

California Health Benefits Review Program

Analysis of Assembly Bill 889: Health Care Coverage: Prescription Drugs

A Report to the 2013-2014 California Legislature

April 25, 2013





The California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analyses of the medical, financial, and public health impacts of proposed health insurance benefit mandates and proposed repeals of health insurance benefit mandates. CHBRP was established in 2002 to respond to requests from the California Legislature to provide 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 as well as Loma Linda University, the University of Southern California, and Stanford University, and designed to provide balanced representation among groups with an interest in health insurance benefit mandates or repeals, reviews draft studies to ensure their quality before they are transmitted to the Legislature. Each report summarizes scientific evidence relevant to the proposed mandate, or proposed mandate repeal, but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work through 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.

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 889. In response to a request from the California Assembly Committee on Health on March 11, 2013, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute.

Janet Coffman, MPP, PhD, and Gina Evans-Young, of the University of California, San Francisco, prepared the medical effectiveness analysis. Penny Coppernoll-Blach, MLIS, of the University of California, San Diego, conducted the literature search. Yali Bair, PhD, a private consultant, prepared the public health impact analysis. Todd Gilmer, PhD, of the University of California, San Diego, prepared the cost impact analysis. Susan Pantely, FSA, MAAA, and Dan Henry, of Milliman, provided actuarial analysis. Debbie Stern, a consultant at Rxperts, provided technical assistance with the literature review and expert input on the analytic approach. Hanh Quach 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, Theodore Ganiats, MD, of the University of California, San Diego, 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:

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 889

The California Assembly Committee on Health requested on March 11, 2013, 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) 889 (Frazier) on fail-first protocols for prescription medications. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.²

In 2014, CHBRP estimates that approximately 25.9 million Californians (67%) will have health insurance that may be subject to a health benefit mandate law passed at the state level.³ Of the rest of the state's population, a portion will be uninsured (and so 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.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state benefit mandates. The California Department of Managed Health Care (DMHC)⁴ 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,⁵ which offer benefit coverage to their enrollees through health insurance policies.

All DMHC-regulated plans and/or CDI-regulated policies that provide benefit coverage for outpatient prescription drugs would be subject to AB 889. Therefore, the mandate would affect the health insurance of approximately 25.3 million enrollees (65% of all Californians).

Developing Estimates for 2014 and the Effects of the Affordable Care Act

The Affordable Care Act (ACA)⁶ is expected to dramatically affect health insurance and its regulatory environment in California, with many changes becoming effective in 2014. It is important to note that CHBRP's analyses of proposed benefit mandate bills typically address the marginal 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 marginal effects are presented in this report. Because expanded enrollment will not occur until January 2014, CHBRP relies on projections from the California

² Available at: www.chbrp.org/docs/authorizing_statute.pdf.

³ CHBRP's estimates are available at: www.chbrp.org/other_publications/index.php.

⁴ The California Department of Managed Health Care (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 The California Department of Insurance (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 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).

Simulation of Insurance Markets (CalSIM) model⁷ to help set baseline enrollment for 2014. From this projected baseline, CHBRP estimates the marginal impact of benefit mandates proposed that could be in effect after January 2014.

Bill-Specific Analysis of AB 889

The full text of AB 889 can be found in Appendix A.

AB 889 prohibits DMHC-regulated health plans and CDI-regulated policies from requiring patients to try and fail more than two medications before allowing patients access to the initially prescribed medication, or a generic version of the same medication. CHBRP uses the term “fail-first protocols” to refer to utilization management protocols where alternative—and less costly—medications must be tried before coverage for the prescribed—usually more expensive—medication is approved.⁸

AB 889 would still permit DMHC-regulated plans and CDI-regulated policies to use fail-first protocols to manage utilization for medications. However, AB 889 would require plans and insurers that apply fail-first protocols to medications to do the following:

- Cover the initially prescribed medication, or a generic version of the same medication, after a trial of no more than two alternative medications.
- Have an expedited process in place to authorize exceptions to step therapy (therapies required before the “step-up” to the prescribed medicine) and ensure that patients can obtain necessary medications.
- Conform to evidence-based practices that are current in published peer-reviewed medical and pharmaceutical literature.

Because AB 889 allows up to two fail-first attempts before a patient can access the initially prescribed medication, or its generic equivalent, CHBRP’s analysis focuses primarily on categories of drugs where health plans and insurers require patients to try and fail three or more “steps” before accessing the prescribed medication.

Background on Fail-First Protocols

Fail-first is among several terms used to describe utilization management techniques applied to prescription drugs at a health plan or insurer. Health plans and insurers employ utilization management for a variety of reasons, including:

- Clinical considerations; and

⁷ 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.

⁸ CHBRP uses the term “fail-first protocols” rather than “step therapy” because the latter term has meanings—both as a utilization management tool used by health insurance carriers, and by providers in a clinical setting.

- To control the cost of prescription drugs, particularly in therapeutic classes where many generics versions exist.

Other terms

Fail-first protocols may also be called:

- *Step therapy*, which when implemented by a health plan or insurer, requires an enrollee to first try an alternative medication (often a generic alternative) prior to receiving coverage for the final medication (often a brand-name medication, although AB 889 permits carriers to provide coverage for a generic version of the same medication).
- *Step edit* or *online edit*, which refer to a process by which a prescription is electronically reviewed when submitted for payment authorization to determine whether a patient used a prior first-line medication.

If a patient's prescription is declined under either step therapy or step/online edit, a patient's health care provider may either reissue the prescription for the first medication that is covered by the patient's health plan or policy, or appeal the decision.

A fail-first protocol may also be the basis for part or all of a *precertification* or *prior authorization*⁹ protocol, which may also require the prescribing provider to confirm to the plan or insurer that an alternative medication or medications have been unsuccessfully tried by the patient before coverage for the prescribed medication is approved.

Alternatively, the patient may either purchase an over-the-counter alternative or the prescribed medication, in both cases paying for the full cost out of pocket.¹⁰

Prevalence of fail-first protocols with more than two steps

There is insufficient data in the literature about the prevalence of more than two steps of fail-first protocols as would be prohibited in AB 889.

CHBRP found that, in the privately funded market, among the most common drug classes, those most commonly subject to three or more fail-first protocol steps in California were:

- Gastrointestinal agents, or proton pump inhibitors, which includes five generic products, with estimated utilization of 229 per 1,000 members and an average cost of \$181.82;
- Beta blockers, which include nine generic products, with estimated utilization of 188 per 1,000 enrollees and an average cost of \$39.17; and
- Bone density regulators, which include seven generic products, with estimated utilization of 32.7 per 1,000 enrollees and an average cost of \$154.81.

⁹ Not all prior authorization protocols have a fail-first component. Some prior authorization protocols are based on other criteria, such as intended use to treat a specific medical problem or diagnosis or confirmation that the patient meets other criteria such as age or specified comorbidities.

¹⁰ Patients may also encounter challenges to filling their prescribed medications, for instance, the physician or pharmacist may not complete the necessary paperwork.

For Medi-Cal Managed Care Plans, no prescription drug cost and utilization data was available. The drug classes most commonly subject to three or more fail-first protocol steps in Medi-Cal Managed Care Plans are:

- Opioid agonists – non-patch, which include 141 generic products;
- Gastrointestinal agents, or proton pump inhibitors, which include five generic products;
- Serotonin-norepinephrine reuptake inhibitors (SNRI), which include four generic products.

Medical Effectiveness

The medical effectiveness review synthesized findings from studies of the impact of fail-first protocols on utilization of prescription medications, utilization of other health care services, and health outcomes.

Study Findings

CHBRP terminology for grading evidence of medical effectiveness

CHBRP uses the following terms to characterize the strength of the evidence it identifies regarding the medical effectiveness of a treatment for which a bill would mandate coverage.

- Clear and convincing evidence
- Preponderance of evidence
- Ambiguous/conflicting evidence
- 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 are of high quality and consistently find that the treatment is either effective or not effective.

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.

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 of equal quality 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 are not of high quality. It does not indicate that a treatment is not effective.

Characteristics of included studies

- CHBRP identified 15 articles that present findings from 13 studies of the impact of fail-first protocols.
- None of the studies identified by CHBRP examined fail-first protocols that required enrollees to try and fail more than two other medications before obtaining the initially prescribed medication, as would be prohibited under AB 889. Most required a trial of only one other prescription drug.
- None of the studies compared the impact of a fail-first protocol involving one or two steps to a fail-first protocol involving more than two steps.
- These studies addressed fail-first protocols for the following classes of prescription medications:
 - Antidepressants
 - Antihypertensives
 - Antipsychotics and anticonvulsants
 - Nonsteroidal anti-inflammatory drugs (NSAIDs)
 - Proton pump inhibitors (PPIs)
- Six of the 13 studies examined effects of fail-first protocols on persons who had private health insurance. Seven studies assessed effects on persons enrolled in Medicaid (Medi-Cal in California).
- Five studies were wholly or partially funded by pharmaceutical companies and three were conducted by employees of a pharmacy benefit management company. Sponsorship of studies of medications or medical devices by manufacturers is associated with results and conclusions that are more favorable to their products. Sponsorship may also affect findings from studies of fail-first protocols aimed at reducing use of a manufacturer's products.

Methodological considerations

- None of the 13 studies CHBRP identified were randomized controlled trials (RCTs). Most were nonrandomized studies with comparison groups.
- The most frequently assessed outcomes were utilization of prescription medications and other medical services, including hospital admissions, emergency department visits, and outpatient visits. Such changes in utilization may be associated with changes in health status but CHBRP identified no studies that provided direct evidence of a change in health outcomes aside from a small study on the impact of step therapy on quality of life.
- Synthesis of findings across studies is difficult because for most classes of medications outcomes were not measured consistently across studies.

Findings of included studies

- The only study to directly evaluate the impact of fail-first protocols on a health outcome found that step therapy for NSAIDs had no statistically significant effect on quality of life among persons with chronic pain.
- Although the stated goal of fail-first protocols is not to prevent persons from receiving prescription medications, the preponderance of evidence suggests that this may occur for some persons. Persons may not obtain prescription medications because they do not ask their pharmacist or physician whether they can obtain an exception to the fail-first protocol, the pharmacist does not contact their physician to obtain an exception or a prescription for an alternative medication covered by the person's plan or policy, or the physician does not submit the documentation needed to obtain an exception.
 - A single controlled study reported that a fail-first protocol was associated with a decrease in initiation of treatment with antipsychotic or anticonvulsant medications among persons with bipolar disorder.
 - Surveys of persons subject to fail-first protocols for antidepressants, NSAIDs, and PPIs found that some persons did not fill a prescription for the preferred medication in the therapeutic class or obtain an exception to the fail-first protocol. Some obtained an over-the-counter medication and others did not obtain any medication.
 - The studies did not address the impact of not obtaining medication on health outcomes.
- Antihypertensives and antipsychotics are the only classes of prescription medications for which there is evidence that fail-first protocols are associated with discontinuation of medication. There is insufficient evidence to determine whether fail-first protocols are associated with discontinuation of antidepressants, NSAIDs, or PPIs.
- For prescription medications that should be taken daily, the number of days' supply dispensed can be an important indicator of adherence to treatment. The preponderance of evidence suggests that fail-first protocols are not associated with the number of days' supply of antidepressant medication dispensed. Findings from studies of the impact of fail-first protocols on days' supply of antihypertensive medication are ambiguous. CHBRP identified no studies of the relationship between fail-first protocols and days' supply of antipsychotics, anticonvulsants, NSAIDs, and PPIs.
- Findings from studies of the impact of fail-first protocols on rates of hospital admissions, emergency department visits, and outpatient visits are inconsistent across classes of prescription medications.
- The generalizability of findings from these studies to AB 889 is unknown because none of these studies assessed fail-first protocols involving more than two steps and none compared a fail-first protocol with one or two steps to a fail-first protocol with more than two steps.

Benefit Coverage, Utilization, and Cost Impacts

This section focuses on the impact of AB 889 on premium costs and utilization among all 25.3 million enrollees with DMHC-regulated plans or CDI-regulated policies subject to the proposed mandate.

CHBRP assumes that implementation of AB 889 would:

- Not result in a change in the number of enrollees who use a specific medication subject to three or more steps in a fail-first protocol; rather, it would allow enrollees to receive access to the prescribed medication in at least one fewer step (two steps, instead of three).
- Not result in a change in the number of enrollees who use a medication in a therapeutic class subject to three or more steps in a fail-first protocol; rather, because enrollees would have access to the prescribed medication more quickly, it would shift utilization from other medications in the therapeutic class to the prescribed drug.
- Not result in a change in the number of enrollees who purchase out-of pocket (i.e., as a noncovered benefit) a specific medication subject to three or more steps in a fail-first protocol.

Coverage impacts

- 18.5% of enrollees subject to AB 889 have outpatient prescription drug coverage that includes medications that are subject to three or more steps in a fail-first protocol. If AB 889 were enacted, this would decline to 0%.

Utilization impacts

- CHBRP used the Milliman 2012 Health Cost Guidelines to estimate the utilization and costs of medications that are subject to three or more steps in fail-first protocols. CHBRP estimates that 11.1 filled prescriptions per 1,000 enrollees annually are for drugs that are prescribed after the second step but before the final step in a specific therapeutic class.
- Postmandate, CHBRP estimates no change in the number of enrollees who use a medication that is currently subject to three or more steps in a fail-first protocol, but that implementation of AB 889 would enable enrollees to obtain the prescribed medication more quickly.
- Postmandate, CHBRP estimates that with implementation of AB 889, the number of prescriptions filled for medications that are subject to three or more steps in a fail-first protocol would increase by 10%, which would be offset by a decrease in the number of prescriptions filled for other drugs within these therapeutic classes.

Cost impacts

- Increases in per member per month (PMPM) premiums for the newly mandated benefit coverage vary by market segment (see Table 4 in *Benefit Coverage, Utilization, and Cost*

Impacts). Increases as measured by PMPM premiums are estimated to range from \$0.01 to \$0.16.

- In the privately funded large-group market, the increase in premiums is estimated to range from \$0.07 PMPM among DMHC-regulated plans to \$0.01 PMPM among CDI-regulated policies (Table 4).
- For enrollees in the privately funded small-group market, health insurance premiums are estimated to increase by approximately \$0.08 PMPM for DMHC-regulated plan contracts, with no change among CDI-regulated policies.
- CHBRP estimates no change in the privately funded individual market.
- For publicly funded DMHC-regulated health plans, CHBRP estimates that premiums would increase by \$0.16 for Medi-Cal Managed Care Plans.
- Total net annual health expenditures are projected to increase \$26 million (0.0180%) (see Table 1). This increase in expenditures is due to a \$24.6 million total increase in health insurance premiums and a \$1.4 million increase in enrollee copayments associated with earlier use of final step medications.

Public Health Impacts

- CHBRP concludes that passage of AB 889 would have unknown public health impact.
- There is insufficient evidence to determine whether fail-first protocols, regardless of the number of steps, directly affect health outcomes.
- The extent of any racial or ethnic disparities in the prevalence of the use of more than two steps in fail-first protocols is unknown due to lack of evidence. Therefore, the extent to which AB 889 would have an impact on possible disparities is unknown.
- There is insufficient evidence about the impact of fail-first protocols on premature death, and therefore the impact of AB 889 is unknown.
- There is insufficient evidence about the impact of fail-first protocols on economic loss, and therefore the impact of AB 889 is unknown.

Interaction with the Affordable Care Act

As previously mentioned, AB 889 does not require DMHC-regulated plans and CDI-regulated policies to *provide* benefit coverage for prescription drugs. However, the ACA (through essential health benefits) requires this expansion for nongrandfathered plans and policies in the small group and individual markets.¹¹ AB 889, therefore, would build on the ACA's expansion, and restrict all nongrandfathered small group and individual market plans and policies from requiring enrollees from trying and failing more than two medications.

¹¹ Large -group plans and policies, and grandfathered small -group and individual policies—those in existence before March 23, 2010—would not be required to include outpatient prescription drug coverage.

The requirement—or restriction—that AB 889 imposes in the design of the plan, is not considered a state-required mandate, according to regulations written by the federal Department of Health and Human Services.^{12,13} Therefore, AB 889 would not require the state to defray any costs for Qualified Health Plans (QHPs) purchased in Covered California, the state’s health insurance exchange.

¹² Department of Health and Human Services, “Proposed Rule: Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation,” *Federal Register*, Vol 77, No. 277, November 26, 2012, at <http://www.gpo.gov/fdsys/pkg/FR-2012-11-26/pdf/2012-28362.pdf>.

¹³ Department of Health and Human Services, “Final Rule: Proposed Rule: Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation,” *Federal Register*, Vol. 78, No. 37, February 25, 2013, at <http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf>.

Table 1. AB 889 Impacts on Benefit Coverage, Utilization, and Cost, 2014

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	25,899,000	25,899,000	0	0%
Total enrollees with health insurance subject to AB 889	25,323,000	25,323,000	0	0%
Percentage of enrollees affected by > 2 fails in step therapy	18.5%	0.0%	-18.5%	-100%
Number of enrollees affected by > 2 fails in step therapy	4,691,000	0.0%	-4,691,000	-100%
Utilization and cost				
Annual number of scripts per 1,000 members for drugs between 2nd step and final drug in therapeutic class	11.1	0	0.0	-100%
Average cost for drugs, paid by health plans and individuals for steps beyond 2nd and prior to final drug in therapeutic class	\$369.51	\$423.97	\$54.45	14.737%
Total annual differential, drugs between 2nd step and final fill				
Costs paid by health plans	\$108,027,000	\$136,817,000	\$28,790,000	26.651%
Costs paid by individuals	\$10,311,000	\$12,066,000	\$1,755,000	17.021%
Costs paid by health plans and individuals	\$118,338,000	\$148,883,000	\$30,545,000	25.812%
Expenditures				
Premium expenditures by private employers for group insurance	\$78,385,161,000	\$78,395,139,000	\$9,978,000	0.0127%
Premium expenditures for individually purchased insurance	\$13,639,719,000	\$13,639,719,000	\$0	0.0000%
Premium expenditures by persons with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (b)	\$21,272,946,000	\$21,275,474,000	\$2,528,000	0.0119%
CalPERS HMO employer expenditures (c)	\$4,016,233,000	\$4,016,233,000	\$0	0.0000%
Medi-Cal Managed Care Plan expenditures	\$12,480,492,000	\$12,491,518,000	\$11,026,000	0.0883%
Healthy Families Plan expenditures (d)	\$667,300,000	\$668,366,000	\$1,066,000	0.1597%
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$14,462,198,000	\$14,463,624,000	\$1,426,000	0.0099%
Enrollee expenses for noncovered benefits (e)	\$0	\$0	\$0	0.000%
Total expenditures	\$144,924,049,000	\$144,950,073,000	\$26,024,000	0.0180%

Source: California Health Benefits Review Program, 2013.

Notes: (a) This population includes persons with privately funded (including Covered California, the state's health insurance exchange) and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans) health insurance

products regulated by DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employer-sponsored health insurance.

(b) Premium expenditures by enrollees include employee contributions to employer-sponsored health insurance, health insurance purchased through Covered California, and enrollee contributions for Medi-Cal Managed Care.

(c) Of the increase in CalPERS employer expenditures, about 57.5%, or \$0, would be state expenditures for CalPERS members who are state employees, state retirees, or their dependents. This percentage reflects the share of enrollees in CalPERS HMOs as of September 30, 2012. CHBRP assumes the same ratio in 2014.

(d) Children in Healthy Families, California's Children's Health Insurance Program, will be moved into Medi-Cal Managed Care by January 1, 2014, as part of the 2012–2013 budget.

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

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

INTRODUCTION

The California Assembly Committee on Health requested on March 11, 2013, 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) 889 (Frazier) on fail-first protocols for prescription medications. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.¹⁴

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Uniquely, California has a bifurcated system of regulation for health insurance subject to state benefit mandates. The California Department of Managed Health Care (DMHC)¹⁶ 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,¹⁷ which offer benefit coverage to their enrollees through health insurance policies.

All DMHC-regulated plans and/or CDI-regulated policies that provide benefit coverage for outpatient prescription drugs would be subject to AB 889. Therefore, the mandate would affect the health insurance of approximately 25.3 enrollees (65% of all Californians).

Developing Estimates for 2014 and the Effects of the Affordable Care Act

The Affordable Care Act (ACA)¹⁸ is expected to dramatically affect health insurance and its regulatory environment in California, with many changes becoming effective in 2014. Beginning in 2014, an expansion of the Medicaid program to cover people up to 133% of the federal poverty level (FPL)¹⁹ and the availability of subsidized and unsubsidized health insurance coverage purchased through newly established state health insurance exchanges are expected to significantly increase the number of people with health insurance in the United States.

¹⁴ Available at: www.chbrp.org/docs/authorizing_statute.pdf.

¹⁵ CHBRP's estimates are available at: www.chbrp.org/other_publications/index.php.

¹⁶ The California Department of Managed Care (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.

¹⁷ The California Department of Insurance (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.

¹⁸ 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).

¹⁹ The Medicaid expansion, which California will pursue, is to 133% of the federal poverty level (FPL)—138% with a 5% income disregard.

State exchanges will sell health insurance in the small-group and individual market²⁰ through qualified health plans (QHPs), which will be certified by and sold in a state's exchange. QHPs sold through California's state exchange, Covered California,²¹ will be 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 marginal 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 marginal effects are presented in this report. Because expanded enrollment will not occur until January 2014, CHBRP relies on projections from the California Simulation of Insurance Markets (CalSIM) model²² to help set baseline enrollment for 2014. From this projected baseline, CHBRP estimates the marginal impact of proposed benefit mandates that could be in effect after January 2014. CHBRP's methods for estimating baseline 2014 enrollment from CalSIM projections are provided in further detail in Appendix D.

Bill-Specific Analysis of AB 889

Bill Language

The full text of AB 889 can be found in Appendix A.

AB 889 prohibits DMHC-regulated plans and CDI-regulated policies from requiring patients to try and fail more than two medications before allowing patients access to the initially prescribed medication, or a generic version of the same medication. CHBRP uses the term “fail-first protocols” to refer to utilization management protocols where alternative medications—usually less expensive—must be tried before coverage for the prescribed medication—usually more expensive—is approved.

AB 889 would still permit DMHC-regulated plans and CDI-regulated policies to use fail-first protocols to manage utilization for medications. However, AB 889 would require plans and insurers that apply fail-first protocols to medications to do the following:

- Cover the initially prescribed medication, or a generic version of the same medication, after a trial of no more than two alternative medications.

²⁰ Effective 2017, states may allow large-group purchasing through the exchange, which may make some large-group plans and policies subject to EHB requirements [ACA Section 1312(f)(2)(B)].

²¹ The California Health Benefits Exchange Authorizing Statute is available here: <http://www.healthexchange.ca.gov/Documents/California%20Codes%20Governing%20the%20Health%20Benefit%20Exchange.pdf>

²² 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.

- Have an expedited process in place to authorize exceptions to step therapy (therapies required before the “step-up” to the prescribed medicine) and ensure that patients can obtain necessary medications.
- Conform to the most current evidence-based practices in published peer-reviewed medical and pharmaceutical literature.

Analytic Approach and Key Assumptions

Because AB 889 allows up to two fail-first attempts before a patient can access a prescribed medication, CHBRP’s analysis focuses primarily on the categories of drugs where health plans and insurers require patients to try and fail three or more medications.

AB 889 does not affect providers

AB 889 would not affect the ability of prescribing providers to direct a patient to try any number of behavior modifications or alternative medications before prescribing a particular medication (a provider practice also known as “step therapy” but one separate from the health plan or insurer use of fail-first protocols). Furthermore, AB 889 would not limit the number of medications a provider may prescribe or prohibit generic drug substitution by pharmacists.

AB 889 does not expand prescription drug coverage

AB 889 would not require health plans or policies to begin providing benefit coverage for prescription drugs if they do not already provide it (or are not required by the ACA). Additionally, AB 889 would not require health plans or policies to provide benefit coverage for prescription drugs not on their formularies. Therefore, if a patient is prescribed a certain medication, the health plan or insurer is not required to provide benefit coverage for that medication if it is not listed in the formulary. The plan may provide an alternative brand or generic version of the drug, or the patient may choose to pay out-of-pocket for the prescribed drug.

Lastly, AB 889 would not alter the ability of health plans and insurers to establish maximum coverage limits on prescription drug benefits or to charge an enrollee a copayment or a deductible for prescription drug benefits.

Interaction with Other California Requirements

There is no *current* California mandate that requires prescription drugs be included in health plans or insurer policies, though this will change for the small group and individual markets in January 2014 with the implementation of essential health benefits in the ACA (discussed below). There are, however, a number of requirements in existing law and regulation that affect coverage of prescription medications.

Prior authorization

DMHC-regulated plans and CDI-regulated policies must respond within two business days to a prior authorization request, or the request “shall be deemed to have been granted.”²³

Cost sharing

The DMHC reviews cost-sharing arrangements and other limitations to ensure that plan contract requirements are “fair, reasonable, and consistent with the objectives of the chapter” and not held to be objectionable by the director.²⁴ Copayments, deductibles, and other limitations cannot render the benefit illusory.²⁵ For outpatient prescription drug benefits, copayment or percentage coinsurance cannot exceed 50% of the cost to the plan.²⁶

The CDI limits expenses paid by the insured, requiring all policies to be economically sound.²⁷ Individual policies must provide “real economic value” to the insured.²⁸

Disclosure and oversight of utilization management

CDI-regulated policies and DMHC regulated plans are required to file their utilization review/utilization management criteria with the DMHC or CDI and ensure that criteria are:

- Developed with involvement from actively practicing health care providers;
- Consistent with sound clinical principals and processes;
- Evaluated and updated if necessary, at least annually; and
- Disclosed to the provider and the enrollee in cases when a decision to modify, delay, or deny services is under review.²⁹

In addition, DMHC-regulated plans:

- May not limit or exclude coverage for a drug that the plan had previously approved to treat an enrollee’s medical condition.³⁰
- Must provide to members of the public, upon request, a copy of the most current list of prescription drugs on the formulary by major therapeutic category and must maintain an expeditious process by which prescribing providers may obtain authorization for a medically necessary nonformulary prescription drug.³¹

²³ Health and Safety Code, Section 1367.241(b) and Insurance Code, Section 10123.191(b)

²⁴ Health and Safety Code, Section 1367(h)(1) and 1367(i)

²⁵ Health and Safety Code Section 1367, California Code of Regulations Title 28 § 1300.67.4

²⁶ California Code of Regulations, title 28, Section 1300.67.24

²⁷ Insurance Code Section, 10291.5(a)(1)

²⁸ Insurance Code Section 10291.5(b)(7)(A) and 10270.95

²⁹ Health and Safety Code, Section 1374.30, 1374.4; Insurance Code Section 10123.135

³⁰ Health and Safety Code, Section 1367.22

³¹ Health and Safety Code Sections 1367.20 and 1367.24

Requirements in Other States

CHBRP is aware of four states that have passed legislation to limit the use of fail-first protocols for all or specific drugs: Mississippi³², Louisiana, and Connecticut³³ passed laws in 2011; Kentucky³⁴ passed legislation in 2012. CHBRP is aware of seven states that have introduced legislation in 2013 that seek to limit the use of fail-first policies, or provide patients with quicker access to prescribed medications: Connecticut³³, Maine³⁵, Maryland,³⁶ Massachusetts,³⁷ New Jersey,³⁸ New York,³⁹ and Vermont.⁴⁰

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 this proposed benefit mandate may interact with requirements in the ACA, including the requirement for certain health insurance to cover “essential health benefits” (EHBs).⁴¹

Essential Health Benefits

Effective 2014, the ACA requires nongrandfathered small-group and individual market health insurance—including but not limited to QHPs that will be sold in Covered California—to cover 10 specified categories of EHBs.⁴² 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

³² Mississippi Legislature:

<http://index.ls.state.ms.us/isysnative/UzpcRG9jdW1lbnRzXDIwMTFcbm90ZGVhZFxzYlwyNzAwLTI3OTlcc2IyNzM3c2cucGRm/sb2737sg.pdf#xml=http://10.240.72.35/isysquery/irlcc9d/1/hilite>³²

³³ Connecticut Legislature’s 2011 limited fail-first protocols for pain drugs. :

<http://www.cga.ct.gov/2011/ACT/PA/2011PA-00169-R00SB-01083-PA.htm>. Connecticut has also introduced legislation in 2013 to restrict fail-first protocols for all classes of medications, not just pain drugs.

³⁴ Kentucky Legislature: <http://www.lrc.ky.gov/krs/304-17a/163.pdf>

³⁵ Maine Legislature: http://www.mainelegislature.org/legis/bills/bills_126th/billtexts/SP032901.asp

³⁶ Maryland Legislature: <http://mgaleg.maryland.gov/2013RS/bills/sb/sb0746F.pdf>

³⁷ Massachusetts Legislature: <http://www.malegislature.gov/Bills/188/Senate/S439>

³⁸ New Jersey Legislature: http://www.njleg.state.nj.us/2012/Bills/A2000/1832_11.HTM

³⁹ New York Legislature: <http://open.nysenate.gov/legislation/api/1.0/lrs-print/bill/A5214-2013>

⁴⁰ Vermont Legislature: <http://www.leg.state.vt.us/docs/2014/bills/Intro/S-147.pdf>

⁴¹ Resources on EHBs and other ACA impacts are available on the CHBRP website:

www.chbrp.org/other_publications/index.php.

⁴² 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)].

specified benchmark plan options.⁴³ California has selected the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan as its benchmark plan.⁴⁴

The ACA allows a state to “require that a qualified health plan offered in [an exchange] offer benefits in addition to the essential health benefits.”⁴⁵ If the state does so, the state must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the QHP. However, as laid out in the Final Rule on EHBs that HHS released in February 2013,⁴⁶ state benefit mandates enacted on or before December 31, 2011, would be included in a 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 exchange 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.⁴⁷

AB 889 and essential health benefits

As previously mentioned, AB 889 does not require DMHC-regulated plans and CDI-regulated policies to provide benefit coverage for prescription drugs. However, the ACA (through essential health benefits) requires this expansion for nongrandfathered plans and policies in the small group and individual markets.⁴⁸

AB 889 would build on the ACA’s expansion, and restrict all nongrandfathered small group and individual market plans and policies from requiring enrollees from trying and failing on more than two medications.

The requirement—or restriction—that AB 889 imposes in the design of the plan, is not considered a state-required mandate, according to regulations written by the federal Department of Health and Human Services.^{49,50} Therefore, AB 889 would not require the state to defray any costs for QHPs purchased in Covered California.

⁴³ CCIIO, Essential Health Benefits Bulletin. Available at: http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf. Accessed December 16, 2011.

⁴⁴ H&SC Section 1367.005; IC Section 10112.27.

⁴⁵ ACA Section 1311(d)(3).

⁴⁶ 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.

⁴⁷ Essential Health Benefits. Final Rule. 12843.

⁴⁸ Large -group plans and policies, and grandfathered small -group and individual policies—those in existence before March 23, 2010—would not be required to include outpatient prescription drug coverage.

⁴⁹ Department of Health and Human Services, “Proposed Rule: Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation,” *Federal Register*, Vol 77. No.

BACKGROUND ON FAIL-FIRST PROTOCOLS

Fail-first is among several terms used to describe utilization management techniques applied to prescription drugs at a health plan or insurer. Health plans and insurers employ utilization management for a variety of reasons, including:

- Clinical considerations; and
- To control the cost of prescription drugs, particularly in therapeutic classes where many generics versions exist.

Other Terms for Fail-First Protocols

Fail-first protocols may also be called:

- *Step therapy*, which when implemented by a health plan or insurer, requires an enrollee to first try an alternative medication (often a generic alternative) prior to receiving coverage for a second or third medication (often a brand-name medication, although AB 889 permits carriers to provide coverage for a generic version of the same medication).
- *Step edit* or *online edit*, which refer to a process by which a prescription is electronically reviewed when submitted for payment authorization to determine whether a patient used a prior first-line medication.

If a patient's prescription is declined under either step therapy or step/online edit, a patient's health care provider may either reissue the prescription for the first medication covered by the patient's health plan contract or policy or appeal the decision.

A fail-first protocol may also be the basis for part or all of a *precertification* or *prior authorization*⁵¹ protocol, which may also require the prescribing provider to confirm to the plan or insurer that an alternative medication or medications have been unsuccessfully tried by the patient before coverage for the prescribed medication is approved.

Alternatively, the patient may either purchase an over-the-counter alternative, or the prescribed medication, in both cases paying for the full cost out of pocket.⁵²

277, November 26, 2012. Available at: <http://www.gpo.gov/fdsys/pkg/FR-2012-11-26/pdf/2012-28362.pdf>, at <http://www.gpo.gov/fdsys/pkg/FR-2012-11-26/pdf/2012-28362.pdf>.

⁵⁰ Essential Health Benefits. Final Rule. 12843.

⁵¹ Not all prior authorization protocols have a fail-first component. Some prior authorization protocols are based on other criteria, such as intended use to treat a specific medical problem or diagnosis or confirmation that the patient meets other criteria such as age or specified comorbidities.

⁵² Patients may also encounter challenges to filling their prescribed medications, for instance, the physician or pharmacist may not complete the necessary paperwork.

More Than Two Steps of Fail-First Protocol Prevalence in California

CHBRP found no literature about prevalence of fail-first protocols involving more than two steps.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, an estimated 18.5% (4,691,000) of covered individuals have outpatient prescription drug coverage that includes medications that are subject to more than two steps in a fail-first protocol. CHBRP estimates that 11.1 filled prescriptions per 1,000 enrollees annually are for drugs that are prescribed after the second step but before the final step in a specific therapeutic class.

The most commonly used medications subject to three or more steps in fail-first protocols for enrollees covered by commercial health plans and policies subject to AB 889 include proton pump inhibitors, beta blockers, and bone density regulators. Additional medications commonly subject to three or more steps in fail-first protocols in Medi-Cal Managed Care Plans include antidepressants, antipsychotics, and opioids.

Table 2 lists the most commonly utilized drug classes in the commercial market, based on the *Benefit Coverage, Utilization, and Cost Impacts* section analysis. The most frequent use drug categories include three classes of drugs that have been identified by carriers in the privately funded market as being subject to fail-first protocols with more than two steps.

- Gastrointestinal agents, or proton pump inhibitors, which include five generic products, with estimated utilization of 229 per 1,000 members and an average cost of \$181.82;
- Beta blockers, which include nine generic products, with estimated utilization of 188 per 1,000 enrollees and an average cost of \$39.17; and
- Bone density regulators, which include seven generic products, with estimated utilization of 32.7 per 1,000 enrollees and an average cost of \$154.81.

Table 2. Drug Classes by Utilization, Commercial Market, California

Drug subclass	Utilization per 1,000 members	Average Charge
Opioid Combinations	378.5	\$17.13
HMG CoA Reductase Inhibitors	345.0	\$81.20
Selective Serotonin Reuptake Inhibitors (SSRIs)	302.0	\$34.42
Thyroid Hormones	230.7	\$20.44
Proton Pump Inhibitors*	229.4	\$181.82
ACE Inhibitors	195.8	\$16.52
Antihypertensive Combinations	188.2	\$101.85
Alpha-Beta Blockers/Beta Blockers Cardio-Selective*	187.6	\$39.17
Nonsteroidal Anti-inflammatory Agents (NSAIDs)	176.0	\$20.45
Beta Agonists	169.6	\$147.80
Nasal Steroids	125.8	\$90.24
Non-Barbiturate Hypnotics	124.4	\$80.78
Anticonvulsants - Misc.	118.4	\$133.59

Table 2. Drug Classes by Utilization, Commercial Market, California (cont'd)

Drug subclass	Utilization per 1,000 members	Average Charge
Calcium Channel Blockers	114.7	\$38.91
Biguanides	98.6	\$22.89
Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)	96.0	\$202.59
Opioid Agonists - Non-Patch	92.8	\$180.12
Fluoroquinolones	78.5	\$47.05
Angiotensin II Receptor Antagonists	74.8	\$119.34
Antidepressants - Misc.	72.6	\$109.58
Fibric Acid Derivatives	52.9	\$109.93
Dibenzapines/Quinolinone Derivatives/Benzisoxazoles	39.7	\$396.46
Antidiabetic Non-Combinations	37.3	\$326.65
Bone Density Regulators*	32.7	\$154.81
Prostatic Hypertrophy Agents	29.0	\$118.53
Platelet Aggregation Inhibitors	27.6	\$202.80
Antidiabetic Combinations	21.8	\$243.31
Urinary Antispasmodics	19.4	\$195.05
Cyclo-oxygenase Inhibitors (COX-2)	17.7	\$272.02
Antiparkinson Dopaminergics	15.0	\$102.67
Valproic Acid	11.8	\$150.69
Soluble Tumor Necrosis Factor Receptor Agents/Anti-TNF-alpha - Monoclonal Antibodies	11.2	\$3,228.00
Prostaglandins - Ophthalmic	9.6	\$110.24
Opioid Agonists - Patch	6.8	\$293.86
Multiple Sclerosis Agents	6.6	\$4,982.93
Antidementia Agents	1.3	\$237.39
Hematopoietic Growth Factors	0.8	\$3,269.02

Source: California Health Benefits Review Program, 2013.

* Drug classes identified by carriers in commercial market as including any fail-first protocol that requires more than two steps.

Burden of More Than Two Steps of Fail-First Protocols

The research literature provides insufficient data about the burden of more than two steps of fail-first protocols. CHBRP found no California-specific literature about the impact of fail-first protocols, in general, and no literature about the impact of more than two steps of fail-first protocols, relative to two or fewer trials.

MEDICAL EFFECTIVENESS

As discussed in the *Introduction*, AB 889 prohibits DMHC-regulated plans and CDI-regulated policies from requiring patients to try and fail more than two medications before allowing patients access to the initially prescribed medication, or a generic version of the same medication. CHBRP uses the term “fail-first protocols” to refer to utilization management protocols where alternative medications must be tried before coverage for the prescribed medication is approved. The medical effectiveness review summarizes findings from a systematic review and individual studies of the impact of fail-first protocols on utilization of prescription medications, other health care services, and health outcomes.

The medical effectiveness review does not address the effectiveness of prescription medications because it is not feasible for CHBRP to review the literature on effectiveness of all medications subject to fail-first protocols with more than two steps within the 60-day timeframe allotted for this analysis. In addition, the Food and Drug Administration assesses the effectiveness of all medications available in the United States and sets forth approved uses for them. Moreover, AB 889 does not mandate that DMHC-regulated plans and CDI-regulated policies provide coverage for prescription medications but instead establishes terms and conditions for coverage. For these reasons, the medical effectiveness review assesses evidence regarding the impact of fail-first protocols on use of health care services and health outcomes. In particular, the review focuses on whether there is evidence that fail-first protocols have adverse effects on health outcomes and use of beneficial health care services.

Research Approach and Methods

Studies of fail-first protocols for prescription medications were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, and Business Source Complete. The search was limited to abstracts of studies published in English from 2000 to present. Of the 307 articles found in the literature review, 58 were reviewed for potential inclusion in this report on AB 889, and a total of 15 articles that presented findings from 13 studies were included in the medical effectiveness review for this report.⁵³ Eleven of these studies (13 articles) were included in a systematic review published in 2011 (Motheral, 2011). The medical effectiveness review also presented findings from two individual studies of fail-first protocols that were not included in the systematic review (Hartung et al., 2004; Momani et al., 2002). The other articles were eliminated because they did not focus on fail-first protocols or did not report findings from research studies that assessed outcomes of interest. 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).

⁵³ Lu and colleagues (2010), Soumerai and colleagues (2008), and Zhang and colleagues (2009) presented three different sets of findings from a study of a single fail -first protocol implemented by Maine’s Medicaid program.

The medical effectiveness review was limited to studies of protocols under which persons were required to try and fail at least one medication before obtaining a prescription for the initially prescribed medication, or a generic version of the same medication. Studies of prior authorization protocols were included only if they required persons to try and fail at least one medication before prior authorization would be granted for the initially prescribed medication.

Methodological Considerations

None of the studies CHBRP identified were randomized controlled trials (RCTs). Most were nonrandomized studies with comparison groups that compared persons whose health plan or health insurance policy had a fail-first protocol to persons whose health plan or health insurance policy did not implement a fail-first protocol. In some cases, persons in the intervention group (i.e., persons subject to the fail-first protocol) and the comparison group did not have similar demographic and socio-economic characteristics prior to implementation of the fail-first protocol (see, for example, Mark et al., 2009, 2010). Although the authors of some studies attempted to use statistical methods to adjust for differences between the groups prior to the intervention, findings from some of the studies may have been affected by these differences.

None of the studies identified by CHBRP examined fail-first protocols that require enrollees to try and fail more than two other medications before obtaining the initially prescribed medication, as would be prohibited under AB 889. Nor did any of the studies compare the impact of a fail-first protocol involving one or two steps to a fail-first protocol involving more than two steps.

Synthesis of findings across studies is difficult because the number of studies within each class of prescription medications is small. In addition, studies of medications within a class often did not assess the same outcomes. Generalizing findings across classes of medication is also difficult because medications are used to treat conditions with varying degrees of severity. The importance of medication to successful treatment also varies across classes of medication. For example, severe mental health conditions cannot be managed effectively without prescription medications. In contrast, some conditions treated with proton pump inhibitors (PPIs) or nonsteroidal anti-inflammatory medications (NSAIDs)⁵⁴ can be managed with over-the-counter (OTC) medications and, in some cases, with lifestyle changes alone.

In addition, the generalizability of findings of the studies CHBRP identified may be limited by changes over time in the availability of generic and over-the-counter versions of brand-name medications. PPIs are one example. PPIs are used to treat stomach ulcers, symptoms of gastroesophageal reflux disease (GERD), and to treat damage to the lower esophagus caused by GERD. Another class of medications known as H2 blockers is also used to treat these conditions.

⁵⁴ NSAIDs are used to relieve pain and inflammation. Frequently used NSAIDs include ibuprofen, naproxen, and Cox-2 inhibitors.

At the time the studies of fail-first protocols for PPIs were conducted⁵⁵, generic versions were available for H2 blockers but not for PPIs. Since that time, generic versions of some PPIs have become available and some PPIs (i.e., Prevacid OTC [lansoprazole] and Prilosec OTC [omeprazole]) are also available over the counter without a prescription.

Outcomes Assessed

CHBRP searched for studies that examined whether fail-first protocols affected health outcomes. The only such study identified was a survey of persons with arthritis and chronic pain disorders enrolled in West Virginia's Medicaid program who were subject to a fail-first protocol for NSAIDs (Momani et al., 2002).

Given the limited evidence of effects on health outcomes, CHBRP reviewed studies that assessed effects of fail-first protocols on utilization of prescription medications and other medical services, including hospital admissions, emergency department visits, and outpatient visits. Utilization may be a proxy for health status. Some enrollees who are subject to fail-first protocols may not obtain prescriptions for medication or may delay or discontinue treatment. Treatment may not be initiated because an enrollee decides not to fill a prescription, or because the enrollee's pharmacist and/or physician does not either obtain authorization for the initially prescribed medication or encourage the enrollee to use an alternative medication covered by his or her health plan or health insurance policy. If a fail-first protocol is associated with a lower rate of initiation, delay, or discontinuation of treatment, the protocol may be associated with worse health outcomes unless patients have access to other equally effective treatments (e.g., psychotherapy for mild depressive episodes; tendon sheath injection for tendonitis). Worse health outcomes may be manifest in higher rates of hospital admissions, emergency department visits, or outpatient visits.

Study Findings

Characteristics of Included Studies

CHBRP identified 15 articles that presented findings from 13 studies of the impact of fail-first protocols. The studies CHBRP identified addressed fail-first protocols for the following classes of prescription medications: antidepressants, antihypertensives, antipsychotics and anticonvulsants, NSAIDs, and PPIs. All of these classes of medication include some prescription medications for which both brand-name and generic versions are available and some for which only brand-name versions are available. Over-the-counter versions of some NSAIDs and PPIs are also available.

Six of the 13 studies examined the impact of fail-first protocols on persons with private health insurance (Cox et al., 2004; Dunn et al., 2006; Mark et al., 2009, 2010; Motheral et al, 2004;

⁵⁵ Delate and colleagues (2005) and Motheral and colleagues (2004) analyzed claims data from 2001 to 2003. Cox and colleagues (2004) conducted a survey of persons subject to a fail-first protocol from September 2002 to January 2003.

Yokoyama et al., 2007). Seven studies (nine articles) assessed effects on persons enrolled in Medicaid (Delate et al., 2005; Farley et al., 2008; Hartung et al., 2004; Law et al., 2008; Lu et al., 2010; Momani et al., 2002; Smalley et al., 1995; Soumerai et al., 2008; Zhang et al., 2009).

Five of the 13 studies were wholly or partially funded by pharmaceutical companies (Farley et al., 2008; Hartung et al., 2004; Mark et al., 2009, 2010; Yokoyama et al., 2007). Three were conducted by employees of a pharmacy benefit management company (Cox et al., 2004; Delate et al., 2005; Motheral et al., 2004). A systematic review of studies of the impact of industry sponsorship on research findings concluded that sponsorship of studies of medications or medical devices by manufacturers is associated with results and conclusions that are more favorable to their products (Lundh et al., 2012). Sponsorship may also affect findings from studies of fail-first protocols aimed at reducing use of a manufacturer's products.

Findings of Included Studies

Effects on health status

CHBRP identified only one study on the impact of fail-first protocols on health outcomes. Momani and colleagues (2002) evaluated the impact of a fail-first protocol for NSAIDs implemented by West Virginia's Medicaid program on health-related quality of life among persons with chronic pain. Under this protocol, patients could not obtain coverage for a prescription for a brand-name NSAID unless they had tried at least two classes of generic NSAIDs for at least two weeks and failed to attain desired outcomes. Surveys were distributed to Medicaid enrollees under age 65 who had osteoarthritis, rheumatoid arthritis, spondylitis, or chronic pain syndromes. Responses from persons who received prescriptions for generic NSAIDs were compared to persons who received prescriptions for brand-name NSAIDs. The study found no differences between the two groups in any of the domains of health-related quality of life measured, including mobility, walking and bending, hand and finger functioning, tension, and ability to perform self-care and engage in household and social activities. However, the response rate was low (22.5%) and the authors did not assess whether respondents and non-respondents were similar at baseline.

There is insufficient evidence to determine whether fail-first protocols, regardless of the number of steps, directly affect health outcomes. The absence of evidence is not evidence of no effect. It is an indication that the impact of fail-first protocols on health outcomes is unknown.

Effects on utilization of prescription medications

Studies of fail-first protocols that assessed their impact on use of prescription medications subject to these protocols found that use of these medications decreased after the fail-first protocols were implemented (Delate et al., 2005; Dunn et al., 2006; Farley et al., 2008; Hartung et al., 2004; Law et al., 2008; Mark et al., 2010; Smalley et al., 1995; Soumerai et al., 2008; Yokoyama et al., 2007; Zhang et al., 2009). This finding is not surprising because fail-first protocols create strong financial incentives for enrollees to avoid filling prescriptions for these medications unless they can demonstrate that they have tried and failed the requisite medications

or obtain authorization for an exception to the protocol. Some enrollees subject to fail-first protocols may not contact their physicians when denied coverage for the medication initially prescribed, some pharmacist may not contact physicians' on enrollees' behalf, and some physicians may not submit documentation needed to obtain authorization for the initially prescribed medication.

Initiation of Medication. Although the stated goal of fail-first protocols is not to prevent persons from receiving prescription medications, the preponderance of evidence suggests that this occurs. The strongest evidence comes from a study that used an interrupted time series with comparison group design to examine the effects of a fail-first protocol implemented by Maine's Medicaid program (Lu et al., 2010). In 2003, Maine implemented a fail-first protocol for antipsychotic medications. Enrollees who had not been prescribed an antipsychotic medication previously could not receive coverage for Abilify (aripiprazole) or Zyprexa (olanzapine) unless they had previously tried and failed treatment with Risperdal (risperidone) and either Seroquel (quetiapine) or Geodon (ziprasidone).⁵⁶ Persons with bipolar disorder who were enrolled in Maine's Medicaid program were compared to persons with bipolar disorder in New Hampshire's Medicaid program, which did not have a fail-first protocol. The authors reported that there was a 32% decrease in the rate of initiation of antipsychotic medications among persons in Maine with bipolar disorder after the fail-first protocol was instituted versus no difference in New Hampshire. Although the study did not directly investigate effects on health outcomes, it is plausible that failure to initiate treatment adversely affected the mental health of persons with bipolar disorder because prescription medications are standard treatments for this condition and have been shown to be effective (VA/DoD, 2010).

Two studies examined how enrollees with private health insurance responded to fail-first protocols (Cox et al., 2004; Motheral et al., 2004). The authors of these studies distributed surveys to enrollees whose physicians prescribed antidepressants, NSAIDs, or PPIs that were subject to fail-first protocols. Major weakness of these two studies included small sample sizes (174 and 201, respectively) and low response rates (23% and 33%, respectively). CHBRP identified no studies of how pharmacists or physicians respond to fail-first protocols.

Motheral and colleagues (2004) reported that 23% of enrollees who were prescribed a medication subject to a fail-first protocol obtained coverage for the prescribed medication and that 29% received a different prescription medication covered by their health plan. Sixteen percent paid out of pocket for the prescribed medication. Five percent used an over-the-counter medication in the same therapeutic class. Overall, 17% did not obtain any medication, with rates of 11% for antidepressants, 15% for NSAIDs, and 22% for PPIs. Cox and colleagues (2004) reported that 10% of enrollees subject to a fail-first protocol for NSAIDs and 13% of enrollees subject to a fail-first protocol for PPIs did not obtain any medication. The implications of Motheral and colleagues' and Cox and colleagues' are uncertain because antidepressants, NSAIDs, and PPIs are used for a wide range of conditions, some of which can be treated effectively without medication. For example, systematic reviews have found that psychotherapy alone is an effective treatment for some persons with anxiety disorders or mild depression

⁵⁶ Persons previously prescribed Abilify or Zyprexa were grandfathered (i.e., not subject to the fail-first protocol).

(CHBRP, 2011). Some persons with GERD or osteoarthritis can manage their conditions effectively with OTC medications and/or lifestyle changes (e.g., avoiding foods that cause GERD, getting more exercise).

The preponderance of evidence suggests that some persons subject to fail-first protocols do not obtain any medication for their conditions, but the studies did not address the impact of not obtaining medication on health outcomes.

Discontinuation of Medication. Studies have assessed the impact of fail-first protocols on discontinuation of antidepressants, antihypertensives, and antipsychotics.

Two studies have examined the impact of the fail-first protocol implemented by Maine's Medicaid program on discontinuation of antipsychotic medications (Soumerai et al., 2008; Zhang et al., 2009). Zhang and colleagues reported that following the implementation of the fail-first protocol, Maine Medicaid enrollees with bipolar disorder were 2.28 times more likely to discontinue antipsychotic medications after 30 or more days of treatment than their counterparts in New Hampshire. Similar effects were found for discontinuation after 50 or more days or 250 or more days of treatment. Soumerai and colleagues (2008) investigated the effect of the fail-first protocol on gaps, switching or augmentation of medication for Medicaid enrollees with schizophrenia. They found that Maine enrollees with schizophrenia were 1.94 times more likely to experience one of these circumstances than New Hampshire enrollees. Although the study did not directly investigate effects on health outcomes, it is plausible that discontinuation of prescription medications or gaps in medication use could have adversely affected the mental health of persons with bipolar disorder or schizophrenia because discontinuing medication for these conditions may exacerbate symptoms.

Mark and colleagues (2009) evaluated a fail-first protocol for antihypertensive medications. They examined fail-first protocols instituted by two employers that required employees and dependents with hypertension who received coverage through the employers to use certain (first-line or preferred) angiotensin-converting enzyme inhibitors (ACE inhibitors) or angiotensin receptor blocker (ARB) for a specified period of time before using another (second-line) ACE inhibitor or ARB. At the time the study was completed, generic equivalents were not available for most ARBs. The authors found that following implementation of the fail-first protocol the rate of discontinuation of antihypertensive medications was larger in the fail-first protocol group than in the comparison group. Discontinuing antihypertensive medications may lead to adverse outcomes unless a person can control his or her blood pressure through diet and exercise alone. If not treated, hypertension increases a person's risk of having a stroke or developing heart disease.

Findings from studies of fail-first protocols for antihypertensives and antipsychotics suggest that fail-first protocols are associated with higher rates of discontinuation of prescription medications for these conditions. The studies did not assess effects on health outcomes. There is insufficient evidence to determine whether there is a relationship between fail-first protocols and discontinuation rates for other classes of prescription medications.

Days' Supply of Medication. Studies have also addressed the impact of fail-first protocols on days' supply of antidepressant and antihypertensive medications. Days' supply measures the

number of days or percentage of days within a specified time period for which doses of a medication have been dispensed. For medications prescribed for daily use, researchers often use days' supply as a proxy for adherence to recommended treatment. For some medications, daily use is associated with medication effectiveness. Findings from two studies of fail-first protocols for antidepressant medications suggest that fail-first protocols do not affect the days' supply of medication dispensed to persons with private insurance (Dunn et al., 2006; Mark et al., 2010). Both of these fail-first protocols required enrollees to try a generic antidepressant before receiving coverage for a brand-name antidepressant. Two studies of the impact of fail-first protocols on days' supply of antihypertensive medication reached opposite conclusions. One study found a small and statistically significant difference in days' supply (Yokoyama et al., 2007), whereas the other found no difference between persons who were and were not subject to a fail-first protocol (Mark et al., 2009). CHBRP identified no studies of the relationship between fail-first protocols and days' supply of antipsychotics, anticonvulsants, NSAIDs, and PPIs.

Fail-first protocols do not affect days' supply of antidepressant medications. Findings regarding effects on days' supply of antihypertensive medications are ambiguous. There is insufficient evidence to determine whether there is a relationship between fail-first protocols and days' supply for other classes of prescription medications.

Effects on utilization of other medical care

Six studies evaluated the effects of fail-first protocols on use of medical services other than prescription medications. Three studies assessed the impact of utilization of other medical services for conditions treated with prescription medications subject to fail-first protocols (Delate et al., 2005; Farley et al., 2008; Mark et al., 2010). Such studies provide better evidence regarding the relationship between fail-first protocols and health outcomes than studies of the effects of utilization for all causes, because they measure utilization most likely to be affected by use of medications for which fail-first protocols have been implemented. Findings from these studies are inconsistent. Mark and colleagues (2010) reported that a fail-first protocol for antidepressants was associated with greater numbers of office visits, emergency department (ED) visits, and hospitalizations for mental health conditions. Farley and colleagues (2008) found that a fail-first protocol for antipsychotics implemented by Georgia's Medicaid program was associated with a decrease in outpatient visits.⁵⁷ Delate and colleagues (2005) found that a Medicaid program's fail-first protocol had no effect on expenditures for office visits, ED visits, and hospitalizations for gastrointestinal conditions.

Three studies assessed the impact of fail-first protocols on use of medical care other than prescription medications for all conditions. A study of a fail-first protocol for antihypertensive medications reported that the fail-first protocol was associated with increases in office visits, ED visits, and hospitalizations for all causes (Mark et al., 2009). Two studies of the impact of fail-first protocols for NSAIDs on all-cause expenditures for office visits, ED visits, and hospitalizations reached opposite conclusions (Hartung et al., 2004; Smalley et al., 1995).

⁵⁷ Farley et al., 2008, found that expenditures for outpatient visits increased despite the decrease in the number of outpatient visits and suggested that providers may have been reimbursed more per visit.

Hartung and colleagues (2004) found an increase in expenditures for ED visits and Smalley and colleagues (1995) found no difference in utilization of office visits, ED visits, and hospitalizations.

Findings from studies of the impact of fail-first protocols on rates of hospital admissions, emergency department visits, and outpatient visits are inconsistent across classes of prescription medications.

Generalizability of findings to AB 889

The generalizability of findings from studies included in the Medical Effectiveness review to AB 889 is unknown. None of these studies assessed fail-first protocols involving more than two steps. In addition, none compared a fail-first protocol with one or two steps to a fail-first protocol with more than two steps.

Summary of Findings

- CHBRP did not identify any studies that examined fail-first protocols that require enrollees to try and fail more than two other medications before obtaining the initially prescribed medication, as would be prohibited under AB 889.
- CHBRP did not identify any studies that compared the impact of a fail-first protocol involving one or two steps to a fail-first protocol involving more than two steps.
- CHBRP identified 13 studies of the effects of fail-first protocols that involved one or two steps.
- The only study that addressed the impact of a fail-first protocol on a health outcome reported that the protocol had no impact on health-related quality of life among persons with chronic pain.
- For some classes of prescription medications, studies suggest that fail-first protocols are associated with
 - Lower rates of initiation of prescription medication
 - Higher rates of discontinuation
- The studies did not address the impact of not obtaining or discontinuing medication on health outcomes.
- Findings from studies of the impact of fail-first protocols on use of medical services other than prescription medications are inconsistent across classes of prescription medications.
- The generalizability of findings from these studies to AB 889 is unknown because none of these studies assessed fail-first protocols involving more than two steps and none compared a fail-first protocol with one or two steps to a fail-first protocol with more than two steps.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

AB 889 prohibits DMHC-regulated plans and CDI-regulated policies from requiring patients to try and fail more than two medications before allowing patients access to the initially prescribed medication, or a generic version of the same medication. CHBRP uses the term “fail-first protocols” to refer to utilization management protocols where alternative medications must be tried before coverage for the prescribed medication is approved.

AB 889 would still permit DMHC-regulated plans and CDI-regulated policies to use fail-first protocols to manage utilization for medications. However, AB 889 would require plans and insurers that apply fail-first protocols to medications to cover the initially prescribed medication, or a generic version of the same medication, after a trial of no more than two alternative medications (i.e., two steps).

CHBRP assumes that implementation of AB 889 would:

- Not result in a change in the number of enrollees who use a specific medication subject to three or more steps in a fail-first protocol; rather, it would allow enrollees to receive access to the prescribed medication in fewer steps (two steps, instead of three).
- Not result in a change in the number of enrollees who use a medication in a therapeutic class subject to three or more steps in a fail-first protocol; rather, because enrollees would have access to the prescribed medication more quickly, it would shift utilization from other medications in the therapeutic class to the prescribed drug.
- Not result in a change in the number of enrollees who purchase out-of pocket (i.e., as a noncovered benefit) a specific medication subject to three or more steps in a fail-first protocol.

The research literature has shown that implementation of pharmaceutical fail-first protocols may reduce utilization of medications that are subject to the protocols (Motheral, 2011). However, most protocols in these studies required enrollees to fail only one other prescription drug, and none of the studies required enrollees to fail more than two prescription drugs. Therefore, it is unknown whether or to what extent requiring three or more steps would reduce the number of enrollees who use a specific medication subject to three or more steps in a fail-first protocol. It is likely that most of the effect on utilization observed in these studies resulted from the first step(s) in the fail-first protocols, and that among enrollees achieving the second step, there is little, if any, additional reduction in utilization by implementing a third or greater step. That is, enrollees who use a medication that is subject to two steps in a fail-first protocol would continue to use the medication even if it were subject to three or more steps.

Given this lack of evidence, CHBRP assumes that implementation of AB 889 would not result in a change in the number of enrollees who use—or individually purchase as a noncovered benefit—a specific medication subject to three or more steps in a fail-first protocol. However, for

enrollees using a medication subject to three or more steps, implementation of AB 889 would enable enrollees to obtain the prescribed medication more quickly

This section will present, first, the current (baseline) benefit coverage, utilization, and costs related to fail-first protocols requiring use of more than two medications, and then provide estimates of the impacts on coverage, utilization, and cost if AB 889 is enacted. For further details on the underlying data sources and methods, please see Appendix D at the end of this document.

Current (Baseline) Benefit Coverage, Utilization, and Cost

Current Coverage of the Mandated Benefit

CHBRP conducts a bill-specific coverage survey of California's largest health plans and insurers. Responses to this survey represented 80.70% of enrollees in the privately funded, CDI-regulated market and 88.11% of enrollees in the privately funded, DMHC-regulated market. Combined, responses to this survey represent 86.33% of enrollees in the privately funded market subject to state mandates.

Currently, 18.5% of enrollees subject to AB 889 have outpatient prescription drug coverage that includes medications that are subject to three or more steps in a fail-first protocol. The most commonly used medications subject to three or more steps in fail-first protocols for enrollees in commercial health plans and policies subject to AB 889 include proton pump inhibitors, beta blockers, and bone density regulators. Additional medications commonly subject to three or more steps in fail-first protocols in Medi-Cal Managed Care Plans include antidepressants and opioids. If AB 889 were enacted, the percentage of enrollees with drug coverage that includes medications that are subject to three or more steps in a fail-first protocol would decline to 0%.

Currently, 18.5% of enrollees subject to AB 889 have outpatient prescription drug coverage that includes medications that are subject to three or more steps in a fail-first protocol. If AB 889 were enacted, this would decline to 0%.
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Current Utilization Levels

CHBRP used the Milliman 2012 Health Cost Guidelines to estimate the utilization and costs of medications that are subject to three or more steps in fail-first protocols. This analysis focused on the therapeutic classes identified by the carrier surveys and described above. CHBRP estimates that 11.1 prescriptions filled per 1,000 enrollees annually are for drugs that are prescribed after the second step but before the final step in a specific therapeutic class. Annual per enrollee costs for medications in these therapeutic classes are estimated to be \$369.51 (see Table 1 in the *Executive Summary*).

Per-Unit Cost of a 30-day supply of Medication

CHBRP estimates that the average cost of a 30-day supply for medications subject to three or more steps in a fail-first protocol to be \$424.60, while the average cost of a 30-day supply for alternative medications within these therapeutic classes is \$145.61.

Current (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. Prior to the mandate, total expenditures vary depending on plan type. Among privately funded state-regulated health insurance segments, the lowest average expenditure (\$468.82) was in the CDI-regulated individual policies, and the highest average expenditure was among the CDI-regulated small group policies (\$821.91).

The Extent to Which Costs Resulting From Lack of Coverage Are Shifted to Other Payers, Including Both Public and Private Entities

CHBRP estimated no shift in costs among private or public payers as a result of AB 889. CHBRP assumes that implementation of AB 889 would not result in a change in the number of enrollees who use medications subject to three or more steps in a fail-first protocol. Therefore, there would be no shift to other payers as the result of implementation of AB 889.

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 the DMHC or CDI and so not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

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 *currently* were no substantive differences.

Given 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.

Impacts of Mandated Benefit Coverage

How Would Changes in Benefit Coverage Related to the Mandate Affect the Availability of the Newly Covered Treatment/Service, the Health Benefit of the Newly Covered Treatment/Service, and the Per-Unit Cost?

Impact on access and health treatment/service availability

CHBRP estimates no change in the number of enrollees who use a medication that is currently subject to three or more steps in a fail-first protocol. Therefore, CHBRP does not estimate any impact on access to these medications.

Impact on the health benefit of the newly covered treatment/service

AB 889 is not expected to expand benefit coverage for outpatient prescription drug benefits. Rather, it would affect the 18.5% of enrollees who have outpatient prescription drug benefits that require three or more steps in a fail-first protocol.

Impact on per-unit cost

CHBRP estimates no change in the number of enrollees who use a medication that is subject to three or more steps in a fail-first protocol. Therefore, CHBRP does not estimate any impact on per-unit cost of these medications.

How Would Utilization Change As a Result of the Mandate?

CHBRP estimates no change in the number of enrollees who use a medication that is currently subject to three or more steps in a fail-first protocol. However, CHBRP estimates that the implementation of AB 889 would reduce the number of steps experienced by enrollees from three or more steps to two or fewer steps for medications subject to three or more steps in a fail-first protocol. Based on analysis of the 2012 Health Cost Guidelines, CHBRP estimates that with implementation of AB 889, the number of prescriptions filled for medications that are subject to three or more steps in a fail-first protocol would increase by 10%, and would be offset by a decrease in the number of prescriptions filled for other drugs within these therapeutic classes.

CHBRP estimates that with implementation of AB 889, the number of prescriptions filled for medications that are subject to three or more steps in a fail-first protocol would increase by 10%, which would be offset by a decrease in the number of prescriptions filled for other drugs within these therapeutic classes.

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

CHBRP assumes that if health care costs increase as a result of increased utilization or changes in premiums, there is a corresponding proportional increase in administrative costs. Although actual administrative costs may decrease slightly due to the reduced need to manage the third and higher steps in fail-first protocols, this is unlikely to affect the standard practice of pricing administrative costs as a percentage of premiums. CHBRP assumes that the administrative cost portion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums. CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and CDI-regulated policies would remain proportional to the increase in premiums.

Impact of the Mandate on Total Health Care Costs

Changes in total expenditures

CHBRP assumes that after implementation of AB 889, drugs that are prescribed after the second step would be replaced by drugs in the final step (i.e., those subject to three or more steps in a fail-first protocol). As a result, AB 889 would increase total net expenditures by \$26 million, or .0180% (see Table 1 in Executive Summary). This is due to a \$24.6 million total increase in health insurance premiums and a \$1.4 million increase in enrollee copayments associated with earlier use of final step medications.

Total net annual health expenditures are projected to increase by \$26 million (0.0180%) (see Table 1). This is due to a \$24.6 million total increase in health insurance premiums and a \$1.4 million increase in enrollee copayments associated with earlier use of final step medications.
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Impact on costs beyond the initial 12 months (post-December 31, 2014)

CHBRP estimates no measurable long-term impacts of the mandate in addition to the 1-year impacts presented early in this section.

Impacts for Each Category of Payer Resulting from the Benefit Mandate

Changes in expenditures and PMPM amounts by payer category

Increases in insurance premiums vary by market segment. Note that the total population in Table 4 reflects the full 25.9 million enrollees in DMHC- or CDI-regulated plans or policies that are included in the mandate under AB 889. The premium increases are estimated to be spread among all enrollees in all plans or policies, regardless of whether they have coverage with medications subject to three or more steps in a fail-first protocol.

Increases in per member per month (PMPM) premiums for the newly mandated benefit coverage vary by market segment (Table 4). The affected market segments are DMHC-regulated large and small group, CDI-regulated large group, and Medi-Cal Managed Care Plans. Increases as measured by PMPM premiums are estimated to range from \$0.01 to \$0.16.

In the privately funded large-group market, the increase in premiums is estimated to range from \$0.07 PMPM among DMHC-regulated plan contracts to \$0.01 PMPM among CDI-regulated policies (Table 4). For enrollees with privately funded small-group insurance policies, health insurance premiums are estimated to increase by approximately \$0.08 PMPM for DMHC contracts, with no changes among CDI policies. CHBRP estimates no changes in the privately funded individual market.

Among publicly funded DMHC-regulated health plans, CHBRP estimates that premiums would increase by \$0.16 for Medi-Cal Managed Care Plans.

Increases as measured by percentage changes in PMPM premiums are estimated to range from 0.001% (for CDI-regulated large group) to 0.0957% (for Medi-Cal Managed Care) in the affected market segments. Increases as measured by PMPM premiums are estimated to range from \$0.01 to \$0.16.
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Impacts on the Uninsured and Public Programs As a Result of the Cost Impacts of the Mandate

Changes in the number of uninsured persons as a result of premium increases

CHBRP estimates premium increases of less than 1% for each market segment. 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. This premium increase would not have a measurable impact on the number of persons who are uninsured.

Impact on public programs as a result of premium increases

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, 2014

	DMHC-Regulated							CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			CalPERS HMOs (b)	Medi-Cal Managed Care Plans			Privately Funded Policies (by Market) (a)			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65	Medi- Cal/Formerly Healthy Families Program (d)	Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state mandates (e)	11,289,000	2,479,000	1,029,000	854,000	688,000	5,203,000	626,000	539,000	1,315,000	1,877,000	25,899,000
Total enrollees in plans/policies subject to AB 889	10,931,021	2,478,979	966,643	854,000	688,000	5,203,000	626,000	524,932	1,315,000	1,735,659	25,323,234
Average portion of premium paid by employer	\$437.53	\$313.63	\$0.00	\$391.90	\$279.00	\$163.00	\$88.83	\$483.35	\$421.89	\$0.00	\$95,549,186,000
Average portion of premium paid by employee	\$83.30	\$169.52	\$546.88	\$97.98	\$0.00	\$0.00	\$8.79	\$135.14	\$190.22	\$305.75	\$34,912,666,000
Total premium	\$520.83	\$483.15	\$546.88	\$489.88	\$279.00	\$163.00	\$97.62	\$618.49	\$612.11	\$305.75	\$130,461,851,000
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$28.54	\$46.99	\$109.38	\$25.99	\$0.00	\$0.00	\$4.51	\$87.22	\$209.80	\$163.07	\$14,462,198,000
Enrollee expenses for benefits not covered (f)	\$-	\$-	\$-	\$-	\$-	\$-	\$-	\$-	\$-	\$-	\$-
Total expenditures	\$549.37	\$530.15	\$656.26	\$515.87	\$279.00	\$163.00	\$102.13	\$705.72	\$821.91	\$468.82	\$144,924,050,000

Source: California Health Benefits Review Program, 2013.

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

(b) As of September 30, 2012, 57.5%, or 469,000, CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2014.

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

(d) Children in Healthy Families, California's Children's Health Insurance Program, will be moved into Medi-Cal Managed Care by January 1, 2014, as part of the 2012–2013 budget.

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

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

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

Table 4. Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2014

	DMHC-Regulated							CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			CalPERS HMOs (b)	Medi-Cal Managed Care Plans			Privately Funded Policies (by Market) (a)			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65	Medi- Cal/Formerly Healthy Families Program (d)	Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state mandates (e)	11,289,000	2,479,000	1,029,000	854,000	688,000	5,203,000	626,000	539,000	1,315,000	1,877,000	25,899,000
Total enrollees in plans/policies subject to AB 889	10,931,021	2,478,979	966,643	854,000	688,000	5,203,000	626,000	524,932	1,315,000	1,735,659	25,323,234
Average portion of premium paid by employer	\$0.06	\$0.05	\$0.00	\$0.00	\$0.16	\$0.16	\$0.14	\$0.01	\$0.00	\$0.00	\$22,070,000
Average portion of premium paid by employee	\$0.01	\$0.03	\$0.00	\$0.00	\$0.00	\$0.00	\$0.01	\$0.00	\$0.00	\$0.00	\$2,528,000
Total premium	\$0.07	\$0.08	\$0.00	\$0.00	\$0.16	\$0.16	\$0.16	\$0.01	\$0.00	\$0.00	\$24,598,000
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$0.01	\$0.01	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$1,425,000
Enrollee expenses for benefits not covered (f)	\$-	\$-	\$-	\$-	\$-	\$-	\$-	\$-	\$-	\$-	\$-
Total expenditures	\$0.08	\$0.08	\$0.00	\$0.00	\$0.16	\$0.16	\$0.16	\$0.01	\$0.00	\$0.00	\$26,024,000
Percentage impact of mandate											
Insured premiums	0.0143%	0.0159%	0.0000%	0.0000%	0.0559%	0.0957%	0.1598%	0.0014%	0.0000%	0.0000%	0.0189%
Total expenditures	0.0151%	0.0160%	0.0000%	0.0000%	0.0559%	0.0957%	0.1527%	0.0014%	0.0000%	0.0000%	0.0180%

Source: California Health Benefits Review Program, 2013.

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

(b) As of September 30, 2012, 57.5%, or 469,000, of CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2014.

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

(d) Children in Healthy Families, California's Children's Health Insurance Program, will be moved into Medi-Cal Managed Care by January 1, 2014, as part of the 2012–2013 budget.

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

(f) “-” means the value is unknown. 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.

PUBLIC HEALTH IMPACTS

This section presents the overall public health impact of AB 889, followed by a discussion of the potential for reduction in gender and racial/ethnic disparities in health outcomes and the potential for the mandate to reduce premature death and societal economic losses.

Estimated Public Health Outcomes

As presented in the *Medical Effectiveness* section, there is insufficient evidence to determine whether fail-first protocols, regardless of the number of steps, directly affect health outcomes. Therefore, the public health impact is unknown. The absence of evidence is not evidence of no effect. If a fail-first protocol is associated with a lower rate of initiation, delay, or discontinuation of treatment, the protocol might be associated with worse health outcomes unless patients have access to other equally effective treatments. Conversely, use of fail-first protocols might improve health outcomes by ensuring compliance with clinical protocols, enforcing documentation of correct diagnoses and/or supporting the use of safer prescriptions.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, 18.5% (4,691,000) of covered individuals have outpatient prescription drug coverage that includes medications that are subject to more than two steps in a fail-first protocol. Because all of the drugs subject to more than two steps in fail-first protocols include a large number of alternative agents (including generics), the *Benefit Coverage, Utilization, and Cost Impacts* section estimates no change in the annual number of prescriptions per 1,000 members for drugs between the second step and the final drug within a therapeutic class. CHBRP estimates that a postmandate reduction in the number of steps required for medications subject to three or more steps in a fail-first protocol will shift utilization to higher cost drugs within a class sooner, but will not change overall utilization within a class. Postmandate, costs for drugs paid by health plans and individuals for steps beyond second and prior to final drug in therapeutic class are expected to increase by 25.8% and individual out-of-pocket expenditures for enrollees are expected to increase by 0.0099%.

The impact of fail-first protocols on health outcomes is unknown. Additionally, CHBRP estimates that a postmandate reduction in the number of steps required for medications subject to three or more steps in a fail-first protocol will shift utilization to higher-cost drugs within a class sooner, but will not change overall utilization within a class. Therefore, CHBRP concludes that passage of AB 889 would have unknown public health impact.

Estimated Impact on Financial Burden

The effect of AB 889 on financial burden for some enrollees is unknown. As discussed in the *Benefit Coverage, Cost, and Utilization* section, AB 889 would increase enrollee out-of-pocket costs by \$1.4 million because they would have earlier access to the final medication. However, to the extent that some enrollees—who previously paid full cost for the final drug—would be able

to access the drug earlier, the change would reduce the financial hardship associated with prescription drugs for those persons.

Impact on Gender and Racial Disparities

Several competing definitions of “health disparities” exist. CHBRP relies on the following definition:

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

Impact on Gender Disparities

The extent of gender disparity on use of more than two steps of fail-first protocols on health outcomes is unknown due to lack of evidence. Therefore, the extent to which AB 889 would have an impact on possible gender disparities is unknown.

Impact on Racial/Ethnic Disparities

Evaluating the impact on racial and ethnic health disparities is particularly important because racial and ethnic minorities report having poorer health status and worse health indicators (KFF, 2007). One important contributor to racial and ethnic health disparities is differences in the prevalence of insurance, where minorities are more likely than whites to be uninsured. However, coverage disparities still exist within the insured population and may contribute to gaps in access and/or utilization among those covered (Kirby et al., 2006; Lille-Blanton and Hoffman, 2005; Rosenthal et al., 2008). To the extent that racial/ethnic groups are disproportionately distributed among policies with more or less coverage, a mandate bringing all policies to parity may impact an existing disparity.

CHBRP analyses are limited to the insured population (because the uninsured would not be affected by a health benefit mandate). Therefore, to assess a mandate’s possible effects on health disparities (assuming the covered intervention is medically effective), CHBRP must answer two questions:

- (1) Are there racial/ethnic disparities in the prevalence or incidence of use of more than two steps of fail-first protocols; and
- (2) Are there racial/ethnic disparities in premandate benefit coverage?

The extent of any racial or ethnic disparities in the prevalence of the use of more than two steps in fail-first protocols is unknown due to lack of evidence. Therefore, the extent to which AB 889 would have an impact on possible disparities is unknown.

Impacts on Premature Death and Economic Loss

Premature death is often defined as death before the age of 75 years (Cox, 2006). The overall impact of premature death due to a particular disease can be measured in years of potential life lost prior to age 75 and summed for the population (generally referred to as “YPLL”) (Cox, 2006; Gardner and Sanborn, 1990). In California, it is estimated that there are nearly 102,000 premature deaths each year, accounting for more than two million YPLL (CDPH, 2011; Cox, 2006). In order to measure the impact of premature mortality across the population impacted by a proposed mandate, CHBRP first collects baseline mortality rates. Next, the literature is examined to determine whether the proposed mandated benefit impacts mortality and whether YPLL have been established for the given condition. Some diseases and conditions do not result in death, and therefore a mortality outcome is not relevant.

Economic loss associated with disease is generally presented in the literature as an estimation of the value of the YPLL in dollar amounts (i.e., valuation of a population’s lost years of work over a lifetime). For CHBRP analyses, a literature review is conducted to determine whether lost productivity has been established in the literature. In addition, morbidity associated with the disease or condition of interest can also result in lost productivity; either by causing the worker to miss days of work due to their illness or due to their role as a caregiver for someone else who is ill.

Premature Death

There is insufficient evidence about the impact of fail-first protocols on premature death; therefore, the impact of AB 889 on premature death is unknown.

Economic Loss

There is insufficient evidence about the impact of fail-first protocols on economic loss; therefore, the impact of AB 889 on economic loss is unknown.

Long-Term Public Health Impacts

CHBRP estimates premium increases of less than 1% for each market segment. 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. This premium increase would not have a measurable impact on the number of persons who are uninsured. CHBRP

estimates no measurable long-term impacts of the mandate in addition to the 1-year impacts presented in the *Benefit Coverage, Utilization, and Cost Impacts* section.

APPENDICES

Appendix A: Text of Bill Analyzed

On March 11, 2013, the Assembly Committee on Health requested that CHBRP analyze AB 889.

Below is the bill language, as it was amended on March 21, 2013.

SECTION 1

Section 1367.243 is added to the *Health and Safety Code* to read:

(a) Notwithstanding any other law, a health care service plan that restricts medications pursuant to step therapy or fail first protocol shall be subject to the following requirements:

(1) The health care service plan shall have an expeditious process in place to authorize exceptions to step therapy when medically necessary and to conform effectively and efficiently to continuity of care.

(2) The duration of any step therapy or fail first protocol shall be consistent with up-to-date evidence-based outcomes and current published peer-reviewed medical and pharmaceutical literature.

(3) The health care service plan shall not require a patient to try and fail on more than two medications before allowing the patient access to the medication, or generically equivalent drug, prescribed by the prescribing provider, unless the FDA-approved label indication, or clinical research trials focusing on clinical outcomes, supports that more than two prior therapies should be used before using the requested medications.

(b) For purposes of this section, the following shall apply:

(1) “Prescribing provider” shall include a provider who is authorized to write a prescription, as described in subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an enrollee.

(2) “Generically equivalent drug” means a drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name, as determined by the United States Adopted Names Council and accepted by the federal Food and Drug Administration, as those drug products having the same chemical ingredient.

(c) This section does not prohibit a health care service plan from charging a subscriber or enrollee a copayment or a deductible for prescription drug benefits or from setting forth, by contract, limitations on maximum coverage of prescription drug benefits, provided that the

copayments, deductibles, or limitations are reported to, and held unobjectionable by, the director and communicated to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.

(d) Nothing in this section shall be construed to require coverage of prescription drugs not in a plan's drug formulary or to prohibit generically equivalent drugs or generic drug substitutions as authorized by Section 4073 of the Business and Professions Code.

SEC. 2.

Section 10123.192 is added to the *Insurance Code* to read:

(a) Notwithstanding any other law, a health insurer that restricts medications pursuant to step therapy or fail first protocol shall be subject to the following requirements:

(1) The health insurer shall have an expeditious process in place to authorize exceptions to step therapy when medically necessary and to conform effectively and efficiently to continuity of care.

(2) The duration of any step therapy or fail first protocol shall be consistent with up-to-date evidence-based outcomes and current published peer-reviewed medical and pharmaceutical literature.

(3) The health insurer shall not require a patient to try and fail on more than two medications before allowing the patient access to the medication, or generically equivalent drug, prescribed by the prescribing provider, unless the FDA-approved label indication, or clinical research trials focusing on clinical outcomes, supports that more than two prior therapies should be used before using the requested medications.

(b) For purposes of this section, the following shall apply:

(1) "Prescribing provider" shall include a provider who is authorized to write a prescription, as described in subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an insured.

(2) "Generically equivalent drug" means a drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name, as determined by the United States Adopted Names Council and accepted by the federal Food and Drug Administration, as those drug products having the same chemical ingredient.

(c) This section does not prohibit a health insurer from charging an insured or policyholder a copayment or a deductible for prescription drug benefits or from setting forth, by contract, limitations on maximum coverage of prescription drug benefits, provided that the copayments,

deductibles, or limitations are reported to, and held unobjectionable by, the commissioner and communicated to the insured or policyholder pursuant to the disclosure provisions of Section 10603.

(d) Nothing in this section shall be construed to require coverage of prescription drugs not in an insurer's drug formulary or to prohibit generically equivalent drugs or generic drug substitutions as authorized by Section 4073 of the Business and Professions Code.

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

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

AB 889 prohibits DMHC-regulated plans and CDI-regulated policies from requiring patients to try and fail on more than two medications before allowing patients access to the initially prescribed medication, or a generic version of the same medication. CHBRP uses the term "fail-first protocols" to refer to utilization management protocols where alternative medications must be tried before coverage for the prescribed medication is approved. The medical effectiveness review summarizes findings from a systematic review and individual studies of the impact of fail-first protocols on utilization of prescription medications, other health care services, and health outcomes.

The effectiveness of prescription medications was not addressed because it is not feasible for CHBRP to review the literature on effectiveness of all drugs subject to fail-first protocols with more than two steps within the 60-day timeframe allotted for this analysis. Moreover, AB 889 does not mandate that carriers provide coverage for prescription medications but instead establishes terms and conditions for coverage. CHBRP focused on the effects of fail-first protocols on utilization and health outcomes.

The medical effectiveness review was limited to studies of protocols under which persons were required to try and fail at least one medication before obtaining a prescription for the initially prescribed medication, or a generic version of the same medication. Studies of prior authorization protocols were included only if they required persons to try and fail at least one medication before prior authorization would be granted for the initially prescribed medication.

The literature search was limited to studies published in English from January 2000 to present. The following databases of peer-reviewed literature were searched: PubMed, the Cochrane Library, Web of Science, EconLit, and Business Source Complete.

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.

Of the 307 articles found in the literature review, 58 were reviewed for potential inclusion in this report on AB 889, and a total of 15 articles that reported findings from 13 studies⁵⁸ were included in the medical effectiveness review for this report. Eleven of these studies were included in a systematic review published in 2011 (Motheral, 2011). The medical effectiveness review also presented findings from two individual studies of fail-first protocols that were not included in the systematic review (Hartung et al., 2004; Momani et al., 2002). The other articles

⁵⁸ Lu and colleagues (2010), Soumerai and colleagues (2008), and Zhang and colleagues (2009) presented three different sets of findings from a study of a single fail-first protocol implemented by Maine's Medicaid program.

were eliminated because they did not focus on fail-first protocols, were of poor quality, or did not report findings from clinical research studies.

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*.⁵⁹ To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and
- Generalizability of findings.

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

- Clear and convincing evidence;
- Preponderance of evidence;
- Ambiguous/conflicting evidence; 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 are of high quality and consistently find that the treatment is either effective or not effective.

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. This can be further subdivided into preponderance of evidence from high-quality studies and preponderance of evidence from low-quality studies.

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 of equal quality suggest the treatment is not effective.

⁵⁹ Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

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 are not of high quality. It does not indicate that a treatment is not effective.

Search Terms

The search terms used to locate studies relevant to AB 889 were as follows:

Major MeSH Terms Used to Search PubMed

- Drug Therapy

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

- Drug
- Drugs
- Fail First
- Generics
- Medication
- Prescription
- Prescriptions
- Prior Authorization
- Step Therapy
- Step-Therapy

Appendix C: Summary Findings on Medical Effectiveness

Appendix C describes the systematic reviews and individual studies on fail-first protocols for prescription medications that were analyzed by the medical effectiveness team. Table C-1 describes the characteristics of the studies included in the medical effectiveness review. Tables C-2a through C-2e present findings from the studies included in the review. Each table describes findings for one of the five classes of prescription medications for which the medical effectiveness team identified studies of fail-first protocols: antidepressants, antihypertensives, antipsychotics and anticonvulsants, nonsteroidal anti-inflammatory drugs (NSAIDs), and proton pump inhibitors (PPIs).

Table C-1. Characteristics of Studies That Examined the Effects of Fail-First Protocols on Prescription Drug Use

Type of Intervention	Citation	Type of Trial ⁶⁰	Intervention versus Comparison Group	Population Studied	Location
Prescription drug class					
Nonsteroidal anti-inflammatory drugs (NSAIDs)	Hartung et al., 2004	Level III study	This study looked at claims data for the use of NSAIDs before and after a fail-first policy was implemented. The study compared data from a Medicaid managed care organization that implemented a fail-first protocol to a Medicaid fee-for-service program that did not have a fail-first protocol.	All enrollees in CareOregon and Oregon's fee-for-service Medicaid program	Oregon, USA
NSAIDs	Momani et al., 2002	Level IV study	This study consisted of data from surveys before and after intervention, which was a two-month period. To identify patients affected by policy implementation, a sample of patients needing prior authorization was collected daily. The sample compared generic to brand users.	Enrollees were Medicaid patients continuously enrolled during the study period, were under 65, and had a diagnosis of rheumatoid arthritis, Osteoarthritis, spondylitis, or chronic pain syndrome.	West Virginia, USA

⁶⁰ Level I = well-designed randomized controlled trials, level II = randomized controlled trials with major weaknesses, level III = nonrandomized studies with comparison groups, level IV = case series, level V = case studies.

Table C-1. Characteristics of Studies That Examined the Effects of Fail-First Protocols on Prescription Drug Use (Cont'd)

Type of Intervention	Citation	Type of Trial	Intervention versus Comparison Group	Population Studied	Location
Five disease classes	Motheral, 2011	Systematic review of level III and level IV studies	Fourteen studies were included in this review. In order to meet criteria, the policy had to be implemented in the US, and had to require use of first-line agents prior to coverage of second-line agents.	Enrollees in either commercial plans of Medicaid plans submitting claims for antidepressants, antihypertensives, antipsychotics, NSAIDs, and proton pump inhibitors (PPIs).	USA

Sources: Hartung et al., 2004; Momani et al., 2002; Motheral, 2011.

Table C-2. Summary of Findings from Studies of the Effectiveness of Fail-First Protocols on Drug Utilization

Table C2-a. Impact of Fail-First Protocols for Antidepressants

Outcome	Citation (s)	Research Design ⁶¹	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
No medication obtained	Motheral, 2011	Systematic Review – 1 Level III study (Motheral et al., 2004)	No formal test of statistical significance, only analyzed data for the intervention group	Worse	No medication obtained by 11% after step therapy edit	Some persons subject to a fail-first protocol did not obtain medication but the study did not assess the impact of this on health outcomes.
Days' supply of number of prescription	Motheral, 2011	Systematic Review – 1 Level III study (Mark et al., 2010)	Not statistically significant	No effect	No difference	Fail-first protocol not associated with days' supply of medication.
Days of therapy per member per month	Motheral, 2011	Systematic Review – 1 Level III study (Dunn et al., 2006)	Not statistically significant	No effect	No difference	Fail-first protocol not associated with days of therapy dispensed.
Outpatient office, Inpatient, and ER visits and spending	Motheral, 2011	Systematic Review – 1 Level III study (Mark et al., 2010)	Not significant	No effect	Mark: Higher utilization for mental health diagnoses and all diagnoses	Fail-first protocols are associated with greater use of other types of health care services.

⁶¹ Level I = well-designed randomized controlled trials, level II = randomized controlled trials with major weaknesses, level III = nonrandomized studies with comparison groups, level IV = case series, level V = case studies.

Table C2-b. Impact of Fail-First Protocols for Antihypertensives

Outcome	Citation (s)	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
No medication obtained	Motheral, 2011	Systematic Review – 1 Level III study (Yokoyama et al., 2007)	Statistically significant	Worse	7% in fail-first protocol group received no anti-hypertension medication vs. 0% in the comparison group	Some persons subject to a fail-first protocol did not obtain medication but the study did not assess the impact of this on health outcomes.
Days' supply	Motheral, 2011	Systematic Review – 2 Level III studies (Mark et al., 2009; Yokoyama et al., 2007)	Statistically significant: 1 of 2 studies (Yokoyama et al., 2007) No statistically significant difference: 1 of 2 studies (Mark et al., 2009)	Worse: 1 of 2 studies (Yokoyama et al., 2007) No effect: 1 of 2 studies (Mark et al., 2009)	Yokoyama: 454 days per year in fail-first protocol group vs. 476 days per year in the comparison group Mark: no difference	Studies of the impact of fail-first protocols on days' supply of medication reached opposite conclusions.
Discontinuation	Motheral, 2011	Systematic Review – 1 Level III study (Mark et al., 2009)	Not reported	Worse	Mark: Higher in the fail-first protocol group: 13% vs. 10% (unadjusted)	Persons subject to a fail-first protocol were more likely to discontinue medication.
Outpatient office, inpatient, and ER visits and spending	Motheral, 2011	Systematic Review – 1 Level III study (Mark et al., 2009)	Not reported	Worse	Higher all-cause spending: Inpatient, ER, and outpatient	Fail-first protocol associated with greater use of other types of health care services.

Table C2-c. Impact of Fail-First Protocols for Antipsychotics and Anticonvulsants

Outcome	Citation (s)	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
Initiation	Motheral, 2011	Systematic Review – 1 Level III study (Lu et al., 2010)	Statistically significant	Worse	Relative reduction in treatment initiation between the fail-first group and the comparison group was 32.3% (95% CI: 24.8, 39.8)	Implementation of a fail-first protocol reduced the percentage of persons initiating medication.
Discontinuation	Motheral, 2011	Systematic Review – 2 Level III studies (Zhang et al., 2009; Soumerai et al., 2008)	Statistically significant	Worse	Zhang: for persons with bipolar disorder relative change in hazard ratio for discontinuation in ≥ 30 days was 2.28 (95% CI: 1.15, 4.52); similar effects at ≥ 50 days and ≥ 250 days ⁶² Soumerai: for persons with schizophrenia relative change in hazard ratio for a gap, switch, or augmentation in therapy in ≥ 45 days was 1.94 (95% CI: 1.14, 3.29); no statistically significant differences for ≥ 15 days and ≥ 30 days	Persons subject to a fail-first protocol were more likely to discontinue medication.
Outpatient office visits	Motheral, 2011	Systematic Review – 2 Level III studies (Farley et al., 2008)	Not reported	Decrease	Decrease in outpatient visits ⁶³	Fail-first protocol associated with a decrease in outpatient visits.

⁶² The authors found no difference in rates of switching or augmentation of medication (Zhang et al., 2009).

⁶³ Farley et al., 2008, found that expenditures for outpatient visits increased despite the decrease in the number of outpatient visits and suggested that providers may have been reimbursed more per visit.

Table C2-d. Impact of Fail-First Protocols for NSAIDs

Outcome	Citation (s)	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
No medication obtained (Rx or OTC) ⁶⁴	Motheral, 2011	Systematic Review – 1 Level III study (Motheral et al., 2004), 1 Level IV study (Cox et al., 2004)	No formal test of statistical significance – only analyzed data for the intervention group	Worse	Motheral: No medication in 15% after step therapy edit Cox: No medication in 9.5% after step therapy edit	Some persons subject to a fail-first protocol did not obtain medication but the study did not assess the impact of this on health outcomes.
All NSAIDs	Hartung et al., 2004	1 Level III study	Not statistically significant	No effect	No difference	Fail-first protocol did not affect total utilization of NSAIDs.
Other drugs	Hartung et al., 2004	1 Level III study	Not statistically significant	No effect	No difference	Fail-first protocol did not affect use of other medications.
Outpatient office, inpatient, and ER visits and spending	Motheral, 2011 Hartung et al., 2004	Systematic Review – 1 Level III study (Smalley et al., 1995) 1 Level III study (Hartung et al., 2004)	Statistically significant: 1 of 2 (Hartung et al., 2004) Not statistically significant: 1 of 2 (Smalley et al., 1995)	Hartung: Worse Smalley: No effect	Hartung: 18% in ER visits Smalley: No difference	Findings regarding effects of fail-first protocols on use of other health care services are inconsistent.
Quality of Life ⁶⁵	Momani et al., 2002	1 Level III study	Not statistically significant	No effect	No difference	Fail-first protocol did not affect health-related quality of life.

⁶⁴ Rx = prescription drug; OTC = over-the-counter drug

⁶⁵ In this study, quality of life was measured using a survey instrument that included items regarding mobility, walking and bending, hand and finger function, self-care, household tasks, social activities, arthritis pain, level of tension, and mood.

Table C2-e. Impact of Fail-First Protocols for PPIs

Outcome	Citation (s)	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Conclusion
No medication obtained (Rx or OTC)	Motheral, 2011	Systematic Review – 1 Level III study (Motheral et al., 2004), 1 Level IV study (Cox et al., 2004)	No formal test of statistical significance, only analyzed data for the intervention group	Worse	Motheral: No medication in 22% after step therapy edit Cox: No medication in 12.7% after step therapy edit	Some persons subject to a fail-first protocol did not obtain medication but the study did not assess the impact of this on health outcomes.
Outpatient office, inpatient, and ER visits spending	Motheral, 2011	Systematic Review – 1 Level III study (Delate et al., 2005 ⁶⁶)	Not statistically significant	No effect	No difference	Fail-first protocol did not affect expenditures for other health care services to treat gastrointestinal conditions.

Sources: Cox et al., 2004; Delate et al., 2005; Dunn et al., 2006; Farley, et al., 2008; Hartung et al., 2004; Lu et al., 2010; Mark et al., 2009, 2010; Momani et al., 2002; Motheral et al., 2004; Motheral, 2011; Smalley et al., 1995; Soumerai et al., 2008; Yokoyama et al., 2007; Zhang et al., 2009.

⁶⁶ In this study, the author limited the analysis of effects on spending to gastrointestinal conditions.

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, San Diego, the University of California, Los Angeles, the University of California, Davis, and University of California, Berkeley, as well as the contracted actuarial firm, Milliman, Inc. (Milliman).⁶⁷

Data Sources

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

Baseline model

1. The California Simulation of Insurance Markets (CalSIM) is used to project health insurance status of Californians aged 64 and under in 2014. CalSIM is a microsimulation model that projects the effects of the Affordable Care Act on firms and individuals.⁶⁸ CalSIM relies on national Medical Expenditure Panel Survey (MEPS) Household Component and Person Round Plan, California Health Interview Survey (CHIS) 2009, and California Employer Health Benefits Survey data.
2. California Health Interview Survey (2011) 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 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 surveyed approximately 23,000 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.
3. The latest (2012) California Employer Health Benefits Survey is used to estimate:
 - a. Size of firm
 - b. Percentage of firms that are purchased/underwritten (versus self-insured)
 - c. Premiums for health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and point of service [POS] plans)

⁶⁷ 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).

⁶⁸ 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*, June 2012. Available at www.healthpolicy.ucla.edu/pubs/files/calsim_methods.pdf. Accessed October 19, 2012.

- d. Premiums for health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service [FFS] plans)

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/2010/12/california-employer-health-benefits-survey.

4. 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 preferred provider organization (PPO) plans. The HCGs currently include claims drawn from plans covering 37 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following:
 - a. The MarketScan databases, which reflects the healthcare 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.
 - b. An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2010 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2010 experience.
 - c. Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.
 - d. These data are reviewed for applicability by an extended group of experts within Milliman but are not audited internally.
5. Premiums and enrollment in DMHC-regulated health plans and CDI-regulated policies by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their dependents who receive their benefits through CalPERS. Enrollment information is provided for DMHC-regulated health care service plans covering non-Medicare beneficiaries—about 74% of CalPERS total

enrollment. CalPERS self-funded plans—approximately 26% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOC) documents publicly available at www.calpers.ca.gov. For the 2013 model, CHBRP assumes CalPERS’s enrollment in 2014 will not be affected by the ACA.

6. Enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System plans) is estimated based on data maintained by the Department of Health Care Services (DHCS). CHBRP assesses enrollment information online at: www.dhcs.ca.gov/dataandstats/statistics/Pages/RASB_Medi-Cal_Enrollment_Trends.aspx. Starting with the 2013 model, the most recent Medi-Cal enrollment data from DHCS is projected to 2014 based on CalSIM’s estimate of the impact of the Medi-Cal expansion in 2014.

Estimate of premium impact of mandates

7. 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 97.5% of the persons with health insurance subject to state mandates. This figure represents an estimated 97.9% of enrollees in full-service (nonspecialty) DMHC-regulated health plans and an estimated 96.1% of enrollees in full-service (nonspecialty) CDI-regulated 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, 2011, 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 2012, provides data on DMHC-regulated plans by segment.⁶⁹

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

⁶⁹ CHBRP assumes DMHC-regulated PPO group enrollees and POS enrollees are in the large-group segment. <http://wpsso.dmhc.ca.gov/flash/>.

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

Data Source	Items
California Simulation of Insurance Markets (CalSIM)	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 (CHIS 2011)	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. By January 1, 2014, children enrolled in Healthy Families will be 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 2014

This subsection discusses adjustments made to CHBRP's Cost and Coverage Model to account for the potential impacts of the ACA effective January 2014. It is important to emphasize that CHBRP's analysis of specific mandate bills typically addresses the marginal effects of the mandate bill—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, *holding all other factors constant*. CHBRP's estimates of these marginal effects are presented in the *Benefit Coverage, Utilization, and Cost Impacts* section of this report.

Baseline premium rate development methodology—2014 post-ACA

Mandate bills introduced during 2013 would, if passed, become effective in 2014. Many significant provisions of the Affordable Care Act also become effective in 2014. In many cases, provisions required in the ACA would become effective on the same date as a mandate proposed to California law.

CHBRP's analyses of mandates effective in 2014 assume that carriers implement the new ACA provisions first. The baseline premiums reflect the estimated 2014 premium levels costs *after* carriers have implemented the 2014 ACA provisions. The estimated cost impact of a proposed mandate is then calculated relative to this post-ACA baseline.

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, CHBRP first obtained an estimate of the insurance premium PMPM by taking the 2012 reported premium from the above-mentioned data sources and trending that value to 2014. CHBRP uses trend rates published in the Milliman Health Cost Guidelines to estimate the health care costs for each plan segment in 2014.

In 2014, four plan segments in the previous CHBRP model⁷⁰ were split into 12 segments. Each of the two small-group segments (CDI-regulated and DMHC-regulated), and individual segments (CDI-regulated and DMHC-regulated) were 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 2012 CHBRP Annual Enrollment and Premium Survey asked the seven

⁷⁰ In the past, CHBRP's model has reflected large-group, small-group, and individual market segments. These market segments were further subdivided by regulator: DMHC-regulated and CDI-regulated. The four plan segments refer to the small and individual market subdivisions by regulator.

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, to estimate premium rates for grandfathered and nongrandfathered plans that were consistent with the NORC results.

The marginal impact of ACA on 2014 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 \times (1 – profit/administration load).
- Gross claims costs PMPM = health care costs paid by the health plan \div percentage paid by health plan
- Member cost sharing PMPM = gross claims costs \times (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 Milliman’s knowledge of the health care market.

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 healthcare costs that are paid by the carrier.

Medi-Cal Managed Care

Given that:

- California has not yet decided on Medi-Cal’s EHBs for Californians newly eligible for Medi-Cal Managed Care; and

- The ACA does not require coverage of EHBs for individuals currently eligible for Medicaid.

CHBRP has estimated that the PMPM cost for Medi-Cal’s newly eligible population—in the absence of further guidance on EHBs for the 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: http://chbrp.org/documents/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: http://chbrp.org/documents/uninsured_010109.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%.

Appendix E: Information Submitted by Outside Parties

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

The Office of Assembly Member Jim Frazier submitted information in March and April 2013.

Carlton RI, Bramley TJ, Nightengale B, Conner TM, Zacker C. Review of Outcomes Associated with Formulary Restrictions: Focus on Step Therapy. *The American Journal of Pharmacy Benefits*. 2010;2(1):50–58 .

Cox E, Seiz BJ. Are There Unintended Consequences of Step-Therapy Programs? *The American Journal of Managed Care*. 2009;15(9):654, 656.

Fox LA. Managed Care Restrictions: Barriers to Product Use in Cancer Care. *The American Journal of Managed Care*. 2013;19(1 Spec No):SP24-5.

Frazier, Jim. AB 889 - Improving Patient Care: Fact Sheet. April, 2013.

Gleason PP. Commentary: Assessing Step-Therapy Programs: A Step in the Right Direction. *Journal of Managed Care Pharmacy*. 2007;13(3):273-275.

Maryland State Medical Society. *Prior Authorization: Impact on Patient Care in Maryland. A Survey of the Members of the Maryland State Medical Society*. July 20, 2011.

Mark TL, Gibson TB, McGuigan KA. The Effects of Antihypertensive Step-Therapy Protocols on Pharmaceutical and Medical Utilization and Expenditures. *The American Journal of Managed Care*. 2009;15(2):123-31.

Ransom G. Md. health insurers' 'fail first' policies jeopardize patient health: In the name of controlling costs, some erect barriers that prevent patients from receiving needed care. *The Baltimore Sun*. March 11, 2013.

Zeng F, Chen CI, Mastey V, Zou KH, Harnett J, Patel BV. Utilization Management for Smoking Cessation Pharmacotherapy: Varenicline Rejected Claims Analysis. *The American Journal of Managed Care*. 2010;16(9):667-74.

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

- Braveman P. Health disparities and health equity: concepts and measurement. *Annual Review of Public Health*. 2006;27:167-194.
- California Department of Public Health (CDPH). *Premature Mortality Trends 2000-2007*. Available at: <http://www.cdph.ca.gov/programs/ohir/Pages/YPLL2007Main.aspx>. Accessed April 2013.
- California Health Benefits Review Program. *Analysis of Assembly Bill 154: Mental Health Services*. Oakland, CA: CHBRP; 2011. CHBRP 11-02.
- 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.
- Cox DH. *Premature mortality in California, 2004*. Center for Health Statistics. December 2006. Available at: www.cdph.ca.gov/pubsforms/Pubs/OHIRprematuremortality2004.pdf. Accessed November 30, 2011.
- Cox ER, Henderson R, Motheral BR. Health plan member experience with point-of-service prescription step therapy. *Journal of Managed Care Pharmacy*. 2004;10(4):291-8.
- Delate T, Mager DE, Sheth J, Motheral BR. Clinical and financial outcomes associated with a proton pump inhibitor prior-authorization program in a Medicaid population. *American Journal of Managed Care*. 2005;11(1):29-36.
- Dunn JD, Cannon HE, Mitchell MP, Curtiss FR. Utilization and drug cost outcomes of a step-therapy edit for generic antidepressants in an HMO in an integrated health system. *Journal of Managed Care Pharmacy*. 2006;12(4):294-302.
- Farley JF, Cline RR, Schommer JC, Hadsall RS, Nyman JA. Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications. *Clinical Therapeutics*. 2008;30(8):1524-1539.
- Gardner JW, Sanborn JS. Years of potential life lost (YPLL)—what does it measure? *Epidemiology*. 1990;1:322-329.
- 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 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.
- Hartung DM, Touchette DR, Ketchum KL, Haxby DG, Goldberg BW. Effects of a prior-authorization policy for celecoxib on medical service and prescription drug use in a managed care Medicaid population. *Clinical Therapeutics*. 2004;26(9):1518-32.
- Kaiser Family Foundation (KFF). *Key Facts: Race, Ethnicity and Medical Care, 2007 Update*. January 2007. Available at: www.kff.org/minorityhealth/upload/6069-02.pdf. Accessed March 2009.

- Kirby JB, Taliaferro G, Zuvekas SH. Explaining racial and ethnic disparities in health care. *Medical Care*. 2006;44(suppl):I64-I72.
- Law MR, Ross-Degnan D, Soumerai SB. Effect of prior authorization of second-generation antipsychotic agents on pharmacy utilization and reimbursements. *Psychiatric Services*. 2008;59(5):540-546.
- Lillie-Blanton M, Hoffman C. The role of health insurance coverage in reducing racial/ethnic disparities in health care. *Health Affairs (Millwood)*. 2005;24:398-408.
- Lu CY, Soumerai SB, Ross-Degnan D, Zhang F, Adams AS. Unintended impacts of a Medicaid prior authorization policy on access to medications for bipolar illness. *Medical Care*. 2010;48(1):4-9.
- Lundh A, Sisonondo S, Lexchin J, Busuioc OA, Bero L. Industry sponsorship and research outcome. *Cochrane Database of Systematic Reviews*. 2012;12:MR000033. doi: 10.1002/14651858.MR000033.pub2.
- Mark TL, Gibson TB, McGuigan KA. The effects of antihypertensive step-therapy protocols on pharmaceutical and medical utilization and expenditures. *American Journal of Managed Care*. 2009;15(2):123-131.
- Mark TL, Gibson TM, McGuigan K, Chu BC. The effects of antidepressant step therapy protocols on pharmaceutical and medical utilization and expenditures. *American Journal of Psychiatry*. 2010;167(10):1202-1209.
- Momani AA, Madhavan SS, Nau DP. Impact of NSAIDs prior authorization policy on patients' Quality of Life. *Annals of Pharmacotherapy*. 2002;36(11):1686-1691.
- Motheral BR, Henderson R, Cox ER. Plan-sponsor savings and member experience with point-of-service prescription step therapy. *American Journal of Managed Care*. 2004;10(7 Pt 1):457-64.
- Motheral BR. Pharmaceutical step-therapy interventions: A critical review of the literature. *Journal of Managed Care Pharmacy*. 2011;17(2):143-155.
- Rosenthal MB, Landon BE, Normand SL, Ahmad TS, Epstein AM. Engagement of health plans and employers in addressing racial and ethnic disparities in health care. *Medical Care Research and Review*. 2008;66:219-231.
- Smalley WE, Griffin MR, Fought RL, Sullivan L, Ray WA. Effect of a prior-authorization requirement on the use of nonsteroidal anti-inflammatory drugs by Medicaid patients. *New England Journal of Medicine*. 1995;333:1612-1617.
- Soumerai SB, Zhang F, Ross-Degnan D, et al. Use of atypical antipsychotic drugs for schizophrenia in Maine Medicaid following a policy change. *Health Affairs*. 2008;27(3):W185-W195.
- U.S. Department of Veterans Affairs and U.S. Department of Defense. *VA/DoD Clinical Practice Guideline for Management of Bipolar Disorder in Adults*. 2010. Available at: http://www.healthquality.va.gov/bipolar/bd_306_sum.pdf. Accessed April 11, 2013.
- Yokoyama K, Yang W, Preblich R, Frech-Tamas F. Effects of a step-therapy program for angiotensin receptor blockers on antihypertensive medication utilization patterns and cost of drug therapy. *Journal of Managed Care Pharmacy*. 2007;13(3):235-44.

Zhang YT Adams AS, Ross-Degnan D, Zhang F, Soumerai SB. Effects of prior authorization on medication discontinuation among Medicaid beneficiaries with bipolar disorder. *Psychiatric Services*. 2009;60(4):520-527.

California Health Benefits Review Program Committees and Staff

A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature. The level of involvement of members of the CHBRP Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others. 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. Milliman also helped with the initial development of CHBRP methods for assessing that impact.

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 and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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