mandate changes to utilization management tools used by health insurance carriers including formularies, tiered prescription drug cost sharing, mandatory generic substitution, or separate deductibles for prescription drugs. Such changes frequently occur independent of benefit mandates and may also occur due to AB 1917. CHBRP does not estimate the impact of these changes.
- AB 1917 would apply to all covered prescription drugs provided in all outpatient settings, including drugs administered by health professionals that are typically covered under

medical benefits rather than outpatient prescription drug pharmacy benefits. These settings include physicians' offices, outpatient hospital clinics, free standing infusion facilities, enrollees' homes, or other similar settings. Prescription drugs covered under medical benefits are those administered by a professional and are frequently injectables or other high-cost and/or specialty drugs that require close monitoring (Kim et al., 2011; McDonald, 2008). The prescription drugs covered under medical benefits frequently have separate cost-sharing levels from those covered under prescription drug benefits or other medical services such as doctor visits (EMD Serono, 2012).

- AB 1917 would impose cost-sharing limits on all outpatient prescription drugs, including generic, brand name, and specialty drugs. Therefore, CHBRP estimates the impact of this mandate on all outpatient prescription drugs with cost sharing above 1/24 of the annual out-of-pocket maximum for up to a 30-day supply in 2015. However, the prescription drugs most likely affected by this mandate will be the most expensive prescriptions in several classes of specialty and biologic drugs used to treat conditions such as cancer, multiple sclerosis, rheumatoid arthritis, immune disorders, anemia, HIV, and infertility. CHBRP uses available data and literature for these classes of prescription drugs for estimates of the impact of AB 1917 on utilization and costs, when appropriate.
- In 2013, AB 219 passed, limiting cost sharing for prescribed, orally administered anticancer medications to no more than \$200 for a single prescription for up to a 30-day supply.⁸⁵ This is a lower cost-sharing level than 1/24 of the annual out-of-pocket maximum for a 30-day supply (\$265). Therefore, the cost impact of AB 1917 excludes these medications.
- No data on outpatient prescription drug utilization is available for enrollees of Covered California plans and policies because these plans and policies were not in existence prior to 2014 and are not reflected in current data available to CHBRP for this analysis. CHBRP assumes that outpatient prescription drug utilization patterns of these enrollees will be similar to other insured populations in 2015.
- A reduction in cost sharing for prescription drugs would lead to fewer enrollees reaching their annual out-of-pocket maximums. These enrollees would continue to have cost sharing for other covered benefits. Increased cost sharing for other covered benefits in general would lead to a decrease in use as explained in the *Medical Effectiveness* section. CHBRP assumes a decline in use of other health services for these enrollees due to the increase in cost sharing.
- CHBRP assumes that 88% of large- and small-group plans and policies have a maximum dollar amount cap on cost sharing for a prescription drug that is set lower than \$265 (1/24 of the annual out-of-pocket maximum) for a 30-day supply (EMD Serono 2012); 12% do not have a per prescription cap on cost sharing and could have cost sharing that would exceed the limit AB 1917 would require. In the absence of specific data on plans and policies in the individual market, CHBRP assumes that these plans and policies do not have a maximum dollar amount cap on cost sharing for a prescription drug.

⁸⁵ H&SC Section 1367.656; IC Section 10123.206.

This section will first present the premandate (baseline) benefit coverage, utilization, and costs related to cost sharing, and then provide estimates of the impacts on coverage, utilization, and cost if AB 1917 were to be enacted (postmandate). For further details on the underlying data sources and methods, please see Appendix D at the end of this document.

Premandate (Baseline) Benefit Coverage, Utilization, and Cost

Premandate (Baseline) Benefit Coverage

Of the 23,389,000 enrollees in DMHC-regulated plans and CDI-regulated policies in California, an estimated 11,701,000 (50%) are in nongrandfathered plans and policies subject to AB 1917 (Table 1). Among those subject to the mandate, an estimated 730,000 enrollees are in CSR products in Covered California and are excluded from this analysis.

CHBRP conducted a bill-specific coverage survey of California's seven largest health plans and insurers to assess cost-sharing requirements for outpatient prescription drugs. Responses to this survey represented 35.74% of enrollees in the privately funded, CDI-regulated market and 73.74% of enrollees in the privately funded, DMHC-regulated market. Combined, responses to this survey represent 65.86% of enrollees in the privately funded market subject to state mandates.

Analysis of the California Employer Benefit Survey⁸⁶ indicated that only 0.3% of group plans and policies offered by California employers did not offer prescription drug benefits. However, all group policies offer medical benefits that include some prescription drug coverage, and nongrandfathered small-group and individual market plans and policies are required to provide prescription drug coverage due to the EHB requirements of the ACA. Therefore, CHBRP assumes that all enrollees subject to this mandate have coverage for at least some generic, brand, and specialty outpatient prescription drugs.

Carrier survey data indicated that 6.71% of enrollees in DMHC-regulated plans and 17.51% of enrollees in CDI-regulated policies subject to the mandate were in HDHPs. Some health plans surveyed did not distinguish specialty drugs as a separate category and only had generic versus brand cost sharing tiers. CalPERS plans did not distinguish specialty drugs as a separate category, however covered infertility prescription drugs have a coinsurance of 50%.

Premandate (Baseline) Utilization

Based on analysis of 2012 MarketScan databases, CHBRP estimates that 1.52% of enrollees in plans and policies subject to AB 1917 have at least one high-cost outpatient prescription drug claim that could have cost sharing greater than 1/24 of the annual out-of-pocket maximum, or \$265, referred to throughout as a “qualifying prescription drug.”⁸⁷ An estimated 3.52% of the claims for these enrollees were for orally administered anticancer medications and were therefore

⁸⁶ Funded by California HealthCare Foundation and conducted by NORC.

⁸⁷ Estimate obtained from the analysis by Milliman of the Thomson Reuters' MarketScan databases from 2012. Prescription drug claims with costs greater than \$1,325 (drug costs associated with cost sharing of \$265, 1/24 of annual out-of-pocket maximum) were identified.

excluded from this analysis as described in the above assumption. Furthermore, 88% of group plans and policies were estimated to have a maximum dollar amount cap on cost sharing for a qualifying prescription drug. AB 1917 affects the 12% of plans and policies that do not have such a cap. No individual market plans and policies were assumed to have such caps, thus all could be affected by AB 1917. Consequently, about 45,410 enrollees (0.41%) in nongrandfathered plans and policies subject to AB 1917 (excluding enrollees in CSRs) are estimated to have prescription drug claims with cost sharing that exceeds 1/24 of the annual out-of-pocket maximum for up to a 30-day supply (\$265).

The 45,410 enrollees with cost sharing for prescription drug claims that exceeds 1/24 of the annual out-of-pocket maximum for up to a 30-day supply have 6.09 qualifying prescription drug claims and 147.98 claims for other medical services, on average.

Premandate (Baseline) Per-Unit Costs

CHBRP estimates that the annual average cost sharing for the enrollee per qualifying prescription drug is \$324.83. These enrollees also have an annual average cost sharing of \$15.82 for other medical services. These estimates of utilization and costs per claim are based on 2012 MarketScan databases (see Appendix D).

Premandate (Baseline) Premiums and Expenditures

Table 6 summarizes per member per month (PMPM) premiums and expenditures for DMHC-regulated plans and CDI-regulated policies prior to the mandate by market segment. Total pre-mandate annual expenditures are estimated at \$128,422,858,000. The total current annual expenditures for all private DMHC-regulated plans is estimated at \$89,332,889,000 and CDI-regulated policies is estimated at \$15,829,094,000. Public expenditures (including CalPERS and Medi-Cal HMO expenditures) are estimated at \$23,260,875,000.

Public Demand for Benefit Coverage

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 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.

Based on conversations with the largest collective bargaining agents in California, CHBRP concluded that unions *currently* do not include cost-sharing arrangements for prescription drugs in their health insurance negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the Preferred Provider Organization (PPO) plans offered by CalPERS currently have the largest number of enrollees.

The CalPERS PPOs *currently* provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate, although there is less use of coinsurance as a cost-sharing mechanism for prescription drugs.

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.

Given the lack of specificity in labor-negotiated benefits and the general match between health insurance that would be subject to the mandate and self-insured health insurance (not subject to state-level mandates), CHBRP concludes that public demand for coverage is essentially satisfied by the current state of the market.

How Lack of Coverage Results in Cost Shifts to Other Payers

Enrollees may delay or forego filling prescriptions proportional to cost-sharing levels. As indicated in the *Medical Effectiveness* section, the existing literature indicates nonadherence to prescription drugs with higher levels of cost sharing, in general and for specific prescriptions (Campbell et al., 2011; Domino et al., 2011; Dusetzina et al., 2014; Gibson et al., 2010a; Hoadley et al., 2012; Ito et al., 2013; Johnston et al., 2012; Kim et al., 2011; Patterson et al., 2011; Pesa et al., 2012; Sacks et al., 2013; Simoens and Sinnaeve, 2014; Wong et al., 2013). The literature also indicates ambiguous evidence on the impact of HDHP enrollment and prescription drug adherence in general, but finds a decline in adherence to prescriptions for HDHP enrollees with chronic conditions such as high cholesterol. In addition, the literature indicates a stronger negative relationship between higher cost sharing and adherence to prescription drugs for low-income populations.

The evidence also indicates that poor adherence to prescription drugs is associated with increased hospitalizations or emergency department visits (see the *Medical Effectiveness* section). Increased use of these services would increase overall health care expenditures to health plans and insurers and to public payers. However, the magnitude of this impact is unknown.

Although not formal payers of prescription drug costs, prescription drug coupons (PDCs) offered by pharmaceutical companies may be used by enrollees with high-cost drugs to cover some of those costs. These coupons are often time-limited and targeted to top grossing pharmaceuticals and those nearing patent expiry dates (Mackey et al., 2013). PDCs are available for a wide range of clinical conditions including cancer and HIV/AIDS and 75% are for chronic conditions with expected drug use of 6 months or longer. The amount of subsidy varies from \$5 to \$5,000, and about 38% of drugs with PDCs are brand names and have no lower-cost alternatives (Ross et al., 2012). Trade organizations report maximum annual benefits provided by these programs may be as high as \$10,000 for drugs such as Stelara for treatment of psoriasis and Enbrel for treatment of rheumatoid arthritis (Zitter Health Insights, 2014). One specialty pharmacy reported about 20,000 members received offsets for specialty drugs in the amount of \$21.2 billion in 2013 (Prime Therapeutics, 2014) though population-based estimates were not available at the time of this analysis.

Impacts of the Mandated Benefit Coverage

Postmandate Benefit Coverage

AB 1917 mandates changes in cost sharing and does not mandate coverage of specific treatments and services. CHBRP does not estimate changes to coverage of benefits due to AB 1917.

Postmandate Utilization

Postmandate, cost sharing for prescription drugs would be limited to 1/24 of the annual out-of-pocket maximum, \$265, for up to a 30-day supply for enrollees in nongrandfathered group and individual market plans and policies. As discussed above, high-cost and/or specialty drugs are the ones most likely affected by AB 1917 because they currently are often subject to high coinsurance levels. These drugs frequently include specialty and biologic drugs and, despite their high cost sharing, their use is relatively inelastic (Goldman et al., 2006). For example, doubling in cost sharing of rheumatoid arthritis drugs would reduce utilization by 21% among privately insured patients. The reduction in utilization is even lower for cancer specialty drugs (1%).

For CalPERS enrollees who are subject to 50% coinsurance for infertility prescription drugs, the price elasticity⁸⁸ is likely to be different. A study of the impact of introducing a 50% coinsurance for in vitro fertilization (IVF) treatment in Germany found a reduction of 36% in use of these drugs (Connolly et al., 2009).

CHBRP uses a price elasticity of 0.1, or an increase of 10% (the midpoint between 21% and 1% identified by Goldman et al., 2006) in use of qualifying prescription drugs for privately insured enrollees. This increase in utilization includes an increase in new enrollees initiating the use of these qualifying prescriptions (5%) and an increase in the number of refills or better adherence (5%).

For CalPERS enrollees, CHBRP uses the price elasticity for IVF treatment, an increase of 36% in use of infertility prescription drugs since prescription drugs used for IVF and other infertility treatments are similarly high costs. CHBRP does not project a separate increase in use of infertility drugs for private employers.

CHBRP assumes a 2.35% reduction in use of other medical services for enrollees who are impacted by AB 1917, as explained in the assumptions for this analysis. This estimate is calculated from 2012 MarketScan databases.

Using the elasticities above, CHBRP estimates postmandate 46,357 enrollees will have a prescription drug claim in a year with cost sharing that would have exceeded 1/24 of the annual out-of-pocket maximum (\$265) for a 30-day supply premandate. This is an increase of 947 enrollees who previously did not use these prescription drugs. The estimated increase in number of new enrollees using these drugs of the total enrollees subject to the mandate is 0.01% (Table 1).

⁸⁸ In this report, price elasticity refers to change in use of prescription drugs or other health care due to an increase/decrease in the cost sharing.

In addition, enrollees will refill 0.17 more qualifying prescription drugs (2.72%) but will reduce use of other medical services by 0.46 (0.31%) on average.

The level of postmandate utilization estimated by CHBRP is relatively low due to low prevalence of conditions that require these prescription drugs, the small number of enrollees with high cost sharing requirements for these prescription drugs, and low number of group plans and policies without a maximum dollar amount cap on cost sharing for these prescription drugs.

The reduction in cost sharing due to AB 1917 may lead to increased advertising of pharmaceuticals to induce demand. However, health plans and policies may attempt to exert greater oversight of the utilization of these products and apply more stringent criteria to restrict utilization.

Postmandate Per-Unit Cost

If AB 1917 is enacted, the cost sharing amount for up to a 30-day supply of an outpatient prescription drug would be limited to 1/24 of the annual out-of-pocket maximum (\$265). CHBRP estimates that the average cost sharing per qualifying prescription drug would decline to \$188.92, or 41.84% less than the premandate level (Table 1). This amount is lower than the limit of \$265 because some enrollees would reach their annual out-of-pocket maximum; these enrollees have no cost sharing after reaching their annual out-of-pocket maximum.

In addition, CHBRP estimates a cost sharing increase of \$1.74 (10.97%) for other medical claims postmandate.

Among those in HDHPs, this cost-sharing level would only apply after the deductible has been met.

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs for DMHC-regulated plans and 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.

Compliance with AB 1917 would require that plans and insurers: modify their product design; adjust their claims processing systems to track enrollees' out-of-pocket expenditure data; change their utilization management practices; disseminate new provider updates; amend policies and procedures; amend provider operations manual; and amend explanations of benefits to enrollees. The costs of these administrative changes would be reflected in the standard administrative cost load associated with premiums.

Postmandate Expenditures

Changes in total expenditures

AB 1917 would increase total net expenditures in 2015 by \$106,114,000, or 0.05% in the nongrandfathered group and individual market (Table 1). This increase in premiums is primarily due to cost sharing shifting from enrollees to DMHC-regulated plans and CDI-regulated policies. The increase in expenditures is also due to the estimated increase in utilization of qualifying prescription drugs.

AB 1917 would reduce cost sharing of enrollees by an estimated \$135.91 on average per prescription drug for enrollees who have high-cost outpatient prescription drug claims that would exceed 1/24 of annual out-of-pocket maximum. This amount varies with price of a particular drug, as well as the benefit structure of a particular health plan or policy. This change will lead to a reduction of \$21,796,000 (0.17%) in enrollee out-of-pocket expenses due to AB 1917. This decline in out-of-pocket expenses corresponds to an increase in premiums paid by employers, enrollees purchasing individual market plans or policies, and CalPERS.

Postmandate premium expenditures and PMPM amounts per category of payer

Increases in premiums as a result of AB 1917 would vary by market segment. Although the increases in premiums are generated by the small proportion of enrollees who will experience the impact of the mandate on their cost sharing, the change in premiums are estimated for the 10,971,000 million enrollees in DMHC-regulated plans and CDI-regulated policies subject to AB 1917 (excluding enrollees in CSRs).

In the privately funded market: Increases in per member per month premiums because of AB 1917 by market segment would be as follows:

- Total premiums for private employers are estimated to increase by \$28,000,000, or 0.05% (Table 1).
- Total premiums for those with individually purchased insurance are estimated to increase by \$79,503,000, or 0.47% (Table 1).
- Total premiums for enrollees with group and CalPERS coverage are estimated to increase by \$12,856,000 or 0.06% (Table 1).
- The portion of the premium paid by the employers would increase by \$0.18 for DMHC-regulated large groups and \$0.27 for CDI-regulated large groups PMPM. The portion of the premium paid by employees would increase between \$0.07 in the DMHC-regulated large-group market and \$2.18 PMPM for the CDI-regulated individual market (Table 7).
- Enrollee out-of-pocket expenses would decrease between \$0.04 and \$0.31 PMPM, depending on market segment (Table 7).

In the publically funded market: Medi-Cal is exempt from AB 1917; AB 1917 will only affect CalPERS.⁸⁹

- CalPERS premiums are estimated to increase by \$7,581,000, or 0.18% (Table 1).
- The total premiums paid by CalPERS is estimated to increase by \$0.93 PMPM, with \$0.75 paid by CalPERS and \$0.19 paid by the employees (Table 7).
- Total employee out-of-pocket expenses would decrease by \$0.45 PMPM (Table 7).

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

As indicated above, the reduction in cost sharing due to AB 1917 would lead to increased use of high-cost drugs among enrollees in nongrandfathered plans and policies. These enrollees may experience better health outcomes, depending on the medical effectiveness of the high-cost drug being used, but evidence of offsets or reduction of other service use such as hospitalizations or emergency department visits are mixed (Chandra et al., 2014). Similarly, the projected decrease in use of other services may have negative health consequences for these enrollees. Because of lack of sufficiently strong evidence, CHBRP does not estimate a cost offset in the first year following implementation.

If the cost sharing limits of AB 1917 were enacted, the difference in enrollee cost sharing pre and postmandate would shift to DMHC-regulated plans and CDI-regulated policies. For example, an enrollee in an individual market non-HDHP plan with a 20% coinsurance and an annual out-of-pocket maximum of \$6,350, who has to purchase a specialty drug costing \$3,000 for up to a 30-day supply would only pay \$265 for that drug rather than \$600 (see *Introduction* Table 3). The remaining balance of \$335 in this example would have to be paid by the health plan or insurer. Under AB 1917, health plans and insurers may choose to negotiate lower rates for high-cost drugs with manufacturers and specialty pharmacies. In return, specialty pharmacies and manufacturers may attempt to recoup these losses by charging higher prices for pharmaceuticals in general.

AB 1917 and Essential Health Benefits

AB 1917 modifies the cost sharing for outpatient prescription drugs. Because state rules related to cost sharing do not meet the definition of state benefit mandates that could exceed EHBs, AB 1917 would therefore not exceed EHBs and would not require the state to defray the costs of this mandate for enrollees in QHPs.

Postmandate Changes in Uninsured and Public Program Enrollment

Changes in the number of uninsured persons

CHBRP estimates premium increases of less than 1% for each market segment; this premium increase 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

⁸⁹ Potential impact of AB 1917 on cost sharing reduction products is not calculated.

contribution rates, changes in take-up of health insurance by employees, or purchase of individual market plans or 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.

Table 6. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2015

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (d)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (e)	8,779,000	2,012,000	2,498,000	845,000	6,364,000	826,000	567,000	662,000	836,000	23,389,000
Total enrollees in plans/policies subject to AB 1917 (excluding enrollees in CSRs in Covered California)	5,290,000	1,575,000	1,563,581	845,000	-	-	530,000	654,000	513,805	10,971,386
Premium costs										
Average portion of premium paid by employer	\$384.24	\$339.01	\$0.00	\$423.82	\$176.26	\$408.00	\$478.73	\$336.01	\$0.00	\$76,392,927,000
Average portion of premium paid by employee	\$140.62	\$135.62	\$454.56	\$105.95	\$0.89	\$0.00	\$160.34	\$240.54	\$329.35	\$39,162,788,000
Total premium	\$524.86	\$474.63	\$454.56	\$529.77	\$177.15	\$408.00	\$639.07	\$576.55	\$329.35	\$115,555,715,000
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$28.53	\$95.87	\$121.22	\$28.10	\$0.41	\$0.00	\$90.13	\$153.75	\$175.65	\$12,867,143,000
Total expenditures	\$553.39	\$570.50	\$575.78	\$557.87	\$177.56	\$408.00	\$729.19	\$730.30	\$505.00	\$128,422,858,000

Source: California Health Benefits Review Program, 2014.

Note: (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 2015.

(c) Includes children formerly in Healthy Families, which was moved into Medi-Cal Managed Care in 2013 as part of the 2012–13 state budget.

(d) Medi-Cal Managed Care Plan expenditures for members over 65 include those who also have Medicare coverage.

(e) 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; CSRs=cost sharing reduction products; DMHC=Department of Managed Health Care; MCMC=Medi-Cal Managed Care.

Table 7. Postmandate Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2015

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (d)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (e)	8,779,000	2,012,000	2,498,000	845,000	6,364,000	826,000	567,000	662,000	836,000	23,389,000
Total enrollees in plans/policies subject to AB 1917 (excluding enrollees in CSRs in Covered California)	5,290,000	1,575,000	1,563,581	845,000	-	-	530,000	654,000	513,805	10,971,386
Premium costs										
Average portion of premium paid by employer	\$0.18	\$0.23	\$0.00	\$0.75	\$0.00	\$0.00	\$0.27	\$0.21	\$0.00	\$35,582,000
Average portion of premium paid by employee	\$0.07	\$0.09	\$1.92	\$0.19	\$0.00	\$0.00	\$0.09	\$0.15	\$2.18	\$92,359,000
Total premium	\$0.24	\$0.33	\$1.92	\$0.93	\$0.00	\$0.00	\$0.36	\$0.36	\$2.18	\$127,940,000
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	-\$0.04	-\$0.05	-\$0.27	-\$0.45	\$0.00	\$0.00	-\$0.05	-\$0.05	-\$0.31	-\$21,796,000
Total expenditures	\$0.21	\$0.28	\$1.65	\$0.49	\$0.00	\$0.00	\$0.30	\$0.31	\$1.87	\$106,145,000
Postmandate percentage change										
Percent change insured premiums	0.0467%	0.0688%	0.4233%	0.1764%	0.0000%	0.0000%	0.0560%	0.0618%	0.6606%	0.1107%
Percent change total expenditures	0.0372%	0.0490%	0.2869%	0.0871%	0.0000%	0.0000%	0.0416%	0.0419%	0.3701%	0.0827%

Source: California Health Benefits Review Program, 2014.

Note: (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, of CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2014.

(c) Includes children formerly in Healthy Families, which was moved into Medi-Cal Managed Care in 2013 as part of the 2012–2013 state budget.

(d) Medi-Cal Managed Care Plan expenditures for members over 65 include those who also have Medicare coverage.

(e) 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; CSRs=cost sharing reduction products; DMHC=Department of Managed Health Care; MCMC=Medi-Cal Managed Care.

PUBLIC HEALTH IMPACTS

AB 1917 would limit cost sharing for outpatient prescription drugs to no more than 1/24 of the annual out-of-pocket maximum for a supply of up to 30 days for all nongrandfathered group and individual market DMHC-regulated plans and CDI-regulated policies, excluding cost sharing reduction products (CSRs). This cost-sharing limit translates to \$265 per prescription.⁹⁰

As discussed earlier in the *Introduction and Benefit Coverage, Utilization, and Cost Impacts* sections, CHBRP is unable to analyze the cost-sharing limit AB 1917 would require for enrollees in CSRs. AB 1917 would render these plans out of compliance with the actuarial value requirements set by the ACA. Therefore, the following estimates relate only to non-high deductible health plans (HDHPs) and HDPHs regulated by DMHC and CDI (heretofore referred to as “plans and policies”).

This section estimates the short-term public health impact⁹¹ of AB 1917 on health outcomes, financial burden, and gender and racial/ethnic disparities. See the *Long-Term Impacts* section for discussion of the impact of reduced cost sharing beyond the first 12 months of the bill implementation.

Estimated Public Health Outcomes

CHBRP included in its analysis all outpatient prescription drugs⁹² with cost sharing above \$265/prescription. The prescription drugs most likely to meet this criterion generally fall into several classes of specialty and biologic drugs used to treat a range of conditions. Many of the conditions treated with high-cost specialty drugs tend to be chronic and progressive in nature and can affect quality of life, along with morbidity and mortality. Most require daily medication treatment that can transition to an increased number of medications according to disease progression.

Estimation of clinical or public health outcomes would require evidence of a direct association between prescription drug cost-sharing and health outcomes; however, there are very few studies evaluating such an association, and those that do attempt to evaluate outcomes rely on prescription drug utilization, hospitalizations, or emergency department visits as proxies for health outcomes. Even if there were robust outcomes literature, the breadth of diseases is too extensive for CHBRP to assess the impact of reduced cost sharing on all conditions. Instead, the public health impact section presents a qualitative analysis of a variety of diseases in aggregate to assess the impact of AB 1917’s cost sharing limits. If possible, CHBRP presents directional effects for subpopulations.

As presented in the *Medical Effectiveness* section, there is a preponderance of evidence that higher enrollee cost-sharing requirements result in poorer medication adherence, decreased use

⁹⁰ Each outpatient prescription drug limit is 1/24 of the annual out-of-pocket maximum — 1/24 of \$6,350 is \$265.

⁹¹ CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

⁹² AB 1917’s language indicates that outpatient prescription drugs may be administered by health providers in outpatient settings; therefore, medications can be covered through an insured’s outpatient prescription drug pharmacy benefit or medical benefit.

of essential and nonessential health care services, and increased hospitalizations and emergency department visits.

In the first 12 months postmandate, CHBRP estimates that AB 1917 would decrease cost sharing for 45,410 enrollees. AB 1917 would also increase the number of enrollees who were able to fill a prescription due to the reduction in cost sharing by an additional 947 enrollees. Thus, postmandate, AB 1917 would reduce the out-of-pocket expenses for 46,357 enrollees who use high-cost prescription drugs.

Although the absolute number of enrollees facing a reduction in cost sharing due to AB 1917 is not large (46,357 of 10.97 million enrollees, 0.42%), the impact of reduced cost sharing for enrollees with chronic diseases such as multiple sclerosis (MS), HIV, and hepatitis C could be important as indicated by the literature summarized in the *Medical Effectiveness* section. The evidence indicated that reduced cost sharing is linked to improved medication initiation and adherence, which results in improved outcomes for some persons across a variety of conditions (Alamanos and Drosos, 2005; Carroll, 2009; Dor et al., 2010; Gleason et al., 2009; Goldman et al., 2006; Karaca-Mandic et al., 2010; Kargiotis et al., 2010; Ryan, 2009).

CHBRP estimates that 46,357 enrollees, including 947 new users, would fill an additional 13,184⁹³ high-cost prescription drugs were AB 1917 enacted. However, CHBRP projects no measurable public health outcomes impact due to the small number of enrollees (46,357 of 10.97 million, 0.42%) with a reduction in cost sharing for prescriptions that would have exceeded the \$265/prescription limit premandate. CHBRP recognizes that on a case-by-case basis, AB 1917 may yield important health and quality of life improvements for some persons.

Estimated Impact on Financial Burden

When possible, CHBRP estimates the marginal impact of mandates on financial burden, defined as noncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (i.e., deductibles, copayments, and coinsurance). In its analysis of a national claims database, CHBRP found that the ten most commonly used high-cost prescription drugs fell into 4 categories — anti-inflammatory, HIV, MS, and infertility — with utilization ranging from 6.3/1,000 to 1.6/1,000. The allowable costs⁹⁴ for these 10 drugs ranged from \$2,300 to \$9,000 per prescription. These numbers provide some context for the high prescription drug costs shared by insurers and enrollees.

AB 1917 would decrease the financial burden for those enrollees who use prescription drugs with cost sharing that exceeds \$265 for up to a 30-day supply premandate. CHBRP estimates that 46,357 enrollees would no longer have out-of-pocket expenses for prescription drugs exceeding the \$265 limit; they would receive an estimated net reduction in out-of-pocket expenses of \$21.8 million postmandate. This translates to an average savings of \$132/high-cost prescription (a reduction from \$325 per prescription to \$185).

⁹³ Calculated as pre-/postmandate enrollees (avg. number of prescriptions): $46,357(6.25) - 45,410(6.09) = 13,184$.

⁹⁴ Allowable cost is the total dollar reimbursement to the provider as agreed upon by the provider and insurance carrier. The allowable cost can include both the carrier and enrollee cost-share.

See further discussion of financial impacts in the *Long-Term Impacts* section.

In the first year postmandate, CHBRP estimates that AB 1917 would reduce the net out-of-pocket expenditures by \$21.8 million for 46,357 of the 10.97 million enrollees whose cost sharing would no longer exceed the cost-sharing limit of \$265/prescription. This translates to a 42% reduction (\$132/prescription) in the average cost sharing for an enrollee's high-cost prescription drug.

To the extent that AB 1917 removes a cost barrier for some enrollees who would then initiate therapy earlier and maintain adherence, the health impact on disease progression and outcomes could be significant on a case-by-case basis.

Impact on Gender and Racial Disparities

There are a variety of determinants of health that influence the health status of different groups. CHBRP estimates the mandate's impact on one of those determinants — access to care through insurance — on existing health disparities; the other determinants of health are generally outside the scope of health insurance mandates (e.g., biological, environmental, social, behavioral, language barriers, etc.). CHBRP analyses are limited to the insured population (because the uninsured would not be affected by a health benefit mandate). Coverage disparities can exist within the insured population and may contribute to gaps in access and/or utilization among those covered (Kirby et al., 2006; Lillie-Blanton and Hoffman, 2005; Rosenthal et al., 2008). To the extent that racial/ethnic groups are disproportionately distributed among plans and policies with more or less coverage, a mandate bringing all plans and policies to parity may impact an existing disparity. The baseline racial/ethnic distribution of the insured population is unknown; therefore, CHBRP is unable to provide a quantitative estimate of a mandate's impact on racial/ethnic disparities. When possible, CHBRP will indicate qualitatively the direction of effect a mandate would have on disparities.

CHBRP investigated the effect that AB 1917 would have on health disparities by gender, race, and ethnicity (including an economic status study). Because AB 1917 would only affect the insured population, a literature review was conducted to determine whether there are gender, racial, or ethnic disparities associated with the impact of cost sharing on prescription drug utilization within the insured population.

Impact on Gender Disparities

Many diseases affect men and women at different rates, and health care costs, including patient out-of-pocket costs, can be quite different depending on the disease. For example, systemic lupus erythematosus, MS, and rheumatoid arthritis disproportionately affect women who have at least two to three times the prevalence of men, depending on type of condition (Chakravarty et al., 2007; Helmick et al., 2008; Noonan et al., 2002). These conditions are also known to have high-cost prescription drug treatment protocols (Alamanos and Drosos, 2005; Boonen and Severens, 2011; Hurwitz, 2011; Noonan et al., 2010). Given that women's income is generally lower than men's, a disproportionate positive impact of reduced financial burden on some women with these conditions might be expected (Hurwitz, 2011; Noonan et al., 2010). Despite these examples,

CHBRP estimates no measurable change in existing gender disparities due to the small number of enrollees (46,357 of 10.97 million, 0.42%) who would no longer exceed the \$265 cost-sharing limit.

Due to the small magnitude of change in the number of enrollees with reduced cost-sharing, CHBRP estimates AB 1917 would have no measurable impact on possible gender disparities across specific disease states.

Impact on Racial/Ethnic and Economic Disparities

Although CHBRP found no evidence regarding the existence of racial/ethnic disparities within or between specific cost sharing benefit designs, the factors identified in the *Unequal Treatment* report indicate that racial/ethnic health disparities exist within the insured population and may be exacerbated by cost sharing (IOM, 2002). The report notes three primary factors related to cost sharing that may contribute to potential disparities. Per Census data, racial/ethnic minorities generally have lower overall income levels, thus out-of-pocket expenses constitute a disproportionate burden. Overall, minorities also experience poorer health status than whites, which likely increases the need for more health care and related cost sharing. Finally, where cost sharing reduces use of health care, racial/ethnic minorities may forgo care due solely to economic burden as compared with whites (IOM, 2002).

Moreover, there is literature that identifies racial/ethnic differences in impact of cost sharing on prescription drug use and adherence and intermediate health outcomes for some disease states. CHBRP's search found limited evidence on disparities in effects of prescription drug cost sharing. CHBRP identified two recent studies that addressed racial disparities in the general population and one that evaluated income disparities. A recent national study using Medical Expenditure Panel Survey data showed that Latinos were less likely to use prescription drugs, but have a higher proportion of out-of-pocket drug costs compared to whites (Chen et al., 2010a). Health insurance, having a usual source of care, and limited English proficiency were contributing factors to the observed disparity. A national study evaluating the initiation of new prescriptions found that African Americans had 22% to 33% less use than whites, and Hispanics had 5% to 16% less use (Wang et al., 2007). An economic disparity study used national census data to estimate the impacts of prescription drug cost sharing on adherence to medications for diabetes and congestive heart failure (Chernew et al., 2008). This study showed that only patients in the lowest income category (<\$30,000/year) were sensitive to drug costs, particularly for congestive heart failure drugs. For patients making above \$30,000/year, there was no consistent relationship between drug cost and drug adherence.

Although there are racial/ethnic disparities in the prevalence of certain diseases and conditions, and evidence that, in general, lower cost sharing can improve adherence, CHBRP estimates AB 1917 would have no measureable impact on racial/ethnic disparities due to the small number of enrollees (46,357 of 10.97 million 0.42%) whose cost sharing would be reduced as a result of AB 1917. This magnitude is too small to measure a change in disparities within the California population.

LONG-TERM IMPACT OF THE MANDATE

In this section, CHBRP estimates the long-term impact of AB 1917, 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, enrollees in DMHC-regulated plans or CDI-regulated policies subject to AB 1917 would continue to benefit from the \$265 limit on cost sharing for outpatient prescription drugs covered by pharmacy and medical benefits.

Long-Term Utilization and Cost Impacts

As discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section, AB 1917 is anticipated to lead to a small annual increase in utilization of prescription drugs with high cost sharing levels due to increased adherence to high cost outpatient prescription drugs and to an increase in the number of enrollees using these prescription drugs. The increased utilization is particularly for specialty drugs used for treatment of disease such as cancer, multiple sclerosis (MS), rheumatoid arthritis, anemia, or infertility. The findings of the RAND HIE study indicated an overall reduction in expenditures with lower overall cost sharing, with a bigger impact for low-income persons (Baicker and Goldman, 2011; Newhouse, 1993). A more specific review of the existing literature on the relationship between prescription drug cost sharing and reduction in health care expenditures did not establish a clear link, particularly due to a dearth of studies addressing economic outcomes (Eaddy et al., 2012). As a result, CHBRP does not estimate the impact of AB 1917 on utilization and costs in the long-term.

Utilization and Cost Impacts

In the first 12 months following enactment, CHBRP estimates that high-cost outpatient prescription drugs would be used by 947 additional enrollees (a 2.09% increase) who previously did not use these drugs. Overall, CHBRP estimates an increase in utilization of these prescription drugs of 2.72% (Table 1). In the long-term, AB 1917 can further accelerate some existing trends in prescription drug and overall expenditures. The specialty pharmaceuticals are the most rapidly growing portion of the pharmaceutical industry both in expenditures and new products and are more frequently provided under medical benefits (McDonald, 2008). Industry groups report that U.S. spending on specialty drugs will increase 72% by 2015, with three of the four costliest therapeutic classes focused on specialty conditions (Stetten, 2013).

As discussed in the *Background on Cost Sharing and Specialty Prescription Drugs* section, these trends have propelled employer sponsored plans to require separate cost sharing in the form of coinsurance rather than copayments for specialty drugs. In 2013, 59% of California employees were subject to tier 3 and 7% were subject to tier 4 cost sharing, an increase from 42% and 2%, respectively, in 2005 (CHCF, 2014). National data indicate that tier 4 drugs often include lifestyle or high-cost biologic and specialty drugs and the enrollees with this level of cost sharing

are subject to copayments of \$80 and coinsurance of 32% on average (Choudhry et al., 2011; KFF/HRET, 2013).

If AB 1917 is enacted, the reduction in cost sharing can accelerate the use of these prescription drugs in the long-term. Insurers will not be able to increase cost sharing as a mechanism to curtail the use of these drugs, but can increase premiums, apply more stringent utilization review criteria, and negotiate discounts with pharmaceutical companies. In return, pharmaceutical companies can accelerate direct to consumer advertising efforts and increase overall prescription drug costs. A limit on cost sharing may also be an incentive for pharmaceutical companies to increase prices and a disincentive to offer coupons.

CHBRP estimates that in the long-term, AB 1917 would increase the use of existing and newly developed high-cost prescription drugs and would lead to an increase in overall expenditures due to a reduction of cost sharing for high-cost prescription drugs. The magnitude of this impact is unknown.

Long-Term Public Health Impacts

Estimated Public Health Outcomes

Although CHBRP estimates that 46,357 enrollees will increase their use of high-cost medications, CHBRP is unable to estimate the long-term public health impacts of AB 1917. This is due to a number of factors including the breadth of conditions affected, variation in disease severity, appropriateness of high-cost prescription drug treatments, large variation in cost-sharing benefit design, and unknown market response to changes.

To the extent that AB 1917 enables enrollees to initiate therapy earlier and maintain adherence due to reduced cost sharing, the long-term impact on disease outcomes such as relapse rates, disability, and early mortality could be significant on a case-by-case basis. For example, the cost of several prescription drugs for MS exceed the AB 1917 monthly cost-sharing limit, and studies have shown that MS patients initiating earlier treatment with some of these drugs (e.g., interferon beta) leads to reduced morbidity (Castrop et al., 2013; Edan et al., 2013). In this example, AB 1917 could not only reduce the economic burden for some who are prescribed the interferon beta, but it could likely delay the progression of the disease for those enrollees. Thus, the downward pressure of this cost sharing reduction may significantly alter the progression and outcome of a variety of illnesses for a small percentage of enrollees.

Despite indications of possible health maintenance or improvements for some enrollees impacted by the cost-sharing limit in AB 1917, CHBRP is unable to estimate future impacts on health, premature death, or economic loss. As noted above, this is due in part to the alternative utilization management techniques beyond cost sharing that insurers may use to restrain growing prescription drug costs. These techniques, such as prior authorization (requiring approval by the health plan or insurer before being covered), step therapy (requiring a patient to fail one drug first before being covered for another), using formularies to exclude certain drugs, and imposing quantity dispensing limits (KFF, 2013), attempt to dampen the upward pressure of escalating costs.

CHBRP is unable to estimate the long-term public health impact of AB 1917 due to uncertainty in the market's response to the downward cost pressure of mandated reductions in enrollee cost sharing and the upward pressure of the increasing number and cost of specialty drugs; however, AB 1917 may provide significant health and quality of life improvements on a case-by-case basis.

Impacts on Premature Death and Economic Loss

Both premature death and economic loss associated with disease are two measures used by economists and public health experts to assess the impact of a condition or disease. Premature death, often defined as death before the age of 75 (Cox, 2006), can be measured in years of potential life lost (YPLL) (Cox, 2006; Gardner and Sanborn, 1990). Economic loss associated with disease is generally an estimation of the value of the YPLL in dollar amounts (i.e., valuation of years of work life lost from premature death or lost productivity due to a disease or condition).

Premature mortality

AB 1917 may decrease premature death resulting from a variety of conditions treated with high-cost, life-saving or life-sustaining prescription drugs, but there is a lack of evidence to inform estimates of the marginal effect on all the possible health outcomes of the 46,357 enrollees who would change behavior due to the reduced cost sharing. Therefore, the magnitude of the prescription drug cost-sharing limit on premature death is unknown.

Economic loss

Although AB 1917 may affect economic loss resulting from a variety of conditions treated with high-cost prescription drugs, there is a lack of evidence to inform changes in future utilization. Therefore, the impact of the prescription drug cost-sharing limit on economic loss is unknown.

APPENDICES

Appendix A: Text of Bill Analyzed

On February 25, 2014, the Assembly Committee on Health requested that CHBRP analyze AB 1917.

ASSEMBLY BILL NO. 1917

Introduced by Assembly Member Gordon

FEBRUARY 19, 2014

An act to add Section 1367.0095 to the Health and Safety Code, and to add Section 10112.298 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 1917, as introduced, Gordon. Outpatient prescription drugs: cost sharing.

Existing federal law, the federal Patient Protection and Affordable Care Act (PPACA), enacts various health care coverage market reforms that take effect January 1, 2014. Among other things, PPACA requires that a health insurance issuer offering coverage in the individual or small group market to ensure that the coverage includes the essential health benefits package, as defined. PPACA requires the essential health benefits package to limit cost-sharing for the coverage in a specified manner. PPACA also requires a group health plan to ensure that any annual cost-sharing imposed under the plan does not exceed those limitations. PPACA specifies that certain of its reforms do not apply to grandfathered plans, as defined. PPACA also requires each state to establish an American Health Benefits Exchange for the purpose of facilitating the enrollment of qualified individuals and qualified small employers in qualified health plans and provides reduced cost sharing for certain low-income individuals who enroll in a qualified health plan in the silver level of coverage through the Exchange.

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 establishes the California Health Benefit Exchange for the purpose of facilitating the enrollment of qualified individuals and qualified small employers in qualified health plans as required under PPACA. Existing law requires a nongrandfathered individual or group health care service plan contract that provides coverage for essential health benefits, as defined, and that is issued, amended, or renewed on or after January 1, 2015, to provide for an annual limit on out-of-pocket expenses for all covered benefits that meet the definition of essential health benefits.

With respect to a health care service plan contract or health insurance policy that is subject to those annual out-of-pocket limits, this bill would require that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual

prescription for a supply of up to 30 days not exceed 1/24 of the annual out-of-pocket limit. The bill would also require that an enrollee who is eligible for a reduction in cost sharing through a qualified health plan offered through the Exchange not be required to pay in any single month more than 1/24 of the annual limit on out-of-pocket expenses for that product. Because a willful violation of the bill's requirements by a health care service plan would be a crime, the bill would impose a state-mandated local program.

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

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

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

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

SECTION 1.

Section 1367.0095 is added to the *Health and Safety Code*, to read:

1367.0095.

(a) (1) With respect to a nongrandfathered individual or group health care service plan contract subject to Section 1367.006, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed 1/24 of the annual out-of-pocket limit set forth in Section 1367.006.

(2) For a health care service plan contract that meets the definition of a high deductible health plan set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraph (1) shall only apply once an enrollee's deductible has been satisfied for the plan year.

(3) Paragraph (1) shall not apply to coverage under a health care service plan contract for the Medicare Program pursuant to Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

(b) Nothing in this section shall be construed to affect the reduction in cost sharing for eligible enrollees described in Section 1402 of PPACA and any subsequent rules, regulations, or guidance issued under that section.

(c) An enrollee who is eligible for a reduction in cost sharing pursuant to Section 1402 of PPACA shall not be required to pay in any single month more than 1/24 of the annual limit on out-of-pocket expenses for the cost sharing reduction product.

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

(1) “Outpatient prescription drug” means a drug approved by the federal Food and Drug Administration that is self-administered by a patient, administered by a licensed health care professional in an outpatient setting, or administered in a clinical setting that is not an inpatient setting.

(2) For nongrandfathered health care service plan contracts in the group market, “plan year” has the meaning set forth in Section 144.103 of Title 45 of the Code of Federal Regulations. For nongrandfathered health care service plan contracts sold in the individual market, “plan year” means the calendar year.

(3) “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.

SEC. 2.

Section 10112.298 is added to the *Insurance Code*, to read:

10112.298.

(a) (1) With respect to a nongrandfathered individual or group health insurance policy subject to Section 10112.28, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed 1/24 of the annual out-of-pocket limit set forth in Section 10112.28.

(2) For a health insurance policy that meets the definition of a high deductible health plan set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraph (1) shall only apply once an insured’s deductible has been satisfied for the plan year.

(3) Paragraph (1) shall not apply to coverage under a health insurance policy for the Medicare Program pursuant to Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

(b) Nothing in this section shall be construed to affect the reduction in cost sharing for eligible insureds described in Section 1402 of PPACA and any subsequent rules, regulations, or guidance issued under that section.

(c) An insured who is eligible for a reduction in cost sharing pursuant to Section 1402 of PPACA shall not be required to pay in any single month more than 1/24 of the annual limit on out-of-pocket expenses for the cost sharing reduction product.

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

(1) “Outpatient prescription drug” means a drug approved by the federal Food and Drug Administration that is self-administered by a patient, administered by a licensed health care professional in an outpatient setting, or administered in a clinical setting that is not an inpatient setting.

(2) For nongrandfathered health insurance policies in the group market, “plan year” has the meaning set forth in Section 144.103 of Title 45 of the Code of Federal Regulations. For nongrandfathered health insurance policies sold in the individual market, “plan year” means the calendar year.

(3) “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.

SEC. 3.

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

Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review conducted for AB 1917. A discussion of CHBRP’s system for grading evidence, as well as lists of MeSH Terms, Publication Types, and Keywords, follows.

The literature search was limited to studies published in English from March 2010 to present. For earlier studies, CHBRP relied on a literature search conducted in 2011 for its issue analysis for AB 1800, a bill that concerned standardization of cost sharing and other aspects of health plans and health insurance policies.

The following databases of peer-reviewed literature were searched: MEDLINE (PubMed), the Cochrane Database of Systematic Reviews, the Cochrane Register of Controlled Clinical Trials, Web of Science, and EconLit. In addition, websites maintained by the following organizations that index or publish systematic reviews and evidence-based guidelines were searched: Agency for Healthcare Research and Quality, International Network of Agencies for Health Technology Assessment, the National Cancer Institute’s Physician Data Query, National Health Service Centre for Reviews and Dissemination, National Institute for Health and Clinical Excellence, and the Scottish Intercollegiate Guideline Network.

Owing to the large volume of literature that has been published on cost sharing for health care services (i.e., the portion of expenditures paid by enrollees), CHBRP relied on meta-analyses, systematic reviews, and narrative reviews to obtain information about the overall findings from this literature.

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

Abstracts for 331 articles were identified. Twenty-two meta-analyses, systematic reviews, narrative reviews, RCTs, and nonrandomized studies with comparison groups were retrieved and reviewed.

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*.⁹⁵ To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Consistency of findings;

⁹⁵ Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

- Generalizability of findings to the population whose coverage would be affected by a mandate; and
- Cumulative impact of evidence.

CHBRP uses a hierarchy to classify studies' research designs by the strength of the evidence they provide regarding a treatment's effects.

CHBRP evaluates consistency of findings across three dimensions: statistical significance, direction of effect, and size of effect.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength, consistency, and generalizability 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 have strong research designs, consistently find that the treatment is either effective or not effective, and have findings that are highly generalizable to the population whose coverage would be affected. This grade is assigned in cases in which it is unlikely that publication of additional studies would change CHBRP's conclusion about the effectiveness of a treatment.

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 and that the findings are generalizable to the population whose coverage would be affected. Bodies of evidence that are graded as *preponderance of evidence* are further subdivided into three categories based on the strength of their research designs: strong research designs, moderate research designs, and weak research designs.

A grade of *ambiguous/conflicting evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies with equally strong research designs suggest the treatment is not effective.

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

In addition to grading the strength of evidence regarding a treatment's effect on specific outcomes, CHBRP also assigns an overall grade to the whole body of evidence included in the medical effectiveness review. A statement of the overall grade is included in the *Executive Summary* and in the *Medical Effectiveness* section of the text of the report. The statement is accompanied by a graphic to help readers visualize the conclusion.

Search Terms

The search terms used to locate studies relevant to **AB 1917** were as follows:

MeSH terms used to search PubMed and Cochrane Library

- arthritis, rheumatoid/ drug therapy/economics/therapeutic use
- chronic disease/drug therapy/economics
- costs
- cost analysis
- cost-benefit analysis
- cost of illness
- cost savings
- cost sharing
- deductibles and coinsurances
- diabetes mellitus/economics/drug therapy/prevention and control
- drug costs
- drug prescriptions
- drug prescriptions/economics
- drug prescriptions/ statistics and numerical data
- drug prescriptions/utilization
- drug utilization
- emergency service, hospital/statistics and numerical data/utilization
- Ethnic Groups
- Healthcare Disparities
- Hemophilia A/drug therapy
- growth hormone/economics/therapeutic use/utilization
- Hepatitis C drug therapy/economics
- HIV Infections/drug therapy
- Leukemia, Myelogenous, Chronic, BCR-ABL Positive/drug therapy
- Leukemia, Myeloid, Chronic, Atypical, BCR-ABL Negative/drug therapy
- Lupus Erythematosus, Systemic/drug therapy medication adherence
- multiple sclerosis/drug therapy
- neoplasms/drug therapy
- prescription drugs
- prescription drugs/economics
- Racism
- Rare Diseases/drug therapy
- Sexism
- Utilization

Keywords used to search PubMed, Cochrane Library, Web of Science, EconLit, and other relevant websites

- benefit cap benefit caps
- biological agent*
- biologics, cancer
- cancer
- chronic myeloid leukemia
- chronic disease*
- co-insurance
- co-pay*
- coinsurance
- compliance
- copay*
- consumer driven health plan*
- consumer driven health plan*
- cost-benefit
- cost benefit*
- cost effective*
- cost offset*
- cost pass-along
- cost saving*
- cost sharing
- cost shifting
- cost utility
- deductible*
- diabetes
- disparities
- disparity*
- drug
- discontinuation of medication
- drug*
- drug cost*
- drug utilization
- economic burden
- economic productivity
- ethnic*
- financial burden
- gender
- health outcome*
- hepatitis c
- hemophilia
- high cost specialty drug*
- high deductible
- hispanic-american*
- hiv
- hdhp
- insurance
- latina
- latino
- life-saving
- limit* (i.e., cost-sharing limit)
- lower cost sharing
- lupus
- maximum
- Kaiser Family Foundation
- medication
- medication adherence
- medication cost
- mexican-american*
- multiple sclerosis

- organ transplant*
 - outpatient *
 - out of pocket
 - patient compliance
 - premature mortality
 - prescription
 - prescription cost*
 - price elasticity
 - price of treatment
 - price sensitivity
 - race
 - racism
 - rare disease
 - rheumatoid arthritis
 - sexism
 - socioeconomic burden
 - socioeconomic difference
 - specialty
 - specialty drug*
 - specialty drugs*
 - tier copayment
 - therapy*
 - treatment*
 - treatment cost*
 - utilisation
 - utilization
 - unit cost
 - willingness to pay
- * indicates that the search term was truncated

Publication Types:

- Comparative Study
- Controlled Clinical Trial
- Meta-Analysis
- Multicenter Studies
- Randomized Controlled Trial
- Review
- Systematic Reviews

Appendix C: Description of Studies on Medical Effectiveness of Cost Sharing

Appendix C describes the meta-analyses, systematic reviews, and individual studies on regarding the effects copayment and cost sharing on use of prescription drugs and other health care services that were analyzed by the medical effectiveness team. Table C-1 describes the research designs, intervention and comparison groups, populations studied, and locations for studies included in this review. Table C-2 summarizes the findings from the studies included in the review.

Table C-1. Characteristics of Published Studies on the Impact of Cost Sharing on Use of Prescription Drugs

Type of Intervention	Citation	Research Design	Intervention and Comparison Groups	Population Studied	Location
Copayment, tiering copayments, and coinsurance	Goldman et al., 2007	Systematic review	Variation in formulary restrictions; Variation in copayments, coinsurance, and/or tiering	Persons enrolled in private health insurance plans, Medicaid, or Medicare	N/A
Copayment and coinsurance	Austvoll-Dahlgren et al., 2008	Systematic review	Increase in fixed copayments Fixed copayments vs. full drug coverage Fixed copayments with cap vs. full drug coverage Fixed copayments with ceiling vs. full drug coverage Fixed copayment and coinsurance with ceiling vs. some drug coverage Three-tier vs. two-tier copayments	Health care consumers and providers within a large jurisdiction or system of care (regional, national, or international). Studies conducted within health maintenance organizations (HMO) were included if the HMO had multiple sites and served a large population.	N/A
Copayment	Eaddy et al., 2012	Literature review	Increase in fixed copayments Introduction of copayment	Persons enrolled in private health insurance plans, Medicaid, or Medicare	N/A
Copayment change	Simoens and Sinnaeve, 2013	Literature review	Increase in fixed copayments Introduction of copayment	Persons enrolled in private health insurance plans, Medicaid, or Medicare	N/A

Table C-1. Characteristics of Published Studies on the Impact of Cost Sharing on Use of Prescription Drugs (Cont'd)

Type of Intervention	Citation	Research Design	Intervention and Comparison Groups	Population Studied	Location
Increase in copayment	Sinnott et al., 2013	Systematic review	Increase in fixed copayments Introduction of copayment	Persons enrolled in public health insurance programs, including Veterans Affairs and Medicare. (N=199,996)	N/A
Copayment	Chernew et al., 2008	Retrospective observational study	Copayment rates for prescription drugs using an employer-specific copayment index (variation in plan generosity)	Persons age 18 years or older with diabetes mellitus (DM) or congestive heart failure (CHF) enrolled in employer-sponsored health insurance plans (N=29,764 DM; N=13,081 CHF)	USA
Copayment	Gibson et al., 2010b	Retrospective, cross-sectional study	Level of prescription drug cost sharing (measured as the cost-sharing index)	Oral antidiabetic medication (OAD) with or without insulin (n = 96,734) and patients on OAD only (n = 55,356) with employer-sponsored insurance	USA
Copayment	Chandra et al., 2010	Retrospective cohort study	Increase in fixed copayments No increase for generics, \$5 increase for name brands, \$10 for formulary name brands, and \$20 for nonformulary name brand prescriptions; mail order prescription copayments increase from \$5 to \$10/\$25/\$45, with a \$1,000 stop-loss in 2001	Retired public employees in California(CALPERS); 93 percent of these members were over the age of 65 (N=70,912)	USA
Copayment	Campbell et al., 2011	Retrospective cohort study	Increase in fixed copayments copayment level per prescription (more than \$5 and less than \$5 average increase in patient copayments per month of medication supplied)	Persons with asthma enrolled in private commercial health plans (N=40,784)	USA

Table C-1. Characteristics of Published Studies on the Impact of Cost Sharing on Use of Prescription Drugs (Cont'd)

Type of Intervention	Citation	Research Design	Intervention and Comparison Groups	Population Studied	Location
Copayment	Kim et al., 2011	Retrospective cohort study	>\$25 increase in copayment vs. no increase in copayment for anti-inflammatory, immunosuppressant, cancer, and multiple sclerosis medications	Long-term users of anti-inflammatory, immunosuppressant, cancer, and multiple sclerosis medications were selected N=178 patients (intervention group) N=202 patients (control group)	USA
Copayment	Domino et al., 2011	Nonrandomized study with comparison group	Increase in copayments for brand name drugs across six medication categories: antihypertensives, antidiabetic medications, lipid-lowering (statins), seizure-disorder drugs, antidepressants, and antipsychotics	Persons 18–64 insured by Medicaid in North Carolina and Georgia (each of the medication cohorts had 8,300–62,000 unique nonelderly adults per state)	USA
Copayment	Patterson et al., 2011	Retrospective cohort design	Variation in copayment amount (\$0–\$50 in \$5 increment increases)	Administrative claims data for 38 million patients aged >50 years who had at least 3 years of continuous health insurance and prescription drug coverage	USA
Copayment	Choudhry et al., 2012	Retrospective cohort study with comparison group	Usual copayment vs. lower copayment for statins	Adult statin users intervention group (n = 3,513) vs. control group (n=49,803)	USA
Sum of copayment and coinsurance	Johnston et al., 2012	Retrospective observational cohort study	Various levels of copayments for combination antiretroviral therapy (cART) Sum of cost sharing=sum of copayment level per prescription: cost-sharing levels of \$25, \$75, and \$144, which represented the 25th, 75th, and 90th percentiles of the cost-sharing distribution, respectively)	Persons with at least 1 inpatient or outpatient medical claim for HIV enrolled in employer-sponsored commercial health plans and who initiated combination antiretroviral therapy (cART) (N=3731)	USA

Table C-1. Characteristics of Published Studies on the Impact of Cost Sharing on Use of Prescription Drugs (Cont'd)

Type of Intervention	Citation	Research Design	Intervention and Comparison Groups	Population Studied	Location
Copayment	Pesa et al., 2012	Retrospective cohort study	Variation in copayment amount participants were assigned to: low-risk group (no comorbidities), high-risk group (1+ selected comorbidities), or very high-risk group (prior hospitalization for 1+ selected comorbidities)	Commercially insured study patients with at least one hypertension diagnosis N=28,688	USA
Copayment	Ito et al., 2013	Hypothetical cohort analysis	Usual copayment (\$20) vs. no copayment	Hypothetical cohort of postmenopausal Medicare beneficiaries with hormone receptor-positive early breast cancer	USA
Copayment	Kazerooni et al., 2013	Retrospective cohort study	Copayment vs. no copayment stratified by income quintiles: quintile 1, \$9,182 to \$40,716; quintile 2, \$40,746 to \$49,599; quintile 3, \$49,696 to \$58,099; quintile 4, \$58,165 to \$72,676; quintile 5, \$72,701 to \$245,431	Adult new statin users enrolled in VA system for at least a year in southern California and Nevada (N=4,748)	USA
Copayment	Sacks et al., 2013	Retrospective cohort study	Variation in level of copayment for brand name and generic OAD in non-low-income subsidy patients vs. low-income subsidy patients	Adults 65 and older who used OADs. (N=231,406 non-low-income subsidy: 81,047; low-income subsidy: 150,359)	USA
Copayment	Wong et al., 2013	Retrospective pre-post design with nonequivalent control group	Exempt from copayment vs. increase in copayment	6,029 diabetes medication users, 20,196 hypertension medication users	USA
Copayment	Chandra et al., 2014	Nonrandomized study with comparison group	Copayment increase vs. no increase	Low income persons age 18–64 enrolled in the Massachusetts Commonwealth Care program	USA

Table C-1. Characteristics of Published Studies on the Impact of Cost Sharing on Use of Prescription Drugs (Cont'd)

Type of Intervention	Citation	Research Design	Intervention and Comparison Groups	Population Studied	Location
Copayment	Dusetzina et al., 2014	Retrospective observational study	Variation in level of copayment required for a 30-day supply of imatinib; median copayments were \$30 (range \$0 to \$4,792)	Adults(18 to 64 years) with chronic myeloid leukemia who initiated imatinib, a tyrosine kinase inhibitor (TKI) who had insurance coverage for at least 3 months before and 6 months after initiation (N=1,541)	USA

Table C-2. Summary of Findings From Studies of the Impact of Cost Sharing on Use of Prescription Drugs

Outcome	Citation	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Price elasticity of demand: ⁹⁶ Wide range of changes in cost sharing	Goldman et al., 2007	Systematic review — 65 studies	Statistically significant	Favors lower cost sharing	Price elasticity of demand = -0.2 to -0.6	The preponderance of evidence from 65 studies suggests that a 10% increase in cost sharing is associated with a 2% to 26% decrease in prescription drug use or expenditures
Impact of copayment on statin adherence	Simoens and Sinnaeve, 2013	Literature review and case studies	Statistically significant	Favors lower copayment for statins	Did not attempt to pool studies and produce a summary quantitative estimate of the association between copayment and statin adherence due to the variability of primary studies	Results from a literature review suggest that a reduction in copayment is likely to improve adherence to statin therapy
Risk of nonadherence	Sinnott et al., 2013	Systematic review and meta-analysis	Statistically significant	Favors lower cost sharing	Odds ratio for nonadherence was 1.11 (95% CI: 1.09 to 1.14; p<0.00001)	Evidence from 7 studies shows an 11% increased odds of nonadherence to medicines in publicly insured populations where copayments for medicines are necessary

⁹⁶ Price elasticity of demand shows how the quantity demanded or supplied will change when the price changes.

Table C-2. Summary of Findings From Studies of the Impact of Cost Sharing on Use of Prescription Drugs (Cont'd)

Outcome	Citation	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Adherence	Eaddy et al., 2012	Literature review	Statistically significant	Favors lower copayment	Of the 66 studies, 56 (85%) demonstrated a statistically significant relationship between increased patient cost sharing and decreased medication adherence; the remaining 10 studies (15%) demonstrated either limited or nonsignificant findings for the cost-sharing/adherence relationship	Results from a literature review suggest that as cost sharing increases, adherence decreases
Adherence	Chernew et al., 2008	Retrospective observational study	Statistically significant	Favors lower copayment for low-income populations	In each case, the ratio between the elasticity of the lowest income area, relative to the highest, was statistically significant at $p < 0.01$. Across all populations: a doubling of copayments (about \$14–\$15) would reduce adherence overall by 2.9% to 5.4%	Patients in low-income zip code areas were more sensitive to copayment changes than in high or middle-income zip code areas The relationship between income and price sensitivity was strong for congestive heart failure patients

Table C-2. Summary of Findings From Studies of the Impact of Cost Sharing on Use of Prescription Drugs (Cont'd)

Outcome	Citation	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Adherence — percentage of days covered	Gibson et al., 2010b	Retrospective, cross-sectional study	Statistically significant	Favors lower copayment	All OAD users:(OR): 0.97 (95% CI: 0.97 to 0.98) OAD-only users: OR: 0.98 (95% CI: 0.97 to 0.98)	Higher levels of patient cost sharing for antidiabetic medications were associated with lower levels of adherence (percentage of days covered); a \$10 increase in the patient cost-sharing index resulted in a 5.4% reduction in adherence to antidiabetic medications for patients on OAD medication only and a 6.2% reduction in adherence for patients on OAD with or without insulin antidiabetic medications
Adherence — average annual days of medication supplied	Campbell et al., 2011	Retrospective cohort study	Statistically significant	Favors lower cost sharing	Decrease adjusted average annual days medication supplied ICS: -47.1 days (95% CI: -43.5 to -50.8) ICOMBO: -35.3 days (95% CI: -32.4 to -38.2) LTRA: -47.5 days (95% CI: -43.2 to -51.7)	The >\$5 average increase in copayment resulted in decreases in adjusted average annual days of medication supply and use

Table C-2. Summary of Findings From Studies of the Impact of Cost Sharing on Use of Prescription Drugs (Cont'd)

Outcome	Citation	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Adherence for black and white Veterans	Wong et al., 2013	Nonrandomized study with comparison group	Statistically significant reduction in adherence for all racial groups No statistically significant racial differences in the impact of the copayment increase	Favors lower cost sharing	Difference between adjusted probability of adherence before and after copayment increase = 5.8% (p<0.001) for white veterans and 6.5% (p<0.05) for black veterans No statistically significant difference between groups	Increasing copayments reduced adherence to diabetes and hypertension medications for both racial groups
Adherence (medication possession ratio)	Patterson et al., 2011	Retrospective cohort study	Statistically significant	Favors lower cost sharing	Copayment levels \$21–\$25 vs. \$0, OR: 1.6 (95% CI: 1.1 to 2.4) Copayment levels \$>26 vs. \$0, OR: 2.5 (95% CI: 1.6 to 4.0)	Patients with higher copayments have up to an average 9% decrease in annual beta-blocker medication supply
Adherence to a generic statin	Hoadley et al., 2012	Retrospective cohort study	Statistically significant	Favors lower cost sharing	Charging a copayment for generic statin drugs decreased the probability of using a generic by about 13%	Beneficiaries who faced any copayment for generic drugs were significantly less likely to use a generic drug than those who had no copayment
Adherence-Proportion of days covered	Pesa et al., 2012	Retrospective cohort study	Statistically significant	Favors lower cost sharing across all risk groups.	For every US\$1.00 increase in cost sharing, PDC decreased by 1.1 days (p<0.0001)	Potential adverse effects of higher patient cost sharing among patients with hypertension

Table C-2. Summary of Findings From Studies of the Impact of Cost Sharing on Use of Prescription Drugs (Cont'd)

Outcome	Citation	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Changes in medication possession ratio associated with copayment (vs. No copayment Group) by income quintiles	Kazerooni et al., 2013	Retrospective cohort study	Higher-income groups: Quintiles 4 and 5: Not significantly significant Lower income: Quintile 1: Not significantly significant Quintile 2 and 3: Statistically significant	Higher-income: (quintiles 4 and 5): No difference Lower income: Quintile 1: No difference Quintiles 2 and 3: Favors lower cost sharing.	Higher-income: (quintiles 4 and 5): No difference Lower income: quintile 2: -0.057, 95% CI: -0.095 to -0.02 quintile 3 (-0.044 MPR, CI (-0.081 to -0.007)	Patients in lowest income group (quintile 1) and higher-income groups (quintiles 4 and 5) show no significant decreases in adherence associated with having a copayment. Patients in quintile 2 and quintile 3 had statistically significant decreases in adherence associated with having a copayment.
Adherence to brand drugs, measured using the proportion of days covered (PDC) — fraction of the days in the quarter for which at least one medication in the target class was received	Domino et al., 2011	Nonrandomized study with comparison group	Antihypertensives, antidiabetic medications, lipid-lowering drugs (statins), and antidepressants: Statistically significant Seizure-disorder: Statistically significant Antipsychotics: Not statistically significant	Antihypertensives, antidiabetic medications, lipid-lowering drugs (statins), and antidepressants: Favors lower cost sharing Seizure-disorder: Favors higher cost sharing Antipsychotics: No effect	Antihypertensives, antidiabetic medications, lipid-lowering drugs (statins), and antidepressants: Decrease 0.4–1.8 percentage points in adherence Seizure-disorder: a 0.67 percentage point increase in adherence Antipsychotic medications: No effect	Significant decrease in medication adherence after the policy changes in antihypertensives, antidiabetic medications, lipid-lowering drugs (statins), and antidepressants. Antipsychotic medications and seizure-disorder medications do not show that same decrease after rise in copayment

Table C-2. Summary of Findings From Studies of the Impact of Cost Sharing on Use of Prescription Drugs (Cont'd)

Outcome	Citation	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Price elasticity/utilization	Chandra et al., 2014	Nonrandomized study with comparison group	Statistically significant	Favors lower cost sharing	Overall elasticity = -0.158; a 10% increase in prices faced by patients would reduce utilization by 1 to 2%.	Health care demand is somewhat sensitive to copayments, but the elasticity is small; chronically ill, especially those with diabetes, high cholesterol, or asthma, have a lower price elasticity of demand
Monthly rates of medication filling	Choudhry et al., 2012	Retrospective cohort study with comparison group	Statistically significant	Favors lower cost sharing	Statins: increased by 7.1 percentage points (95% CI: 5.3 to 8.8 percentage points; p<0.001. Clopidogrel: increased by 5.9 percentage points (95% CI: 3.5 to 8.2 percentage points; p<0.001.)	No copayment vs. usual copayment resulted in an increase in the monthly rate of both statin and clopidogrel filling
Price elasticity/utilization	Chandra et al., 2014	Nonrandomized study with comparison group	Statistically significant	Favors lower cost sharing	Overall elasticity, is -0.158; a 10% increase in prices faced by patients would reduce utilization by 1% to 2%	Health care demand is somewhat sensitive to copayments, but the elasticity is small; those who are chronically ill, especially those with diabetes, high cholesterol, or asthma, have a lower price elasticity of demand
Adherence	Dusetzina et al., 2014	Retrospective observational study	Statistically significant	Favors lower cost sharing	Adjusted risk ratio, 1.42 (95% CI: 1.19 to 1.69)	Patients with higher copayments were 42% more likely to be nonadherent

Table C-2. Summary of Findings From Studies of the Impact of Cost Sharing on Use of Prescription Drugs (Cont'd)

Outcome	Citation	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Adherence odds (Medication possession ratio) of OAD medication: Generic drugs	Sacks et al., 2013	Retrospective observational study	Low income vs. non-low income: Biguanides: Not statistically significant Low income vs. non-low-income: Sulfonylureas/glinides: Statistically significant	Low income vs. non-low income: Biguanides: No difference Low income vs. non-low income: Sulfonylureas/glinides: Slightly favors lower cost sharing	Biguanides: No difference N=21,377) Sulfonylureas/glinides: small differences (N=19,240; OR: 0.91 (95% CI: 0.86 to 0.97; p=0.002) in adherence odds	Biguanides show no difference in adherence. Sulfonylureas/ Glinides show small increase in odds of adherence for non-low-income patients than low-income patients for generic drugs.
Adherence odds (Medication possession ratio) of OAD medication: Brand name drugs	Sacks et al., 2013	Retrospective observational study	DPP-4 inhibitor and thiazolidinedione: Low income vs. non-low income: Statistically significant	DPP-4 inhibitor and thiazolidinedione: Low income vs. non-low income: Favors lower cost sharing	DPP-4 inhibitor : Non-low income: 0.52 times odds of adherence (95% CI: 0.43 to 0.63; p<0.001) Thiazolidinedione: Non-low income 0.57 times odds of adherence (95 % CI: 0.52 to 0.63; p<0.001)	DPP-4 inhibitor and thiazolidinedione show increase in odds of adherence for non-low-income patients than low-income patients for generic drugs

Table C-2. Summary of Findings From Studies of the Impact of Cost Sharing on Use of Prescription Drugs (Cont'd)

Outcome	Citation	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Specialty drugs						
Cost per quality-adjusted life-year (QALY)	Ito et al., 2013	Nonrandomized study with comparison group	Not reported	Favors lower cost sharing	Usual prescription coverage: 11.35 QALYs Full prescription coverage: 11.38 QALYs	Prescription coverage for aromatase inhibitors to Medicare beneficiaries with hormone receptor-positive early breast cancer can improve health outcomes
Adherence	Johnston et al., 2012	Nonrandomized study with comparison group	Statistically significant	Favors lower cost sharing	78% adherence level: Cost-sharing levels 0 to 20th percentiles (96.7%) compared to >80th percentile 89.9%.	Increasing cART prescription cost sharing was associated with decreased odds of maintaining clinically meaningful levels of cART adherence
Tyrosine kinase inhibitor (TKI) discontinuation	Dusetzina et al., 2014	Retrospective observational study	Statistically significant	Favors lower cost sharing	Adjusted risk ratio 1.70 (95% CI: 1.30 to 2.22)	There was a 70% increase in the risk of discontinuing TKIs among patients with higher copayment requirements

Appendix D: Cost Impact Analysis: Data Sources, Estimation Methodology, 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 the contracted actuarial firm, Milliman, Inc. (Milliman).⁹⁷

Data Sources

In preparing cost estimates, the cost team relies on a variety of data sources as described below.

Baseline model

- The California Simulation of Insurance Markets (CalSIM) is used to project health insurance status of Californians aged 64 and under in 2015. CalSIM is a microsimulation model that projects the effects of the Affordable Care Act on firms and individuals.⁹⁸ CalSIM relies on national Medical Expenditure Panel Survey (MEPS) Household Component and Person Round Plan 2006–2010, California Health Interview Survey (CHIS) 2011/2012, and California Employer Health Benefits Survey data 2013.
- California Health Interview Survey (2011/2012) 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 2011/2012 is 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. CHIS 2011/2012 surveyed approximately 44,600 households and was conducted in multiple languages by the UCLA Center for Health Policy Research. More information on CHIS is available at: www.chis.ucla.edu.
- The latest (2013) California Employer Health Benefits Survey was used to estimate:
 - Size of firm;
 - Percentage of firms that are purchased/underwritten (versus self-insured);
 - Premiums for employment-based health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and point of service [POS] plans); and

⁹⁷ CHBRP’s authorizing legislation requires that CHBRP use a certified actuary or “other person with relevant knowledge and expertise” to determine financial impact (www.chbrp.org/docs/authorizing_statute.pdf).

⁹⁸ UC Berkeley Center for Labor Research and Education and UC Los Angeles Center for Health Policy Research. *Methodology & Assumptions, California Simulation of Insurance Markets (CalSIM) Version 1.8*, March 2013. Available at: http://healthpolicy.ucla.edu/publications/Documents/PDF/calsim_methods.pdf. Accessed March 25, 2014.

- Premiums for employment-based health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs]. Premiums for fee-for-service [FFS] plans 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. Information on the CHCF/NORC data are available at: www.chcf.org/publications/2014/01/employer-health-benefits.

- Milliman data sources are relied on to estimate the premium impact of mandates. Milliman’s projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States; see: www.milliman.com/expertise/healthcare/products-tools/milliman-care-guidelines/index.php. Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed health care plans, generally those characterized as PPO plans. The HCGs currently include claims drawn from plans covering 41.2 million members. In addition to the Milliman HCGs, CHBRP’s utilization and cost estimates draw on other data, including the following:
 - The MarketScan databases, which reflects the health care claims experience of employees and dependents covered by the health benefit programs of large employers. These claims data are collected from approximately 100 different 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 approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.
 - These data are reviewed for applicability by an extended group of experts within Milliman but are not audited internally.
- Premiums and enrollment in DMHC-regulated health plans and CDI-regulated policies by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their dependents who receive their benefits through CalPERS. Enrollment information is provided for DMHC-regulated health care service plans covering non-Medicare beneficiaries — about 74% of CalPERS total enrollment. CalPERS self-funded plans — approximately 26% of enrollment — are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOC) documents publicly available at: www.calpers.ca.gov. For the 2014 model, CHBRP assumes CalPERS’s enrollment in

2015 will not be affected by continuing shifts in the health insurance market as a result of the ACA.

- Enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System plans) is estimated based on data maintained by the Department of Health Care Services (DHCS). CHBRP assesses enrollment information online at: www.dhcs.ca.gov/dataandstats/statistics/Pages/Monthly_Trend_Report.aspx. The most recent Medi-Cal enrollment data from DHCS is projected to 2015 based on CalSIM's estimate of the continuing impact of the Medi-Cal expansion implemented in 2014.

Estimate of Premium Impact of Mandates

- CHBRP's Annual Enrollment and Premium Survey collects information from the seven largest providers of health insurance in California (Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and United Healthcare/PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC-regulated or CDI-regulated), grandfathered and nongrandfathered status, and average premiums. Enrollment in plans or policies offered by these seven insurers represent an estimated 97.4% of the persons with health insurance subject to state mandates. This figure represents an estimated 97.8% of enrollees in full-service (nonspecialty) DMHC-regulated health plans and an estimated 95.9% of enrollees in full-service (nonspecialty) CDI-regulated policies. The Annual Enrollment and Premium Survey is representative of enrollment in September 2013; CalSIM and market trends were applied to the 2013 enrollment to project 2015 health insurance enrollment in state-regulated plans and policies.

For CHBRP reports analyzing specific benefit mandates, CHBRP surveys the seven major carriers on current coverage relevant to the benefit mandate. CHBRP reports the share of enrollees — statewide and by market segment — reflected in CHBRP's bill-specific coverage survey responses. The proportions are derived from data provided by CDI and DMHC. CDI provides data by market segment (large, small, and individual) based on "CDI Licenses With HMSR Covered Lives Greater Than 100,000" as part of the Accident and Health Covered Lives Data Call September 30, 2012, by the California Department of Insurance, Statistical Analysis Division. The Department of Managed Health Care's interactive website "Health Plan Financial Summary Report," July–September 2013, provides data on DMHC-regulated plans by segment.⁹⁹

The following table describes the data sources mentioned above, and the data items that they inform.

⁹⁹ CHBRP assumes DMHC-regulated PPO group enrollees and POS enrollees are in the large-group segment. <http://wps0.dmhc.ca.gov/flash/>.

Table D-1. Population and Cost Model Data Sources and Data Items

Data Source	Items
California Simulation of Insurance Markets (CalSIM) 1.9 (projections for 2015)	Uninsured, age: 0–17; 18–64 yrs 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
California Health Interview Survey, 2011/2012 (CHIS 2011/2012)	Uninsured, age: 65+ yrs Medi-Cal (non-Medicare), age: 65+ Other public, age: 65+ Employer-sponsored insurance, age: 65+
CalPERS data, annually, enrollment as of September 30	CalPERS HMO and PPO enrollment <ul style="list-style-type: none"> • Age: 0–17; 18–64; 65+ yrs • HMO premiums
California Employer Survey, conducted annually by NORC and funded by CHCF	Enrollment by HMO/POS, PPO/indemnity self-insured, fully insured, Premiums (not self-insured) by: <ul style="list-style-type: none"> • 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
DHCS administrative data for the Medi-Cal program, annually, 11-month lag from the end of November	Distribution of enrollees by managed care or FFS distribution by age: 0–17; 18–64; 65+ yrs Medi-Cal Managed Care premiums
CMS administrative data for the Medicare program, annually (if available) as of end of September	HMO vs. FFS distribution for those 65+ (noninstitutionalized)
CHBRP enrollment survey of the seven largest health plans in California, annually as of end of September	Enrollment by: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • DMHC vs. CDI regulated • Grandfathered vs. nongrandfathered
Department of Finance population projections, for intermediate CHIS years	Projected civilian, noninstitutionalized CA population by age: 0–17; 18–64; 65+ yrs
Medical trend influencing annual premium increases	Milliman estimate

Source: California Health Benefits Review Program, 2014.

Notes: (a) Includes children previously enrolled in Healthy Families, California’s CHIP. As of January 1, 2014, children enrolled in Healthy Families were transitioned into Medi-Cal as required in the 2012–2013 state budget agreement.

(b) Includes individuals dually eligible for Medi-Cal and Medicare.

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; PPO=preferred provider organization.

Projecting the Effects of the Affordable Care Act in 2015

This subsection discusses adjustments made to CHBRP’s Cost and Coverage Model to account for the continuing impacts of the ACA in January 2015. It is important to emphasize that CHBRP’s analysis of specific mandate bills typically addresses the incremental effects of the mandate bill — specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, *holding all other factors constant*. CHBRP’s estimates of these incremental effects are presented in the *Benefit Coverage, Utilization, and Cost Impacts* section of this report.

Baseline premium rate development methodology — 2015

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.

For each plan type, we first obtained an estimate of the insurance premium PMPM by taking the 2013 reported premium from the above-mentioned data sources and trending that value to 2015. CHBRP uses trend rates published in the Milliman Health Cost Guidelines to estimate the health care costs for each plan segment in 2015.

The individual segments (CDI-regulated and DMHC-regulated) are split into: grandfathered non-exchange; nongrandfathered non-exchange; and exchange groups in order to separately calculate the impact of ACA and specific mandates that may apply differently to these three subgroups. The premium rate information received from NORC did not split the premiums based on grandfathered or exchange status. The 2013 CHBRP Annual Enrollment and Premium Survey asked the seven largest insurance carriers in California to provide their average premium rates separately for grandfathered and nongrandfathered plans. The ratios from the carrier survey data are then applied to the 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 2013 premium rates received from the 2013 CHBRP Annual Enrollment and Premium Survey were used directly.

The marginal impact of ACA on 2015 premiums was established as follows:

- For nongrandfathered small-group and individual market segments, a 3% increase in medical costs is applied to reflect the total cost of requiring each plan to cover the essential health benefits.
- For nongrandfathered small-group plans, a 5% increase in medical costs is applied to reflect the other additional costs of ACA (e.g., age rating, health status, increased premium taxes and fees, change in actuarial value, etc.).
- For DMHC-regulated individual plans and CDI-regulated individual policies, an increase of 20% and 31%, respectively, in medical costs is applied to reflect the other additional costs of ACA.

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

- Health care costs paid by the health plan = insurance premiums PMPM \times (1 – profit/administration load);
- Gross claims costs PMPM = health care costs paid by the health plan \div percentage paid by health plan; and
- Member cost sharing PMPM = gross claims costs \times (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’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 Milliman, 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, Milliman estimated the member cost sharing for the average or typical plan in that category. Milliman then priced these plans using the Milliman Health Cost Guidelines to estimate the percentage of gross health care costs that are paid by the carrier.

Medi-Cal Managed Care

CHBRP has estimated that the PMPM cost for Medi-Cal’s newly eligible population will equal the projected cost of Medi-Cal’s currently eligible family population, excluding maternity costs.

General Caveats and Assumptions

The projected cost estimates are estimates of the 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.
- The impact of ACA on the mandated benefit cost may be different from CHBRP assumptions.

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.
- Several studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew et al., 2005; Glied and Jack, 2003; Hadley, 2006). Chernew et al. (2005) estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, whereas Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and a 0.84 percentage point decrease in the number of insured, respectively. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the simplifying assumption that the elasticity is the same across different types of markets. For more information on CHBRP's criteria for estimating impacts on the uninsured, please see: www.chbrp.org/analysis_methodology/docs/Uninsured_paper_Final_01012009.pdf.

There are other variables that may affect costs, but which CHBRP did not consider in the cost projections 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 benefit plans: To help offset the premium increase resulting from a mandate, subscribers/policyholders may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and policies and enrollees, and may also result in utilization

reductions (i.e., high levels of patient 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, individuals or employer groups who had previously foregone health insurance may now elect to enroll in a health plan or policy, postmandate, because they perceive that it is to their economic benefit to do so.
- Medical management: Health plans and 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 types that previously had the least effective medical management (i.e., PPO plans).
- Geographic and delivery systems variation: Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the health insurance 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 by type. 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 or 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 coverage levels, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the coverage requirements of the bill. Therefore, the typical postmandate coverage rates for populations subject to the mandate are assumed to be 100%.

Bill Analysis-Specific Caveats and Assumptions

- CHBRP identified qualifying prescription drug claims for this analysis as those with charges of at least \$1,325. An average 20% coinsurance for such a claim would result in an enrollee cost sharing of \$265, which is 1/24 of the 2014 annual out-of-pocket maximum of \$6,350.
- CHBRP assumed that no copayments for high-cost and/or specialty drugs would exceed the limits set by AB 1917. There was no evidence to dispute this assumption in the literature. In addition, a previous analysis by CHBRP found no copayments above \$150 for prescription drugs in 2011.¹⁰⁰
- In the absence of data, CHBRP assumes that 100% of the plans and policies in the individual market do not have maximum dollar amount caps per prescription and AB 1917 could affect all those enrollees. This assumption may overestimate the cost impacts

¹⁰⁰ See CHBRP's report on AB 310 (Ma) Prescription drugs for further information, available at: www.chbrp.org/completed_analyses/index.php.

provided in this report. In addition, CHBRP assumes both large- and small-group plans and policies have the same rate of maximum dollar amount caps per prescription. However, small employers may be less likely to apply such per prescription caps.

- CHBRP makes the simplifying assumption there would be no changes to benefit design postmandate other than changes in the prescription drug cost sharing. Health plans and policies may implement changes to benefit design in response to AB 1917. However, the magnitude and direction of those changes are not estimated by CHBRP.
- CHBRP does not include the CSR products (cost sharing reduction products) in the analysis of AB 1917 for reasons explained in the body of the report. This exclusion is likely to lead to an under estimation of the potential cost impact of AB 1917.
- Elasticity of demand estimates were not available for all high-cost and/or specialty prescription drugs. The elasticity estimates used in this analysis may not be representative of every condition or prescription drug.
- The claims experience of the enrollees in HDHPs were included in the cost model. These claims were adjudicated for each member according to simplified versions of the California Standard metal-tier plans of bronze, silver, gold, and platinum. Adjudication for Bronze and Silver limits were used for the HDHPs, and Gold and Platinum limits were used for non-HDHPs. The mandate was applied in the adjudication of HDHP claims after enrollees satisfied their deductible in compliance with AB 1917 language. This may be an overestimate of the number of enrollees in HDHPs, which would result in an underestimate of the potential cost impact of AB 1917.
- All estimates of cost sharing in this report are based on self-only rather than family coverage. Calculations do not consider different effects on self-only compared to family annual out-of-pocket maximums. Information on family coverage is not available in the data systems used to project changes in costs and utilization. CHBRP assumes the same effects for annual out-of-pocket maximums observed among individuals and families.
- CHBRP does not estimate the impact of AB 1917 on specialized health plans and policies. The scope of enrollee coverage and outpatient prescription drug coverage in these specialized health plans and policies in 2015 is not known to CHBRP. Therefore, the impact of AB 1917 described in this report may be underestimated.

Appendix E: Information Submitted by Outside Parties

In accordance with CHBRP policy to analyze information submitted by outside parties during the first two weeks of the CHBRP review, the following parties chose to submit information.

No information was submitted by interested parties for this analysis.

For information on the processes for submitting information to CHBRP for review and consideration please visit: www.chbrp.org/requests.html.

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