California Health Benefits Review Program

Analysis of Assembly Bill 2418: Prescription Drug Refills

A Report to the 2013-2014 California Legislature April 25, 2014

This page is intentionally blank.

KEY FINDINGS

Analysis of California Assesmbly Bill (AB) 2418: Health Care Coverage: Prescription Drug Refills

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

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

AT A GLANCE

AB 2418 (as introduced on February 21, 2014) would require state-regulated health plans and insurers that provide prescription drug benefits to comply with three provisions: (1) plans and insurers that impose a mandatory-mail-order requirement for refills would have to implement and maintain an AB 2418–compliant opt-out process; (2) coverage denials for synchronizing refills would be prohibited; and (3) coverage denials for topical ophthalmic products at or after 70% of the prescription's expected days of use would be prohibited.

- **Enrollees.** CHBRP estimates that in 2015, 23.4 million Californians will be enrolled in state-regulated health insurance and that 23.1 million of these enrollees will have coverage for outpatient prescription drugs and so could be affected by AB 2418. These figures include some Medi-Cal beneficiaries and some enrollees associated with CalPERS.
- **Impact on expenditures.** Total expenditures are estimated to increase by $3.3 million (0.003%), due to AB 2418.
- **EHBs.** AB 2418 affects terms of benefit coverage and would not exceed California's definition of essential health benefits (EHBs).
- **Medical effectiveness.** CHBRP evaluated the literature relating to the effect on adherence of AB 2418's three provisions (mandatory mail opt-out requirement, synchronization denial prohibition, and early topical ophthalmic product refill denial prohibition). CHBRP found *insufficient evidence* to determine the effect these provisions may have on adherence. Please note that the absence of evidence is not evidence of no effect.
- **Benefit coverage.** Postmandate, CHBRP estimates the following changes: 1.07 million enrollees (who had mandatory mail order requirements) would gain an AB 2418–compliant opt-out process for mandatory mail order; 10.28 million enrollees would gain coverage for synchronization refills; 10.43 enrollees (who had coverage for topical ophthalmic product refills at 75-85%) would have coverage for topical ophthalmic product refills at 70% of expected days of use.
- **Utilization.** Postmandate, CHBRP estimates the following changes: retail pharmacy refills would increase by 0.26% (with a commensurate decrease in mandatory mail refills due to switching from mail to retail refills); topical ophthalmic product refills would increase by 0.12%.
- **Public health.** Although AB 2418 would result in a limited increase in filled prescriptions, CHBRP found *insufficient evidence* to estimate any impact on adherence, so AB 2418's impact on the public's health is unknown.

BILL SUMMARY

AB 2418 would institute three provisions: one requirement and two prohibitions on DMHC-regulated plans and CDI-regulated insurers — including those enrolling Medi-Cal beneficiaries and enrollees associated with CalPERS, as described below.

Provision 1: AB 2418 would require plans and insurers that both (1) provide a prescription drug benefit and (2) impose a mandatory-mail-order restriction for all or some covered prescription drugs to establish and maintain an AB 2418–compliant opt-out process for mail-order restriction.

Plans and insurers would not be required to initiate the opt-out option process for (1) drugs not available at an in-network retail pharmacy due to manufacturer's instructions or restriction (2) drugs subject to risk evaluation or management, or strategies approved by the FDA.

Provision 2: AB 2418 would prohibit plans and insurers that provide prescription drug benefits from denying coverage for the refill of an otherwise covered drug when the refill is ordered for the purpose of placing medications on the same schedule for refill.

Provision 3: AB 2418 would prohibit plans and insurers that provide prescription drug benefits from denying coverage for the refill of covered prescription topical ophthalmic products at or after 70% of the predicted days of use.

CHBRP KEY FINDINGS: INCREMENTAL IMPACT OF AB 2418

CHBRP is aware that many factors may influence implementation and details of the terms of benefit coverage addressed by AB 2418. In this report, the *Medical Effectiveness* section focuses on medication adherence and the *Benefits Coverage, Utilization, and Cost Impacts* section focuses on cost.

Medical Effectiveness

Prescription drugs are used to treat a wide variety of diseases and conditions. CHBRP did not examine the effectiveness of prescription drugs in treating the many conditions for which they are prescribed. For the purposes of this review, CHBRP assumed Food and Drug Administration (FDA)-approved drugs are effective when used as directed.

Topical ophthalmic products are also used to treat a variety of illnesses, including glaucoma, uveitis allergic conjunctivitis, and chronic dry eye disease. Topical ophthalmic products may prevent vision loss (including blindness) and may prevent pain, inflammation, and other symptoms. For the purposes of this review, CHBRP assumed that FDA-approved topical ophthalmic products are effective when used as directed.

For all three terms of benefit coverage AB 2418 would affect, CHBRP assessed the quality of the evidence as *insufficient* to determine an effect on adherence. The lack of evidence is not evidence of no effect.

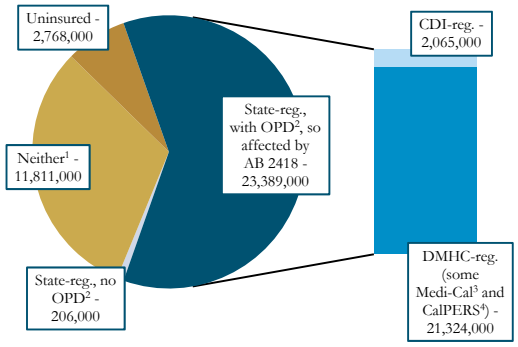
Public Health

Although some additional prescriptions would be filled, because there is insufficient evidence to determine the impact of AB 2418's provisions on adherence, the public health impact is unkown.

Benefit Coverage, Utilization and Cost

As illustrated in Table 1, of the 23.4 million enrollees in DMHC-regulated plans and CDI-regulated policies subject to state mandates, 23.1 million enrollees have an outpatient drug benefit that could be affected by AB 2418. These figures include some Medi-Cal beneficiaries and some enrollees associated with CalPERS.

Figure 1. AB 2418 and California Health Insurance – by Number of Persons/Enrollees



Source: California Health Benefits Review Program, 2014
Notes: 1. Neither = Federally regulated health insurance, such as Medicare, veterans, or self-insured plans. 2. Outpatient Prescription Drug benefit. 3. Many, but not all, Medi-Cal beneficiaries are enrolled in DMHC-regulated plans. 4. Some, but not all, enrollees affiliated with the California Public Employees Retirement System are in DMHC-regulated plans.

Benefit coverage impacts: Estimates of baseline and postmandate benefit coverage figures follow:

- At baseline, 1.07 million enrollees have benefit coverage that includes a mandatory-mail-order refill requirement. Opt-out processes that are not compliant with AB 2418 are in place for these enrollees. Postmandate, all of these enrollees would have an AB 2418–compliant opt-out process.
- At baseline, 10.28 million enrollees could have a refill coverage denial when synchronizing prescriptions. Postmandate, no enrollees could see such a denial.
- At baseline, 10.43 million enrollees could have a topical ophthalmic product refill coverage denial when the predicted use period is at or at or after 75% to 85%. Postmandate, no enrollee could see a denial at or after 70% of predicted use.

Utilization impacts: Postmandate, CHBRP estimates the following changes: retail pharmacy refills would increase by 0.26% (with a commensurate decrease in mandatory-mail-order refills) and topical ophthalmic product refills would increase by 0.12%.

Cost impacts: Postmandate, CHBRP projects an increase of $3.3 million (0.003%) in terms of total expenditures (premiums and enrollee expenses) as a result of AB 2418.

A Report to the 2013–2014 California State Legislature

Analysis of Assembly Bill 2418:
Prescription Drug Refills

April 25, 2014

California Health Benefits Review Program
1111 Franklin Street, 11th Floor
Oakland, CA 94607
Tel: 510-287-3876
Fax: 510-763-4253
www.chbrp.org

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

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

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

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

PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 2418. In response to a request from the California Assembly Committee on Health on February 25, 2014, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute, which established CHBRP to provide independent and impartial analysis of proposed health insurance benefit mandates and repeals.

Laura Trupin, MPH, and Margaret Fix, MPH, both of the University of California, San Francisco, prepared the medical effectiveness analysis. Bruce Abbott, MLS, of the University of California, Davis, conducted the literature search. Stephen McCurdy, MD, MPH, and Meghan Soulsby, MPH, both of the University of California, Davis, prepared the public health impact analysis. Ying-Ying Meng, PhD, and AJ Scheitler, MEd, both of the University of California, Los Angeles, prepared the cost impact analysis. Susan Pantely, FSA, MAAA, of Milliman, provided actuarial analysis. Debbie Stern, RPh, of Rxperts, Inc., and Jacque L. Duncan, MD, of the University of California, San Francisco, provided technical assistance with the literature review and expert input on the analytic approach. John Lewis, MPA, of CHBRP staff prepared the *Introduction* and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Brent Fulton, PhD, of the University of California, Berkeley, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

California Health Benefits Review Program
1111 Franklin Street, 11th Floor
Oakland, CA 94607
Tel: 510-287-3876
Email: chbrpinfo@chbrp.org
www.chbrp.org

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

Garen Corbett, MS
Director

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 2418

The California Assembly Committee on Health requested on February 25, 2014, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 2418, Prescription Drug Refills. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute,[2] which allows for the review of benefit mandates affecting health insurance regulated by the state.

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

The mandate would affect the health insurance of approximately 23.4 million enrollees (60% of all Californians). Specifically, DMHC-regulated plans and/or CDI-regulated policies, would be subject to AB 2418.

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

The Affordable Care Act (ACA)[7] is substantially affecting health insurance and its regulatory environment in California. It is important to note that CHBRP's analysis of proposed benefit mandate bills typically address the incremental effects of the proposed bills — specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these incremental effects are presented in this report. In order to accommodate continuing changes in health insurance enrollment, CHBRP is relying on projections from the California Simulation of Insurance Markets (CalSIM)

---

[2] Available at: www.chbrp.org/docs/authorizing_statute.pdf.
[3] California has a bifurcated system of regulation for health insurance. The Department of Managed Health Care (DMHC) regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers, which offer benefit coverage to their enrollees through health insurance policies.
[4] DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code (H&SC) Section 1340.
[5] CDI licenses "disability insurers." Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code (IC) Section 106(b) or subdivision (a) of Section 10198.6.
[6] CHBRP's estimates are available at: www.chbrp.org/other_publications/index.php.
[7] The federal "Patient Protection and Affordable Care Act" (P.L.111-148) and the "Health Care and Education Reconciliation Act" (P.L 111-152) were enacted in March 2010. Together, these laws are referred to as the Affordable Care Act (ACA).

model[8] to help estimate baseline enrollment for 2015. From this projected baseline, CHBRP estimates the incremental impact of proposed benefit mandates that could be in effect after January 2015.

Bill-Specific Analysis of AB 2418

AB 2418 would institute three provisions: one requirement and two prohibitions on DMHC-regulated plans and CDI-regulated insurers, as described below.

Provision 1 (requirement): AB 2418 would require plans and insurers that both (1) provide a prescription drug benefit and (2) impose a mandatory-mail-order restriction for all or some covered prescription drugs, to establish and maintain an opt-out process for mail-order restrictions.

An AB 2418–compliant opt-out process:

- Would not impose conditions, including but not limited to requiring prescriber approval or submission of documentation by the enrollee or prescriber.
- Would allow the enrollee to opt out or revoke an opt-out at any time.
- Would make the enrollee's choice to opt out (or not) valid throughout the enrollee's enrollment.
- Would provide enrollees with written notice of the mandatory-mail-order restriction for each drug subject to the restriction. The written notices:
    - Would be provided within 30 days prior to the restriction for a particular drug taking effect.
    - Would be in addition to any evidence of coverage (EOC) or evidence of benefits document.
    - Would inform the enrollee of the right to opt out of the restriction and how to do so.
    - Would include carrier contact information for use by the enrollee initiating the opt-out, and would include toll-free numbers if the carrier suggests phone or fax communication.
- Plans and insurers would not be required to initiate the opt-out process for:
    - Drugs not available at an in-network retail pharmacy due to manufacturer's instructions or restrictions.
    - Drugs subject to risk evaluation or management, or strategies approved by the federal Food and Drug Administration (FDA).

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

Provision 2 (prohibition): AB 2418 would prohibit plans and insurers that provide prescription drug benefits from denying coverage for the refill of an otherwise covered drug when the refill is ordered for the purpose of placing drugs on the same refill schedule.

Provision 3 (prohibition): AB 2418 would prohibit plans and insurers that provide prescription drug benefits from denying coverage for the refill of covered prescription topical ophthalmic products after 70% of the predicted days of use.

CHBRP is aware of laws in other states that are similar (or relevant) to the requirements AB 2418 proposes.

- Laws prohibiting or restricting mandatory-mail-order requirements for outpatient prescription drug benefits are present in 37 other states.
- A law requiring coverage of refills for synchronization is present in one other state.
- Laws requiring coverage of early refills for topical ophthalmic products are present in four other states.

In addition, CHBRP is aware regulations and directives make similar provisions effective for Medicare beneficiaries.

Analytic Approach and Key Assumptions

The bill refers to placing "all of the enrollee's medications on the same schedule for refill." Because the length of intended use may vary by prescription, CHBRP has assumed that AB 2418 would affect the efforts of enrollees to synchronize scheduled refills for "some or all" drugs (not just efforts to synchronize "all"). The bill refers to "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 2418 would affect the efforts of enrollees seeking refills at and after 70% of predicted use (not just "at" 70%).

CHBRP is aware that many factors may influence implementation and details of the terms of benefit coverage addressed by AB 2418. In this report, the *Medical Effectiveness* section focuses on medication adherence and the *Benefits Coverage, Utilization, and Cost Impacts* section focuses on cost.

Background on Disease or Condition

Prescription drugs are a part of standard treatment regimens for many diseases and conditions. In the analysis of the medical effectiveness related to the three provisions of AB 2418, CHBRP did not examine the effectiveness of prescription drugs in treating the many conditions for which they are prescribed. For the purposes of this review, therefore, CHBRP makes the assumption that FDA-approved drugs are effective for treatment of the conditions for which they have been approved when taken as prescribed.

Similarly, the report does not attempt to provide background information on all of the diseases or conditions that may be treated with prescription drugs. CHBRP would note, however, that topical ophthalmic products can be prescribed for a number of serious and prevalent conditions,

including glaucoma, uveitis, allergic conjunctivitis, and chronic dry eye disease. In the presence of such conditions, drugs, including topical ophthalmic products, are used to prevent vision loss (including blindness), as well as pain, inflammation, and other symptoms.

Medical Effectiveness

CHBRP evaluated the literature relevant to the particular terms and conditions of insurance and health plans that would be affected by this bill: establishing a process for enrollees to opt out of mandatory mail order, synchronizing prescription drugs to the same schedules, and refilling topical ophthalmic products at or after 70% days of expected use.

- For the mail order opt-out provision, CHBRP did not identify any studies comparing mandatory mail order with opt-out to mandatory mail order without opt-out. One study that examined the effects of mandatory mail order, in comparison to optional mail order, found that mandatory mail order was associated with lower medication adherence. Because of the limited number of studies on this topic, CHBRP assessed the quality of the evidence as *insufficient* to make a determination on effectiveness.
- For the refill synchronization provision, CHBRP identified two relevant studies, but only one provided evidence for or against refill synchronization specifically. That study found that medication adherence was improved for patients with all drug refills synchronized in comparison to patients with no refill synchronization. Again, because of the limited literature on this topic, CHBRP found the quality of the evidence to be *insufficient* to make a determination on effectiveness.
- For the topical ophthalmic products refill provision, CHBRP did not identify any studies or practice guidelines that examined either refill or brief lapses in treatment of these drugs. The lack of studies in this area again led to a determination of *insufficient* evidence.

Benefit Coverage, Utilization, and Cost Impacts

Coverage impact

- Postmandate there would be no changes in benefit coverage. However, as noted in Table 1, there would be changes in the terms of benefit coverage for prescription drugs as follows:
    - 1.1 million enrollees who currently have mandatory-mail-order requirements for some prescription drugs (usually for maintenance drugs) would have an AB 2418–compliant opt-out process.
    - 10.28 million enrollees would have coverage for refills ordered for the purpose of placing drugs on a synchronized refill schedule.
    - 10.43 million enrollees would have coverage for topical ophthalmic product refills at or after 70% of the predicted days of use, which is earlier than the premandate average of at or after 75% to 85% of the predicted days of use.

Utilization impact

- Although utilization would not increase due to implementation of the AB 2418–compliant opt-out process, there would be some switches from existing mandatory-mail-order refills to retail pharmacy refills. CHBRP estimates the switch rates would be at 23.3% postmandate.
- CHBRP cannot estimate the impact on utilization due to synchronizing refills. However, CHBRP anticipates that there would be minimal impact.
- CHBRP estimates that in one year, 0.1 more prescriptions per 1,000 covered enrollees would be refilled for topical ophthalmic products.

Cost impact

- Total net expenditures are estimated to increase by $3.3 million or 0.003% for the year following implementation of the mandate, mainly due to changes in the terms of benefit coverage and utilization for topical ophthalmic products, as well as the administrative costs associated with providing changed terms of benefit coverage for the some enrollees.
- The mandate is estimated to increase premiums by about $1.35 million. The distribution of the impact on premiums is as follows:
    - Total premiums for private employers purchasing group health insurance are estimated to increase by $845,000, or 0.0015%.
    - Total employer premium expenditures for CalPERS HMOs are estimated to increase by $6,000, or 0.0001%.
    - Enrollee contributions toward premiums for group insurance are estimated to increase by $332,000, or 0.001%.
    - Total premiums for purchasers of individual market health insurance are estimated to increase by $165,000, or 0.001%.
    - State expenditures for Medi-Cal Managed Care Plans are estimated to increase by $154,000, or 0.0009%.

Increases in per member per month premiums for the newly mandated terms of benefit coverage in all markets as a result of AB 2418 would be less than $0.01 in DMHC-regulated plans and CDI-regulated policies subject to AB 2418.

Public Health Impacts

- CHBRP finds insufficient evidence to suggest that opt-outs from mandatory mail order, refill synchronization, or early refills for topical ophthalmic products would improve medication adherence. Although CHBRP estimates a very limited increase in filled prescriptions for topical ophthalmic medications due to the 70% refill provision, CHBRP estimates these enrollees could (on average) have filled their prescriptions at 75 to 80%; the extra time (generally a single day) of use is unlikely to have a measurable impact on adherence. Due to insufficient medical effectiveness evidence and unlikely impact on adherence despite very limited increases in filled prescriptions, the public health impact on health outcomes, gender or racial/ethnic disparities, and premature death in the first year postmandate is 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 an estimate.

- CHBRP estimates that AB 2418 would modify coverage and increase the financial burden for enrollees who would be using the mail order opt-out process by increasing out-of-pocket expenses by $61.87 per enrollee among approximately 29,821 enrollees switching from mandatory-mail-order refills to retail pharmacy refills.

Long Term Impacts

- *Medical Effectiveness* found insufficient evidence to suggest that opt-outs from mandatory mail order, refill synchronization, or early refills for topical ophthalmic products would improve medication adherence; therefore, any potential long-term impacts of AB 2418 on public health are unknown.

Interaction With the Federal Affordable Care Act

Because AB 2418 specifies terms and conditions of existing benefit coverage, but does not require new benefit coverage, it would not directly interact with essential health benefits (EHBs) or the ACA's preventive services mandate.[9]

[9] Resources on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.

Table 1. AB 2418 Impacts on Benefit Coverage, Utilization, and Cost, 2015

	Premandate	Postmandate	Increase/ Decrease	Change Postmandate
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	23,389,000	23,389,000	0	0%
Total enrollees with health insurance subject to AB 2418	23,083,000	23,083,000	0	0%
Number of enrollees subject to mandatory-mail-order provision with:				
Noncompliant opt-out process	1,071,000	0	-1,071,000	-100%
No opt-out process	0	0	0	0%
Percentage of enrollees subject to mandatory-mail-order provision with:				
Noncompliant opt-out process	4.6%	0.0%	-4.6%	-100%
No opt-out process	0.0%	0.0%	0.0%	0%
Number of enrollees with possible refill denial when synchronizing refill schedule	10,283,000	-	-10,283,000	-100.000%
Percentage of enrollees with possible refill denial when synchronizing refill schedule	44.5%	0.0%	-44.5%	-100.000%
Number of enrollees with possible denial when refilling TOPs at or after 70%	10,428,000	-	-10,428,000	-100.000%
Percentage of enrollees with possible denial when refilling TOPs at or after 70%	45.2%	0.0%	-45.2%	-100.000%
Utilization and cost				
Outpatient prescription drug utilization				
(Filled prescriptions per 1,000 covered enrollees)				
Retail	5,373.0	5,387.1	14.0	0.261%
Mail order – Mandatory	22.0	16.9	-5.1	-23.200%
Mail order – Optional	813.0	813.0	0	0.000%
Total	6,208.1	6,217.0	9.0	0.143%
Outpatient prescription drug unit cost				
(Average cost per filled prescription)				
Retail for < 30-day supply	$82.98	$82.92	-$0.05	-0.066%
Mail order – Mandatory for 60- to 90-day supply	$143.92	$143.92	$0.00	0.000%

Table 1. AB 2418 Impacts on Benefit Coverage, Utilization, and Cost, 2015 (Cont'd)

	Premandate	Postmandate	Increase/ Decrease	Change Postmandate
Mail order – Optional for 60- to 90-day supply	$224.91	$224.91	$0.00	0.000%
Total	$101.78	$101.66	-$0.12-	-0.122%
Outpatient prescription drug cost sharing				
(Average enrollee cost sharing per filled prescription)				
Retail for < 30-day supply	$13.99	$13.99	$0.00	0.017%
Mail order – Mandatory for 60- to 90-day supply	$25.48	$25.48	$0.00	0.000%
Mail order – Optional for 60- to 90-day supply	$25.73	$25.73	$0.00	0.000%
Total	$15.57	$15.56	-$0.01-	-0.062%
TOPs utilization				
(Filled prescriptions per 1,000 covered enrollees)	91.6	91.7	0.1	0.123%
TOPs unit cost				
(Average cost per filled prescription)	$91.20	$91.21	$0.01	0.011%
TOPs cost sharing				
(Average enrollee cost sharing per filled prescription)	$20.43	$20.42	-$0.01	-0.060%
Expenditures				
Premium expenditures by payer				
Private employers for group insurance	$54,590,722,000	$54,591,567,000	$845,000	0.002%
CalPERS HMO employer expenditures (c)	$4,297,494,000	$4,297,500,000	$6,000	0.000%
Medi-Cal Managed Care Plan expenditures	$17,504,711,000	$17,504,865,000	$154,000	0.001%
Enrollees for individually purchased insurance	$16,930,080,000	$16,930,245,000	$165,000	0.001%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (a) (b)	$22,232,708,000	$22,233,040,000	$332,000	0.001%
Enrollee expenses				
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	$12,867,143,000	$12,868,988,000	$1,845,000	0.014%
Enrollee expenses for noncovered benefits (d)	$0	$0	$0	0.000%
Total expenditures	$128,422,858,000	$128,426,203,000	$3,345,000	0.003%

Source: California Health Benefits Review Program, 2014

Notes:
(a) This population includes persons with privately funded and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans, Healthy Families Program) health insurance products regulated DMHC or CDI. Population includes enrollees aged 0-64 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 enrollee contributions for publicly purchased insurance.
(c) Of the increase in CalPERS employer expenditures, about 57% or $3,000 would be state expenditures for CalPERS members who are state employees or their dependents.
(d) 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 Care; TOPs= topical ophthalmic products

INTRODUCTION

The California Assembly Committee on Health requested on February 25, 2014, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 2418, Prescription Drug Refills. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute,[10] which allows for the review of benefit mandates affecting health insurance regulated by the state.

State benefit mandates apply to a subset of health insurance in California, those regulated by one of California's two health insurance regulators:[11] the California Department of Managed Health Care (DMHC)[12] and the California Department of Insurance (CDI).[13] In 2015, CHBRP estimates that approximately 23.4 million Californians (60%) will have health insurance that may be subject to any state health benefit mandate law.[14] Of the rest of the state's population, a portion will be uninsured (and therefore will have no health insurance subject to any benefit mandate), and another portion will have health insurance subject to other state laws or only to federal laws.

The mandate would affect the health insurance of approximately 23.4 million enrollees (60% of all Californians). Specifically, DMHC-regulated plans and/or CDI-regulated policies, would be subject to AB 2418.

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

The Affordable Care Act (ACA)[15] is substantially affecting health insurance and its regulatory environment in California. As of January 2014, an expansion of the Medi-Cal program, California's Medicaid program,[16]and the availability of subsidized and nonsubsidized health insurance purchased through Covered California,[17] the state's newly established state health

[10] Available at: www.chbrp.org/docs/authorizing_statute.pdf.
[11] California has a bifurcated system of regulation for health insurance. The Department of Managed Health Care (DMHC) regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers, which offer benefit coverage to their enrollees through health insurance policies.
[12] DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code (H&SC) Section 1340.
[13] CDI licenses "disability insurers." Disability insurers may offer forms of insurance that are not health insurance. This report considers only the impact of the benefit mandate on health insurance policies, as defined in Insurance Code (IC) Section 106(b) or subdivision (a) of Section 10198.6.
[14] CHBRP's estimates are available at: www.chbrp.org/other_publications/index.php.
[15] The federal "Patient Protection and Affordable Care Act" (P.L.111-148) and the "Health Care and Education Reconciliation Act" (P.L 111-152) were enacted in March 2010. Together, these laws are referred to as the Affordable Care Act (ACA).
[16] The Medicaid expansion, which California will pursue, is to 133% of the federal poverty level (FPL) — 138% with a 5% income disregard.
[17] The California Health Benefits Exchange Authorizing Statute is available here: www.healthexchange.ca.gov/Documents/California%20Codes%20Governing%20the%20Health%20Benefit%20Exchange.pdf.

insurance marketplace, are significantly increasing the number of people with health insurance in California.

State health insurance marketplaces, such as Covered California, are responsible for certifying and selling qualified health plans (QHPs) in the small-group and individual markets.[18] QHPs sold through Covered California are DMHC-regulated plans or CDI-regulated policies, and as such will be subject to California state benefit mandates.

It is important to note that CHBRP's analysis of proposed benefit mandate bills typically address the incremental effects of the proposed bills — specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these incremental effects are presented in this report. In order to accommodate continuing changes in health insurance enrollment, CHBRP is relying on projections from the California Simulation of Insurance Markets (CalSIM) model[19] to help estimate baseline enrollment for 2015. From this projected baseline, CHBRP estimates the incremental impact of proposed benefit mandates that could be in effect after January 2015. CHBRP's methods for estimating baseline 2015 enrollment from CalSIM projections are provided in further detail in Appendix D.

Bill-Specific Analysis of AB 2418

Bill Language and Analysis

AB 2418 would institute three provisions: one requirement and two prohibitions on DMHC-regulated plans and CDI-regulated insurers, as described below.

Provision 1 (requirement): AB 2418 would require plans and insurers that both (1) provide a prescription drug benefit and (2) impose a mandatory-mail-order restriction for all or some covered prescription drugs, to establish and maintain an opt-out process for mail-order restrictions. The opt-out process would be required to meet the following stipulations:

An AB 2418–compliant opt-out process:

- Would not impose conditions, including but not limited to requiring prescriber approval or submission of documentation by the enrollee or prescriber.
- Would allow the enrollee to opt out or revoke an opt-out at any time.
- Would make the enrollee's choice to opt out (or not) valid throughout the enrollee's enrollment.

[18] Effective 2017, states may allow large-group purchasing through health insurance marketplaces, which may make some large-group plans and policies subject to the requirement to provide essential health benefits [ACA Section 1312(f)(2)(B)].

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

- Would provide enrollees with written notice of the mandatory-mail-order restriction for each drug subject to the restriction. The written notices:
  - Would be provided within 30 days prior to the restriction for a particular drug taking effect.
  - Would be in addition to any evidence of coverage (EOC) or evidence of benefits document.
  - Would inform the enrollee of the right to opt out of the restriction and how to do so.
  - Would include carrier contact information for use by the enrollee initiating the opt-out, and would include toll-free numbers if the carrier suggests phone or fax communication.
- Plans and insurers would not be required to initiate the opt-out process for:
  - Drugs not available at an in-network retail pharmacy due to manufacturer's instructions or restrictions.
  - Drugs subject to risk evaluation or management, or strategies approved by the federal Food and Drug Administration (FDA).

Provision 2 (prohibition): AB 2418 would prohibit plans and insurers that provide prescription drug benefits from denying coverage for the refill of an otherwise covered drug when the refill is ordered for the purpose of placing drugs on the same refill schedule.

Note regarding language — the bill refers to placing "all of the enrollee's medications on the same schedule for refill." Because the length of intended use may vary by prescription, CHBRP has assumed that the AB 2418 would affect the efforts of enrollees to synchronize scheduled refills for "some or all" drugs (not just efforts to synchronize "all").

Provision 3 (prohibition): AB 2418 would prohibit plans and insurers that provide prescription drug benefits from denying coverage for the refill of covered prescription topical ophthalmic products after 70% of the predicted days of use.

Note regarding language — the bill refers to "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 2418 would affect the efforts of enrollees seeking refills at and after 70% of predicted use (not just "at" 70%).

The full text of AB 2418 can be found in Appendix A.

CHBRP is aware that many factors may influence implementation and details of the terms of benefit coverage addressed by AB 2418. In this report, the *Medical Effectiveness* section focuses on medication adherence and the *Benefits Coverage, Utilization, and Cost Impacts* section focuses on cost.

Interaction With Other California Requirements

CHBRP is not aware of benefit mandates that would directly interact with AB 2418's specific requirement and two prohibitions.

However, there are state-level benefit mandates that require some DMHC-regulated plans and some CDI-regulated policies to provide coverage for some groups of outpatient prescription drugs. The requirements of AB 2418 would indirectly interact with such benefit mandates, in that AB 2418 would place requirements on the term and conditions of benefit coverage required by such mandates.

There are state-level benefit mandates that require some (but not all) DMHC-regulated plans and some (but not all) CDI-regulated policies to cover outpatient prescription drugs or to cover particular drugs related to particular conditions.

Some (but not all) small-group and individual market plans and policies are required to provide coverage for outpatient drugs (as part of coverage for Essential Health Benefits coverage specified by the ACA).

- California Health & Safety Code: 1367.005, 1367.006, 1367.0065
- California Insurance Code: 10112.27, 10112.28, 10112.285

Some (but not all) large-group, small-group, and individual market plans and policies are required to provide coverage for specified drugs (as part of preventive services coverage specified by the ACA).

- California Health & Safety Code: 1367.002
- California Insurance Code: 10112.2

There are also state-level benefit mandates that require all DMHC-regulated plans and all CDI-regulated polices to cover particular drugs related to particular conditions, while not requiring coverage for all outpatient prescription drugs.

All large-group, small-group, and individual market plans and policies are required to provide coverage for insulin and prescription drugs for the treatment of diabetes.

- California Health & Safety Code: 1367.51
- California Insurance Code: 10176.61

All large-group, small-group, and individual market plans and policies are required to provide coverage for treatment of osteoporosis.

- California Health & Safety Code: 1367.67
- California Insurance Code: 10123.185

All large-group, small-group, and individual market plans and policies are required to provide coverage for prescription drugs related to treatment of severe mental illness or severe emotional disturbance of a child.

- California Health & Safety Code: 1374.72

- California Insurance Code: 10144.5 and 10123.15

Requirements in Other States

As noted in Table 2, CHBRP is aware of a number of laws similar (or relevant) to the requirements passage of AB 2418 would enact.

Table 2. Laws Similar (or Relevant) to AB 2418 in Other States

Similar Laws	Other States
Mandatory mail order prohibited	AZ, AR, CT, DE, GA, ID, LA, MS, NE, NJ, NC, IL, KS, MD, OK, RI, TX, WV
Mandatory mail order restricted	HI, KY, NY,TN, UT, WI
Incentives for mail order restricted	AL, AR, DE, GA, ID, LA, MD, MS, NE, NJ, NC, PA, WI
Synchronization refill required	OR
Early refills for topical ophthalmic products required	AK, MO, NJ, OR

Source: California Health Benefits Review Program, 2014

In addition, CHBRP is aware that the Centers for Medicare and Medicaid Services (CMS) has made instituted provisions similar to the three AB 2418 would require. CMS instructed Medicare Part D sponsors to allow refills at retail pharmacies,[20] to have a daily cost-sharing rate (which would allow for synchronization),[21] and, for topical ophthalmic products, to cover refills at and after 70% of the predicted days of use.[22]

Interaction With the Affordable Care Act

A number of ACA provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 2418 may interact with requirements in the ACA, including the requirement for certain health insurance to cover "essential health benefits" (EHBs).[23]

Essential Health Benefits

The ACA requires nongrandfathered[24] small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories

[20] Title 42 CFR Sec. 423.120(a)(1)
[21] Title 42 CFR 423.153(b)(4)
[22] Centers for Medicare and Medicaid Services (CMS), memo to Part D Plan Sponsors, "Early Refill Edits on Topical Ophthalmic Products," June 2, 2010.
[23] Resources on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.
[24] A grandfathered health plan is defined as: "A group health plan that was created — or an individual health insurance policy that was purchased — on or before March 23, 2010. Grandfathered plans are exempted from many

of EHBs.[25] California has selected the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan as its benchmark plan.[26,27]

The ACA allows a state to require that a QHP offered in a health insurance marketplace, such as Covered California, offer benefits that exceed EHBs.[28] However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the QHP.[29] However, as laid out in the Final Rule on EHBs HHS released in February 2013,[30] state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs for 2014 and 2015 and there would be no requirement that the state defray the costs of those state mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost. State benefit mandates that could exceed EHBs would "be specific to the care, treatment, and services that a state requires issuers to offer to its enrollees," whereas "state rules related to provider types, cost-sharing, or reimbursement methods" would not meet the definition of state benefit mandates that could exceed EHBs. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.[31]

AB 2418 and essential health benefits

Because AB 2418 specifies terms for existing benefit coverage, but does not require new benefit coverage, it would not directly interact with EHBs.

---

changes required under the ACA. Plans or policies may lose their "grandfathered" status if they make certain significant changes that reduce benefits or increase costs to consumers." (www.healthcare.gov/glossary/grandfathered-health-plan/)

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

[26] The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options. CCIIO, Essential Health Benefits Bulletin. Available at: http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf. Accessed December 16, 2011.

[27] H&SC Section 1367.005; IC Section 10112.27.

[28] ACA Section 1311(d)(3).

[29] State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs for 2014 and 2015, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

[30] Department of Health and Human Services. Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78 , No. 37. February 25, 2013. 12843. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

[31] Essential Health Benefits. Final Rule.

Preventive Services

The ACA requires that nongrandfathered group and individual health insurance plans and policies cover certain preventive services without cost sharing when delivered by in-network providers and as soon as 12 months after a recommendation appears in any of the following:[32]

- The United States Preventive Services Task Force (USPSTF) A and B recommendations;[33]
- The Health Resources and Services Administration (HRSA)-supported health plan coverage guidelines for women's preventive services;[34]
- The HRSA-supported comprehensive guidelines for infants, children, and adolescents, which include:
  - The Bright Futures Recommendations for Pediatric Preventive Health Care;[35] and
  - The recommendations of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children;[36] and
- The Advisory Committee on Immunization Practices (ACIP) recommendations that have been adopted by the Director of the Centers for Disease Control and Prevention (CDC).[37]

AB 2418 and the preventive services mandates

Because AB 2418 specifies terms for existing benefit coverage, but does not require new benefit coverage, it would not directly interact with the preventive services mandate.

---

[32] A resource on this ACA requirement is available on the CHBRP website: www.chbrp.org/other_publications/index.php.

[33] USPSTF created a concise document summarizing its A and B recommendations (last updated in August 2010), available at: www.uspreventiveservicestaskforce.org/uspstf/uspsabrecs.htm. However, for this resource CHBRP consulted USPSTF's A-Z Topic Guide because up-to-date summaries of recommendations are available through links on that webpage: www.uspreventiveservicestaskforce.org/uspstopics.htm.

[34] Available at: www.hrsa.gov/womensguidelines/.

[35] Available at: http://brightfutures.aap.org/pdfs/AAP%20Bright%20Futures%20Periodicity%20Sched%20101107.pdf.

[36] Available at: www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendedpanel/uniformscreeningpanel.pdf

[37] "Recommended immunization schedules for persons aged 0 through 18 years — United States, 2013." Available at: www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-schedule.pdf.
"Catch-up immunization schedule for persons aged 4 months through 18 years who start late or are more than 1 month behind — United States, 2013." Available at: www.cdc.gov/vaccines/schedules/downloads/child/catchup-schedulepr.pdf.
"Recommended adult immunization schedule — United States, 2013." Available at: www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule.pdf.

MEDICAL EFFECTIVENESS

As discussed in the *Introduction*, AB 2418 has three separate provisions mandating specific terms of coverage for prescription refills. The medical effectiveness review is presented for each provision of the bill separately.

Prescription drugs are a part of standard treatment regimens for many diseases and conditions. For this report on AB 2418, CHBRP will not summarize the literature on the effectiveness of prescription drugs across all medical conditions not only because it would not be feasible given the time constraints, but also because the bill does not require coverage for prescription drugs but instead focuses on the terms and conditions of coverage. For the purposes of this review, therefore, CHBRP makes the assumption that FDA-approved drugs are effective for treatment of the conditions for which they have been approved when taken as prescribed.

A key concept for the analysis of this bill is medication adherence. Adherence can be defined as "...the extent to which patients take medications as prescribed by their health care providers" (p. 487) (Osterberg and Blaschke, 2005). Although in any analysis of medical effectiveness, the most important outcomes would be measures of improved health, adherence is a relevant endpoint for the current analysis for the following reasons. First, prescription drugs are an important component of treatment for many diseases and are most effective when taken as directed. Second, in studies of multiple chronic conditions across multiple populations, poor medication adherence has been found to be associated with poor clinical outcomes and mortality (Ho et al., 2006; Ho et al., 2008; Munger et al., 2007; Simpson et al., 2006). Finally, adherence in the United States is estimated at 75% or less (DiMatteo, 2004), indicating that improvements in adherence have the potential to improve the health of a large segment of the population.

Direct measurement of adherence is very difficult as it requires either observation of the patients actually taking their medication or measurement of a metabolite of the medication through laboratory testing (Osterberg and Blaschke, 2005). Another method involves pill counting, in which patients' supply of a medication is quantified by study personnel on a regular basis. Patient surveys often include patient reported measures of adherence, some of which have been validated against pill counts. However, the literature on the effect of specific insurance benefits typically uses proxy measures of adherence based on pharmacy claims data. Two common metrics used in these studies are the medication possession ratio (MPR), sometimes referred to as the proportion of days covered (PDC). The measure involves comparing the number of days' supply dispensed (i.e., picked up by or delivered to the patient) to the amount of time passed, usually over a 12-month timeframe. Thus, if the patient obtained a 30-day supply 10 times in 12 months, the MPR would be 300/365, or 0.82. Studies sometimes use a cut-point for adequate adherence an MPR of 0.80 (Peterson et al., 2007; Sattler et al., 2013).

Use of claims data to estimate adherence has known limitations. First, it is based on the assumption that patients refill their prescriptions only when they have used up their prior prescription, and does not have a way of accounting for waste or stockpiling of medications. Moreover, medication possession measures do not assess correct administration and dosing of the medications, which are also factors in adherence. Nevertheless, use of claims data has been well-established in the literature, and it allows for large-scale studies that would not be possible

using direct assessment. Use of pharmacy claims data also has the advantage in the context of CHBRP analyses in that it limits the study population to those with insurance for prescription drugs.

Research Approach and Methods

CHBRP searched for studies related to mail order pharmacy benefit designs, synchronization of refills, and timing of refills for topical ophthalmic products. 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 2004 to the present. 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.

In the literature review for the mail order opt-out provision of AB 2418, only one study of mandatory mail order for prescription drugs was found and included in the medical effectiveness review for this report. Eleven articles that discussed the effects of optional mail order were summarized but excluded from the medical effectiveness analysis because they were not directly applicable to the bill.

In the literature review for the refill synchronization provision, CHBRP found and included two studies in the medical effectiveness review.

CHBRP searched for studies related to early refill of topical ophthalmic products 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 over-use (such as due to difficulty instilling eye drops) of topical ophthalmic products was studied in a systematic way in a clinical research study.

A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B: Literature Review Methods. Appendix C includes a table describing the studies that CHBRP reviewed (Table C-1) and a table summarizing evidence of effectiveness (Table C-2).

Provision 1 — Opt-out Process for Mandatory Mail Order

This provision would mandate that DMHC-regulated plans and CDI-regulated insurers that require enrollees to obtain prescription drug refills through mail order would have to institute an AB 2418–compliant opt-out process by which individuals can opt out of mail order delivery, in order to make use of retail pharmacies. Therefore, the relevant subpopulation for this provision is

enrollees with a mandatory-mail-order pharmacy benefit. As detailed below, there is limited literature on the impact of mandatory mail order or on the impact of permitting enrollees to opt-out of mandatory mail order. Mandatory mail order refill programs typically limit the drugs included to those that are used on a chronic basis, and that do not require frequent dosage adjustment or intense monitoring processes.

Making mail order delivery optional could increase enrollees' access to face-to-face consultations with pharmacists, which could in turn allow for pharmacist-based interventions at retail pharmacies. Although there is some evidence in the literature that such interventions may increase medication adherence (Lee et al., 2006; Rubio-Valera et al., 2011), the mandate in this bill does not specifically require such interventions. Therefore, CHBRP did not include these studies in the medical effectiveness analysis of this bill.

Methodological Considerations

CHBRP did not identify any studies reported in the published literature, as detailed in Appendix B, that compare mandatory mail order with opt-out to mandatory mail order without opt-out. One study was found that examines the effects of mandatory mail order, in comparison to optional mail order (Liberman et al., 2011a). This study is essentially a comparison of mandatory mail order to opt-in mail order because under optional mail order enrollees choose whether or not to refill prescriptions via mail order. Although this study does not directly address the provision of AB 2418, it offers insights as to whether medication adherence differs depending on whether enrollees have an option to choose whether or not to use mail order.

There is a substantial body of research on the effects of mail order compared to retail pharmacies. However, these studies, which are briefly reviewed below, are of limited relevance to AB 2418 because they all involved either optional mail order participants or an undifferentiated combination of optional and mandatory participants. There are known differences in the characteristics of individuals who choose mail order over retail pharmacies, with the former group more likely to be white/non-Hispanic, aged 65 or over, and have private insurance (Stagnitti, 2008). In addition, several researchers have found that optional mail order users have different behaviors related to medication use, such as higher adherence even before beginning to use mail order (Devine et al., 2010; Iyengar et al., 2013). Therefore, studies that do not specifically focus on enrollees with a mandatory-mail-order provision do not provide evidence for or against the medical effectiveness of either a mandatory-mail-order provision or an opt-out from mandatory mail.

Several of the studies that CHBRP examined were conducted by organizations with an interest in the outcomes of the study, such as retail pharmacy chains (Khandelwal et al., 2011) or mail order pharmacy companies (Devine et al., 2010; Iyengar et al., 2013). A systematic review of studies of the impact of industry sponsorship on research findings concluded that sponsorship of studies of drugs or medical devices by manufacturers is associated with results and conclusions that are more favorable to their products (Lundh et al., 2012). It is worth noting that each type of organization found that its own medication delivery method resulted in higher adherence rates.

Outcomes Assessed

Outcomes of interest for this provision of AB 2418 would include medication safety (i.e., avoiding adverse effects), preventable hospitalizations and emergency department visits, clinical endpoints of the particular diseases under study, morbidity, and mortality. CHBRP searched for studies of the effect of mandatory mail order on health outcomes, but identified no such studies in the literature at this time. Instead, the medical effectiveness review for this provision of the bill focuses on medication adherence, as described above.

Study Findings

Study comparing optional mail order to mandatory mail order

CHBRP found *no studies* on the effectiveness of permitting enrollees to opt out of mandatory-mail-order pharmacy. Such studies would be the most relevant to this provision of AB 2418.

CHBRP did identify one study in the literature that compared enrollees who were required to use mail order for refills to enrollees who chose mail order refills (Liberman et al., 2011a). This study was a retrospective analysis of pharmacy claims data. In this study, 14,000 patients with mandatory-mail-order refills and recent prescriptions for any of seven medication classes used to treat diabetes, hypertension, or high cholesterol were matched to those voluntarily using mail refills on the basis of demographics, type of medication, and out-of-pocket costs. The two groups were compared on the basis of MPR >80%, an accepted measure of adequate medication adherence. Compared to the optional mail order group, mandatory-mail-order users had 30% lower odds of adequate adherence over a one year period when all medication classes were considered together. Taken individually, mandatory-mail-order users in all but two classes of drugs were found to have statistically significant lower adherence rates than optional mail-order users.

This quasi-experimental study provides some indication that mandatory-mail-order use may be detrimental to medication adherence. However, because it is a single study that includes data from only one pharmacy benefit manager (PBM) and did not randomize patients, it cannot be taken as conclusive evidence for the effect of permitting enrollees to opt out of mandatory mail order. The study is summarized in Appendix C, Tables C-1 and C-2.

CHBRP finds insufficient evidence as to the medical effectiveness of requiring health plans and insurers to permit enrollees to opt out of mandatory-mail-order refill requirements. The absence of evidence is not evidence of no effect. It is an indication that the impact of opt-outs from mandatory-mail-order refills on medication adherence and other health outcomes is unknown.

Excluded studies: Comparing optional mail order to retail pharmacies

The CHBRP literature review found a number of large-scale studies on optional participation in mail order pharmacy delivery in comparison to use of retail pharmacies. *CHBRP determined that these studies do not provide evidence for or against the effectiveness of permitting enrollees to opt out of mandatory mail order, because the literature suggests that there are underlying*

differences between those who choose mail order and those who do not. Nevertheless, these studies are briefly summarized here as relevant background information.

Two studies used data from a single integrated health system to compare outcomes and safety for optional mail order and retail pharmacy users. Both studies used statistical techniques to control for differences between the two groups. The first study (Schmittdiel et al.. 2011) found that patients opting to obtain lipid-lowering drugs (statin) through mail order were 20% more likely to achieve their target cholesterol level. The second study (Schmittdiel et al., 2013), compared mail order and retail pharmacy use among diabetic patients and found a 20% reduction in preventable emergency department (ED) visits among mail order users and no differences in hospitalizations or laboratory monitoring. However, among patients aged 65 or over, mail order usage was associated with a 50% increase in potentially serious drug interactions. Despite the fact that the population aged 65 or over is not typically insured by DMHC-regulated plans or CDI-regulated insurers, this finding is relevant to the current analysis in that it indicates that, *among some segments of the population, mail order pharmacy use could increase the risk of adverse events*.

The rest of the studies of optional mail order focused on medication adherence, measured through pharmacy claims data from samples of over 10,000 enrollees. One of the common differences between mail order and retail pharmacy benefits is that the former is more likely to allow longer refill periods, e.g., 90 days. Four studies (Adams et al., 2013; Devine et al., 2010; Duru et al., 2010; Iyengar et al., 2013) compared adherence in mail order and retail pharmacy use without reference to the number of days' supply. Two of these studies attempted to control for the underlying differences in the two groups by statistical means, adjusting for prior adherence patterns (Devine et al., 2010; Iyengar et al., 2013). Devine et al. (2010) found switching to mail order to be associated with a 30% improvement in MPR, while Iyengar et al. (2013) found a smaller but statistically significant improvement. Among the three studies that were limited to 90-day refills in both groups, the results were mixed, with two studies showing a small statistically significant reduction in adherence for mail order users (Khandelwal et al., 2011; Patwardhan et al., 2011), and one showing a small statistically significant improvement for mail order (Iyengar et al., 2013).

The studies of optional mail order versus retail pharmacy with the most relevance to this provision of AB 2418 have *ambiguous findings* regarding effects on health outcomes and medication adherence.

Provision 2 — Synchronization of Refills

The second provision of AB 2418 would prohibit DMHC-regulated plans and CDI-regulated insurers from denying refill coverage of an otherwise covered drug when the refill is requested for the purpose of placing drugs on the same refill schedule. The relevant subpopulation for analyzing the medical effectiveness of this provision of the bill is individuals with prescriptions for more than one chronic medication. The situation of having multiple medications is sometimes called "polypharmacy." It is common among individuals with chronic diseases, such as diabetes, hypertension, and hyperlipidemia, but also frequent across the entire population over the age of 60. Polypharmacy has been the subject of concern due to the possibility of adverse medication

events arising from drug interactions and poor medication adherence because of the complexity of the medication regimen (George et al., 2008). By synchronizing drugs to the same refill schedule, some of this complexity could be ameliorated.

Methodological Considerations

Studies most relevant to this provision of AB 2418 would compare synchronization of refills among persons who take multiple drugs to no synchronization. Neither of the studies CHBRP identified for this review was a randomized controlled trial (RCT). One was an observational study of the impact of lack of refill synchronization on medication adherence (Choudhry et al., 2011) and the other was an intervention study in which a convenience sample of study volunteers was compared to other pharmacy customers (Holdford and Inocencio, 2013).

The concept of refill synchronization has not been formalized in the literature, and there is no established method of measuring it. In the Choudhry et al. (2011) study, refill synchronization was operationalized as the ratio of the number of pharmacy visits to the number of prescriptions filled, subtracted from 1. In other words, 12 visits to collect 12 prescriptions would have a refill synchronization score of 0 (1- 12/12), and 3 visits for the same 12 prescriptions would have a score of 0.75 (1 - 3/12).

In contrast to the lack of RCTs focused on refill synchronization as a way to improve medication adherence, there is a large body of RCTs on other such interventions (Kripalani et al. 2007; Viswanathan et al., 2012), including a review of interventions focused on adherence issues in polypharmacy specifically (George et al., 2008). A systematic review of barriers to adherence in elderly found several studies identifying the number of drugs as a contributing factor in nonadherence, but none of those studies addressed the timing of refills as a problem in polypharmacy (Gellad et al., 2011).

Outcomes Assessed

Outcomes of interest would include medication safety (i.e., avoiding adverse effects), preventable hospitalizations and emergency department visits, clinical endpoints of the particular diseases under study, morbidity, and mortality. CHBRP found no studies of the effect of refill synchronization on health outcomes in the literature at this time. Since such studies have not been published to date, the medical effectiveness review for this provision of the bill focuses on medication adherence.

Study Findings

Two studies met the CHBRP criteria for eligibility for inclusion in this medical effectiveness analysis. One retrospective cohort study assessed the contribution of the lack of synchronization of refills to nonadherence (Choudhry et al. 2011). This study was based on claims data from a large, national PBM. The researchers obtained data for two groups of patients: one taking drugs to lower cholesterol and one taking blood pressure drugs. The two cohorts were assessed separately. Refill synchronization, as defined above, was established over a three-month period, and adherence over the following 12 months, defined as the proportion of days covered (PDC). In both cohorts, full refill synchronization (i.e., single visit for all refills vs. same number of

refills as visits) was associated with an 8 percentage point improvement in adherence, after accounting for differences in patient demographics, comorbidity, out-of-pocket costs, and number of drugs.

The second study (Holdford and Inocencio, 2013) was an intervention study, but not an RCT. Participants were recruited through participating pharmacies, and those who agreed to participate were included in the intervention. For a comparison group, the researchers used pharmacy claims data to match study participants by drug class, age, gender, region, and date. Other than matching on these characteristics, no attempt was made to account for differences in prior adherence or other health-seeking behaviors in the two groups. The outcome measures included PDC (continuous measure), PDC>80% (indicating adequate adherence), and medication persistence (number of days until medication stopped for at least 30 days). The authors report better adherence and greater persistence in the intervention group across the 6 medication classes under study. Besides the methodological concerns related to the control group, the intervention under study involved much more than refill synchronization. In addition to synchronizing refills to the same schedule, it included an initial meeting and monthly calls from a pharmacist, coordination with the physician, and setting up flexible payment schedules for copays. Since the effects of these various services were not disaggregated in the study, it is not possible to infer anything from the results about the effectiveness of refill synchronization alone.

CHBRP finds *insufficient evidence* to make any conclusions about the effect of refill synchronization on medication adherence or health outcomes. The absence of evidence is not evidence of no effect. It is an indication that the impact of refill synchronization on medication adherence and health outcomes is unknown.

Provision 3 — Refills of Topical Ophthalmic Products

This provision of AB 2418 would mandate refill coverage for covered topical ophthalmic products after 70% of the expected days of use. Early refill is of particular interest for users of topical ophthalmic products because of issues related to dispensing and administering of this group of drugs, which includes eye drops and ointments. Topical ophthalmic products are not dispensed in a pre-set, quantifiable dose (such as a pill). For eye drops in particular, accidental over-use can be the result of either allowing too many drops to fall at once or not successfully instilling the drops into the eye.

Topical ophthalmic products can be prescribed for both acute and chronic conditions. However, the focus here is on drugs for chronic disease subject to multiple refills because AB 2418 would be most likely to affect this subset of users of topical ophthalmic products. Therefore, the relevant subpopulation for analyzing the medical effectiveness of this provision of the bill is individuals with prescriptions for topical ophthalmic products used to treat chronic diseases of the eye. The most serious and prevalent of these conditions are described below and include glaucoma, uveitis, allergic conjunctivitis, and chronic dry eye disease. Drugs are used to prevent vision loss including blindness, as well as pain, inflammation, and other symptoms. Topical drugs to treat these four illnesses, primarily in the form of eye drops, are the subject of this review.

- **Glaucoma:** Glaucoma is a term for a group of conditions with the common feature of a distinctive form of damage to the optic nerve that is often, although not exclusively, associated with elevated intraocular pressure. Risk factors for glaucoma differ for different clinical subsets, but the common and most important risk factors are age over 40 years and family history (Yanoff and Duker, 2014). The most common type of glaucoma in the United States, open-angle glaucoma, affects approximately 2.8 million people and has three-fold increased prevalence among African-Americans (Quigley and Broman, 2006). Glaucoma, especially if untreated, can lead to acute episodic eye pain and eventual blindness. Glaucoma is the second-leading cause of blindness in the United States (Yanoff and Duker, 2014) and is the most frequent cause of blindness among African-Americans, who are at approximately four- to five-fold increased risk compared to U.S. whites (Thomas, 2000). Treatment typically involves topical ophthalmic products to lower intraocular pressure.
- **Uveitis:** Uveitis is inflammation of the uvea, the middle portion of the eye. Uveitis can be caused by a number of underlying conditions, including infection, immunological disorders (e.g., systemic lupus erythematosus, ankylosing spondylitis, and others), certain drugs, and genetic disorders. Inflammation associated with uveitis can cause pain and blurred vision. (Power, 2000) Uveitis may also lead to cataracts, glaucoma, and blindness. Uveitis affects approximately 2 per 1,000 persons (Power, 2000) and is responsible for approximately 10% to 20% of blindness cases in the United States (Suttorp-Schulten and Rothova, 1996).
- **Allergic conjunctivitis:** Allergic conjunctivitis is a common allergic condition developing on exposure to an allergen. Although this condition rarely threatens vision, its symptoms of burning, itching, and tearing eyes cause significant suffering. Allergic conjunctivitis affects approximately 20% of the population on an annual basis (Rosario and Bielory, 2011) and is typically treated with topical ophthalmic products including corticosteroids.
- **Chronic dry eye disease:** Sometimes known as keratoconjunctivitis sicca (KCS), chronic dry eye disease describes a syndrome of reduced lachrymal gland tear production, leading to xerophthalmia, or dry eyes. Prevalence varies with age, from approximately 8% in persons younger than 60 up to 20% in persons 80 and older; women have approximately 50% increased prevalence compared to men (Moss et al., 2000). Untreated, there is an increased in risk for damage to the ocular surface (International Dry Eye Workshop 2007). Chronic dry eye syndrome is treated with topical ophthalmic products, including artificial tears and anti-inflammatory medications.

The difficulties of administration and the problem of accidental over-use of eye drops has been described in the peer-reviewed literature (Stone et al., 2009) and in practice guidelines (AAO Glaucoma Panel, 2010; AAO Cornea/External Disease Panel, 2013). In this situation, patients may come to the end of the supply of their drugs before they would have coverage for a refill. *According to an expert in ophthalmologic disease, in advanced cases of glaucoma or uveitis, lapses in therapy of only 2 to 3 days could result in further vision loss.*[38]

[38] Personal communication, J Duncan, University of California, San Francisco, March 2014.

Methodological Considerations

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 topical ophthalmic products.

Outcomes Assessed

For glaucoma, preservation of vision and prevention of blindness are the primary goals of treatment. Frequently studies will use intermediate markers for risk of vision loss, such as intraocular pressure (IOP). For uveitis, the goals of treament include prevention of vision loss and blindness, as well as treatment of outcomes related to inflammation, such as pain, blurred vision, and overall quality of life. In chronic dry eye disease and allergic conjunctivitis relevant outcomes include reduction in inflammation, pain, blurred vision, and overall quality of life. As in the prior two provisions, CHBRP also sought studies on adherence related to early refills of topical ophthalmic products.

Study Findings

As noted above, CHBRP found no clinical research studies nor practice guidelines directly applicable to this provision of AB 2418. *In particular, no studies were identified that examined the effect of brief periods of nonadherence, such as might occur if there are problems with coverage for an early prescription refill for topical ophthalmic products.*

CHBRP finds *insufficient evidence* to conclude that coverage of refills for topical ophthalmic products at or after 70% of the expected days of use would affect eye health. The absence of evidence is not evidence of no effect. It is an indication that the impact of early refills on adherence, vision loss, and other health outcomes is unknown.

Summary of Findings

In the analysis of the medical effectiveness related to the three provisions of AB 2418, CHBRP did not examine the effectiveness of prescription drugs in treating the many conditions for which they are prescribed. CHBRP evaluated the literature relevant to the particular terms and conditions of insurance and health plans that would be affected by this bill: establishing a process for enrollees to opt out of mandatory mail order, synchronizing prescription drugs to the same schedules, and refilling topical ophthalmic products at or after 70% days of expected use.

For the mail order opt-out provision, CHBRP did not identify any studies comparing mandatory mail order with opt-out to mandatory mail order without opt-out. One study that examined the effects of mandatory mail order in comparison to optional mail order, found that mandatory mail order was associated with lower medication adherence. Because of the limited number of studies on this topic, CHBRP assessed the quality of the evidence as insufficient to make a determination on effectiveness.

For the refill synchronization provision, CHBRP identified two relevant studies, but only one provided evidence for or against refill synchronization specifically. That study found that medication adherence was improved for patients with all drug refills synchronized in comparison to patients with no refill synchronization. Again, because of the limited literature on this topic, CHBRP found the quality of the evidence to be insufficient to make a determination on effectiveness.

For the topical ophthalmic products refill provision, CHBRP did not identify any studies or practice guidelines that examined either refill or brief lapses in treatment of these drugs. The lack of studies in this area again led to a call of insufficient evidence.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

AB 2418 would require DMHC-regulated plans and CDI-regulated insurers that both provide a prescription drug benefit and impose a mandatory-mail-order restriction for all or some covered prescription drugs to establish and maintain an opt-out process for mail-order restrictions (Provision 1). AB 2418 would prohibit plans and insurers that provide prescription drug benefits from denying coverage for the refill of an otherwise covered drug when the refill is ordered for the purpose of placing drugs on a synchronized refill schedule (Provision 2). AB 2418 would prohibit plans and insurers that provide prescription drug benefits from denying coverage for the refill of covered prescriptions for topical ophthalmic products after 70% of the predicted days of use (Provision 3). According to CHBRP's estimates, there are 23.4 million insured Californians currently enrolled in either DMHC- or CDI-regulated health plans or policies that may be subject to any state health benefit mandate law, of which 23.1 million (98.7%) have outpatient prescription drug coverage subject to AB 2418.

The impacts modeled in this section rely on some key assumptions. CHBRP has assumed that the percentage of enrollees (1.3%) without outpatient prescription drug benefits would remain the same, as AB 2418 would not mandate coverage of outpatient prescription drugs. CHBRP has also assumed that benefit design and utilization management would be constant except for what the mandate specifies. The bill refers to placing "all of the enrollee's medications on the same schedule for refill." Because the length of intended use and doctor prescribing dates may vary by prescription, CHBRP has assumed that AB 2418 would affect the efforts of enrollees to synchronize scheduled refills for "some or all" drugs (not just to synchronize "all"). 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 2418 would affect the efforts of enrollees seeking refills at and after 70% of predicted use (not just "at" 70%).

This section first presents the premandate (baseline) benefit coverage, utilization, and costs related to this prescription drug refill mandate, and then provide estimates of the impacts on coverage, utilization, and cost if AB 2418 is enacted. For further details on the underlying data sources and methods, please see Appendix D at the end of this document.

Premandate (Baseline) Benefit Coverage, Utilization, and Cost

Premandate (Baseline) Benefit Coverage

In 2015, CHBRP estimates that 98.7% of 23.4 million persons enrolled in DMHC-regulated plans or CDI-regulated policies would have outpatient prescription drug coverage subject to AB 2418 (Table 1).

Current coverage of proposed prescription drug refills was determined by responses to a survey of the seven largest providers of health insurance in California. Responses to this survey represent:

- 91% of enrollees in the privately funded, DMHC-regulated market;
- 71% of enrollees in the CDI-regulated market; and
- 87% of enrollees in the privately funded market subject to state mandates.

Among enrollees in plans and policies with outpatient prescription drug benefits, CHBRP estimates that 4.6% (1.1 million) of enrollees have mandatory-mail-order requirements for some prescription drugs without an AB 2418–compliant opt-out process. Around 44.5% (10.28 million) of enrollees would not have coverage when the refill is ordered for the purpose of placing drugs on a synchronized refill schedule. Around 45.2% (10.43 million) of enrollees would not have refill coverage for topical ophthalmic products at or after 70% of the predicted days of use[39]. There are also override options, which is an approval to allow the prescription claim to be processed by the pharmacy processor under certain approved conditions.

Among CalPERS enrollees, all members have an AB 2418–compliant opt-out process for mandatory mail orders, while only 50% of enrollees have an AB 2418–compliant option for synchronizing drug refill schedules, and early refills of topical ophthalmic products at or after 70% of the predicted days of use. However, enrollees can refill their prescriptions when 75% of their topical ophthalmic products have been used.

Among Medi-Cal Managed Care plans, CHBRP estimates that most enrollees have an AB 2418–compliant opt-out process for mandatory mail orders for qualified prescription drugs. Most enrollees **do not have coverage** when the refill is ordered for the purpose of synchronizing refill schedules. Also, enrollees are subject to refill coverage denial for topical ophthalmic products at or after 70% of the predicted days of use. However, enrollees can refill their prescriptions when 75%, 80%, or 85% of their topical ophthalmic products' expected days of use have been used**.**

Premandate (Baseline) Utilization

CHBRP estimates that in one year, 5,373 prescriptions per 1,000 covered enrollees with health insurance subject to the mandate have been refilled at retail pharmacies, 22 prescriptions per 1,000 covered enrollees with health insurance subject to the mandate have been refilled through mandatory mail order; and 813 prescriptions per 1,000 covered enrollees with health insurance subject to the mandate have been refilled through optional mail order. For mandatory mail order utilization, CHBRP used a representative list of drugs based on health plan survey and discussion with experts in the fields.

For the baseline utilization rate of placing drugs on a synchronized refill schedule, the existing data (2012 MarketScan Commercial Claims and Encounter Database) cannot provide direct estimates. As mentioned in the *Medical Effectiveness* section, there is no established method of measuring refill synchronization in the literature. In the Choudhry study, refill synchronization was operationalized as the ratio of the number of pharmacy visits to the number of prescriptions filled, subtracted from 1 (Choudhry et al., 2011). The authors stated they were unable to identify

[39] CHBRP is aware of refill coverage being available to enrollees no later than when 74% of their prescriptions have been used at a retail pharmacy and 67% of their prescriptions have been used for mail order prescription refills according to survey responses of the health plans.

the specific reasons why patients chose to fill prescriptions on multiple visits, and patients might do so to better manage their out-of-pocket expenditures. Given pharmacists could dispense less than standard number of days' supply of one or more drugs in order to synchronize a patient refill schedule, plus insurers usually allow their enrollees to refill their prescriptions as soon as 74% of their prescription has been used, the additional cost in a year for each medication subject to refill schedule synchronizing could be minimal. As a result, CHBRP anticipates that the financial impact would be minimal if the mandate is enacted and believe it would be appropriate to omit the further analyses of cost impact for refill synchronizing.

CHBRP estimates that in one year, 92 prescriptions per 1,000 covered enrollees with health insurance subject to the mandate that have been refilled are topical ophthalmic products.

Premandate (Baseline) Per-Prescription Cost

CHBRP estimates that the average cost paid by plans or insurers per filled prescription, usually for less than a 30-day supply, is $82.98 at retail pharmacies, $143.92 per prescription filled through mandatory mail order, and $224.91 per prescription filled through optional mail orders, usually for a 60- to 90-day supply, Also, mandatory mail orders are usually for maintenance drugs, which are mostly available in generic forms (Liberman et al., 2011b). The average cost share paid by enrollees per prescription is $13.99 at retail pharmacies, $25.48 per prescription filled through mandatory mail orders, and $25.73 per prescription filled through optional mail orders. To encourage the use of mail orders, plans and insurers usually lower the copays of mail order, sometimes at the equivalent of 2 month's worth of copays for a 3-month supply, based on the responses to the CHBRP survey of providers of insurance and the literature review (Liberman et al., 2011b).

CHBRP cannot provide baseline unit cost estimates for placing drugs on a synchronized refill schedule due to lack of data and appropriate method as mentioned above.

For refilled topical ophthalmic products, CHBRP estimates that the average cost paid by plans or insurers per filled prescription (more than 90% of filled prescriptions for a 30-day supply) is $91.20, and the average cost share paid by enrollees is $20.43.

Premandate (Baseline) Premiums and Expenditures

Table 3 (at the end of this 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: $553.39 and $729.19;
- Small group: $570.50 and $730.30; and
- Individual market: $575.78 and $505.00.

Total current annual expenditures for all DMHC-regulated plans and CDI-regulated policies are $128.4 billion. The distribution of annual expenditures by employers and employees can be found in Table 3.

Public Demand for Benefit Coverage

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

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

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions *currently* do not generally include details such as mandatory-mail-order refill opt-outs, synchronization refill coverage, or early refills for topical ophthalmic products in their health insurance negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the Preferred Provider Organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. The CalPERS PPOs *currently* provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

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

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

How Lack of Coverage Results in Cost Shifts to Other Payers

CHBRP estimates that lack of compliant benefit coverage would result in some cost shifts to enrollees, but not to other payers.

Impacts of the Mandated Benefit Coverage

Postmandate Benefit Coverage

Postmandate there would be no coverage increase for outpatient prescription drugs due to changes to an AB 2418–compliant mail order opt-out process. However, 1.1 million enrollees who have mandatory-mail-order requirements for some prescription drugs without a compliant opt-out process would have coverage with an AB 2418–compliant opt-out, a change in the terms of their benefit coverage.

If they chose to do so, 10.28 million enrollees would have coverage for refills ordered for the purpose of placing drugs on a synchronized refill schedule, a change in the terms of their benefit coverage.

Around 10.43 million enrollees would have changed terms of benefit coverage for topical ophthalmic products, allowing refills at or 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 topical ophthalmic products being used). Estimates are found in Table 1.

Postmandate Utilization

CHBRP estimates that there would be no utilization increase in prescription drugs due to the provision to opt out of mail orders. However, there would be some switches from existing mandatory mail orders to retail pharmacies. CHBRP estimates the switch rates would be at 23.2% postmandate based on the findings of the study conducted by Liberman and colleagues (Liberman et al., 2011b). The authors indicated that during the 4 months after the benefit design change, a total of 55,714 previous mail order users (23.2%) elected to transfer maintenance prescriptions from mail order to retail pharmacy. The switch would lead to an increase of 14 prescriptions per 1,000 covered enrollees being refilled at retail pharmacies within one year, and a decrease of 5.1 prescriptions per 1,000 covered enrollees being refilled through mandatory mail orders within one year.

CHBRP estimates minimal impact on utilization due to refill synchronization.

CHBRP also estimates that within one year, 0.1 more prescriptions per 1,000 covered enrollees would be refilled for topical ophthalmic products.

Impact on access and health treatment/service availability

Making mail order optional could increase enrollees' access to face-to-face consultations with pharmacists and chances of pharmacist-based interventions at retail pharmacies, which may increase patient adherence to his or her medication (Lee et al., 2006; Rubio-Valera et al., 2011). However, mandatory mail orders may increase the ability for health plans and insurers to negotiate a discounted rate for drugs (Johnsrud et al., 2007; Visaria et al., 2012). The decrease in use of mail orders may increase overall cost for prescribed drugs in the long run. As discussed in the *Medical Effectiveness* section, one study on medication refill synchronization showed that full refill synchronization was associated with an 8 percentage point improvement in adherence,

after accounting for differences in patient demographics, comorbidity, out-of-pocket costs, and number of drugs (Choudhry et al., 2011). The findings indicate that synchronizing refill schedule may improve prompt access to the medication. Early refill of topical ophthalmic products would improve access to the drugs when they are needed, though no study is found to support this assumption.

Postmandate Per-Prescription Cost

CHBRP estimates that the per-prescription unit cost will stay the same postmandate. However, postmandate, there would be a decrease of $0.05 per prescription for drugs ordered through retail pharmacies since some of the low-cost prescriptions will be switched from mail orders. There would also be an increase of $0.01 per prescription for topical ophthalmic products due to early refills.

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. Therefore, although there may be administrative costs associated with the mandate, administrative costs as a portion of premiums would not change. In addition, compliance with AB 2418 would require that plans and insurers notify members and applicants of their outpatient prescription policy changes. Health plans and insurers would also need to modify their computer and claims systems in order to allow pharmacy and medical claim systems to process the claims and related data. Health plans and insurers may also need to increase staff specialized in utilization management. These administrative changes were reflected in the standard administrative cost load associated with premiums. 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. All health plans and insurers include a component for administration and profit in their premiums.

Postmandate Expenditures

Changes in total expenditures

Total net expenditures are estimated to increase by $3.3 million or 0. 003% for the year following implementation of the mandate, mainly due to increased coverage and utilization, as well as the administrative costs associated with providing coverage for the benefit of persons who do not currently have it.

Postmandate premium expenditures and PMPM amounts per category of payer

- The mandate is estimated to increase premiums by about $1.35 million. The distribution of the impact on premiums is as follows:
    - Total premiums for private employers purchasing group health insurance are estimated to increase by $845,000, or 0.0015%.

- Total employer premium expenditures for CalPERS HMOs are estimated to increase by $6,000, or 0.0001%.
- Enrollee contributions toward premiums for group insurance are estimated to increase by $332,000, or 0. 001%.
- Total premiums for purchasers of individual market health insurance are estimated to increase by $165,000, or 0.001%.

State expenditures for Medi-Cal Managed Care Plans are estimated to increase by $154,000, or 0.0009%. Increases in per member, per month premiums for the newly mandated benefit coverage in all markets as a result of AB 2418 would be less than $0.01 in DMHC-regulated plans and CDI-regulated policies subject to AB 2418.

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

No potential cost offsets or savings are anticipated.

Postmandate Changes in Uninsured and Public Program Enrollment

Changes in the number of uninsured persons

CHBRP estimates premium increases of less than 1% for each market segment; this premium increase would not have a measurable impact on the number of persons who are uninsured. CHBRP does not anticipate loss of health insurance, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of health insurance, changes in employer 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.

Table 3. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2015

	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+) (d)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (e)	8,779,000	2,012,000	2,498,000	845,000	6,364,000	826,000	567,000	662,000	836,000	23,389,000
Total enrollees in plans/policies subject to AB 2418	8,503,539	2,010,607	2,482,122	845,000	6,364,000	826,000	556,865	661,929	833,128	23,083,190
Premium costs										
Average portion of premium paid by employer	$384.24	$339.01	$0.00	$423.82	$176.26	$408.00	$478.73	$336.01	$0.00	$76,392,927,000
Average portion of premium paid by employee	$140.62	$135.62	$454.56	$105.95	$0.89	$0.00	$160.34	$240.54	$329.35	$39,162,788,000
Total premium	**$524.86**	**$474.63**	**$454.56**	**$529.77**	**$177.15**	**$408.00**	**$639.07**	**$576.55**	**$329.35**	**$115,555,715,000**
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	$28.53	$95.87	$121.22	$28.10	$0.41	$0.00	$90.13	$153.75	$175.65	$12,867,143,000
Enrollee expenses for benefits not covered (f)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Total expenditures	**$553.39**	**$570.50**	**$575.78**	**$557.87**	**$177.56**	**$408.00**	**$729.19**	**$730.30**	**$505.00**	**$128,422,858,000**

Source: California Health Benefits Review Program, 2014.
Note: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, inside and outside the exchange.
(b) As of January, 2014, 57% of CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2015.
(c) Includes children formerly in Healthy Families, which was moved into Medi-Cal Managed Care on January 1, 2014, as part of the 2012-13 state budget.

(d) Medi-Cal Managed Care Plan expenditures for members over 65 include those who also have Medicare coverage.
(e) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.
(f) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.
Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; MCMC=Medi-Cal Managed Care.

Table 4. Postmandate Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2015

	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+) (d)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (e)	8,779,000	2,012,000	2,498,000	845,000	6,364,000	826,000	567,000	662,000	836,000	23,389,000
Total enrollees in plans/policies subject to AB 2418	8,503,539	2,010,607	2,482,122	845,000	6,364,000	826,000	556,865	661,929	833,128	23,083,190
Premium costs										
Average portion of premium paid by employer	$0.00	$0.01	$0.00	$0.00	$0.00	$0.00	$0.01	$0.00	$0.00	$1,06,000
Average portion of premium paid by employee	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.01	$497,000
Total premium	$0.01	$0.01	$0.00	$0.00	$0.00	$0.00	$0.01	$0.01	$0.01	**$1,503,000**
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	$0.01	$0.02	$0.00	$0.00	$0.00	$0.00	$0.01	$0.01	$0.01	$1,843,000
Enrollee expenses for benefits not covered (f)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Total expenditures	$0.02	$0.03	$0.00	$0.00	$0.00	$0.00	$0.02	$0.02	$0.03	**$3,346,000**
Postmandate percentage change										
Percent change insured premiums	0.0013%	0.0031%	0.0003%	0.0001%	0.0010%	0.0004%	0.0014%	0.0013%	0.0036%	0.0013%
Percent change total expenditures	0.0029%	0.0060%	0.0005%	0.0002%	0.0010%	0.0004%	0.0029%	0.0023%	0.0052%	0.0026%

Source: California Health Benefits Review Program, 2014.
Note: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, inside and outside the exchange.
(b) As of January, 2014, 57% of CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2015.
(c) Includes children formerly in Healthy Families, which was moved into Medi-Cal Managed Care in 2014 as part of the 2013-14 state budget.
(d) Medi-Cal Managed Care Plan expenditures for members over 65 include those who also have Medicare coverage.
(e) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.
(f) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.
Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; MCMC=Medi-Cal Managed Care.

PUBLIC HEALTH IMPACTS

As discussed in the *Introduction*, AB 2418 has three separate provisions, mandating specific terms of coverage for prescription drug refills for DMHC-regulated plans and CDI-regulated policies. The first provision would mandate that plans and insurers requiring enrollees to obtain prescription drugs through mail order would have to implement a procedure by which enrollees can opt out of mail-order delivery. The second provision would prohibit plans and insurers from denying a refill of an otherwise covered drug when the refill is ordered for the purpose of placing drugs on the same refill schedule. The third provision would mandate that refills for covered topical ophthalmic products be allowed at and after 70% of the expected days of use.

Estimated Public Health Outcomes

As presented in the *Medical Effectiveness* section, there is insufficient evidence on the effect of all three mandate provisions on adherence to prescription drugs. The absence of evidence is not evidence of no effect. The absence of evidence is an indication that the impact of opt-outs from mandatory mail order, refill synchronization, and early refills for topical ophthalmic products on medication adherence is unknown.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP estimates that AB 2418 will not increase prescription drug coverage but will alter the terms of benefit coverage for some enrollees. CHRBP estimates that while the mandate will establish an opt-out process for approximately 1.1 million enrollees with some mandatory-mail-order requirements for some prescription drugs and there is no overall utilization increase projected, CHBRP estimates that 23% of enrollees will switch from existing mandatory-mail-order refills to retail pharmacy refills. CHBRP estimates that 11.9 million additional enrollees will have coverage for refills ordered for the purpose of placing drugs on the same refill schedule, but CHBRP is unable to estimate any changes in utilization due to the synchronization; however, any anticipated impact would be minimal. CHBRP estimates that 13.6 million additional enrollees will have coverage for topical ophthalmic refills at and after 70% of the predicted days of use and that this will result in an additional 0.2 filled prescriptions per 1,000 enrollees per year.

CHBRP finds insufficient evidence to suggest that any of the provisions in AB 2418 — opt-outs from mandatory mail order, refill synchronization, or early refills for topical ophthalmic products — would improve medication adherence. Although CHBRP estimates a very limited increase in filled prescriptions for topical ophthalmic medications due to the 70% refill provision, CHBRP estimates that these enrollees (on average) could have filled their prescriptions at 75% to 80%; the extra time (generally a single day) of use is unlikely to have a measurable impact on adherence. Due to insufficient medical effectiveness evidence and unlikely impact on adherence despite very limited increases in filled prescriptions, the public health impact on health outcomes, gender or racial/ethnic disparities, and premature death in the first year, postmandate, is 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 an estimate.

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). AB 2418 would increase the financial burden for those enrollees who choose to utilize the opt-out process for mandatory mail order under this mandate, due to differences in copays for prescription drugs obtained from mail order versus retail pharmacies. The *Benefit Coverage, Utilization, and Cost* section estimates enrollee out-of-pocket expenses will increase by around $1.8 million in the first year postmandate, or approximately $61.87 per enrollee among approximately 29,821 enrollees choosing to switch from mandatory-mail-order refills to retail pharmacy refills. CHBRP estimates are based on claims data and may underestimate the cost for enrollees due to carriers' ability to negotiate discounted rates that are unavailable to patients and their families.

CHBRP estimates that AB 2418 would modify coverage and increase the financial burden for enrollees who choose to opt out of a mandatory-mail-order drug refill process by increasing out-of-pocket expenses by $61.87 per enrollee among approximately 29,821 enrollees switching from mandatory-mail-order refills to retail pharmacy refills.

LONG-TERM IMPACT OF THE MANDATE

In this section, CHBRP estimates the long-term impact of AB 2418, 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

There are likely to be long-term cost impacts but the magnitude is unknown. As discussed in the *Utilization Impact* section, there may be decreased discount rates for mail-order drugs due to the decrease in demand for mail orders by consumers as a result of AB 2418 (Visaria et al., 2012). While demand for refills at local pharmacies increases, insurers and employers could respond in a variety of ways, including increasing the copayments, or engaging in additional utilization management strategies.

Long-Term Public Health Impacts

Since the Medical Effectiveness review found insufficient evidence to suggest that opt-outs from mandatory mail order, refill synchronization, or early refills for topical ophthalmic products would improve medication adherence, any potential long-term impacts of AB 2418 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.

APPENDICES

Appendix A: Text of Bill Analyzed

On February 25, 2014, the Assembly Committee on Health requested that CHBRP analyze AB 2418.

ASSEMBLY BILL No. 2418

Introduced by Assembly Members Bonilla and Skinner

February 21, 2014

An act to add Section 1367.247 to the Health and Safety Code, and to add Section 10123.192 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2418, as introduced, Bonilla. Health care coverage: prescription drug 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 contracts and policies that cover prescription drug benefits. Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and prohibits the refilling of a prescription without the authorization of the prescriber, except as specified.

This bill would require a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2015, that provides prescription drug benefits and imposes a mandatory mail order restriction for all or some covered prescription drugs to establish a process allowing enrollees and insureds to opt out of the restriction, as specified. This bill would prohibit a health care service plan contract or a health insurance policy issued, amended, or renewed on or after January 1, 2015, that provides prescription drug benefits from denying coverage for the refill of an otherwise covered drug when the refill is ordered for the purpose of placing all of the enrollee's or insured's medications on the same schedule for refill. The bill would also prohibit the contract or policy from denying coverage for the refill 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 1367.247 is added to the *Health and Safety Code*, to read:

1367.247.

(a) (1) A health care service plan contract issued, amended, or renewed on or after January 1, 2015, that provides prescription drug benefits and that imposes a mandatory mail order restriction for some or all covered prescription drugs shall establish a process for enrollees to opt out of that restriction. The opt out process shall comply with all of the following requirements:

(A) Not impose conditions or restrictions on an enrollee opting out of the mandatory mail order restriction. For purposes of this subparagraph, "conditions or restrictions" include, but are not limited to, requiring prescriber approval or submission of documentation by the enrollee or prescriber.

(B) Allow an enrollee to opt out of the mandatory mail order restriction, and revoke his or her prior opt out of the restriction, at any time.

(C) The choice by an enrollee to opt out shall be valid for as long as the enrollee remains enrolled in the plan contract or elects to revoke the opt out.

(D) A health care service plan shall provide an enrollee who obtains a covered prescription drug that is subject to the mandatory mail order restriction with a separate written notice of the restriction no less than 30 days prior to the restriction taking effect for each drug subject to the restriction. This written notice shall be in addition to any information contained in the plan's evidence of coverage or evidence of benefits. The notice shall inform the enrollee of the right to opt out of the mandatory mail order restriction and instructions on how to do so, including designating a mailing address, electronic mail address, and, if the plan chooses to receive opt out elections by telephone or facsimile, a toll-free telephone or facsimile number, to which the enrollee may deliver his or her opt out election.

(2) This subdivision shall not apply to drugs that are not available at an in-network community pharmacy due to a manufacturer's instructions or restrictions, or due to any risk evaluation and management strategy approved by the federal Food and Drug Administration.

(b) A health care service plan contract issued, amended, or renewed on or after January 1, 2015, that provides prescription drug benefits shall not deny coverage for the refill of an otherwise

covered drug when the refill is ordered for the purpose of placing all of the enrollee's medications on the same schedule for refill.

(c) A health care service plan contract issued, amended, or renewed on or after January 1, 2015, that provides prescription drug benefits shall not deny coverage for the refill of covered topical ophthalmic products at 70 percent of the predicted days of use.

(d) 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 10123.192 is added to the *Insurance Code*, to read:

10123.192.

(a) (1) A health insurance policy issued, amended, or renewed on or after January 1, 2015, that provides prescription drug benefits and that imposes a mandatory mail order restriction for some or all covered prescription drugs shall establish a process for insureds to opt out of that restriction. The opt out process shall comply with all of the following requirements:

(A) Not impose conditions or restrictions on an insured opting 38out of the mandatory mail order restriction. For purposes of this 39subparagraph, "conditions or restrictions" include, but are not limited to, requiring prescriber approval or submission of documentation by the insured or prescriber.

(B) Allow an insured to opt out of the mandatory mail order restriction, and revoke his or her prior opt out of the restriction, at any time.

(C) The choice by an insured to opt out shall be valid for as long as the insured remains covered under the policy or elects to revoke the opt out.

(D) A health insurer shall provide an insured who obtains a covered prescription drug that is subject to the mandatory mail order restriction with a separate written notice of the restriction no less than 30 days prior to the restriction taking effect for each drug subject to the restriction. This written notice shall be in addition to any information contained in the insurer's evidence of coverage or evidence of benefits. The notice shall inform the insured of the right to opt out of the mandatory mail order restriction and instructions on how to do so, including designating a mailing address, electronic mail address, and, if the insurer chooses to receive opt out elections by telephone or facsimile, a toll-free telephone or facsimile number, to which the insured may deliver his or her opt out election.

(2) This subdivision shall not apply to drugs that are not available at an in-network community pharmacy due to a manufacturer's instructions or restrictions, or due to any risk evaluation and management strategy approved by the federal Food and Drug Administration.

(b) A health insurance policy issued, amended, or renewed on or after January 1, 2015, that provides prescription drug benefits shall not deny coverage for the refill of an otherwise covered drug when the refill is ordered for the purpose of placing all of the insured's medications on the same schedule for refill.

(c) A health insurance policy issued, amended, or renewed on or after January 1, 2015, that provides prescription drug benefits shall not deny coverage for the early refill of covered topical ophthalmic products at 70 percent of the predicted days of use.

(d) 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 policy.

SEC. 3.

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

Appendix B: Literature Review Methods

CHBRP searched for studies related to mail-order pharmacy benefit designs, synchronization of refills, and timing of refills for topical ophthalmic products. 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 2004 to the present. 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.

Because the provisions of AB 2418 concern specific terms of pharmacy benefits that have not been well-developed in the medical or health services literature, the literature search was as broad as possible. Many of the initial group of 226 articles were determined irrelevant to the specific benefit terms mandated by AB 2418. 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. For the mail-order provision of AB 2418, CHBRP reviewed 85 abstracts and 14 full text articles for potential inclusion, and found one study was eligible for the medical effectiveness review. For the refill synchronization provision, CHBRP found 21 articles in the literature, 5 were reviewed for potential inclusion, and 2 studies were included in the medical effectiveness review. For the topical ophthalmic products refill provision, no studies were identified in which either early refill or accidental overuse of topical ophthalmic products was studied in a systematic way in a clinical research study

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.*[40] 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.

[40] Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

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

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

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

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

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

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

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

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

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

Search Terms

The search terms used to locate studies relevant to AB 2418 were as follows:

MeSH Terms Used to Search PubMed

- Prescription drugs
- Medication adherence
- Pharmacies
- Postal service
- Health benefit plans, employee
- Treatment outcome

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

- Mail OR mail-order
- Refill
- Barrier
- Refill synchronization
- Refill consolidation
- Medication consolidation
- Topical ophthalmic medication
- Glaucoma
- Uveitis
- Keratoconjunctivitis sicca
- Allergic conjunctivitis
- Atopic keratoconjunctivitis

Publication Types:

- Clinical Trial
- Comparative Study
- Controlled Clinical Trial
- Meta-Analysis
- Practice Guideline
- Randomized Control Trial
- Systematic Reviews

Appendix C: Summary Findings on Medical Effectiveness

Table C-1. Characteristics of Studies That Examined the Effectiveness of Specific Pharmacy Benefit

Type of Benefit	Citation	Type of Trial	Intervention versus Comparison Group	Population Studied	Location
Mandatory mail order	Liberman et al., 2011a	Level III: Matched retrospective cohort	Mandatory mail order vs. optional mail order n=13,914 per group Total sample = 27,828	Pharmacy claims data for users of statins, ACEI, ARB, PAI, metformin, glitazones, or sulfonylureas	U.S.
Synchronized refills	Choudhry et al., 2011	Level III: Observational, retrospective cohort	Refill synchronization compared in 2 separate cohorts: n=1,827,395 (statins) n=1,480,304 (ACEI/ARB) Total sample = 1,967,699	Pharmacy claims data for users of ACEI/ARB or statins	U.S.
Appointment-based medication synchronization	Holdford and Inocencio, 2013	Level III: Quasi-experimental study	ABMS vs. usual care (from claims data) n=973 intervention group n=1,899 usual care group Total sample = 2,872	Users of multiple chronic drugs for hypertension, cardiovascular disease, or diabetes	Midwestern U.S. states

Source: Liberman et al., 2011a; Choudhry et al., 2011; Holdford and Inocencio, 2013.
Key: ACEI = Angiotensin converting enzyme inhibitor; ARB =angiotensin receptor blocker; PAI = platelet aggregation inhibitors

Table C-2. Summary of Findings from Studies Related to the Medical Effectiveness of (a) Opt Out of Mandatory Mail Order and (b) Synchronization of Medication Refills

Outcome	Citation (s)	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
a) Studies of the effectiveness of mandatory vs. optional mail-order Provision						
Adherence to maintenance drugs for diabetes, high cholesterol, or hypertension, as measured by MPR >80% over a 1-year period	Liberman et al., 2011a	Level III: Matched retrospective cohort	Statistically significant: across all classes and for statins, ACEI, ARB, metformin, or sulfonylureas Not significant: glitazones, PAI	Mandatory mail order group less likely to achieve MPR>80%	Adjusted odds ratio = 0.70 overall, ranged from 0.55 - 0.94 for individual drugs	Mandatory mail order associated with lower adherence. Large study of insured persons in employer-sponsored plans in a single PBM. Generalizability: good. Compares mandatory to optional mail order for insured population with common chronic conditions.
b) Studies of the effectiveness of synchronized refill schedules						
Adherence, as measured by PDC, over 12 months, in two cohorts: statin and ACEI/ARB users	Choudhry et al., 2011	Level III: Observational retrospective cohort	Statistically significant: both cohorts	Synchronized refills associated with better adherence	8.4% higher adherence for statin users 8.1% higher adherence for ACEI/ ARB users	Refill synchronization associated with higher adherence. Large observational study of two cohorts with a high degree of polypharmacy. Generalizability: good. Two very common classes of medication. Source of data is large national PBM.

Table C-2. Summary of Findings from Studies Related to the Medical Effectiveness of (a) Opt Out of Mandatory Mail Order and (b) Synchronization of Medication Refills (Cont'd)

Outcome	Citation (s)	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Adherence, as measured by PDC >80%, and non-persistence, over 12 months, in users of 6 classes of chronic drugs.	Holdford and Inocencio, 2013	Level III: Non-randomized intervention study.	Statistically significant: all outcomes, all drug classes	Intervention group had better adherence	Odds ratio for PDC>80% : 3.4 - 6.1	No evidence for effectiveness of refill synchronization alone. Intervention included synchronized refills & multiple contacts from pharmacist, no way to disaggregate effects. Convenience sample compared to matched controls (not recruited for study); no information on prior adherence rates.

Source: Liberman et al., 2011a; Choudhry et al., 2011; Holdford and Inocencio, 2013.
Key: MPR = medication possession ratio, a measure of adherence derived from pharmacy claims data; PBM = pharmacy benefit manager; PDC = proportion of days covered, a similar measure to MPR.

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

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

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm, Milliman, Inc. (Milliman).[41]

Data Sources

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

Baseline model

- The California Simulation of Insurance Markets (CalSIM) is used to project health insurance status of Californians aged 64 and under in 2015. CalSIM is a microsimulation model that projects the effects of the Affordable Care Act on firms and individuals.[42] CalSIM relies on national Medical Expenditure Panel Survey (MEPS) Household Component and Person Round Plan 2006-2010, California Health Interview Survey (CHIS) 2011/ 2012, and California Employer Health Benefits Survey data 2013.
- California Health Interview Survey (2011/2012) data is used to estimate the number of Californians aged 65 and older, and the number of Californians dually eligible for both Medi-Cal and Medicare coverage. CHIS 2011/2012 is also used to determine the number of Californians with incomes below 400% of the federal poverty level. CHIS is a continuous survey that provides detailed information on demographics, health insurance coverage, health status, and access to care. CHIS 2011/2012 surveyed approximately 44,600 households and is conducted in multiple languages by the UCLA Center for Health Policy Research. More information on CHIS is available at: www.chis.ucla.edu.
- The latest (2013) California Employer Health Benefits Survey is used to estimate:
  - Size of firm;
  - Percentage of firms that are purchased/underwritten (versus self-insured);

[41] CHBRP's authorizing legislation requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact (www.chbrp.org/docs/authorizing_statute.pdf).
[42] UC Berkeley Center for Labor Research and Education and UC Los Angeles Center for Health Policy Research. *Methodology & Assumptions, California Simulation of Insurance Markets (CalSIM) Version 1.7*, March 2013. Available at: http://healthpolicy.ucla.edu/publications/Documents/PDF/calsim_methods.pdf. Accessed March 25, 2014.

- Premiums for employment-based health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and point of service [POS] plans); and
- Premiums for employment-based health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs]. Premiums for fee-for-service [FFS] plans are no longer available due to scarcity of these policies in California).

This annual survey is currently released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. Information on the CHCF/NORC data is available at: www.chcf.org/publications/2014/01/employer-health-benefits.

- Milliman data sources are relied on to estimate the premium impact of mandates. Milliman's projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States; see: www.milliman.com/expertise/healthcare/products-tools/milliman-care-guidelines/index.php. Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed health care plans, generally those characterized as PPO plans. The HCGs currently include claims drawn from plans covering 41.2 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following:
  - The MarketScan databases, which reflects the health care claims experience of employees and dependents covered by the health benefit programs of large employers. These claims data are collected from approximately 100 different insurance companies, Blue Cross Blue Shield plans, and third-party administrators. These data represent the medical experience of insured employees and their dependents for active employees, early retirees, individuals with COBRA continuation coverage, and Medicare-eligible retirees with employer-provided Medicare Supplemental plans. No Medicaid or Workers Compensation data are included.
  - Ingenix MDR Charge Payment System, which includes information about professional fees paid for health care services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.
  - These data are reviewed for applicability by an extended group of experts within Milliman but are not audited internally.
- Premiums and enrollment in DMHC-regulated health plans and CDI-regulated policies by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their dependents who receive their benefits through CalPERS. Enrollment information is provided for DMHC-regulated health care service plans covering non-Medicare beneficiaries — about 74% of CalPERS total enrollment. CalPERS self-funded plans — approximately 26% of enrollment — are not

subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOC) documents publicly available at: www.calpers.ca.gov. For the 2014 model, CHBRP assumes CalPERS's enrollment in 2015 will not be affected by continuing shifts in the health insurance market as a result of the ACA.

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

Estimate of premium impact of mandates

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

  For CHBRP reports analyzing specific benefit mandates, CHBRP surveys the seven major carriers on current coverage relevant to the benefit mandate. CHBRP reports the share of enrollees — statewide and by market segment — reflected in CHBRP's bill-specific coverage survey responses. The proportions are derived from data provided by CDI and DMHC. CDI provides data by market segment (large, small, and individual) based on "CDI Licenses With HMSR Covered Lives Greater Than 100,000" as part of the Accident and Health Covered Lives Data Call September 30, 2012, by the California Department of Insurance, Statistical Analysis Division. The Department of Managed Health Care's interactive website "Health Plan Financial Summary Report," July–September 2013, provides data on DMHC-regulated plans by segment.[43]

[43] CHBRP assumes DMHC-regulated PPO group enrollees and POS enrollees are in the large-group segment. http://wpso.dmhc.ca.gov/flash/.

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

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

Data Source	Items
California Simulation of Insurance Markets (CalSIM) 1.9 (projections for 2015)	Uninsured, age: 0–17; 18–64 Medi-Cal (non-Medicare) (a), age: 0–17; 18–64 Other public (b), age: 0–64 Individual market, age: 0–17; 18–64 Small group, age: 0–17; 18–64 Large group, age: 0–17; 18–64
California Health Interview Survey, 2011/2012 (CHIS 2011/2012)	Uninsured, age: 65+ Medi-Cal (non-Medicare), age: 65+ Other public, age: 65+ Employer-sponsored insurance, age: 65+
CalPERS data, annually, enrollment as of September 30	CalPERS HMO and PPO enrollment • Age: 0–17; 18–64; 65+ HMO premiums
California Employer Survey, conducted annually by NORC and funded by CHCF	Enrollment by HMO/POS, PPO/indemnity self-insured, fully insured, Premiums (not self-insured) by: • Size of firm (3–25 as small group and 25+ as large group) • Family vs. single • HMO/POS vs. PPO/indemnity vs. HDHP employer vs. employer premium share
DHCS administrative data for the Medi-Cal program, annually, 11-month lag from the end of November	Distribution of enrollees by managed care or FFS distribution by age: 0–17; 18–64; 65+ Medi-Cal Managed Care premiums
CMS administrative data for the Medicare program, annually (if available) as of end of September	HMO vs. FFS distribution for those 65+ (noninstitutionalized)
CHBRP enrollment survey of the seven largest health plans in California, annually as of end of September	Enrollment by: • Size of firm (2–50 as small group and 51+ as large group), • DHMC vs. CDI regulated • Grandfathered vs. nongrandfathered Premiums for individual policies by: • DMHC vs. CDI regulated • Grandfathered vs. nongrandfathered
Department of Finance population projections, for intermediate CHIS years	Projected civilian, noninstitutionalized CA population by age: 0–17; 18–64; 65+
Medical trend influencing annual premium increases	Milliman estimate

Notes: (a) Includes children previously enrolled in Healthy Families, California's CHIP. As of January 1, 2014, children enrolled in Healthy Families were transitioned into Medi-Cal as required in the 2012–2013 state budget agreement.
(b) Includes individuals dually eligible for Medi-Cal and Medicare.
Key: CDI=California Department of Insurance; CHCF=California HealthCare Foundation; CHIS= California Health Interview Survey; CMS=Centers for Medicare & Medicaid Services; DHCS=Department of Health Care Services; DMHC=Department of Managed Health Care; FFS=fee-for-service; HMO=health maintenance organization; NORC=National Opinion Research Center; PPO=preferred provider organization.

Projecting the Effects of the Affordable Care Act in 2015

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

Baseline premium rate development methodology — 2015

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

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

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

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

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

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

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

- Health care costs paid by the health plan = insurance premiums PMPM × (1 − profit/administration load).
- Gross claims costs PMPM = health care costs paid by the health plan ÷ percentage paid by health plan
- 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's administration and profit. These values vary by insurance category, and under the ACA, are limited by the minimum medical loss ratio requirement. CHBRP estimated these values based on actuarial expertise at Milliman, and their associated expertise in health care.

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

Medi-Cal Managed Care

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

General Caveats and Assumptions

The projected cost estimates are estimates of the costs that would result if a certain set of assumptions were exactly realized. Actual costs will differ from these estimates for a wide variety of reasons, including:

- Prevalence of mandated benefits before and after the mandate may be different from CHBRP assumptions.

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

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

- Cost impacts are shown only for plans and policies subject to state benefit mandate laws.
- Cost impacts are only for the first year after enactment of the proposed mandate.
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of the premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for 1 year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts, please see: www.chbrp.org/analysis_methodology/docs/longterm_impacts08.pdf.
- Several studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew et al., 2005; Glied and Jack, 2003; Hadley, 2006). Chernew et al. (2005) estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, whereas Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and a 0.84 percentage point decrease in the number of insured, respectively. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the simplifying assumption that the elasticity is the same across different types of markets. For more information on CHBRP's criteria for estimating impacts on the uninsured, please see: www.chbrp.org/analysis_methodology/docs/Uninsured_paper_Final_01012009.pdf.

There are other variables that may affect costs, but which CHBRP did not consider in the cost projections presented in this report. Such variables include but are not limited to:

- Population shifts by type of health insurance: If a mandate increases health insurance costs, some employer groups and individuals may elect to drop their health insurance. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefit plans: To help offset the premium increase resulting from a mandate, subscribers/policyholders may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and policies and enrollees, and may also result in utilization

reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). CHBRP did not include the effects of such potential benefit changes in its analysis.

- Adverse selection: Theoretically, individuals or employer groups who had previously foregone health insurance may now elect to enroll in a health plan or policy, postmandate, because they perceive that it is to their economic benefit to do so.
- Medical management: Health plans and insurers may react to the mandate by tightening medical management of the mandated benefit. This would tend to dampen the CHBRP cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., PPO plans).
- Geographic and delivery systems variation: Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the health insurance types CHBRP modeled (HMO, including HMO and POS plans, and non-HMO, including PPO and FFS policies), there are likely variations in utilization and costs by type. Utilization also differs within California due to differences in the health status of the local population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between providers and health plans or insurers. Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, CHBRP has estimated the impact on a statewide level.
- Compliance with the mandate: For estimating the postmandate coverage levels, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the coverage requirements of the bill. Therefore, the typical postmandate coverage rates for populations subject to the mandate are assumed to be 100%.

AB 2418 Specific Caveats and Assumptions

CHBRP has assumed that the percentage of enrollees (1.3%) without outpatient prescription drug benefits will remain the same, as AB 2418 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 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 placing "all of the enrollee's medications on the same schedule for refill." Because the length of intended use and doctor prescribing dates may vary by prescription, CHBRP has assumed that the AB 2418 would affect the efforts of enrollees to synchronize scheduled refills for "some or all" drugs (not just to synchronize "all"). 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 2418 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:

- 2012 MarketScan® Commercial Claims and Encounters Database was used to develop baseline cost and utilization information for outpatient prescription drugs. Baseline cost prescription and utilization rate per 1,000 members were developed separately for prescription drugs dispensed at retail pharmacies and prescription drugs dispensed via mail order. 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. Prescription drugs subject to a mandatory-mail-order restrictions were identified from a list of prescription drugs in the mandatory-mail-order restrictions provided by HP 86 in its response to Carrier Survey. Baseline cost per prescription was trended at a 4% annual rate of increase from 2012 to 2015, and baseline utilization rate was trended at a 3% annual rate of increase from 2012 to 2015.
- To model the cost impact of enrollees opting out of the mandatory-mail-order restrictions, 23.2% of baseline mail-order prescriptions were assumed to be dispensed from retail pharmacy post mandate. CHBRP estimates the switch rates based on the findings of the study conducted by Liberman and colleagues (2011b). The authors indicated that during the 4 months after the benefit design change, a total of 55,714 previous mail users (23.2%) elected to transfer maintenance prescriptions from mail service to retail pharmacy. The ratio of average days supplied per mail-order prescription and average days supplied per retail prescription was used to estimate the increase in retail utilization rate. Baseline cost per prescription was used as the cost per prescription post mandate. The modeling of cost impact was done separately for each prescription drug subject to a mandatory-mail-order restriction.
- Topical ophthalmic products were identified using Milliman internal resources. Baseline utilization and cost per prescription were calculated separately for original and refill prescriptions. To model the cost impact of enrollees being able to refill topical ophthalmic products at the 70% threshold, the utilization rate of refill prescriptions was assumed to increase by the following factor:
- Adjustment Factor = (Refill threshold pre mandate) / (Refill threshold post mandate) * (Dampening Factor)
- The ratio of (Refill threshold pre mandate) / (Refill threshold post mandate) estimates the change in utilization if every person shifted from refilling at the current threshold to the 70% threshold. We assumed that members would not refill every prescription at the 70% threshold and a reasonable assumption was that the average member would refill one script per year at the 70% threshold. Therefore, a dampening factor of 8.3% (= 1 / 12) was used to model anticipated take-up rate of enrollees.

- Baseline cost per prescription was used as the cost per prescription postmandate. The modeling of cost impact was done separately for each topical ophthalmic product.

Appendix E: Information Submitted by Outside Parties

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

Sunovion Pharmaceuticals, Inc. submitted comments regarding additional challenges the opt-out process, as outlined in the bill, may pose to patients with mental illnesses such as schizophrenia, on March 11, 2014.

The following information was submitted by the Office of Assembly Member Susan A. Bonilla in March 2014.

Allegan Managed Markets. *The Eye Care Trend Report, 2013 Edition.*

Allergan Managed Markets. *Preventable Blindness*.

American Academy of Ophthamology. *Primary Open-Angle Glaucoma*. 2010.

American Academy of Ophthamology. *Preferred Practice Pattern: Dry Eye.* September 21, 2013.

American Glaucoma Society. *AAO and AGS Joint Position Statement on Glaucoma Eye Drop Availability*. January 2014.

Anthem Blue Cross Mail Order Notice. November 12, 2012.

Caroll NV. *A comparison of the costs of dispensing prescriptions through retail and mail order pharmacies.* Final report to the NCPA Foundation. February 2013.

Centers for Medicare and Medicaid Services, HSS. *§423.120 Medicare Regulations: Mail Order Requirements*.

Centers for Medicare and Medicaid Services, HSS. *§423.150 Medicare Regulations.*

CMS 2014 Final Call Letter, Mail Order Problems (excerpt – describes annual changes to Medicare).

CMS 2014 Final Call Letter, Synchronization (excerpt – describes annual changes to Medicare).

Department of Health & Human Services, Center for Medicare: Memo to all Part D plan sponsors regarding early refill edits on topical ophthalmic products. June 2, 2010.

Congressional Budget Office. *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services.* November 2012.

Department of Legislative Services, Maryland General Assembly 2011 Session. *Fiscal and Policy Note Revised.House Bill 888 (Kach): Health Insurance – Prescription Eye Drops – Refills.*

Holdford D, Inocencio T. *Appointment-based Model (ABM) Data Analysis Report.* Prepared for Thrify White Pharmacy.

IMS Institute for Healthcare Informatics. *Avoidable Costs in US Healthcare: The $200 Billion Opportunity from Using Medicines More Responsibly.* July 2013.

Khandelwahl N, Duncan I, Rubenstein E, Ahmed T, Pegus C, Murphy P, Kudrak K. Medication adherence for 90-day quantities of medication dispensed through retail and mail order pharmacies. *The American Journal of Managed Ca*re. 2011;17(11):e427-e434.

Liberman JN, Hitchens DS, Shrank WH, Slezak J, Brennan TA. Adherence to medication under mandatory and voluntary mail benefit designs. *The American Journal of Managed Care.* 2011; 17 (7):e260-e269.

Medicare and You 2014: Official Medicare Handbook (Excerpt). *Section 6: Get Information About Your Prescription Drug Coverage*.

National Community Pharmacists Association. *Waste Not, Want Not: Examples of Mail-Order Pharmacy Waste.*

NEHI. *A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease.* A NEHI Issue Brief; August 2009.

NEHI. *Improving Patient Medication Adherence: Key Issues and Challenges in the Daily Practice of Medicine*. A NEHI Issue Brief; January 2013.

State of Alaska 2013 Legislative Session: Fiscal Note. *Topical Eye Meds Prescription Refill.* April 2, 2013.

State of Utah 2014 General Session: Fiscal Note. *SB 78 Prescription Eye Drop Guidelines (Vickers).* March 5, 2014.

State of Utah 2014 General Session. *SB 78 Prescription Eye Drop Guidelines (Vickers)*. March 3, 2014.

States with Laws Governing Mail Order Choice.

Stone JL, Robin AL, Novack GD, Covert DW, Cagle GD. An objective evaluation of eyedrop instillation in patients with glaucoma. *Arch Opthalmol.* 2009; 127 (6) 732-736.

Tax Payers Protection Alliance. *The Expensive Truth Behind Taxpayer-Funded Mail Order Pharmaceuticals.* April 2013.

Thomsen LA, Winterstein AG, Sendergaard B, Haugbelle LS, Melander A. Systematic review of the incidence and characteristics of preventable adverse drug events in ambulatory care. *The Annals of Pharmacotherapy.* 2007; 41: 1411-1415.

Submitted information is available upon request.

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

REFERENCES

American Academy of Ophthalmology (AAO) Cornea/External Disease Panel. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; 2013. Available at: www.aao.org/ppp.

American Academy of Ophthalmology (AAO) Glaucoma Panel. Preferred Practice Pattern Guidelines. Primary Open-Angle Glaucoma. San Francisco, CA: American Academy of Ophthalmology; 2010. Available at: www.aao.org/ppp.

Adams AS, Uratsu C, Dyer W, et al.. Health System Factors and Antihypertensive Adherence in a Racially and Ethnically Diverse Cohort of New Users. *JAMA Internal Medicine*. 2013;173(1): 54-61.

Chernew M, Cutler M, Seliger Keenan P. Competition, markets, and insurance: Increasing health insurance costs and the decline in insurance coverage. *Health Services Research.* 2005;40:1021-1039.

Choudhry NK, Fischer MA, Avorn J, et al. The implications of therapeutic complexity on adherence to cardiovascular medications. *Archives of Internal Medicine*. 2011;171(9): 814-822.

Devine S, Vlahiotis A, Sundar H. A comparison of diabetes medication adherence and healthcare costs in patients using mail order pharmacy and retail pharmacy. *Journal of Medical Economics.* 2010;13(2): 203-211.

DiMatteo MR. Variations in patients' adherence to medical recommendations: a quantitative review of 50 years of research. *Medical Care*. 2004;42(3): 200-209.

Duru OK, Schmittdiel JA, Dyer WT, Parker MM, Uratsu CS, Chan J, Karter AJ. Mail-order pharmacy use and adherence to diabetes-related medications. *American Journal of Managed Care*. 2010;16(1): 33-40.

Gellad WF, Grenard JL, Marcum ZA. A systematic review of barriers to medication adherence in the elderly: looking beyond cost and regimen complexity. American Journal of Geriatric Pharmacotherapy. 2011; 9(1): 11-23.

George J, Elliott RA, Stewart DC. A systematic review of interventions to improve medication taking in elderly patients prescribed multiple medications. *Drugs & Aging*. 2008;25(4): 307-324.

Glied S, Jack K. *Macroeconomic conditions, health care costs and the distribution of health insurance.* Cambridge, MA: National Bureau of Economic Research. 2003. Working Paper (W10029). Available at: www.nber.org/papers/W10029. Accessed on August 2, 2010.

Hadley J. The effects of recent employment changes and premium increases on adults' insurance coverage. *Medical Care Research and Review*. 2006;63:447-476.

Ho PM., Magid DJ, Shetterly SM, et al. Medication nonadherence is associated with a broad range of adverse outcomes in patients with coronary artery disease. *American Heart Journal*. 2008;155(4): 772-779.

Ho PM., Rumsfeld JS, Masoudi FA, McClure DL, Plomondon ME, Steiner JF, Magid DJ. Effect of medication nonadherence on hospitalization and mortality among patients with diabetes mellitus. *Archives of Internal Medicine*. 2006;166(17): 1836-1841.

Holdford DA, Inocencio TJ. Adherence and persistence associated with an appointment-based medication synchronization program. *Journal of the American Pharmacists Association* (2003). 2013;53(6): 576-583.

International Dry Eye Workshop. The definition and classification of dry eye disease: report of the Definition and Classification Subcommittee of the International Dry Eye WorkShop (2007). Ocular Surface. 2007;5(2): 75-92.

Iyengar R, Henderson R, Visaria J, Glave Frazee S. Dispensing channel and medication adherence: Evidence across 3 therapy classes. *American Journal of Managed Care*. 2013;19(10): 798-804.

Johnsrud M., Lawson KA, Shepherd MD. Comparison of mail-order with community pharmacy in plan sponsor cost and member cost in two large pharmacy benefit plans. Journal of Managed Care Pharmacy. 2007;13(2): 122-134.

Khandelwal N, Duncan I, Rubinstein E, Ahmed T, Pegus C, Murphy P, Kudrak KE. Medication adherence for 90-day quantities of medication dispensed through retail and mail order pharmacies. *American Journal of Managed Care.* 2011;17(11): e427-e434.

Kripalani S, Yao X, Haynes RB. Interventions to enhance medication adherence in chronic medical conditions: A systematic review. *Archives of Internal Medicine*. 2007;167(6): 540-549.

Lee JK, Grace KA, Taylor AJ. Effect of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: a randomized controlled trial. *Journal of the American Medical Assocation*. 2006;296(21): 2563-2571.

Liberman JN, Hutchins DS, Shrank WH, Slezak J, Brennan TA. Adherence to medication under mandatory and voluntary mail benefit designs. *American Journal of Managed Care.* 2011a;17(7): e260-e269.

Liberman JN, Wang Y, Hutchins DS, Slezak J, Shrank WH. Revealed preference for community and mail service pharmacy. *Journal of the American Pharmacists Association*. 2011b;51(1): 50-57.

Lundh A., Sismondo S, Lexchin J, Busuioc OA, Bero L. Industry sponsorship and research outcome. *Cochrane Database of Systematic Reviews.* 2012;12: MR000033.

Moss SE, Klein R, Klein BE. Prevalence of and risk factors for dry eye syndrome." Arch Ophthalmology. 2000;118(9):1264-1268.

Munger MA, Van Tassell BW, LaFleur J. Medication nonadherence: an unrecognized cardiovascular risk factor. *MedGenMed: Medscape General Medicine*. 2007;9(3): 58.

Osterberg L, Blaschke T. Adherence to medication. *New England Journal of Medicine*. 2005;353(5):487-497.

Patwardhan AJ, Davis J, Murphy P, Khandelwal N, Sherman B, Manfred. The impact of 90-day prescriptions on adherence at workplace pharmacies compared to traditional mail order. P*opulation Health Management.* 2011;14(6): 285-291.

Peterson AM, Nau DP, Cramer JA, Benner J, Gwadry-Sridhar F, Nichol M. A checklist for medication compliance and persistence studies using retrospective databases. *Value in Health.* 2007;10(1): 3-12.

Power WJ. Introduction to Uveitis. In: Albert DM, Jakobiec FA, Azar DT, Gragoudas ES, ed. *Principles and practice of ophthalmology*. Philadelphia, W.B. Saunders Co.: 2000;1189-1197.

Quigley H.A, Broman AT. The number of people with glaucoma worldwide in 2010 and 2020. *British Journal of Ophthalmology*. 2006;90(3): 262-267.

Rosario N, Bielory L. Epidemiology of allergic conjunctivitis. *Current Opinion in Allergy and Clinical Immunology*. 2011;11(5): 471-476.

Rubio-Valera MA, Serrano-Blanco, Magdalena-Belío J, Fernández A, García-Campayo J, Pujol MM, del Hoyo YL. Effectiveness of pharmacist care in the improvement of adherence to antidepressants: a systematic review and meta-analysis. *The Annals of pharmacotherapy*. 2011;45(1): 39-48.

Sattler EL, Lee JS, Perri M 3rd. Medication (re)fill adherence measures derived from pharmacy claims data in older Americans: a review of the literature. *Drugs & Aging*. 2013;30(6): 383-399.

Schmittdiel JA, Karter AJ, Dyer W, Parker M, Uratsu C, Chan J, Duru OK. The comparative effectiveness of mail order pharmacy use vs. local pharmacy use on LDL-C control in new statin users. *Journal of General Internal Medicine*. 2011;26(12): 1396-1402.

Schmittdiel JA, Karter AJ, Dyer WT, Chan J, Duru OK. Safety and effectiveness of mail order pharmacy use in diabetes. *American Journal of Managed Care*. 2013;19(11): 882-887.

Simpson SH, Eurich DT, Majumdar SR, Padwal RS, Tsuyuki RT, Varney J, Johnson JA. A meta-analysis of the association between adherence to drug therapy and mortality. *BMJ*. 2006;333(7557): 15.

Stagnitti MN. *Comparing Population Characteristics of Persons Purchasing Prescribed Drugs from Mail Order Pharmacies with Persons Purchasing Prescribed Drugs from Other Outlets, 2005*. Statistical Brief. 2008. Agency for Healthcare Research and Quality, Rockville, MD.

Stone JL, Robin AL, Novack GD, Covert DW, Cagle GD. An objective evaluation of eyedrop instillation in patients with glaucoma. *Archives of Ophthalmology*. 2009;127(6): 732-736.

Suttorp-Schulten MS, Rothova A. (1996). The possible impact of uveitis in blindness: a literature survey. *British Journal of Ophthalmology.* 1996;80(9): 844-848.

Thomas JV. Primary Open-Angle Glaucoma. In: Albert DM, Jakobiec FA, Azar DT, Gragoudas ES, ed. *Principles and practice of ophthalmology*. Philadelphia, W.B. Saunders Co.: 2000;2682-2685.

Visaria J, Seoane-Vazquez E, Szeinbach SL, Rodriguez-Monguio R. Comparing the cost of community pharmacy and mail-order pharmacy in a US retirement system. *International Journal of Health Planning & Management*. 2012;27(1): e41-50.

Viswanathan M, Golin CE, Jones CD, et al. Closing the quality gap: revisiting the state of the science (vol. 4: medication adherence interventions: comparative effectiveness). *Evidence Report/Technology Assessment* (Full Rep). 2012;(208.4): 1-685.

Yanoff M, Duker JS. *Ophthalmology*. 4th Ed. London, Elsevier; 2014.

.

California Health Benefits Review Program Committees and Staff

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

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

Faculty Task Force

Joy Melnikow, MD, MPH, *Vice Chair for Public Health*, University of California, Davis
Ninez Ponce, PhD, *Vice Chair for Cost*, University of California, Los Angeles
Ed Yelin, PhD, *Vice Chair for Medical Effectiveness*, University of California, San Francisco
Susan L. Ettner, PhD, University of California, Los Angeles
Theodore Ganiats, MD, University of California, San Diego
Sheldon Greenfield, MD, University of California, Irvine
Sylvia Guendelman, PhD, LCSW, University of California, Berkeley

Task Force Contributors

Wade Aubry, MD, University of California, San Francisco
Janet Coffman, MA, MPP, PhD, University of California, San Francisco
Gina Evans-Young, University of California, San Francisco
Margaret Fix, MPH, University of California, San Francisco
Ronald Fong, MD, MPH, University of California, Davis
Brent Fulton, PhD, University of California, Berkeley
Erik Groessl, PhD, University of California, San Diego
Shana Lavarreda, PhD, MPP, University of California, Los Angeles
Stephen McCurdy, MD, MPH, University of California, Davis
Sara McMenamin, PhD, University of California, San Diego
Ying-Ying Meng, PhD, University of California, Los Angeles
Jack Needleman, PhD, University of California, Los Angeles
Nadereh Pourat, PhD, University of California, Los Angeles
Dominique Ritley, MPH, University of California, Davis
Dylan Roby, PhD, University of California, Los Angeles
AJ Scheitler, MEd, University of California, Los Angeles
Riti Shimkhada, PhD, University of California, Los Angeles
Meghan Soulsby, MPH, University of California, Davis
Steven Tally, PhD, University of California, San Diego
Chris Tonner, MPH, University of California, San Francisco
Laura Trupin, MPH, University of California, San Francisco
Byung-Kwang (BK) Yoo, MD, MS, PhD, University of California, Davis
Patricia Zrelak, PhD, RN, CNRN, NEA-BC, University of California, Davis

National Advisory Council

Lauren LeRoy, PhD, Fmr. President and CEO, Grantmakers In Health, Washington, DC, *Chair*

Stuart H. Altman, PhD, Professor of National Health Policy, Brandeis University, Waltham, MA
Deborah Chollet, PhD, Senior Fellow, Mathematica Policy Research, Washington, DC
Joseph P. Ditré Esq, Executive Director, Consumers for Affordable Health Care, Augusta, ME
Allen D. Feezor, Fmr. Deputy Secretary for Health Services, North Carolina Department of Health and Human Services, Raleigh, NC
Charles "Chip" Kahn, MPH, President and CEO, Federation of American Hospitals, Washington, DC
Jeffrey Lerner, PhD, President and CEO, ECRI Institute Headquarters, Plymouth Meeting, PA
Trudy Lieberman, Director, Health and Medicine Reporting Program, Graduate School of Journalism, City University of New York, New York City, NY
Donald E. Metz, Executive Editor, Health Affairs, Bethesda, Maryland
Marilyn Moon, PhD, Vice President and Director, Health Program, American Institutes for Research, Silver Spring, MD
Carolyn Pare, CEO, Buyers Health Care Action Group, Bloomington, MN
Michael Pollard, JD, MPH, Senior Fellow, Institute for Health Policy Solutions, Washington, DC
Christopher Queram, President and CEO, Wisconsin Collaborative for Healthcare Quality, Madison, WI
Richard Roberts, MD, JD, Professor of Family Medicine, University of Wisconsin-Madison, Madison, WI
Frank Samuel, LLB, Former Science and Technology Advisor, Governor's Office, State of Ohio, Columbus, OH
Patricia Smith, President and CEO, Alliance of Community Health Plans, Washington, DC
Prentiss Taylor, MD, Corporate Medical Director, Advocate At Work, Advocate Health Care, Chicago, IL
J. Russell Teagarden, Vice President, Clinical Practices and Therapeutics, Medco Health Solutions, Inc, Brookfield, CT
Alan Weil, JD, MPP, Executive Director, National Academy for State Health Policy, Washington, DC

CHBRP Staff

Garen Corbett, MS, Director
John Lewis, MPA, Associate Director
Laura Grossmann, MPH, Principal Policy Analyst
Hanh Kim Quach, MBA, Principal Policy Analyst
Nimit Ruparel, MPP Policy Analyst
Karla Wood, Program Specialist

California Health Benefits Review Program
University of California
Office of the President
1111 Franklin Street, 11th Floor
Oakland, CA 94607
Tel: 510-287-3876 Fax: 510-763-4253
chbrpinfo@chbrp.org
www.chbrp.org

The California Health Benefits Review Program is administered by the Division of Health Sciences and Services at the University of California, Office of the President. The Division is led by John D. Stobo, MD, Senior Vice President.