



**CALIFORNIA**  
HEALTH BENEFITS REVIEW PROGRAM

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## Analysis of Assembly Bill 310: Prescription Drugs

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A Report to the 2011-2012 California Legislature  
April 14, 2011

CHBRP 11-10



The California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analyses of the medical, financial, and public health impacts of proposed health insurance benefit mandates and proposed repeals of health insurance benefit mandates. CHBRP was established in 2002 by statute (California Health and Safety Code, Section 127660, et seq). 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 individuals 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; or (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.

A small 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, as well as Loma Linda University, the University of Southern California, and Stanford University, 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, and 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 and designed to provide balanced representation among groups with an interest in health insurance benefit mandates or repeals, reviews draft studies to ensure their quality before they are transmitted 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 a small annual assessment on health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available at the CHBRP Web site, [www.chbrp.org](http://www.chbrp.org).

# **A Report to the 2011-2012 California State Legislature**

## **Analysis of Assembly Bill 310: Prescription Drugs**

**April 14, 2011**

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## PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 310. In response to a request from the California Assembly Committee on Health on February 10, 2011, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute.

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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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## EXECUTIVE SUMMARY

### California Health Benefits Review Program Analysis of Assembly Bill 310

The California Assembly Committee on Health requested on February 10, 2011, 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) 310, a bill that would impose a health benefit mandate. Specifically, AB 310 would prohibit coinsurance as a basis for cost sharing for outpatient prescription drugs; limit copayments to \$150 per one-month supply; and require that a health plan's or policy's out-of-pocket maximum include the outpatient prescription drug benefit. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.<sup>1</sup>

Approximately 21.9 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.<sup>2</sup> Of the rest of the state's population, a portion is uninsured (and so has no health insurance subject to any benefit mandate) and another portion has health insurance subject to other state law or only to federal laws.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state-level benefit mandates. The California Department of Managed Health Care (DMHC)<sup>3</sup> 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<sup>4</sup>, which offer benefit coverage to their enrollees through health insurance policies.

Enrollees in health insurance products not subject to state-level benefit mandates would not be affected by AB 310. Examples would include those enrolled in Medicare (including Medicare Advantage plans) or those who have coverage through self-insured employer plans. In addition, only DMHC-regulated plans and CDI-regulated policies that cover outpatient prescription drugs would be subject to AB 310. Therefore, the mandate would not affect about 968,000 enrollees who do not have an outpatient prescription drug benefit through their health plan or policy. Thus, the mandate would affect the health insurance of approximately 20.9 million Californians (56%).

### Bill Language and Key Definitions

The full text of AB 310 can be found in Appendix A.

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<sup>1</sup> CHBRP's authorizing statute is available at: [http://www.chbrp.org/documents/authorizing\\_statute.pdf](http://www.chbrp.org/documents/authorizing_statute.pdf)

<sup>2</sup> CHBRP's estimates are available at: [http://www.chbrp.org/other\\_publications/index.php](http://www.chbrp.org/other_publications/index.php).

<sup>3</sup> The DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.

<sup>4</sup> The 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, Section 106(b) or subdivision (a) of Section 10198.6.

AB 310 would:

- Prohibit coinsurance (i.e., percentage cost of the prescription) as the basis for cost sharing for outpatient prescription drug benefits;
- Limit copayments for outpatient prescription drugs to \$150 per one-month supply or its equivalent for prescriptions for longer periods, adjusted for inflation; and,
- If a plan or policy has an annual out-of-pocket maximum, require outpatient prescription drug benefit cost sharing to be included under that annual out-of-pocket maximum.

AB 310 would not:

- require plans or policies without an outpatient prescription drug benefit to begin to cover prescription drugs.
- require coverage of specific drugs or require plans or policies to make changes to their formularies.

The definitions of “inflation” and “one-month supply” are not further specified by AB 310.

A *copayment* is a fixed, flat-dollar amount that an enrollee pays when filling a prescription. *Coinsurance* is where the enrollee pays a percentage cost of the prescription, rather than a fixed amount. An *out-of-pocket maximum* is an annual limit on the total out-of-pocket costs (excluding premium payments) that an enrollee is responsible for during plan year.<sup>5</sup>

## **Analytic Approach and Key Assumptions**

AB 310 is not a typical benefit mandate, in that it does not mandate coverage of specific treatments or services. Therefore, CHBRP’s analysis regarding medical effectiveness, cost, and public health impacts has been adjusted to address the questions relevant to this bill. Because AB 310 would not require coverage of any specific prescription drugs or classes of drugs nor require changes to a plan or policy’s formulary, the *Medical Effectiveness* section reviews and analyzes the literature related to the effects of cost sharing on utilization of prescription drugs.

The *Benefit Coverage, Utilization, and Cost Impacts* section addresses the effects of AB 310’s three key provisions on overall utilization of the prescription drug benefit, premiums, and health care expenditures. The impacts modeled in the *Benefit Coverage, Utilization, and Cost Impacts* section rely on some key assumptions. The analysis assumes there are no changes in benefit design (such as changes to deductibles, out-of-pocket maximums, or annual limits) other than that copayments exceeding \$150 per one-month supply would be lowered to that number, coinsurance exceeding \$150 per one-month supply would become a copayment at that number, and prescription drug cost sharing would be included under the plan or policy’s out-of-pocket maximum, if it already includes one.

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<sup>5</sup> Out-of-pocket maximums may alternately or additionally apply in other ways, such as per service, per month, per quarter, or per family.

The *Public Health Impacts* section provides analysis of specific drugs or classes of drugs for which cost sharing for some enrollees is currently high (defined as above \$150), and therefore, would be reduced by this bill. The section also discusses how changes in cost sharing would affect certain subpopulations of enrollees who use specific drugs, when there is available evidence and data.

#### *Existing California requirements*

Current regulations governing DMHC-regulated health plans include provisions regarding outpatient prescription drug benefits. Rules related to cost sharing (copayments, coinsurance, and deductibles) state that copayment may not be more than the retail price of the drug; that a copayment or percentage coinsurance may not exceed 50% of the “cost to the plan.” It also specifies that if a plan uses coinsurance it must either: have a maximum dollar amount cap on the percentage coinsurance that would be charged for an individual prescription; apply towards an annual out-of-pocket maximum for the plan; or, apply towards an annual out-of-pocket maximum for the prescription drug benefit. CDI-regulated policies have no analogous requirements except that they provide that health insurers must cover benefits mandated under the Insurance Code.

CHBRP is aware of one other state with a similar law. In 2010, New York prohibited the implementation of “specialty tiers” for prescription drug benefits. Similar legislation has also been recently introduced in other states but has not passed into law.

### **Medical Effectiveness**

Prescription drugs can be divided into two major categories: traditional agents and specialty drugs.

- Specialty drugs are new, high-cost drugs, primarily biologics.
  - Specialty drugs are primarily used to treat complex chronic conditions, such as anemia, cancer, growth hormone deficiency, hemophilia, hepatitis, multiple sclerosis, and rheumatoid arthritis.
  - Specialty drugs are administered by injection, intravenously, or orally.
  - Specialty drugs are more expensive than traditional oral agents because they are more expensive to produce and because no generic or “biosimilar” (biologics with properties similar to existing biologics) versions of them are available.
- Traditional agents consist of generic and brand-name drugs that are produced using traditional pharmaceutical manufacturing processes.
  - Traditional agents are used to treat a wide range of chronic and acute conditions. They play major roles in the prevention and treatment of common conditions such as heart disease, diabetes, asthma, and depression.
  - Most traditional agents are administered orally as tablets or capsules, although some are inhaled (e.g., aerosol and dry powder medications for asthma and chronic obstructive

pulmonary disease), injected (e.g., cortisone injections for inflammation associated with arthritis or other conditions), or administered transdermally (e.g., transdermal patches for contraception and pain relief).

CHBRP's medical effectiveness analysis for AB 310 focuses on the impact of cost sharing (i.e., the portion of expenditures paid by enrollees) on use of prescription drugs. CHBRP chose this analytic approach because AB 310 would not increase the number of Californians who have coverage for prescription drugs, but would instead affect the terms and conditions of prescription drug coverage for enrollees who have such coverage.

### Methodological Considerations

- No randomized controlled trials (RCTs) of the impact of variation in prescription drug cost sharing on the use of prescription drugs or other health care services have been conducted since the RAND Health Insurance Experiment was conducted in the late 1970s and early 1980s.
- Newer studies of the impact of cost sharing for prescription drugs have not randomized participants, which limits confidence that differences in use of prescription drugs or other services between persons facing higher and lower cost sharing for prescription drugs are due to cost sharing versus other factors.

The best nonrandomized studies of cost sharing for prescription drugs have used rigorous methods to control for other factors that may affect use of prescription drugs, such as health behaviors, health status, income, and expenses for other types of health care services.

### Study Findings

#### *Specialty drugs*

- Only a small number of studies of the impact of cost sharing on use of specialty drugs have been published.
- The *preponderance of evidence* from these studies suggests that demand for specialty drugs is sensitive to price but that the size of the effect is small. Estimates of the price elasticity of demand<sup>6</sup> for specialty drugs suggest that each 10% increase in cost sharing for specialty drugs would reduce spending for these drugs by 0.1% to 2.1% depending on the disease a specialty drug is used to treat.
  - Demand for specialty drugs to treat multiple sclerosis and rheumatoid arthritis appears to be more sensitive to cost sharing than demand for specialty drugs for cancer and kidney disease.
- Findings from a single study suggest that the impact of cost sharing on use of specialty drugs for multiple sclerosis varies depending on whether a person's coverage is subject to coinsurance or a copayment. Reductions in use associated with higher cost sharing were greater for persons who were required to pay coinsurance instead of a copayment.

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<sup>6</sup> Price elasticity of demand shows how the quantity demanded or supplied will change when the price changes.

- CHBRP identified no studies of the effects of cost sharing for specialty drugs on use of other types of health care services. No evidence of effect is not evidence of no effect. It is possible that some persons who face higher cost sharing for specialty drugs have more hospitalizations, emergency department visits, and outpatient visits than persons who face lower cost sharing.

#### *Traditional agents*

- A large number of studies on the effects of cost sharing on use of traditional agents have been published.
- The *preponderance of evidence* from these studies suggests that demand for traditional agents is more sensitive to price than demand for specialty drugs.
  - A systematic review of 65 studies of the impact of cost sharing on use of traditional agents found that increases in cost sharing are consistently associated with decreases in use of traditional oral agents. Each 10% increase in cost sharing for traditional agents is associated with a 2% to 6% reduction in their use. Subsequent studies reported similar findings.
  - Findings from studies that compared the impact of cost sharing on use of different types of traditional agents are *ambiguous*. Some studies have found large differences across classes of traditional agents, whereas others have found no differences across drug classes.
- Two studies examined whether responses to cost sharing differ between persons whose pharmacy benefits require coinsurance versus copayments for traditional agents.
  - One study reported that higher cost sharing is associated with poorer adherence to prescription drug regimens for diabetes and that the effect was more pronounced for persons with coinsurance than persons with copayments.
  - One study found that changing cost sharing for prescription drugs from a tiered copayment to tiered coinsurance is associated with small and clinically insignificant reductions in use of prescription drugs when combined with maximums on out-of-pocket costs for each tier of coinsurance.
- Findings from studies that have assessed the effects of differences in cost sharing for prescription drugs on use of other types of health care services are *ambiguous*.
  - Some studies have found no differences in hospitalizations, emergency department visits, or outpatient visits.
  - Others have found that higher cost sharing is associated with higher rates of hospitalization, emergency department visits, and/or outpatient visits among persons with acute coronary syndrome, congestive heart failure, lipid disorders, and diabetes.

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

AB 310 applies to all plans and policies that have an outpatient prescription drug benefit (96% of the plans and policies that may be subject to state level mandates). Therefore, the mandate would directly affect the health insurance of 20.9 million people (56% of Californians). Table 1 summarizes the expected benefit coverage, cost, and utilization impacts for AB 310.

### Analytic Approach and Assumptions

- If AB 310 were enacted, use of coinsurance as a cost-sharing mechanism for the outpatient prescription drug benefit would be prohibited. Therefore, outpatient prescription drug designs would be altered to eliminate the use of coinsurance and would use copayments as the cost-sharing mechanism.
- For those plans or policies that have an annual out-of-pocket maximum (OOP maximum), out-of-pocket costs (copayments, deductibles) for prescription drugs would be applied toward the annual OOP maximum. For the purposes of this analysis, CHBRP assumes that the total annual OOP maximum amount would not increase.

### Benefit Coverage Impacts

- Among the enrollees with an outpatient prescription drug benefit, CHBRP estimates that:
  - 12% of enrollees (2,520,000) with health insurance subject to the mandate have coinsurance requirements for outpatient prescription drug benefits;
  - No enrollees have copayments for outpatient prescription drugs over \$150 for a one-month supply; and
  - 66.9% of enrollees (14,015,000) have an annual out-of-pocket maximum for their plan or policy but their outpatient prescription drug benefit is excluded from that annual out-of-pocket maximum.
- Medi-Cal Managed Care plans and MRMIB plans provide coverage for outpatient prescription drugs at no charge or with minimal copayment requirements. Therefore, CHBRP estimates no impact on these publicly funded plans.
- CalPERS HMOs' OOP maximum (set at \$1,500 per enrollee and \$3,000 per family) excludes the outpatient prescription drug benefit. Therefore CalPERS HMOs would have to make adjustments to the outpatient prescription drug benefits to become compliant with AB 310.
- CHBRP estimates no measurable impact of the mandate on the number of uninsured due to premium increases.

### Utilization Impacts

- Premandate, CHBRP estimates that 0.018% of enrollees with outpatient prescription drug benefit have filled prescriptions where the cost share exceeded \$150 for a one-month supply. The utilization rate among such persons was approximately 8.8 prescriptions per 1,000

enrollees with the coinsurance provision per year. These enrollees' out-of-pocket costs were on average \$271 per prescription.

- Postmandate, overall utilization rates and resulting out-of-pocket expenses are expected to change as a result of the mandate. Prescriptions for which coinsurance cost sharing would have exceeded \$150 per one-month supply would be limited to that amount. The average cost share for those prescriptions would therefore fall from \$271 premandate to \$150 per one-month supply postmandate. As a result of this decrease in cost share, CHBRP estimates an 4% increase in utilization for these prescriptions.

### Cost Impacts

- Increases in per member per month (PMPM) premiums vary by market segment. Increases as measured by percentage changes in PMPM premiums are estimated to range from 0.00% (for Medi-Cal Managed Care plans) to an average 0.74% (for CDI-regulated large group policies) in the affected market segments. Increases as measured by PMPM premiums are estimated to range from an average of \$0.00 to \$3.69.
- In the privately funded large-group market, the increase in premiums is estimated to range from an average \$1.12 PMPM among DMHC-regulated plans and \$3.69 PMPM among CDI-regulated policies.
- In the privately funded small-group market, health insurance premiums are estimated to increase by an average of \$0.74 PMPM for DMHC-regulated plans and \$1.16 PMPM for CDI-regulated policies.
- In the privately funded individual market, health insurance premiums are estimated to increase by an average of \$0.36 PMPM and \$0.53 PMPM in the DMHC- and CDI-regulated markets, respectively.
- The premiums for CalPERS HMOs are estimated to increase by \$1.38 PMPM. This impact is attributable to the OOP maximum provision of AB 310.
- Total net health expenditures are projected to increase by \$31.7 million (0.033%) (Table 1). This is due to a \$220.3 million increase in health insurance premiums partially offset by reductions in enrollee cost sharing (\$188.6 million).
- There are likely to be long-term cost impacts but the magnitude is unknown at this time. Advances in drug development are likely to yield new, higher-cost drugs. CHBRP recognizes that a decrease in out-of-pocket expenditures may interact with these trends and thereby further increase the demands for these medications as a result of AB 310. While demand and availability of high-cost drugs increases, insurers and employers could respond in a variety of ways, including increasing the total out of pocket maximum for plans and policies, varying the cost-sharing structure so additional prescription drugs are associated with higher copayments (capped at \$150 per one-month supply), or engaging in additional utilization management strategies. Over time, the combined effects of demand for higher cost prescription drugs with lower out-of-pocket expenditures may lead to increased utilization for these prescription drugs and overall premium increases.

## Public Health Impacts

- CHBRP estimates no public health impact of the provision capping copayments at \$150 per prescription per one-month supply since CHBRP estimates that no enrollees are currently in plans and policies with outpatient prescription drug copayments exceeding \$150.
- AB 310's provision requiring those plans or policies that have an annual OOP maximum to include out-of-pocket cost for the prescription drug benefit may have a public health impact; however, given lack of evidence and data, the potential public health impact is unknown. CHBRP estimates that approximately 0.07% of enrollees have prescription drug cost sharing that currently exceeds the total annual OOP maximum, and approximately 2.77% of enrollees have medical cost sharing that exceeds the cap.
- The public health impact of AB 310's provision prohibiting the use of coinsurance as a cost-sharing mechanism for the prescription drug benefit is limited to those drugs for which coinsurance is currently used and with cost sharing exceeding \$150. CHBRP further limited discussion of potential impacts to those drugs and conditions for which there is existing evidence from the literature of the association between cost sharing and prescription drug utilization. The public health impact analysis is therefore limited to the following drugs and conditions:
  - Etanercept and adalimumab for rheumatoid arthritis (RA): An estimated 460 enrollees would be subject to a 21% reduction in cost sharing for RA drugs postmandate. This represents approximately 60% of all enrollees who have drug claims for the RA drugs etanercept and adalimumab subject to coinsurance. Based on existing evidence, these enrollees may increase utilization depending on various factors, including whether cost was a barrier to use.
  - Interferon beta-1a for multiple sclerosis (MS): An estimated 78 enrollees would be subject to a 41% reduction in cost sharing for MS drugs postmandate. This represents approximately 62% of all enrollees who have drug claims for interferon beta-1a subject to any coinsurance. Based on existing evidence, these enrollees may increase utilization depending on various factors, including whether cost was a barrier to use.
  - Imatinib mesylate for chromosome-positive chronic myeloid leukemia: CHBRP estimates no public health impacts from the mandate, given existing evidence that cost sharing does not affect utilization for this subpopulation.
- To the extent that more people have access to these drugs, there is the potential for beneficial long term health impacts for people who have chronic conditions such as multiple sclerosis and rheumatoid arthritis. However, the long-term public health impacts due to AB 310 are unknown given the uncertainty of how the market may respond to the lower cost-sharing requirements of AB 310.

## Potential Effects of the Federal Affordable Care Act

The federal “Patient Protection and Affordable Care Act” (P.L.111-148) and the “Health Care and Education Reconciliation Act” (H.R.4872) were enacted in March 2010. These laws (together referred to as the “Affordable Care Act [ACA]”) are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government. The provisions that go into effect during these transitional years would affect the baseline, or current enrollment, expenditures, and premiums. It is important to note that CHBRP’s analysis of specific mandate bills typically address the marginal 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 marginal effects are presented in this report.

### Essential Health Benefits Offered by Qualified Health Plans in the Exchange and Potential Interactions with AB 310

The ACA requires beginning 2014 that states “make payments...to defray the cost of any additional benefits” beyond the essential health benefits (EHBs) required to be covered by qualified health plans (QHPs) sold in the Exchange.<sup>7</sup> AB 310 does not require coverage of additional benefits as it specifically states, that “Nothing in this section shall be construed to require a [health care service plan/health insurance policy] to provide coverage not otherwise required by law for any prescription drug.”

In addition, AB 310 would make the requirements of the bill inoperative if the Director of the DMHC or the Insurance Commissioner determines that the requirements would result in the “assumption by the state of additional costs pursuant to Section 1311(d)(3)(B) of the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by Section 10104(e) of Title X of that act, relative to benefits required by the state to be offered by qualified plans in the California Health Benefit Exchange that exceed the requirements imposed by federal law.”

EHBs explicitly include “prescription drugs.”<sup>8</sup> In order for the Director or the Commissioner to determine whether any additional state fiscal liability as it relates to the Exchange would be incurred under AB 310, the following factors would need to be examined:

- a determination of whether AB 310 actually constitutes a requirement of “additional benefits,” given provision (e) stating that the bill does not mandate coverage of prescription drugs;
- the scope of “prescription drug” benefits in the final EHB package;

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<sup>7</sup> Affordable Care Act, 1311(d)(3)(B).

<sup>8</sup> Affordable Care Act, Section 1302(b)(1)(F).

- a determination of whether the cost-sharing requirement under AB 310 is consistent with the cost-sharing structures of the QHPs to be offered in the California Exchange;
- the number of enrollees in QHPs; and
- the methods used to define and calculate the cost of additional benefits.

If AB 310 were determined by the Director or Commissioner to incur state fiscal liability under the ACA provisions governing QHPs, the section would become inoperative, meaning the requirements would be nullified for all plans and policies.

#### ACA's Provisions Related to Annual Out-of-Pocket Maximums

Additionally, beginning in 2014, all plans and policies in the small-group and individual markets (including QHPs sold in the Exchange) will be required to have an annual limit on cost sharing not exceeding the levels for high-deductible health plans (HDHPs) qualifying as Health Savings Accounts (HSAs).<sup>9,10</sup> This would increase the number of enrollees in plans with an annual out-of-pocket maximum, and, concomitantly, increase the number of enrollees whose out-of-pocket expenses for prescription drugs would be required to be included under the out-of-pocket maximum per AB 310.

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<sup>9</sup> Affordable Care Act, Section 1302(c)(1).

<sup>10</sup> CMS estimates these limits would be \$6,645 for an individual and \$13,290 for a family in 2014, as the limits are adjusted annually. See: [https://www.cms.gov/ActuarialStudies/Downloads/PPACA\\_2010-04-22.pdf](https://www.cms.gov/ActuarialStudies/Downloads/PPACA_2010-04-22.pdf).

**Table 1. AB 310 Impacts on Benefit Coverage, Utilization, and Cost, 2011**

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
<b>Benefit Coverage</b>				
Total enrollees with health insurance subject to state-level benefit mandates (a)	21,902,000	21,902,000	0	0.0%
Total enrollees with health insurance subject to AB 310	20,934,000	20,934,000	0	0.0%
Percentage of enrollees with coverage for the mandated benefit				
Outpatient prescription drug benefit requiring coinsurance for any tier	12.0%	0.0%	-12.0%	-100%
Outpatient prescription drug benefit with copayment exceeds \$150	0.0%	0.0%	0.0%	0.0%
Outpatient prescription drug benefit cost share not included in OOPM	66.9%	0.0%	-66.9%	-100%
Outpatient prescription drug benefit compliant with AB 310	30.0%	100.0%	70.0	234%
Number of enrollees with coverage for the mandated benefits				
Outpatient prescription drug benefit requiring coinsurance for any tier	2,520,000	0	-2,520,000	-100%
Outpatient prescription drug benefit with copayment exceeds \$150	0	0	0	0.0%
Outpatient prescription drug benefit Rx cost share not included in OOPM	14,015,000	0	-14,015,000	-100%
Outpatient prescription drug benefit compliant with AB 310	6,270,000	20,934,000	12,664,000	234%
<b>Utilization and cost for those enrollees affected by the coinsurance provision (2,520,000 enrollees)</b>				
Claims without coinsurance:				
Prescriptions per 1,000 enrollees per year	9,840	9,840	0	0.0%
Average cost per prescription	\$97	\$97	\$0	0.0%
Average cost share per prescription	\$13	\$13	\$0	0.0%
Claims with coinsurance and cost share amount ≤ \$150				
Prescriptions per 1,000 enrollees per year	2,941	2,941	0	0.0%
Average cost per prescription	\$105	\$105	\$0	0.0%
Average cost share per prescription	\$20	\$20	\$0	0.0%
Claims with coinsurance and cost share > \$150				
Prescriptions per 1,000 enrollees per year	8.8	9.1	0	4.0%
Average cost per prescription	\$1,638	\$1,638	\$0	0.0%
Average cost share per prescription	\$271	\$150	-\$121	-44.7%
Combined				
Prescriptions per 1,000 enrollees per year	12,789.9	12,790.2	0	0.0%
Average cost per prescription	\$100	\$100	\$0.04	0.0%
Average cost share per prescription	\$14.99	\$14.91	-\$0.08	-0.5%

**Table 1. AB 310 Impacts on Benefit Coverage, Utilization, and Cost, 2011 (Cont'd)**

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
<b>Expenditures</b>				
Premium expenditures by private employers for group insurance	\$52,713,266,000	\$52,866,488,000	\$153,222,000	0.2907%
Premium expenditures for individually purchased insurance	\$6,724,851,000	\$6,736,556,000	\$11,708,000	0.1741%
Premium expenditures by persons with group insurance, CalPERS HMOs, Healthy Families Program, AIM or MRMIP(b)	\$15,173,472,000	\$15,217,892,000	\$44,420,000	0.2927%
CalPERS HMO employer expenditures (c)	\$3,465,785,000	\$3,476,762,000	\$10,977,000	0.3167%
Medi-Cal Managed Care Plan expenditures	\$8,657,688,000	\$8,657,688,000	\$0	0.0000%
MRMIB Plan expenditures (d)	\$1,050,631,000	\$1,050,631,000	\$0	0.0000%
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$7,548,415,000	\$7,359,776,000	-\$188,639,000	-2.4991%
<b>Total Expenditures</b>	<b>\$95,334,108,000</b>	<b>\$95,365,796,000</b>	<b>\$31,688,000</b>	<b>0.0332%</b>

Source: California Health Benefits Review Program, 2011.

Notes: (a) This population includes persons with privately funded and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans, Healthy Families Program, AIM, MRMIP) 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) Premium expenditures by enrollees include employee contributions to employer-sponsored health insurance and enrollee contributions for publicly purchased insurance.

(c) Of the increase in CalPERS employer expenditures, about 58% or \$6,367,000 would be expenditures for CalPERS members who are state employees or their dependents.

(d) MRMIB Plan expenditures include expenditures for 874,000 enrollees of the Healthy Families Program, 8,000 enrollees of MRMIP, and 7,000 enrollees of the AIM program.

Key: AIM=Access for Infants and Mothers; CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health; MRMIB=Managed Risk Medical Insurance Board; MRMIP=Major Risk Medical Insurance Program.

## INTRODUCTION

The California Assembly Committee on Health requested on February 10, 2011, 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) 310, a bill that would impose a health benefit mandate. Specifically, AB 310 would prohibit coinsurance as a basis for cost sharing for outpatient prescription drugs; limit copayments to \$150 per one-month supply; and require that a health plan's or policy's out-of-pocket maximum include the outpatient prescription drug benefit. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.<sup>11</sup>

Approximately 21.9 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.<sup>12</sup> Of the rest of the state's population, a portion is uninsured (and so has no health insurance subject to any benefit mandate) and another portion has health insurance subject to other state law or only to federal laws.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state-level benefit mandates. The California Department of Managed Health Care (DMHC)<sup>13</sup> 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,<sup>14</sup> which offer benefit coverage to their enrollees through health insurance policies.

Enrollees in health insurance products not subject to state-level benefit mandates would not be affected by AB 310. Examples would include those enrolled in Medicare (including Medicare Advantage plans) or those who have coverage through self-insured employer plans. In addition, only DMHC-regulated plans and CDI-regulated policies that cover outpatient prescription drugs would be subject to AB 310. Therefore, the mandate would not affect about 968,000 enrollees who do not have an outpatient prescription drug benefit through their health plan or policy. Thus, the mandate would affect the health insurance of approximately 20.9 million Californians (56%).

### Bill Language and Analytic Approach

The full text of AB 310 can be found in Appendix A.

AB 310 would:

- Prohibit coinsurance (i.e., percentage cost of the prescription) as the basis for cost sharing for outpatient prescription drug benefits;

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<sup>11</sup> CHBRP's authorizing statute is available at: [http://www.chbrp.org/documents/authorizing\\_statute.pdf](http://www.chbrp.org/documents/authorizing_statute.pdf)

<sup>12</sup> CHBRP's estimates are available at: [http://www.chbrp.org/other\\_publications/index.php](http://www.chbrp.org/other_publications/index.php).

<sup>13</sup> The DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.

<sup>14</sup> The 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, Section 106(b) or subdivision (a) of Section 10198.6.

- Limit copayments for outpatient prescription drugs to \$150 per one-month supply or its equivalent for prescriptions for longer periods, adjusted for inflation; and
- If a plan/policy has an annual out-of-pocket maximum, require outpatient prescription drug benefit cost sharing to be included under that annual out-of-pocket maximum.

AB 310 would not:

- require plans or policies without an outpatient prescription drug benefit to begin to cover prescription drugs.
- require coverage of specific drugs or require plans or policies to make changes to their formularies.

The definitions of “inflation” and “one month-supply” are not further specified by AB 310.

According to the bill author, the intent of the bill is to cap the highest cost share for prescription medications at \$150 per one-month supply. The bill is co-sponsored by the MS (Multiple Sclerosis) Society and the Alliance for Plasma Therapies. Per the author and sponsors, the problem that the bill attempts to address is that an increasing number of health insurers are placing critical, life-saving drugs on tiers that require patients to pay high out-of-pocket costs. They state that these costs can be very expensive and can prohibit patients in some cases from accessing the medication. They state that the problem began with the implementation in Medicare Part D of a “specialty tier” (in which enrollees pay coinsurance for specified drugs) in 2006, and that commercial plans and insurers are now starting to move toward the approach.<sup>15</sup>

### Prescription Drug Benefit Structure

AB 310 deals primarily with three features of benefit design: copayments, coinsurance, and the out-of-pocket maximum. A *copayment* is a fixed, flat-dollar amount that an enrollee pays when filling a prescription. *Coinsurance* is where the enrollee pays a percentage cost of the prescription, rather than a fixed amount. An *out-of-pocket maximum* is an annual limit on the total out-of-pocket costs (excluding premium payments) that an enrollee is responsible for during plan year.<sup>16</sup> Generally, out-of-pocket maximums have tended to exclude prescription drug cost sharing from counting toward the maximum. Prescription drug benefits may also be subject to a *deductible*, where the enrollee pays the full cost of covered treatments and services (including prescription drugs) until a certain amount has been met.<sup>17</sup>

In general, benefit designs can be characterized by the number of tiers into which they divide drugs, each tier having a distinct cost-sharing level and/or form.

- One-Tier designs have the same cost sharing regardless of drug type.

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<sup>15</sup> Personal correspondence with Maxine Mantell, National Multiple Sclerosis Society, California Network (co-sponsor of AB 310).

<sup>16</sup> Out-of-pocket maximums may alternately or additionally apply in other ways, such as per service, per month, per quarter, or per family.

<sup>17</sup> There may also be a separate deductible for prescription drugs, though as of 2008 this was limited to 12% of enrollees in employer-sponsored insurance nationally and averaged \$108 (KFF, 2010).

- Two-Tier designs generally have one payment for *generic*<sup>18</sup> drugs and another for *brand-name* drugs.
- Three-Tier designs generally have one payment for generics, and two different payments for brand-name drugs, dividing them into *preferred*<sup>19</sup> (lower cost sharing) and *nonpreferred*<sup>20</sup> (higher cost sharing).
- Four-Tier designs generally have the three tiers above, plus a fourth cost-sharing level for specific drugs, such as “lifestyle” drugs (e.g., erectile dysfunction, weight loss), specialty drugs, (e.g., self-injectable drugs, biologics), or others for which a plan may want to impose differential cost sharing (CHCF, 2010; KFF/HRET, 2010).

Table 2 shows the prevalence of these different prescription drug benefit structures among employer-sponsored health insurance in California and nationally.

**Table 2.** Distribution of the types of prescription drug benefit structure for health insurance plans in California and Nationally, 2010

	California	United States
<b>One-Tier</b>	8%	5%
<b>Two-Tier</b>	27%	11%
<b>Three-Tier</b>	59%	65%
<b>Four-Tier</b>	3%	13%
<b>Other</b>	4%	5%

Sources: CHCF, 2010; KFF/HRET, 2010

Two-tier benefit designs—which generally impose differential cost sharing only by generic and brand-name—are more pervasive among California employer-based health insurance plans. Approximately 27% of California “workers” (defined as subscribers to employer-sponsored insurance and their dependents) have such plans compared to 11% nationally. Another difference is that 3% of California workers have a four-tier design, whereas the analogous figure is 13% nationally.

The share of designs with greater than two tiers has grown rapidly since 2000. In 2000, 27% of workers nationally were in plans with three-tier benefits, and close to none of these had a fourth tier. In 2010, 65% of workers nationally had a three-tier design with 13% having a four-tier design, or 78% combined (KFF, 2010).

The California Employer Health Benefits Survey found that average copayments among California workers in 2010 was \$10.58 for generics, \$24.99 for preferred, and \$42.31 for nonpreferred drugs (CHCF, 2010), meaning that for a California worker a preferred drug is, on average, 60% the cost of a nonpreferred drug. While the design is relatively uncommon in

<sup>18</sup> A *generic* drug is no longer covered by patent protection and thus may be produced and/or distributed by multiple drug companies.

<sup>19</sup> A *preferred* drug is one included on a formulary or preferred drug list; for example, a brand-name drug without a generic substitute.

<sup>20</sup> A *nonpreferred* drug is one not included on a formulary or preferred drug list; for example, a brand-name drug with a generic substitute.

California, a national survey found that fourth-tier drug copayments averaged \$85 in 2009 (KFF, 2010).

Differential cost sharing is one utilization management technique plans have employed to restrain the growth of health spending, but plans have also adopted other techniques to control drug costs by enrollees. These include step therapy (requiring a patient to fail one drug first before being covered for another), prior authorization (requiring approval by the plan before being covered), using formularies to exclude certain drugs, and imposing quantity dispensing limits (KFF, 2010).

Prescription drug benefit design is complex and varies widely. For example, plans may require coinsurance on a tier, but cap the amount paid per 30- or 90-day supply. Plans may mix copayments on some tiers with coinsurance on others (e.g., flat copayment levels for three tiers, and coinsurance for a fourth). Plans 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 for some plans and the prescription drug benefit for others.

### Existing California Requirements

DMHC-regulated plans are subject to specific limitations regarding prescription drug cost sharing.<sup>21</sup> Outpatient prescription drugs are defined in regulations 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.”<sup>22</sup> “Self-administered” means those drugs that need not be administered in a clinical setting or by a licensed health care provider.

Cost sharing (copayments, coinsurance, and deductibles) rules are under subsection (c); it requires the following:

1. The copayment cannot exceed the retail price of the drug.
2. A copayment or percentage coinsurance shall not exceed 50 percent of the “cost to the plan.”
3. If a plan uses coinsurance, it must either:
  - a. Have a maximum dollar amount cap on the percentage coinsurance that will be charged for an individual prescription; it must apply towards an annual out-of-pocket maximum for the product; or apply towards an annual out-of-pocket maximum for the prescription drug benefit.
4. The “cost to the plan” means the actual cost incurred by the plan or its contracting pharmacy benefit manager. (The regulations include certain examples in how this might be calculated.)

CDI-regulated policies do not have analogous limits on prescription cost sharing.

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<sup>21</sup> California Code of Regulations, Section 1300.67.24

<sup>22</sup> California Code of Regulations, Section 1300.67.24(a)(1)

DMHC-regulated plans are also subject to other requirements that may interact with AB 310. DMHC-regulated plans are required to cover prescription drugs if the drug previously had been approved for coverage by the plan (i.e., “continuity drugs”) for the enrollee’s medical condition 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. DMHC-regulated plans are also required to have a process by which enrollees may obtain authorization for nonformulary prescription drugs and that process is also subject to DMHC review and approval. Nonformulary prescription drugs are permitted to have a differential cost sharing as long as it complies with regulations governing the limitation of prescription drug benefits cost sharing.<sup>23</sup>

Both DMHC-regulated plans and CDI-regulated policies are also required 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.<sup>24</sup>

### Requirements in Other States

CHBRP is aware of one similar existing requirement in another state: New York prohibited the implementation of “specialty tiers” in 2010.<sup>25</sup> Legislation similar to AB 310 has been introduced in at least nine other states (Massachusetts, Iowa, Virginia, Nebraska, Minnesota, Wisconsin, Washington, Vermont, and Maryland), but each addresses the issue of prescription drug cost sharing in different ways.

### Consumer Complaints

CHBRP inquired with the two state regulatory agencies regarding complaints related to affordability or high costs for drugs with: (1) copayments exceeding \$150, and (2) coinsurance. DMHC does not capture the complaints in the manner described above. However, since January 1, 2007, the DMHC Help Center has received 770 complaints regarding prescription drugs where out-of-pocket costs were listed as part of the complaint. In at least 372 of these complaints, consumers cited concerns related to cost sharing.<sup>26</sup> The CDI does not track complaints at this level of detail, but a poll of staff indicated that they do not receive complaints for copayments above \$150, and that they do not receive many complaints for prescription drug copayments.<sup>27</sup>

### Key Assumptions and Caveats

AB 310 is not a typical benefit mandate, in that it does not mandate coverage of specific treatments or services. Therefore, CHBRP’s analysis regarding medical effectiveness, cost, and public health impacts have been adjusted to address the questions relevant to this bill.

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<sup>23</sup> California Health & Safety Code, Section 1367.24

<sup>24</sup> California Health & Safety Code, Section 1367.21 and California Insurance Code 10123.195.

<sup>25</sup> New York Assembly Bill 8278B/Senate Bill 5000B (2009-10 Legislative Session).

<sup>26</sup> Personal correspondence with Abal Amu-Rahma, California Department of Managed Health Care, March 8, 2011.

<sup>27</sup> Personal correspondence with Josephine Figueroa, California Department of Insurance, March 4, 2011.

- Because AB 310 would not require coverage of any prescription drugs nor require changes to a plan or policy's formulary, the *Medical Effectiveness* section reviews and analyzes the literature related to the effects of cost sharing on utilization of prescription drugs.
- The *Benefit Coverage, Utilization, and Cost Impacts* section addresses the effects of AB 310's three key provisions on overall utilization of the prescription drug benefit, premiums, and health care expenditures.
- The *Public Health Impacts* section summarizes the potential impact of the legislation on specific drugs or classes of drugs for which enrollee cost sharing is currently high (defined as above \$150), and would be expected to be reduced by this bill.

The impacts modeled in the *Benefit Coverage, Utilization, and Cost Impacts* section rely on some key assumptions. The analysis assumes there are no changes in benefit design (such as changes to deductibles, out-of-pocket maximums, or annual limits) other than that copayments exceeding \$150 would be lowered to that number, coinsurance exceeding \$150 would become a copayment at that number, and prescription drug cost sharing would be included under the plan or policy's out-of-pocket maximum, if it already includes one. Alternative compliance approaches would lead to different impacts.

For example, plans and insurers may respond to the bill by increasing the out-of-pocket maximum, which would offset some portion of the increase in premiums by imposing higher annual out-of-pocket costs to enrollees. Plans and insurers may also change copayments for other drugs (for example, by increasing the copayment amount on generic or brand tiers to offset the premium impact from the reduction in cost sharing for high-cost drugs). The impacts, however, would vary widely by drug, and it would be difficult to attribute the impact from changes in copayment amounts specifically to AB 310 when plans and insurers may change copayment amounts for other reasons.

The analysis relies on the standard assumption that the number of enrollees in plans subject to the bill remains constant. AB 310 may result in employers (especially large employers) choosing to "carve out" their outpatient prescription drug benefit by contracting with a third-party pharmacy benefit manager (PBM) thereby providing the benefit separately from the general health benefit. Depending on how AB 310 is interpreted, these carved out PBMs – that are directly contracted by large employer groups (rather than subcontracted by health plans) – may not be subject to AB 310, as AB 310 only applies to those health plans and policies that cover prescription drugs directly or through a subcontracting PBM. Therefore, the population enrolled in plans and policies subject to AB 310 may change over time.

## **Potential Effects of the Federal Affordable Care Act**

The federal "Patient Protection and Affordable Care Act" (P.L.111-148) and the "Health Care and Education Reconciliation Act" (H.R.4872) were enacted in March 2010. These laws (together referred to as the "Affordable Care Act [ACA]") are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming

effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government. The provisions that go into effect during these transitional years would affect the baseline, or current enrollment, expenditures, and premiums. It is important to note that CHBRP's analysis of specific mandate bills typically address the marginal 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 marginal effects are presented in this report.

### Essential Health Benefits Offered by Qualified Health Plans in the Exchange and Potential Interactions with AB 310

The ACA requires beginning 2014 that states “make payments...to defray the cost of any additional benefits” beyond the essential health benefits (EHBs) required to be covered by qualified health plans (QHPs) sold in the Exchange.<sup>28</sup> AB 310 does not require coverage of additional benefits as it specifically states, that “Nothing in this section shall be construed to require a [health care service plan/health insurance policy] to provide coverage not otherwise required by law for any prescription drug.”

In addition, AB 310 would make the requirements of the bill inoperative if the Director of the DMHC or the Insurance Commissioner determines that the requirements would result in the “assumption by the state of additional costs pursuant to Section 1311(d)(3)(B) of the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by Section 10104(e) of Title X of that act, relative to benefits required by the state to be offered by qualified plans in the California Health Benefit Exchange that exceed the requirements imposed by federal law.”

EHBs explicitly include “Prescription drugs.”<sup>29</sup> In order for the Director or the Commissioner to determine whether any additional state fiscal liability as it relates to the Exchange would be incurred under AB 310, the following factors would need to be examined:

- a determination of whether AB 310 actually constitutes a requirement of “additional benefits,” given provision (e) stating that the bill does not mandate coverage of prescription drugs;
- the scope of “prescription drug” benefits in the final EHB package;
- a determination of whether the cost-sharing requirement under AB 310 is consistent with the cost-sharing structures of the QHPs to be offered in the California Exchange;
- the number of enrollees in QHPs; and
- the methods used to define and calculate the cost of additional benefits.

If AB 310 were determined by the Director or Commissioner to incur state fiscal liability under the ACA provisions governing QHPs, the section would become inoperative, meaning the requirements would be nullified for all plans and policies.

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<sup>28</sup> Affordable Care Act, 1311(d)(3)(B).

<sup>29</sup> Affordable Care Act, Section 1302(b)(1)(F).

### ACA's Provisions Related to Annual Out-of-Pocket Maximums

Additionally, beginning in 2014, all plans and policies in the small group and individual markets (including QHPs sold in the Exchange) will be required to have an annual limit on cost sharing not exceeding the levels for high-deductible health plans (HDHPs) qualifying as Health Savings Accounts (HSAs).<sup>30,31</sup> This would increase the number of enrollees in plans with an annual out-of-pocket maximum, and, concomitantly, increase the number of enrollees whose out-of-pocket expenses for prescription drug would be required to be included under the out-of-pocket maximum per AB 310.

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<sup>30</sup> Affordable Care Act, Section 1302(c)(1).

<sup>31</sup> CMS estimates these limits would be \$6,645 for an individual and \$13,290 for a family in 2014, as the limits are adjusted annually. See: [https://www.cms.gov/ActuarialStudies/Downloads/PPACA\\_2010-04-22.pdf](https://www.cms.gov/ActuarialStudies/Downloads/PPACA_2010-04-22.pdf).

## MEDICAL EFFECTIVENESS

Prescription drugs are used to treat most diseases and conditions. Some prescription drugs are used to treat infections and other acute conditions. Others are used to prevent or manage chronic conditions such as anemia, arthritis, asthma, depression, diabetes, and heart disease. Still others are used as part of chemotherapy to treat cancer. In some cases, such as the human immunodeficiency virus (HIV), the development of effective prescription drugs has transformed a life-threatening condition into a chronic disease. In other cases, such as ulcers, prescription drugs have replaced other health care services as the primary treatment for a condition.

Prescription drugs can be divided into two major categories: traditional agents and specialty drugs. Specialty drugs are new, high-cost drugs, primarily biologics. These drugs are generally used to treat complex chronic conditions, such as anemia, cancer, growth hormone deficiency, hemophilia, hepatitis, multiple sclerosis, and rheumatoid arthritis. Specialty drugs are administered by injection, intravenously, or orally. They are more expensive than traditional oral agents because they are more expensive to produce and because no generic or “biosimilar” versions (biotechnology-derived medications with properties similar to existing biotechnology-derived medications) of them are available.

Traditional agents consist of generic and brand-name drugs that are produced using traditional pharmaceutical manufacturing processes. Most traditional agents are administered orally as tablets or capsules, although some are inhaled (e.g., aerosol and dry powder medications for asthma and chronic obstructive pulmonary disease), injected (e.g., cortisone injections for inflammation associated with arthritis or other conditions) or administered transdermally (e.g., transdermal patches for contraception and pain relief).

### Research Approach and Methods

CHBRP’s medical effectiveness analysis for AB 310 focuses on the impact of cost sharing (i.e., the portion of expenditures paid by enrollees) for prescription drugs on use of drugs and other health care services. CHBRP chose this analytic approach because AB 310 would not increase the number of Californians who have coverage for prescription drugs, but would instead affect the terms and conditions of prescription drug coverage for enrollees who have such coverage.

#### Literature Review Methods

Studies of the effects of cost sharing on use of prescription drugs were identified through searches of PubMed, PsycINFO, EconLit, and other databases. The search was limited to abstracts of peer-reviewed research studies that were published in English and conducted in the United States. The search was limited to studies published from 2007 to present. CHBRP relied on two systematic reviews published in 2007 for findings from studies published prior to 2007.

The medical effectiveness review focused on studies of cost sharing for prescription drugs among persons receiving health insurance through commercial health plans and health insurers because AB 310 would primarily affect coverage for persons enrolled in commercial health plans. Findings from studies of persons enrolled in Medicare or Medicaid (Medi-Cal in

California) are less generalizable to the population affected by AB 310 because persons enrolled in Medicare and Medicaid tend to be older or poorer than persons who obtain coverage through commercial health plans and health insurers. The review also focused on studies conducted in the United States, because findings from studies of changes in prescription drug cost sharing in countries with different types of health insurance and health care systems may not be generalizable to Californians.

A total of 17 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. Appendix C includes a table describing the studies that CHBRP reviewed (Table C-1) and a table summarizing evidence of effectiveness (Table C-2).

### **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 multi-site randomized controlled trial (RCT) conducted in the late 1970s and early 1980s. The RAND HIE found that persons enrolled in fee-for-service health insurance plans who paid a larger share of costs for prescription drugs bought fewer prescription drugs than persons with more generous coverage. The magnitude of the effect of cost sharing on expenditures for prescription drugs was similar to the magnitude of its effect on expenditures for ambulatory medical care (Leibowitz et al., 1985). One important limitation of the RAND HIE is that persons were randomized to health insurance plans that provided more or less generous coverage for all covered medical services not just prescription drugs. As a consequence, the RAND HIE only compares prescription drug use in health plans that are more or less generous overall. It does not assess the impact of differences in cost sharing for prescription drugs in isolation from differences in cost sharing for other medical services.

Newer studies of the impact of cost sharing on use of prescription drugs have not randomized subjects. The lack of randomization limits confidence that differences in use of prescription drugs or other services between persons facing higher and lower cost sharing for prescription drugs are due to cost sharing versus other factors that may affect use of prescription drugs. These factors include health behaviors, severity of illness, income, education, and the health care expenses of other family members.

Most studies of cost sharing for prescription drugs are conducted using health insurance claims data from health plans and health insurers. Health insurance claims often contain limited information about enrollees' health behaviors, health status, or socioeconomic characteristics (Goldman et al., 2007). The best nonrandomized studies of cost sharing for prescription drugs have used rigorous methods to take such factors into account in their analyses. For example, some studies have controlled for demographic characteristics, such as age, sex, and co-morbid conditions. Some studies have used median household income at the three-digit or five-digit ZIP code level as a proxy for enrollees' incomes (Gleason et al., 2009; Goldman et al., 2010; Hodgkin et al., 2008; Karaca-Mandic et al., 2010). One study used claims data for other members of an enrollee's family to assess whether other family members' health expenses

influence an enrollee's decision to initiate prescription drug therapy or continue taking a drug (Karaca-Mandic et al., 2010).

In addition, pharmacy claims data only indicate whether prescriptions have been filled and the amount dispensed. Persons who fill prescriptions may not always use the drugs they have received or may not use them as directed. Data on actual usage is difficult to obtain. While persons can be asked about their use of prescription drugs, their responses may be subject to recall bias.

## **Outcomes Assessed**

Most studies of cost sharing for prescription drugs have examined effects on use of drugs. These effects have been measured in a variety of ways. Some studies have examined differences in the number of prescriptions filled or the number of days of supply of a drug in an enrollee's possession. Some studies of cost sharing for prescription drugs for chronic conditions that are taken on a daily basis have used information on days of supply to calculate a *medication possession ratio*, a measure of adherence to recommended drug therapy for chronic conditions. The medication possession ratio is a ratio of days of supply to the total number of days in a fixed period of time, such as one year. Other studies have assessed the impact of differences in cost sharing on initiation, continuation, or discontinuation of drug therapy. Still others have estimated the price elasticity of demand, a measure that shows how the quantity demanded or supplied will change when the price changes.

A few studies have evaluated the impact of cost sharing for traditional agents on use of other types of health care services. These studies seek to determine whether higher cost sharing for prescription drugs leads people to substitute other types of health care services, either intentionally or because their conditions are not as well controlled. These studies have described the impact of cost sharing for prescription drugs on hospital admissions, emergency department visits, and outpatient visits. CHBRP identified no studies of the effects of cost sharing for specialty drugs on use of other health care services.

CHBRP identified no studies that directly examined the impact of cost sharing on health outcomes. One study of cost sharing for diabetes drugs indirectly addressed health outcomes by demonstrating that higher cost sharing was associated with a lower medication possession ratio and that persons with lower medication possession ratios, in turn, had higher levels of hemoglobin A<sub>1c</sub> (Barron et al., 2008). Higher hemoglobin A<sub>1c</sub> levels are associated with poorer control of blood sugar, which increases the risk for diabetes-related complications.

## **Study Findings**

### Specialty drugs

#### *Effects of cost sharing on use of specialty drugs*

CHBRP identified eight studies that examined the effects of cost sharing on use of specialty drugs. The first of these studies was published by Goldman and colleagues in 2006. The authors estimated price elasticities of demand for specialty drugs used to treat cancer, kidney disease, multiple sclerosis, and rheumatoid arthritis. Pharmacy claims for persons who received health

insurance through 15 large employers were analyzed. The authors found that use of these four classes of specialty drugs is not very sensitive to cost sharing and that price elasticities of demand varied across the four classes of specialty drugs, ranging from 0.01 for cancer drugs to 0.21 for rheumatoid arthritis drugs. This finding means that each 10% increase in cost sharing for specialty drugs would reduce spending for cancer drugs by 0.1% and spending for rheumatoid arthritis drugs by 2.1%. The price elasticities of demand were statistically significant for specialty drugs used to treat rheumatoid arthritis or multiple sclerosis but not for specialty drugs used for cancer or kidney disease (Goldman et al., 2006).

Other studies of cost sharing for specialty drugs have focused more narrowly on one or two classes of drugs. A study by Goldman et al. (2010) calculated the price elasticity of demand for five specialty drugs used to treat cancer. The authors analyzed pharmacy claims for persons who received health insurance through 15 employers. The authors found that a 10% decrease in out-of-pocket costs for one specialty drug, Rituxan (rituximab), was associated with a 2.6% increase in the probability of initiating treatment with this drug. The same decrease in out-of-pocket costs was associated with a 1.9% decrease in use of the other specialty drugs included in the study but the finding was not statistically significant.<sup>32</sup>

Two studies have assessed the impact of cost sharing on use of specialty drugs for multiple sclerosis (Dor et al., 2010; Gleason et al., 2009). Both studies analyzed pharmacy claims for persons with commercial insurance. Gleason et al. (2009) found that persons with multiple sclerosis who faced out-of-pocket costs of more than \$200 per prescription for specialty drugs<sup>33</sup> were less likely to initiate treatment with such drugs than persons whose out-of-pocket costs were less than \$200 per prescription. Dor et al. (2010) reported that the effect of higher cost sharing on adherence to specialty drugs for multiple sclerosis<sup>34</sup> (as measured by the medication possession ratio) differed between persons whose coverage required copayments or coinsurance. For persons required to pay coinsurance, higher cost sharing was associated with a statistically significant decrease in adherence (i.e., persons with higher cost sharing had lower supplies of medication on hand). Among persons paying coinsurance, a 10% increase in cost sharing was associated with an 8.6% reduction in adherence. In contrast, the effect of higher copayments on adherence was small and not statistically significant.

Studies by Curkendall et al. (2008), Gleason et al. (2009), and Karaca-Mandic et al. (2010) have examined the effects of cost sharing on use of tumor necrosis factor  $\alpha$  blockers, a class of specialty drugs used to treat rheumatoid arthritis.<sup>35</sup> The authors of all three studies analyzed

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<sup>32</sup> The other drugs included in the study were Avastin (bevacizumab), Gleevec (imatinib mesylate), Herceptin (trastuzumab), and Tarceva (erlotinib) (Goldman et al., 2010).

<sup>33</sup> Gleason et al. (2009) analyzed effects of out-of-pocket costs on use of Avonex (interferon beta-1a intramuscular), Betaseron (interferon beta-1b), and Copaxone (glatiramer acetate).

<sup>34</sup> Dor et al. (2010) analyzed effects of coinsurance and copayments on use of Avonex (interferon beta-1a intramuscular), Betaseron (interferon beta-1b), Copaxone (glatiramer acetate), and Rebif (interferon beta-1 supcutaneous).

<sup>35</sup> Tumor necrosis factor  $\alpha$  blockers encompass three specialty drugs that are administered by injection: Enbrel (etanercept), Humira (adalimumab), and Remicade (infliximab) (Curkendall et al., 2008; Gleason et al., 2009; Karaca-Mandic, et al., 2010). Curkendall et al., 2008, and Gleason et al., 2009, only analyzed the effects of cost sharing on use of Enbrel (etanercept) and Humira (adalimumab) because these drugs are self-injected, whereas

pharmacy claims for persons with commercial insurance. Two studies found that persons with rheumatoid arthritis who had higher out-of-pocket costs for specialty drugs were less likely to initiate treatment with tumor necrosis factor  $\alpha$  blockers and that the difference was statistically significant (Gleason et al., 2009; Karaca-Mandic et al., 2010). Among all persons with rheumatoid arthritis, Karaca-Mandic et al. (2010) reported that the association between cost sharing and continuation of specialty drug treatment was weaker and not statistically significant. Karaca-Mandic et al. (2010) also found that persons with rheumatoid arthritis who lived in households in which other family members had high out-of-pocket expenditures for health care services were less likely to initiate treatment with a specialty drug. Curkendall et al. (2008), reported that persons with rheumatoid arthritis who had higher cost sharing for tumor necrosis factor  $\alpha$  blockers had lower rates of adherence to these drugs (as measured by medication possession ratio) and were more likely to discontinue using them.<sup>36</sup>

One study has evaluated the impact of cost sharing on use of Forteo (teriparatide), an injectable specialty drug used to treat osteoporosis (Foster et al., 2009). The authors calculated the average copayment per day for persons with osteoporosis who were enrolled in commercial health insurance plans or Medicare. The authors found that higher cost sharing was associated with poorer adherence to Forteo. Persons with osteoporosis who faced higher cost sharing discontinued filling prescriptions for Forteo more quickly than persons who faced lower cost sharing and had a shorter time to the first 60-day gap in prescriptions filled for the drug.

Recognizing that income may affect a person's use of prescription drugs, the authors of four of the eight studies of specialty drugs took median income in the ZIP codes in which persons resided into consideration when estimating the effects of cost sharing (Gleason et al., 2009; Goldman et al., 2006, 2010; Karaca-Mandic, et al., 2010). The authors used median household income at the ZIP code level because the pharmaceutical claims data they analyzed did not include measures of household income. The use of median household income at the ZIP code level as a proxy for household income enables authors to estimate the impact of cost sharing on use of prescription drugs while controlling for differences in income that may also affect utilization.

#### *Effects of cost sharing for specialty drugs on use of other health care services*

CHBRP identified no studies of the effects of cost sharing for specialty drugs on use of other types of health care services. *The absence of evidence is not evidence of no effect.* It is possible that higher cost sharing for specialty drugs is associated with greater use of other types of health care services. However, the effect may be small because use of specialty drugs is not very sensitive to price.

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Remicade (infliximab) is infused in a physician's office. Karaca-Mandic et al. (2010), analyzed effects of cost sharing on use of all three drugs.

<sup>36</sup> New specialty drugs for rheumatoid arthritis have entered the market since the time periods during which the data analyzed by Curkendall et al. (2008), Gleason et al. (2009), and Karaca-Mandic et al. (2010) were collected. Although no studies of the impact of cost sharing on the use of these new drugs were identified, it is likely that the effects of cost sharing on the use of these drugs would be similar to the effects of cost sharing associated with the specialty drugs for rheumatoid arthritis that have been studied.

## Traditional agents

### *Effects of cost sharing on use of traditional oral agents*

A large number of studies on the effects of cost sharing on use of traditional agents have been published. Two systematic reviews have synthesized findings from studies published prior to 2007 (Austvoll-Dahlgren et al., 2008; Goldman et al., 2007). CHBRP relied on these systematic reviews for findings from literature on traditional oral agents published prior to 2007 and only reviewed individual studies published since that time.

**Multiple classes of traditional oral agents.** Both systematic reviews found that in general higher cost sharing for traditional agents is associated with less use of these drugs (Austvoll-Dahlgren et al., 2008; Goldman et al., 2007). Findings from these systematic reviews also suggest that demand for traditional agents is more price sensitive than demand for specialty drugs. The authors of one systematic review that included 65 studies found that each 10% increase in cost sharing for traditional agents is associated with a 2% to 6% decrease in their use.

Findings from studies that compared the impact of cost sharing on use of different classes of traditional agents are *ambiguous*. Austvoll-Dahlgren et al. (2008) summarized a study that found that implementation of a copayment was associated with larger reductions in the use of “discretionary” drugs than “essential” drugs. Another study summarized by Austvoll-Dahlgren et al. (2008) found that increasing copayments was associated with reductions in the use of antidepressants and sedatives among men but not among women and did not affect use of anti-anxiety drugs by either sex. Goldman et al. (2007) identified one study that found that the effect of each 10% increase in cost sharing varied across eight classes of prescription drugs, ranging from a 2.5% reduction in use of oral diabetes medications to a 4.5% reduction for anti-inflammatory medications. In contrast, another study identified by Goldman et al. (2007) reported no statistically significant difference in the effect of increasing cost sharing across nine classes of prescription drugs.

CHBRP identified one study that assessed the impact of replacing copayments for prescription drugs with coinsurance (Klepser et al., 2007). The authors compared use of prescription drugs among persons enrolled in a health plan whose pharmacy benefit was converted from a three-tier copayment design to a four-tier coinsurance design to persons enrolled in the same health plan who continued to have a three-tier copayment benefit. The four-tier coinsurance benefit design incorporated minimum and maximum out-of-pocket costs for each tier. For drugs in the highest tier, which consisted of specialty drugs, persons were charged coinsurance at a rate of 25% with an out-of-pocket minimum of \$50 and an out-of-pocket maximum of \$100. The authors found that implementation of the four-tiered coinsurance design was associated with small and clinically insignificant reductions in days of supply of prescription drugs dispensed for all prescription drugs and for three widely used classes of traditional oral agents (antihypertensive medications, cholesterol lowering drugs, and selective serotonin reuptake inhibitors/serotonin norepinephrine reuptake inhibitors). Findings from this study suggest that changing cost sharing for prescription drugs from a tiered copayment to tiered coinsurance has minimal effects on use of prescription drugs when combined with maximums on out-of-pocket costs for each tier of coinsurance.

**Individual classes of traditional agents.** Seven studies published subsequent to the studies included in the systematic reviews have assessed the impact of cost sharing on use of traditional agents for acute coronary syndrome, congestive heart failure, depression, and diabetes. The authors of all seven studies analyzed pharmacy claims for persons with commercial health plans or health insurance.

Two studies have examined the impact of cost sharing on use of prescription drugs by persons who have been hospitalized for coronary heart disease (Philipson et al., 2010; Ye et al., 2007). Philipson et al. (2010) evaluated the effect of the coinsurance rate, defined as the percentage of total expenditures for prescription drugs that enrollees pay out-of-pocket, on use of antiplatelet agents by persons with acute coronary syndrome who had received a stent. The authors compared persons with high mean cost sharing rates (37%) to persons with low mean cost sharing rates (14%). They found that persons who faced higher cost sharing were less likely to fill a prescription for an antiplatelet drug within one month of stent implantation and were more likely to discontinue antiplatelet therapy within one year after implantation.

Ye et al. (2007) assessed the impact of copayments on use of statins (prescription drugs used to control cholesterol) among persons who had been hospitalized for coronary heart disease. The authors used the medication possession ratio as a proxy for adherence. The medication possession ratio is a good proxy for adherence for statins and other prescription drugs used to control heart disease, because persons with heart disease who are prescribed these drugs should take them on a daily basis. The authors found that persons who had a mean copayment of \$20 or more were less than half as likely to be adherent to statin therapy (i.e., to have sufficient medication on hand to take it on a daily basis) than persons who had a mean copayment of less than \$10.

Chernew et al. (2008) examined the effect of variation in copayments on use of prescription drugs used to manage congestive heart failure. These drugs included angiotensin converting enzyme inhibitors/angiotensin receptor blockers, beta blockers, and statins. The authors used the medication possession ratio as a proxy for adherence to recommended pharmacotherapy for congestive heart failure. They found that persons with congestive heart failure who had higher copayments had poorer adherence than persons who had lower copayments.

Four recent studies have assessed the impact of cost sharing on use of orally administered prescription drugs to control diabetes (Barron et al., 2008; Chernew et al., 2008; Colombi et al., 2008; Dor and Encinosa, 2010). The authors of all four studies used the medication possession ratio as a proxy for adherence. As with heart disease, the medication possession ratio is a good proxy for adherence for diabetes drugs, because persons with diabetes who are prescribed prescription drugs to control their condition should take them on a daily basis. All four studies found that persons who had higher copayments had poorer adherence to oral diabetes drugs than persons who had lower copayments (i.e., had lower medication possession ratios). Barron et al. (2008) also reported that persons who had higher copayments were more likely to discontinue use of oral diabetes drugs. Dor and Encinosa (2010) compared rates of adherence to oral diabetes medications between persons with copayments and coinsurance. They found that persons who faced higher cost sharing in either the form of copayments or coinsurance had poorer adherence

and that the effect of higher cost sharing was more pronounced among persons with coinsurance than among persons with copayments.

One recent study examined the impact of instituting a three-tier copayment benefit design on use of antidepressant medications (Hodgkin et al., 2008). The authors analyzed data from a large health plan that staggered implementation of a three-tiered copayment design across the employers to which it provided coverage. Under the three-tier design, the health plan distinguished between “preferred” and “nonpreferred” brand-name drugs within therapeutic classes. Enrollees were charged higher copayments for nonpreferred brand-name drugs than for preferred brand-name drugs. (Copayments for generic drugs were lower than copayments for both types of brand-name drugs). The authors found the number of prescriptions filled per enrollee for nonpreferred antidepressants decreased among both persons who had a three-tier pharmacy benefit and those who had other pharmacy benefit designs but that the magnitude was greater among persons who had a three-tier benefit (11% vs. 5%). However, out-of-pocket costs for prescription drugs simultaneously increased for persons who had a three-tier benefit, suggesting that demand for nonpreferred drugs was not very sensitive to price.

Two of the seven studies of the effects of cost sharing on use of traditional agents also addressed the effects of income. Hodgkin et al. (2008) included a variable measuring median household income at the five-digit ZIP code level to control for the effect of income on utilization of antidepressant medications. This approach enabled the authors to more precisely estimate the effect of cost sharing on utilization. Chernew et al. (2009) compared the effects of increases in copayments for traditional agents among persons living in ZIP codes with four categories of median household income (<\$30,000, \$30,000 to \$42,000, \$42,000 to \$62,000, >\$62,000). The authors found that persons in ZIP codes with the lowest category of median household income were more sensitive to copayment increases than persons in ZIP codes with higher median household incomes for all classes of medication studied except oral anti-diabetes medications. (For oral anti-diabetes medication, persons in ZIP codes with low median household incomes were as sensitive to copayment increases as those in ZIP codes with higher median household incomes.)

#### *Effects of cost sharing for traditional oral agents on use of other health care services*

The two systematic reviews also examined the impact of cost sharing for traditional agents on use of other types of health care services (Austvoll-Dahlgren et al., 2008; Goldman et al., 2007). Both systematic reviews found that studies that examined the impact of increasing copayments for drugs used to treat a wide range of diseases and conditions found no overall effects on hospitalizations, emergency department visits, or outpatient visits.<sup>37</sup> However, studies that have focused on the effects of cost sharing on use of health care services by persons with certain chronic conditions reached the opposite conclusion. Goldman et al. (2007) identified three studies that examined the impact of higher cost sharing for traditional agents on hospitalizations and/or emergency department visits among persons with congestive heart failure, lipid disorders, and diabetes. These studies consistently found that persons with these conditions who had higher cost sharing for traditional agents used to treat their conditions were more likely to be hospitalized or visit the emergency department.

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<sup>37</sup> The authors do not indicate whether the prescription drugs included in the study were traditional agents or specialty drugs. However, it is likely that the vast majority of the prescriptions analyzed were for traditional agents because rates of use of traditional agents are much higher than rates of use for specialty drugs.

Two studies published subsequent to the studies included in the systematic reviews have assessed the impact of cost sharing for traditional agents on use of other health care services among persons with acute coronary syndrome or diabetes. Colombi et al. (2008) reported that persons with diabetes who faced higher cost sharing for prescription drugs were more likely to have an emergency room visit and had more outpatient visits than persons who faced lower cost sharing. However, the authors found no difference in the likelihood of hospitalization. In contrast, Philipson et al. (2010) reported a small but statistically significant difference in the number of re-hospitalizations within one year of stent implantation between persons with acute coronary syndrome who faced high versus low cost sharing for prescription drugs.

## Conclusions

### *Specialty drugs*

- Only a small number of studies of the impact of cost sharing on use of specialty drugs have been published.
- The *preponderance of evidence* from these studies suggests that demand for specialty drugs is sensitive to price but that the size of the effect is small. Estimates of the price elasticity of demand for specialty drugs suggest that each 10% increase in cost sharing for specialty drugs would reduce spending for these drugs by 0.1% to 2.1% depending on the disease a specialty drug is used to treat.
  - Demand for specialty drugs to treat multiple sclerosis and rheumatoid arthritis appears to be more sensitive to cost sharing than demand for specialty drugs for cancer and kidney disease.
- Findings from a single study suggest that the impact of cost sharing on use of specialty drugs for multiple sclerosis varies depending on whether a person's coverage is subject to coinsurance or a copayment. Reductions in use associated with higher cost sharing were greater for persons who were required to pay coinsurance instead of a copayment.
- CHBRP identified no studies of the effects of cost sharing for specialty drugs on use of other types of health care services. No evidence of effect is not evidence of no effect. It is possible that some persons who face higher cost sharing for specialty drug have more hospitalizations, emergency department visits, and outpatient visits than persons who face lower cost sharing.

### *Traditional agents*

- A large number of studies on the effects of cost sharing on use of traditional agents have been published.
- The *preponderance of evidence* from these studies suggests that demand for traditional agents is more sensitive to price than demand for specialty drugs.
  - A systematic review of 65 studies of the impact of cost sharing on use of traditional oral agents found that increases in cost sharing are consistently associated with

- decreases in use of traditional agents. Each 10% increase in cost sharing for traditional agents is associated with a 2% to 6% reduction in their use. Subsequent studies reported similar findings.
- Findings from studies that have compared the impact of cost sharing on use of different types of traditional agents are *ambiguous*. Some studies have found large differences across classes of traditional agents, whereas others have found no differences across drug classes.
  - Two studies examined whether responses to cost sharing differ between persons whose pharmacy benefits require coinsurance versus copayments for traditional agents.
    - One study reported that higher cost sharing is associated with poorer adherence to prescription drug regimens for diabetes and that the effect was more pronounced for persons with coinsurance than persons with copayments.
    - One study found that changing cost sharing for prescription drugs from a tiered copayment to tiered coinsurance is associated with small and clinically insignificant reductions in use of prescription drugs when combined with maximums on out-of-pocket costs for each tier of coinsurance.
  - Findings from studies that have assessed the effects of differences in cost sharing for prescription drugs on use of other types of health care services are *ambiguous*.
    - Studies that have looked broadly at persons with a wide range of diseases and conditions have found no differences in hospitalizations, emergency department visits, or outpatient visits.
    - Other studies have found that higher cost sharing is associated with higher rates of hospitalization, emergency department visits, and/or outpatient visits among persons with acute coronary syndrome, congestive heart failure, lipid disorders, and diabetes.

## **BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS**

AB 310 would prohibit DMHC-regulated health plan contracts and CDI-regulated insurance policies that provide outpatient prescription drug benefits from requiring coinsurance (i.e., a percentage cost of a prescription) as cost sharing for outpatient prescription drug benefits, limit copayments for outpatient prescription drugs to \$150 per one-month supply or its equivalent for prescriptions for longer periods, and require that outpatient prescription drug benefit cost sharing be included under the annual out-of-pocket (OOP) maximum if one exists in the plan or policy. According to CHBRP's estimates, there are 21.9 million insured Californians currently enrolled in either DMHC- or CDI-regulated health plans or policies, of which 20.9 million (96%) have outpatient prescription drug coverage.

The impacts modeled in this section rely on some key assumptions. CHBRP has assumed that the percentage of enrollees (4.42%) without outpatient prescription drug benefits will remain the same, as the bill explicitly states that AB 310 would not mandate coverage of drugs. CHBRP has also assumed the mandate would not impact any other forms of cost sharing, such as deductibles, for outpatient prescription drug benefits. It was also assumed that the bill would not affect plan/insurer methods of utilization management that may impact the coverage of outpatient prescription drugs, such as use of formularies, tiered copayments, mandatory generic substitution, or prior authorization requirements. For the enrollees subject to coinsurance for prescription drugs, the analysis assumes there are no changes in benefit design (such as deductibles, out-of-pocket maximums, or annual limits) other than that coinsurance payments exceeding \$150 would be lowered to that number and converted to copayments, coinsurance at or below \$150 would become a copayment at the same value, and prescription drug cost sharing would be included under the plan or policy's out-of-pocket maximum. For enrollees with outpatient prescription drug cost sharing excluded from the annual out-of-pocket maximum, CHBRP has assumed out-of-pocket costs (copayments, deductibles) for prescription drugs would be applied toward the annual OOP maximum postmandate. For the purposes of this analysis, CHBRP assumes that the total annual OOP maximum amount would not increase.

This section will first present the current (or baseline) costs and coverage related to outpatient prescription drug cost sharing, and then provide estimates of the impacts on coverage, utilization, and cost were AB 310 to be enacted. For further details on the underlying data sources and methods, please see Appendix D at the end of this document.

### **Current (Baseline) Benefit Coverage, Utilization and Cost**

#### Current Coverage of the Mandated Benefit

Although 21.9 million persons are enrolled in DMHC-regulated plans or CDI-regulated policies, CHBRP estimates that the mandate would only affect the coverage of the 20.9 million enrollees with outpatient prescription drug benefits that would be subject to AB 310 (Table 1).

CHBRP conducted a Bill-Specific Coverage Survey of California's seven largest health plans and insurers to estimate the current coverage for outpatient prescription drugs. Responses to this

survey represented 71.8% of enrollees in the privately funded, CDI-regulated market and 84.9% of enrollees in the privately funded, DMHC-regulated market. Combined, responses to this survey represent 82.2% of enrollees in the privately funded market subject to state mandates.<sup>38</sup>

Among enrollees in plans and policies with outpatient prescription drug benefits, CHBRP estimates that 12% (2,520,000 enrollees) have coinsurance requirements for outpatient prescription drug benefits, 0% of enrollees have copayments for outpatient prescription drugs over \$150 per one-month supply, and 66.9% (14,015,000 enrollees) have outpatient prescription drug benefit cost sharing with limits excluded from the limits applied to the remainder of health care services.

Among those with annual OOP maximum (that exclude the outpatient prescription drug benefit), the median annual amount ranges from \$1,500 to \$5,700 per enrollee. Cost sharing provisions for medications covered through outpatient prescription drug benefits vary by the provisions of an enrollee's plan contract or policy. Among those with coinsurance requirements for outpatient prescription drug benefits, some enrollees are required to pay coinsurance for specialty drugs, such as home self-administered injectables.<sup>39</sup> Some enrollees have a coinsurance for these drugs but it is already capped at \$150 per prescription.

CHBRP reviewed the impact the mandate could have on Medi-Cal Managed Care enrollees, the Healthy Families Program (HFP), the Major Risk Medical Insurance Program (MRMIP), and the Access for Infants and Mother (AIM) program beneficiaries. Medi-Cal Managed Care, AIM, and HFP plans provide coverage for outpatient prescription drugs at no charge or with minimal copayment requirements (see Table 3). MRMIP's cost-sharing requirements would be minimally affected by AB 310.<sup>40</sup> Therefore, the foregoing plans are already in compliance with AB 310, and there would be no impact on the enrollees.

CalPERS HMOs and some DMHC-regulated plans only require coinsurance for "continuity drugs",<sup>41</sup> drugs related to sexual dysfunction treatment, and drugs related to infertility treatment (for those plans that cover infertility services). CHBRP assumes that plans that only have coinsurance for these types of drugs would have to convert to a copayment but there would be no measureable impact of that conversion. This is because cost sharing for the majority of these drugs is likely to be under \$150 per one-month supply currently, and therefore could be converted to a similar flat-dollar copayment postmandate.

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<sup>38</sup> CHBRP analysis of the share of enrollees included in CHBRP's Bill-Specific Coverage Survey of the major carriers in the state is based on "CDI Licenses with HMSR Covered Lives Greater than 100,000" as part of the Accident and Health Covered Lives Data Call, December 31, 2009, by the California Department of Insurance, Statistical Analysis Division, data retrieved from the Department of Managed Health Care's interactive Web site "Health Plan Financial Summary Report," July-September 2010, and CHBRP's Annual Enrollment and Premium Survey.

<sup>39</sup> Some enrollees were required to pay up to 50% coinsurance for drugs for infertility services, sexual dysfunction disorder, weight loss, and smoking cessation; CalPERS HMOs only require coinsurance on continuity drugs and drugs related to sexual dysfunction and infertility services for those plans that cover infertility services.

<sup>40</sup> One MRMIP plan requires coinsurance on prescription drug payments, but only represents 36 enrollees as of November 2010. Some purchases through out-of-network pharmacies are subject to coinsurance on some plans.

<sup>41</sup> Under Section 1367.24, DMHC-regulated plans are required to cover prescription drugs if the drug previously had been approved for coverage by the plan.

**Table 3.** Percent of Enrollees Affected by Each Provision of AB 310, by Market Segment, California, 2011

	<b>Requires Coinsurance at Any Tier (a)</b>	<b>Requires Copayment Greater Than \$150 (b)</b>	<b>Drug Cost Share Excluded from OOP Maximum (c)</b>
<b>DMHC-regulated plans</b>			
Large group	10%	0%	93%
Small group	18%	0%	86%
Individual	15%	0%	87%
All	12%	0%	92%
<b>CDI-regulated policies</b>			
Large group	24%	0%	80%
Small group	48%	0%	52%
Individual	35%	0%	52%
All	39%	0%	55%
<b>CalPERS HMO</b>	0%	0%	100%
<b>Medi-Cal Managed Care</b>	0%	0%	0%
<b>Healthy Families</b>	0%	0%	0%
<b>MRMIP</b>	0%	0%	0%
<b>AIM</b>	0%	0%	0%
<b>Total</b>	<b>12%</b>	<b>0%</b>	<b>67%</b>

Source: California Health Benefits Review Program, 2011

Notes: (a) Percentage of enrollees with a plan or policy that includes coinsurance as a cost-sharing mechanism for the prescription drug benefit for any tier. Plans that only have coinsurance for certain types of drugs (e.g. “lifestyle” or continuity drugs) would have to convert to a copayment. There is likely to be no measureable impact of that conversion, as the cost sharing for the majority of these drugs is likely to be under \$150 per one-month supply premandate.

(b) Percentage of enrollees with a plan or policy that includes copayments exceeding \$150.

(c) Percentage of enrollees whose plan or policy excludes outpatient prescription drug benefit cost sharing from the plan’s or policy’s OOP maximum. Some plans have OOP maximums only for their mail-order prescription drugs. However, because the broader outpatient prescription drug benefit was considered to have no OOP maximum, those plans were considered to not have an OOP maximum for their outpatient prescription drug benefit.

Key: CalPERS=California Public Employees’ Retirement System; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; AIM=Access for Infants and Mothers; MRMIP=Major Risk Medical Insurance Program.

### Current Utilization Levels

CHBRP estimates that 66.2% of enrollees with health insurance subject to the mandate use outpatient prescription medications in a year. CHBRP estimates that 0.018% of enrollees with an outpatient prescription drug benefit have filled prescriptions where the cost share exceeded \$150 for a one-month supply. This cost-sharing threshold was used based on the assumption that, postmandate, coinsurance would be eliminated and cost sharing for these high cost-share drugs would be set to the maximum allowable copayment of \$150 per prescription per one-month supply. CHBRP estimates that the utilization rate for enrollees who have cost sharing exceeding \$150 for a one month supply was approximately 8.8 prescriptions per 1,000 enrollees with the

coinsurance provision per year. The enrollees exceeding \$150 per prescription for a one-month supply paid on average \$271.47 per prescription for these drugs as part of their cost sharing.

The details of premandate utilization of the medications in California in 2009 for enrollees with coinsurance requirements are shown in Table 4. This includes the number of prescriptions per 1,000 enrollees, the average cost paid by health plans, and the average cost paid by enrollees per prescription. The estimated 2011 average costs per prescription were calculated using the 2009 actual costs.

**Table 4.** Current Utilization and Average Cost Paid by Plans and Enrollees Per Prescription, 2011

<b>Claims without coinsurance</b>	Number of prescription/1,000 enrollees	9,839.8
	Average plan cost	\$97.20
	Average patient cost	\$13.21
<b>Claims with coinsurance and cost-share amount <i>less than or equal to</i> \$150 per prescription</b>	Number of prescription/1,000 enrollees	2,941.3
	Average plan cost	\$105.04
	Average patient cost share	\$20.17
<b>Claims with coinsurance and cost-share amount <i>greater than</i> \$150 per prescription</b>	Number of prescription/1,000 enrollees	8.8
	Average plan cost	\$1,637.57
	Average patient cost share	\$271.47
<b>All claims combined</b>	Number of prescriptions/1,000 enrollees	12,789.9
	Average plan cost	\$100.06
	Average patient cost share	\$14.99

Source: California Health Benefits Review Program, 2011, based on 2009 MedStat data trended to 2011 for group plans in California and applied to all markets including the individual market,

### Current Average Cost

For those claims associated with cost-sharing amounts that exceed \$150, the average cost share paid by enrollees per prescription is \$271.47 (Table 4).

### Current (Baseline) Premiums and Expenditures

Table 5 summarizes per member per month (PMPM) premiums and expenditures for DMHC-regulated plans and CDI-regulated policies prior to the mandate. The final column in Table 5 gives the total annual PMPM for all DMHC-regulated plans and CDI-regulated policies.

### The Extent to Which Costs Resulting from Lack of Coverage Are Shifted to Other Payors, Including Both Public and Private Entities

CHBRP estimates that 4.4% of enrollees (or approximately 968,000) have a health plan or policy that does not include coverage for outpatient prescription drug benefits (Table 1). For some of these enrollees with large group-sponsored health insurance, their group may directly contract with a pharmacy benefit manager (PBM) to provide the outpatient prescription drug benefit. For others with no outpatient prescription drug benefits, CHBRP recognizes that some portion of

these expenses may be paid for by enrollees directly or other sources (such as public programs, charities, etc.).

### Public Demand for 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 so not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

On the basis of conversations with the largest collective bargaining agents in California, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.<sup>42</sup>

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 provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate. These plans do not currently require cost sharing above \$150. However, coinsurance is required for drugs in certain tiers (such as drugs for the treatment of sexual dysfunction and infertility). In addition, the plans' OOP maximum does not include the outpatient prescription drug benefit.

To further investigate public demand, CHBRP used the bill-specific coverage survey. In the survey, CHBRP asked 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), it is unclear whether there is public demand for the specific benefit design elements for prescription drug benefits that would be required under AB 310.

## **Impact of the Mandate on Benefit Coverage, Utilization and Cost**

### How Would Utilization Change As a Result of the Mandate?

#### *Coinsurance prohibition and cost share exceeding \$150*

Postmandate, prescriptions for which cost sharing would have exceeded \$150 would be limited to that amount. The average cost share for those prescriptions would therefore fall from an estimated \$271.47 premandate to \$150 postmandate. For prescriptions with such cost-share

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<sup>42</sup> Personal communication, S Flocks, California Labor Federation, January 2011.

reductions, CHBRP estimated there would be a 4% increase in utilization of specialty drugs given a 45% decline in cost sharing. CHBRP's assumptions are supported by the following evidence:

- As discussed in the *Public Health Impacts* section, most of the prescriptions subject to high cost sharing are in specialty drug categories. Price elasticity of demand<sup>[1]</sup> has been estimated to be -0.01 for specialty anticancer drugs, -0.07 for multiple sclerosis, and -0.21 for rheumatoid arthritis (Goldman et al., 2006). Thus, CHBRP uses the midpoint of these estimates, assuming a price elasticity of demand of -0.1 for specialty drugs as a whole, which means 1% increase in utilization for each 10% decrease in cost sharing. Given the estimated decline in cost sharing resulting from AB 310 of about 45% (see Table 1), CHBRP estimates that there would be a 4% increase in utilization of specialty drugs.
- The low price elasticity for these drugs is also related to fact that the possibility to substitute lower cost drugs for high-cost specialty drugs is limited. For many diseases treated by specialty drugs, there are no substitutes or the substitutes do not work as well. This is in contrast to, for example, diabetes and heart disease, two common conditions for which there are generic drugs that are as effective as brand name drugs.
- Less than 0.02% of enrollees with coverage subject to the mandate currently face outpatient prescription drug cost sharing exceeding \$150 for a one-month supply. The small number of enrollees facing such cost sharing may be related to the small number of enrollees with medical needs for specialty medications, small number of enrollees with high coinsurance requirements, as well as the existence of public and private pharmacy assistance programs.

As with other health benefits, CHBRP recognizes that a decrease in out-of-pocket expenditures may make it more likely for some patients to initiate usage of or continue using high-cost medications (Karaca-Mandic, 2010), or demand more drugs or more expensive drugs, regardless of their medical effectiveness. Such decreased costs may induce some patients to use certain medications when they would otherwise have forgone, delayed, or abandoned their use (Gleason et al., 2009). There may also be pharmaceutical company-induced demand. These are all secular trends that currently exist in the market and AB 310 may interact with these trends since the bill decreases out-of-pocket expenditures. The potential long-term cost impacts are discussed further in the *Impacts on long-term costs* section.

#### *Out-of-pocket maximum*

CHBRP does not estimate a change in utilization as a result of the provision of AB 310 to include the outpatient prescription drug benefit into the OOP maximum for a plan or policy that has such a maximum. This would require analyzing the impact of this provision on not only the use of the outpatient prescription drug benefit, but of all other benefits that are subject to the OOP maximum. Available data sources and time constraints do not allow for such an analysis. Instead, CHBRP is able to assess the impact of how cost sharing that currently exceeds the OOP maximum would impact total expenditures, premiums, and out-of-pocket expenditures. This is discussed in further detail in Appendix D. However, it is also possible that health plans and

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<sup>[1]</sup> Price elasticity of demand shows how the quantity demanded or supplied will change when the price changes.

insurers (in response to employer groups' requests) will respond to this provision by offering products with increased annual OOP maximums instead of products with higher premiums. If that occurs, the cost impact of the mandate will be smaller than the current estimates. (Please see detailed cost estimates in Appendix D for this scenario.)

### To What Extent Would the Mandate Affect Administrative and Other Expenses?

Health care plans and policies include a component for administration and profit in their premiums. In estimating the impact of this mandate on premiums, actuarial analysis assumes that health plans will apply their existing administration and profit loads to the increase in health care costs produced by the mandate. Therefore, although there may be administrative costs associated with the mandate, administrative costs as a portion of premiums would not change. In addition, compliance with AB 310 would require that plans and insurers notify members and applicants of their out-patient prescription coverage changes. Health plans and insurers would also need to modify their computer and claims systems in order to allow pharmacy and medical claim systems to communicate and track enrollees' out-of-pocket expenditure data. Health plans and insurers may also need to increase staff specialized in utilization management. These administrative changes were reflected in the standard administrative cost load associated with premiums.

### Impact of the Mandate on Total Health Care Costs

CHBRP estimates that total net expenditures (including total premiums and out-of-pocket expenditures) for outpatient prescription drugs would increase by \$31,688,000, or 0.0332%, as a result of AB 310 (Table 1). For enrollees with outpatient prescription drug cost sharing excluded from the annual OOP maximum, out-of-pocket costs (copayments, deductibles) for prescription drugs would be included in the annual OOP maximum postmandate. However, the total OOP maximum amount is assumed to remain constant, resulting in a premium increase that accounts for the reduction in enrollee out-of-pocket expenditures. The impact of AB 310's OOP maximum provision on premiums was calculated according to a typical benefit design by CDI-regulated and DMHC-regulated large-group, small-group, and individual market segments. This includes typical amounts for deductible, OOP maximum, copayments for inpatient care, and emergency department and office visits. (For more details regarding the methods for determining the impacts of OOP maximum provision, see Appendix D.)

- Total premiums for private employers are estimated to increase by \$153,222,000, or 0.2907%.
- Enrollee contributions toward premiums for group insurance are estimated to increase by \$44,420,000, or 0.2927%.
- Total premiums for those with individually purchased insurance are estimated to increase by \$11,708,000, or 0.1741%.
- The portion of the premium paid by the employer would increase between on average \$0.56 and \$2.78 per member per month (PMPM), and the portion of the premium paid by employees would increase between on average \$0.18 and \$0.90 PMPM, depending on market segment (Table 6).

- Enrollees out-of-pocket costs would decrease between on average \$0.59 and \$3.12 PMPM, depending on market segment.
- Premiums paid by purchasers of individual CDI-regulated products are estimated to increase \$0.53 PMPM, and the cost sharing paid by enrollees in these policies to decrease by approximately \$0.41 PMPM.
- Premiums paid by purchasers of individual DMHC-regulated products are estimated to increase \$0.36 PMPM, and the cost sharing paid by enrollees in these policies to decrease by approximately \$0.28 PMPM.
- Total premiums would increase by about \$220,327,000, but out-of-pocket expenditures paid by enrollees for covered prescription drugs would decrease by \$188,639,000.

The major impact of the bill would be to shift some prescription medication costs from patients to health plans and policies, ranging from \$0.02 to \$1,579 per prescription for users who currently have outpatient prescription drug coverage with coinsurance requirements. On average, the amount of the shift is estimated to be \$121.47 per prescription postmandate for those prescriptions with a cost share exceeding \$150. The wide variations in cost sharing are related to the price of a particular oral medication, as well as the benefit structure of a particular health plan or policy.

#### *Potential cost offsets or savings in the short term*

In some cases, an increase in cost due to an expansion in benefit coverage is accompanied by a decrease in the cost for other health care services, known as a “cost offset.” There is not sufficiently strong evidence to support health cost savings within the one-year time frame of this cost analysis. Therefore, CHBRP does not estimate a cost offset in the first year following implementation.

#### *Impact on long-term costs*

There are likely to be long-term cost impacts but the magnitude is unknown at this time. Advances in drug development are likely to yield new, higher-cost drugs for the treatment of cancer, coagulation and platelet aggregation disorders, central nervous system disorders (such as multiple sclerosis, Alzheimer’s disease, and pain), immune-mediated disorders (such as inflammatory bowel disease and rheumatoid arthritis), enzyme-deficiency disorders, and many “orphan” diseases (rare or ignored common diseases). There are 140 drugs in the pipeline and about 40 first-time generics expected to come to market over the next few years. It is estimated that approximately 40% of the pipeline drugs are likely to fall into the specialty drug category, and up to 25% could be for orphan diseases (Medco, 2010). Many of these new medications are likely to be expensive. As a result, costs for these medications, especially the more targeted and chronic medications, will continue to grow over the next several years. As discussed, in the Utilization Impact section, there may be an increase in demand for these drugs by consumers due to secular trends in the market. CHBRP recognizes that a decrease in out-of-pocket expenditures may interact with these secular trends and thereby further increase the demands for these medications as a result of AB 310. While demand and availability of high-cost drugs increases, insurers and employers could respond in a variety of ways, including increasing the total out of pocket maximum for plans and policies, varying the cost-sharing structure so additional prescription drugs are associated with higher copayments (capped at \$150 per one month supply),

or engaging in additional utilization management strategies. Over time, the combined effects of demand for higher costs prescription drugs with lower out-of-pocket expenditures may lead to increased utilization for these prescription drugs and overall premium increases.

#### Impacts for Each Category of Payor Resulting From the Benefit Mandate

The impact varies for CDI-regulated policies and for DMHC-regulated plans, especially in the small-group and individual markets, specifically, as shown in Table 6. AB 310 is estimated to increase expenditures by:

- 0.0317% for the large group DMHC-regulated plans;
- 0.1004% for the large group CDI-regulated policies;
- 0.0389% for the small group DMHC-regulated plans;
- 0.0553% for the small group CDI-regulated policies;
- 0.0163% for the individual DMHC-regulated plans;
- 0.047% for the individual CDI-regulated policies; and
- 0.0452% for CalPERS HMOs.

For affected markets, premiums are expected to increase on average by 0.251%. The increases in premiums vary by market segment:

- \$1.12 PMPM in the large group DMHC-regulated plans;
- \$3.69 PMPM in the large group CDI-regulated policies;
- \$0.74 PMPM in the small group DMHC-regulated plans;
- \$1.16 PMPM in the small group CDI-regulated policies;
- \$0.36 PMPM in the individual DMHC-regulated plans;
- \$0.53 PMPM in the individual CDI-regulated policies; and
- \$1.38 PMPM for CalPERS HMO policies.

As discussed previously, Medi-Cal Managed Care and MRMIB plans are already in compliance with AB 310 and would therefore face no impact.

#### Impact on Access and Health Service Availability

CHBRP expects that there would be impacts on the access to and availability of expensive medication as a result of AB 310 in the long run. To the extent that cost sharing would be reduced and limits will be removed, access to expensive medications would be expected to

increase for the small number of enrollees who seek these medications. Nonetheless, possible implementation of prior authorization requirements and formularies are expected to mediate the response by the health plans and insurers to this increase in demand. For example, higher-cost oral and injectable drugs that may be subject to more generous coverage under the outpatient prescription drug benefit may be dropped from formularies or become subject to prior authorization. CHBRP is unable to estimate these effects quantitatively.

**Table 5. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2011**

	DMHC-Regulated							CDI-Regulated			Total
	Privately Funded Plans (by market)			CalPERS HMOs (b)	Medi-Cal Managed Care Plans		MRMIB Plans (d)	Privately Funded Policies (by market)			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65		Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state Mandates (a)	10,526,000	2,241,000	733,000	831,000	285,000	3,539,000	889,000	397,000	1,118,000	1,343,000	21,902,000
Total enrollees in plans/policies subject to AB 310	9,885,008	2,212,386	694,452	831,000	285,000	3,539,000	889,000	337,143	1,037,000	1,343,000	20,933,686
Average portion of premium paid by Employer	\$317.59	\$267.09	\$0.00	\$347.55	\$346.00	\$176.00	\$98.48	\$375.44	\$270.30	\$0.00	\$65,887,370,000
Average portion of premium paid by Employee	\$82.91	\$83.47	\$399.69	\$86.89	\$0.00	\$0.00	\$13.79	\$122.08	\$64.15	\$199.13	\$21,898,323,000
<b>Total Premium</b>	\$400.51	\$350.57	\$399.69	\$434.44	\$346.00	\$176.00	\$112.27	\$497.52	\$334.45	\$199.13	\$87,785,693,000
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$21.82	\$32.63	\$84.77	\$22.41	\$0.00	\$0.00	\$4.68	\$63.15	\$123.11	\$58.53	\$7,548,415,000
<b>Total Expenditures</b>	\$422.34	\$383.20	\$484.46	\$456.86	\$346.00	\$176.01	\$116.96	\$560.67	\$457.57	\$257.67	\$95,334,108,000

Source: California Health Benefits Review Program, 2011.

Notes: (a) This population includes persons insured with private funds (group and individual) and insured with public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans, Healthy Families Program, AIM, MRMIP) enrolled in health plans or policies regulated by the DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance.

(b) Of these CalPERS HMO members, about 58% or 482,000 are state employees or their dependents.

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

(d) MRMIB Plan expenditures include expenditures for 874,000 enrollees of the Healthy Families Program, 8,000 enrollees of MRMIP, and 7,000 enrollees of the AIM program.

**Table 6.** Impacts of AB 310 on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2011

	DMHC-Regulated							CDI-Regulated			Total
	Privately Funded Plans (by market)			CalPERS HMOs (b)	Medi-Cal Managed Care Plans		MRMIB Plans (d)	Privately Funded Policies (by market)			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65		Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state Mandates (a)	10,526,000	2,241,000	733,000	831,000	285,000	3,539,000	889,000	397,000	1,118,000	1,343,000	21,902,000
Total enrollees in plans/policies subject to AB 310	9,885,008	2,213,386	694,452	831,000	285,000	3,539,000	889,000	397,143	1,037,527	1,233,170	20,933,686
Average portion of premium paid by Employer	\$0.8909	\$0.5564	\$0.0000	\$1.1008	\$0.0000	\$0.0000	\$0.0000	\$2.7822	\$0.9296	\$0.0000	\$164,199,000
Average portion of premium paid by Employee	\$0.2326	\$0.1834	\$0.3605	\$0.2752	\$0.0000	\$0.0000	\$0.0000	\$0.9047	\$0.2277	\$0.5297	\$56,128,000
<b>Total Premium</b>	<b>\$1.1235</b>	<b>\$0.7398</b>	<b>\$0.3605</b>	<b>\$1.3760</b>	<b>\$0.0000</b>	<b>\$0.0000</b>	<b>\$0.0000</b>	<b>\$3.6869</b>	<b>\$1.1573</b>	<b>\$0.5297</b>	<b>\$220,327,000</b>
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	-\$0.9897	-\$0.5906	-\$0.2814	-\$1.1696	\$0.0000	\$0.0000	\$0.0000	-\$3.1241	-\$0.9044	-\$0.4086	-\$188,639,000
<b>Total Expenditures</b>	<b>\$0.1338</b>	<b>\$0.1492</b>	<b>\$0.0791</b>	<b>\$0.2064</b>	<b>\$0.0000</b>	<b>\$0.0000</b>	<b>\$0.0000</b>	<b>\$0.5629</b>	<b>\$0.2529</b>	<b>\$0.1211</b>	<b>\$31,688,000</b>
<b>Percentage Impact of Mandate</b>											
Insured Premiums	0.2805%	0.2110%	0.0902%	0.3167%	0.0000%	0.0000%	0.0000%	0.7411%	0.3460%	0.2660%	0.2510%
Total Expenditures	0.0317%	0.0389%	0.0163%	0.0452%	0.0000%	0.0000%	0.0000%	0.1004%	0.0553%	0.0470%	0.0332%

Source: California Health Benefits Review Program, 2011.

Notes: (a) This population includes persons insured with private funds (group and individual) and insured with public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans, Healthy Families Program, AIM, MRMIP) enrolled in health plans or policies regulated by the DMHC or CDI. This population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance.

(b) Of these CalPERS members, about 58% or 482,000 are state employees or their dependents.

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

(d) MRMIB Plan expenditures include expenditures for 874,000 enrollees of the Healthy Families Program, 8,000 enrollees of MRMIP, and 7,000 enrollees of the AIM program.

## PUBLIC HEALTH IMPACTS

CHBRP evaluated each of the provisions included in AB 310 with regard to public health impact. This is an atypical analysis in that the intervention in question is a change in cost-sharing structure and the medical effectiveness outcome is utilization of prescription drugs. The public health impact analysis therefore focuses on those populations for which the legislation has an impact—by reducing the out-of-pocket expenses for drugs currently with high cost sharing for some enrollees (based on claims analysis)—and those therapies and conditions for which there exists evidence in the literature of the effects of cost sharing on utilization of those drugs.

### Public Health Impact Analysis

#### Provision Capping Copayments at No More Than \$150 per Prescription per Month

The *Medical Effectiveness* section finds a preponderance of evidence that cost sharing affects drug utilization, with smaller effects for specialty drugs and varying effects across drug classes. As discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section, there are currently no plans or policies having copayments that are greater than \$150 per prescription for a one-month supply. Therefore, CHBRP projects no public health impact from this provision.

#### Provision Requiring Prescription Drug Cost Sharing to Be Included Under the Plan's Annual Out-of-Pocket Maximum

*Medical Effectiveness* finds insufficient evidence to determine the impact of the inclusion of prescription drug cost sharing in the out-of-pocket maximum on prescription drug utilization. CHBRP estimates that 0.07% of enrollees currently have outpatient prescription drug expenditures that exceed the total annual out-of-pocket maximum for the plan or policy. CHBRP also estimates that 2.77% of enrollees with outpatient prescription drug coverage reach their plan or policy's out-of-pocket maximum based solely on their use of and cost sharing associated with their other health care benefits. This provision may therefore have a public health impact by reducing the financial burden on these enrollees. However, the given lack of specific evidence and data, other potential public health impacts are unknown.

#### Provision Prohibiting Coinsurance

Claims data analysis shows that 0.018% of enrollees with outpatient prescription drug coverage have filled prescriptions where the cost share exceeded \$150 for a one-month supply. This cost-sharing threshold was used based on the assumption that, postmandate, coinsurance would be eliminated and cost sharing for these high cost-share drugs would be set to the maximum allowable copayment of \$150 per prescription per one-month supply. Based on claims data analysis, there are several categories of drugs represented by claims with coinsurance exceeding \$150. Of these, 25 drugs represent the top out-of-pocket costs per prescription, subject to coinsurance exceeding \$150 per prescription per one-month supply. Table 7 shows the major categories represented among these top 25 drugs.

**Table 7.** Top 25 Drugs Associated with Coinsurance Exceeding \$150 Per Prescription, by Category

Categories	Examples
Specialty drugs	Biologic therapies for multiple sclerosis, rheumatoid arthritis and immune disorders; some injectable treatments; new drugs for which no generic is available
Lifestyle drugs	Erectile dysfunction treatments; weight loss treatments; infertility treatments; smoking cessation drugs
Single or combined oral drugs for HIV treatment	Antiretrovirals
Cancer treatments	Chemotherapy agents; some biologic therapies; anemia treatments
Other	Brand-name narcotics; treatments for drug addiction; treatments for narcolepsy; brand-name treatments for acid reflux; brand-name antibiotics

Source: California Health Benefits Review Program, 2011, based on 2009 MedStat data trended to 2011

CHBRP narrowed the public health impact analysis to those enrollees affected by the AB 310 coinsurance provision—i.e., premandate faced cost sharing greater than \$150 per prescription per one-month supply—and those therapies and conditions for which there exists evidence in the literature of the effects of cost sharing on utilization of the drug. Therefore, the public health impact analysis is limited to the impacts of cost sharing on potential health outcomes related to the following treatments and conditions:

- Etanercept and adalimumab for rheumatoid arthritis
- Interferon beta-1a for multiple sclerosis
- Imatinib mesylate for chromosome-positive chronic myeloid leukemia

Estimation of clinical or public health outcomes would require evidence of a direct association between prescription drug utilization and health outcomes. There are very few studies evaluating such an association, and those that do attempt to evaluate outcomes use hospitalizations or emergency department visits as proxies for health outcomes. Instead, the PH impact section estimates the number of enrollees likely to be affected by the coinsurance provision and the potential impact of expected reduced cost sharing among this population. If possible, directional effects on utilization for subpopulations are discussed.

*Etanercept and adalimumab for rheumatoid arthritis (RA)*

The prevalence of rheumatoid arthritis (RA) in North America is between 0.5 and 1% (Noonan et al., 2010). Rheumatoid arthritis is characterized by chronic joint inflammation, which can lead to destruction of the joints and result in significant disability. RA is associated with diminished health-related quality of life, increased disability and health services utilization, loss of productivity and employment income, and early mortality (Alamanos and Drosos, 2005; Boonen and Severens, 2011; Sullivan, 2010; Yelin, 2007). Tumor necrosis factor inhibitors, such as adalimumab and etanercept, are self-administered injectable therapies. These therapies are relatively new and are considered more effective at treating the symptoms and halting disease

progression than prior treatments. Adalimumab and etanercept have been shown to reduce symptoms, slow joint damage, improve physical function, and increase work hours. (Chen et al., 2006; Nam et al., 2010; Yelin et al., 2003). Newer therapies have entered the market since the time periods during which the current studies were conducted. Although no studies of the impact of cost sharing on the use of these new drugs were identified, it is likely that the effects of cost sharing on these use of these drugs would be similar to the effects of cost sharing associated with the specialty drugs for RA that have been studied.

*Medical Effectiveness* indicates a preponderance of evidence that increased cost sharing reduces utilization of prescription drugs for rheumatoid arthritis. Of the studies specific to rheumatoid arthritis, all indicated an association between increased cost sharing and decreased drug utilization (Alamanos and Drosos, 2005; Boonen and Severens, 2011; Chen et al., 2006; Curkendall et al., 2008; Gleason et al., 2009; Karaca-Mandic et al., 2010). One study estimated the effects of cost sharing specifically for adalimumab and etanercept among patients with rheumatoid arthritis. This study found a 2.1% decrease in utilization for every 10% increase in cost sharing (Goldman et al., 2006). The effects were significant for those patients initiating therapy rather than those already on continuous treatment.

Based on claims data analysis, CHBRP estimates that approximately 460 enrollees subject to AB 310 would face reductions in cost sharing for these RA drugs (see calculations in Appendix F). The estimated average cost share amount for these drugs when it exceeds \$150 is \$189.80. Assuming that coinsurance cost sharing reverts to \$150 copayments postmandate, this represents, on average, a 21% reduction in cost sharing per prescription. The 460 enrollees with cost sharing exceeding \$150 premandate represent approximately 60% of all enrollees who have drug claims for etanercept and adalimumab subject to coinsurance. Based on CHBRP's findings of current coverage terms, the affected population would be in the privately purchased DMHC-regulated plans and CDI-regulated policies where coinsurance exists in the benefit structure (i.e., these would not be enrollees in Medi-Cal Managed Care, CalPERS, HMOs, or MRMIB plans).

While the absolute number of individuals facing a reduction in cost sharing due to AB 310 is not large, the impact of reduced cost sharing for individuals with chronic diseases such as RA could be important. In particular, it is important to note that a preponderance of the evidence in the literature indicates that initiation of specialty drug therapy for RA is more sensitive to cost sharing than continuation of therapy (Goldman et al., 2006; Karaca-Mandic et al., 2010; Gleason et al., 2009). To the extent that individuals initiate therapy earlier due to reduced cost sharing, the long-term impact on disease outcomes such as relapse rates, disability, and early mortality could be significant. While it is beyond the scope of CHBRP to calculate these clinical and public health impacts, for approximately 460 enrollees, the coinsurance provision in this bill may lead to these enrollees increasing utilization depending on various factors including whether cost was a barrier to use. Thus, this provision may alter the course of their illness.

#### *Interferon beta-1a for multiple sclerosis (MS)*

Multiple sclerosis (MS) is a disease that affects the central nervous system. The majority of MS patients have recurring episodes, while a smaller proportion have severe progressive disease

from the onset. There are a wide variety of symptoms at the onset of the disease, but there is also a highly predictable course of progression once a characteristic disability threshold is reached. MS therapy typically aims to delay the time between onset of symptoms and reaching this disability threshold, which includes limited mobility, diminishing cognitive function and significant limitations in daily living. MS is associated with diminished health-related quality of life, increased disability and health services utilization, and early mortality (Hurwitz, 2011; Noonan, 2010).

One of the most common therapies for MS is interferon beta-1a which has been shown to reduce symptoms, slow disease progression, and improve physical function (Carroll, 2009; Kargiotis, 2010; Steinberg, 2010). These treatments are injectable biologic agents that are given at a physician's office or infusion center. There are no reliable current prevalence estimates of MS in North America. Worldwide estimates range between 3.6 cases to more than 100 cases per 100,000 people (Alonso and Hernan, 2008; Noonan et al., 2010). The California Multiple Sclerosis Society estimates that there were approximately 36,373 individuals in the California MS registry in 2010. This underestimates the number of people with the disease, but provides a lower bound estimate of the population of interest specifically in California.

*Medical Effectiveness* indicates a preponderance of evidence that increased cost sharing reduces use of prescription drugs for multiple sclerosis. Of the studies specific to multiple sclerosis, all indicated some degree of association between increased cost sharing and decreased drug utilization (Carroll, 2009; Dor et al., 2010; Gleason et al., 2009; Kargiotis et al., 2010; Ryan, 2009). One study estimated the effects of cost sharing specifically for interferon beta-1a among patients with multiple sclerosis (Goldman et al., 2006). This study found a 0.7% decrease in utilization for every 10% increase in cost sharing. The effects were significant for those patients initiating therapy rather than those already on continuous treatment.

CHBRP estimates that approximately 78 enrollees subject to AB 310 would face cost sharing reductions for interferon beta-1a (see Appendix F). The current average cost-sharing amount when it exceeds \$150 is approximately \$254.26. Assuming that coinsurance cost sharing reverts to \$150 copayments postmandate, this represents, on average, a 41% reduction in cost sharing per prescription. The 78 affected enrollees represent approximately 62% of all enrollees who have drug claims for interferon beta-1a subject to any coinsurance. Again, based on coverage findings, these enrollees would be in the privately purchased market where coinsurance exists.

While the absolute number of individuals facing a reduction in cost sharing due to AB 310 is not large, the impact of reduced cost sharing for individuals with chronic diseases such as MS could be important. In particular, it is important to note that a preponderance of the scientific literature indicates that initiation of specialty drug therapy for MS is more sensitive to cost sharing than continuation of therapy. To the extent that individuals initiate therapy earlier due to reduced cost sharing, the long-term impact on disease outcomes such as relapse rates, disability, and early mortality could be significant. While it is beyond the scope of CHBRP to calculate these clinical and public health impacts, for approximately 78 enrollees, the coinsurance provision in this bill may lead to these enrollees increasing utilization depending on various factors including whether cost was a barrier to use. Thus this provision may alter the course of their illness.

### *Imatinib mesylate for chromosome-positive chronic myeloid leukemia (CML)*

According to the California Cancer Registry, chromosome-positive chronic myeloid leukemia (CML) affects 1.31 per 100,000 people statewide. As with all types of leukemia, CML is a disorder of the blood cells. Resulting from an abnormality identified in two chromosomes, certain stem cells in the bone marrow proliferate abnormally, causing the resulting symptoms and disease. Treatment with the relatively new drug imatinib mesylate has been shown to be significantly more effective than previous treatments and appears to result in long-term disease remission (Moen et al., 2007).

Effects of cost sharing on utilization of imatinib mesylate for chromosome-positive chronic myeloid leukemia were evaluated in a 2009 study (Goldman et al., 2010). The study estimated the effects of a 25% reduction in cost sharing on initiation and continuation of therapy. The study found that there is no evidence for an effect of cost sharing on initiation or ongoing utilization of imatinib mesylate. Therefore, CHBRP estimates no public health impact related to utilization of this drug.

### **Impact of the Proposed Mandate on Health Disparities**

Several competing definitions of “health disparities” exist. CHBRP relies on the following definition: *A health disparity/inequality is a particular type of difference in health or in the most important influences of health that could potentially be shaped by policies; it is a difference in which disadvantaged social groups (such as the poor, racial/ethnic minorities, women or other groups that have persistently experienced social disadvantage or discrimination) systematically experience worse health or great health risks than more advantaged groups* (Braveman, 2006).

CHBRP investigated the effect that AB 310 would have on health disparities by gender, race, and ethnicity. Evaluating the impact on racial and ethnic disparities is particularly important because racial and ethnic minorities report having poorer health status and worse health indicators (Kaiser Family Foundation, 2007). One important contributor to racial and ethnic health disparities is differential rates of insurance, where minorities are more likely than whites to be uninsured; however, disparities still exist within the insured population (Kirby et al, 2006; Lillie-Blanton and Hoffman, 2005). Since AB 310 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 outside of disparities attributable to differences between insured and uninsured populations.

#### Impact on Gender Disparities

The extent of gender disparity in impact of cost sharing on prescription drug utilization is unknown due to lack of evidence. Therefore, the extent to which AB 310 would have an impact on disparities is unknown.

#### Impact on Racial/Ethnic and Economic Disparities

Racial/ethnic disparities in impact of cost sharing on prescription drug utilization exist. However, no clinical or public health outcome data related to disparities in cost sharing are available, therefore, the impact of AB 310 on reducing racial and ethnic disparities is unknown. Below is a summary of the limited literature found related to cost sharing and racial/ethnic and economic disparities.

The Institute of Medicine report, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, devotes one chapter to the impacts of cost sharing on racial and ethnic disparities (IOM, 2003). The report notes three primary mechanisms for potential disparities due to cost sharing in health care. First, in cases where racial and ethnic minorities continue to use services despite cost sharing, the out-of-pocket expenditures constitute a disproportionate burden. Census data shows that African American and Hispanic individuals have significantly lower incomes than whites, therefore the same level of cost sharing constitutes a significantly larger proportion of income for racial and ethnic minorities than for whites. Second, national data indicate that certain racial and ethnic minority groups experience poorer health than whites. To the extent that this influences need for services and an inability to forgo certain treatments, cost sharing places a disproportionate burden on these populations. Third, in cases where cost sharing does reduce utilization of services, many racial and ethnic minorities forgo necessary services solely due to economic burden, much more so than whites, who have higher incomes.

CHBRP's search found limited evidence on disparities in effects of prescription drug cost sharing. Two recent studies were identified 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 and have higher out-of-pocket drug costs, compared to whites (Chen et al., 2010). 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). The 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/yr.) were sensitive to drug costs, particularly for congestive heart failure drugs. For patients making above \$30,000/yr., there was no consistent relationship between drug cost and drug adherence.

RA is significantly associated with gender and ethnicity (Alamanos and Drosos, 2005; Boonen and Severens, 2010). However, CHBRP found no evidence regarding disparities in impact of cost sharing on RA patients by gender, race, or ethnicity. There is evidence that RA has a disproportionate impact on low-income patients with regard to disease severity (Alamanos and Drosos, 2005). Given that women have a higher prevalence of RA and women's income is generally lower than men's, a disproportionate positive impact of reduced financial burden on women might be expected.

MS is significantly associated with gender and ethnicity, reflected in the wide geographic variations in prevalence of the disease worldwide (Hurwitz, 2011; Noonan et al., 2010). However, CHBRP found no evidence regarding disparities in impact of cost sharing on MS

patients by gender, race, or ethnicity. Given that women have a higher prevalence of MS and women's income is generally lower than men's, a disproportionate positive impact of reduced financial burden on women might be expected.

## **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

RA is associated with premature mortality, with an estimated reduction in survival of 3 to 10 years, based on age of onset and disease severity (Alamanos and Drosos, 2005). A recent study of MS registries worldwide provides estimates of early mortality ranging between 4 and 10 years. Additionally, approximately 50% of deaths among MS patients are due to the disease, rather than other causes. MS patients have an increased risk of suicide and an excess death rate of 13/1,000 (number of deaths in excess of expected rates) (Hurwitz, 2011).

While AB 310 may have an effect on premature mortality from both conditions through its impact on drug utilization, the impact of the mandate is unknown because there is insufficient evidence for CHBRP to estimate the change in patient behavior, or clinical or public health outcomes based on projected changes in drug utilization.

### Economic Loss

Patients with RA are more likely to face job loss than the general population. A review of the literature estimates that the odds of RA patients being unemployed range between 1.2 and 3.4 (Boonen and Severens, 2011). Additional studies indicate that 30 to 50% of RA patients lost their jobs within 2.5 years of diagnosis, and approximately 8.7% RA patients per year leave the work force in the United States (Boonen and Severens, 2011). A study by Yelin et al estimated that treatment with etanercept increased work hours for RA patients by approximately 7.4 hours per week (Yelin, 2007). Based on the available data, CHBRP is unable to quantify any potential impact of the mandate on economic loss, but these studies indicate that a reduction in disease severity and symptoms could reduce economic loss for these patients, contingent upon the extent to which projected drug utilization impacts affect these health outcomes.

CHBRP did not find any evidence related to economic loss associated with MS. However, several reviews describe significant increases in physical and cognitive disability associated with the disease (Carroll, 2009; Kargiotis et al., 2010). This implies that, similar to RA, reductions in symptom severity, relapse, and disease progression could potentially have an economic impact on MS patients.

While AB 310 may have an effect on economic loss from both conditions, the impact of the mandate is unknown because there is insufficient evidence for CHBRP to estimate the change in patient behavior, or clinical or public health outcomes based on projected changes in drug utilization.

### Long-term Public Health Impacts

Cost estimates postmandate average premium increases of less than 1%, therefore no increase in the number of uninsured is expected based on the mandate. Other long-term public health impacts due to AB 310 are unknown. To the extent that more people have access to these drugs, there is the potential for beneficial long term health impacts for people who have chronic conditions such as multiple sclerosis and rheumatoid arthritis. As discussed in the *Impact on long-term costs*, development and use of high-cost specialty drugs is increasing (Goldman et al., 2006). This trend combined with lower cost-sharing requirements of AB 310 imply potential long-term impacts of this mandate. If enrollee cost sharing is limited, while demand and availability of high-cost drugs increases, insurers and employers could find other mechanisms to offset increased spending. These may include increasing the total out-of-pocket maximum for plans and policies, varying the cost-sharing structure so additional prescription drugs are associated with higher copayments (capped at \$150), or enforcing additional utilization controls. For example, higher-cost oral and injectable drugs that may be subject to more generous coverage under the outpatient prescription drug benefit may be dropped from formularies or become subject to additional utilization authorization restrictions. In addition, there may be a disincentive to move some treatments to infusion-based therapy since these will no longer be in a separate cost-sharing pool from outpatient prescription drugs. These may lead to other public health impacts in the long term.

## APPENDICES

### Appendix A: Text of Bill Analyzed

On February 10, 2011, the Assembly Health Committee requested that CHBRP undertake an analysis of Assembly Bill 310 (Ma) per its authorizing statute. On February 18, 2011, CHBRP received amendments that will be taken to the bill. CHBRP's analysis reflects the amended version of the bill language received on February 18, 2011, included directly below, followed by the language as introduced.

Amended version of AB 310 submitted to CHBRP for analysis on February 18, 2011:

SEC. 2. Section 1367.225 is added to the Health and Safety Code, to read:

1367.225. (a) A health care service plan contract issued, amended, or renewed on or after January 1, 2012, that covers *outpatient* prescription drugs shall not provide for specialty tiers that require payment of a percentage cost of prescription drugs by enrollees. *require co-insurance as a basis for cost-sharing with the enrollee for outpatient prescription drug benefits.*

(b) A health care service plan contract issued, amended, or renewed on or after January 1, 2012, shall not require an enrollee to pay a copayment for *outpatient* prescription drugs in excess of *\$150 dollars per one month supply of medication, or its equivalent for prescriptions for longer periods, as adjusted for inflation.* 500 percent of the lowest copayment required by the plan for prescription drugs in the plan's formulary.

*(c) If a health care service plan provides for a limit on enrollees' annual out-of-pocket expenses, enrollees' out-of-pocket costs of covered prescription drugs shall be included in that limit.*

~~(e) If a health care service plan provides a limit for out-of-pocket expenses for benefits other than prescription drugs, the plan shall include one of the following provisions in the plan that would result in the lowest out-of-pocket prescription drug cost to the enrollee:~~

~~—(1) Out-of-pocket expenses for prescription drugs shall be included under the plan's total limit for out-of-pocket expenses for all benefits provided under the plan.~~

~~—(2) Out-of-pocket expenses for prescription drugs per contract year shall not exceed one thousand dollars (\$1,000) per enrollee or, in the case of covered dependents, two thousand dollars (\$2,000) including dependents of the enrollee, as adjusted for inflation.~~

(d) For purposes of this section, "copayment" means a flat dollar amount an enrollee pays, out-of-pocket, at the time of receiving a

health care service or when paying for a prescription drug, *is required in cost sharing for covered health services, items and supplies including prescription drugs* after any applicable deductible. The term shall not be construed to include any other forms of cost sharing.

*(e) For purposes of this section, "co-insurance" means a cost sharing payment by an enrollee that is based on a percentage of the cost for a prescription.*

(f) ~~(e)~~ Nothing in this section shall be construed to require a health care service plan contract to provide coverage not otherwise required by law for any prescription drug.

(g) ~~(f)~~ This section shall become inoperative upon a determination by the department that the requirements of this section would result in the assumption by the state of additional costs pursuant to Section 1311(d)(3)(B) of the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by Section 10104(e) of Title X of that act, relative to benefits required by the state to be offered by qualified plans in the California Health Benefit Exchange that exceed the requirements imposed by federal law.

SEC. 3. Section 10123.197 is added to the Insurance Code, to read:

10123.197. (a) A health insurance policy issued, amended, or renewed on or after January 1, 2012, that covers *outpatient* prescription drugs shall not provide for specialty tiers that require payment of a percentage cost of prescription drugs by insureds.

*require co-insurance as a basis for cost-sharing with the insured for outpatient prescription drug benefits.*

(b) A health insurance policy issued, amended, or renewed on or after January 1, 2012, shall not require an insured to pay a copayment for *outpatient* prescription drugs in excess of *\$150 dollars per one month supply of medication, or its equivalent for prescriptions for longer periods, as adjusted for inflation.* 500 percent of the lowest copayment required by the plan for prescription drugs in the plan's formulary.

*(c) If a health insurance policy provides for a limit on insureds' annual out-of-pocket expenses, insureds' out-of-pocket costs of covered prescription drugs shall be included in that limit.*

~~(c) If a health insurance policy provides a limit for out-of-pocket expenses for benefits other than prescription drugs, the policy shall include one of the following provisions in the policy that would result in the lowest out-of-pocket prescription drug cost to the insured:~~

~~—(1) Out-of-pocket expenses for prescription drugs shall be included under the policy's total limit for out-of-pocket expenses for all benefits provided under the policy.~~

~~—(2) Out-of-pocket expenses for prescription drugs per contract year shall not exceed one thousand dollars (\$1,000) per insured or, in the case of covered dependents, two thousand dollars (\$2,000) including dependents of the insured, as adjusted for inflation.~~

(d) For purposes of this section, "copayment" means a flat dollar amount an enrollee pays, ~~out of pocket, at the time of receiving a health care service or when paying for a prescription drug,~~ *is required in cost sharing for covered health services, items and supplies including prescription drugs* after any applicable deductible. The term shall not be construed to include any other forms of cost sharing.

*(e) For purposes of this section, "co-insurance" means a cost sharing payment by an enrollee that is based on a percentage of the cost for a prescription.*

(f) ~~(e)~~ Nothing in this section shall be construed to require a health insurance policy to provide coverage not otherwise required by law for any prescription drug.

(g) ~~(f)~~ This section shall become inoperative upon a determination by the commissioner that the requirements of this section would result in the assumption by the state of additional costs pursuant to Section 1311(d)(3)(B) of the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by Section 10104 (e) of Title X of that act, relative to benefits required by the state to be offered by qualified plans in the California Health Benefit Exchange that exceed the requirements imposed by federal law.

AB 310 as introduced on February 9, 2011:

BILL NUMBER: AB 310 INTRODUCED  
BILL TEXT

INTRODUCED BY Assembly Member Ma

FEBRUARY 9, 2011

An act to add Section 1367.225 to the Health and Safety Code, and to add Section 10123.197 to the Insurance Code, relating to health care coverage.

#### LEGISLATIVE COUNSEL'S DIGEST

AB 310, as introduced, Ma. Prescription drugs.

(1) Existing law provides for licensing and regulation of health care service plans by the Department of Managed Health Care. Existing law provides that the willful violation of provisions regulating health care service plans is a crime. Existing law provides for the licensing and regulation of health insurers by the Insurance Commissioner. Existing law requires health care service plans and health insurers to provide certain benefits, but generally does not require plans and insurers to cover prescription drugs. Existing law imposes various requirements on plans and insurers if they offer coverage for prescription drugs.

This bill would prohibit health care service plans and health insurers that offer prescription drug coverage from creating specialty tiers for prescription drugs that require payment by an enrollee or insured of a percentage cost of the drugs. The bill would also impose certain limitations on copayments and out-of-pocket expenses. The bill would make these provisions inoperative upon a determination by the department and commissioner that these provisions would result in additional costs to the state as a result of laws governing federal health care reform.

Because this bill would impose new requirements on health care service plans, the willful violation of which would be a crime, it would thereby impose a state-mandated local program.

(2) 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. The Legislature finds and declares all of the following:

(a) California, along with other states, has experienced the creation of a new cost-sharing mechanism by some health plans known as prescription drug specialty tiers.

(b) Specialty tiers include prescription drugs for which some health care service plans and health insurers are requiring patients to pay a percentage cost of the drug instead of a copayment. These drugs are typically new, infusible, or injectible biologics or plasma-derived therapies produced in lesser quantities than other drugs and not available as less costly brand name or generic prescription drugs.

(c) The specialty drugs found on the fourth tier are used to treat conditions that affect less than 5 percent of the population, but that number is expected to grow as new drugs are approved and the drugs that are already on the market are used to treat an expanding number of conditions. Many of these specialty drugs are used to treat conditions such as cancer; autoimmune conditions, such as Crohn's disease, lupus, multiple sclerosis, myasthenia gravis, myositis, scleroderma, and rheumatoid arthritis; hemophilia and other bleeding disorders; hepatitis; primary and secondary immune deficiencies; neuropathy; and transplant patients. These drugs are used to treat complex and chronic conditions and require special administration, handling, and care management.

(d) Plans and insurers are also increasing prescription drug copayments to amounts beyond the reach of most patients. The amounts charged for drug copayments should not have the effect of unfairly denying access to medicine. This has resulted in some patients paying more than \$3,000 for one month's supply of medication. For example, currently a person with multiple sclerosis might pay a \$55 copayment for medication. But, if the person's drug plan had specialty tiering and charged 25 percent to 33 percent in coinsurance, the same medication would cost between \$750 and \$990 for one month. In another example, for cancer patients, in one year the coinsurance increased for one of the most-used therapies from \$854 per month to \$1,366 per month.

(e) Paying hundreds or even thousands of dollars each month for prescription drugs would be a strain for any person, but for people

with chronic illnesses and life-threatening conditions, this unfortunate social policy has the potential to destroy a family's financial solvency or end the ability to take a necessary medication.

(f) The practice of specialty tiers violates the basic principle of insurance whereby individuals and employers purchase health insurance plans so that they are protected from the risk of needing to pay for highly expensive medical treatments. Specialty tier coinsurance rates can change unpredictably, which makes it impossible for patients to anticipate and budget for health care costs. Those rate changes also impede patients from having informed discussions with their doctors about containing the cost of their treatment.

(g) Where the practice of specialty tiering is allowed, the out-of-pocket costs for medications are high enough to preclude patients from complying with the treatment protocols prescribed by their doctors and force patients to choose between paying for basic living expenses or taking their medications. As patients forgo treatment because of cost concerns, their health deteriorates, often necessitating more expensive emergency care.

(h) Many patients who cannot afford their copayments have been forced to go on disability, resulting in additional costs to the state.

(i) Specialty tiers are contrary to the original purpose of insurance, which was the spreading of costs. Specialty tiers create a structure where those who are sickest pay more, and those who are healthy pay less. Additionally, this type of cost-sharing arrangement will not keep health care costs down because there are no generic alternatives available for the biologic treatments that make up the vast majority of drugs placed on specialty tiers. Therefore, the creation of specialty tiers is a discriminatory practice.

SEC. 2. Section 1367.225 is added to the Health and Safety Code, to read:

1367.225. (a) A health care service plan contract issued, amended, or renewed on or after January 1, 2012, that covers prescription drugs shall not provide for specialty tiers that require payment of a percentage cost of prescription drugs by enrollees.

(b) A health care service plan contract issued, amended, or renewed on or after January 1, 2012, shall not require an enrollee to pay a copayment for prescription drugs in excess of 500 percent of the lowest copayment required by the plan for prescription drugs in the plan's formulary.

(c) If a health care service plan provides a limit for out-of-pocket expenses for benefits other than prescription drugs, the plan shall include one of the following provisions in the plan that would result in the lowest out-of-pocket prescription drug cost to the enrollee:

(1) Out-of-pocket expenses for prescription drugs shall be included under the plan's total limit for out-of-pocket expenses for all benefits provided under the plan.

(2) Out-of-pocket expenses for prescription drugs per contract year shall not exceed one thousand dollars (\$1,000) per enrollee or, in the case of covered dependents, two thousand dollars (\$2,000) including dependents of the enrollee, as adjusted for inflation.

(d) For purposes of this section, "copayment" means a flat dollar amount an enrollee pays, out of pocket, at the time of receiving a health care service or when paying for a prescription drug, after any applicable deductible. The term shall not be construed to include any other forms of cost sharing.

(e) Nothing in this section shall be construed to require a health care service plan contract to provide coverage not otherwise required by law for any prescription drug.

(f) This section shall become inoperative upon a determination by the department that the requirements of this section would result in the assumption by the state of additional costs pursuant to Section 1311(d)(3)(B) of the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by Section 10104(e) of Title X of that act, relative to benefits required by the state to be offered by qualified plans in the California Health Benefit Exchange that exceed the requirements imposed by federal law.

SEC. 3. Section 10123.197 is added to the Insurance Code, to read:

10123.197. (a) A health insurance policy issued, amended, or renewed on or after January 1, 2012, that covers prescription drugs shall not provide for specialty tiers that require payment of a percentage cost of prescription drugs by insureds.

(b) A health insurance policy issued, amended, or renewed on or after January 1, 2012, shall not require an insured to pay a copayment for prescription drugs in excess of 500 percent of the lowest copayment required by the policy for prescription drugs in the policy's formulary.

(c) If a health insurance policy provides a limit for out-of-pocket expenses for benefits other than prescription drugs, the policy shall include one of the following provisions in the policy that would result in the lowest out-of-pocket prescription drug cost to the insured:

(1) Out-of-pocket expenses for prescription drugs shall be included under the policy's total limit for out-of-pocket expenses for all benefits provided under the policy.

(2) Out-of-pocket expenses for prescription drugs per contract year shall not exceed one thousand dollars (\$1,000) per insured or, in the case of covered dependents, two thousand dollars (\$2,000) including dependents of the insured, as adjusted for inflation.

(d) For purposes of this section, "copayment" means a flat dollar amount an insured pays, out of pocket, at the time of receiving a health care service or when paying for a prescription drug, after any applicable deductible. The term shall not be construed to include any other forms of cost sharing.

(e) Nothing in this section shall be construed to require a health insurance policy to provide coverage not otherwise required by law for any prescription drug.

(f) This section shall become inoperative upon a determination by the commissioner that the requirements of this section would result in the assumption by the state of additional costs pursuant to Section 1311(d)(3)(B) of the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by Section 10104 (e) of Title X of that act, relative to benefits required by the state to be offered by qualified plans in the California Health Benefit Exchange that exceed the requirements imposed by federal law.

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

## **Appendix B: Literature Review Methods**

Appendix B describes methods used in the medical effectiveness literature review for Assembly Bill (AB) 310. AB 310 would impose a health benefit mandate on DMHC-regulated health plan contracts and CDI-regulated policies to (a) prohibit coinsurance (i.e., percentage cost of the prescription) as the basis for cost sharing for outpatient prescription drug benefits (b) limit copayments for outpatient prescription drugs to \$150 per one month supply or its equivalent for prescriptions for longer periods, adjusted for inflation; and, (c) if a plan/policy has an annual out-of-pocket maximum, require outpatient prescription drug benefit cost sharing to be included under that annual out-of-pocket maximum.

The literature search included studies published in English from January 2007 to present. The studies included males and females, and study participants could be of any age. 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, Business Source Complete, and Econlit. In addition, Web sites maintained by the following organizations that index or publish systematic reviews and evidence-based guidelines were searched: the Agency for Healthcare Research and Quality, International Network of Agencies for Health Technology Assessment, National Health Service Centre for Reviews and Dissemination, National Institute for Health and Clinical Excellence, and the Scottish Intercollegiate Guideline Network.

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 311 articles, meta-analyses, and systematic reviews were identified. Seventeen articles, meta-analyses, and systematic reviews were included in the review.

In making a “call” for each outcome measure, the team and the content expert consider the number of studies as well the strength of the evidence. To grade the evidence for each outcome measured, the team uses a grading system that has the following categories.

- Research design
- Statistical significance
- Direction of effect
- Size of effect
- Generalizability of findings

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

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

The conclusion states that there is “clear and convincing” evidence that an intervention has a favorable effect on an outcome, if most of the studies included in a review are well-implemented randomized controlled trials and report statistically significant and clinically meaningful findings that favor the intervention.

The conclusion characterizes the evidence as “preponderance of evidence” that an intervention has a favorable effect if most but not all five criteria are met. For example, for some interventions the only evidence available is from nonrandomized studies or from small RCTs with weak research designs. If most such studies that assess an outcome have statistically and clinically significant findings that are in a favorable direction and enroll populations similar to those covered by a mandate, the evidence would be classified as a “preponderance of evidence favoring the intervention.” In some cases, the preponderance of evidence may indicate that an intervention has no effect or has an unfavorable effect.

The evidence is presented as “ambiguous/conflicting if their findings vary widely with regard to the direction, statistical significance, and clinical significance/size of the effect.

The category “insufficient evidence” of an intervention’s effect indicates that available evidence is not sufficient to determine whether or not a health care service is effective. It is used when no research studies have been completed or when only a small number of poorly designed studies are available. It is not the same as “evidence of no effect”. A health care service for which there is insufficient evidence might or might not be found to be effective if more evidence were available.

### Search Terms

The search terms used to locate studies relevant to **AB 310 prescription drugs** were as follows:

#### *MeSH Terms Used to Search PubMed and Cochrane Library*

arthritis, rheumatoid/ drug therapy/economics/therapeutic use  
chronic disease/drug therapy/economics  
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/ statistics and numerical data/utilization  
drug utilization  
emergency service, hospital/statistics and numerical data/utilization  
growth hormone/economics/therapeutic use/utilization

hepatitis c/drug therapy/economics/prevention and control  
insurance coverage  
insurance, pharmaceutical services  
managed care programs  
medication adherence  
multiple sclerosis/drug therapy/economics/therapeutic use  
neoplasms/drug therapy/economics/therapeutic use  
office visits  
patient Compliance  
prescription drugs  
prescription fees  
treatment outcome  
treatment refusal

*Keywords used to search PubMed, Cochrane Library, Web of Science, EconLit, Business Source Complete and other relevant web sites*

Adherence to medication  
benefit cap\*  
biological agent\*  
biologics, cancer  
ceiling  
chronic disease\*  
coinsurance  
co-payment  
copayment, cost\*  
cost effective\*  
cost of treatment  
cost offset, cost saving\*  
cost sharing  
cost utility  
CVS/CareMark  
deductible\*  
demand  
diabetes  
discontinuation of medication  
drug cost\*  
drug utilization  
economic burden  
effect\*  
emergency department visit\*  
Express Scripts  
filling a prescription  
growth hormone  
health outcome\*  
hepatitis c

high cost specialty drug\*  
hospital admissions  
hospitalization  
inpatient admissions  
impact  
maximum  
Kaiser Family Foundation  
Medco  
medication adherence  
multiple sclerosis  
number of prescriptions filled  
number of refills  
office visit\*  
out of pocket  
patient compliance  
prescription drug\*  
prescription drug benefit\*  
prescription drug trend\*  
price elasticity of demand  
price of treatment  
rheumatoid arthritis  
socioeconomic difference  
specialty drug\*  
specialty medication\*  
specialty prescription\*  
supply  
tier copayment  
unit cost of treatment

### Publication Types

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

### Years Covered:

2007 to present

## Appendix C: Summary Findings on Medical Effectiveness

**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
<i>Multiple Classes of Drugs</i>					
Copayment and coinsurance policies	Austvoll-Dahlgren et al., 2008	Systematic Review	<p>Increase in fixed copayments</p> <p>Fixed copayments vs. full drug coverage</p> <p>Fixed copayments with cap vs. full drug coverage</p> <p>Fixed copayments with ceiling vs. full drug coverage</p> <p>Fixed copayment and coinsurance with ceiling vs. some drug coverage</p> <p>Three-tier vs. two-tier copayments</p>	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, tiering copayments, coinsurance	Goldman et al., 2007	Systematic Review	Copayment, tiering, and/or coinsurance vs. variation in drug coverage	Health care consumers and providers within a large jurisdiction or system of care (regional, national, or international); for example, members enrolled in privately insured plans, drug insurance plans, employer-sponsored health plans, managed care organizations and Medicare HMOs.	N/A
Coinsurance (switch prescription benefit from copayment to coinsurance)	Klepser et al., 2007	Retrospective cohort study	Coinsurance vs. copayment	Members enrolled in mostly privately insured and preferred provider organization groups. Intervention group = 69,331 Comparison group = 12,241	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
<i>Specialty Drugs</i>					
Coinsurance, copayment, copayment level for drugs used to treat multiple sclerosis (MS)	Dor et al., 2010	Cross-sectional observational study	Coinsurance vs. copayment High vs. low coinsurance rates High vs. low copayment rates	Persons with MS enrolled in commercial health plans	USA
Copayments	Foster et al., 2009	Retrospective observational study	Variable average copayment per day	Persons with osteoporosis (Commercial/Medicare, N=2,218)	USA
Out-of-pocket costs for tumor necrosis factor (TNF) blocker or multiple sclerosis (MS) biologic agent	Gleason et al., 2009	Cross-sectional observational study	Higher specialty medication out-of-pocket expenses vs. lower specialty medication out of pocket expenses Categories of spending: \$0-\$100; \$101-\$150; \$151-\$200; \$201-\$250; \$251-\$350; \$351-\$500; or > \$500	Persons with multiple sclerosis or rheumatoid arthritis enrolled in commercial health plans (N =13, 172,480)	USA
Out-of-pocket costs and percentage of total cost paid by enrollees for tumor necrosis factor (TNF agents)	Curkendall et al., 2008	Retrospective observational study	More generous coverage vs. less generous coverage (variable out of pocket expenses across medications)	Persons with rheumatoid arthritis (RA) who had newly initiated TNF agents therapy and were enrolled in self-insured employer health plans (N=2285)	USA
Plan generosity: ratio of total out-of-pocket payments for certain specialty drugs relative to total payments	Goldman et al., 2006	Cross-sectional observational study	More generous coverage vs. less generous coverage (variation in plan generosity)	Persons with cancer, kidney disease, multiple sclerosis or rheumatoid arthritis enrolled in employer-sponsored commercial health plans (N=1.5 million)	USA
Plan generosity for five cancer drugs <sup>43</sup>	Goldman et al., 2010	Observational study using longitudinal data	Variable out of pocket spending costs across medications:	Persons with cancer enrolled in employer-sponsored commercial health plans (N=29,539)	USA
Plan generosity for rheumatoid arthritis	Karaca-Mandic et al., 2010	Cross-sectional observational study	More generous coverage vs. less generous coverage (variation in plan generosity)	Persons with rheumatoid arthritis enrolled in employer-sponsored commercial health plans (newly diagnosed sample, N=8,557; continuation sample, N= 2,066)	USA

<sup>43</sup> Bevacizumab, Trastuzumab, Rituximab, Imatinib mesylate, Erlotinib

**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
<i>Traditional Oral Drugs</i>					
Coinsurance rate (percentage of total pharmaceutical expenditures paid out-of-pocket by patients)	Philipson et al., 2010	Retrospective observational study	Persons in the highest quartile of cost sharing (mean = \$41.19 per prescription) vs. persons in the lowest quartile of cost sharing (mean = \$9.41 per prescription)	Persons with acute coronary syndrome enrolled in employer-sponsored commercial health plans (N=14,325)	USA
Coinsurance vs. copayment	Dor and Encinosa, 2010	Retrospective observational study	Copayment range: \$5.01-\$16.89 Coinsurance: 6%, 10%, 18%	Persons age 18 years or older with diabetes mellitus insured by employer-sponsored health plans and also inclusive of retirees for whom employers provided Medicare supplemental insurance (N= 28,031)	USA
Change in 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
Copayments	Barron et al., 2008	Retrospective observational study	Copayment level per prescription (less than \$10; \$10 -\$20; \$20-\$30; \$30 or more)	Persons with type 2 diabetes enrolled in commercial health plans (N=18,658)	USA
Copayments	Colombi et al., 2008	Retrospective observational study	Copayment level per prescription (0-9\$; \$10-\$19; \$20 or more)	Persons with type 2 diabetes enrolled in employer-sponsored commercial health plans (N=2052)	USA
Copayments	Ye et al., 2007	Longitudinal retrospective cohort study	Copayment level per prescription (0-9\$; \$10-\$19; \$20 or more)	Persons who initiated statin treatment following a hospitalization discharge in which they had a primary diagnosis of coronary heart disease (CHD) (N= 5,548)	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
<i>Specialty Drugs</i>					
Three-tier formulary	Hodgkin et al., 2008	Pre-test post-test quasi-experimental design	Persons enrolled in health plans that introduced a three-tier formulary for anti-depressants vs. a comparison group of persons in plans with no tiered formulary.	Persons utilizing anti-depressants who were enrolled in a large nonprofit managed care organization. (N=109,686)	USA

*Sources:* Austvoll-Dahlgren et al., 2008; Barron et al., 2008; Chernew et al., 2008; Colombi et al., 2008; Curkendall et al., 2008; Dor and Encinosa, 2010; Dor et al., 2010; Foster et al., 2009; Gleason et al., 2009; Goldman et al., 2006, 2007, 2010; Hodgkin et al., 2008; Karaca-Mandic et al., 2010; Klepser et al., 2007; Philipson et al., 2010; Ye et al., 2007.

**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
<i>All Types of Drugs</i>						
Price elasticity of demand <sup>44</sup> : 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.
Average # of prescription per month – all drugs: Shift from copayment to coinsurance	Klepser et al., 2007	Retrospective cohort study	Not statistically significant: 1 of 1 study	No difference: 1 of 1 study	No effect: 1 of 1 study	Findings from a single study suggest that changing from a copayment to a coinsurance design has no effect on the average number of prescriptions per month for all drugs.
Average # of prescriptions per enrollee: Increase copayment	Austvoll-Dahlgren et al., 2008; Goldman et al., 2007	2 systematic review – 3 nonrandomized studies with comparison group	Not reported: 3 of 3 studies	Favors lower cost sharing: 3 of 3 studies	All drugs: 3.8% to 22.5% reduction <sup>45</sup>  9 classes of drugs: Similar reductions across the 9 classes <sup>46</sup>  8 classes of drugs: from 25% for antidiabetes drugs to 45% for anti-inflammatories <sup>47</sup>	Higher copayments associated with filling fewer prescriptions. Findings regarding differences in effects across classes of drugs are ambiguous.

<sup>44</sup> Price elasticity of demand shows how the quantity demanded or supplied will change when the price changes.

<sup>45</sup> Motheral et al., 1999, 2001, as cited in Austvoll-Dahlgren et al., 2008.

<sup>46</sup> Landesman et al., 2005, as cited in Goldman et al., 2007.

<sup>47</sup> Goldman et al., 2004, as cited in Goldman et al., 2007.

**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
<i>All Types of Drugs</i>						
Average # of prescriptions per enrollee: Institute copayment	Austvoll-Dahlgren et al., 2008	Systematic review – 5 nonrandomized studies with comparison group; 1 interrupted time series study	Statistically significant for both essential and discretionary drugs: 6 of 6 studies	Favors no cost sharing: 6 of 6 studies	All drugs: Reduction of 0.3 drugs per enrollee <sup>48</sup>  Essential drugs: 4% to 13% reduction <sup>49</sup>  Discretionary drugs: 13% to 19% reduction	Instituting a copayment reduces the number of prescriptions per enrollee
Days' supply – all drugs plus antihypertensives, SSRIs/SNRIs, and statins: Shift from copayment to coinsurance	Klepser et al., 2007	Retrospective cohort study	All drugs: statistically significant (1 out of 1 study)  Antihypertensives: statistically significant (1 out of 1 study)  SSRIs/SNRIs: statistically significant (1 out of 1 study)  Statins: statistically significant (1 out of 1 study)	Favors copayment: 1 out of 1 study	All drugs: DD <sup>50</sup> : -1.63 days  Antihypertensives: DD: -1.54 days  SSRIs/SNRIs: DD: -1.26 days  Statins: DD: -0.87 days	Findings from a single study suggest that changing from a copayment to a coinsurance design reduces days supply of medications overall, and impacts subclasses of drugs similarly (antihypertensives, SSRIs/SNRIs, and statins).

<sup>48</sup> Reeder et al., 1985, as cited in Austvoll-Dahlgren et al., 2008.

<sup>49</sup> Harris et al., 1990, as cited in Austvoll-Dahlgren et al., 2008.

<sup>50</sup> DD stands for difference in differences.

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

<b>Outcome</b>	<b>Citation</b>	<b>Research Design</b>	<b>Statistical Significance</b>	<b>Direction of Effect</b>	<b>Size of Effect</b>	<b>Conclusion</b>
<i>All Types of Drugs</i>						
Number of hospitalizations: Increase copayment	Austvoll-Dahlgren et al., 2008; Goldman et al., 2007	2 systematic review – 3 nonrandomized studies with a comparison group	Not statistically significant	No difference	No effect	Higher copayment does not affect the number of hospitalization
Number of emergency department visits: Increase copayment	Austvoll-Dahlgren et al., 2008; Goldman et al., 2007	2 systematic review – 3 nonrandomized studies with a comparison group	Not statistically significant	No difference	No effect	Higher copayment does not affect the number of emergency department visits
Number of physician visits: Increase copayment	Austvoll-Dahlgren et al., 2008; Goldman et al., 2007	2 systematic review – 3 nonrandomized studies with a comparison group	Not statistically significant	No difference	No effect	Higher copayment does not affect the number of office visits

**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
<i>Specialty Drugs</i>						
Price elasticity of demand for initiation of a specialty drug for cancer <sup>51</sup> : Variation in cost sharing across health plans	Goldman et al., 2010	Observational study using longitudinal data	<b>Rituximab</b> Statistically significant: 1 out of 1 study  <b>Bevacizumab, trastuzumab, imatinib mesylate, and erlotinib</b> Not statistically significant: 1 out of 1 study	<b>Rituximab</b> Favors lower cost sharing: 1 out of 1 study  <b>Bevacizumab, trastuzumab, imatinib mesylate, and erlotinib</b> No difference: 1 out of 1 study	<b>Price elasticity:</b> <b>Rituximab:</b> -0.258  <b>Bevacizumab, trastuzumab, imatinib mesylate, and erlotinib</b> -0.189 (not significant)	Findings from one study suggest that demand for Rituximab is sensitive to cost sharing, with a reduction in out-of-pocket costs increasing likelihood that patients will initiate treatment. Use of four other specialty drugs for cancer is not associated with out-of-pocket costs.
Price elasticity of demand for use of specialty drugs for multiple sclerosis (MS), rheumatoid arthritis (RA), kidney disease, or cancer: Variation in cost sharing across health plans	Goldman et al., 2006	Cross-sectional observational study	<b>MS and RA specialty drugs:</b> Statistically significant: 1 out of 1 study  <b>Kidney disease and cancer specialty drugs:</b> Not statistically significant: 1 out of 1 study	<b>MS and RA specialty drugs:</b> Favors lower cost sharing: 1 out of 1 study  <b>Kidney disease and cancer specialty drugs:</b> No difference: 1 out of 1 study	<b>Price elasticity:</b> Rheumatoid arthritis (RA) drugs: -0.21  Multiple Sclerosis (MS) drugs: -0.07	Findings from one study suggest that higher out-of-pocket costs increasing the likelihood that patients with MS or RA will forgo use of specialty drugs. Out-of-pocket costs did not affect use of specialty drugs for kidney disease or cancer.

<sup>51</sup> rituximab, bevacizumab, trastuzumab, imatinib, mesylate, or erlotinib

**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
<i>Specialty Drugs</i>						
Medication possession ratio [MPR] (measure of adherence) for disease modifying therapy <sup>52</sup> for multiple sclerosis	Dor et al., 2010	Cross-sectional observational study	<p><b>High vs. low coinsurance rates</b> Statistically significant: 1 out of 1 study</p> <p><b>High vs. low copayment rates</b> Not statistically significant: 1 out of 1 study</p> <p><b>Copayment vs. coinsurance</b> Statistically significant: 1 out of 1 study</p>	<p><b>High vs. low coinsurance rates</b> Favors higher cost sharing: 1 out of 1 study</p> <p><b>High vs. low copayment rates</b> No difference: 1 out of 1 study</p> <p><b>Copayment vs. coinsurance</b> Favors higher cost sharing: 1 out of 1 study</p>	<p>Increased cost sharing in coinsurance cohort was significantly associated with decreased adherence to therapy, with a 10% increase in cost sharing leading to an 8.6% decline in adherence</p> <p><b>No effect:</b> copayment and adherence (as measured by MPR – least compliant vs. highly compliant)</p> <p>Increased coinsurance was associated with lower adherence across various MPR levels vs. no variation for those with copayments</p>	<p>Findings from one study suggest that increased cost sharing/coinsurance is associated with decreased adherence to specialty drugs for multiple sclerosis</p> <p>When using copayments to pay for specialty drugs, costs are stable among those least compliant and those most compliant.</p> <p>Those with copayments did not vary in adherence to therapy, although there was little variation in copayment levels in this study data</p>

<sup>52</sup> avonex, betaseron, copaxone, rebif

**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
<i>Specialty Drugs</i>						
Medication possession ratio for specialty drug for rheumatoid arthritis (RA) – converted to days supply <sup>53</sup>	Curkendall et al., 2008	Retrospective observational study	Statistically significant: 1 out of 1 study	Favors lower cost sharing	One week of treatment was lost with either an increase of \$5.50 in weekly out of pocket cost or an increase of 2.2 percentage points in the share of drug cost paid for by patients	Findings from one study suggest that increased cost sharing is associated with decreased adherence to specialty drugs for rheumatoid arthritis
Number of claims for a specialty drug for cancer <sup>54</sup> : Variation in cost sharing across health plans	Goldman et al., 2010	Observational study using longitudinal data	Statistically significant: 1 out of 1 study	Favors lower cost sharing	<b>Price elasticity:</b>  Rituximab: -0.0367  Bevacizumab, erlotinib, imatinib, mesylate, trastuzumab: -0.108	Findings from one study suggest that reduction in out-of-pocket costs for rituximab, bevacizumab, erlotinib, imatinib, mesylate, and trastuzumab reduces the number of claims for these specialty drugs.

<sup>53</sup> adalimumab or etanercept

<sup>54</sup> bevacizumab, trastuzumab, rituximab, imatinib mesylate, or erlotinib

**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
<i>Specialty Drugs</i>						
Probability of initiating use of a specialty drug <sup>55</sup> for rheumatoid arthritis (RA) – enrollees newly diagnosed with RA and all enrollees with RA: Variation in cost sharing across health plans	Karaca-Mandic et al., 2010	Cross-sectional observational study	<p><b>Newly diagnosed:</b> Statistically significant: 1 out of 1 study</p> <p><b>All:</b> Not statistically significant: 1 out of 1 study</p>	<p><b>Newly diagnosed:</b> Favors copayment: 1 out of 1 study</p> <p><b>All:</b> No difference: 1 out of 1 study</p>	<p><b>Newly diagnosed:</b> Probit regression co-efficient: -0.012</p> <p><b>All:</b> Probit regression co-efficient: -0.01 (not significant)</p>	<p>Findings from one study suggest that increasing out-of-pocket costs reduces the probability of initiating use of a specialty drug among those newly diagnosed with RA.</p> <p>Among all enrollees with RA, out-of-pocket costs were not associated with initiating use of a specialty drug.</p>

<sup>55</sup> etanercept, adalimumab, or infliximab

**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
<i>Specialty Drugs</i>						
Probability of not initiating use of specialty drug <sup>56</sup> used to treat multiple sclerosis (MS) or rheumatoid arthritis (RA): Variation in cost sharing across health plans	Gleason et al., 2009	Cross-sectional study observational study	<b>MS and RA specialty drugs:</b> Statistically significant: 1 out of 1 study	<b>MS and RA specialty drugs:</b> Favors lower cost sharing	<p><b>Odds ratios (OR) for MS specialty drugs:</b> compared to \$0-200 copayment, those with copayments greater than \$200 had lower odds of initiating or continuing a specialty drug (all ORs are greater than 6).</p> <p><b>Odds ratios (OR) for tumor necrosis factor blocker for RA:</b> Compared to \$0-100 copayment, those with copayments greater than \$100 had lower odds of initiating or continuing a specialty drug (range of OR: 2.1-7.0)</p>	Findings from a single study suggest that increased cost sharing for specialty drugs to treat MS or RA is associated with a higher probability of not initiating or continuing use of specialty drugs.

<sup>56</sup> interferon beta-1a intramuscular, interferon beta-1a subcutaneous, interferon beta-1b, glatiramer acetate; TNF: etanercept, adalimumab

**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
<i>Specialty Drugs</i>						
Time until discontinuation of a specialty drug for rheumatoid arthritis (RA): Variation in cost sharing across health plans <sup>57</sup>	Curkendall et al., 2008	Retrospective observational study	Statistically significant: 1 out of 1 study	Favors lower cost sharing	<p>The probability of continuing with drug therapy for 1 year: 32% for patients with OOP costs above \$50/week vs. 57% for patients with OOP costs less than \$50/week.</p> <p>Patients with OOP costs greater than \$50/week were 58% more likely to stop using drug within 1 year than those with lower OOP costs (adjusted hazard ratio: 1.579)</p> <p>Patients were 8% more likely to stop using drug within 1 year for every \$10 increase in weekly OOP costs (adjusted hazard ratio: 1.008)</p>	Findings from one study suggest that higher out-of-pocket costs are associated with higher rates of discontinuing a specialty drug for rheumatoid arthritis

<sup>57</sup> Adalimumab or etanercept

**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
<i>Specialty Drugs</i>						
Time until discontinuation of teriparatide (a specialty drug for osteoporosis) : Variation in cost sharing across health plans	Foster et al., 2009	Retrospective observational study	Statistically significant: 1 out of 1 study	Favors lower copayments	Hazard ratio for time to discontinuation of teriparatide: 1.10	Findings from one study suggest that increasing the average copayment per day leads to shorter time to discontinuation of teriparatide.
Time until first 60-day gap in use of teriparatide (a specialty drug for osteoporosis): Variation in cost sharing across health plans	Foster et al., 2009	Retrospective observational study	Statistically significant: 1 out of 1 study	Favors lower copayments	Hazard ratio for time to first 60 day gap in teriparatide use:1.09	Findings from one study suggest that increasing the average copayment per day leads to shorter time to first 60 day gap in teriparatide 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
<i>Traditional Oral Drugs</i>						
Change in adherence to oral diabetes medication: Increase in copayment or coinsurance from 25 <sup>th</sup> to 75 <sup>th</sup> percentile	Dor and Encinosa, 2010	Retrospective observational study	Statistically significant: 1 out of 1 study	Favors cost sharing	<p><b>Impact of increase in cost sharing from 25<sup>th</sup> to 75<sup>th</sup> percentile on adherence</b></p> <p><b><u>Copayment</u></b>  <b>Never comply:</b> 39%</p> <p><b>Partially comply:</b> 3%</p> <p><b>Always comply:</b> -24%</p> <p><b><u>Coinsurance/expected out of pocket</u></b>  <b>Never comply:</b> 71%</p> <p><b>Partially comply:</b> -18%</p> <p><b>Always comply:</b> -56%</p>	Findings from one study suggest that increased cost sharing results in lower rates of adherence for both copayments and coinsurance and that the effect is greater for coinsurance than for copayments.

**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
<i>Traditional Oral Drugs</i>						
Daily doses per 1,000 patients: Increase copayment	Austvoll-Dahlgren et al., 2008	Systematic review – 1 times series study	<u>Antidepressants and sedatives</u> Statistically significant for men but not for women  <u>Anxiolytics</u> Not statistically significant for both men and women	<u>Antidepressants and sedatives</u> Favors lower copayment (men only)  <u>Anxiolytics</u> No effect	<u>Antidepressants</u> -5275 doses per 1,000 male enrollees <sup>58</sup>  <u>Sedatives</u> -5838 doses per 1,000 female enrollees  <u>Anxiolytics</u> No effect	Higher copayment associated with less use of antidepressants and sedatives by men.
Daily doses per 1,000 patients: Increase copayment and combine with coinsurance	Austvoll-Dahlgren et al., 2008	Systematic review – 1 times series study	<u>Antidepressants and anxiolytics</u> Statistically significant for men and women  <u>Sedatives</u> Statistically significant for men but not for women	<u>Antidepressants and anxiolytics</u> Favors lower copayment (men only)  <u>Sedatives</u> Favors lower copayment for men, no difference for women	<u>Antidepressants</u> -4393 to -21,129 doses per 1,000 enrollees <sup>59</sup>  <u>Sedatives</u> -3415 doses per 1,000 male enrollees  <u>Anxiolytics</u> -1600 to -3548 doses per 1,000 enrollees	Higher copayment plus coinsurance with ceiling is associated with less use of antidepressants and anxiolytics among both men and women and with less use of sedatives among men.
Medication possession ratio for oral drugs for congestive heart failure and diabetes: Variation in copayments	Chernew et al., 2008	Retrospective observational study	Statistically significant: 1 out of 1 study	Favors lower copayments	Price elasticity range: -0.029 to -0.054	Findings from a single study suggest that increasing copayments is associated with decreased adherence to oral drugs for congestive heart failure and diabetes.

<sup>58</sup> Ong et al., 2003, as cited in Austvoll-Dahlgren et al., 2008.

<sup>59</sup> Ong et al., 2003, as cited in Austvoll-Dahlgren et al., 2008.

**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
<i>Traditional Oral Drugs</i>						
Medication possession ratio for an oral drug to control diabetes: Variation in cost sharing across health plans	Barron et al., 2008	2 retrospective observational studies	Statistically significant: 1 out of 1 study	Favors lower cost sharing	Adherence as measured by medication possession ratio (MPR) <sup>60</sup>  Mean MPR decreased from 0.58 for those with copayment less than \$10 to 0.52 for patients with a copayment of \$20 or more (Barron et al., 2008)  For those aged less than 65 years, MPR for copayment level of 0-9\$ was 74%, copayment of \$10-\$19 was 71% and copayment of \$20+ was 55% (unadjusted adherence: Columbi et al.)	Findings from one study show that increased cost sharing, with higher costs associated with reduced adherence.

<sup>60</sup> MPR definition: the number of days that a patient had a supply of the index drug during the year after the index fill by 365 days.

**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
<i>Traditional Oral Drugs</i>						
Medication possession ratio for statins: Variation in copayments for 30-day supply of medication	Ye et al., 2007	Longitudinal retrospective cohort study	Statistically significant: 1 of 1 study	Favors lower cost sharing	<p><b>Odds ratio</b></p> <p>Referent copayment: &lt; \$10</p> <p>\$10 to &lt;\$20 OR: 0.96 (95% CI: 0.83,1.10)</p> <p>≥\$20 OR: 0.42 (95% CI: 0.36,0.49)</p>	Compared with those who had a mean copayment of < \$10 per 30-day supply, patients with mean copayment of ≥\$20 were less than half as likely to adhere to statin treatment.
Number of prescriptions: Increase in copayment for some brand-name drugs	Austvoll-Dahlgren et al., 2008	Systematic review – 1 times series study	Statistically significant: 1 of 1 study	Favors lower cost sharing	<p><u>ACE inhibitors and statins</u> 2% to 24% reduction<sup>61</sup></p> <p><u>Proton Pump Inhibitors</u> 5% to 34% reduction</p>	Increase in copayment associated with less use of ACE Inhibitors, statins and proton pump inhibitors.

<sup>61</sup> Huskamp et al., 2005, as cited in Austvoll-Dahlgren et al., 2008.

**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
<i>Traditional Oral Drugs</i>						
Probability of discontinuing a traditional oral drug for diabetes or acute coronary syndrome: Variation in cost sharing across health plans	Barron et al., 2008; Philipson et al., 2010	2 retrospective observational studies	Statistically significant: 2 out of 2 studies	Favors lower cost sharing	Percentage of patients who discontinued oral diabetes treatment by copayment level:  <\$10=55.4% \$10-<\$20 =56.7% \$20-<\$30 =65.0% >\$30=67% (Barron et al., 2008)  For those on anti-platelet therapy, in each month after stent implantation the probability of discontinuation was 1.8 percentage points higher for patients with higher vs. lower cost sharing (Philipson et al., 2010)	Findings from two studies show that the probability of discontinuation of drug therapy for diabetes and acute coronary syndrome is associated with higher cost sharing.
Proportion of persons with acute coronary syndrome initiating an antiplatelet drug: Variation in cost sharing across health plans	Philipson et al., 2010	Retrospective observational study	Statistically significant: 1 out of 1 study	Favors lower cost sharing	At 40 days after implantation of a stent, 90% of patients with low cost sharing adopted anti-platelet therapy vs. 86% of patients with high cost sharing.	Findings from one study suggest that increased cost sharing leads to reduction in adoption of anti-platelet therapy

**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
<i>Traditional Oral Drugs</i>						
Use of antidepressant medication among persons with mental illness: Increase in copayment for some brand-name medications	Hodgkin et al., 2008	Pre-test post-test quasi-experimental design	Statistically significant: 1 out of 1 study	Favors lower cost sharing	For nonpreferred (higher cost) antidepressants, prescriptions per enrollee decreased 11% in the experimental group, while increasing 5% in the comparison group.	Findings from one study show that increased cost sharing leads to reduction in utilization of non-preferred antidepressants.
Hospitalization for congestive heart failure or lipid disorders: Variation in cost sharing across health plans	Goldman et al., 2007	Systematic review: 3 studies	Statistically significant	Favors lower cost sharing	Not stated	The preponderance of evidence from 3 studies suggests that higher cost sharing is associated with greater use of inpatient care among persons with congestive heart failure or lipid disorders.
Probability of having at least one diabetes-related hospitalization: Variation in cost sharing across health plans	Colombi et al., 2008	Retrospective observational study	Not statistically significant: 1 out of 1 study	No difference: 1 out of 1 study	No effect: 1 out of 1 study	Findings from a single study suggest that there is no association between cost sharing and having a diabetes-related hospitalization.

**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
<i>Traditional Oral Drugs</i>						
Number of rehospitalizations for acute coronary syndrome (ACS): Variation in cost sharing across health plans	Philipson et al., 2010	Retrospective observational study	Statistically significant: 1 out of 1 study	Worse: 1 out of 1 study	ACS hospitalizations:  <b>First three months</b> after stent implantation:  Low-cost sharing: 0.19 ACS hospitalizations High cost sharing: 0.21 ACS hospitalizations  <b>Through 12 months</b> after stent implantation:  Low-cost sharing: 0.40 ACS hospitalizations High cost sharing: 0.47 ACS hospitalizations	Findings from a single study suggest that higher cost sharing is associated with more rehospitalizations for those with acute coronary syndrome.
Emergency department visits for lipid disorders or diabetes: variation in cost sharing across health plans: Variation in cost sharing across health plans	Goldman et al., 2007	Systematic review: 3 studies	Statistically significant	Favors lower cost sharing	Not stated	The preponderance of evidence from 3 studies suggests that higher cost sharing is associated with greater emergency department use among persons with lipid disorders or diabetes.

**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
<i>Traditional Oral Drugs</i>						
Probability of having at least one emergency department visit among persons with diabetes: Variation in cost sharing across health plans	Colombi et al., 2008	Retrospective observational study	Statistically significant: 1 out of 1 study	Favors lower cost sharing	Copayment per month: 0-9\$: 2% visited ER \$10-19\$: 6% visited ER 20\$+: 15% visited ER	Findings from a single study suggest that higher cost sharing is associated with a greater likelihood of visiting the ER among persons with diabetes.
Number of outpatient visits among persons with diabetes: Variation in cost sharing across health plans	Colombi et al., 2008	Retrospective observational study	Statistically significant: 1 out of 1 study	Favors lower cost sharing	Copayment per month and outpatient visits [N(SD)]: 0-9\$: 11.2 (10) \$10-19\$: 15.0 (14.2) 20\$+: 15.6 (16.4)	Findings from a single study suggest that higher cost sharing is associated with more outpatient visits among persons with diabetes.

*Sources:* Austvoll-Dahlgren, et al., 2008; Barron et al., 2008; Chernew et al., 2008; Colombi et al., 2008; Curkendall et al., 2008; Dor and Encinosa, 2010; Dor et al., 2010; Foster et al., 2009; Gleason et al., 2009; Goldman et al., 2006, 2007, 2010; Hodgkin et al., 2008; Karaca-Mandic et al., 2010; Klepser et al., 2007; Philipson et al., 2010; Ye et al., 2007.

## Appendix D: Cost Impact Analysis: Data Sources, Caveats, and Assumptions

This appendix describes data sources, 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 Web site at [http://www.chbrp.org/analysis\\_methodology/cost\\_impact\\_analysis.php](http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php).

The cost analysis in this report was prepared by the members of cost team, which consists of CHBRP task force members and contributors from the University of California, San Diego, and the University of California, Los Angeles, as well as the contracted actuarial firm, Milliman, Inc. (Milliman). Milliman provides data and analyses per the provisions of CHBRP's authorizing legislation.

### Data Sources

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

#### *Health insurance*

1. The latest (2009) California Health Interview Survey (CHIS), which is used to estimate health insurance for California's population and distribution by payor (i.e., employment-based, individually purchased, or publicly financed). The biennial CHIS is the largest state health survey conducted in the United States, collecting information from approximately 50,000 households. More information on CHIS is available at <http://www.chis.ucla.edu>.
2. The latest (2010) California Employer Health Benefits Survey is used to estimate:
  - size of firm,
  - percentage of firms that are purchased/underwritten (versus self-insured),
  - premiums for health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and Point of Service Plans [POS]),
  - premiums for health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service plans [FFS]), and
  - premiums for high deductible health plans (HDHPs) for the California population with employment-based health insurance.
  - 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 is available at: <http://www.chcf.org/publications/2010/12/california-employer-health-benefits-survey>.

3. 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 <http://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, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed healthcare plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP’s utilization and cost estimates draw on other data, including the following:
  - The MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
  - An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2010 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2010 experience.
  - Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare 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 externally.
4. An annual survey by CHBRP of 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 PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC- or CDI-regulated), cost sharing arrangements with enrollees, and average premiums. Enrollment in plans or policies offered by these seven firms represents an estimated 93.7% of the persons with health insurance subject to state mandates. This figure represents an estimated 94.4% of enrollees in full service (non-specialty) DMHC-regulated health plans and an estimated 90.1% of enrollees in full service (non-specialty) CDI-regulated policies.<sup>62</sup>

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<sup>62</sup> CHBRP analysis of the share of enrollees included in CHBRP’s Bill-Specific Coverage Survey of the major carriers in the state is based on “CDI Licenses with HMSR Covered Lives Greater than 100,000” as part of the Accident and Health Covered Lives Data Call, December 31, 2009, by the California Department of Insurance, Statistical Analysis Division, data retrieved from The Department of Managed Health Care’s interactive Web site “Health Plan Financial Summary Report,” July-September 2010, and CHBRP’s Annual Enrollment and Premium Survey.

*Publicly funded insurance subject to state benefit mandates*

5. 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 (EOCs) documents publicly available at <http://www.calpers.ca.gov>.
6. 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 CHIS and data maintained by the Department of Health Care Services (DHCS). DHCS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the current scope of benefits. CHBRP assesses enrollment information online at [http://www.dhcs.ca.gov/dataandstats/statistics/Pages/RASS\\_General\\_Medi\\_Cal\\_Enrollment.aspx](http://www.dhcs.ca.gov/dataandstats/statistics/Pages/RASS_General_Medi_Cal_Enrollment.aspx).
7. Enrollment data for other public programs—Healthy Families Program (HFP), Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (MRMIP)—are estimated based on CHIS and data maintained by the Managed Risk Medical Insurance Board (MRMIB). The basic minimum scope of benefits offered by participating health plans under these programs must comply with all requirements for DMHC-regulated health plans, and thus these plans are affected by state-level benefit mandates. CHBRP does not include enrollment in the Post-MRMIP Guaranteed-Issue Coverage Products as these persons are already included in the enrollment for individual market health insurance offered by DMHC-regulated plans or CDI-regulated insurers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at <http://www.mrmib.ca.gov/>. Average statewide premium information is provided to CHBRP by MRMIB staff.

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.

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 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 one 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: [http://www.chbrp.org/analysis\\_methodology/cost\\_impact\\_analysis.php](http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php).
- Several recent 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, while Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and 0.84 percentage point decrease in the number of insured, respectively. The price elasticity of demand for insurance can be calculated from these studies in the following way. First, take the average percentage point decrease in the number of insured reported in these studies in response to a 1% increase in premiums (about -0.088), divided by the average percentage of insured persons (about 80%), multiplied by 100%, i.e.,  $(\{-0.088/80\} \times 100) = -0.11$ . This elasticity converts the *percentage point* decrease in the number of insured into a *percentage* decrease in the number of insured persons for every 1% increase in premiums. 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: [http://www.chbrp.org/analysis\\_methodology/cost\\_impact\\_analysis.php](http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php).

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 point of service [POS] plans—and non-HMO—including PPO and fee for service [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%.

### Potential Effects of the Federal Affordable Care Act

As discussed in the *Introduction*, there are a number of the ACA provisions that have already gone into or will go into effect over the next three years. Some of these provisions affect the baseline or current enrollment, expenditures, and premiums. This subsection discusses adjustments made to the 2011 Cost and Coverage Model to account for the potential impacts of the ACA that have gone into effect by January 2011. It is important to emphasize that CHBRP's analysis of specific mandate bills typically address the marginal 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 marginal effects are presented in the *Benefit Coverage, Utilization, and Cost Impacts* section of this report.

CHBRP reviewed the ACA provisions and determined whether and how these provisions might affect:

1. The number of covered lives in California, and specifically the makeup of the population with health insurance subject to state mandates
2. Baseline premiums and expenditures for health insurance subject to state mandates, and

### 3. Benefits required to be covered in various health insurance plans subject to state mandates

There are still a number of provisions that have gone into effect for which data are not yet available. Where data allows, CHBRP has made adjustments to the 2011 Cost and Coverage model to reflect changes in enrollment and/or baseline premiums and these are discussed here.

#### *Coverage for adult children*

PPACA Section 2714, modified by HR 4872, Section 2301, requires coverage for adult children up to age 26 as dependants to primary subscribers on all individual and group policies, effective September 23, 2010. California's recently enacted law, SB 1088 (2010) implements this provision. This could potentially affect both premiums and enrollment in 2011. According to the California Health Interview Survey (CHIS) approximately 22% of Californians aged 19-25 (1,063,000) were estimated to be uninsured at some point in 2009. As a result of the ACA, many of these young adults will likely gain access to health insurance through a parent. This dynamic may diminish the number of uninsured and may also shift some young adults from the individually purchased health insurance market into the group market. The Departments of Treasury, Labor, and Health and Human Services estimate, for 2011, the number of young adults newly covered by his/her parent's plan would be about 0.78 to 2.12 million (using high and low take-up rate assumptions respectively). Of these young adults, about 0.2 to 1.64 million would have previously been uninsured. The corresponding incremental cost impact to group insurance policies is estimated to be a premium increase of 0.5% to 1.2%. Based on the responses to the Annual Enrollment and Premium survey, there has been an increase of 1% to 1.5% in enrollment for the 19-25 year olds and the increase varies depending on whether the parents were enrolled in the large-group, small-group or individual markets. Based on analysis of the estimates from the Departments of Treasury, Labor and Health and Human Services as well as CHIS 2009 data, approximately 25% of the increase in enrollment represents a shift from the individual market and approximately 75% were previously uninsured. CHBRP took these estimates into account and adjusted underlying population data since source data did not reflect the effects of this provision, because shift in populations were expected to be significant, and to account for potential lags in enrollment (e.g., due to awareness).

#### *Minimum Medical Loss Ratio requirement*

PPACA Section 2718 requires health plans offering health insurance in group and individual markets to report to the Secretary of Health and Human Services the amount of premium revenue spent on clinical services, activities to improve quality, and other non-claim costs. Beginning in 2011, large-group plans that spend less than 85% of premium revenue and small-group/individual market plans that spend less than 80% of premium revenue on clinical services and quality must provide rebates to enrollees. According to the Interim Final Rule (45 CFR Part 158), "Issuers will provide rebates to enrollees when their spending for the benefit of policyholders on reimbursement for clinical services and quality improvement activities, in relation to the premiums charged, is less than the MLR standards established pursuant to the statute."<sup>63</sup> The requirement to report medical loss ratio is effective for the 2010 plan year, while

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<sup>63</sup> Department of Health and Human Services, *Interim Final Rule: Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act*. 45 CFR Part 158. December 1, 2010.

the requirement to provide rebates is effective January 1, 2011. The MLR requirement, along with the rebate payment requirement, will affect premiums for 2011, but the effects are unknown and data are not yet available. There is potential for substantial impact on markets with higher administrative costs, including the small and individual group markets. Responses to CHBRP's Annual Enrollment and Premiums Survey indicate that carriers intend to be in compliance with these requirements. For those that may not be in compliance, the requirement to pay rebates is intended to align the MLR retrospectively. Therefore, for modeling purposes, CHBRP has adjusted administrative and profit loads to reflect MLRs that would be in compliance with this provision.

#### *Pre-Existing Condition Insurance Plan (PCIP)*

PPACA Section 1101 establishes a temporary high-risk pool for individuals with pre-existing medical conditions, effective 90 days following enactment until January 1, 2014. In 2010, California enacted AB 1887 and SB 227, providing for the establishment of the California Pre-Existing Condition Insurance Plan (PCIP) to be administered by the Managed Risk Medical Insurance Board (MRMIB) and federally funded per Section 1101. MRMIB has projected average enrollment of 23,100 until the end of 2013, when the program will expire. As of December 2010, there were approximately 1,100 subscribers (MRMIB, 2010). The California PCIP is not subject to state benefit mandates,<sup>64</sup> and therefore this change does not directly affect CHBRP's Cost and Coverage Model. CHBRP has revised its annual update of *Estimates of the Sources of Health Insurance in California*<sup>65</sup> to reflect that a slight increase in the number of those who are insured under other public programs that are not subject to state level mandates.

#### *Prohibition of pre-existing condition exclusion for children*

PPACA Sections 1201& 10103(e): Prohibits pre-existing condition exclusions for children. This provision was effective upon enactment). California's recently enacted law, AB 2244 (2010) implements this provision. AB 2244 also prohibits carriers that sell individual plans or policies from refusing to sell or renew policies to children with pre-existing conditions. Carriers that do not offer new plans for children are prohibited from offering for sale new individual plans in California for five years.<sup>66</sup> This provision could have had significant premium effects, especially for the DMHC- and CDI-regulated individual markets. The premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision.

#### *Prohibition of lifetime limits and annual benefit limit changes*

PPACA Section 2711 prohibits individual and group health plans from placing lifetime limits on the dollar value of coverage, effective September 23, 2010. Plans may only impose annual limits on coverage and these annual limits may be no less than \$750,000 for "essential health benefits" (EHBs). The minimum annual limit will increase to \$1.25 million on Sept. 23, 2011, and to \$2 million Sept. 23, 2012. Earlier in 2010, CHBRP conducted an analysis of SB 890, which sought to prohibit lifetime and annual limits for "basic health care services" covered by CDI-regulated policies. CHBRP's analysis indicated that DMHC-regulated plans were generally prohibited

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<sup>64</sup> Correspondence with John Symkowitz, Legislative Coordinator, MRMIB, October 19, 2010.

<sup>65</sup> See: [http://www.chbrp.org/other\\_publications/index.php](http://www.chbrp.org/other_publications/index.php).

<sup>66</sup> See enacted language at: [http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab\\_2201-2250/ab\\_2244\\_bill\\_20100930\\_chaptered.pdf](http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab_2201-2250/ab_2244_bill_20100930_chaptered.pdf).

from having annual or lifetime limits. The analysis also indicated that less than 1% of CDI-regulated policies in the state had annual benefit limits and of those, the average annual benefit limit was approximately \$70,000 for the group market and \$100,000 for the individual market. Almost all CDI-regulated policies had lifetime limits in place and the average lifetime limits was \$5 million. After the effective date of the PPACA Section 2711, removal of these limits may have had an effect on premiums. As mentioned, premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision to remove lifetime limits and to increase annual limits for those limited number of policies that had annual limits that fell below \$750,000.

### *Medi-Cal Managed Care Enrollment: Seniors and Persons with Disabilities*

While the PPACA allows states the option to expand coverage to those not currently eligible for Medicaid (Medi-Cal in California), large scale expansions are not expected to be seen during 2011. However, as a result of the 2010-2011 California Budget Agreement, there are expected to be shifts in coverage for seniors and persons with disabilities. Specifically, "Seniors and persons with disabilities who reside in certain counties which have managed care plans, and who are not also eligible to enroll in Medicare, will be required to enroll in a managed care plan under a phased-in process" (LAO, 2010). The Medi-Cal Managed Care enrollment in CHBRP's 2011 Cost and Coverage Model has been adjusted to reflect this change. Baseline premium rates have also been adjusted to reflect an increase in the number of seniors and persons with disabilities in Medi-Cal Managed Care. Information from DHCS indicates these changes will go into effect July 1, 2011 and would affect approximately 427,000 Medi-Cal beneficiaries.<sup>67</sup> CHBRP used data from DHCS to adjust enrollment in Medi-Cal Managed Care, and to adjust premiums to account for the change in acuity in the underlying populations (Mercer, 2010).

### Bill Analysis-Specific Caveats and Assumptions

#### *Provision prohibiting coinsurance*

CHBRP determined the utilization rate and average per-unit charge based on the 2009 MedStat claims data for enrollees whose outpatient prescription drug benefit requires member coinsurance. The utilization rate and average per-unit charge were trended to 2011 to estimate the current utilization rate and average per-unit charges for prescription drugs that are subject to coinsurance requirements.

To estimate the postmandate utilization rate and average per-unit charges, CHBRP used the following assumptions:

1. The utilization rate and average per-unit charge will not change for the drugs not subject to coinsurance.
2. The utilization rate and average per-unit charge will not change for the drugs subject to coinsurance where the coinsurance amount is not currently greater than \$150.

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<sup>67</sup> Data from the Department of Health Care Services, Medi-Cal Managed Care Division. Received January 14, 2011.

3. For the drugs subject to coinsurance, where the coinsurance amount is greater than \$150, the utilization will increase by 4%. In addition, the average per-unit charge of the drug will not change, and the cost share will be reduced to \$150.

The impact from this provision is an increase in utilization, a decrease in enrollee cost share, and an increase in premiums.

*Provision limiting copayments to \$150*

CHBRP estimates that there will be no cost impact as a result of this provision of AB 310, based on CHBRP's bill-specific coverage survey. Results of the survey showed that no plans or policies currently had copayments exceeding \$150.

*Provision including prescription cost sharing in OOP maximum*

**Premandate estimates.** CHBRP used the Milliman Managed Care Rating Model (MCRM) to estimate the premium for six medical plans. The MCRM estimates the premium of medical benefit plans based on average charge and utilization by broad service category.

Milliman estimated the premium for six typical benefit designs (DMHC vs. CDI; large-group, small-group, and individual markets). Milliman calibrated the model to the average premiums included in CHBRP's baseline cost and coverage model.

The variables used to calibrate the model are the provider discounts and degree of healthcare management (DoHM). The provider discounts reflect the expected discount off of the provider charged to the insurance companies. The DoHM reflects the efficiency of the providers. Utilization assumptions automatically vary by benefit design in the MCRM.

**Postmandate estimates.** The cost estimates attributed to this provision in AB 310 ("OOP maximum PMPM cost estimate") were calculated as follows:

1. Estimate the "OOP threshold" which is the total dollars that need to be spent on medical costs in order to reach the OOP maximum. The OOP maximum claim cost is the portion of the total claim cost that exceeds the OOP maximum. For example, assuming that the average coinsurance amount is 10% and there is no deductible, to reach a \$1,500 OOP maximum, an enrollee's underlying medical cost would have to be over \$15,000. Thus the OOP threshold in this example is \$15,000. The OOP maximum claim cost is any costs incurred after that initial \$15,000 in claims costs is reached.
2. To estimate the OOP maximum claims costs in terms of PMPM costs, Milliman estimated the PMPM for claims above the OOP threshold by
  - a. using a claims probability distribution (CPD). A CPD is a distribution of annual average claims by enrollee.
  - b. multiplying the PMPM cost as identified by the CPD by 100% minus the plan's coinsurance. For example, if the plan is responsible for paying 60% of the claim, this factor is 40%. This is because the initial pricing assumes the enrollee's coinsurance applies to all claims. Once the OOP maximum is reached, the enrollee is not required to pay additional coinsurance. Therefore, the expected enrollee coinsurance above the OOP threshold is added to the premium.

CDI-regulated products typically have coinsurance plan designs. Milliman estimated the current premium for these plans assuming the OOP maximum applies to medical claims only. Postmandate, plans are priced with the OOP maximum applying to both medical and prescription drug claims. The resulting difference in premium is the increase in cost due to the provision of AB 310 that would require outpatient prescription drugs be included in the plans or policies OOP maximum.

For DMHC-regulated products, Milliman used an approach similar to the approach used for CDI-regulated products with one exception: a dampening factor was applied to the OOP maximum PMPM cost estimate. For the DMHC-regulated products, the typical benefit designs apply copayments to certain services. These copayments do not translate into a flat coinsurance percentage across service categories. Some services may have no cost sharing, while other services may have a copayment that translates into 10% or 20% of the average charge. Therefore, using a flat coinsurance percentage to determine the total dollars spent on medical costs creates a bias and overstates the impact attributable to this provision of AB 310. Milliman adjusted for this by multiplying the OOP maximum PMPM cost estimate by a dampening factor of 0.15.

The dampening factor was determined based on an analysis of claims by enrollee for several plan designs. The actual value of the OOP maximum was determined using this seriatim approach. It was compared to the OOP maximum claims cost estimate derived using the CPD approach. The value of the OOP maximum using a seriatim claim approach was between 10% and 20% of the value of the OOP maximum using a CPD approach. Therefore, Milliman applied a factor of 0.15 to adjust the OOP maximum cost estimate for DMHC-regulated products.

*Estimates for alternative response (increasing annual OOP maximum instead of premiums)*

It is also possible that health plans/insurers will respond to this provision (in response to purchaser requests (such as large group purchasers)) by offering products with increased annual OOP maximums instead of products with higher premiums. If that occurs, the cost impact of the mandate will be smaller than the current estimates. Under this alternative scenario, CHBRP estimates that the total net health expenditures are projected to increase by \$6.5 million (0.0069%). This is due to a \$4.8 million increase in health insurance premiums partially offset by reductions in enrollee cost sharing (\$1.8 million). Total premiums for private employers are estimated to increase by \$2.9 million, or 0.0056%. Enrollee contributions toward premiums for group insurance are estimated to increase by \$784,000, or 0.0052%. Total premiums for those with individually purchased insurance are estimated to increase by \$1.1 million, or 0.0157%.

## **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.

*The following information was submitted by the Office of Assembly Member Fiona Ma and the National Multiple Sclerosis Society-California Action Network on February 25, 2011:*

AARP. *The Tier 4 Phenomenon: Shifting the High Cost of Drugs to Consumers*. Strategic Analysis and Intelligence (SAI) Report. Washington, DC: AARP; 2009.

Burden of Patient Cost Sharing in the United States. (No sources were indicated.)

California Tier Specialty Fact Sheet 2011.

Prime Therapeutics, LLC. *Multiple Sclerosis Medication Out-of-Pocket (OOP) Expense Association with Decline to Fill Rate*. Orlando, FL: Prime Therapeutics; 2009.

Submitted information is available upon request.

For information on the processes for submitting information to CHBRP for review and consideration please visit: [http://www.chbrp.org/recent\\_requests/index.php](http://www.chbrp.org/recent_requests/index.php).

## Appendix F: Public Health Calculations

CHBRP estimated the proportion of the mandate population represented in the claims data. CHBRP then applied this ratio to estimate the number of enrollees expected to benefit from cost share reductions for RA and MS drugs due to the ban on coinsurance.

### *Calculations for etanercept and adalimumab for rheumatoid arthritis (RA)*

Total population affected by AB 310: 20,933,686  
Total enrollees impacted by mandate in claims database: 2,684,916  
Proportion of mandate population represented in claims data: 1/7.79

#### **RA drug claims subject to coinsurance with cost sharing >\$150 per prescription**

Total enrollees with RA drug claims subject to coinsurance: 59  
Estimated number of RA drug users facing reduced cost sharing in mandate population:  
 $(59)(7.79)=460$

#### **RA drug claims subject to coinsurance with cost sharing <\$150 per prescription**

Total enrollees with RA drug claims subject to coinsurance: 101  
Total enrollees with RA drug claims subject to coinsurance in mandate population: 708

### *Calculations for Interferon beta-1a for multiple sclerosis (MS)*

Total population affected by AB 310: 20,933,686  
Total enrollees impacted by mandate in claims database: 2,684,916  
Proportion of mandate population represented in claims data: 1/7.79

#### **MS drug claims subject to coinsurance with cost sharing >\$150 per prescription**

Total enrollees with MS drug claims subject to coinsurance: 10  
Estimated number of MS drug users facing reduced cost sharing in mandate population:  
 $(10)(7.79)=78$

#### **MS drug claims subject to coinsurance with cost sharing <\$150 per prescription**

Total enrollees with MS drug claims subject to coinsurance: 16  
Total enrollees with MS drug claims subject to coinsurance in mandate population: 125

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