California Health Benefits Review Program

Analysis of California Assembly Bill (AB) 1831 Topical Ophthalmic Refills

A Report to the 2015-2016 California State Legislature

April 11, 2016



Key Findings: Analysis of California Assembly Bill (AB) 1831 Topical Ophthalmic Refills



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

AT A GLANCE

Assembly Bill (AB) 1831 (introduced February 2016) would prohibit denial of refill coverage for covered topical ophthalmic products (TOPs) at and after 70% of predicted use.

Enrollees covered. CHBRP estimates that in 2017, 25.2 million Californians will have health insurance that would be subject to AB 1831.

- **Benefit coverage.** The terms of coverage for 85% of enrollees would change, where coverage had been available for TOPs refills at and after 75% to 85% of projected use, refills would be covered at 70% of projected use.
- **Utilization.** Due to earlier refills, annual utilization of TOPs would increase by 0.5%.
- **Expenditures.** An increase of 0.0007% (premiums and cost sharing) would occur.
- **EHBs.** The mandate would alter the terms but not require new benefit coverage and so would not exceed EHBs.
- Medical effectiveness and public health. There is insufficient evidence to suggest that the limited number of additional days of adherence made possible by AB 1831 would measurably impact the effectiveness of treatment or related health outcomes.

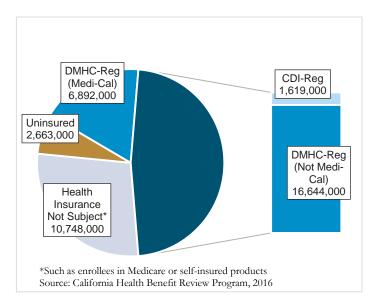
Background

Topical ophthalmic products (TOPs), which include eye drops and ointments, are prescribed for both acute and chronic conditions, but AB 1831 would most likely affect only patients who require multiple refills to treat chronic diseases and conditions, including ocular hypertension, glaucoma, uveitis, and chronic dry eye disease. TOPs are applied to the eyes as drops or small amounts of ointment. TOPs are not dispensed in a pre-set, quantifiable dose (such as a pill). Accidental over-use or wastage (too many drops at once or drops outside of the eye) can result in early exhaustion: exhaustion before the projected period of use for a bottle or tube of TOPs.

BILL SUMMARY

AB 1831 would be relevant to the 25.2 million Californians who have health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI).





For enrollees who have outpatient prescription drug (OPD) benefit regulated by DMHC or CDI, AB 1831 would prohibit refill coverage denials for TOPs at and after 70% of predicted of use.

IMPACT OF AB 1831

Benefit Coverage, Utilization, and Cost

Currently, 15% of enrollees have benefit coverage compliant with AB 1831, refills for TOPs at and after 70% of projected use. The remaining 85% of enrollees have coverage for TOPs refills at and after 75 to 85% of projected use. Although not all enrollees with affected health insurance would use of the earlier refill coverage,

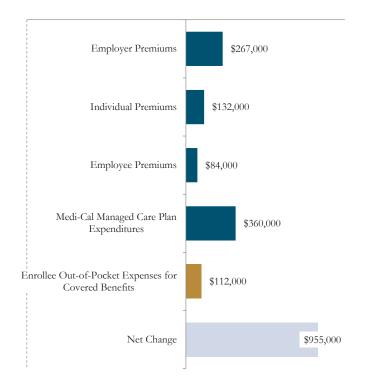


AB 1831 would require refill coverage for a 30-day TOPs prescription at/after day 21 (instead of at/after day 23 or day 26).

CHBRP expects that, on average, the postmandate possibility of earlier refill coverage would result in one additional refill per year among enrollees with a chronic condition and changed benefit coverage.

AB 1831 would be expected to increase total expenditures (premiums and cost sharing) by 0.0007% in the 12 months following implementation of the mandate. Figure 2 presents details of the expected expenditure impacts.

Figure 2. Expenditure Impacts of AB 1831



Medical Effectiveness and Public Health Impacts

Along with accidental overuse and wastage, systematic adherence to a treatment regimen contributes to early bottle exhaustion. Therefore, AB 1831 is mostly likely to improve adherence among typically adherent patients.

There is insufficient evidence to suggest that the limited number of additional days (often as few as 1-3 days) of

adherence made possible by AB 1831 would measurably impact the effectiveness of treatment.

For this reason, CHBRP does not project a measurable impact on the population's health outcomes within the first year of the bill's passage into law.

Long-Term Impacts

As is the case for the first year, there is insufficient evidence to suggest that the limited number of additional days of adherence made possible by AB 1831 would measurably impact health outcomes in the years following the bill's passage into law. However, the average age of Californians has been increasing, and is expected to continue to do so. Resulting increases in age-related chronic eye conditions may lead to greater use of TOPs and so to greater use of the earlier refills that AB 1831 would require.

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REVISION HISTORY

Date	Description of Revisions
May 3, 2016	 Number in text of Key Findings on page iii On page ii and on page iii of the Key Findings, the expenditure impact was misquoted as 0.0004% - though it was elsewhere (in Table 1, etc), correctly quoted as 0.0007. The number in Key Findings has been corrected in this revised version. Table 7 on page D-12, Appendix D In Table 7 (Outpatient Prescription Drug Coverage in the Large-Group and Publicly Funded Markets, 2017), CHBRP corrected two mislabeled rows. In the original report, the rows for "No OPD Coverage" and "Other OPD Coverage" were mislabeled. The error is corrected in this revised version.

ABOUT CHBRP

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



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

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

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AB 1831 IMPACTS ON BENEFIT COVERAGE, UTILIZATION, AND COST

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

	Premandate	Postmandate	Increase/ Decrease	Change Postmandate
senefit coverage				
Total enrollees with health insurance subject to state benefit mandates ^(a)	25,155,000	25,155,000	0	0%
Total enrollees with health insurance subject to AB 1831	25,155,000	25,155,000	0	0%
Number of enrollees with health insurance compliant with AB 1831 ^(b)	3,858,000	25,155,000	21,297,000	552%
Percentage of enrollees with health insurance compliant with AB 1831 ^(b)	15%	100%	85%	552%
tilization and cost				
Total enrollees using topical ophthalmic products	691,000	691,000	0	0%
Topical ophthalmic products utilization (filled prescriptions per 1,000 covered enrollees)	48.43	48.69	0.26	0.5%
Average per unit cost (per prescription)	\$121	\$121	\$0	0%
xpenditures				
Premium expenditures by payer				
Private employers for group insurance	\$64,837,024,000	\$64,837,287,000	\$263,000	0.0004%
CalPERS HMO employer expenditures ^(c)	\$4,756,143,000	\$4,756,147,000	\$4,000	0.0001%
Medi-Cal Managed Care Plan expenditures ^(d)	\$16,670,700,000	\$16,671,060,000	\$360,000	0.0022%
Enrollees for individually purchased insurance	\$22,073,116,000	\$22,073,248,000	\$132,000	0.0006%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care ^{(a)(e)}	\$20,496,488,000	\$20,496,572,000	\$84,000	0.0004%
Enrollee expenses				
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$16,248,327,000	\$16,248,439,000	\$112,000	0.0007%
Total expenditures	\$145,081,798,000	\$145,082,753,000	\$955,000	0.0007%

Source: California Health Benefits Review Program, 2016.

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

(b) Premium expenditures by enrollees include employee contributions to employer-sponsored health insurance and

enrollee contributions for publicly purchased insurance.

(c) Of the increase in CalPERS employer expenditures, about 56.7% or \$2,268 would be state expenditures for CalPERS members who are state employees or their dependents.

(d) Does not include enrollees in COHS.

(e) Includes only those expenses that are paid directly by enrollees to providers for services related to the mandated benefit that are not currently covered by insurance. In addition, 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; COHS=County Operated Health Systems

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)¹ conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 1831, Topical Ophthalmic Refills.

If enacted, AB 1831 would affect the health insurance of approximately 25.2 million enrollees (65% of all Californians). This represents 100% of the 25.2 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law — health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would affect the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies.

Bill-Specific Analysis of AB 1831, Topical Ophthalmic Refills

AB 1831 would prohibit DMHC-regulated plans and CDI-regulated insurers that provide outpatient prescription drug (OPD) benefits from denying coverage for the refill of covered topical ophthalmic products (TOPs) at and after 70% of the predicted days of use.

Note regarding language — the bill refers to "topical ophthalmic products at 70 percent of the predicted days of use." Because refills might be requested "at and after" 70% of use, CHBRP has assumed that AB 1831 would affect the efforts of enrollees seeking refills at and after 70% of predicted use (not just "at" 70%).

The full text of AB 1831 can be found in Appendix A.

General Caveat for All CHBRP Analyses

It is important to note that CHBRP's analyses of proposed benefit mandate bills address incremental effects — how the proposed legislation would impact benefit coverage, utilization, costs, and public health. CHBRP's estimates of these incremental effects are presented in this report.

Analytic Approach and Key Assumptions

As further discussed in Appendix D, approximately 1.8% of enrollees in DMHC-regulated plans and CDIregulated policies have no coverage for outpatient prescription drugs (OPDs) and 3.1% have OPD coverage that is not regulated by DMHC or CDI. The health insurance of all these enrollees is considered to be compliant with AB 1831 (which is applicable only if the enrollee has an OPD benefit subject to regulation by DMHC or CDI) and so CHBRP has projected no mandate impacts related to enrollees without a DMHC- or CDI-regulated OPD benefit.

Interaction with Existing Requirements

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

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

State Requirements

California law and regulations

CHBRP is unaware of state laws placing requirements similar to the AB 1831 mandate on DMHCregulated plans or CDI-regulated policies.

Similar requirements in other states

CHBRP is aware, through a variety of sources, including the Blue Cross Blue Shield Association (BCBSA, 2015), of laws relevant to coverage for early refills for TOPs in a number of other states, including AK, CT, KY, MO, NJ, NY, OR, RI, and WY.

Federal Requirements

CHBRP is unaware of federal laws placing requirements similar to the AB 1831 mandate on DMHCregulated plans or CDI-regulated policies.

CHBRP is aware that the Centers for Medicare and Medicaid Services (CMS) has issued guidance to Medicare Part D sponsors regarding coverage for refills for TOPs at and after 70% of the predicted days of use.² However, although CMS' guidance cites complaints and offers general reasoning as to why eye drops refills should be available earlier than pill refills (greater difficulty in administration), the guidance does not cite evidence related to any clinical effect of the limited number of additional days' of medication such coverage could make available.

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to interact with state benefit mandates. However, because AB 1831 specifies terms of existing benefit coverage, it appears that AB 1831 would not exceed essential health benefits (EHBs), and so would not trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in qualified health plans (QHPs)³ in Covered California.

² Centers for Medicare and Medicaid Services (CMS), memo to Part D Plan Sponsors, "Early Refill Edits on Topical Ophthalmic Products," June 2, 2010. Available at <u>https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoEarlyRefillOpth_060210.pdf</u>

³ In California, QHPs are nongrandfathered small-group and individual market DMHC-regulated plans and CDIregulated policies sold in Covered California, the state's health insurance marketplace.

BACKGROUND ON TOPICAL OPHTHALMIC PRODUCTS

Topical ophthalmic products (TOPs) are a class of drugs that include eye drops and ointments that are used to treat multiple eye diseases and conditions. TOPs can be prescribed for both acute and chronic conditions. Acute eye conditions include short-term illnesses, such as viral or bacterial infections, injuries, or post-surgical recovery. Chronic eye conditions would include diseases with long-term treatments, lasting months, years, or the rest of patients' lives. AB 1831 would most likely affect a subset of patients who require **multiple refills of TOPs** to treat **chronic diseases**. As the treatment of acute diseases typically involves a single, closed-end prescription taken to completion, acute conditions treated with TOPs are not included in this analysis.

Prevalence of Chronic Eye Diseases Treated with Topical Ophthalmic Products in California

The most serious and prevalent chronic conditions treated with TOPs are described below, including ocular hypertension, glaucoma, uveitis, chronic dry eye disease, and allergic conjunctivitis. For chronic diseases, TOPs are used to prevent vision loss, pain, inflammation, and other symptoms caused by these diseases. California-specific prevalence data is presented for uveitis, while data on the other diseases are from studies conducted elsewhere in the U.S. No evidence suggests that the prevalence of these diseases in California would differ significantly from other U.S. locations.

Ocular hypertension, or increased pressure within one or both eyes (i.e., intraocular pressure), is a risk factor for developing open-angle glaucoma. Untreated, undiagnosed, or poorly controlled ocular hypertension can progress to irreversible visual loss. Ocular hypertension affects approximately 4.5% of all U.S. adults age 40 and older (Leske, 1983; Tielsch et al., 1991a).

Glaucoma is a term for a group of conditions with the common feature of damage to the optic nerve, often associated with elevated intraocular pressure. If untreated, glaucoma can lead to acute eye pain or eventual blindness. The prevalence of glaucoma is approximately 2.0% among adults age 40 and older in the U.S., and is the second-leading cause of blindness (Leske, 1983; Tielsch et al., 1991b; Yanoff and Duker, 2014).

Uveitis is inflammation of the uvea, the middle layer of tissue in the eye. Uveitis can be caused by several underlying conditions, including infection, genetic and immune disorders (e.g., lupus, ankylosing spondylitis), and certain medications. Uveitis can cause pain and blurred vision, and may lead to cataracts, glaucoma, and blindness (Power, 2000). A population study of uveitis in Northern California found that the disease affects approximately 2 to 6 per 1,000 persons (Gritz and Wong, 2004). Furthermore, uveitis may be responsible for 10% to 15% of blindness cases (Suttorp-Schulten and Rothova, 1996).

Chronic dry eye disease, sometimes known as keratoconjunctivitis sicca (KCS), describes a syndrome of inadequate quantity or quality of tears, leading to dry eyes and discomfort or pain. If untreated, there is a risk for damage to the ocular surface (International Dry Eye Workshop, 2007). Chronic dry eye disease affects approximately 14% of the population (Moss et al., 2000).

Allergic conjunctivitis is a common condition developing on exposure to an allergen. This condition rarely threatens vision, but symptoms of burning, itching, and tearing eyes cause significant discomfort, similar to dry eye disease (Hom et al., 2012). Estimates of the prevalence of allergic conjunctivitis in the U.S. range from 15% to 40% of the population (Rosario and Bielory, 2011).

Prevalence of Refill Issues and Early Bottle Exhaustion for Topical Ophthalmic Products

Limited research suggests that a proportion of patients with these chronic eye conditions could face issues with TOP refills. Studies using pharmacy claims data have shown that up to 90% of glaucoma patients do not refill their TOP medication consistently (i.e., in a way that would permit continuous availability of TOPs) and that approximately 25% of patients may be without eye drops an average of 109 days per year (Gurwitz et al., 1998; Nordstrom et al., 2005; Quigley and Broman, 2006). However, these studies could not clarify the reasons or consequences of refill inconsistency, such as if this is due to behavioral factors or issues with obtaining a refill, or if patients' vision was deteriorating as a result. Specific to the issue of running out of TOP medication, 25% of a sample of glaucoma patients reported experiencing any early exhaustion of eye drop bottles (i.e., running out of eye drops before they were due to be refilled), with 5% reporting early bottle exhaustion five or more times a year (Moore et al., 2014). Poor vision was a risk factor for early exhaustion among those who run out at least five times per year. The top reasons patients cited for early TOP exhaustion were that more than one drop came out (31%), there was an insufficient amount in the bottle (18%), or the drop size was too large or inconsistent (18%) (Moore et al., 2014).

Burden of Chronic Illnesses Treated with Topical Ophthalmic Products and Inconsistent Adherence to Treatment

This section outlines the cost burden of these chronic eye diseases and issues of inconsistent adherence to TOPs in the U.S., as California-specific estimates were not available. Although no specific cost or burden analyses were found for **uveitis**, the remaining four diseases (chronic dry eye disease, allergic conjunctivitis, glaucoma, and ocular hypertension) described in the previous section contribute to direct and indirect costs estimated at \$68 billion (Blaiss, 2007; Rein et al., 2006; Yu et al., 2011).⁴ The burden of age-related chronic visual disorders including ocular hypertension, glaucoma, uveitis, and chronic dry eye disease is expected to increase as the U.S. population ages (Rein et al., 2006) and an increasing burden of allergies and respiratory disease worldwide, including allergic conjunctivitis, potentially due to increased urbanization and exposure to pollution-related allergens (Hansen et al., 2013; Sly, 1999).

Although only a portion of these disease-associated costs could be attributed to the consequences of inconsistent adherence to TOP medication, CHBRP found no studies to quantify this burden, or the fractional burden associated with early exhaustion of TOP prescriptions.

⁴ Glaucoma, which includes ocular hypertension to an extent, generates \$2.9 billion in medical costs per year in the U.S. (Rein et al., 2006). Total costs associated with allergic rhinoconjunctivitis, which includes **allergic conjunctivitis**, have been estimated to be between \$3.2 to \$6.0 billion per year in direct medical costs and indirect losses in productivity (Blaiss, 2007). The costs of **chronic dry eye disease** have been estimated at \$3.8 billion in direct medical costs and \$55.4 billion in productivity losses and other indirect costs per year (Yu et al., 2011).

Social Determinants of Health⁵ and Disparities⁶ in Chronic Eye Diseases Treated with Topical Ophthalmic Products

Per statute, CHBRP now includes discussion of disparities under the broader umbrella of social determinants of health (SDoH). SDoH include factors outside of the traditional medical care system that influence health status and health outcomes. CHBRP will consider the full range of SDoH and related disparities (e.g., income, education, and social constructs around age, race/ethnicity, gender, and gender identity/sexual orientation) that are relevant to this bill and where evidence is available. In the case of AB 1831, evidence shows that SDoH regarding environmental issues may play a role in the growing prevalence of allergic conjunctivitis. In addition, education, income, and health literacy may contribute to racial/ethnic disparities in access to care and vision problems associated with glaucoma. However, there is little evidence that these disparities are clearly related to access or use of TOPs, with the exception of racial/ethnic disparities related to health literacy.

Disparities in Chronic Eye Diseases Treated with Topical Ophthalmic Products

Age

Three out of five chronic illnesses treated with TOPs previously described in this report are more prevalent among specific age groups. **Ocular hypertension**, **glaucoma**, and **chronic dry eye disease** are more prevalent in adults over 40, and increasingly prevalent in older adults. Figure 3 compares prevalence rates for these four diseases between middle-aged and older adults based on estimates from available literature, and demonstrates that these diseases are up to three times more prevalent in older adults. These disparities are attributed to the physiological issues of aging, and not age-related SDoH such as income or education levels.

Moore and colleagues' study on early TOP exhaustion in glaucoma patients found a significant association between running out of eye drops and disease severity, but no similar significant association with older age (Moore et al., 2014). However, the issues of medication availability and early refills of TOPs for these four diseases addressed by AB 1831 may be more relevant to adults age 65 and older due to greater disease severity and difficulty administering eye drops in older adults. Medicare is the primary payer for TOPs and TOPs refills for these older adults, and already covers TOPs refills at and after 70% (see *Policy Context* section). In any case, Medicare is not subject to state-level mandates, and so these persons' benefit coverage and utilization would not be affected by AB 1831. Nonetheless, these conditions also affect a proportion of the population aged 40 to 64, and a DMHC-regulated plan or a CDI-regulated policy would be the primary payer for many of these persons. The *Benefit Coverage, Utilization, and Cost Impacts* section includes impacts for these persons.

⁵ CHBRP defines SDoH as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from APHA, 2014; Healthy People 2020, 2015). See *Incorporating Relevant Social Determinants of Health into CHBRP Benefit Mandate Analyses*, available at www.chbrp.org/analysis_methodology/public_health_analysis.php.

⁶ Several competing definitions of "health disparities" exist. CHBRP relies on the following definition:

[&]quot;Health disparities are potentially avoidable differences in health (or health risks that policy can influence) between groups of people who are more or less advantaged socially; these differences systematically place socially disadvantaged groups" at risk for worse health outcomes (Braveman, 2006).

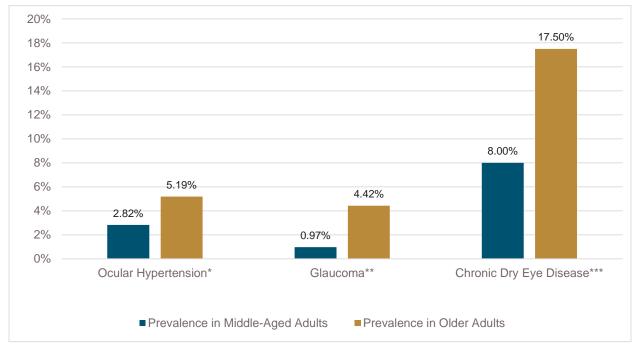


Figure 3. Comparison of the Prevalence of Ocular Hypertension, Glaucoma, and Chronic Dry Eye Disease among Middle-Aged and Older Adults in the U.S.

Source: Leske, 1983; Moss et al., 2000; Tielsch et al., 1991a; Varma et al., 2004

Variance in age ranges due to limitations of available data:

* Ocular hypertension age ranges: 40-59 (middle-aged) vs. 60+ (older adults). Point-prevalence presented.

** Glaucoma age ranges: 40-64 (middle-aged) vs. 65+ (older adults). Point-prevalence presented.

*** Chronic Dry Eye Disease age ranges: 48-59 (middle-aged) vs. 60+ (older adults). Point-prevalence presented.

In contrast to these four diseases, children and young adults may be more affected by **allergic conjunctivitis** than older adults, with prevalence estimates ranging from nearly 30% in individuals aged 17 to 29 and 8% in those aged 70 to 79 (Nathan et al., 1997; Rosario and Bielory, 2011; Singh et al., 2010). Research suggests that the SDoH regarding **environmental risks** may play a role in the prevalence of allergic conjunctivitis among children and young adults. Individuals who live in urban settings may be at greater risk for allergies that cause conjunctivitis, while growing up on a farm or living in a rural environment is a protective factor; this has been attributed to increasing exposure to allergens in urban areas due to crowding and pollution, and desensitization to seasonal allergens such as pollen in rural areas due to repeated exposure early in life (Kilpelainen et al., 2000; Majkowska–Wojciechowska et al., 2007; Pawankar et al., 2012). Urban pollution and respiratory health outcomes may also be linked to the concept of "environmental segregation," whereby minority racial and ethnic groups living in socioeconomically depressed urban areas face increased pollution and toxic contaminants from industrial activities, which are often relegated to these same depressed urban areas, in part due to political marginalization of the inhabitants (Morello-Frosch and Lopez, 2006).

Gender

Uveitis and **chronic dry eye disease** are 30% to 50% more prevalent among women than men (Acharya et al., 2013; Gritz and Wong, 2004; Moss et al., 2000). There is limited research that indicates women are at greater risk of blindness resulting from **glaucoma** and having the less-common "angle closure" type of

glaucoma compared to men; these disparities in glaucoma have been attributed primarily to greater longevity among women, and possibly to SDoH of lower socioeconomic status and less access to care among women (Vajaranant et al., 2010). However, it is unclear if this is relevant for individuals under age 65, as the prevalence of uveitis also increases with age.

Race/ethnicity

Two of these conditions showed racial/ethnic disparities in prevalence. Findings from the Pacific Ocular Inflammation Study in Hawaii indicated that whites had higher prevalence of **uveitis** than Pacific Islanders or other races (Acharya et al., 2013). Open-angle **glaucoma** has four-fold greater prevalence among blacks (5.7%) compared to non-Hispanic whites (1.6%) (Tielsch et al., 1991a). Furthermore, glaucoma is the leading cause of blindness among blacks, who are at approximately four- to five-fold increased risk of blindness compared to U.S. whites (Quigley and Broman, 2006; Thomas, 2000; Tielsch et al., 1991b). Latinos, particularly of Mexican descent, may also be at elevated risk for open-angle glaucoma, with a prevalence of 4.7% (Varma et al., 2004).

Importantly, there may also be racial/ethnic differences in **access to care, medication use, and glaucoma-related vision outcomes** that may be explained by a lack of health literacy, defined as the ability to access and understand health-related information to make informed decisions relating to healthcare, which is closely related to SDoH regarding socioeconomic status. In the context of glaucoma treatment, low health literacy may be demonstrated by a lack of understanding that glaucoma treatment is lifelong, that vision loss from glaucoma is permanent, and that attending follow-up visits is important (Murakami et al., 2011). Low health literacy among glaucoma patients has been associated with being of black or, to a lesser extent, Latino race/ethnicity, lower levels of income and education, a lower likelihood of attending follow up visits or poor treatment adherence, and worsening vision (Dreer et al., 2012; Juzych et al., 2008; Murakami et al., 2011). These findings suggest that blacks, and to a lesser extent Latinos, may face greater barriers to glaucoma-related care and may experience greater loss of vision due to SDoH related to systemic inequalities in education and income, and consequently health literacy.

MEDICAL EFFECTIVENESS

The following review will present the findings of studies relevant to analysis of the impact of allowing early refills of covered ophthalmic products at 70% of the predicted days of use. The review makes the assumption that FDA-approved topical ophthalmic products (TOPs) are effective when used as directed, and focuses on how that effectiveness would be impacted by factors relevant to the AB 1831 bill language; specifically, the modification of the allowable refill threshold to 70% of predicted usage.

As the current allowable refill threshold differs by plan or policy, if AB 1831 is implemented the actual difference between current thresholds and the proposed 70% threshold with regard to the number of days earlier that a prescription could be refilled would vary, but most likely would represent a small change over a 30-day supply (see Table 2 in the *Benefit Coverage, Utilization, and Cost Impacts* section). For example, at the 70% of predicted usage threshold as proposed by the bill, the consumer would be allowed to refill on day 21 (.7 X 30). If an insurer allowed refills at 75% of predicted usage of a 30-day supply, they would be allowed to refill at 22.5 days. Therefore, the difference for the consumer would allow refills 1.5 days earlier for a 30-day supply if the insurer already allowed refills at 75% of predicted usage.

Research Approach and Methods

CHBRP searched for studies related to timing of refills for TOPs. Relevant literature was identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, Business Sources Complete, and Embase. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality, the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Care Excellence (NICE), the Scottish Intercollegiate Guideline Network, the Cumulative Index of Nursing and Allied Health Literature, PsycInfo, and International Pharmaceutical Abstracts. The search was limited to abstracts of studies published in English from 2014 to the present. A similar literature review was undertaken in 2014 for the analysis of AB 2418; therefore, this literature review provided an update of more recent literature and relied on the previous review for literature prior to 2014. Studies were eliminated if they did not focus on the U.S. insured population, were of poor quality, or did not report findings from research studies. CHBRP searched for studies related to early refill of TOPs used to treat four severe and/or prevalent chronic eye diseases - glaucoma, allergic conjunctivitis, chronic dry eye disease (keratoconjunctivitis sicca), and uveitis. Despite the extensive literature search, no studies were identified in which either early refill or accidental overuse (such as due to difficulty instilling eye drops) TOPs was studied in a systematic way in a clinical research study.

Details regarding the literature review can be found in Appendix B.

Study Findings

CHBRP did not identify any studies of the impact of requiring coverage for refills after 70% of expected days. Nor were any studies found that examined the effect of brief lapses in treatment with TOPs. Outside of that, some literature was identified that is useful in understanding early exhaustion of TOPs and is described below.

Administration Methods of TOPs and Reasons for Early Bottle Exhaustion

TOPs are prescribed in bottles and tubes that include a measured amount of product, but are applied to the eyes as drops or small amounts of ointment, and not dispensed in a pre-set, quantifiable dose (such as a pill). For eye drops in particular, the total amount of medication in an eye drop bottle may not accurately predict the number of drops a patient will get out of that bottle (Platt et al., 2004; Queen et al., 2016). In addition, accidental overuse or wastage can result from either allowing too many drops to fall at once or not successfully instilling the drops into the eye (i.e., having the drops fall outside of the eye). These situations may result in patients running out of their eye drops before they can refill their prescription, known as early exhaustion (Moore et al., 2014). This issue has been acknowledged by the American Glaucoma Society, which indicated that users who run out of drops may reduce their dosage from twice to once a day, or from daily to once every other day, add water to the eye drop bottle to extend its use, or simply not administer eye drops until they can refill their prescription (American Glaucoma Society, 2014).

Early Bottle Exhaustion and Medication Adherence

The situations mentioned above are relevant to AB 1831 as they discuss issues involved with depleting the prescribed medication before the allowable time for a refill. This should not be confused with the concept of adherence, and although AB 1831 would increase a very specific type of access to prescribed TOPs, it would not impact medication adherence as traditionally conceptualized. Medication adherence has been defined as the extent to which patients take medications as prescribed by their healthcare providers (Osterberg and Blaschke, 2005). Multiple reasons for nonadherence have been proposed, such as patient forgetfulness, lack of belief about the efficacy or knowledge about treatment instructions, or prohibitive costs of eye drops (Dreer et al., 2012; Lacey et al., 2009; Taylor et al., 2002). AB 1831 would impact patients who have run out of medication early due to accidental overuse or other types of wastage (as described in the paragraph above). These individuals are typically adherent to their treatment regimen up to the point that their medication has been exhausted, and are unable to take their medication until a refill has been obtained. This type of involuntary noncompliance is in direct contrast to the patient who systematically does not take their medication as prescribed by their healthcare provider (i.e., nonadherent). In short, patients who would most likely be impacted by AB 1831 are those who are already systematically adherent to their treatment regimen, which then contributes to early bottle exhaustion. Therefore, although there are many types of adherence, AB 1831 would only improve adherence for those who run out of medication early, and are thus temporarily nonadherent for that specific reason. In addition, it should be mentioned that early bottle exhaustion may not affect all TOPs users across the board. These concerns may be greater for older individuals requiring treatment for chronic eye conditions, who may often have problems with manual dexterity or decreasing visual acuity.

Impact of Brief Periods Without TOPs for Adherent Patients

Although there been multiple studies examining the impact of systematic nonadherence to prescribed treatment regimens for chronic eye conditions, there were no studies found that examined the impact on medical effectiveness of going without prescribed medication for the typical time periods relevant to AB 1831 (e.g., 1.5 to 9 days for a 30-day prescription) for patients who were otherwise systematically administering their medication as prescribed. For example, although one study found that up to 5% of glaucoma patients may regularly exhaust their eye drop supply, and up to 25% could potentially experience eye drop exhaustion at least once during their treatment (Moore et al., 2014), there are no studies that examined the outcomes of being without the prescribed medication for the relevant time for otherwise adherent patients. However, it seems unlikely that, for the adherent patients on TOPs for a

chronic condition (who are those most likely to exhaust a bottle early), a lapse in medication of a few days would measurably affect health outcomes.⁷

Conclusion

CHBRP concludes that there is insufficient evidence to suggest that AB 1831's allowance of covered TOPs refills at and after 70% of the predicted days of use would impact the medical effectiveness of the prescribed treatment. Please note that the absence of evidence is not evidence of no effect. It is possible that an impact — positive or negative — could result, but current evidence is insufficient to inform an estimate. It stands to reason, however, that the reduction in the allowable refill threshold may help those who have the greatest need for the medication; those with severe chronic conditions resulting in diminishing visual acuity.

⁷ Personal communication, W. Haw, MD, March 30, 2016.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

AB 1831 would prohibit DMHC-regulated health plans and CDI-regulated policies that provide outpatient prescription drug benefits from denying coverage for the refill of covered topical ophthalmic products (TOPs) at and after 70% of the predicted days of use. AB 1831 does not affect cost-sharing terms and conditions and it does not require coverage of drugs not on the plan or policy formulary.

CHBRP assessed coverage, utilization, and cost impacts of AB 1831. The impacts modeled in this section rely on a few basic assumptions.

CHBRP assumes that the bill would not affect plan/insurer methods of utilization management that may impact the coverage of outpatient prescription drugs, such as use of formularies, tiered copayments, mandatory generic substitution, or prior authorization requirements. For the enrollees subject to coinsurance for prescription drugs, the analysis assumes there are no changes in benefit design (such as copayments, deductibles, out-of-pocket maximums, or annual limits).

The bill refers to "topical ophthalmic products at 70 percent of the predicted days of use." Because refills might be requested "at and after" 70% of use, CHBRP has assumed that AB 1831 would affect the efforts of enrollees seeking refills at and after 70% of predicted use (not just "at" 70%). For a typical 30-day supply of TOPs, a person seeking a refill at 70% of predicted days of use translates into seeking a refill at day 21 of their eye drops supply.

While AB 1831 may be applicable to prescription and over-the-counter (OTC) TOPs, OTC coverage is mostly only offered by Medi-Cal Managed Care plans and the vast majority of commercial carriers surveyed by CHBRP reported that they do not cover OTC products. Due to the lack of data available to CHBRP on OTC TOP utilization and cost from Medi-Cal Managed Care plans, CHBRP is unable to quantify the any potential impacts for OTC TOPs due to AB 1831.

CHBRP assumes that the percentage of enrollees (1.8%) without outpatient prescription drug (OPD) benefits will remain the same, as AB 1831 would not mandate coverage of outpatient prescription drugs. Some enrollees in DMHC-regulated plans and CDI-regulated policies have no coverage for OPDs and some enrollees have OPD coverage that is not regulated by DMHC or CDI; however, such health insurance is compliant with AB 1831 and as such CHBRP projects no mandate impacts related to enrollees without a DMHC- or CDI-regulated OPD benefit. For further detail, please see Appendix D.

This section reports the potential incremental impact of AB 1831 on estimated baseline benefit coverage, utilization, and overall cost. For further details on the underlying data sources and methods, please see Appendix C.

Benefit Coverage

Premandate (Baseline) Benefit Coverage

In 2017, CHBRP estimates there will be 25.2 million enrollees with health insurance subject to AB 1831. Approximately 15% of these enrollees have health insurance coverage that is currently compliant with AB 1831 (i.e., overall compliance by all plans allowing topical ophthalmic product refills at and after 70% of the predicted days of use). Of these enrollees, 85% are subject to refill coverage denial for TOPs at and after 70% of the predicted days of use.

Current coverage of TOPs was determined by a survey of the seven largest providers of health insurance in California. Responses to this survey represent 97% of enrollees in the privately funded market subject to state mandates.

CHBRP estimates about 15% of commercial plan enrollees are currently enrolled in plans that are compliant with AB 1831 and thus these plans currently allow refills of TOPs at and after 70% of days of predicted use (i.e., day 21 or later for 30-day supply) (see Table 2). Most commercial plan enrollees are currently enrolled in plans that are not compliant with AB 1831. Approximately 45% of enrollees are in plans that allow TOP refills at 75% of days of predicted use, or day 22.5 of 30-day supply; and, close to 40% are in plans that allow TOP refills at 85%, or day 25.5 of 30-day supply. For enrollees currently in the plans that are farthest away from being in compliance with the proposed legislation (85% of days of predicted use), AB 1831 would allow refill of TOPs up to 4.5 days earlier for a 30-day supply.

Table 2. Premandate Commercial Carrier Compliance with AB 1831

AB 1831 Compliance	% of Predicted Days of Supply	Days Expended before Refill Eligible (30-day supply)	% of Commercial Plan Enrollees (premandate)*
Compliant	70% or lower	21 or fewer	15.0%
Non-compliant	75%	22.5	45.1%
	85%	25.5	39.9%
		Total	100.0%

Source: California Health Benefits Review Program, 2016.

Notes: *CHBRP carrier survey on TOP coverage reflects the carrier survey respondents, thus only represents commercial enrollees, only for retail drugs, and 30-day supply.

Postmandate Benefit Coverage

Postmandate, 100% of enrollees in DMHC-regulated plans and CDI-regulated policies that provide outpatient prescription drug benefits would have mandate-compliant coverage of TOPs refills at and after 70% (see Table 1).

In 2017, around 21.3 million enrollees would have changed terms of benefit coverage for TOPs, allowing refills at and after 70% of the predicted days of use, which would be a lower threshold than current terms of benefit coverage (ranging from 75% to 85% of their TOPs being used).

Utilization

Premandate (Baseline) Utilization

Using 2014 MarketScan® Commercial Claims and Encounter Database, CHBRP estimates that in one year, 48.43 prescriptions per 1,000 covered enrollees with health insurance subject to the mandate that have been refilled are TOPs.

Postmandate Utilization

CHBRP examined the peer-reviewed literature on utilization of TOPs and patient refill behavior to determine the prevalence of early eye drops bottle exhaustion — when patients use up bottles of medication before they can refill their prescription — and the likely increase in utilization of refills when coverage is allowed at and after 70% of predicted days of use. CHBRP identified a key study by Moore et al. (2014) that examined the prevalence of early exhaustion of glaucoma eye drops prior to a scheduled refill and found approximately 25% of patients had a problem of early exhaustion in the past year. Using the results of Moore et al., CHBRP assumed that chronic TOP users on average would receive one additional refill per year due to the 70% refill requirement (see Appendix C for more detail). To model the cost impact of the mandate, CHBRP used the MarketScan data to create a continuance table, which provides the distribution of TOP users by the number of refills in a year. CHBRP assumed that those TOP users with nine or more refills in a year would receive an average of one additional refill. This resulted in a total TOP utilization increase of 0.5%. This adjustment was applied uniformly across brand/generic and retail/mail TOP utilization.

CHBRP estimates that within one year, 0.26 more prescriptions per 1,000 covered enrollees would be refilled for TOPs.

Impact on access and health treatment/service availability

AB 1831 would increase access to an earlier TOPs refill at and after 70% for enrollees who are currently denied access at this level. CHBRP estimates that the current supply TOPs would be able to meet the demand for earlier refills. CHBRP estimates there would be no change postmandate in the service availability of obtaining TOPs and thus there would be no shortage of these products caused by AB 1831.

Per-Unit Cost

Premandate (Baseline) and Postmandate Per-Unit Cost

Based on MarketScan data, CHBRP estimates unit cost (average cost per refill prescription for TOP) is \$121 premandate (see Table 1). Postmandate, CHBRP projects there would be no change in the average per-unit costs.

Premiums and Expenditures

Premandate (Baseline) Premiums and Expenditures

Table 3 (at the end of the *Benefit Coverage, Utilization, and Cost Impacts* section) presents per member per month (PMPM) premandate estimates for premiums and expenditures by market segment for DMHC-regulated plans and CDI-regulated policies.

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

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

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

Postmandate Expenditures

Changes in total expenditures

AB 1831 would increase total net annual expenditures by \$955,000 or 0.0007% for enrollees with DMHCregulated plans and CDI-regulated OPD policies. This is due to a slight increase in total health insurance premiums paid by employers and enrollees for the change in covered benefits for TOPs. There are no applicable enrollee expenditures for previously noncovered benefits or changes to enrollee out-of-pocket expenditures.

Postmandate premium expenditures and PMPM amounts per category of payer

Increases in insurance premiums as a result of AB 1831 would vary by market segment. Note that the total population in Table 3 reflects the full 25,155,000 million enrollees in DMHC-regulated plans and CDI-regulated policies with OPD benefits subject to AB 1831.

Overall, across plan type, CHBRP estimates a 0.0007% increase in PMPM postmandate (Table 4), which translates into a 0.0007% increase in total expenditures. Among publicly funded DMHC-regulated health plans, total expenditures for CalPERS HMOs, Medi-Cal Managed Care (under 65 years), and Medi-Cal Managed Care (over 65 years) is 0.0001%, 0.0025%, and 0.0006%, respectively.

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

CHBRP estimates there are no cost offsets or savings in the first 12 months after enactment.

Postmandate administrative expenses and other expenses

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

Related Considerations for Policymakers

Cost of exceeding essential health benefits

Coverage for TOP refills at the 70% predicted days of use is the only requirement on the terms and conditions for existing benefits, and so would not trigger the requirement to cover mandates that exceed EHBs, and the state would not need to defray the costs.

Postmandate Changes in Uninsured and Public Program Enrollment

*Changes in the number of uninsured persons*⁸

CHBRP estimates premium increases of less than 0.001% for each market segment; this premium increase would not have a measurable impact on the number of persons who are uninsured. CHBRP does not anticipate loss of health insurance, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of health insurance, changes in employer contribution rates, changes in take-up of health insurance by employees, or purchase of individual market policies, due to the small size of the increase in premiums after the mandate.

Changes in public program enrollment

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

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

CHBRP finds there is no evidence to suggest the lack of (or insufficient) benefit coverage prompts enrollees to seek care from public programs or other payers, including charities and other state departments (e.g., Department of Education for autism).

In general, CHBRP assumes that enrollees who do not have benefit coverage pay for treatments/services directly (e.g., self-pay); however, in some cases, those noncovered benefits may be provided by public programs or by other, alternative sources.

⁸ See also CHBRP's *Criteria and Methods for Estimating the Impact of Mandates on the Number of Uninsured*, available at: http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

	DMHC-Regulated							CDI-Regulated			
	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+) ^(c)	Large Group	Small Group	Individual	Total	
Enrollee counts											
Total enrollees in plans/policies subject to state mandates ^(d)	9,138,000	2,805,000	3,840,000	861,000	6,331,000	561,000	309,000	731,000	579,000	25,155,000	
Total enrollees in plans/policies subject to AB 1831	9,138,000	2,805,000	3,840,000	861,000	6,331,000	561,000	309,000	731,000	579,000	25,155,000	
Premium Costs											
Average portion of premium paid by employer	\$444.39	\$309.74	\$0.00	\$460.33	\$180.00	\$445.00	\$523.71	\$426.22	\$0.00	\$86,263,866,000	
Average portion of premium paid by employee	\$109.27	\$160.90	\$423.95	\$115.08	\$0.00	\$0.00	\$138.66	\$159.06	\$365.22	\$42,569,604,000	
Total premium	\$553.67	\$470.64	\$423.95	\$575.41	\$180.00	\$445.00	\$662.37	\$585.28	\$365.22	\$128,833,470,000	
Enrollee expenses											
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$44.43	\$93.55	\$112.36	\$31.43	\$0.00	\$0.00	\$111.69	\$177.13	\$108.98	\$16,248,327,000	
Enrollee expenses for benefits not covered ^(e)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0	
Total expenditures	\$598.10	\$564.19	\$536.30	\$606.84	\$180.00	\$445.00	\$774.06	\$762.41	\$474.20	\$145,081,797,000	

Table 3. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2017

Source: California Health Benefits Review Program, 2016.

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

(b) As of September 2015, 57% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2017.

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

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

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

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

			DMHC-R	egulated	CD					
	Privately Funded Plans (by Market) ^(a)			Publicly Funded Plans			CDI-Regulated Privately Funded Plans (by Market) ^(a)			
	Large Group	Small Group	Individual	CalPERS HMOs ^(b)	MCMC (Under 65) ^{(c}	MCMC (65+) ^(c)	Large Group	Small Group	Individual	Total
Enrollee counts										
Total enrollees in plans/policies subject to state mandates ^(d)	9,138,000	2,805,000	3,840,000	861,000	6,331,000	561,000	309,000	731,000	579,000	25,155,000
Total enrollees in plans/policies subject to AB 1831	9,138,000	2,805,000	3,840,000	861,000	6,331,000	561,000	309,000	731,000	579,000	25,155,000
Premium Costs										
Average portion of premium paid by employer	\$0.0017	\$0.0018	\$0.0000	\$0.0004	\$0.0045	\$0.0026	\$0.0013	\$0.0019	\$0.0000	\$628,000
Average portion of premium paid by employee	\$0.0004	\$0.0009	\$0.0025	\$0.0001	\$0.0000	\$0.0000	\$0.0003	\$0.0007	\$0.0022	\$217,000
Total premium	\$0.0021	\$0.0027	\$0.0025	\$0.0006	\$0.0045	\$0.0026	\$0.0016	\$0.0026	\$0.0022	\$845,000
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$0.0005	\$0.0006	\$0.0006	\$0.0001	\$0.0000	\$0.0000	\$0.0004	\$0.0006	\$0.0005	\$112,000
Enrollee expenses for benefits not covered ^(e)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
Total expenditures	\$0.0026	\$0.0033	\$0.0031	\$0.0007	\$0.0045	\$0.0026	\$0.0020	\$0.0032	\$0.0027	\$957,000
Postmandate Percent Change										
Insured premiums	0.0004%	0.0006%	0.0006%	0.0001%	0.0025%	0.0006%	0.0002%	0.0005%	0.0006%	0.0007%
Total expenditures	0.0004%	0.0006%	0.0006%	0.0001%	0.0025%	0.0006%	0.0003%	0.0004%	0.0006%	0.0007%

Table 4. Postmandate Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2017

Source: California Health Benefits Review Program, 2016.

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

(b) As of September 2015, 57% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2017.

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

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

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

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

PUBLIC HEALTH IMPACTS

This section estimates the short-term impact⁹ of AB 1831 on public health outcomes, disparities and social determinants of health, and financial burden. See the *Long-Term Impact of AB 1831* section for discussion of public health, social determinants of health, and economic loss beyond the first 12 months of the bill implementation.

As discussed in the *Policy Context* section, AB 1831 would prohibit carriers that provide outpatient prescription drug benefits from denying coverage for the refill of covered topical ophthalmic products (TOPs) at and after 70% of the predicted days of use. The benefit changes described in AB 1831 would be most relevant to enrollees who use TOPs to treat chronic eye diseases and conditions, such as ocular hypertension, glaucoma, uveitis, chronic dry eye disease, and allergic conjunctivitis. Treatment for these conditions is long term, requiring multiple refills and consistent use as directed by providers to prevent disease progression and/or vision loss. Furthermore, this bill would be most relevant to a small proportion of TOP users who are mostly adherent to their medication, but run out of medication early due to wastage or other reasons.

Estimated Public Health Outcomes

The measurable public health outcome relevant to AB 1831 is how early TOP exhaustion and access to early refills may impact adherence to TOP treatment regimens for chronic eye diseases, which can in turn impact outcomes of ocular hypertension, irritation and inflammation, visual acuity, and eventual blindness.

As presented in the *Medical Effectiveness* section, there is insufficient evidence on the effect of early refills for TOPs on overall medication adherence, and consequently on medical outcomes of chronic eye diseases treated with TOPs. The absence of evidence is not evidence of no effect, but an indication that the impact is unknown.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP estimates that AB 1831 would not increase prescription drug coverage but would alter the terms of benefit coverage for some enrollees. CHBRP estimates that as a result of AB 1831, 21.3 million additional enrollees would have coverage for TOP refills at and after 70% of the predicted days of use and that this would result in an additional 0.26 filled prescriptions per 1,000 enrollees per year, a 0.5% increase.

CHBRP finds insufficient evidence to suggest that AB 1831's 70% refill threshold would improve treatment outcomes. Although CHBRP estimates a very limited increase in filled prescriptions for topical ophthalmic medications due to the 70% refill provision, the additional 1 to 3 days of use is unlikely to have a measurable impact on the population's health outcomes. It stands to reason that there would be no measurable public health impact on health outcomes in the first year postmandate.

Social Determinants of Health and Disparities

CHBRP defines social determinants of health (SDoH) as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (e.g., economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from CDC, 2014; Healthy People 2020, 2015). These factors generally occur prior to or outside of the health care system and are highly correlated with downstream events such as

⁹ CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

avoidable illnesses and premature death. However, the relationship between SDoH and health status/outcomes is complex and, periodically, health insurance mandates can influence SDoH.¹⁰ CHBRP will consider the full range of SDoH (e.g., income, education, or social construct around age, race/ethnicity, gender, and gender identity/sexual orientation) that are relevant to this bill and where evidence is available. Evidence presented in the *Background on Topical Ophthalmic Products* section indicated there are disparities in the prevalence of chronic eye diseases treated with TOPs by age, gender, and race/ethnicity. Furthermore, some of these disparities may be explained by SDoH such as environmental issues, in which living in urban environments and crowding may exacerbate allergic conjunctivitis, and low health literacy levels, which may partially explain poor treatment adherence and outcomes for African American and Latino glaucoma patients. However, no evidence linking these disparities to adherence issues related to early TOP exhaustion was found in the literature.

No evidence was found linking disparities or SDoH to the impact of early refills on treatment adherence. Therefore, CHBRP estimates that the impact of AB 1831 on these disparities and SDoH is unknown.

Estimated Impact on Financial Burden

When possible, CHBRP estimates the marginal impact of mandates on financial burden, defined as uncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (i.e., deductibles, copayments, and coinsurance). Table 1 estimates that AB 1831 would have no change in enrollee out-of-pocket expenses, although patients who are able to obtain an additional refill under the lower 70% threshold would pay an additional prescription copay. However, it is unlikely that out-of-pocket costs related to an additional refill would significantly increase the financial burden for those enrollees.

¹⁰ For more information about SDoH see CHBRP's publication: <u>Incorporating Relevant Social Determinants of Health</u> <u>into CHBRP Benefit Mandate Analyses</u>.

LONG-TERM IMPACT OF AB 1831

In this section, CHBRP estimates the long-term impact¹¹ of AB 1831, defined as impacts occurring beyond the first 12 months of implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization Impacts

In the 12 months following enactment, CHBRP estimates AB 1831 would result in a small increase (0.5%) in utilization in topical ophthalmic products (TOPs), which is likely to be sustained beyond the first year of enactment. It is unlikely that the bill would impact the demand of topical ophthalmic products such that there would be a measurable increase in utilization long term. Furthermore, the medical effectiveness review found insufficient evidence to suggest early refills for TOPs would improve treatment outcomes, thus any potential long-term impacts of AB 1831 are unknown. Please note that the absence of evidence is not evidence of no effect. It is possible that an impact — positive or negative — could result, but current evidence is insufficient to inform any qualitative long-term estimate.

Cost Impacts

As discussed above, CHBRP estimates AB 1831 would have minimal impacts on utilization and unknown impacts on treatment outcomes and thus it is unlikely there would be measurable cost impacts of this bill in the long term.

Long-Term Public Health Impacts

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

In the case of AB 1831, CHBRP estimates the change in utilization would be 0.5% in the first year; however, longer-term changes in utilization are largely unknown. As discussed in the *Background on Topical Ophthalmic Products* section, the prevalence of age-related chronic diseases treated with TOPs, such as ocular hypertension, glaucoma, uveitis, and chronic dry eye disease is predicted to increase as the U.S. population grows, as is the prevalence of allergic conjunctivitis due to urbanization and pollution. These factors may contribute to some increase in utilization of TOPs and subsequently, seeking refills at the 70% threshold proposed by AB 1831, as more people are diagnosed with these illnesses and are treated with TOPs. However, the medical effectiveness review found insufficient evidence to suggest that early refills for TOPs would improve outcomes related to these chronic diseases. Therefore, the long-term impacts on public health, social determinants of health/disparities, and economic loss are unknown.

¹¹ See also CHBRP's *Criteria and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at: <u>http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php</u>

Please note that the absence of evidence is not evidence of no effect. It is possible that an impact — positive or negative — could result, but current evidence is insufficient to inform any qualitative long-term estimate.

APPENDIX A TEXT OF ASSEMBLY BILL AB 1831

On February 11, 2016, the California Assembly Committee on Health requested that CHBRP analyze AB 1831.

ASSEMBLY BILL

No. 1831

Introduced by Assembly Member Low

February 9, 2016

An act to add Section 1367.249 to the Health and Safety Code, and to add Section 10123.209 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 1831, as introduced, Low. Health care coverage: prescription drugs: refills.

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 imposes various requirements on health care service plan contracts and health insurance policies that cover prescription drug benefits.

This bill would require a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2017, that provides coverage for prescription drugs benefits to allow for early refills of covered topical ophthalmic products at 70% of the predicted days of use. Because a willful violation of the bill's requirements by a health care service plan would be a crime, the bill would impose a state-mandated local program.

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

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

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

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

SECTION 1. Section 1367.249 is added to the Health and Safety Code, to read:

1367.249. (a) A health care service plan contract issued, amended, or renewed on or after January 1, 2017, that provides coverage for prescription drug benefits shall allow for early refills of covered topical ophthalmic products at 70 percent of the predicted days of use.

(b) Nothing in this section shall be construed to establish a new mandated benefit or to prevent the application of deductible or copayment provisions in a plan contract.

SEC. 2. Section 10123.209 is added to the Insurance Code, to read:

10123.209. (a) A health insurance policy issued, amended, or renewed on or after January 1, 2017, that provides coverage for prescription drug benefits shall allow for early refills of covered topical ophthalmic products at 70 percent of the predicted days of use.

(b) Nothing in this section shall be construed to establish a new mandated benefit or to prevent the application of deductible or copayment provisions in a health insurance policy.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

APPENDIX B LITERATURE REVIEW METHODS

Appendix B describes methods used in the medical effectiveness literature review conducted for AB 1831. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, Publication Types, and Keywords, follows

The literature search was limited to studies published in English, for which abstracts were available, from January 2014 to present.

The following databases of peer-reviewed literature were searched: MEDLINE (PubMed), Business Sources Complete, the Cochrane Library (includes Cochrane Register of Controlled Clinical Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects [DARE], Health Technology Assessment Database, and NHS Economic Evaluation Database), EconLit, Web of Science (includes Science Citation Index Expanded and the Social Science Citation Index), Embase, Cumulative Index of Nursing and Allied Health Literature, Pharmaceuticals - BIOSIS, Pharmaceuticals – International Pharmaceutical Abstracts (if available), and Pharmaceuticals -Micromedex (if available). In addition, websites maintained by the following organizations that index or publish systematic reviews and evidence-based guidelines were searched: National Institutes of Health, Institute for Clinical Systems Improvement, and the World Health Organization.

Two reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria. Abstracts for 122 articles were identified. Eight metaanalyses, systematic reviews, narrative reviews, RCTs, and nonrandomized studies with comparison groups were retrieved and reviewed.

Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach.*¹² To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

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

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

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

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

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

¹² Available at:

www.chbrp.org/analysis_methodology/docs/med effect_methods_detail.pdf.

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies have strong research designs, consistently find that the treatment is either effective or not effective, and have findings that are highly generalizable to the population whose coverage would be affected. This grade is assigned in cases in which it is unlikely that publication of additional studies would change CHBRP's conclusion about the effectiveness of a treatment.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective and that the findings are generalizable to the population whose coverage would be affected. Bodies of evidence that are graded as *preponderance of evidence* are further subdivided into three categories based on the strength of their research designs: strong research designs, moderate research designs, and weak research designs.

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

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

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

Search Terms

The search terms used to locate studies relevant to AB 1831 were as follows:

Glaucoma Uveitis Keratoconjunctivitis sicca Allergic conjunctivitis Ocular hypertension Refill Medication Topical ophthalmic medications Eve drops Adherence Exhaustion of eye drops Visual acuity Blindness Intra-ocular pressure Eye pain Race racial disparities ethnicity gender sex differences prevalence incidence premature death economic loss morbidity mortality long term impacts productivity and cost of illness comorbidity age medication adherence ophthalmic solutions eve drops risk factors visual acuity glaucoma uveitis allergic conjunctivitis chronic dry eye disease blindness Price of treatment unit cost of treatment cost of treatment cost offset associated with treatment cost savings associated with treatment cost-effectiveness of treatment cost-utility associated with treatment utilization of treatment utilization of early refills

Publication Types:

- Review
- Meta-Analysis
- Randomized Controlled Trial
- Controlled Clinical Trial
- Comparative Study
- Case Reports
- Evaluation Studies
- Practice Guideline
- Guideline
- Other Study Types

policy change for early refills demand for treatment supply of treatment price elasticity of demand for treatment

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

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

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as contracted actuarial firms, Milliman, Inc, and Pricewaterhouse Coopers (PwC).¹³

Data Sources

This subsection discusses the variety of data sources CHBRP uses. Key sources and data items are listed below, in Table 5. Data for 2017 Projections.

Table 5. Data for 2017 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, 2015	Distribution of DMHC-regulated plans by market segment*					
California Department of Insurance (CDI) Statistical Analysis Division data; data as of December 31, 2015	Distribution of CDI-regulated policies by market segment					
California Health Benefits Review Program (CHBRP) Annual Enrollment and Premium Survey of California's largest (by enrollment) health care service plans and health insurers; data as of September 30, 2015; responders' data represent approximately 97% of persons not associated with CalPERS or Medi-Cal with health insurance subject to state mandates (full-service (nonspecialty) DMHC-regulated plan enrollees and of full-service (nonspecialty) CDI-regulated policy enrollees).	 Enrollment by: Size of firm (2–50 as small group and 51+ as large group) DMHC vs. CDI regulated Grandfathered vs. nongrandfathered Premiums for individual policies by: DMHC vs. CDI regulated Grandfathered vs. nongrandfathered 					

¹³ CHBRP's authorizing statute, available at <u>www.chbrp.org/docs/authorizing_statute.pdf</u>, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

Data Source	Items					
California Employer Health Benefits Survey, 2014 (conducted by NORC and funded by CHCF)	 Enrollment by HMO/POS, PPO/indemnity self- insured, fully insured, Premiums (not self-insured) by: Size of firm (3–25 as small group and 25+ as large group) Family vs. single HMO/POS vs. PPO/indemnity vs. HDHP employer vs. employer premium share 					
California Health Interview Survey (CHIS)	Uninsured, age: 65+ Medi-Cal (non-Medicare), age: 65+ Other public, age: 65+ Employer-sponsored insurance, age: 65+					
California Public Employees' Retirement System (CalPERS) data, enrollment as of October 1, 2015	CalPERS HMO and PPO enrollment • Age: 0–17; 18–64; 65+ • HMO premiums					
California Simulation of Insurance Markets (CalSIM) (projections for 2017)	Uninsured, age: 0–17; 18–64 Medi-Cal (non-Medicare) (a), age: 0–17; 18–64 Other public (b), age: 0–64 Individual market, age: 0–17; 18–64 Small group, age: 0–17; 18–64 Large group, age: 0–17; 18–64					
Centers for Medicare and Medicaid (CMS) administrative data for the Medicare program, annually (if available) as of end of September	HMO vs. FFS distribution for those 65+ (noninstitutionalized)					
Milliman estimate	Medical trend influencing annual premium increases					

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

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

Further discussion of external and internal data follows.

Internal data

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

External sources

- California Department of Health Care Services (DHCS) data are used to estimate enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System plans), which may be subject to state benefit mandates, as well as enrollment in Medi-Cal Fee For Service (FFS), which is not. The data are available at: www.dhcs.ca.gov/dataandstats/statistics/Pages/Monthly_Trend_Report.aspx.
- California Employer Health Benefits Survey data are used to make a number of estimates, including: premiums for employment-based enrollment in DMHC-regulated health care service plans (primarily health maintenance organizations [HMOs] and point of service [POS] plans) and premiums for employment-based enrollment in CDI-regulated health insurance policies regulated by the (primarily preferred provider organizations [PPOs]). Premiums for fee-for-service (FFS) policies are no longer available due to scarcity of these policies in California. This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. More information on the CHCF/NORC data is available at: www.chcf.org/publications/2014/01/employer-health-benefits.
- California Health Interview Survey (CHIS) data are used to estimate the number of Californians aged 65 and older, and the number of Californians dually eligible for both Medi-Cal and Medicare coverage. CHIS data are also used to determine the number of Californians with incomes below 400% of the federal poverty level. CHIS is a continuous survey that provides detailed information on demographics, health insurance coverage, health status, and access to care. More information on CHIS is available at: www.chis.ucla.edu.
- California Public Employees Retirement System (CalPERS) data are used to estimate premiums and enrollment in DMHC-regulated plans, which may be subject to state benefit mandates, as well as enrollment in CalPERS' self-insured plans, which is not. CalPERS does not currently offer enrollment in CDI-regulated policies. Data are provided for DMHC-regulated plans enrolling non-Medicare beneficiaries. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOC) documents publicly available at: <u>www.calpers.ca.gov</u>. California Simulation of Insurance Markets (CalSIM) estimates are used to project health insurance status of Californians aged 64 and under. CalSIM is a microsimulation model that projects the effects of the Affordable Care Act on firms and individuals. More information on CalSIM is available at: http://healthpolicy.ucla.edu/programs/health-economics/projects/CalSIM/Pages/default.aspx.
- To estimate the premium impact of certain mandates, PwC's projections may derive from its proprietary comprehensive pricing model, which provides benchmark data and pricing capabilities for commercial health plans. The pricing model factors in health plan features such as deductibles, copays, out-of-pocket maximums, covered services, and degree of healthcare management. The pricing model uses normative data and benefit details to arrive at estimates of allowed and net benefit costs. The normative benchmarking utilization metrics within the pricing model are developed from a database of commercial (under 65) health plan experience representing approximately 20 million annual lives.

- The MarketScan databases, which reflect the health care claims experience of employees and dependents covered by the health benefit programs of large employers, are used to estimate utilization and unit cost. These claims data are collected from insurance companies, Blue Cross Blue Shield plans, and third party administrators. These data represent the medical experience of insured employees and their dependents for active employees, early retirees, individuals with COBRA continuation coverage, and Medicare-eligible retirees with employer-provided Medicare Supplemental plans. No Medicaid or Workers Compensation data are included.
- Ingenix MDR Charge Payment System, which includes information about professional fees paid for health care services, based upon claims from commercial insurance companies, HMOs, and self-insured health plans.

Projecting 2017

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

Baseline premium rate development methodology

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

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

For each market segment, CHBRP first obtained an estimate of the insurance premium PMPM by taking the 2015 reported premium from the abovementioned data sources and trending that value to 2017. CHBRP uses trend rates published in the Milliman HCGs to estimate the health care costs for each market segment in 2017.

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

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

- Health care costs paid by the health plan = insurance premiums PMPM \times (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.

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 specifically to an analysis of AB 1831.

CHBRP has assumed that the percentage of enrollees (1.8%) without outpatient prescription drug benefits would remain the same, as AB 1831 would not mandate coverage of outpatient prescription drugs. CHBRP has also assumed that the mandate would not impact any other forms of cost sharing, such as deductibles, for outpatient prescription drug benefits. It was also assumed that the bill would not affect plan/insurer methods of utilization management that may impact the coverage of outpatient prescription, or prior authorization requirements. For the enrollees subject to coinsurance for prescription drugs, the analysis

assumes there are no changes in benefit design (such as copayments, deductibles, out-of-pocket maximums, or annual limits). The bill refers to "topical ophthalmic products at 70 percent of the predicted days of use." Because refills might be requested "at and after" 70% of use, CHBRP has assumed that AB 1831 would affect the efforts of enrollees seeking refills at and after 70% of predicted use (not just "at" 70%).

Additionally, the following is a brief description of methodology and assumptions used to develop the estimates of cost impacts:

- Topical ophthalmic products (TOPs) were identified with the assistance of a content expert. The content expert also assisted in the categorization of TOPs into those used to treat acute conditions and those used to treat chronic conditions, which were believed to be most likely to receive additional refills under the mandate. TOP names were matched to the Truven Health Analytics Red Book™ to identify all national drug codes (NDCs) for each product. The TOP NDC codes were used to extract data from the MarketScan® Commercial Claims and Encounters Database.
- 2014 MarketScan® Commercial Claims and Encounters Database was used to develop baseline cost and utilization information for TOPs. Baseline cost and utilization rates per 1,000 members were developed separately for prescription drugs dispensed at retail pharmacies and through mail order, and brand drugs separate from generic drugs. Prescription drugs dispensed at retail pharmacies are typically intended for use of 30 days or less. Prescription drugs dispensed via mail order are typically intended for use of greater than 30 days (e.g., 60 or 90 days). Not all prescription drugs available at retail pharmacies may be available via mail order. Based on the MarketScan® data, over 95% of prescriptions for TOPs were filled at retail pharmacies. Approximately 56% of TOP prescriptions were for brand-name drugs.
- Baseline average cost per prescription was trended at a 6.5% annual rate of increase from 2014 to 2017 based on values in the most recent Express Scripts Drug Trend Report (released March 2015), and baseline utilization rate was trended at a 0% annual rate of increase from 2014 to 2017.
- Moore et al. (2014) examined the self-reported prevalence of early exhaustion of glaucoma eye drops prior to a scheduled refill using a cross-sectional study of 260 glaucoma patients. In their study, approximately 25% of all patients had any report of early exhaustion of eye drops in the past year (75% reported none, 12% reported rarely (1-2 times/yr), 8% reported sometimes (3-4 times/yr), 0% reported often (5-7 times/yr), 2% reported usually (8-11 times/yr), and 3% reported always). Based on these results, a weighted average was calculated and used as an estimate of number of times in the past year early exhaustion was a problem — the value calculated was 1 time per year. CHBRP thus assumed that chronic TOP users would receive on average one additional refill per year due to the 70% refill requirement. Patients using TOPs for glaucoma are chronic users as glaucoma cannot be cured, rather must be controlled using medication. In Moore et al. (2014) the average duration of treatment for glaucoma was approximately 8 years. Thus, those likely to use the additional refill per year postmandate are chronic users who have maintained TOP use for the entirety of the year; however, there are new users/newly diagnosed who start medication at any point during the year and may not yet have a full year of medications. To model the cost impact of the mandate, CHBRP used the MarketScan® data to create a continuance table, which provides the distribution of TOP users by the number of refills in a year. CHBRP assumed that those TOP users with nine or more refills in a year would receive an average of one additional refill: 9 months was selected as a conservative estimate of the average for a pool of existing chronic users who have full 12 months and newly diagnosed who have not yet completed a full year (since data are not available, CHBRP assumed an average of 6 months

since new prescriptions might occur anywhere between 1 and 12 months), whereby the average for the old and new users is 9 months. This resulted in a TOP utilization increase of 0.5%. This adjustment was applied uniformly across brand/generic and retail/mail TOP utilization.

- The cost per prescription was assumed not to change postmandate. The mix of drugs between brand and generic and between retail and mail was assumed not to change postmandate.
- There are likely out-of-pocket cost savings to enrollees postmandate who were in plans that were not compliant with AB 1831 and were paying for TOPs out of pocket because coverage was denied for their refills at 70% of predicted days of use. However, there are no data to suggest what the current prevalence is for TOP users who pay for early refills out of pocket when coverage is denied and how much they pay out of pocket, thus CHBRP is unable to quantitatively determine the out-of-pocket cost savings for these users.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits AB 1831 would mandate. Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

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

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include specifics regarding refills for TOPs 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 CaIPERS currently have the largest number of enrollees. The CaIPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

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

APPENDIX D OUTPATIENT PRESCRIPTION DRUG BENEFITS AND STATE-LEVEL MANDATES

As noted in Table 6, for 2017, CHBRP estimates that approximately 1.8% of enrollees in plans regulated by DMHC or policies regulated by CDI have no coverage for outpatient prescription drugs (OPDs) and 3.1% of these enrollees have OPD coverage that is not regulated by DMHC or CDI.

Table 6. Outpatient Prescription Drug Coverage, 2017

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

Source: California Health Benefits Review Program, 2016.

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

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

Additional detail about the presence and absence of OPD coverage in various market segments is presented below, in Table 7 and

Table 8.

Relevant state and federal law

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

- Some (but not all) small-group and individual market health care service plans and health insurance policies are required to provide coverage for OPDs as part of coverage for Essential Health Benefits.¹⁴
- Some (but not all) large-group, small-group, and individual market health care service plans and health insurance policies are required to provide coverage for particular drugs as part of preventive services, but not for all OPDs.¹⁵
- Some state-level mandates, applicable to some or all plans and policies regulated by DMHC or CDI, require coverage for particular drugs. For example, there is a mandate that requires coverage for insulin and prescription drugs for the treatment of diabetes but does not require coverage for drugs that treat diabetes-related conditions.¹⁶

However, this mix of laws does not require that all enrollees in plans and policies regulated by DMHC or CDI have an OPD benefit.

Presence or absence of coverage for outpatient prescription drugs and related regulation

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

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

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

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

¹⁴ California Health & Safety Code: 1367.005, 1367.006, 1367.0065; California Insurance Code: 10112.27, 10112.28, 10112.285; Federal Affordable Care Act of 2010: Section 1301, 1302, and Section 1201 modifying Section 2707 of the PHSA

California Health & Safety Code: 1367.002; California Insurance Code: 10112.2; Federal Affordable Care Act of 2010: Section 1001 modifying Section 2713 of the PHSA ¹⁶ California Health & Safety Code: 1367.51 and California Insurance Code: 10176.61

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

		DN	CDI-Regulated Policies					
	Privately Large (Put	olicly Funded Pl	Privately Funded Large Group			
	Grand- fathered	Nongrand- fathered	CaIPERS HMOs ^(a)	MCMC (Under 65) ^(b)	MCMC (65+) ^(b)	Grand- fathered	Nongrand- fathered	
Enrollee counts								
Total enrollees in plans/policies subject to state mandates ^(c)	2,362,000	6,776,000	861,000	6,331,000	561,000	27,000	282,000	
Outpatient prescription drug (OPD) coverage								
DMHC- or CDI-regulated brand-name and generic OPD coverage	94.1%	89.0%	74.4%	100.0%	100.0%	85.0%	94.1%	
DMHC- or CDI-regulated generic-only coverage								
No OPD coverage	5.4%	3.2%					2.1%	
Other OPD coverage	0.5%	7.8%	25.6%			15.0%	3.8%	

Table 7. Outpatient Prescription Drug Coverage in the Large-Group and Publicly Funded Markets, 2017

Source: California Health Benefits Review Program, 2016.

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

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

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

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Operated Health Systems; MCMC = Medi-Cal Managed Care; OPD = Outpatient Prescription Drug.

Table 8. Outpatient Prescription Drug Coverage in the Small-Group and Individual Markets, 2017

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

Source: California Health Benefits Review Program, 2016.

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

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

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Operated Health Systems; MCMC = Medi-Cal Managed Care; OPD = Outpatient Prescription Drug

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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, PricewaterhouseCoopers, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

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

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The California Health Benefits Review Program is administered by UC Health at the University of California, Office of the President. UC Health is led by John D. Stobo, MD, Executive Vice President.

ACKNOWLEDGEMENTS

Steven Tally, PhD, of the University of California, San Diego, prepared the medical effectiveness analysis. Min-Lin Fang, MLIS, of the University of California, San Francisco, conducted the literature search. Sara McMenamin, PhD, and Sarah Hiller, MA, both of the University of California, San Diego, prepared the public health impact analysis. Riti Shimkhada, PhD, of the University of California, Los Angeles, prepared the cost impact analysis. Peter Davidson, FSA, MAAA, of PricewaterhouseCoopers, provided actuarial analysis. Weldon H. Haw, MD, of the University of California, San Diego, provided technical assistance with the literature review and expert input on the analytic approach. John Lewis, MPA, of CHBRP staff prepared the Policy Context and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Brent Fulton, PhD, of the University of California, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

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

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

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

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