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 in 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.