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Outpatient Prescription Drugs

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California Health Benefits Review Program

Analysis of California Assembly Bill AB 339 Outpatient Prescription Drugs

A Report to the 2015-2016 California State Legislature

May 19, 2015



Key Findings:

Analysis of California Assembly Bill AB 339 Outpatient Prescription Drugs

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



AT A GLANCE

Assembly Bill AB 339 (amended April 7, 2015) would reduce cost sharing for prescription drugs by imposing a variety of restrictions and requirements on health insurers, including limiting cost sharing per 30-day prescription to 1/24 of the total annual out-of-pocket (OOP) maximum, and the placement of drugs on tiers to differentiate tiers beyond cost sharing. The bill does not take into account the underlying cost of prescription drugs.

- **Enrollees covered.** CHBRP estimates that 70% of enrollees with state-regulated health insurance (17.1 million enrollees) would be affected by AB 339.
- **Impact on expenditures.** For the bill provision that limits cost sharing per 30-day prescription to 1/24 of the annual OOP, CHBRP estimates the net increase in overall expenditures would be \$322.3 million, or 0.24%. Increases in premium costs would be offset by reductions in enrollees OOP expenses.
- **EHBs.** AB 339 does not appear to exceed essential health benefits (EHBs).
- **Medical effectiveness.** As cost sharing increases, adherence to drug regimens decreases. Decreased adherence is related to worse health outcomes.
- **Benefit coverage.** No change in benefit coverage.
- **Utilization.** CHBRP estimates postmandate 133,675 enrollees will have a prescription drug claim in a year with cost sharing that would have exceeded 1/24 of the annual out-of-pocket maximum for a 30-day supply premandate. This is an increase of 3,174 enrollees (2.43%) who previously did not use these prescription drugs. Postmandate, CHBRP estimates enrollees will refill 0.18 more qualifying prescription drugs (2.75%).
- **Public health.** No measurable impact due to the small number of enrollees with a reduction in cost sharing for prescription drugs, though AB 339 may yield important health and quality of life impacts for some persons.
- **Long-term impacts.** AB 339 would increase the use of existing and newly developed high-cost prescription drugs, and lead to an increase in overall expenditures. AB 339 may provide significant quality of life improvements on a case-by-case basis.
- **Interaction with existing state mandates.** State regulators require coverage of medically necessary prescriptions and have requirements around "reasonable" cost sharing or "economic value."
- **Background on cost sharing and prescription drugs.** Health insurance carriers require different levels of cost-sharing for drugs, depending on whether they are generic, brand, or specialty. Specific formularies vary.

BILL SUMMARY

AB 339 would reduce cost sharing for prescription drugs through a number of mechanisms, such as:

- Cost-sharing limits, per 30-day prescription, to 1/24 of the annual OOP;
- Coverage of both single- and extended-release regimens;
- Prohibitions on the placement of drugs treating a specific condition on the highest cost tiers, regardless of the underlying cost of the drug;
- Parity between individual market coverage formularies and group market formularies;
- Plans may not place prescription drugs on formulary tiers based solely on the cost of the prescription drug, but rather based on clinical indication and reasonable medical management practices. A plan is not required to have fourth tier, but if one does it shall comply with standardized definition of Tier 4. These definitions are:
 - Tier 1: Preferred generic; preferred brand (if cost is comparable to generic);
 - Tier 2: Nonpreferred generic; preferred brand; other drugs recommended by health insurers' Pharmaceutical/ Therapeutics committee;
 - Tier 3: Nonpreferred brand recommended by health insurers' Pharmaceutical/ Therapeutics committee;
 - Tier 4: Biologics distributed via specialty pharmacies or requires special training for self-administration or monitoring.

CHBRP KEY FINDINGS: INCREMENTAL IMPACT OF ASSEMBLY BILL AB 339

The breadth of AB 339 would have required CHBRP to individually assess each provision of the bill. CHBRP was able to quantitatively assess the first provision listed in the bill summary above. Provisions 2 through 5 could not be quantitatively addressed due to a number of factors, including:

- Lack of data about which single- vs. multi-tablet regimens are used;
- Unpredictability of which drugs would be moved into which tiers;
- Ambiguity in the term “generosity of the benefit.”

In order to provide some value to policymakers, CHBRP qualitatively describes current issues, in the form of case studies, related to tiered drugs for three conditions, which were identified by CHBRP’s content expert as having drugs in the highest cost tiers: Multiple sclerosis, HIV, and hepatitis C.

Medical Effectiveness

Studies of the effects of cost sharing on the population to which AB 339 applies indicate there is a preponderance of evidence that:

- Persons who face higher cost sharing for a prescription drug are less likely to maintain meaningful levels of adherence than persons who face lower cost sharing.
- Poorer adherence to prescription drugs therapy for chronic conditions is associated with higher rates of hospitalization and emergency department visits and poorer health outcomes.
- The effect of cost sharing on use of specialty drugs is similar to the effects for all kinds of prescription drugs, that is, as cost sharing increases, usage decreases. However, there is some evidence that the effect of cost sharing may differ depending on the specific disease and specific specialty drug.

Additionally, among low-income persons, there is a preponderance of evidence from the RAND Health Insurance Experiment and many subsequent observational studies that cost sharing has stronger effects on use of health care services by low-income persons than high-income persons. However, this effect was not observed in a recent well-done observational study of this issue in Massachusetts after its health reform was implemented.

Benefit Coverage, Cost, Utilization

Currently, 17.1 million enrollees (45% of all Californians) are subject to AB 339. This represents 70% of the 23.4 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law or law affecting the terms and conditions of coverage. AB 339 mandates changes in prescription benefit formulary design and does not mandate coverage of specific treatments and services. Based on analysis of 2013 MarketScan databases, CHBRP estimates that 0.8% of enrollees in plans and policies subject to AB 339 have at least one high-cost outpatient prescription drug claim that could have cost sharing greater than 1/24 of the annual out-of-pocket maximum, or \$260, referred to throughout as a “qualifying prescription drug.”¹ These individuals would have an average of 6.5 prescription drug claims that exceed the AB 339 limit on cost sharing per year. Postmandate, cost sharing for prescription drugs would be limited to 1/24 of the annual out-of-pocket maximum, \$260, for up to a 30-day supply for enrollees in nongrandfathered group and individual market plans and policies. High-cost and/or specialty drugs are the ones most likely affected by AB 339 because they currently are often subject to high coinsurance levels. CHBRP estimates that the annual average cost sharing for the enrollee per qualifying prescription drug is \$325. CHBRP estimates that the average cost sharing per qualifying prescription drug would decline to \$158 postmandate, or 49% less than the premandate level. AB 339 would reduce enrollee expenses, out-of-pocket expenses for covered benefits such as deductibles, and copayments by 0.42%. There will be corresponding increases in premiums: Increases in

¹ Estimate obtained from the analysis by Milliman of the Thomson Reuters’ MarketScan databases from 2013. Prescription drug claims with costs greater than \$1,325 (drug costs associated with cost sharing of \$260, 1/24 of annual out-of-pocket maximum) were identified.

insurance premiums as a result of AB 339 would vary by market segment. Private employer premium increases are expected to increase by 0.28%, and 0.35% for enrollees with group insurance. Enrollees for individually purchased insurance have the highest increases of 0.71%.

Public health

Overall Public Health Impact

CHBRP estimates that 46,357 enrollees, including 947 new users, would fill an additional 13,184 high-cost prescription drugs were AB 339 enacted. However, CHBRP projects no measurable public health outcomes impact due to the small number of enrollees (46,357 of 10.97 million, 0.42%) with a reduction in cost sharing for prescriptions that would have exceeded the \$260/prescription limit premandate. CHBRP recognizes that on a case-by-case basis, AB 339 may yield important health and quality of life improvements for some persons.

Impact on Financial Burden

In the first year postmandate, CHBRP estimates that AB 339 would reduce net out-of-pocket expenditures by \$21.8 million for 46,357 of the 10.97 million enrollees whose cost sharing would no longer exceed the cost-sharing limit of \$260/prescription. This translates to a 42% reduction (\$132/prescription) in the average cost sharing for an enrollee's high-cost prescription drug.

To the extent that AB 339 removes a cost barrier for some enrollees who would then initiate therapy earlier and maintain adherence, the health impact on disease progression and outcomes could be significant on a case-by-case basis.

Long-term Impacts

Cost

CHBRP estimates that in the long term, AB 339 would increase the use of existing and newly developed high-cost prescription drugs and would lead to an increase in overall expenditures due to a reduction of cost sharing for high-cost prescription drugs. The magnitude of this impact is unknown. CHBRP is unable to estimate the long-term public health impact of AB 339 due to uncertainty in the market's response to the downward cost pressure of

mandated reductions in enrollee cost sharing and the upward pressure of the increasing number and cost of specialty drugs; however, AB 339 may provide significant health and quality of life improvements on a case-by-case basis.

Essential Health Benefits and the Affordable Care Act

Exceeding EHBs

Requirements that would be mandated by AB 339 appear not to exceed EHBs, and therefore would not trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in qualified health plans (QHPs) in Covered California.

EHB Discriminatory Coverage Requirements

A requirement of EHB coverage is that benefits are designed to ensure there is not discrimination against enrollees because of their age, disability, or expected length of life. The Final 2015 EHB rule addressed possible discriminatory benefit designs in outpatient prescription drug coverage, specifically cautioning against benefit designs that might discourage the enrollment of people with chronic health conditions. Examples included not covering single-tablet or extended release prescription drugs that are commonly prescribed and are as effective as multitablet drug regimens without an appropriate reason for refusal, and placing most or all drugs that treat a specific condition on the highest cost tiers without a nondiscriminatory reason for this benefit design. A nondiscriminatory reason for placing most or all drugs that treat a specific condition on the highest cost tiers is if all of the drugs are high cost. In comparison, AB 339 requires plans and policies not place most or all drugs that treat a specific condition on the highest cost tier, regardless of cost.

A Report to the California State Legislature

Analysis of California Assembly Bill AB 339 Outpatient Prescription Drugs

May 19, 2015

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ABOUT CHBRP

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

An analytic staff in the University of California's Office of the President supports a task force of faculty and research staff from several campuses of the University of California to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact, and content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, as well as all CHBRP reports and publications are available at www.chbrp.org.

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POLICY CONTEXT

The California Assembly Committee on Health has requested² that the California Health Benefits Review Program (CHBRP)³ conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 339, which was amended on April 7, 2015.⁴

If enacted, AB 339 would affect the health insurance of approximately 17.1 million enrollees (45% of all Californians). This represents 70% of the 24.6 million Californians who will have health insurance regulated by the state⁵ that may be subject to any state health benefit mandate law or law affecting the terms and conditions of coverage.^{6,7} Specifically, Department of Managed Health Care (DMHC)-regulated plans and/or California Department of Insurance (CDI)-regulated policies, exempting Medi-Cal managed care plans and plans and policies that do not provide outpatient prescription drug coverage, would be subject to AB 339.

Bill-Specific Analysis of AB 339, Outpatient Prescription Drugs

Bill Language

AB 339 would:

- Require a plan contract or policy to use specified definitions for each tier of a drug formulary as outlined in AB 339's body of text. Plans may not place prescription drugs on formulary tiers based solely on the cost of the prescription drug, but rather based on clinical indication and reasonable medical management practices.
 - Tier 1 – preferred generic and preferred brand if the cost is comparable to those for generic drugs.
 - Tier 2 – nonpreferred generic and preferred brand and any other drugs recommended by the health insurer's pharmaceutical and therapeutics committee.
 - Tier 3 – nonpreferred brand recommended by the health insurer's pharmaceutical and therapeutics committee.
 - Tier 4 – biologics required to be distributed through a specialty pharmacy or that the insured have special training for self-administration or special monitoring. May include prescription

² April 16, 2015, available at: www.chbrp.org/.

³ CHBRP is authorized to review legislation affecting health insurance regulated by the state. CHBRP's authorizing statute is available at www.chbrp.org/docs/authorizing_statute.pdf.

⁴ This was the second request from the Assembly Committee on Health related to AB 339. The first request was on February 17, 2015 for the earlier introduced version of this bill.

⁵ State benefit mandates apply to a subset of health insurance in California, those regulated by one of California's two health insurance regulators: the California Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI).

⁶ CHBRP's estimates of the source of health insurance available at: www.chbrp.org/other_publications/index.php.

⁷ Of the rest of the state's population, a portion will be uninsured (and therefore will have no health insurance subject to any benefit mandate), and another portion will have health insurance subject to other state laws or only to federal laws.

drugs that cost more than Medicare part D threshold⁸ if recommended based on safety and efficacy but not solely on the cost.

- Plans would not be required to have fourth tier, but if a health plan does include a fourth tier it shall comply with the above definitions.

The full text of AB 339 can be found in Appendix A.

Analytic Approach

AB 339 broadly targets pharmacy benefit administration through its requirements that affect coverage of outpatient prescription drugs, structure of formularies, and definitions used to establish tiers. Because of the breadth of this bill, it would require an analysis that forecasts how carriers might respond and anticipates all relevant coverage scenarios, examining the restructuring of entire formularies. In CHBRP's survey of carriers, each carrier independently stated that that carrier was unable to determine how AB 339 would be implemented because of its complexity.

AB 339 could affect coverage for numerous outpatient prescription drugs that treat many conditions. It is not feasible for CHBRP to review the medical effectiveness of and to estimate the benefit coverage, utilization, and cost impacts and the public health impacts of all of these prescription drugs and the conditions they treat within the time frame allotted for this analysis. Furthermore, there were a number of identified ambiguities that make it impossible to conduct a full analysis of impact (see *AB 339 Impacts on Benefit Coverage, Utilization, and Cost, 2015* for list).

Therefore, CHBRP's AB 339 analysis provides:

- Quantitative assessment of the bill mandate that requires copayments, coinsurance, and other cost sharing for these drugs to be *reasonable, and requires that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription not exceed 1/24 of the annual out-of-pocket limit applicable to individual coverage for a supply of up to 30 days, which translates into \$260 for an individual prescription.*⁹
- Qualitative (case-study) approach to highlight the issues around current coverage of prescription drugs and placement on formulary tiers for HIV, multiple sclerosis, and hepatitis C, three conditions identified by content expert as those typically on the highest formulary tiers.

As such, this approach provides examples of the potential impact AB 339 could have in the health insurance market, but does not offer the full scope of the benefit coverage, utilization, and cost impacts of AB 339 were it to be enacted.

⁸ Medicare Part D Cost Threshold and Cost Limit amounts for 2015 are \$320 and \$6,600. The Cost Threshold is a federally defined amount of gross covered retiree plan-related prescription drug costs paid by a qualified retiree prescription drug plan and/or by Qualifying Covered Retirees. The amount up to the Cost Threshold is not eligible for subsidy. It is adjusted in the same manner as the annual Medicare Part D deductible and the annual Medicare Part D out-of-pocket threshold and is adjusted annually as defined in 42 C.F.R. §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. The Medicare Part D Cost Limit is a federally defined amount of gross covered retiree plan-related prescription drug costs paid by a qualified retiree prescription drug plan and/or by Qualifying Covered Retirees. The amount exceeding the Cost Limit is not eligible for subsidy. It is adjusted in the same manner as the annual Medicare Part D deductible and the annual Medicare Part D out-of-pocket limit and is adjusted annually as defined in 42 C.F.R. §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively.

⁹ While the federal government has set a higher allowable maximum out of pocket threshold, which would equate to \$275 (in 2015) using the 1/24 limit, California has not elected to do so.

Interaction with Existing Requirements

State Requirements

California law and regulations

CDI limits expenses paid by the insured, requiring all policies to be economically sound,¹⁰ and requires that individual policies provide “real economic value” to the insured.¹¹ Further, CDI requires the coverage of all medically necessary prescription drugs (as previously discussed).

DMHC-regulated plans are subject to statutory and regulatory requirements regarding coverage of outpatient prescription drugs.¹² DMHC-regulated plans are required to:

- Cover medically necessary prescription drugs, and to ensure access to these medically necessary prescription drugs by establishing reasonable cost sharing.
- Set limits and exclusions on outpatient prescription drug coverage that is consistent with current evidence-based outcomes and peer-reviewed medical and pharmaceutical literature.

In addition, when reviewing cost sharing on outpatient prescription drugs, DMHC will base approval or disapproval of proposed cost-sharing structures on the availability of therapeutic equivalents and the effect on affordability and access of coverage, among other factors. It is important to note that California’s essential health benefits (EHBs) in compliance with the Affordable Care Act (discussed further below), are based on a DMHC-regulated plan. Therefore, nongrandfathered small-group and individual market CDI-regulated policies that are required to cover EHBs are also subject to these DMHC-regulated requirements on outpatient prescription drug coverage.

Independent Medical Review

Plans and policies are subject to the IMR process for covered benefits. CHBRP examined IMRs since 2013 in the category of pharmacy/prescription drugs for both DMHC and CDI.

- In the DMHC IMR process, there were 445 complaints related to pharmacy/prescription drugs, of which 372 were related to medical necessity. Of those, in 245 reviews, the health plan decision was upheld and in 127, the health plan decision was overturned.¹³
- In the CDI IMR process¹⁴, there were 134 complaints related to pharmacy/prescription drugs, of which 110 were related to medical necessity. Of those, in 43 reviews the insurer decision was upheld, in 61 reviews it was overturned, in one review the decision was partially overturned, and in five cases the insured withdrew the request for IMR.

¹⁰ IC Section 10291.5(a)(1).

¹¹ IC Section 10291.5(b)(7)(A) and 10270.95.

¹² H&SC Sections 1342.7 and 1367; California Code of Regulations Section 1300.67.24.

¹³ IMR Statistics for DMHC, available at:

www.dmhc.ca.gov/FileaComplaint/IndependentMedicalReviewandComplaintReports.aspx#.VRzwb-He-4q. Accessed on March 12, 2015.

¹⁴ IMR statistics for CDI, available at: https://interactive.web.insurance.ca.gov/IMR/faces/caseResultSet?_adf.ctrl-state=6mcmbyb4nn_4. Accessed on March 12, 2015.

Covered California

The Board of Covered California has voted to make adjustments to the prescription drug coverage benefit within the health insurance marketplace in 2016, including establishing requirements for access to chronic care drugs across tiers. In 2016, qualified health plans (QHPs)¹⁵ sold in Covered California will have to meet the following requirement:

- If a drug would otherwise qualify for placement on tier 4 and at least three treatment options are available for that particular condition as determined by either a plan's pharmaceutical and therapeutics (P&T) committee or indicated by the Food and Drug Administration (FDA) or according to applicable treatment guidelines for that condition, at least one drug for that condition must be placed on either prescription drug tier 1, 2, or 3.¹⁶

Similar requirements in other states

No state appears to have introduced legislation that closely mirrors AB 339. In Mississippi, a 2015 bill was introduced that aimed to limit cost sharing for specialty prescription drugs, identifying as the impetus for the bill enrollees with conditions such as multiple sclerosis and hepatitis C who were facing large out-of-pocket costs for the specialty prescription drugs needed for treatment.¹⁷ In West Virginia, a bill aims to define specialty prescription drugs.¹⁸ The West Virginia bill would define specialty prescription drugs as “a prescription drug requiring special handling, special administration, unique inventory management, a high level of patient monitoring, or more intense patient support than conventional drug therapies.” Cost of the prescription drug is not included as a factor in the definition.

Federal Requirements

Affordable Care Act

The Affordable Care Act (ACA) requires nongrandfathered plans and policies in the small-group and individual market to cover EHBs, which are made up of ten coverage categories.¹⁹ One of the EHB coverage categories is prescription drugs.

The state may require QHPs sold in Covered California to offer benefits that exceed EHBs.²⁰ However, if the state chooses to do this it must make payments to defray the cost of the additionally mandated benefits, either by paying the purchaser directly or by paying the QHP.²¹

¹⁵ In California, QHPs are nongrandfathered small-group and individual market DMHC-regulated plans and CDI-regulated policies sold in Covered California, the state's health insurance marketplace.

¹⁶ Covered California Board Meeting March 5, 2015, Covered California Policy and Actions Items, available at: http://board.coveredca.com/meetings/2015/3-15/PPT%20-Covered%20California%20Policy%20and%20Action%20Items_March%205,%202015.pdf.

¹⁷ Mississippi House Bill 90, available at: <https://legiscan.com/MS/text/HB90/2015>. This bill is no longer active in the Mississippi Legislature, having died in the Legislative Insurance Committee.

¹⁸ West Virginia Senate Bill 16, available at: www.legis.state.wv.us/Bill_Text_HTML/2015_SESSIONS/RS/bills/sb16%20intr.pdf. As of May 4, 2015, the bill was still active.

¹⁹ For more information on essential health benefits, including how they have been defined in California, see CHBRP's brief, *California's State Benefit Mandates and the Affordable Care Act's "Essential Health Benefits,"* available at: www.chbrp.org/other_publications/index.php.

²⁰ ACA Section 1311(d)(3).

AB 339 and EHBs

Exceeding EHBs: Requirements that would be mandated by AB 339 appear not to exceed EHBs, and therefore would not trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in QHPs in Covered California.

EHB Discriminatory Coverage Requirements: A requirement of EHB coverage is that benefits are designed to ensure there is not discrimination against enrollees because of their age, disability, or expected length of life.²² The Final 2015 EHB rule addressed possible discriminatory benefit designs in outpatient prescription drug coverage, specifically cautioning against benefit designs that might discourage the enrollment of people with chronic health conditions.²³ Examples included not covering single-tablet or extended release prescription drugs that are commonly prescribed and are as effective as multitablet drug regimens without an appropriate reason for refusal, and placing most or all drugs that treat a specific condition on the highest cost tiers without a nondiscriminatory reason for this benefit design. A nondiscriminatory reason for placing most or all drugs that treat a specific condition on the highest cost tiers is if all of the drugs are high cost. In comparison, AB 339 requires that plans and policies not place most or all drugs that treat a specific condition on the highest cost tier, regardless of cost.

²¹ As laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the a state's EHBs and there would be no requirement that the state defray the costs of those state mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost. Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

²² ACA Section 1302(b)(4).

²³ HHS Notice of Benefit and Payment Parameters for 2016. Final Rule. Federal Register, Vol. 80, No. 39. February 27, 2015. Available at: www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf.

BACKGROUND ON COST SHARING FOR OUTPATIENT PRESCRIPTION DRUGS

Outpatient Prescription Drugs

Prescription drug benefits are a specific type of covered benefit usually subject to cost sharing. Outpatient prescription drug coverage can fall within the medical benefit, for example when a medication is administered by an infusion at a medical setting and/or a designated outpatient prescription drug benefit under a separate pharmacy benefit. The designs are complex and vary widely within and between plans and policies. AB 339 specifies coverage and/or cost sharing requirements for outpatient prescription drugs in regards to the following specific types of drugs, which are discussed in more detail below: therapeutically equivalent drugs, single tablet and multiple tablet drug regimens, extended release and nonextended release drugs, drugs placed on the highest cost-sharing tiers, and specialty prescription drugs.

Prescription Drug Types Relevant to AB 339

Therapeutic equivalents

Therapeutic equivalent has two different meanings depending on the context. In the context of pharmacy benefit design, therapeutic equivalence generally denotes a drug that has essentially the same clinical response as one or more other drugs.²⁴ In this definition, a drug that is a therapeutic equivalent may or may not be chemically equivalent, bioequivalent, or generically equivalent. In the FDA's Orange Book²⁵, drug products are considered to be therapeutically equivalent "only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling" (FDA, 2015). For therapeutic equivalent prescription drugs, the federal Food and Drug Administration (FDA) definition is used in this analysis.

Single and multiple tablet regimens

Single-tablet regimens typically refer to fixed-dose pills that combine multiple drugs from the same or different drug classes into a single tablet (FDA, 2011). This is in contrast to multiple tablet regimens where prescribed medications to treat a condition are taken as separate tablets (Sax et al., 2012). This is primarily seen in chronic conditions requiring multiple pills each day. The advantages of the single-tablet combination drug regimen are that taking one single daily pill simplifies treatment, cuts down on errors, and leads to better adherence with the treatment regimen (Sax et al., 2012).

Extended release and nonextended release drugs

The typical mechanism for the release of active ingredients in regular medications (i.e., nonextended release medications) is that the effect takes hold within 15 to 30 minutes of when they are ingested (Schoenwald, 2000). Some types of medications are prescribed to be taken three or four times a day. For these types of medications, there also may be an extended release equivalent drug in which medications are released over a much longer period of time and are usually taken only once or twice a day

²⁴ An example of this usage can be found at: https://www.pbplus.com/docs/Pharmacy_Benefit_Design.pdf.

²⁵ The FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations is commonly known as "The Orange Book", found at: <http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm>.

(Schoenwald, 2000). The advantages of extended release medications are a more stable level of medications in the body over the course of a day and a higher adherence rate (Wen and Park, 2011). The main disadvantage of extended release drugs is that missing a single dose means that the patient missed a whole day of medication as opposed to one-third or one-fourth of their daily medications.

Specialty prescription drugs

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

Cost Sharing for Outpatient Prescription Drugs in California

Payment for covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Specifically, the patient cost-share is the portion that enrollees are responsible for paying out of pocket directly to the provider for the health care service or treatment (including prescription drugs) covered by the plan or policy. Noncovered services or treatments are always paid in full by the enrollee, heretofore referred to as "noncovered expenses." Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium payments). CHBRP refers to these as enrollee out-of-pocket expenses.²⁶ Health plans and insurers use many different combinations of cost-sharing mechanisms to help assure medically necessary treatment and control costs.

Common Cost-Sharing Mechanisms

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

Step 1: Deductibles

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

Step 2: Copayments and/or coinsurance

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

²⁶ See CHBRP's Glossary of Key Terms available at: www.chbrp.org/analysis_methodology/glossary_key_terms.php.

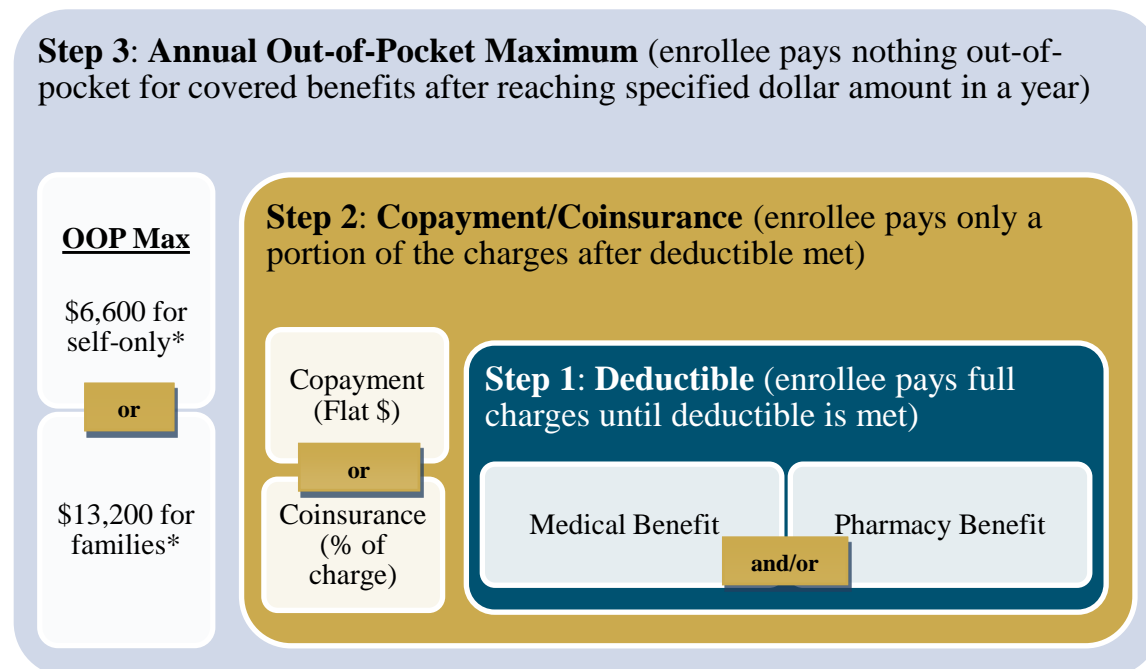
- **Copayment** is a form of cost sharing in which an enrollee pays a predetermined, flat dollar amount out of pocket at the time of receiving a health care service or when paying for a prescription, such as a \$5 copayment for a generic prescription drug. Copayments can vary across covered benefits, and a plan or policy may not require any copayments or may only require copayments for some covered benefits.
- **Coinsurance** is the percentage of covered health care costs for which an enrollee is responsible, such as 25% of a hospitalization charge. As with copayments, coinsurance percentages can vary across covered benefits, and a plan or policy may not require any coinsurance or may only require coinsurance for some covered benefits.

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

Step 3: Annual out-of-pocket maximums

Annual out-of-pocket maximums are limits on the enrollee’s cost-sharing (copayments, coinsurance, and deductibles) obligations in a 1-year period. After the amount an enrollee has paid for copayments, coinsurance, and deductibles reaches this limit, insurance pays 100% of the cost of covered care. Health care services that are not covered by the health plan or insurer would not be included in the maximum; enrollees are responsible for the full charges associated with noncovered services.

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



Source: California Health Benefits Review Program, 2014.

Note: * The annual out-of-pocket amounts in this figure are the maximum amounts allowed in 2014 (and still used in California in 2015); some plans and policies may have lower annual out-of-pocket maximums. The figure assumes that the enrollee is in a plan with a deductible. If no deductible, then enrollee pays a coinsurance and/or a copayment beginning with the first dollar spent (Step 2).

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

Cost Sharing and Outpatient Prescription Drug Benefits

Prescription drug benefits are a specific type of covered benefit usually subject to cost sharing. Outpatient prescription drug coverage can fall within the medical benefit and/or a designated outpatient prescription drug benefit. The designs are complex and vary widely within and between plans and policies. For example, a drug benefit design may require coinsurance on a prescription drug, but cap the amount paid per 30- or 90-day supply. A health plan or insurer may have lower cost-sharing rates for prescriptions filled at a mail-order pharmacy service instead of a retail pharmacy, or at preferred versus nonpreferred pharmacies. Self-administered injectable drugs may be covered under the medical benefit by some health plans or insurers, and the prescription drug benefit by others. In addition, a health plan or insurer may require copayments for generic or preferred drugs and coinsurance on nonpreferred or specialty drugs (see discussion of prescription drug tiers below).

Outpatient prescription drug tier structures

In general, outpatient prescription drug benefit designs can be characterized by the number of tiers into which the drugs are divided, each tier having a distinct cost-sharing level. The prescription drugs in the lower tiers are less costly to both the enrollee and to the health plan or insurer. Some health plans or insurers use a four-tier system that generally includes life-style drugs (e.g., infertility, erectile dysfunction, weight loss) and specialty drugs (in the fourth tier); typically, these are the most costly drugs. The four-tier design frequently results in greater enrollee out-of-pocket expenses, thus this discussion is particularly relevant to the analysis of AB 339, which would limit cost sharing to no more than 1/24 of the annual out-of-pocket maximum (\$260).

- One-tier designs have the same cost sharing regardless of drug type.
- Two-tier designs generally have one payment for (1) generic²⁷ drugs and another for (2) brand-name drugs.
- Three-tier designs generally have one payment for (1) generics, and two different payments for brand-name drugs, dividing them into (2) preferred,²⁸ with lower cost sharing, and (3) nonpreferred,²⁹ with higher cost sharing.
- Four-tier designs generally have the three tiers above, plus a fourth and/or fifth cost-sharing level for specific drugs, such as “lifestyle” drugs (e.g., infertility, erectile dysfunction, weight loss),

²⁷ A generic drug is no longer covered by patent protection and thus may be produced and/or distributed by multiple drug companies.

²⁸ A preferred drug is one included on a formulary or preferred drug list; for example, a brand-name drug without a generic substitute.

²⁹ A nonpreferred drug is one included on a formulary, but not on the preferred drug list; for example, a brand-name drug with a generic substitute.

and/or specialty drugs, or others for which a plan may want to impose differential cost sharing (CHCF, 2014; KFF/HRET, 2013).

Average copayment/coinsurance by tier level in California

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

Distribution of prescription drugs by tiers in California

As noted previously, a 2011 national survey of commercial and public payers identify high cost as the top defining feature of specialty drugs, and there is no standard industry definition of specialty prescription drugs. Yet, the number and cost of specialty prescription drugs continues to increase and payers are managing these high-cost drugs with different cost-sharing methods. For example, in the aforementioned survey, 49% of plans place specialty drugs in tier 4, and 51% distribute specialty drugs among tiers 2 and 3 depending on their preferred status. About 40% of plans used a coinsurance benefit design rather than copayments. Of the commercial plan respondents, 25% reported an average copayment of \$120, and 72% reported an average coinsurance of 22% for specialty drugs. Specialty drug copayments among all tiers ranged from \$10 to \$250 per prescription, and coinsurance ranged from 10% to 50%. In 2011, 71% of plans with coinsurance had a maximum dollar amount cap on cost sharing for a prescription drug with an average cap of \$218 (EMD Serono, 2012).

Payment for covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium payments). CHBRP refers to these as enrollee out-of-pocket expenses.³⁰ Health plans and insurers use many different combinations of cost-sharing mechanisms to help assure medically necessary treatment and control costs.

Overall, it appears that insured Californians have less exposure to the highest levels of cost sharing for prescription drugs than their counterparts in other states. Table 1 shows the prevalence of different prescription drug benefit structures among employer-sponsored health insurance (ESHI) in California and nationally. The proportion of workers in tier 4 cost-sharing structures has increased in California from 2% in 2005 to 7% in 2013. Nationally, there was a statistically significant increase in the percent of workers shifting to a four-tier structure between 2005 and 2013 (7% to 23%, respectively) (CHCF, 2014).

Table 1. Distribution of the Types of Prescription Drug Benefit Structures for Health Insurance Products in California and Nationally, 2013

Tiered Prescription Drug Design	California	United States
1 Tier	9%	5%

³⁰ See CHBRP's Glossary of Key Terms available at: www.chbrp.org/analysis_methodology/glossary_key_terms.php.

Tiered Prescription Drug Design	California	United States
2 Tier	22%	10%
3 Tier	59%	59%
4 Tier	7%	23%
Other	3%	4%

Source: CHCF, 2014.

MEDICAL EFFECTIVENESS

CHBRP's medical effectiveness analysis for AB 339 focuses on the impact of cost sharing on use of outpatient prescription drugs. CHBRP chose this focus because AB 339 would not increase the number of Californians who have health insurance coverage for prescription drugs in general. Instead, AB 339 would affect the terms and conditions of cost sharing for specific types of prescription drugs.

Research Approach and Methods

CHBRP could find no studies of cost sharing that analyzed cost-sharing provisions as specific as those outlined in AB 339. Instead, CHBRP presents reviews of literature whose findings are relevant to AB 339. For a general overview of the topic, we review studies of the effect of cost sharing on prescription drug use, including specialty drugs. Further searches on single-tablet combination drugs as well as extended release drugs were conducted using the search terms and methodology described in the appendix labeled, Literature Review Method. In addition, a search of the literature for the three case study conditions (hepatitis C, HIV/AIDS, and multiple sclerosis) was conducted with a focus on the impact of cost-sharing on the utilization of medication and any literature describing the relative efficacy of single-tablet combination drugs and extended release drugs.

Studies of the effects of cost sharing on use of health care services were identified through searches of the Cochrane Library, EconLit, Google Scholar, PubMed, and Web of Science. The search was limited to abstracts of peer-reviewed research studies that were published in English, conducted in the United States, and published from 2014 to present. For studies published prior to 2014, CHBRP relied on a literature search conducted in 2014 for its analysis of AB 1917 that also concerned the effects of cost sharing.

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

General Study Findings

Cost Sharing

It is well established in the literature that persons who face higher cost sharing use fewer services than persons with lower cost sharing (CHBRP, 2014). In addition, there is a preponderance of evidence across multiple health conditions that, as cost sharing increases, adherence to drug regimens decreases, with a majority of studies indicating that decreased adherence is associated with worse outcomes (CHBRP, 2014). The results are more mixed for current long-term specialty drug users where cost-sharing increases among some conditions did not seem to influence adherence while others did (Kim et al., 2011). Goldman et al. (2007) found that for every 10% increase in cost sharing, there was a 2% to 6% decrease in utilization. The results are clear for those with chronic conditions that increased cost sharing is associated with decreased adherence and worse health outcomes (Goldman et al., 2007). Similar results were found in a meta-analysis of publicly insured patients (Sinnott et al., 2013).

Cost Sharing and Single-Tablet Combination Drug Regimens

A review article on single-tablet combination drug regimens found that there have been nearly 150 single-tablet combination drugs approved by the FDA (Ugurlu and Ozayden, 2014). Of these, the largest number fall into the category of cardiovascular drugs followed by endocrinological diseases. This review identified seven advantages of single-tablet combination drug regimens: 1) increased patient adherence; 2) simple dosing schedule leading to fewer medication errors; 3) greater efficacy; 4) decreased adverse reactions; 5) inhibition of microbial resistance; and 6) reduced shipping and packaging costs (Ugurlu and Ozayden, 2014). The disadvantages of combination pills include: 1) reduced flexibility in dosing; 2) interactions between the combined medications leading to a destabilization of the pill; and 3) not being able to identify the cause of an adverse patient reaction (Ugurlu and Ozayden, 2014).

Cost-sharing impacts of switching to single-tablet combination drug regimens from multiple tablet regimens depends on the specific type of drugs and condition and the cost-sharing tier each are typically placed. For example, a review of cost sharing for diabetes single-tablet combination drugs found that although the diabetes single-tablet combination drug regimens and multiple tablet regimens were similar in terms of total regimen price, many insurers placed the single-tablet combination drug in a higher tier, thus representing a higher level of cost sharing for the patient (Bell, 2013). The cost is also greatly determined by the degree to which the single-tablet combination drug is a new advance in therapeutic treatment and thus placed in the highest cost tier like the newer hepatitis C drug, Harvoni. In addition, a generic single-tablet combination drug consisting of all generic drugs may actually have lower cost sharing compared to purchasing each included drug individually. It is not possible to state that there is a universal effect of single-tablet combination drugs on cost sharing. In some cases the single tablet is more expensive than the individual tablets and in some cases the copay for the single combination tablet is equal to the copay for each individual tablet, making it a less expensive treatment regimen overall.

Cost Sharing and Adverse Tiering

Effects of cost sharing on use of specialty drugs

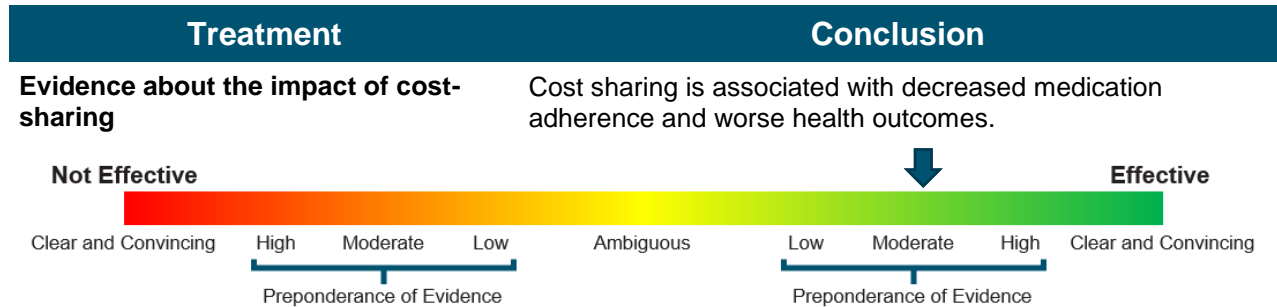
CHBRP identified four studies that examined the effects of cost sharing on use of specialty drugs.

The first of these studies analyzed the association between combination antiretroviral therapy (cART) prescription drug cost sharing and adherence³¹ to initial cART in commercially insured patients with HIV. The authors found that increasing cost sharing (the combination of copayments, coinsurance, and deductibles) was associated with significantly lower odds of reaching the clinically meaningful adherence thresholds (Johnston et al., 2012). Another study looked at cancer treatment among adults with chronic myeloid leukemia who initiated imatinib, a tyrosine kinase inhibitor (TKI). TKIs are considered by some to be the most successful class of targeted therapies developed in cancer for improving survival (Experts in Chronic Myeloid Leukemia, 2013). The authors found that there was a 70% increase in the risk of discontinuing TKIs among patients with higher copayment requirements and patients with higher copayments were 42% more likely to be nonadherent. Another study consistent with these findings also showed that lower cost sharing contributes to a small improvement in quality of life (Ito et al., 2013). Other studies have shown mixed responses to changes in cost sharing. For multiple sclerosis drugs, anti-inflammatory drugs, and cancer drugs, when cost sharing was increased, patients did not show a statistically significant change in adherence compared to patients whose copayments stayed the same. However, there was a small, but statistically significant, decrease in adherence for immunosuppressant

³¹ Persons with a medication ratio above 0.8 are deemed to be adherent to daily drug therapy (e.g., had a sufficient supply of medication dispensed to enable them to take medication on 80% of days in the time period studied).

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

Figure 2. Summary of Evidence About Cost Sharing for Outpatient Prescription Drugs



Source: California Health Benefits Review Program, 2015.

Effect of Cost Sharing Among Low-Income Persons

Prescription drugs

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

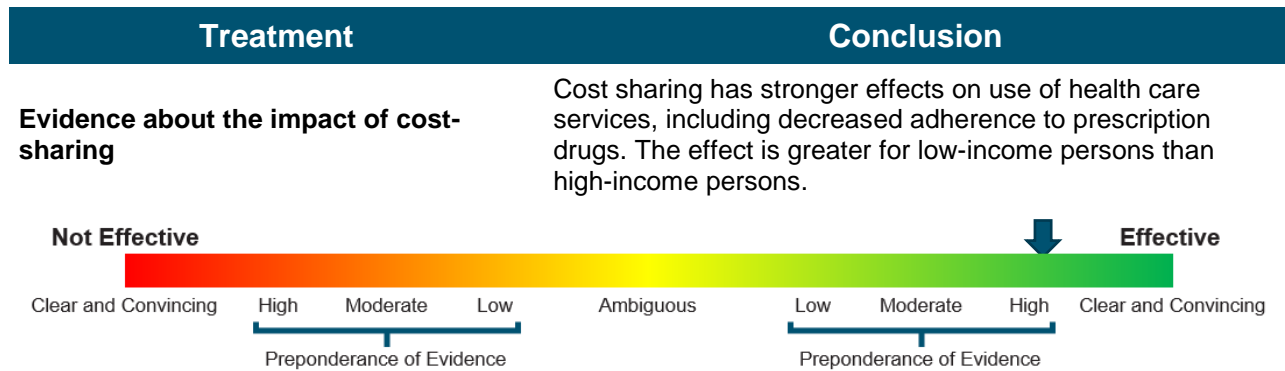
Another study examined the relationship between changes in drug copayments and adherence with medications for the treatment of diabetes mellitus and congestive heart failure (CHF). Patients in low-income areas were more sensitive to copayment changes than patients in high-income areas. The relationship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

All covered benefits

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

A more recent study evaluating the impact of cost sharing after implementation of Massachusetts' health reform found that for all medical services among those eligible for subsidized premiums for private insurance or Medicaid, a 10% increase in prices faced by patients would reduce overall utilization by 1% to 2%. Those who were chronically ill, and especially those with diabetes, high cholesterol, and asthma, showed a lower price elasticity of demand; that is, they were less responsive to increases in cost sharing (Chandra et al., 2014).

Figure 3. Summary of Evidence About Cost Sharing Among Low-Income Persons



Source: California Health Benefits Review Program, 2015.

Summary of Findings

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

Prescription Drug Cost Sharing

- A large number of studies have been published on the effects of cost sharing on the use of prescription drugs by persons with health insurance.
- Studies of the effects of cost sharing on the population to which AB 339 applies indicate:
 - There is a preponderance of evidence from studies with strong research designs that persons who face higher cost sharing for a prescription drug are less likely to maintain meaningful levels of adherence than persons who face lower cost sharing.
 - There is a preponderance of evidence from studies with moderate research designs that poorer adherence to prescription drugs therapy for chronic conditions is associated with higher rates of hospitalization and emergency department visits and poorer health outcomes.
 - There is a preponderance of evidence from studies with moderate research designs that the effect of cost sharing on use of specialty drugs is similar to the effects for all kinds of prescription drugs; that is, as cost sharing increases, usage decreases. However, there is some evidence that the effect of cost sharing may differ depending on the specific disease and specific specialty drug.

Cost Sharing Among Low-Income Persons

- There is a preponderance of evidence from the RAND Health Insurance Experiment that cost sharing has stronger effects on use of health care services by low-income persons than high-income persons.

AB 339 IMPACTS ON BENEFIT COVERAGE, UTILIZATION, AND COST, 2015

AB 339 would impact the terms of coverage of outpatient prescription drugs that treat many conditions through a number of provisions. It was not feasible for CHBRP to estimate the benefit coverage, utilization, and cost impacts of the all the provisions of the bill and for all prescription drugs and the conditions they treat within the 60-day time frame allotted for this analysis.

Cost Approach

Summarized in this section are the specific provisions of AB 339 and the analysis approach taken to address each part of the bill, including ambiguities identified by CHBRP that were determined to preclude conducting a full analysis of AB 339's impact.

Table 2. CHBRP's Analytical Approach to AB 339 Bill Provisions

AB 339 would:	CHBRP Approach
Require a health care service plan contract or a health insurance policy that is offered, renewed, or amended on or after January 1, 2016, and that provides coverage for outpatient prescription drugs, to provide coverage for medically necessary prescription drugs, including those for which there is not a therapeutic equivalent.	CHBRP does not examine the impact of this provision as it is already mandatory under EHB provision of the ACA.
Require copayments, coinsurance, and other cost sharing for outpatient prescription drugs to be reasonable, and would require that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription not exceed 1/24 of the annual out-of-pocket limit applicable to individual coverage for a supply of up to 30 days.	CHBRP examines this provision quantitatively in the Cost Section of this report.
Require a plan contract or policy to cover single-tablet and extended release prescription drug regimens, unless the plan or insurer can demonstrate that multitablet and nonextended release drug regimens, respectively, are more effective, as specified.	<p>CHBRP does not examine this provision due to the following ambiguities:</p> <ul style="list-style-type: none"> • By requiring a carrier to cover single tablet regimens and extended release prescription drugs, carriers lose negotiating power with drug manufacturers to determine cost. It is unknown how much the cost of these regimens will increase. • It is also difficult to quantify the number of people who will be helped by this piece of

AB 339 would:	CHBRP Approach
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Require a plan contract to not place most or all of the prescription medications that treat a specific condition on the highest cost tiers of a formulary unless the health care service plan can demonstrate to the satisfaction of the director that such placement does not reduce the generosity of the benefits for enrollees with a particular condition. In no instance in which there is more than one treatment that is the standard of care for a condition shall most or all prescription medications to treat that condition be placed on the highest cost tiers. This shall not apply to any medication for which there is a therapeutic equivalent available on a lower cost tier.

CHBRP **does not** examine this provision due to the following ambiguities:

- This provision will require some drugs that are currently on the highest cost tiers be moved to other lower cost tiers. What makes this provision difficult to quantify is predicting which drugs will be moved and how this provision interacts with the provision of the bill (below) that defines the formulary tiers.
- It is unclear what “generosity of the benefit” means. A conservative interpretation of this bill is that the actuarial value of coverage for each condition must be the same. Some conditions may require a single generic or preventive drug while others may require a cocktail of expensive brand and specialty drugs. Requiring the “generosity of the benefit” to be the same for these two conditions perhaps requires making the cost sharing the same, however it is unclear how cost sharing might be made equivalent for the conditions.³²

Require for coverage offered in the individual market, that the health care service plan shall demonstrate to the satisfaction of the director that the formulary or formularies maintained for coverage in the individual market are the same or comparable to those maintained for coverage in the group market.

CHBRP **does not** examine this provision due to the following ambiguities:

- It is unclear how markets will react. Given the definition of the formulary in AB 339, covered drugs will be placed on the same cost sharing tiers in individual and group plans. In some cases, plans exist on a

³² The simplest way to not reduce the generosity of benefits would be to eliminate all pharmaceutical cost sharing, which would certainly have a significant impact as there would not be any way to incentivize people to use lower cost drugs and overall drug utilization would increase. With eliminated cost sharing, pharmaceutical companies may increase the cost of each drug.

closed formulary only covering the generic and preferred drugs. If an insurance company is currently offering a closed formulary on the individual market, they will likely offer one on the group market as well to remain in compliance.

Require a plan contract or policy to use specified definitions for each tier of a drug formulary as outlined in AB 339's body of text.

- Tier 1 – preferred generic and preferred brand if the cost is comparable to those for generic drugs
- Tier 2 – nonpreferred generic and preferred brand and any other drugs recommended by the health insurer's pharmaceutical and therapeutics committee
- Tier 3 – nonpreferred brand recommended by the health insurer's pharmaceutical and therapeutics committee
- Tier 4 – biologics required to be distributed through a specialty pharmacy or the insured is to have special training for self-administration or special monitoring. May include prescriptions that cost more than Medicare part D threshold if recommended based on safety and efficacy but not solely on the cost
 - Plans are not required to have 4 tiers

CHBRP **does not** examine this provision due to the following ambiguities:

- It is unclear how each insurance carrier will move drugs in their formularies to be compliant with the new tier definitions in AB 339.
- CHBRP further would not be able to properly assign cost sharing amounts to each of tiers post AB 339 without knowing the definition of "generosity of the benefit" (above). And, without cost sharing information, quantifying the impact of this component of the bill is not possible.
- CHBRP has included in this report three qualitative *Case Studies* that describe the current distribution of prescription drugs for Hep C, HIV/AIDS, and MS by tier based on CHBRP's carrier data.

Thus, the analysis in this section takes two approaches:

- Quantitative assessment of the bill mandate that requires copayments, coinsurance, and other cost sharing for these drugs to be *reasonable, and requires that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription not exceed 1/24 of the annual out-of-pocket limit applicable to individual coverage for a supply of up to 30 days.*
- Qualitative (case-study) approach to highlight the issues around current coverage of prescription drugs and placement on formulary tiers for HIV, multiple sclerosis, and hepatitis C, three conditions identified by content expert as those typically on the highest cost tiers.

As such, this approach provides examples of the potential impact AB 339 could have in the health insurance market, but does not offer the full scope of the benefit coverage, utilization, and cost impacts of AB 339 were it to be enacted. CHBRP arrived at this approach after much discussion and consultation with content experts about the likely response of carriers to the mandates of AB 339 as well as potential consumer behavioral changes due to the changes in prescription drug provisions.

Quantitative Approach of the 1/24 Provision of AB 339

Cost Sharing: AB 339 would impose cost-sharing limits on all outpatient prescription drugs, including generic, brand-name, and specialty drugs. Therefore, CHBRP estimates the impact of this mandate on all outpatient prescription drugs with cost sharing above 1/24 of the annual out-of-pocket maximum for up to a 30-day supply in 2016. However, the prescription drugs most likely affected by this mandate will be the most expensive prescriptions in several classes of specialty and biologic drugs used to treat conditions such as cancer, multiple sclerosis, rheumatoid arthritis, immune disorders, anemia, HIV, and infertility. CHBRP uses available data and literature for these classes of prescription drugs for estimates of the impact of AB 339 on utilization and costs, when appropriate. Table 3 describes the highest costing drugs nationwide by showing utilization, the average charge/price of the drug, and the cost per member per month (PMPM). Sovaldi®, which is used to treat hepatitis C is the most costly drug from the carrier’s perspective, as its PMPM makes up 3.4% of the total PMPM for all drugs. The most recent hepatitis C drugs to come to market, such as Harvoni®, have not yet been added to this data set and thus do not appear in this table. It is important to note that the average charges shown in Table 3 do not reflect the costs incurred to the patient.³³ To illustrate the interaction between the cost of a product and how it affects out-of-pocket costs to the enrollee, an example of the impact of AB 339 on cost sharing for a hypothetical specialty prescription drug that costs \$3,000 for up to a 30-day supply is provided in Table 3.

Table 3. Top 25 High-Cost Drugs in U.S. by Total Expenditure

Top 25 High Cost Specialty Pharmacy ^(a) Drugs Nationally by Total Spend					
Product ^(b) (condition ^(c))	Utilization per 1,000	Average Charge	Cost PMPM	Utilization as a % of All Rx Utilization	PMPM as a % of All Rx PMPM Cost
Sovaldi® (sofosbuvir) (hepatitis C)	1.38	\$32,113.41	\$3.70	0.013%	3.401%
Humira pen® (adalimumab) (inflammatory arthritis)	8.10	4,579.86	3.09	0.079%	2.844%
Enebreel SureClick® (etanercept autoinjector) (inflammatory arthritis)	5.10	4,693.19	2.00	0.050%	1.835%
Atripla® (efavirenz, emtricitabine, and tenofovir) (HIV/AIDS)	4.01	3,500.81	1.17	0.039%	1.077%
Copaxone® (glatiramer acetate) (multiple sclerosis)	1.43	9,798.50	1.17	0.014%	1.074%
Enebreel® (etanercept) (inflammatory arthritis)	2.82	4,537.20	1.07	0.027%	0.981%
glatiramer acetate (generic) (multiple sclerosis)	1.43	8,818.65	1.05	0.014%	0.967%
Rebif® (interferon beta-1a) (multiple sclerosis)	1.24	8,106.16	0.84	0.012%	0.772%
Humira® (adalimumab) (inflammatory arthritis)	1.96	4,841.51	0.79	0.019%	0.727%

³³ As described in Background on Cost Sharing for Outpatient Prescription Drugs, most insurance plans have out-of-pocket maximums, which may be met for example when spending comes from specialty drugs (for which a 20% coinsurance must be paid) or from other medical spending, such as an in-patient stay.

Top 25 High Cost Specialty Pharmacy ^(a) Drugs Nationally by Total Spend					
Gilenya® (fingolimod) (multiple sclerosis)	0.99	9,242.38	0.76	0.010%	0.698%
Avonex® (interferon beta-1a) (multiple sclerosis)	1.11	8,203.74	0.76	0.011%	0.698%
Stelara® (ustekinumab) (psoriasis)	0.58	13,792.11	0.66	0.006%	0.609%
Gleevec® (imatinib) (leukemia)	0.61	13,030.36	0.66	0.006%	0.608%
Truvada® (emtricitabine and tenofovir disoproxil fumarate) (HIV/AIDS)	3.43	2,215.55	0.63	0.033%	0.582%
Norditropin Flexpro® (somatropin injection) (growth hormone deficiency)	1.09	6,754.09	0.61	0.011%	0.564%
Pegasys® (peginterferon alfa-2a) (hepatitis B & C)	1.84	3,957.59	0.61	0.018%	0.559%
Pegasys ProClick TM (peginterferon alfa-2a autoinjector) (hepatitis B & C)	1.82	3,892.47	0.59	0.018%	0.542%
Avonex Pen® (interferon beta-1a injection) (multiple sclerosis)	0.73	8,445.23	0.52	0.007%	0.474%
Betaseron® (interferon beta-1b) (multiple sclerosis)	0.79	7,836.19	0.51	0.008%	0.473%
Revlimid® (lenalidomide) (anemia caused by myelodysplastic syndrome and cancer of the blood)	0.51	11,985.32	0.51	0.005%	0.467%
Follistim AQ® (follitropin beta injection) (infertility)	1.59	3,689.91	0.49	0.016%	0.451%
Xolair® (omalizumab) (asthma)	1.10	4,298.89	0.39	0.011%	0.362%
Acthar HP® (repository corticotropin injection) (multiple sclerosis)	0.07	59,367.13	0.37	0.001%	0.337%
Remicade® (infliximab) (inflammatory arthritis)	0.61	6,368.04	0.32	0.006%	0.296%
Advate® (recombinant antihemophilic factor) (hemophilia)	0.10	39,075.72	0.32	0.001%	0.294%

Source: Milliman 2015 Commercial Health Cost Guidelines

Notes: This information is intended to provide users with additional pharmacy cost detail to assist in developing more specific claim cost targets. It reflects historical drug data adjusted for brand drugs expected to lose patent during or before 2015, and projected to July 1, 2015.

(a) Reflects a cross-section of commonly listed specialty pharmacy products. Specialty pharmacy programs do not consistently use the same list of products.

(b) Lowercase text denotes generic product.

(c) Most common condition for which drug is used to treat/manage

Table 4. Example of the Impact of AB 339 on Cost Sharing for a Hypothetical Specialty Prescription Drug that Costs \$3,000 for up to a 30-Day Supply

Plan ^a (Individual) Medical Deductible	Coinsurance on Specialty Drug	Self-Only Annual OOP Maximum	Cost Sharing Premandate	Cost Sharing Postmandate	Cost Sharing Change After Mandate
\$2,000	20%	\$6,250	<u>With medical deductible 100% unmet</u> \$2,000 deductible + 20% of remaining balance of \$1,000 = \$2,200 enrollee pays out of pocket	<u>With medical deductible 100% unmet</u> 1/24 of annual OOP limit of \$6,250 = \$260 enrollee pays out of pocket	Enrollee pays \$1,940 less
			After medical deductible met 20% of \$3,000 = \$600 enrollee pays out of pocket	After medical deductible met 1/24 of annual OOP limit of \$6,250 = \$260 enrollee pays out of pocket	Enrollee pays \$340 less
			After annual OOP maximum met	After annual OOP maximum met	No change
			\$0	\$0	

Source: California Health Benefits Review Program.

Note: (a) The plan used in this example is based on the standard benefit designs of a silver-level Covered California plan. This is just an example; there is broad range of plan and policy designs that would have varying levels of coinsurance charged for a specialty prescription drug. This example assumes a specialty drug administered in an outpatient setting that is subject to coinsurance separate from the cost sharing required for the office, clinic, or other outpatient setting visit. Some plans and policies require additional cost sharing on specialty drugs administered in an outpatient setting and others do not.

Key: OOP = out-of-pocket

The medications most likely to have the highest out-of-pocket maximums and thus exceed the 1/24 limit mandated by AB 339 are those presented in Table 3 above. In 2013, AB 219 passed, limiting cost sharing for prescribed, orally administered anticancer medications to no more than \$200 for a single prescription for up to a 30-day supply. This is a lower cost-sharing level than 1/24 of the annual out-of-pocket maximum (\$260) for a 30-day supply. Therefore, the cost impact of AB 339 excludes these anticancer medications.

Estimating the Annual Maximum Dollar Amount: In a previous analysis of a similar bill (AB 1917 in 2014), CHBRP assumed carriers changed their plans to the federal maximum allowed out of pocket (which was \$6,350 in 2014). However, in 2015 Covered California plans (bronze, silver, gold) have kept their maximums at \$6,250. Therefore, for this analysis of the 1/24 maximum dollar amount provision of AB 339, the 2015 out-of-pocket maximum is calculated to be $\$6,250/24 = \260.42 for bronze, silver, and gold plans, and, for platinum plans, which have an out-of-pocket maximum of \$4,000, the 1/24 maximum dollar amount is \$166.67. CHBRP assumes the same out-of-pocket levels as 2015 plans because it is not expected that carriers will be making changes to their plan designs in 2016.

Cost-sharing reductions: Enrollees eligible for cost-sharing reductions under the ACA are enrollees with incomes between 100% and 250% of the federal poverty level (FPL) who enroll in a silver--level³⁴ QHP in Covered California.³⁵ These products have reduced cost sharing, including a lower annual out-of-pocket maximum. This report refers to these products as “CSRs” (cost-sharing reduction products). Enrollees in CSRs are excluded from the analysis of AB 339’s 1/24 maximum dollar amount.

Cost Approach Assumptions

The cost impact of the 1/24 provision of AB 339 is based on the following key assumptions:

- **Independence from the other AB 339 provisions:** This analysis ignores all other proposed provisions in AB 339. If this bill is passed, these other provisions will impact the tier classification and cost sharing of the drugs included in this analysis. Thus, the quantitative analysis assumes there are no other changes in benefit design other than cost sharing for an outpatient prescription drug cannot exceed 1/24 of the annual out-of-pocket maximum for a single prescription for a supply of up to 30 days, or that cost sharing per month for all covered benefits cannot exceed 1/24 of the annual out-of-pocket maximum. For plans where drugs are subject to a deductible, this analysis assumes that the maximum allowed amount of member cost share was applied to the deductible instead of the full cost of the drug. Alternative compliance approaches would lead to different impacts.
- **Impact on HDHPs:** In order for high-deductible health plans (HDHPs) to maintain their HSA-qualified status³⁶, all items must be subject to deductible. This bill does not make an exception for

³⁴ Section 1302(d) of the ACA requires coverage within specified levels of coverage, or “precious metal” levels: bronze, silver, gold, and platinum. These precious metal levels correspond to an actuarial value for the plan or policy based on the cost-sharing features, not the benefits covered. The actuarial levels are as follows: 60% actuarial value for bronze-level plans; 70% actuarial value for silver-level plans; 80% actuarial value for gold-level plans; and 90% actuarial value for platinum-level plans.

³⁵ ACA Section 1402.

³⁶ A Health Savings Account (HSA) personal savings account allows an enrollee pay for medical expenses with tax-free dollars. HSAs are designed to complement HSA-qualified high-deductible health plans (HDHPs). HDHP deductibles and out-of-pocket limits are set by the Internal Revenue Service if health insurers want their HDHPs to be HSA-qualified, meaning enrollees could save money for health expenses in tax-advantaged savings accounts. IRS

HDHPs. By limiting the cost sharing of these drugs, it would cause the plans to lose HDHP status. Once these plans lose HSA-qualified status, members may decide to purchase more generous plans. This analysis did not account for the shift from HDHPs once they lose HSA status.

- **Underlying drug costs:** Currently, high-cost drugs are covered by coinsurance. With patient out-of-pocket costs tied to the cost of the drug, pharmaceutical companies may feel some pressure to keep specialty drug costs down. If cost sharing is switched to a copayment structure, it may remove this downward pressure and increase the overall cost of the drug. This analysis did not account for such an increase in the underlying cost of the drug.
- **The data used to perform this analysis is from 2013 Marketscan.** Claims were trended forward 3 years to a 2016 basis using a 12% pharmacy cost trend and 3.9% cost trend on all other services. There were several high cost drugs released late 2013 and 2014 that are not fully reflected in the baseline data and are not accounted for in this analysis, thus understating the full impact of AB339.
- **Outpatient prescription drugs:** AB 339 would apply to all covered outpatient prescription drugs provided in all outpatient settings, including drugs administered by health professionals that are typically covered under medical benefits rather than outpatient prescription drug pharmacy benefits.
- **Covered California drug utilization data:** No data on outpatient prescription drug utilization is available for enrollees of Covered California plans and policies because these plans and policies were not in existence prior to 2014 and are not reflected in current data available to CHBRP for this analysis. CHBRP assumes that outpatient prescription drug utilization patterns of these enrollees will be similar to other insured populations in 2015.
- **Use of other health services:** A reduction in cost sharing for prescription drugs would lead to fewer enrollees reaching their annual out-of-pocket maximums. These enrollees would continue to have cost sharing for other covered benefits. Increased cost sharing for other covered benefits in general would lead to a decrease in use as explained in the *Medical Effectiveness* section. CHBRP assumes a decline in use of other health services for these enrollees due to the increase in cost sharing. CHBRP assumes a 2.35% reduction in use of other medical services for enrollees who are impacted by AB 339. This estimate is calculated from 2012 MarketScan databases.
- **Maximum dollar amount cap:** CHBRP assumes that 88% of large group plans and policies have a maximum dollar amount cap on cost sharing for a prescription drug that is set lower than \$260 (1/24 of the annual out-of-pocket maximum) for a 30-day supply.³⁷ 12% do not have a per prescription cap on cost sharing and could have cost sharing that would exceed the limit AB 339 would require. In the absence of specific data on plans and policies in the small group and individual markets, CHBRP assumes that these plans and policies do not have a maximum dollar amount cap on cost sharing for a prescription drug.

regulations dictate that HDHP deductibles: For single coverage, cannot be less than \$1,300 (in 2015); For a family, cannot be less than \$2,600 (in 2015), whether paid for a one member in the family or multiple family members.

³⁷ CHBRP bill analysis of AB 1917 (CHBRP, 2014).

Benefit Coverage

Premandate (Baseline) Benefit Coverage

Currently, 17.1 million enrollees (45% of all Californians) are subject to AB 339. This represents 70% of the 23.4 million Californians who will have health insurance regulated by the state³⁸ that may be subject to any state health benefit mandate law or law affecting the terms and conditions of coverage.^{39,40}

For the analysis of the 1/24 provision of AB 1917 in 2014, CHBRP conducted a bill-specific coverage survey of California's seven largest health plans and insurers to assess cost-sharing requirements for outpatient prescription drugs; these responses were used for the analysis of the 1/24 provision of AB 339. Responses to this survey represented 35.74% of enrollees in the privately funded, CDI-regulated market and 73.74% of enrollees in the privately funded, DMHC-regulated market. Combined, responses to this survey represent 65.86% of enrollees in the privately funded market subject to state mandates. In 2015, for the analysis of prescription drug coverage and tier level of drugs for AB 339, CHBRP conducted carrier calls (telephone interviews); carrier membership of the respondents represent 90% of the total market share.

Analysis of the California Employer Benefit Survey⁴¹ indicated that only 0.3% of group plans and policies offered by California employers did not offer prescription drug benefits. However, all group policies offer medical benefits that include some prescription drug coverage, and nongrandfathered small-group and individual market plans and policies are required to provide prescription drug coverage due to the EHB requirements of the ACA. Therefore, CHBRP assumes that all enrollees subject to this mandate have coverage for at least some generic, brand, and specialty outpatient prescription drugs.

Postmandate Benefit Coverage

AB 339 mandates changes in prescription benefit formulary design and does not mandate coverage of specific treatments and services. All enrollees subject to AB 339 have coverage for outpatient prescription drugs, as defined by AB 339, and all have some form of cost sharing for these drugs. The number of enrollees with coverage for outpatient prescription drugs will remain the same postmandate.

Utilization

Premandate (Baseline) Utilization

Based on analysis of 2013 MarketScan databases, CHBRP estimates that 0.8% of enrollees in plans and policies subject to AB 339 have at least one high-cost outpatient prescription drug claim that could have cost sharing greater than 1/24 of the annual out-of-pocket maximum, or \$260⁴², referred to throughout as

³⁸ State benefit mandates apply to a subset of health insurance in California, those regulated by one of California's two health insurance regulators: the DMHC and the CDI.

³⁹ CHBRP's estimates of the source of health insurance available at: www.chbrp.org/other_publications/index.php.

⁴⁰ Of the rest of the state's population, a portion will be uninsured (and therefore will have no health insurance subject to any benefit mandate), and another portion will have health insurance subject to other state laws or only to federal laws.

⁴¹ Funded by California HealthCare Foundation and conducted by NORC.

⁴² The 1/24 maximum dollar amount differs by plan level; it is calculated to be $\$6,250/24 = \260.42 for bronze, silver, and gold plans, and for platinum plans, which have an out-of-pocket maximum of \$4,000, the 1/24th maximum dollar amount is \$166.67

a “qualifying prescription drug.”⁴³ There is an average of 6.5 prescription drug claims per person with one or more such prescriptions that exceed the AB 339 limit on cost sharing. Table 3 shows the top 25 high-cost drugs nationally by total expenditure.

Postmandate Utilization

Postmandate, cost sharing for prescription drugs would be limited to 1/24 of the annual out-of-pocket maximum for up to a 30-day supply of prescription drugs. As discussed above, high-cost and/or specialty drugs are the ones most likely affected by AB 339 because they currently are often subject to high coinsurance levels. These drugs frequently include specialty and biologic drugs and, despite their high cost sharing, their use is relatively inelastic (Goldman et al., 2007). For example, doubling in cost sharing of rheumatoid arthritis drugs would reduce utilization by 21% among privately insured patients. The reduction in utilization is even lower for cancer specialty drugs (1%).

For CalPERS enrollees who are subject to 50% coinsurance for infertility prescription drugs, the price elasticity⁴⁴ is likely to be different. A study of the impact of introducing a 50% coinsurance for in vitro fertilization (IVF) treatment in Germany found a reduction of 36% in use of these drugs (Connolly et al., 2009).

CHBRP uses a price elasticity of 0.1, or an increase of 10% (the midpoint between 21% and 1% identified by Goldman et al., 2007) in use of qualifying prescription drugs for privately insured enrollees. This increase in utilization includes an increase in new enrollees initiating the use of these qualifying prescriptions (5%) and an increase in the number of refills or better adherence (5%).

CHBRP assumes a 2.35% reduction in use of other medical services for enrollees who are impacted by AB 339; a reduction in cost sharing for prescription drugs would lead to fewer enrollees reaching their annual out-of-pocket maximums and thus increased cost sharing for other covered benefits, which impacts use of these services. This estimate is calculated from 2013 MarketScan databases.

Using the elasticities above, CHBRP estimates that postmandate 133,675 enrollees will have a prescription drug claim in a year with cost sharing that would have exceeded 1/24 of the annual out-of-pocket maximum for a 30-day supply premandate. This is an increase of 3,174 enrollees who previously did not use these prescription drugs (increase of 2.43%). Premandate, an estimated 0.76% of enrollees have prescription drug claims exceeding the 1/24 annual out-of-pocket maximum; postmandate, it is estimated to increase by 0.02% such that 0.78% of enrollees postmandate have drug claims exceeding the 1/24 maximum level. In addition, enrollees will refill 0.18 more qualifying prescription drugs (2.75%).

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

The reduction in cost sharing due to AB 339 may lead to increased advertising of pharmaceuticals to induce demand. However, health plans and policies may attempt to exert greater oversight of the utilization of these products and apply more stringent criteria to restrict utilization.

⁴³ Estimate obtained from the analysis by Milliman of the Thomson Reuters' MarketScan databases from 2013 trended forward to a 2016 basis. Prescription drug claims with costs greater than \$1,300 (drug costs associated with cost sharing of \$260, 1/24 of annual out-of-pocket maximum) were identified.

⁴⁴ In this report, price elasticity refers to change in use of prescription drugs or other health care due to an increase/decrease in the cost sharing.

Per-Unit Cost

Premandate (Baseline) and Postmandate Per-Unit Cost

CHBRP estimates that the annual average cost sharing for the enrollee per qualifying prescription drug is \$309. These enrollees also have an annual average cost sharing of \$15.82 for other medical services. These estimates of utilization and costs per claim are based on 2013 MarketScan databases (see **Error! eference source not found.**).

If AB 339 is enacted, the cost sharing amount for up to a 30-day supply of an outpatient prescription drug would be limited to 1/24 of the annual out-of-pocket maximum. CHBRP estimates that the average cost sharing per qualifying prescription drug would decline to \$158 or 49% less than the premandate level. This amount is lower than the limit of \$260 (for bronze, silver, gold plans) because some enrollees would reach their annual out-of-pocket maximum; these enrollees have no cost sharing after reaching their annual out-of-pocket maximum. The average per-claim cost sharing per prescription drugs exceeding the AB 339 limit will decrease from \$309 to \$158 (48.94%). The average annual cost sharing on other services for members impacted by AB339 will increase from \$2278 to \$2610. Many enrollees will still hit their annual out-of-pocket maximums, albeit later in the year.

Premiums and Expenditures

Premandate (Baseline) Premiums and Expenditures

Table 6 summarizes per member per month (PMPM) premiums and expenditures for DMHC-regulated plans and CDI-regulated policies prior to the mandate by market segment. Total premandate annual expenditures are estimated at \$128.4 billion. The total current annual expenditures for all private DMHC-regulated plans is estimated at \$89.3 billion and CDI-regulated policies is estimated at \$15.8 billion. Public expenditures (including CalPERS and Medi-Cal HMO expenditures) are estimated at \$23.3 billion.

Postmandate Expenditures

Changes in total expenditures

AB 339 would increase total net expenditures by \$322,282,000 or 0.2370% for the year following implementation of the 1/24 mandate of AB 339.

AB 339 would reduce cost sharing of enrollees by an estimated \$151 on average per prescription drug for enrollees who have high-cost outpatient prescription drug claims that would exceed 1/24 of annual out-of-pocket maximum. This amount varies with price of a particular drug, as well as the benefit structure of a particular health plan or policy. This change will lead to a reduction of \$65,330,000 (0.42% decline) in enrollee out-of-pocket expenses due to AB 339. This decline in out-of-pocket expenses corresponds to an increase in premiums paid by employers or enrollees purchasing individual market plans or policies.

Postmandate premium expenditures and PMPM amounts per category of payer

Increases in insurance premiums as a result of AB 339 would vary by market segment. Private employer premium increases are expected to increase by 0.28%, and 0.35% for enrollees with group insurance. Enrollees for individually purchased insurance have the highest increases of 0.71%.

Related Considerations for Policymakers

How Lack of Coverage Results in Cost Shifts to Other Payers

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

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

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

Postmandate Administrative Expenses and Other Expenses

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

Compliance with AB 339 would require that plans and insurers modify their product design; adjust their claims processing systems to track enrollees' out-of-pocket expenditure data; change their utilization management practices; disseminate new provider updates; amend policies and procedures; amend provider operations manual; and amend explanations of benefits to enrollees. The costs of these administrative changes would be reflected in the standard administrative cost load associated with premiums.

Summary: In the first 12 months following enactment, CHBRP estimates that high-cost outpatient prescription drugs (i.e., exceeding the AB 339 limit on out-of-pocket expenditures) would be used by

3,174 additional enrollees (a 2.43% increase) who previously did not use these drugs due to the reduction in out-of-pocket expenditures postmandate. CHBRP estimates that with the reduction in cost sharing, AB 339 would increase the use of high-cost prescription drugs and would lead to a small increase in overall expenditures (increase in net expenditures of \$322,282,000 or 0.2370% for the year following implementation of the 1/24 mandate), led by premium increases (which vary by market segment and range from increases of 0.28% to 0.71%).

Table 5. AB 339 Impacts on Benefit Coverage, Utilization, and Cost, 2016

	Premandate	Postmandate	Increase/ Decrease	Change Postmandate
Benefit coverage				
Total enrollees with health insurance subject to state benefit mandates ^(a)	24,557,000	24,557,000	0%	0%
Total enrollees with health insurance subject to AB 339	17,133,000	17,133,000	0%	0%
Total enrollees with health insurance subject to AB 339 enrolled in Covered California CSR products and excluded from the analysis	964,625	964,625	-	0%
Number of enrollees with coverage for the mandated benefit	16,168,375	16,168,375	-	0%
Utilization and cost				
Number of enrollees with prescription drug claims exceeding the AB 339 limit on cost sharing	130,502	133,675	3,174	2%
Percent of enrollees with prescription drug claims exceeding the AB 339 limit on cost sharing	0.76%	0.78%	0.02%	2%
Average number of prescription drug claims exceeding AB 339 limit on cost sharing	6.49	6.66	0.18	3%
Average per-claim cost sharing per prescription drugs exceeding AB 339 limit on cost-sharing	\$309	\$158	(\$151)	-49%
Average annual cost sharing on prescription drugs exceeding AB 339 limit per enrollee impacted by the AB339 limit	\$1,940	\$1,022	(\$917)	-47%
Average annual cost sharing of other medical services per enrollee impacted by the AB 339 limit	\$2,278	\$2,610	\$332	15%
Average annual cost sharing per enrollee impacted by the AB 339 limit	\$4,218	\$3,632	(\$586)	-14%
Expenditures				
<i>Premium expenditures by payer</i>				
Private employers for group insurance	\$58,393,205,000	\$58,555,334,000	\$162,129,000	0.28%
CalPERS HMO	\$4,391,552,000	\$4,400,382,000	\$8,830,000	0.20%

employer expenditures ^(c)				
Medi-Cal Managed Care Plan expenditures	\$17,667,731,000	\$17,667,731,000	\$0	0.00%
Enrollees for individually purchased insurance	\$21,319,735,000	\$21,470,519,000	\$150,784,000	0.71%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care ^(b)	\$18,703,917,000	\$18,769,786,000	\$65,869,000	0.35%
Enrollee expenses				
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$15,510,004,000	\$15,444,674,000	-\$65,330,000	-0.42%
Enrollee expenses for noncovered benefits ^(d)	\$0	\$0	\$0	0.000%
Total expenditures	\$135,986,144,000	\$136,308,426,000	\$322,282,000	0.24%

Source: California Health Benefits Review Program, 2015.

Notes: (a) This population includes persons with privately funded (including Covered California) health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employer-sponsored health insurance.

(b) Of the increase in CalPERS employer expenditures, about 55.4% or \$4,888,000., would be state expenditures for CalPERS members who are state employees, state retirees, or their dependents. This percentage reflects the share of enrollees in CalPERS HMOs as of September 30, 2013. CHBRP assumes the same ratio in 2015.

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

(d) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

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

Table 6. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2016

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) ^(a)			Publicly Funded Plans			Privately Funded Plans (by Market) ^(a)			
	Large Group	Small Group	Individual	CalPERS HMOs ^(b)	MCMC (Under 65) ^(c)	MCMC (65+) ^(d)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates ^(e)	8,651,000	2,094,000	3,757,000	836,000	6,891,000	533,000	534,000	690,000	571,000	24,557,000
Total enrollees in plans/policies subject to AB 339	8,651,000	2,094,000	2,815,211	836,000	-	-	534,000	690,000	548,164	16,168,375
Premium costs										
Average portion of premium paid by employer	\$423.58	\$304.59	\$0.00	\$437.75	\$179.24	\$445.00	\$511.84	\$421.06	\$0.00	\$80,452,488,000
Average portion of premium paid by employee	\$114.05	\$147.22	\$422.03	\$109.44	\$0.76	\$0.00	\$134.80	\$137.71	\$334.65	\$40,023,653,000
Total premium	\$537.63	\$451.81	\$422.03	\$547.19	\$180.00	\$445.00	\$646.64	\$558.76	\$334.65	\$120,476,140,000
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$36.95	\$89.15	\$141.84	\$29.78	\$0.00	\$0.00	\$99.91	\$166.51	\$105.38	\$15,510,004,000
Enrollee expenses for benefits not covered ^(f)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
Total expenditures	\$574.58	\$540.97	\$563.87	\$576.98	\$180.00	\$445.00	\$746.55	\$725.28	\$440.03	\$135,986,144,000

Source: California Health Benefits Review Program, 2015.

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

(b) As of September 30, 2013, 57.5%, or 462,580 CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2015.

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

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

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

(f) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

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

Table 7. Postmandate Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2016

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) ^(a)			Publicly Funded Plans			Privately Funded Plans (by Market) ^(a)			
	Large Group	Small Group	Individual	CalPERS HMOs ^(b)	MCMC (Under 65) ^(c)	MCMC (65+) ^(d)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates ^(e)	8,651,000	2,094,000	3,757,000	836,000	6,891,000	533,000	534,000	690,000	571,000	24,557,000
Total enrollees in plans/policies subject to AB 339	8,651,000	2,094,000	2,815,211	836,000	-	-	534,000	690,000	548,164	16,168,375
Premium costs										
Average portion of premium paid by employer	\$0.39	\$3.36	\$0.00	\$0.88	\$0.00	\$0.00	\$0.44	\$4.10	\$0.00	\$170,959,000
Average portion of premium paid by employee	\$0.11	\$1.62	\$2.80	\$0.22	\$0.00	\$0.00	\$0.11	\$1.34	\$3.61	\$216,653,000
Total premium	\$0.50	\$4.98	\$2.80	\$1.10	\$0.00	\$0.00	\$0.55	\$5.44	\$3.61	\$387,612,000
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	-\$0.08	-\$0.76	-\$0.47	-\$0.53	\$0.00	\$0.00	-\$0.09	-\$0.81	-\$0.55	-\$65,330,000
Enrollee expenses for benefits not covered ^(f)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
Total expenditures	\$0.42	\$4.22	\$2.33	\$0.57	\$0.00	\$0.00	\$0.46	\$4.64	\$3.06	\$322,282,000

Source: California Health Benefits Review Program, 2015.

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

(b) As of September 30, 2013, 57.5%, or 462,580 CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2015.

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

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

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

(f) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

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

CASE STUDIES

Background and Approach

CHBRP's content experts identified conditions that would be illustrative of the potential impact of AB 339 and to highlight examples of conditions where:

- Pharmaceutical drug costs are high, the condition is not curable, thus requiring taking these pharmaceutical drugs for the rest of a person's lifetime, and there is a single tablet combination pill commonly used in treatment — example, HIV/AIDS.
- Pharmaceutical drug costs are high such that drugs are often placed in the highest cost tier, the condition is not curable, thus requiring taking these pharmaceutical drugs for the rest of a person's lifetime, the condition has treatment options in both the medical benefit and the prescription drug benefit — example, multiple sclerosis (MS).
- Pharmaceutical drug costs are high and the condition is curable, thus requiring a short course, but expensive treatment — example, hepatitis C (hep C).

For this analysis, the outpatient prescription formularies for Covered California were used. Small-group formularies outside of Covered California generally align with the formularies of these Covered California plans. First, complete drug lists for the treatment of HIV/AIDS, MS, and hep C were created and then the insurance formularies were examined to determine prescription drug coverage and tiering of the prescription drugs for the identified conditions. The following 4 tiers were used in the analysis for consistency across the formularies:

- Tier 1 – Generic drugs. Tier 1 drugs usually cost the least.
- Tier 2 – Preferred, brand-name drugs. Brand-name drugs cost more than tier 1 drugs.
- Tier 3 – Nonpreferred, brand-name drugs. Brand-name drugs but are “nonpreferred.” Tier 3 drugs cost more than tier 1 and tier 2 drugs.
- Tier 4 – Specialty drugs. The drugs in these tiers are often very high-cost, brand-name drugs.⁴⁵

Case Study 1: HIV/AIDS

Background

HIV/AIDS is a chronic condition currently effecting more than 122,000 Californians.⁴⁶ It disproportionately impacts males more than females and African Americans more than any other racial or ethnic group. The current recommended treatment for patients with HIV/AIDS includes lifelong, daily intake of multiple antiretroviral medications (DHHS, 2014). To reduce the burden on patients and improve compliance, single-tablet combination drugs were developed. There are currently 11 FDA-approved single-tablet combination drugs to treat HIV. Of these, four can be used on their own as a complete treatment regimen

⁴⁵ Typical silver--level plan in Covered California cost-sharing is as follows: \$15 generic drugs; \$50 preferred brand-name drugs; \$70 nonpreferred brand-name drugs; and 20% coinsurance for specialty drugs.

⁴⁶ http://www.cdph.ca.gov/programs/aids/Documents/June_2014_SemiAnnualReport.pdf.

(Atripla®, Complera®, Stribild®, and Triumeq®).⁴⁷ The other seven single-tablet combination drugs still require additional medications to complete the treatment regimen.

A review of the literature found the effectiveness of single-tablet combination drugs to be similar to that of a multitablet regimen in terms of reduction of viral loads and virologic suppression (Jarcho, 2014; Nachega et al., 2014). A 2014 meta analysis of 19 RCTs comparing once-daily and twice daily antiretroviral HIV/AIDS treatment regimens found that once-daily treatment improved adherence rates by 2.55 percentage points (Nachega et al., 2014). Observational studies have also shown increases in adherence among specific populations such as the homeless, Medicaid enrollees, and U.S. Veterans (Jarcho, 2014).

This review identified one extended release drug, Viramune EX®, used to treat HIV. Typical regimens including Viramune® require the patient to take two pills a day whereas Viramune EX® is only required once daily (Bhatti and Gladstein, 2012). The effectiveness of Viramune® and Viramune EX® was reviewed and found to be similar (Bhatti and Gladstein, 2012). In addition, while adherence rates were slightly higher for Viramune EX®, the difference was not statistically significant (Bhatti and Gladstein, 2012). The National Institutes for Health is supporting the development of other forms of HIV/AIDS extended release drugs so that in the future it may be possible to extend the dose to last a week or longer.⁴⁸

Placement of HIV/AIDS Drugs on the Highest Cost Tiers

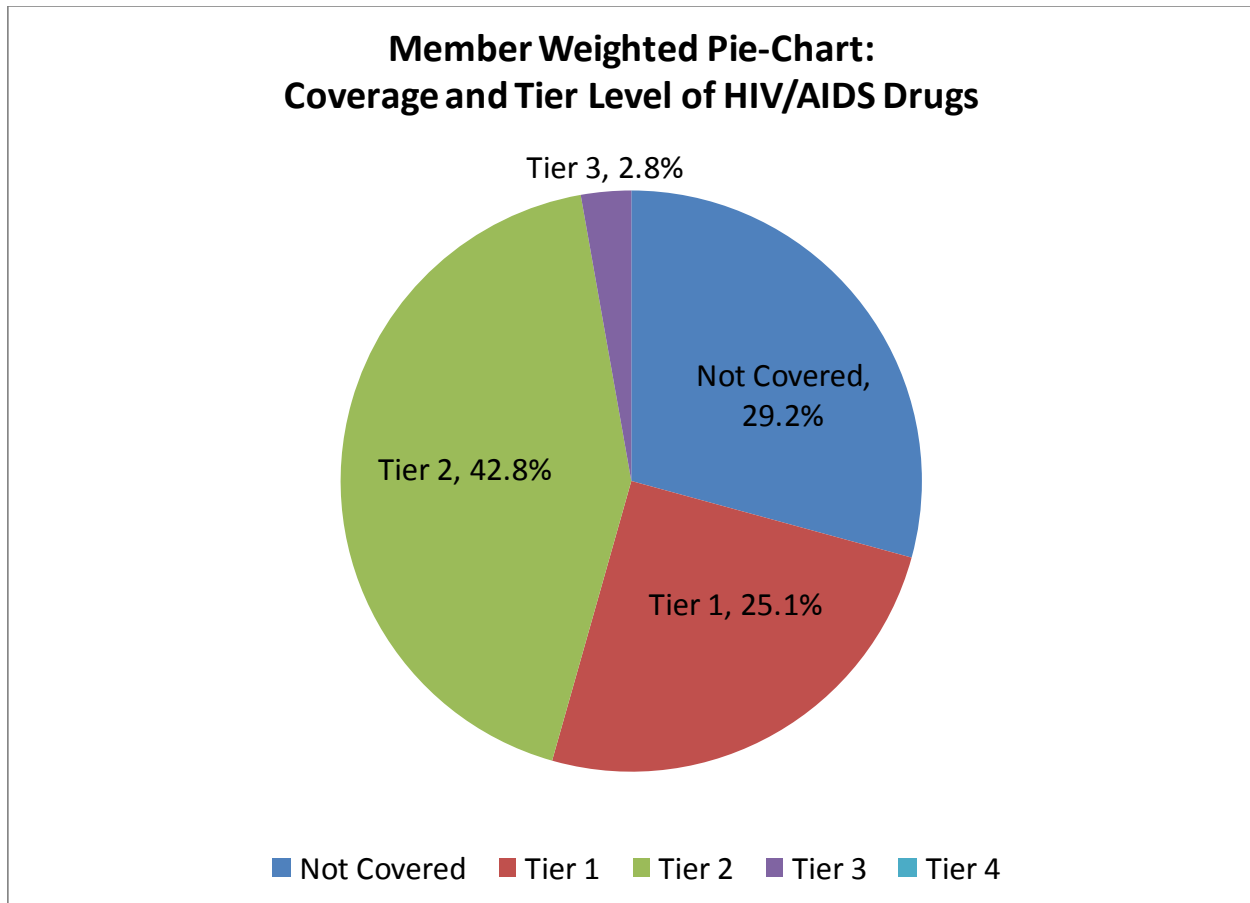
AB 339 requires a plan to not place most or all of the prescription medications that treat a specific condition on the highest cost tiers of a formulary unless the health care service plan can demonstrate to the satisfaction of the director that such placement does not reduce the generosity of the benefits for enrollees with a particular condition. In no instance in which there is more than one treatment that is the standard of care for a condition shall most or all prescription medications to treat that condition be placed on the highest cost tiers. Researchers recently examined whether drugs to treat HIV/AIDS are often placed on the highest cost tiers by insurance carriers in an article published in the New England Journal of Medicine (Jacobs and Sommers, 2015). Jacobs and Sommers (2015) examined this practice in 12 states (Delaware, Florida, Louisiana, Michigan, South Carolina, Utah, Illinois, New Jersey, Ohio, Pennsylvania, Texas, and Virginia) using the federal marketplace, looking specifically at plans with the lowest, second-lowest, median, and highest premiums on the silver level in each state. HIV/AIDS was chosen because it is associated with high insurance costs, requires lifelong treatment, and is treated with an expensive and disease-specific class of medications, specifically nucleoside reverse-transcriptase inhibitors (NRTIs). They found that enrollees in adverse tiered plans (defined adverse tiering as placement of all NRTIs in tiers with a coinsurance or copayment level of at least 30%) had a yearly cost per drug that was almost \$4900, versus about \$1600 in nonadverse tiered plans. About half of the adverse tiered plans had a deductible that was drug specific, compared to fewer than 20% of other plans. This means, someone with HIV/AIDS pays more than \$3,000 a year in an adverse tiered plan versus another plan. Another study by the California Healthcare Foundation examined Covered California exchange plan 2014 formularies and found that tier placement for HIV/AIDS drugs varied across the plans, with a few insurance carriers actually placing all HIV/AIDS drugs (generic and brand) on the specialty tier (CHCF, 2014).

⁴⁷ Data on combination drugs used to treat HIV/AIDS found at: <http://aidsinfo.nih.gov/drugs>

⁴⁸ <http://grants.nih.gov/grants/guide/pa-files/PAR-13-349.html>

CHBRP examined coverage and tier level of all HIV/AIDS prescription drugs among CHBRP’s surveyed carriers⁴⁹ (**Figure 4**). Member-weighted pie charts show the proportion of HIV/AIDS drugs that are not covered, and the tier level for those drugs that are covered (Tier 1, Tier 2, Tier 3, and Tier 4).

Figure 4. Member-Weighted Pie Chart^(a) of Coverage and Tier Level of All HIV/AIDS Drugs



Source: California Health Benefits Review Program, 2015.

Note: (a) A drug is considered “not covered” if it does not appear on the plan’s formulary. Tier information was obtained from each plan’s formulary. Member weights reflect percent of enrollees on each tier, calculated using plan membership data to obtain number of enrollees per plan.

Approximately 30% of HIV/AIDS drugs are not covered. AB 339 requires a plan contract or policy to cover single-tablet and extended-release prescription drug regimens where the multitablet or non–extended-release drugs are currently covered. Examining the CHBRP surveyed formularies, there are single-tablet and extended-release drugs that are currently not covered by plans. Table 8 includes a list of these drugs and the proportion of enrollees in California that currently do not have coverage. Following implementation of AB 339, there will be an increase (CHBRP did not quantify) in the proportion of enrollees who will be offered coverage of single-tablet and extended-release regimens.

⁴⁹ Where information was not submitted to CHBRP by carriers, the carrier’s corresponding Covered California silver-level plan formulary were used to obtain coverage and tier information.

Table 8. Proportion of Enrollees with HIV/AIDS Prescription Drug Coverage that Does Not Currently Include Single-Tablet and Extended-Release Regimens

	% enrollees currently without coverage ^a
Atripla®	35%
Complera®	35%
Stribild®	35%
Triumeq®	92%
Viramune EX®	90%

Source: California Health Benefits Review Program, 2015.

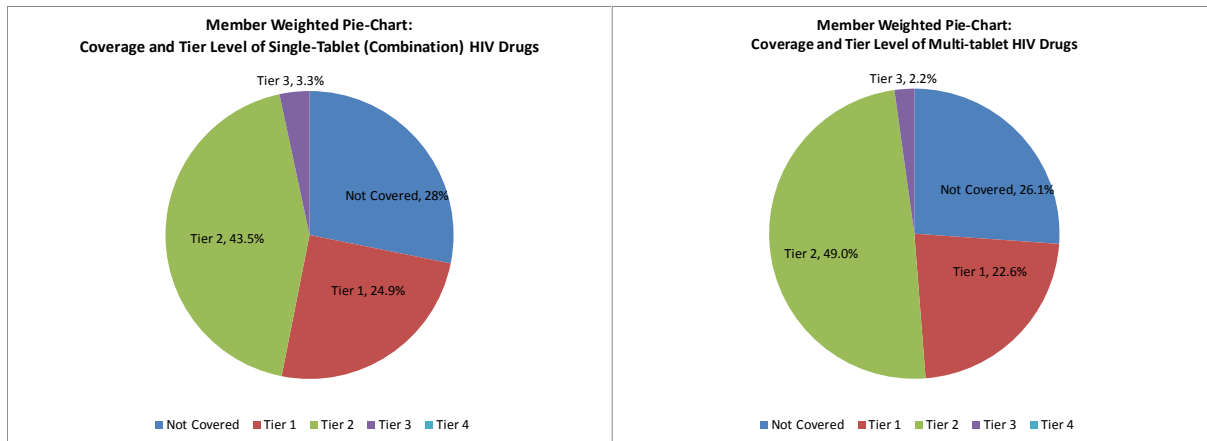
Note: (a) A drug is considered “not covered” if it does not appear on the plan’s formulary. The percent of enrollees without coverage calculated using membership data to obtain number of enrollees per plan.

Per Figure 4, close to 68% of HIV/AIDS drugs are in Tiers 1 and 2. And, none of the examined formularies placed HIV/AIDS prescription drugs on Tier 4, thus none of the HIV/AIDS drugs would require a 20% specialty drug copayment and thus would not be affected by the 1/24 out-of-pocket limit provision of AB 339. Furthermore, because there are no HIV/AIDS drugs that are in Tier 4, AB 339 will unlikely affect the proportion of drugs in the highest-cost tiers, per the AB 339 mandate that a plan to not place most or all of the prescription medications that treat a specific condition on the highest cost tiers of a formulary.

CHBRP further compared coverage and tier level of the single-tablet drugs⁵⁰ to their equally effective multitablet regimens. When this comparison is made, there appears to be only small differences between the tier levels of single-tablet HIV/AIDS drugs compared to the tier levels of drugs that make up a multitablet HIV/AIDS drug regimen (e.g., 2%-3% in tier 3).

⁵⁰ Single-tablet drugs Atripla®, Complera®, Stribild®, and Triumeq® compared to their multitablet regimens.

Figure 5. Member-Weighted Pie Charts^(a) of Coverage and Tier Level of Single-Tablet HIV/AIDS Drugs Versus Multitabilet HIV/AIDS Drugs

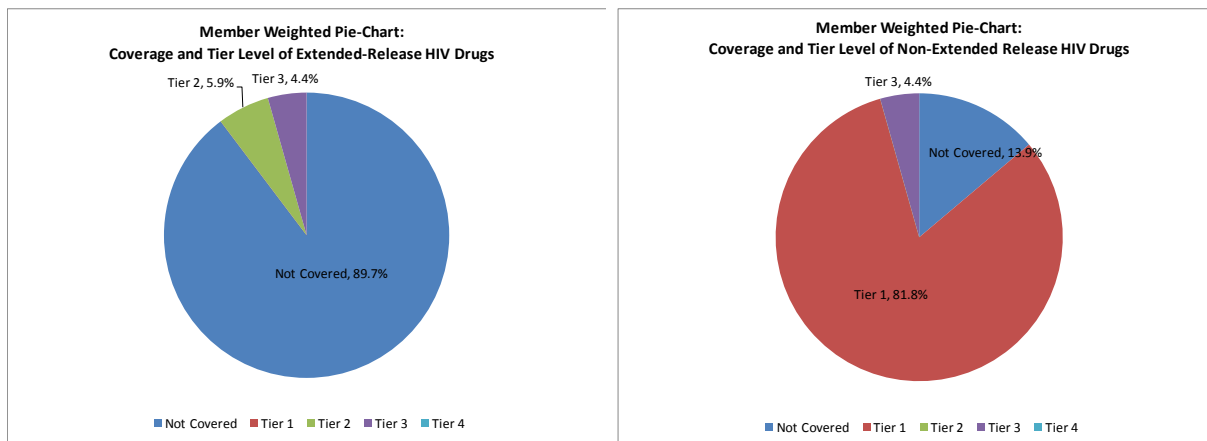


Source: California Health Benefits Review Program, 2015.

Note: (a) A drug is considered “not covered” if it does not appear on the plan’s formulary. Tier information was obtained from each plan’s formulary. Member weights reflect percent of enrollees on each tier, calculated using plan membership data to obtain number of enrollees per plan.

CHBRP similarly examined coverage and tier level of extended release HIV/AIDS compared to the non-extended release HIV/AIDS drugs.⁵¹ In this case, coverage of Virmune XR® (extended release version of Virmune®) was limited (close to 90% of plans did not include Virmune XR® on their formularies) compared to its non-extended-release alternative, which is generally is covered on Tier 1 by most plans.

Figure 6. Member-Weighted Pie Charts^(a) of Coverage and Tier Level of Extended-Release HIV/AIDS Drugs Versus Non-extended-Release HIV/AIDS Drugs



Source: California Health Benefits Review Program, 2015.

Note: (a) A drug is considered “not covered” if it does not appear on the plan’s formulary. Tier information was obtained from each plan’s formulary. Member weights reflect percent of enrollees on each tier, calculated using plan membership data to obtain number of enrollees per plan.

⁵¹ Extended-release Virmune XR® compared to non-extended release Virmune®.

The establishment of cost sharing parity of the regimens is not required by AB 339, but it is a recognized issue CHBRP notes that single tablet and multi-tablet regimens currently do not cost the same (see example in Table 9).

Table 9. Example of Cost-Sharing for a Therapeutically Equivalent HIV/AIDS Drug Regimen^(a)



Sustiva®, Emtriva®, and Viread® ^(b) : Multitabular Drug Regimen	Atripla® ^(b) : Single-Tablet Drug Regimen
3 prescription drugs all covered as preferred brand-name prescription drugs	1 single-tablet prescription drug (combination drug) covered as preferred brand-name prescription drug
Cost sharing for drug regimen: <ul style="list-style-type: none"> • \$50 copayment for preferred brand-name prescription x 3 = \$150 total^(c) 	Cost sharing for drug regimen: <ul style="list-style-type: none"> • \$50 copayment per preferred brand-name prescription = \$50 total^(c)

Source: California Health Benefits Review Program, 2015.

Notes: (a) This table presents only one example. There are many differing examples depending on the prescription drug and a plan's or policy's cost-sharing requirements.

(b) Atripla® is a single-tablet (combination drug) used to treat HIV/AIDS. It is made up of three different drugs – Sustiva®, Emtriva®, and Viread® – that are the multitabular drug regimen of Atripla®.

(c) The cost sharing used in this example for these prescription drugs is based on prescription drug cost sharing for a silver-level plan in Covered California. Cost sharing is as follows: \$15 generic; \$50 preferred brand-name; \$70 nonpreferred brand-name; and 20% coinsurance for specialty drugs.

Implications

Perhaps more than other conditions, HIV/AIDS treatment requires strict adherence as rapid disease progression and survival depend on it. A 95% adherence rate is recommended for antiretroviral therapy (Langness, 2014). Lower compliance can result in development of drug resistance, rapid disease progression, and death, and is a primary cause of treatment failure (DHHS, 2014). Adherence rates can vary with the population of HIV-infected individuals, but on average around 70% seem to be compliant (Machtinger and Bangsberg, 2006).

Single-tablet combination drugs have led to improved adherence for HIV/AIDS treatment (Langness, 2014; Johnson, 2014). This analysis found that there are between 35%-92% of enrollees subject to AB 339 that currently do not have coverage for specific single-tablet combination drugs (Table 8). To the extent that AB 339 increases coverage for these treatments, there is the potential to increase adherence to the HIV/AIDS treatment regimen among persons living with HIV/AIDS in California.

In addition, there is evidence to suggest that there is an inverse relationship between cost-sharing for HIV/AIDS antiretroviral medication and adherence to medication regimen (Johnson et al., 2012). This analysis found that HIV/AIDS single-tablet combination drugs can have lower patient cost-sharing than treatment regimens that include copayments for multiple individual drugs (Table 9). The extent to which AB 339 would impact cost sharing for single-tablet combination drugs, is unknown, but if coverage for

treatments with lower-cost sharing were to increase, there is the potential to increase utilization of these treatments and increase adherence rates to HIV/AIDS treatment regimens.

At least one extended-release formulation has also become available to patients as a more convenient alternative (Bogner, 2012). This analysis found that there are very low coverage rates (10%) for Viramune EX®. The evidence identified in the literature review indicated that there is no statistically significant difference in adherence rates for Viramune and Viramune EX®, therefore it is unlikely that any potential increase in coverage for Viramune EX® as a result of AB 339 would impact overall adherence rates or health outcomes.

Case Study 2: Multiple Sclerosis (MS)

Background

Multiple sclerosis (MS) is a condition of the nervous system, leading to chronic and disabling symptoms such as problems walking, numbness and tingling, fatigue, depression, and muscle spasms (Carroll et al., 2014). Although no registry exists for MS, it is estimated that there are approximately 33,000 Californians living with the disease.⁵² Pharmacological treatments for multiple sclerosis fall into three general categories: (1) Disease Modifying Therapies (DMTs), (2) Relapse Control; and (3) Symptom Treatment. For the purposes of this report, this review will focus on the disease modifying therapies as they most directly bear on primary treatment, and are the most costly. The first MS DMT to be approved by the FDA was Betaseron®, which was approved in 1993. According to the National MS Society (2015), as of January 2015, there were 12 FDA-approved MS DMTs. MS DMTs work by modifying the immune response that occurs in MS (Menge et al., 2008).

Table 10. Administration Route and Dosing Information for 12 FDA-Approved MS DMTs

Drug Name	Year Approved	Administration Route	Dosing
Aubagio®	2012	Pill taken orally	Every day; 7 mg or 14 mg
Avonex®	1996	Intramuscular injection	Once a week; 30 mcg
Betaseron®	1993	Subcutaneous injection	Every other day; 250 mcg
Copaxone®	1996	Subcutaneous injection	Every day; 20 mg (20,000 mcg) OR Three times a week; subcutaneous (under the skin) injection; 40 mg (40,000 mcg)
Extavia®	2009	Subcutaneous injection	Every other day; 250 mcg.
Gilenya®	2010	Capsule taken orally	Every day; 0.5 mg.
Lemtrada™	2014	Intravenous infusion	5 consecutive days, followed by 3 consecutive days one year later (12 mg)
Novantrone®	2000	Intravenous infusion	4 times a year; 140 mg/m2
Plegridy™	2014	Subcutaneous injection	Every 14 days; 125 mcg.

⁵² (e) NINDS. Publication No. 12-75. June 2012. Available at: www.ninds.nih.gov/disorders/multiple_sclerosis/detail_multiple_sclerosis.htm. Calculated for California using a U.S. rate of 85/100,00 * 38.8 million people;

Drug Name	Year Approved	Administration Route	Dosing
Rebif®	2002	Subcutaneous injection	Three times a week; 44 mcg.
Tecfidera®	2013	Capsule taken orally	Twice a day; 120 mg for one week and 240 mg thereafter
Tysabri®	2006	Intravenous infusion	Every 4 weeks; 300 mg

As many of the first-line MS DMT drugs require injection or infusion-based administration, such administration methods create adherence issues. Injectable drugs can have serious side effects including injection-site reactions, flu-like symptoms, and liver issues. Additionally, the inconvenience associated with these administration methods can also impact adherence (Kim et al., 2015). As shown in the medication list above, there are now three orally administered MS DMTs available: Aubagio®, Gilenya®, and Tecfidera®. The three drugs have been shown to be clinically comparably effective as compared to injection-based alternatives (Kim et al., 2015); however, there are not yet any long-term efficacy and safety data available, which leads many clinicians to prescribe the more known injectable drug therapies (Cross and Naismith, 2014). Yet, due to the nature of the injection-based therapies, adherence is a major issue, as it has been reported that between 13% and 72% of MS patients do not adhere to their DMT treatment regime (Brandes, 2009; Reynolds, 2009). Studies examining the adherence rates of the orally administered Gilenya® as compared with injection-based treatment groups revealed that the Gilenya® group had significantly higher adherence rates (Agashivala et al., 2013).

It is important to note, that despite lower adherence rates, the current reimbursement structure incentivizes the use of injectables over oral medications for both physicians and patients. Many injectables are part of the medical benefit and less likely to have the same level of cost sharing as the oral treatments. In addition, physicians often get an additional payment through the infusion centers when their patients are treated with that modality.

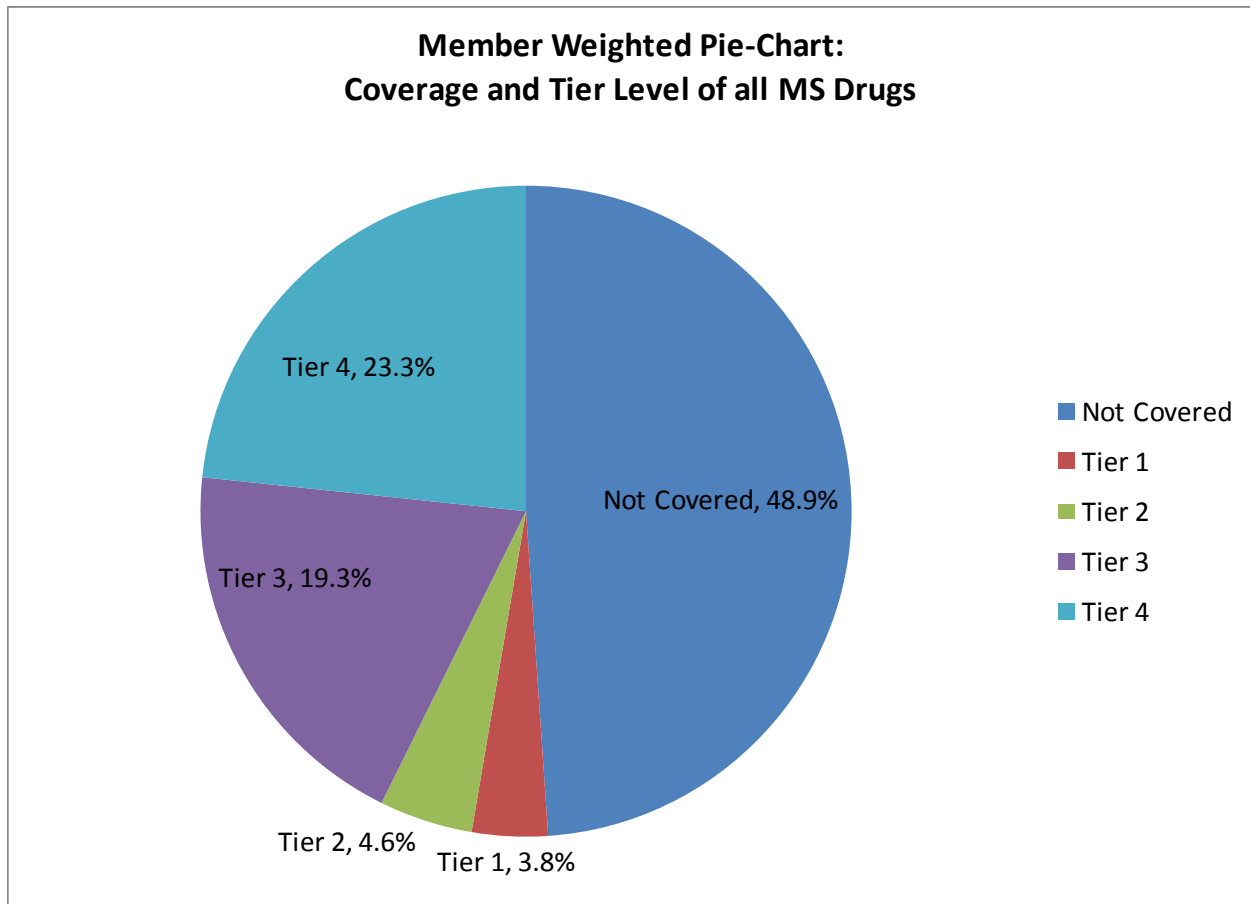
Placement of MS Drugs on the Highest Cost Tiers

There has been a recognized increase in the costs of drugs, including those that are used to slow progression of MS or reduce the frequency of attacks. Examined along with rheumatoid arthritis and cancer, trends in specialty drug spending for MS among Medicare beneficiaries was found to have increased considerably during 2007 to 2011, from \$2,641 to \$8,976 (Trish et al., 2014). Typically, when there is an increase in the number of drugs for a condition, this leads to lower or stabilized costs for patients who use those drugs, especially for first-generation therapies. However, despite the increase in number of drugs available for MS, there has been a rise in the costs of drugs. Hartung et al. (2015) examined the trend in annual drug costs for nine disease-modifying therapies (DMTs) for multiple sclerosis using published drug pricing data from 1993 to 2013. They compared changes in DMT costs to general and prescription drug inflation during the same period. First-generation DMTs, which used to cost between \$8,000 and \$11,000, now cost about \$60,000 per year. Researchers find that the costs of these agents have increased annually at rates 5 to 7 times higher than for other prescription drugs.

Prescription drug pricing of new drugs might be a contributing factor to the rising costs as DMTs commonly enter the market with a cost 25% to 60% higher than existing DMTs. Hartung et al. (2015) also found that increases in the cost trajectory of the first-generation DMTs occurred following the Food and Drug Administration approvals of IFN-β-1a SC (2002) and natalizumab (reintroduced 2006) and remained high after introduction of fingolimod (2010). However, changes did not occur with TNF inhibitor biologics during these time intervals. Lastly, DMT costs in the United States currently are 2 to 3 times higher than in other comparable countries.

CHBRP examined tier level of MS prescription drugs among CHBRP’s surveyed California carriers. Nearly 50% of all MS drugs were determined to be not covered based on the formularies (Table 10 provides a list of these drugs). Where drugs were covered, they tended to be placed on the higher cost tiers (Tiers 3 and 4). Nearly 43% of MS prescription drugs are placed on Tiers 3 and 4. Only about 4% of drugs are on Tier 1. In the case of MS, it appears AB 339 would shift the proportion of drugs in the highest-cost tiers (3 and 4) towards lower. CHBRP does not quantify this shift.

Figure 7. Member-Weighted Pie Chart^(a) of Coverage and Tier Level of All MS Drugs



Source: California Health Benefits Review Program, 2015.

Note: (a) A drug is considered “not covered” if it does not appear on the plan’s formulary. Tier information was obtained from each plan’s formulary. Member weights reflect percent of enrollees on each tier, calculated using plan membership data to obtain number of enrollees per plan.

Table 11 includes a list of MS drugs and the proportion of members in California that currently do not have coverage. Following implementation of AB 339, there will be a reduction in the proportion that are on the highest-cost tier; however, CHBRP could not quantify these changes (refer to *Cost Approach* section above for the limitations).

Table 11. Proportion of Enrollees Without Coverage of Prescription Drugs to Treat MS and Proportion on Highest (4th) Tier^(a)

Drug Name	% enrollees currently without coverage	For MS Drugs that Are Covered	
		Covered on 4 th Tier	Covered on Other Tiers (1-3)
Ampyra®	58%	24%	18%
Extavia®	7%	33%	60%
Aubagio®	65%	20%	15%
Tysabri®	24%	27%	49%
Avonex®	0%	40%	60%
Betaseron®	65%	20%	15%
Rebif®	45%	45%	11%
Tecfidera®	69%	20%	11%
Copaxone®	20%	25%	55%
Gilenya®	65%	20%	15%
Lemtrada™	100%	0%	0%
mitoxantrone (generic)	31%	20%	49%
Plegridy™	88%	7%	5%

Source: California Health Benefits Review Program, 2015.

Note: (a) A drug is considered “not covered” if it does not appear on the plan’s formulary. The percent of enrollees without coverage calculated using membership data to obtain number of enrollees per plan.

Implications

Long-term adherence to disease-modifying therapy is a challenge for patients with MS. Evaluations of treatment adherence indicate that between 60% and 76% of patients adhere to therapy for 2 to 5 years, with the majority of those who stop treatment doing so within the first 2 years (Costello et al., 2008). Nonadherence to treatment can result in worse health outcomes, increased disability, relapse, and more significant disease progression (Costello et al., 2008). Additionally, lower treatment dosages have been shown to lead to increased disease activity (Clerico, 2007). Extended release medications for MS have led to meaningful improvements (e.g., improved movement and walking ability), while maintaining these effects between dosages (Goodman et al., 2010). Combined medications for the treatment of MS have also led to favorable results, including reduced symptom severity, improved quality of life among patients, and improved functional status (Oreja-Guevara, 2012).

The three oral forms of DMT (Aubagio®, Gilenya®, and Tecfidera®) are only covered for approximately one-third of the enrollees subject to AB 339. In addition, of those that cover, the vast majority cover in the 3rd or 4th tier, making oral treatments for MS more expensive than other delivery routes. The evidence regarding oral DMTs suggest that that oral delivery is clinically as effective as injections and infusions with better adherence rates and fewer side effects. Therefore, to the extent that AB 339 increases coverage of DMTs used to treat MS or decreases the out-of-pocket expenditures, especially for oral forms of treatment, there is a potential to increase adherence to the treatment regimen, thus improving health outcomes of people with MS.

Case Study 3: Hepatitis C

Background

Hepatitis C is a viral infection of the liver. hepatitis C can be either acute, where the patient clears the virus from their body either with or without treatment, or chronic, where the patient is prescribed a lifelong course of medications to minimize the damage to their liver. California currently has more than 33,000 reported cases of Hepatitis C, with higher rates being reported among males, African Americans, and whites.⁵³

Treatment for hepatitis C typically involves the use of 1 to 4 medications daily for 12 to 48 weeks, and has undergone significant changes and advances in recent years. Currently, four main drugs comprise the most common forms of treatment: Sovaldi®, Harvoni®, Olysio®, and Viekira Pak™. Although all of these drugs are single-tablet combination drugs, only Harvoni® is a complete treatment regimen, as the other three drugs need to be used in combination with other treatments. Harvoni® is the newest treatment, and the only hepatitis C treatment regimen that does not require the administration of additional drugs such as Ribavirin or pegylated interferon and ribavirin (PEG/Riba); however, it is not effective for all genotypes of hepatitis (FDA, 2014).

Adherence to treatment regimens for hepatitis C therapies has been shown to be strongly related to effectiveness (Re V, et al., 2009). However, therapies involving PEG/Riba can last 6 to 12 months and are often accompanied by severe side effects, increasing the likelihood that patients will not comply with recommended treatment plans (Mitra et al., 2010). The reported side effects for Harvoni® were not as severe compared to PEG/Riba, and did not significantly affect adherence as did the side effects for PEG/Riba therapy (FDA, 2014). Harvoni® is administered as a once-daily tablet, for 8 to 12 weeks, which greatly increases the likelihood of patient adherence over combination therapies involving multiple pills and injections. Harvoni® is also more effective than other recently approved treatments. For example, the results of clinical trials showed Harvoni® to have up to 94% to 99% effectiveness, depending on patient treatment experience and genotype, versus 74% to 94% for Sovaldi®.

Extended release drugs can enhance adherence rates (Lo Re V III et al., 2009). However, with the exception of the once daily Harvoni®, other once daily pills such as Solvaldi®, often must be taken in combination with PEG/Riba therapy. There are no extended-release versions of Interferon, and it must be administered through injection three times per week. Extended-release versions of Ribavirin have been tested and are shown to increase patient adherence (Weiss et al., 2009).

⁵³ CDC, 2014; and CDPH, 2013b.; <http://www.natap.org/2013/HCV/531-546.pdf> (Page 9 of PDF)

Placement of Hepatitis C Drugs on the Highest-Cost Tiers

Hepatitis C drugs are typically placed into the highest-cost/specialty drug tier by insurance carriers, especially the recent breakthrough drugs that have arrived in the market in the past 2-3 years. Sovaldi®, Harvoni®, Olysio®, and Viekira Pak™ are the most discussed of the recent drugs to arrive in the market. However, these new drugs are costly and have created a good deal of recent discussion on pharmaceutical pricing and how carriers respond to high-cost drugs and the impact on enrollees with hepatitis C.

Sovaldi®, for example, costs about \$1,000 per pill (wholesale list price). Indeed, it is likely that Sovaldi® is expensive, in part, because it is so effective. Similarly, the manufacturer has priced Harvoni® at \$1,125 per pill (wholesale list price) that would also place it in the highest patient cost tier. Pharmaceutical companies have argued that breakthrough drugs, such as Sovaldi® and Harvoni®, require a good deal of investment in research and development and are thus costly (Acosta et al., 2014). Pricing is also highly dependent on the other comparable products that are available on the market. The new hepatitis C drugs accounted for more than \$11 billion of the \$374 billion total spending on prescription drugs in the U.S. in 2014 (IMS Institute for Healthcare Informatics). The Wall Street Journal⁵⁴ analyzed how much state Medicaid programs spent in 2014 for hepatitis C treatment and found that states spent \$1.08 billion on Sovaldi® in the first nine months of 2014, representing 82% of all hepatitis C drug spending. States are entitled to get a portion of their money back through legally mandated rebates of at least 23%. Rebates are expected to be higher in 2015 after the launch of new products. Most analyses of costs never include a consideration of these rebates. Out-of-pocket costs to the enrollee are not currently available for hepatitis C through CHBRP's usual data sources.

Recent analyses by the California Technology Assessment Forum (CTAF) suggests that while it is expensive to cover Sovaldi® for all chronic HCV patients, Sovaldi® might be cost-saving in the long run, thus costs would be recouped over the course of decades. In contrast, in the short-term, benefits to the insurance companies that pay for it are less clear and likely significantly smaller. CTAF's analysis included a demonstration of a hypothetical large employer-sponsored plan with 1 million members. If the plan had a baseline hepatitis C prevalence rate similar to that of the general population, and just half of those infected were treated in one year, the resulting increase in spending by insurance companies due to new regimens — Sovaldi® and Olysio® — would be about *\$50 per member per month*, or \$600 per member per year. CTAF also estimated that applying that same model to California as a whole would increase drug expenditures by all payers in the state by *\$22 billion* in a single year. These increases in PMPMs would likely result in premium increases across the board. This is why limiting hepatitis C drugs to enrollees who meet certain clinical criteria is currently being done by many carriers; for example, for patients with extensive liver damage. The same CTAF analysis suggests that only treating patients with advanced fibrosis with the new therapies would be cost-saving, saving the state's payers as a whole \$1 billion over 20 years.

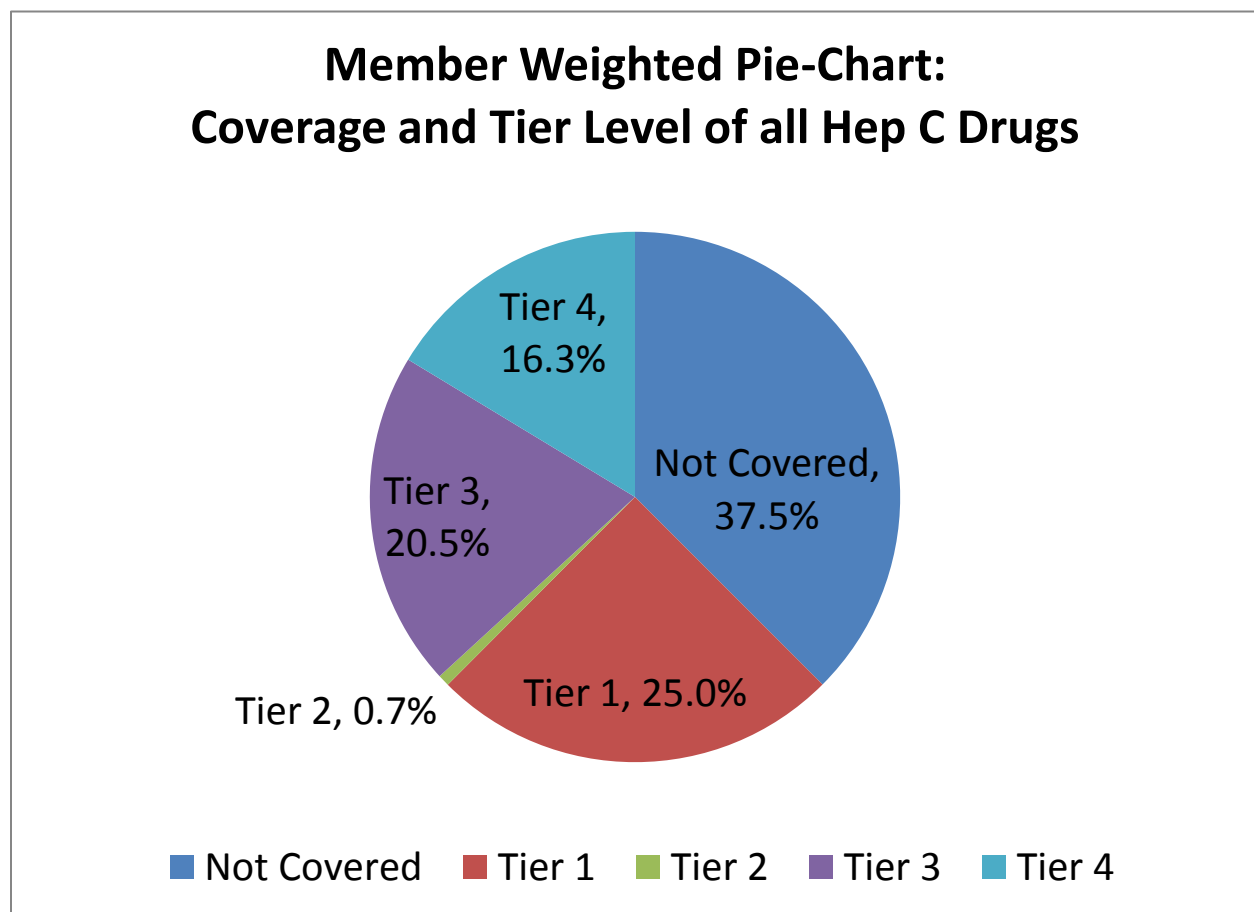
There are some indications that the price of the newest hepatitis C drugs may come down in the near future because in the pipeline are other efficacious hepatitis C drugs that are scheduled to come into the market, which may reduce prices of existing products. It is not clear at what point pharmaceutical companies recoup the costs of research and development. A recent article by Lakdawalla et al. (2015) offers some insight into the careful examination of costs versus benefits using the example of colorectal cancer treatment, which much like hepatitis C, had breakthrough costly drugs introduced about a decade ago. In the early 1990s, almost all colorectal cancer patients were treated with fluorouracil and leucovorin

⁵⁴ <http://www.wsj.com/articles/expensive-hepatitis-c-medications-drive-prescription-drug-spending-1425960214>

(24 weeks of treatment cost \$121). In 1998, a colorectal cancer regimen that included irinotecan became popular (treatment cost \$688). In the early 2000s, four new drugs were introduced for the treatment of colorectal cancer: capecitabine, oxaliplatin, bevacizumab, and cetuximab, for which the cost of a treatment cycle was more than \$35,000. Health care costs increased by \$34,493 as a result of the new products. However, health improved by 0.33 QALYs, valued at \$33,115 per person. Thus, the quality-adjusted cost of care increased by \$1,377 during this time period, for which the authors suggest society got what it paid for.

CHBRP examined tier level of hepatitis C prescription drugs among CHBRP's surveyed California carriers. Much like MS drugs, most of the drugs for hepatitis C were either not covered on the formularies, or placed in Tiers 3 and 4. Less than 26% of hepatitis p C drugs are on Tiers 1 and 2. As with the case of MS, it appears AB 339 would shift the proportion of hepatitis C drugs out of the highest-cost tiers (3 and 4) towards lower tiers. CHBRP does not quantify this shift.

Figure 8. Member-Weighted Pie Chart^(a) of Coverage and Tier Level of All Hepatitis C Drugs



Source: California Health Benefits Review Program, 2015.

Note: (a) A drug is considered “not covered” if it does not appear on the plan’s formulary. Tier information was obtained from each plan’s formulary. Member weights reflect percent of enrollees on each tier, calculated using plan membership data to obtain number of enrollees per plan.

Table 12 includes a list of hepatitis C drugs and the proportion of members in California that currently do not have coverage. Following implementation of AB 339, there will be some decrease (CHBRP did not quantify) in the proportion of enrollees who will be offered coverage of hepatitis C on the highest tier.

Table 12. Proportion of Enrollees Without Coverage of Prescription Drugs to Treat Hepatitis C and Proportion on Highest (4th) Tier^(a)

Drug Name	% enrollees without coverage	For Hep C Drugs that Are Covered	
		Covered on 4 th Tier	Covered on Other Tiers (1-3)
Victrelis®	24%	27%	49%
Olysio®	82%	7%	11%
Sovaldi®	48%	7%	45%
Harvoni®	48%	7%	45%
Viekira Pak™	80%	20%	0%
Pegasys®	11%	45%	45%
Pegasys Proclick®	75%	25%	0%
Copegus®	65%	7%	28%
Peg-Intron®	11%	45%	45%
Peg-Intron Redipen®	89%	11%	0%
ribavirin (generic)	0%	0%	100%
Rebetol®	0%	7%	93%

Source: California Health Benefits Review Program, 2015.

Note: (a) A drug is considered “not covered” if it does not appear on the plan’s formulary. The percent of enrollees without coverage calculated using membership data to obtain number of enrollees per plan.

There are a number of cases where pharmaceutical benefits are assigning a particular hepatitis C drug as their preferred or exclusive option for patients they cover. For example, CVS Health Corp has made Gilead Science’s products, Sovaldi® and Harvoni®, the exclusive options for patients with hepatitis C, which means other hepatitis C drugs would be excluded from the formulary except in cases where it is deemed medically necessary. Medical necessity is determined by the physician and requires an appeal to the carrier.

Implications

Adherence rates are difficult to determine in the literature, as there are disagreements on how to represent adherence for hepatitis C treatment. This AHRQ review estimates that compliance for the older hepatitis C medications ranges from 43-78%, while other sources find this rate is as low as 40%, likely due to cost and side effects (Mitra, 2010). Adherence rates overall have most likely improved since the introduction of newer treatments like Harvoni® and Sovaldi®. What has been shown is that there may be a significant health and financial cost to low adherence (Mitra, 2010).

CHBRP found that for the most part, hepatitis C treatments were either not covered or covered in the highest-cost tiers. One of the most promising new treatments, Harvoni®, is only covered for half of enrollees despite its demonstrated improved effectiveness and adherence rates over current treatments. To the extent that AB 339 increases coverage or decreases cost-sharing for Harvoni, there is a potential to improve health outcomes as Harvoni has been shown to have higher adherence rates and fewer side effects than other treatments.

Conclusions

It has been argued that while tiered formularies are designed to encourage enrollees to select generic or preferred brand-name drugs instead of higher-cost alternatives, when carriers place all the drugs for a particular condition in the highest cost-sharing tier(s), enrollees with the particular condition incur high costs regardless of which drugs (generic or not) they take. Policy approaches like AB 339 may be applied to better deal with discriminatory practices that place certain drugs on the highest-cost tier (Jacobs and Sommers, 2015). An example is from Medicare Part D, which has identified several “protected classes” of drugs, including those used for HIV, seizures, and cancer, and mandates that patients have access to them in all plans. Other policy approaches might be (1) setting an upper limit on cost sharing for medications for protected conditions, (2) limits on prior-authorization requirements, and (3) requiring marketplace plans to offer drug benefits that meet a given actuarial value. Nondiscrimination requirements have precedent. The Final 2015 EHB rule addressed possible discriminatory benefit designs in outpatient prescription drug coverage, specifically cautioning against benefit designs that might discourage the enrollment of people with chronic health conditions.⁵⁵ Benefits are thus designed to ensure there is not discrimination against enrollees because of their age, disability, or expected length of life.⁵⁶ Examples included not covering single-tablet or extended-release prescription drugs that are commonly prescribed and are as effective as multitablet drug regimens without an appropriate reason for refusal, and placing most or all drugs that treat a specific condition on the highest-cost tiers without a nondiscriminatory reason for this benefit design. A nondiscriminatory reason for placing most or all drugs that treat a specific condition on the highest-cost tiers is if all of the drugs are high cost.

⁵⁵ HHS Notice of Benefit and Payment Parameters for 2016. Final Rule. Federal Register, Vol. 80, No. 39. February 27, 2015. Available at: www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf.

⁵⁶ ACA Section 1302(b)(4).

PUBLIC HEALTH IMPACTS

This section estimates the short-term public health impact⁵⁷ of AB 339 on health outcomes, financial burden, and gender and racial/ethnic disparities. See the *Long-Term Impact of AB 339* section for discussion of the impact of reduced cost sharing beyond the first 12 months of the bill implementation.

Estimated Public Health Outcomes

As reported in the *Medical Effectiveness* section, it is well established in the literature that persons who face higher cost sharing use fewer services than persons with lower cost sharing, and that among people with chronic conditions as cost sharing increases, adherence to drug regimens decreases leading to worse health outcomes (CHBRP, 2014; Goldman et al., 2007). To the extent that AB 339 reduces cost sharing for people with chronic conditions, there is potential for increased adherence to treatment regimens and improved health outcomes.

CHBRP included in its analysis all outpatient prescription drugs⁵⁸ with cost sharing above \$260/prescription. The prescription drugs most likely to meet this criterion generally fall into several classes of specialty and biologic drugs used to treat a range of conditions. Many of the conditions treated with high-cost specialty drugs tend to be chronic and progressive in nature and can affect quality of life, along with morbidity and mortality. Most require daily medication treatment that can transition to an increased number of medications according to disease progression.

As presented in the *Medical Effectiveness* section, there is a preponderance of evidence that higher enrollee cost-sharing requirements result in poorer medication adherence, decreased use of essential and nonessential health care services, and increased hospitalizations and emergency department visits.

In the first 12 months postmandate, CHBRP estimates that AB 339 would decrease cost sharing for 45,410 enrollees. AB 339 would also increase the number of enrollees who were able to fill a prescription due to the reduction in cost sharing by an additional 947 enrollees. Thus, postmandate, AB 339 would reduce the out-of-pocket expenses for 46,357 enrollees who use high-cost prescription drugs.

Although the absolute number of enrollees facing a reduction in cost sharing due to AB 339 is not large (46,357 of 10.97 million enrollees, 0.42%), the evidence indicated that reduced cost sharing is linked to improved medication initiation and adherence, which results in improved outcomes for some persons across a variety of conditions (Alamanos and Drosos, 2005; Carroll, 2009; Dor et al., 2010; Gleason et al., 2009; Goldman et al., 2007; Karaca-Mandic et al., 2010; Kargiotis et al., 2010; Ryan, 2009).

CHBRP estimates that 46,357 enrollees, including 947 new users, would fill an additional 13,184⁵⁹ high-cost prescription drugs were AB 339 enacted. Although across the state of California this is a relatively small number, CHBRP recognizes that on a case-by-case basis, AB 339 may yield important health and quality of life improvements for some persons.

⁵⁷ CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

⁵⁸ AB 339's language indicates that outpatient prescription drugs may be administered by health providers in outpatient settings; therefore, medications can be covered through an insured's outpatient prescription drug pharmacy benefit or medical benefit.

⁵⁹ Calculated as pre-/postmandate enrollees (avg. number of prescriptions): $46,357(6.25) - 45,410(6.09) = 13,184$.

Estimated Impact on Financial Burden

When possible, CHBRP estimates the marginal impact of mandates on financial burden, defined as noncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (i.e., deductibles, copayments, and coinsurance). AB 339 would decrease the financial burden for those enrollees who use prescription drugs with cost sharing that exceeds \$260 (1/24th of the annual out-of-pocket maximum) for up to a 30-day supply premandate. CHBRP estimates that 46,357 enrollees would no longer have out-of-pocket expenses for prescription drugs exceeding the \$260 limit; they would receive an estimated net reduction in out-of-pocket expenses of \$65.33 million postmandate. This translates to an average savings of \$151/high-cost prescription.

See further discussion of financial impacts in the *Long-Term Impact of AB 339* section.

In the first year postmandate, CHBRP estimates that AB 339 would reduce the net out-of-pocket expenditures by \$65.33 million for 46,357 enrollees whose cost sharing would no longer exceed the cost-sharing limit of \$260/prescription. This translates to a 42% reduction (\$151/prescription) in the average cost sharing for an enrollee's high-cost prescription drug.

To the extent that AB 339 removes a cost barrier for some enrollees who would then initiate therapy earlier and maintain adherence, the health impact on disease progression and outcomes could be significant on a case-by-case basis.

Impact on Gender and Racial Disparities

There are a variety of determinants of health that influence the health status of different groups. CHBRP estimates AB 339's impact on one of those determinants — access to care through insurance — on existing health disparities; other important determinants of health are generally outside the scope of health insurance mandates (e.g., biological, environmental, social, behavioral, language barriers, etc.).

CHBRP analyses are limited to the insured population affected by a health benefit mandate. Coverage disparities can exist within the insured population and may contribute to gaps in access and/or utilization among those covered (Kirby et al., 2006; Lille-Blanton and Hoffman, 2005; Rosenthal et al., 2008). To the extent that racial/ethnic groups are disproportionately distributed among policies with more or less coverage, a mandate bringing all policies to parity may reduce an existing disparity.

Impact on Gender Disparities

Many diseases affect men and women at different rates, and health care costs, including patient out-of-pocket costs, can be quite different depending on the disease. For example, MS disproportionately affects women who have at least two to three times the prevalence as men, depending on type of condition (Chakravarty et al., 2007; Helmick et al., 2008; Noonan et al., 2002) and typically has a high-cost prescription drug treatment protocols (Alamanos and Drosos, 2005; Boonen and Severens, 2011; Hurwitz, 2011; Noonan et al., 2010). Given that women's income is generally lower than men's, a disproportionate positive impact of reduced financial burden on some women with MS be expected (Hurwitz, 2011; Noonan et al., 2010). Despite these examples, CHBRP estimates no measurable change in existing gender disparities due to the small number of enrollees (46,357, 0.42%) who would no longer exceed the \$260 cost-sharing limit (which represents 1/24th of the annual out-of-pocket maximum, as stipulated in the bill language).

Due to the small magnitude of change in the number of enrollees with reduced cost sharing, CHBRP estimates AB 339 would have no measurable impact on possible gender disparities across specific disease states.

Impact on Racial/Ethnic Disparities

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

Moreover, there is literature that identifies racial/ethnic differences in impact of cost sharing on prescription drug use and adherence. CHBRP identified two recent studies that addressed racial disparities in the general population and one that evaluated income disparities. A recent national study using Medical Expenditure Panel Survey data showed that Latinos were less likely to use prescription drugs, but have a higher proportion of out-of-pocket drug costs compared to whites (Chen et al., 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). An economic disparity study used national census data to estimate the impacts of prescription drug cost sharing on adherence to medications for diabetes and congestive heart failure (Chernew et al., 2008). This study showed that only patients in the lowest income category (<\$30,000/year) were sensitive to drug costs, particularly for congestive heart failure drugs. For patients making above \$30,000/year, there was no consistent relationship between drug cost and drug adherence.

Adherence rates for medications have been shown to be lower for minority racial/ethnic populations (Simoni, 2012). Specifically, African American/black and Hispanic populations have reportedly lower levels of adherence across a variety of treatments including antiretroviral therapy for HIV/AIDS and anti-hypertensive medications (Ishisaka, 2012; Simoni, 2012). This is also true for the older adult black population (Roth, 2010). Some of the adherence issues across different race/ethnicities can be attributed to higher copayments (Choudhry, 2014), though higher copayments are associated with lowered adherence for whites as well (Wong, 2013). Some variables to explore that may increase compliance in this population include the number of pills required and the relationship between the patient and healthcare providers (Colby, 2012). Patient relationship with providers has been cited as a barrier to adherence due to distrust formed from experiencing discrimination, and racial minorities reported poorer adherence specifically to antiretrovirals (Thrasher, 2008).

Although there is evidence that, in general, lower cost sharing can improve adherence, CHBRP estimates AB 339 would have no measureable impact on racial/ethnic disparities due to the small number of enrollees (46,357 or 0.42%) whose cost sharing would be reduced as a result of AB 339. This magnitude is too small to measure a change in disparities within the California population.

LONG-TERM IMPACT OF AB 339

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

In the long term, enrollees in DMHC-regulated plans or CDI-regulated policies subject to AB 339 would continue to benefit from the \$260 limit (1/24th of the annual out-of-pocket maximum) on cost sharing for outpatient prescription drugs covered by pharmacy and medical benefits.

Long-Term Utilization and Cost Impacts

As discussed in the *AB 339 Impacts on Benefit Coverage, Utilization, and Cost, 2015* section, AB 339 is anticipated to lead to a small annual increase in utilization of prescription drugs due to increased adherence to high-cost outpatient prescription drugs and to an increase in the number of enrollees using these prescription drugs. The increased utilization is particularly large for specialty drugs used for treatment of disease such as cancer, multiple sclerosis (MS), rheumatoid arthritis, anemia, or infertility. The findings of the RAND HIE study indicated an overall reduction in expenditures with lower overall cost sharing, with a bigger impact for low-income persons (Baicker and Goldman, 2011; Newhouse, 1993). A more specific review of the existing literature on the relationship between prescription drug cost sharing and reduction in health care expenditures did not establish a clear link, particularly due to a dearth of studies addressing economic outcomes (Eaddy et al., 2012). As a result, CHBRP does not estimate the impact of AB 339 on utilization and costs in the long term.

Utilization and Cost Impacts

In the first 12 months following enactment, CHBRP estimates that high-cost outpatient prescription drugs (i.e., exceeding the AB 339 limit on cost sharing) would be used by 3,174 additional enrollees (a 2.43% increase) who previously did not use these drugs. CHBRP estimates that in the long term, with the reduction in cost sharing, AB 339 would increase the use of existing and newly developed high-cost prescription drugs and would lead to an increase in overall expenditures, led by premium increases. Specialty pharmaceuticals are the most rapidly growing portion of the pharmaceutical industry both in expenditures and new products and are more frequently provided under medical benefits (McDonald, 2008). Industry groups report that U.S. spending on specialty drugs will increase 72% by 2015, with three of the four costliest therapeutic classes focused on specialty conditions (Stetten, 2013).

As discussed in the *Background on Cost Sharing for Outpatient Prescription Drugs* section, these trends have propelled employer-sponsored plans to require separate cost sharing in the form of coinsurance rather than copayments for specialty drugs. In 2013, 59% of California employees were subject to tier 3 and 7% were subject to tier 4 cost sharing, an increase from 42% and 2%, respectively, in 2005 (CHCF, 2014). National data indicate that tier 4 drugs often include lifestyle or high-cost biologic and specialty drugs and the enrollees with this level of cost sharing are subject to copayments of \$80 and coinsurance of 32% on average (Choudhry et al., 2011; KFF/HRET, 2013).

If AB 339 is enacted, the reduction in cost sharing can accelerate the use of these prescription drugs in the long term. Insurers will not be able to increase cost sharing as a mechanism to curtail the use of these

drugs, but can increase premiums, apply more stringent utilization review criteria, and negotiate discounts with pharmaceutical companies. In return, pharmaceutical companies can accelerate direct-to-consumer advertising efforts and increase overall prescription drug costs. A limit on cost sharing may also be an incentive for pharmaceutical companies to increase prices and a disincentive to offer coupons.

CHBRP estimates that in the long term, AB 339 would increase the use of existing and newly developed high-cost prescription drugs and would lead to an increase in overall expenditures due to a reduction of cost sharing for high-cost prescription drugs. The magnitude of this impact is unknown.

Long-Term Public Health Impacts

Estimated Public Health Outcomes

Although CHBRP estimates that 46,357 enrollees will increase their use of high-cost medications, CHBRP is unable to estimate the long-term public health impacts of AB 339. This is due to a number of factors including the breadth of conditions affected, variation in disease severity, appropriateness of high-cost prescription drug treatments, large variation in cost-sharing benefit design, and unknown market response to changes.

To the extent that AB 339 enables enrollees to initiate therapy earlier and maintain adherence due to reduced cost sharing, the long-term impact on disease outcomes such as relapse rates, disability, and early mortality could be significant on a case-by-case basis. For example, the cost of several prescription drugs for MS exceed the AB 339 monthly cost-sharing limit, and studies have shown that MS patients initiating earlier treatment with some of these drugs (e.g., interferon beta) leads to reduced morbidity (Castrop et al., 2013; Edan et al., 2013). In this example, AB 339 could not only reduce the economic burden for some who are prescribed the interferon beta, but it could likely delay the progression of the disease for those enrollees. Thus, the downward pressure of this cost sharing reduction may significantly alter the progression and outcome of a variety of illnesses for a small percentage of enrollees.

Despite indications of possible health maintenance or improvements for some enrollees impacted by the cost-sharing limit in AB 339, CHBRP is unable to estimate future impacts on health, premature death, or economic loss. As noted above, this is due in part to the alternative utilization management techniques beyond cost sharing that insurers may use to restrain growing prescription drug costs. These techniques, such as prior authorization (requiring approval by the health plan or insurer before being covered), step therapy (requiring a patient to fail one drug first before being covered for another), using formularies to exclude certain drugs, and imposing quantity dispensing limits (KFF, 2013), attempt to dampen the upward pressure of escalating costs.

CHBRP is unable to estimate the long-term public health impact of AB 339 due to uncertainty in the market's response to the downward cost pressure of mandated reductions in enrollee cost sharing and the upward pressure of the increasing number and cost of specialty drugs; however, AB 339 may provide significant health and quality of life improvements on a case-by-case basis.

Impacts on Premature Death and Economic Loss

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

the value of the YPLL in dollar amounts (i.e., valuation of years of work life lost from premature death or lost productivity due to a disease or condition).

Premature mortality

AB 339 may decrease premature death resulting from a variety of conditions treated with high-cost, life-saving, or life-sustaining prescription drugs, but there is a lack of evidence to inform estimates of the marginal effect on all the possible health outcomes of the 46,357 enrollees who would change behavior due to the reduced cost sharing. Therefore, the magnitude of the prescription drug cost-sharing limit on premature death is unknown.

Economic loss

Although AB 339 may affect economic loss resulting from a variety of conditions treated with high-cost prescription drugs, there is a lack of evidence to inform changes in future utilization. Therefore, the impact of the prescription drug cost-sharing limit on economic loss is unknown.

APPENDIX A TEXT OF BILL ANALYZED

On February 17, 2015, the California Assembly Committee on Health requested that CHBRP analyze AB 339. On April 7th, the language was amended, and the Assembly Committee on Health submitted a new request to CHBRP to analyze the amended language.

ASSEMBLY BILL NO. 339

Introduced by Assembly Member Gordon

AMENDED APRIL 7, 2015

Amended in Assembly April 7, 2015

California Legislature—2015–16 Regular Session

Assembly Bill No. 339

Introduced by Assembly Member Gordon

(Coauthor: Assembly Member Atkins)

February 13, 2015

An act to add Section 1342.71 to the Health and Safety Code, and to add Section 10123.193 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 339, as amended, Gordon. Health care coverage: outpatient prescription drugs.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan or insurer that provides prescription drug benefits and maintains one or more drug formularies to make specified information regarding the formularies available to the public and other specified entities. Existing law also specifies requirements for those plans and insurers regarding coverage and cost sharing of specified prescription drugs.

This bill would require a health care service plan contract or a health insurance policy that is offered, renewed, or amended on or after January 1, 2016, and that provides coverage for outpatient prescription drugs, to provide coverage for medically necessary prescription drugs, including those for which there is not a therapeutic equivalent. The bill would require copayments, coinsurance, and other cost sharing for these drugs to be reasonable, and would require that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription not exceed 1/24 of the annual out-of-pocket limit applicable to individual coverage for a supply of up to 30 days. The bill would

require a plan contract or policy to cover single-tablet and extended release prescription drug regimens, unless the plan or insurer can demonstrate that multitablet and nonextended release drug regimens, respectively, are more effective, as specified. The bill would prohibit, except as specified, a plan contract or policy from placing prescription medications that treat a specific condition on the highest cost tiers of a drug formulary. The bill would require a plan contract or policy to use specified definitions for each tier of a drug formulary.

Because a willful violation of the bill's requirements relative to health care service plans would be a crime, this bill would impose a state-mandated local program.

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

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

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

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

SECTION 1.

Section 1342.71 is added to the *Health and Safety Code*, to read:

1342.71.

(a) A health care service plan contract that is offered, amended, or renewed on or after January 1, 2016, shall comply with this section. This section shall not apply to Medi-Cal managed care contracts.

(b) (1) A health care service plan that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs.

(2) A health care service plan that provides coverage for outpatient prescription drugs shall cover a medically necessary prescription drug for which there is not a therapeutic equivalent.

(c) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs. The health care service plan shall demonstrate to the director that proposed cost sharing for a medically necessary prescription drug will not discourage medication adherence.

(d) Consistent with federal law and guidance, and notwithstanding Section 1342.7 and any regulations adopted pursuant to that section, a health care service plan that provides coverage for outpatient prescription drugs shall demonstrate to the satisfaction of the director that the formulary or formularies

maintained by the health care service plan do not discourage the enrollment of individuals with health conditions and do not reduce the generosity of the benefit for enrollees with a particular condition.

(1) A health care service plan contract shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless the health care service plan is able to demonstrate to the director that consistent with clinical guidelines and peer-reviewed scientific and medical literature that the multitablet regimen is clinically more effective and more likely to result in adherence to a drug regimen. A health care service plan contract shall cover an extended release prescription drug that is clinically as effective as a nonextended release product unless the health care service plan is able to demonstrate to the director that consistent with clinical guidelines and peer-reviewed scientific and medical literature that the nonextended release product is clinically more effective.

(2) A health care service plan contract shall not place most or all of the prescription medications that treat a specific condition on the highest cost tiers of a formulary unless the health care service plan can demonstrate to the satisfaction of the director that such placement does not reduce the generosity of the benefits for enrollees with a particular condition. In no instance in which there is more than one treatment that is the standard of care for a condition shall most or all prescription medications to treat that condition be placed on the highest cost tiers. This shall not apply to any medication for which there is a therapeutic equivalent available on a lower cost tier.

(3) For coverage offered in the individual market, the health care service plan shall demonstrate to the satisfaction of the director that the formulary or formularies maintained for coverage in the individual market are the same or comparable to those maintained for coverage in the group market.

4) A health care service plan shall demonstrate to the director that any limitation or utilization management is consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.

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

(f) (1) If a health care service plan contract maintains a drug formulary grouped into tiers, including a fourth tier or specialty

tier, a health care service plan contract shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of preferred generic drugs and preferred brand name drugs if the cost to the health care service plan for a preferred brand name drug is comparable to those for generic drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health care service plan's pharmaceutical and therapeutics committee based on safety and efficacy and not solely based on the cost of the prescription drug.

(C) Tier three shall consist of nonpreferred brand name drugs that are recommended by the health care service plan's pharmaceutical and therapeutics committee based on safety and efficacy and not solely based on the cost of the prescription drug.

(D) Tier four shall consist of specialty drugs that are biologics, which, according to the federal Food and Drug Administration or the manufacturer, require distribution through a specialty pharmacy or the enrollee to have special training for self-administration or special monitoring. Specialty drugs may include prescription drugs that cost more than the Medicare Part D threshold if those drugs are recommended for Tier four by the health care service plan's pharmaceutical and therapeutics committee based on safety and efficacy, but placement shall not be solely based on the cost of the prescription drug.

2) Nothing in this section shall be construed to require a health care service plan contract to include a fourth tier, but if a health care service plan contract includes a fourth tier, the health care service plan contract shall comply with this section.

(g) A health care service plan contract shall ensure that the placement of prescription drugs on formulary tiers is not based solely on the cost of the prescription drug to the health care service plan, but is based on clinically indicated, reasonable medical management practices.

Nothing in this section shall be construed to require or authorize a health care service plan that contracts with the State Department of Health Care Services to provide services to Medi-Cal beneficiaries to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.

SEC. 2.

Section 10123.193 is added to the *Insurance Code*, to read:

10123.193.

(a) A policy of health insurance that is offered, amended, or renewed on or after January 1, 2016, shall comply with this section.

(b) (1) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs.

(2) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover a medically necessary prescription drug for which there is not a therapeutic equivalent.

(c) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs. The health insurer shall demonstrate to the commissioner that proposed cost sharing for a medically necessary prescription drug will not discourage medication adherence.

(d) Consistent with federal law and guidance, a policy of health insurance that provides coverage for outpatient prescription drugs shall demonstrate to the satisfaction of the commissioner that the formulary or formularies maintained by the health insurer do not discourage the enrollment of individuals with health conditions and do not reduce the generosity of the benefit for insureds with a particular condition.

(1) A policy of health insurance shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless the health insurer is able to demonstrate to the commissioner that consistent with clinical guidelines and peer-reviewed scientific and medical literature that the multitablet regimen is clinically more effective and more likely to result in adherence to a drug regimen. A policy of health insurance shall cover an extended release prescription drug that is clinically as effective as a nonextended release product unless the health insurer is able to demonstrate to the commissioner that consistent with clinical guidelines and peer-reviewed scientific and medical literature that the nonextended release product is clinically more effective.

(2) A policy of health insurance shall not place most or all of the prescription medications that treat a specific condition on the highest cost tiers of a formulary unless the health insurer can demonstrate to the satisfaction of the commissioner that such placement does not reduce the generosity of the benefits

for insureds with a particular condition. In no instance in which there is more than one treatment that is the standard of care for a condition shall most or all prescription medications to treat that condition be placed on the highest cost tiers. This shall not apply to any medication for which there is a therapeutic equivalent available on a lower cost tier.

(3) For coverage offered in the individual market, the health insurer shall demonstrate to the satisfaction of the commissioner that the formulary or formularies maintained for coverage in the individual market are the same or comparable to those maintained for coverage in the group market.

(4) A health insurer shall demonstrate to the commissioner that any limitation or utilization management is consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.

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

(f) (1) If a policy of health insurance maintains a drug formulary grouped into tiers, including a fourth tier or specialty tier, a policy of health insurance shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of preferred generic drugs and preferred brand name drugs if the cost to the health insurer for a preferred brand name drug is comparable to those for generic drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health insurer's pharmaceutical and therapeutics committee based on safety and efficacy and not solely based on the cost of the prescription drug.

(C) Tier three shall consist of nonpreferred brand name drugs that are recommended by the health insurer's pharmaceutical and therapeutics committee based on safety and efficacy and not solely based on the cost of the prescription drug.

(D) Tier four shall consist of specialty drugs that are biologics, which, according to the federal Food and Drug Administration or the manufacturer, require distribution through a specialty pharmacy or the insured to have special training for self-administration or special monitoring. Specialty drugs may

include prescription drugs that cost more than the Medicare Part D threshold if those drugs are recommended for Tier four by the health insurer's pharmaceutical and therapeutics committee based on safety and efficacy, but placement shall not be solely based on the cost of the prescription drug.

(2) Nothing in this section shall be construed to require a policy of health insurance to include a fourth tier, but if a policy of health insurance includes a fourth tier, the policy of health insurance shall comply with this section.

(g) A policy of health insurance shall ensure that the placement of prescription drugs on formulary tiers is not based solely on the cost of the prescription drug to the health insurer, but is based on clinically indicated, reasonable medical management practices.

SEC. 3.

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

APPENDIX B LITERATURE REVIEW METHODS

Studies of the effects of cost sharing on use of health care services were identified through searches of the PubMed, Business Source Complete (EBSCO Host platform), EconLit (ProQuest platform), the Web of Science, and the Cochrane Library (which includes the Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effect, the Cochrane Register of Controlled Clinical Trials, Cochrane Methodology Register, Health Technology Assessment Database, NHS Economic Evaluation Database. The search was limited to abstracts of peer-reviewed research studies that were published in English, for all years, all genders, all age groups, and all types of research designs. For studies published on general cost-sharing mechanisms, CHBRP relied on a literature search conducted in 2014 for its analysis of AB 1917 (CHBRP, 2014).

CHBRP could find no studies of cost sharing that analyzed cost-sharing provisions as specific as those outlined in AB 339. Instead, CHBRP presents reviews of literature whose findings are relevant to AB 339. For a general overview of the topic, we review studies of the effect of cost sharing on prescription drug use, including specialty drugs. Further searches on combination drug tablets as well as extended drug tables were conducted using the search terms described below. In addition, a search of the literature for the case studies (hepatitis C, HIV/AIDS, and multiple sclerosis) were conducted with a focus on the impact of cost-sharing on the utilization of medication and any literature describing multi drug combination tablets and extended release drugs.

The following databases of peer-reviewed literature were searched:

Search Terms

The search terms used to locate studies relevant to AB 339 were as follows:

PubMed

Medical Subject Headings (MeSH)

NOTE: Terms designated as “[Majr]” are treated as major focuses of the retrieved articles. “NoExp” = does not include more specific terms indexed under the specific heading. [sh] = floating MeSH subheading.

- "Acquired Immunodeficiency Syndrome"[Mesh]
- "Anti-HIV Agents"[Mesh]
- "Anti-HIV Agents/economics"[Mesh]
- "Capsules"[Mesh]
- "Cost of Illness"[Majr]
- "Cost Sharing"[Majr]
- "Cost Sharing"[Mesh]
- "Delayed-Action Preparations"[Pharmacological Action]
- "Delayed-Action Preparations"[Majr:noexp]
- "Delayed-Action Preparations"[Mesh]
- "Diabetes Insipidus"[Mesh]
- "Diabetes Mellitus"[Mesh]
- "Dosage Forms"[Mesh]
- "Drug Combinations"[Majr:NoExp]
- "Drug Combinations"[Majr]
- "Drug Combinations"[Mesh:NoExp]
- "Drug Combinations"[Mesh]
- "Drug Prescriptions"[Mesh:NoExp]

- "Drug Prescriptions"[Mesh]
- "Drug Prescriptions/utilization"[Majr]
- "Drug Prescriptions/utilization"[Mesh]
- "Drug Substitution"[Mesh]
- "Drug Therapy, Combination"[Majr]
- "Drug Therapy, Combination"[Mesh]
- "Drug Utilization Review"[Mesh]
- "Drugs, Essential"[Mesh]
- "Drugs, Generic" [Mesh]
- "Health Expenditures"[Mesh]
- "Health Services Accessibility"[Mesh]
- "Healthcare Disparities"[Mesh]
- "Hepatitis C"[Majr]
- "Hepatitis C"[Mesh]
- "Hepatitis C/drug therapy"[Mesh]
- "HIV Long-Term Survivors"[Mesh]
- "HIV"[Mesh]
- "Hypertension"[Mesh:NoExp]
- "Insurance Coverage"[Mesh]
- "Insurance, Health"[Majr]
- "Insurance, Health"[Mesh:NoExp]
- "Insurance, Health"[Mesh]
- "Insurance, Health, Reimbursement"[Mesh]
- "Insurance, Pharmaceutical Services"[Majr]
- "Insurance, Pharmaceutical Services"[Mesh]
- "Medication Adherence"[Majr]
- "Medication Adherence"[Mesh]
- "Mortality, Premature"[Mesh]
- "Multiple Sclerosis"[Mesh]
- "Pharmaceutical Preparations"[Mesh:NoExp]
- "Prescription Drugs"[Majr]
- "Prescription Drugs"[Mesh]
- "Prescription Drugs/economics"[Majr]
- "Prescription Drugs/economics"[Mesh]
- "Tablets"[Mesh]
- "Tablets, Enteric-Coated"[Mesh]
- "Therapeutic Equivalency"[Majr]
- "Therapeutic Equivalency"[Mesh]
- "Utilization"[sh]

Keywords and Keyword Phrases

NOTE: “[ti]” = Article title field only. “[tiab]” = Article title and abstract fields only. Multiple word terms in double quotation marks are searched as exact phrases. “*” = wildcard character. Words connected with hyphens are searched as exact phrases.

- "clinical equivalencies"
- "clinical equivalency"
- "clinical equivalent"
- "combination regimen"
- "combination regimens"
- "combination therapies"
- "combination therapies"[ti]
- "combination therapy"
- "combination therapy"[ti]
- "combination treatments"[ti]
- "combo drugs"
- "cost sharing"
- "cost sharing"[ti]
- "economic productivity"
- "extended release"
- "extended tab"
- "extended tabs"
- "financial burden"
- "fixed dose"
- "generic equivalencies"
- "generic equivalency"
- "generic equivalent"
- "generic substitution"
- "hep c"
- "hep c"[ti]
- "hep c"[tiab]
- "hepatitis c"[ti]
- "hepatitits c"
- "hepatitits c"[ti]
- "hepatitits c"[tiab]
- "high-cost drug"
- "high-cost drugs"
- "high-cost prescription"
- "high-cost prescriptions"

- "high cost sharing"
- "high cost"
- "high cost"[ti]
- "immediate release"
- "immediate release"
- "multi tab"
- "multi tabs"
- "multiple drug"
- "multiple sclerosis"
- "non-extended release"
- "nonextended release"
- "premature death"
- "prescription drug"
- "prescription drugs"
- "prolonged-release"
- "single pill"
- "single pills"
- "single tab"
- "single tablet regimen"
- "single tablet regimens"
- "single tablet"
- "single tablets"
- "single tabs"
- "specialty drug"
- "specialty drugs"
- "specialty prescription"
- "specialty prescriptions"
- "therapeutic equivalencies"
- "therapeutic equivalency"
- "therapeutic equivalent"
- "therapeutic interchange"
- "therapeutic substitution"
- "triple therapy"
- access
- accessibility
- accessible
- acquired immunodeficiency syndrome
- adherence[ti]
- aids
- aids[tiab]
- alternative*[ti]
- bioequivalence
- bioequivalence[ti]
- bioequivalences
- bioequivalences[ti]
- bioequivalent
- bioequivalent[ti]
- burden[ti]
- co-pay
- combination regimens
- combination therapy
- combo-drugs
- compliance[ti]
- controlled-release
- copay
- costly[ti]
- demand[ti]
- depot preparation
- diabetes
- diabetes[ti]
- disparities[ti]
- disparity
- disparity[ti]
- double-pill
- drug[ti]
- drugs[ti]
- dual-drug
- effective
- effectiveness
- efficacious
- efficacy
- equivalencies
- equivalencies[ti]
- equivalency
- equivalency[ti]
- equivalent
- equivalent[ti]
- expensive[ti]
- extended-tab
- extended-tablets
- extended-tabs
- extended release
- fixed-dose
- hiv
- hiv[ti]
- hiv[tiab]
- hypertension[tiab]
- immediate-release
- insurance
- insurance[ti]
- interchangeable
- interchangeably
- medically necessary
- medication*[ti]

- medication[ti]
- medications[ti]
- monotherapy
- mtr
- multi-pill
- multi-pill
- multi-tab
- multi-tablet*
- multiple-pill
- multitablet*
- necessary[tiab]
- non-adherence[ti]
- non-extended release
- noncontrolled-release
- nonextended release
- nonprolonged-action
- nonsustained-release
- nontimed-release
- out-of-pocket
- pharmaceutical* insurance
- pharmaceutical*[ti]
- pharmacy[ti]
- polypharmacy
- prescription
- prescription drug
- prescription drugs
- prescription[ti]
- prescriptions
- prescriptions[ti]
- productivity[ti]
- prolonged-action
- prolonged release
- reimburse
- reimbursement
- single-pills
- single-tablet
- single-tabs
- specialty drug
- specialty[ti]
- str
- strs
- substitution*[ti]
- sustained-release
- therapies[ti]
- therapy[ti]
- three-pill
- tier
- tier[ti]
- tiers
- timed-release
- treatment*[ti]
- triple-drug
- triple-pill
- two-drug
- two-pill
- utilization[ti]

Business Source Complete

Subject Terms

- su Health Insurance
- su Drug Utilization

Keywords

NOTE: Terms preceded with “ti” searched in title field only. “*” and “#” = wildcard characters. Words connected with hyphens are searched as exact phrases. Multiple word terms in double quotation marks are searched as exact phrases.

- "clinical equivalencies"
- "clinical equivalency"
- "clinical equivalent"
- "combination pill#"
- "combination regimens"
- "delayed-action"

- "enteric-coated"
- "extended release"
- "generic equivalencies"
- "generic equivalency"
- "hep c"
- "hepatitis c"
- "high-cost prescription*"
- "high blood pressure"
- "high cost sharing"
- "multi tab"
- "multi tabs"
- "multiple drug"
- "multiple pill"
- "multiple pills"
- "multiple sclerosis"
- "pharmaceutical pricing combination pill"
- "pharmaceutical pricing extended release"
- "pharmaceutical tier pricing"
- "prolonged release"
- "single pill"
- "single tab"
- "single tablet"
- "single tablets"
- "specialty drug*"
- "specialty prescription*"
- "therapeutic equivalencies"
- "therapeutic equivalency"
- "therapeutic equivalent"
- "tier pricing"
- acquired immune deficiency syndrome
- acquired immunodeficiency syndrome
- bioequivalence
- bioequivalences
- bioequivalent
- co-pay
- combination regimen*
- combo-drugs
- combo-pill#
- combo drug*
- controlled-release
- copay
- cost sharing
- costly
- delayed-action
- depot preparation
- diabetes
- diabetic
- disparities
- disparity
- double-pill
- drug
- drug utilization
- drug*
- drugs
- enteric-coated
- expensive
- extended-tab
- extended-tab*
- extended-tablets
- extended-tabs
- health care access*
- healthcare access
- hiv*
- hypertension
- medication adherence
- medication*
- multi-pill
- multi-tab
- multi-tab*
- multi-tablet*
- multi tab
- multi tablet*
- multi tabs
- multiple-pill
- multiple pill*
- multiple pills
- multitab*
- multitablet*
- patient compliance
- pharmaceutical*
- pharmaceutical* insurance
- pharmaceutical* insurance
- pharmacy
- prescription
- prescription*
- prolonged-action
- single-pills
- single-tablet
- single-tabs
- single pill*
- single tab*
- specialty

- statin#
- statins
- sustained-release
- therapies
- therapy
- three-pill
- ti "clinical equivalencies"
- ti "clinical equivalency"
- ti "clinical equivalent"
- ti "extended release"
- ti "generic equivalencies"
- ti "generic equivalency"
- ti "generic equivalent"
- ti "prolonged release"
- ti "therapeutic equivalencies"
- ti "therapeutic equivalency"
- ti "therapeutic equivalent"
- ti access*
- ti bioequivalence
- ti bioequivalences
- ti bioequivalent
- ti controlled-release
- ti delayed-action
- ti depot preparation
- ti depot preparations
- ti enteric-coated
- ti extended-tab
- ti extended-tablets
- ti extended-tabs
- ti multitablet*
- ti prescription
- ti prescription
- ti prolonged-action
- ti sustained-release
- ti timed-release
- tier
- timed-release
- treatment*
- triple-drug
- triple-pill
- two-drug
- two-pill
- utilisation
- utilization

EconLit

Keywords

NOTE: "*" = wildcard character. "n/#" = words within # characters in any order. Words connected with hyphens are searched as exact phrases. Multiple word terms in double quotation marks are searched as exact phrases.

- "combination drug*"
- "combination pill*"
- "combination regimen*"
- "combination tablet*"
- "cost sharing"
- "delayed-action"
- "drug combinations"
- "enteric-coated"
- "extended release"
- "hep c"
- "hepatitis c"
- "high-cost prescription*"
- "high blood pressure"
- "high cost sharing"
- "high cost"
- "multi tab"
- "multi tabs"
- "multiple drug"
- "multiple sclerosis"
- "pharmaceutical pricing combination pill"
- "pharmaceutical pricing extended release"
- "pharmaceutical tier pricing"
- "prolonged release"
- "single pill*"
- "single tab*"
- "specialty drug*"
- "specialty prescription*"
- "tier pricing"

- access*
- acquired immune deficiency syndrome
- acquired immunodeficiency syndrome
- co-pay
- combination drug*
- combination pill*
- combination regimen*
- combination tablet*
- combo-drug*
- combo-pill*
- combodrug*
- controlled-release
- copay
- cost-sharing
- cost sharing
- costly
- delayed-action
- depot preparation
- depot preparation*
- depot preparations
- diabetes
- diabetic
- disparities
- disparity
- double-pill
- drug
- drug combinations
- drug*
- drugs
- economic productivity
- enteric-coated
- expensive
- extended-tab
- extended-tab*
- extended-tablets
- extended-tabs
- financial burden
- high-cost n/3 prescription*
- hiv*
- hypertension
- immediate-release
- immediate release
- immediaterelease
- insurance
- insurance coverage
- medical insurance
- medication adherence
- medication*
- medication* adherence
- multi-pill
- multi-tab
- multi-tablet*
- multiple-pill
- multitablet*
- patient compliance
- pharmaceutical n/3 pricing n/3 "combination pill"
- pharmaceutical n/3 pricing n/3 "extended release"
- pharmaceutical n/3 tier n/3 pricing
- pharmaceutical*
- pharmaceutical* insurance
- pharmacy
- polypill
- premature death
- premature mortality
- prescription*
- prolonged-action
- single-pill*
- single-tablet*
- single pill*
- single tab*
- single tablet*
- specialty
- specialty n/3 drug*
- specialty n/3 prescription*
- statin*
- statin*
- sustained-release
- therapies
- therapy
- three-pill
- tier
- timed-release
- treatment*
- triple-drug
- triple-pill
- two-drug
- two-pill
- utilisation
- utilization

Web of Science

Keywords

NOTE: Terms preceded with "TITLE:" searched in title field only. "*" = wildcard character. Words connected with hyphens are searched as exact phrases. Multiple word terms in double quotation marks are searched as exact phrases.

- "clinical equivalencies"
- "clinical equivalency"
- "clinical equivalent"
- "combination drug*"
- "combination pill*"
- "combination regimen*"
- "combination tablet*"
- "cost sharing"
- "delayed-action"
- "enteric-coated"
- "extended release"
- "generic equivalencies"
- "generic equivalency"
- "hep c"
- "hepatitis c"
- "high-cost prescription*"
- "high blood pressure"
- "high cost sharing"
- "high cost"
- "immediate release"
- "multi tab"
- "multi tabs"
- "multiple drug"
- "multiple pill*"
- "multiple sclerosis"
- "pharmaceutical pricing combination pill"
- "pharmaceutical pricing extended release"
- "pharmaceutical tier pricing"
- "prolonged release"
- "single pill*"
- "single tab*"
- "single tablet*"
- "specialty drug*"
- "specialty prescription*"
- "therapeutic equivalencies"
- "therapeutic equivalency"
- "therapeutic equivalent"
- "tier pricing"
- access*
- acquired immune deficiency syndrome
- acquired immunodeficiency syndrome
- bioequivalence
- bioequivalences
- bioequivalent
- co-pay
- combo-drug*
- combo-pill*
- combodrug*
- controlled-release
- copay
- cost-sharing
- costly
- delayed-action
- depot preparation
- depot preparation*
- depot preparations
- diabetes
- diabetic
- disparities
- disparity
- double-pill
- drug
- drug*
- drugs
- economic productivity
- expensive
- extended-tab
- extended-tab*
- extended-tablets
- extended-tabs

- financial burden
- hiv*
- hypertension
- immediate-release
- immediaterelease
- insurance coverage
- medical insurance
- medication adherence
- medication*
- medication* adherence
- multi-pill
- multi-tab
- multi-tab*
- multi-tablet*
- multiple-pill
- multiple drug pill*
- multiple drug tablet*
- multitablet*
- non-extended release pill*
- non-extended release tablet*
- non-extended tab*
- non-extended tablet*
- nonextended tab*
- patient compliance
- patient* complian*
- pharmaceutical*
- pharmaceutical* insurance
- pharmacy
- polypill
- premature death
- premature mortality
- prescription
- prescription*
- prolonged-action
- single-pill*
- single-tablet*
- specialty
- statin*
- sustained-release
- therapies
- therapy
- three-pill
- tier
- timed-release
- Timespan: All years. Indexes: SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH.
- TITLE:(\"clinical equivalencies\")
- TITLE:(\"clinical equivalency\")
- TITLE:(\"clinical equivalent\")
- TITLE:(\"cost sharing\")
- TITLE:(\"extended release pill*\")
- TITLE:(\"extended release tablet*\")
- TITLE:(\"extended release\")
- TITLE:(\"extended tab\")
- TITLE:(\"extended tablets\")
- TITLE:(\"extended tabs\")
- TITLE:(\"generic equivalencies\")
- TITLE:(\"generic equivalency\")
- TITLE:(\"generic equivalent\")
- TITLE:(\"high cost sharing\")
- TITLE:(\"high cost\")
- TITLE:(\"immediate release\")
- TITLE:(\"prolonged release\")
- TITLE:(\"therapeutic equivalencies\")
- TITLE:(\"therapeutic equivalency\")
- TITLE:(\"therapeutic equivalent\")
- TITLE:(\"tier pricing\")
- TITLE:(access*)
- TITLE:(access*)
- TITLE:(acquired immune deficiency syndrome)
- TITLE:(acquired immunodeficiency syndrome)
- TITLE:(bioequivalence)
- TITLE:(bioequivalences)
- TITLE:(bioequivalent)
- TITLE:(co-pay)
- TITLE:(controlled-release)
- TITLE:(copay)
- TITLE:(cost-sharing)
- TITLE:(costly)
- TITLE:(delayed-action)
- TITLE:(depot preparation)
- TITLE:(depot preparations)
- TITLE:(disparities)
- TITLE:(disparity)
- TITLE:(drug)
- TITLE:(drugs)
- TITLE:(effective)
- TITLE:(effectiveness)
- TITLE:(efficacy)
- TITLE:(enteric-coated)
- TITLE:(expensive)

- TITLE:(extended-tab)
- TITLE:(extended-tablets)
- TITLE:(extended-tabs)
- TITLE:(hiv*)
- TITLE:(immediate-release)
- TITLE:(immediaterelease)
- TITLE:(insurance)
- TITLE:(medication adherence)
- TITLE:(patient compliance)
- TITLE:(patient* complian*)
- TITLE:(prescription)
- TITLE:(prolonged-action)
- TITLE:(specialty)
- TITLE:(sustained-release)
- TITLE:(tier)
- TITLE:(timed-release)
- TITLE:(utilisation)
- TITLE:(utilization)
- treatment*
- triple-drug
- triple-pill
- two-drug
- two-pill
- utilisation
- utilization

Cochrane Library

Keywords

NOTE: “*” = wildcard character. Words connected with hyphens are searched as exact phrases. Multiple word terms in double quotation marks are searched as exact phrases.

- "clinical equivalencies"
- "clinical equivalency"
- "clinical equivalent"
- "combination drug*"
- "combination pill*"
- "combination regimen*"
- "combination tablet*"
- "cost sharing"
- "extended release"
- "generic equivalencies"
- "generic equivalency"
- "generic equivalent"
- "immediate release"
- "multiple pill*"
- "prolonged release"
- "single pill*"
- "single tab*"
- "single tablet*"
- "therapeutic equivalencies"
- "therapeutic equivalency"
- "therapeutic equivalent"
- access*
- bioequivalence
- bioequivalences
- bioequivalent
- combo-drug*
- combodrug*
- controlled-release
- cost-sharing
- delayed-action
- depot preparation
- depot preparations
- disparities
- disparity
- drug
- drug*
- drugs
- economic productivity
- enteric-coated
- extended-tab
- extended-tablets
- extended-tabs
- financial burden
- immediate-release
- immediaterelease
- insurance
- medication adherence

- medication* adherences
- multi-tab*
- multi-tablet*
- multi tablet
- multiple drug pill*
- multiple drug tablet*
- multitablet*
- patient compliance
- polypill
- premature death
- premature mortality
- prescription*
- prolonged-action
- single-pill*
- single-tablet*
- sustained-release
- timed-release
- utilisation
- utilization

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

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

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm, Milliman, Inc.⁶⁰

Data Sources

This subsection discusses the variety of data sources CHBRP uses. Key sources and data items are listed below, in **Table 13**.

Table 13. Data for 2016 Projections

Data Source	Items
California Department of Health Care Services (DHCS) administrative data for the Medi-Cal program, data available as of end of December 2014	Distribution of enrollees by managed care or FFS distribution by age: 0–17; 18–64; 65+ Medi-Cal Managed Care premiums
California Department of Managed Health Care (DMHC) data from the interactive website “Health Plan Financial Summary Report,” August–October, 2014	Distribution of DMHC-regulated plans by market segment*
California Department of Insurance (CDI) Statistical Analysis Division data; data as of December 31, 2013	Distribution of CDI-regulated policies by market segment
California Health Benefits Review Program (CHBRP) Annual Enrollment and Premium Survey of California’s largest (by enrollment) health care service plans and health insurers; data as of September 30, 2014; responders’ data represent approximately 97.3% of	Enrollment by: <ul style="list-style-type: none"> • Size of firm (2–50 as small group and 51+ as large group) • DMHC vs. CDI regulated

⁶⁰ CHBRP’s authorizing legislation requires that CHBRP use a certified actuary or “other person with relevant knowledge and expertise” to determine financial impact (www.chbrp.org/docs/authorizing_statute.pdf).

Data Source	Items
<p>persons not associated with CalPERS or Medi-Cal with health insurance subject to state mandates—98.0% of full-service (nonspecialty) DMHC-regulated plan enrollees and 97.0% of full-service (nonspecialty) CDI-regulated policy enrollees.</p>	<ul style="list-style-type: none"> • Grandfathered vs. nongrandfathered <p>Premiums for individual policies by:</p> <ul style="list-style-type: none"> • DMHC vs. CDI regulated • Grandfathered vs. nongrandfathered
<p>California Employer Health Benefits Survey, 2014 (conducted by NORC and funded by CHCF)</p>	<p>Enrollment by HMO/POS, PPO/indemnity self-insured, fully insured,</p> <p>Premiums (not self-insured) by:</p> <ul style="list-style-type: none"> • Size of firm (3–25 as small group and 25+ as large group) • Family vs. single • HMO/POS vs. PPO/indemnity vs. HDHP employer vs. employer premium share
<p>California Health Interview Survey (CHIS) 2012/2013/T7 (“T7” representing the first 6 months of 2014)</p>	<p>Uninsured, age: 65+</p> <p>Medi-Cal (non-Medicare), age: 65+</p> <p>Other public, age: 65+</p> <p>Employer-sponsored insurance, age: 65+</p>
<p>California Public Employees’ Retirement System (CalPERS) data, enrollment as of October 1, 2014</p>	<p>CalPERS HMO and PPO enrollment</p> <ul style="list-style-type: none"> • Age: 0–17; 18–64; 65+ <p>HMO premiums</p>
<p>California Simulation of Insurance Markets (CalSIM) Version 1.9.1 (projections for 2016)</p>	<p>Uninsured, age: 0–17; 18–64</p> <p>Medi-Cal (non-Medicare) (a), age: 0–17; 18–64</p> <p>Other public (b), age: 0–64</p> <p>Individual market, age: 0–17; 18–64</p> <p>Small group, age: 0–17; 18–64</p>

Data Source	Items
	Large group, age: 0–17; 18–64
Centers for Medicare and Medicaid (CMS) administrative data for the Medicare program, annually (if available) as of end of September	HMO vs. FFS distribution for those 65+ (noninstitutionalized)
Milliman estimate	Medical trend influencing annual premium

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

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

Further discussion of external and internal data follows.

Internal data

- CHBRP’s Annual Enrollment and Premium Survey collects data from the seven largest providers of health insurance in California (including Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and United Healthcare/PacificCare) to obtain estimates of enrollment not associated with CalPERS or Medi-Cal by purchaser (i.e., large and small group and individual), state regulator (DMHC or CDI), grandfathered and nongrandfathered status, and average premiums. CalSIM and market trends were applied to project 2016 health insurance enrollment in DMHC-regulated plans and CDI-regulated policies.
- CHBRP’s other surveys of the largest plans/insurers collect information on benefit coverage relevant to proposed benefit mandates CHBRP has been asked to analyze. In each report, CHBRP indicates the proportion of enrollees—statewide and by market segment—represented by responses to CHBRP’s bill-specific coverage surveys. The proportions are derived from data provided by CDI and DMHC.

External sources

- California Department of Health Care Services (DHCS) data are used to estimate enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System plans), which may be subject to state benefit mandates, as well as enrollment in Medi-Cal Fee For Service (FFS), which is not. The data are available at: www.dhcs.ca.gov/dataandstats/statistics/Pages/Monthly_Trend_Report.aspx. Medi-Cal enrollment is projected to 2016 based on CalSIM’s estimate of the continuing impact of the Medi-Cal expansion implemented in 2014.
- California Employer Health Benefits Survey data are used to make a number of estimates, including: premiums for employment-based enrollment in DMHC-regulated health care service plans (primarily health maintenance organizations [HMOs] and point of service [POS] plans) and premiums for employment-based enrollment in CDI-regulated health insurance policies regulated by the (primarily preferred provider organizations [PPOs]). Premiums for fee-for-service (FFS)

policies are no longer available due to scarcity of these policies in California. This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. More information on the CHCF/NORC data is available at: www.chcf.org/publications/2014/01/employer-health-benefits.

- California Health Interview Survey (CHIS) data are used to estimate the number of Californians aged 65 and older, and the number of Californians dually eligible for both Medi-Cal and Medicare coverage. CHIS data are also used to determine the number of Californians with incomes below 400% of the federal poverty level. CHIS is a continuous survey that provides detailed information on demographics, health insurance coverage, health status, and access to care. More information on CHIS is available at: www.chis.ucla.edu.
- California Public Employees Retirement System (CalPERS) data are used to estimate premiums and enrollment in DMHC-regulated plans, which may be subject to state benefit mandates, as well as enrollment in CalPERS' self-insured plans, which is not. CalPERS does not currently offer enrollment in CDI-regulated policies. Data are provided for DMHC-regulated plans enrolling non-Medicare beneficiaries. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOC) documents publicly available at: www.calpers.ca.gov. CHBRP assumes CalPERS's enrollment in 2016 will not be affected by continuing shifts in the health insurance market as a result of the ACA.
- California Simulation of Insurance Markets (CalSIM) estimates are used to project health insurance status of Californians aged 64 and under. CalSIM is a microsimulation model that projects the effects of the Affordable Care Act on firms and individuals. More information on CalSIM is available at: <http://healthpolicy.ucla.edu/programs/health-economics/projects/CalSIM/Pages/default.aspx>.
- 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. Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed health care plans, generally those characterized as PPO plans. More information on the Milliman HCGs is available at: <http://us.milliman.com/Solutions/Products/Resources/Health-Cost-Guidelines/Health-Cost-Guidelines---Commercial/>.
- The MarketScan databases, which reflect the health care claims experience of employees and dependents covered by the health benefit programs of large employers. These claims data are collected from insurance companies, Blue Cross Blue Shield plans, and third party administrators. These data represent the medical experience of insured employees and their dependents for active employees, early retirees, individuals with COBRA continuation coverage, and Medicare-eligible retirees with employer-provided Medicare Supplemental plans. No Medicaid or Workers Compensation data are included.
- Ingenix MDR Charge Payment System, which includes information about professional fees paid for health care services, based upon claims from commercial insurance companies, HMOs, and self-insured health plans.

Projecting 2016

This subsection discusses adjustments made to CHBRP's Cost and Coverage Model to project 2016, the period when mandates proposed in 2015 would, if enacted, generally take effect. It is important to emphasize that CHBRP's analysis of specific mandate bills typically addresses the incremental effects of a mandate—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, *holding all other factors constant*. CHBRP's estimates of these incremental effects are presented in the *AB 339 Impacts on Benefit Coverage, Utilization, and Cost, 2015* section of this report.

Baseline premium rate development methodology

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

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

For each market segment, CHBRP first obtained an estimate of the insurance premium PMPM by taking the 2014 reported premium from the abovementioned data sources and trending that value to 2016. CHBRP uses trend rates published in the Milliman HCGs to estimate the health care costs for each market segment in 2016.

The large-group market segments for each regulator (CDI and DMHC) are split into grandfathered and nongrandfathered status. For the small-group and individual markets, further splits are made to indicate association with Covered California, the state's health insurance marketplace. Doing so allows CHBRP to separately calculate the impact of ACA and of specific mandates, both of which may apply differently among these subgroups. The premium rate data received from the CHCF/NORC California Employer Health Benefits survey did not split the premiums based on grandfathered or exchange status. However, CHBRP's Annual Enrollment and Premium (AEP) survey asked California's largest health care service plans and health insurers to provide their average premium rates separately for grandfathered and nongrandfathered plans. The ratios from the CHBRP survey data were then applied to the CHCF/NORC aggregate premium rates for large and small group, to estimate premium rates for grandfathered and nongrandfathered plans that were consistent with the NORC results. For the individual market, the premium rates received from CHBRP's AEP survey were used directly.

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

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

In the above formulas, the quantity “profit/administration load” is the assumed percentage of a typical premium that is allocated to the health plan/insurer's administration and profit. These values vary by

insurance category, and under the ACA, are limited by the minimum medical loss ratio requirement. CHBRP estimated these values based on actuarial expertise at Milliman, and their associated expertise in health care.

In the above formulas, the quantity “percentage paid by health plan” is the assumed percentage of gross health care costs that are paid by the health plan, as opposed to the amount paid by member cost sharing (deductibles, copays, etc.). In ACA terminology, this quantity is known as the plan’s “actuarial value.” These values vary by insurance category. For each insurance category, Milliman estimated the member cost sharing for the average or typical plan in that category. Milliman then priced these plans using the Milliman Health Cost Guidelines to estimate the percentage of gross health care costs that are paid by the carrier.

General Caveats and Assumptions

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

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

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

- Cost impacts are shown only for plans and policies subject to state benefit mandate laws.
- Cost impacts are only for the first year after enactment of the proposed mandate.
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of the premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for 1 year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP’s criteria for estimating long-term impacts, please see: www.chbrp.org/analysis_methodology/docs/longterm_impacts08.pdf.
- Several studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew et al., 2005; Glied and Jack, 2003; Hadley, 2006). Chernew et al. (2005) estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, whereas Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and a 0.84 percentage point decrease in the number of insured, respectively. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the

simplifying assumption that the elasticity is the same across different types of markets. For more information on CHBRP's criteria for estimating impacts on the uninsured, please see *Criteria and Methods for Estimating the Impact of Mandates on the Number of Individuals Who Become Uninsured in Response to Premium Increases*, available at:

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 estimates presented in this report. Such variables include, but are not limited to:

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

Analysis Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions relevant to specifically to an analysis of AB 339.

AB 339 broadly targets pharmacy benefit administration through its requirements that affect coverage of outpatient prescription drugs, structure of formularies, and definitions used to establish tiers. Because of

the breadth of this bill, it would require an analysis that forecasts how carriers might respond and anticipates all relevant coverage scenarios, examining the restructuring entire formularies. In CHBRP's survey of carriers, each carrier independently expressed their inability to determine how AB 339 would be implemented. As such, this analysis does not offer the full scope of the benefit coverage, utilization, and cost impacts of AB 339 were it to be enacted.

Public Demand for Benefit Coverage

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

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

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

Among publicly funded self-insured health insurance policies, the Preferred Provider Organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate, although there is less use of coinsurance as a cost-sharing mechanism for prescription drugs.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

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

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A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, Milliman Inc., to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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

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

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

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