California Health Benefits Review Program

Executive Summary

Analysis of Assembly Bill 889: Prescription Drugs

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

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

A Report to the 2013–2014 California State Legislature

Analysis of Assembly Bill 889
Prescription Drugs

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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.[1]

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.[2] 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)[3] 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,[4] 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)[5] 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

[1] Available at: www.chbrp.org/docs/authorizing_statute.pdf.
[2] CHBRP's estimates are available at: www.chbrp.org/other_publications/index.php.
[3] 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.
[4] 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.
[5] 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) model[6] 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.[7]

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

[6] 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.

[7] 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.

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*[8] 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.[9]

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.

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;

[8] 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.

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

- 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 Federal 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.[10] 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.

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.[11,12] 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.

[10] 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.
[11] 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.
[12] 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.

ACKNOWLEGMENTS

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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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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