



**CALIFORNIA**  
HEALTH BENEFITS REVIEW PROGRAM

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**Executive Summary**  
Analysis of Assembly Bill 369:  
Health Care Coverage:  
Prescription Drugs

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A Report to the 2011-2012 California Legislature  
April 14, 2011

# **A Report to the 2011-2012 California State Legislature**

## **Analysis of Assembly Bill 369 Health Care Coverage: Prescription Drugs**

**April 14, 2011**

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## EXECUTIVE SUMMARY

### California Health Benefits Review Program Analysis of Assembly Bill 369

The California Assembly Committee on Health requested on February 14, 2011, 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) 369, a bill that would impose a health benefit mandate. In response to this request, CHBRP undertook this analysis pursuant to the provisions of the program's authorizing statute.<sup>1</sup> AB 369 establishes limits on the manner in which health plans and health insurers can use fail-first protocols, or step therapy, as a condition of payment for medications prescribed for the treatment of pain. The effective date of AB 369 is January 1, 2012.

Approximately 21.9 million Californians (59%) have health insurance that may be subject to a health benefit mandate law passed at the state level.<sup>2</sup> Of the rest of the state's population, a portion is uninsured (and so has no health insurance subject to any benefit mandate) and another portion has health insurance subject to other state law or only to federal laws.

Uniquely, California has a bifurcated system of regulation for health insurance subject to state-level benefit mandates. The California Department of Managed Health Care (DMHC)<sup>3</sup> 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<sup>4</sup>, which offer benefit coverage to their enrollees through health insurance policies.

DMHC-regulated plans and CDI-regulated policies would be subject to a health benefit mandate law passed at the state level. AB 369 does not mandate coverage of outpatient prescription drugs. Therefore, it could affect the health insurance of the approximately 20.9 million Californians already with benefit coverage (56%).

#### Analysis of AB 369

Throughout this report, CHBRP uses the phrase "fail-first protocols" to reference the heterogeneous group of utilization management protocols for pain medications in which alternate medications must be tried before coverage for the prescribed pain medication is approved. Cost control and clinical considerations (e.g., proof of medication intolerance, prevention of use for unapproved indications, or adherence to clinical guidelines) are common reasons for plans and insurers to implement fail-first protocols.

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<sup>1</sup> CHBRP's authorizing statute is available at [http://www.chbrp.org/documents/authorizing\\_statute.pdf](http://www.chbrp.org/documents/authorizing_statute.pdf)

<sup>2</sup> CHBRP's estimates are available at [http://www.chbrp.org/other\\_publications/index.php](http://www.chbrp.org/other_publications/index.php).

<sup>3</sup> The DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan Act of 1975; see Health and Safety Code, Section 1340.

<sup>4</sup> The 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, Section 106(b) or subdivision (a) of Section 10198.6.

Fail-first protocols may be implemented as methods of utilization management in a variety of ways and are known by a number of terms. *Step therapy*, when implemented by a health plan or insurer, requires an enrollee to try a first-line medication (often a generic alternative) prior to receiving coverage for a second-line medication (often a brand-name medication). *Step edit* is a process by which a prescription, submitted for payment authorization, is electronically reviewed at point of service for use of a prior, first-line medication. For either step therapy or step edit, upon decline of coverage for the prescription, a patient's health care provider may reissue the prescription for a first-line agent covered by the patient's health plan contract or policy or appeal the decision. Alternatively, the patient may purchase the prescription despite the lack of coverage. A fail-first protocol may also be the basis for part or all of a *precertification* or *prior authorization* protocol, which may also require the prescribing provider to confirm to the plan or insurer that an alternate medication or medications have been unsuccessfully tried by the patient before the coverage for the prescribed medication is approved. However, 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.

AB 369 would allow DMHC-regulated plans and CDI-regulated policies to use fail-first protocols as methods of utilization management for pain medications.

However, AB 369 would require plans and insurers that apply fail-first protocols to pain medications to do the following:

- cover the initially prescribed pain medication, or its generic equivalent, after a trial of no more than two alternate medications.
- accept that the duration of any trial of an alternate medication for a fail-first protocol be determined by the prescribing provider.
- accept a note in the patient's chart as proof that the patient has tried and failed alternate medications specified by a fail-first protocol and accept this note as prior authorization.
- accept a prescribing provider's note on a prescription as proof that a fail-first protocol has been met and allow a pharmacist to process the prescription without additional communication with the plan or insurer.

This analysis focuses on the effect of removing one utilization management criterion used to make coverage determinations for prescription drug benefits – the number of alternate medication that must be tried before coverage for a medication will be provided. This analysis does not attempt to evaluate the effect of removing the health plan and health insurer role in determining the duration of the medication trials specified by a fail-first protocol, or the effect of requiring plans and insurers to accept chart notes as documentation of a compliance with a fail-first protocol, or requiring plans or policies to accept a note of such compliance on a prescription eliminating the need for additional communication with a pharmacist before a payment is processed.

AB 369, as a health insurance benefit mandate, does not directly affect providers. Therefore, AB 369 would not alter the ability of prescribing providers to direct a patient to try any number of alternate medications before prescribing a particular pain medication (a provider practice also known as “step therapy” but one separate from the health plan or insurer use of fail-first protocols). Nor would AB 369 limit the number of medications a provider may prescribe, or prohibit generic drug substitution by pharmacists. Therefore, AB 369 would not directly affect provider practice; rather, AB 369 would affect the criteria used by health plans and health insurers for making coverage determinations for prescribed medications.

Although AB 369 would enact a health insurance benefit mandate for DMHC-regulated plans and CDI-regulated policies, the bill would not require health plans or policies to provide coverage for prescription drugs that are not included in their formularies.

Additionally, AB 369 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. However, AB 369 would require that any such copayments, deductibles, and limits be disclosed in plan contracts or policies and held “unobjectionable” by the DMHC or CDI. Language with respect to copayment, deductible, and limits being not “held objectionable,” exists in current law for DMHC-regulated plans but not for CDI-regulated policies. Extending this language to CDI-regulated policies may broaden the authority of the Insurance Commissioner with respect to cost sharing arrangements. CHBRP cannot predict what effect, if any, this language could have on cost sharing for pain medications.

### California Laws and Regulations

There is no current California mandate that requires prescription drugs be included in health plans or insurer policies, although there is a mandate for DMHC-regulated plans (but not CDI-regulated policies) that cover prescription drug benefits to provide coverage for pain management medications for terminally-ill patients when medically necessary.<sup>5</sup> No current California mandate prohibits the use of fail-first protocols as a criteria for coverage determinations. There are a number of requirements in existing law and regulation that affect coverage of prescription medications.

#### *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.<sup>6</sup> Copayments, deductibles, and other limitations cannot render the benefit illusory.<sup>7</sup> For outpatient prescription drug benefits, copayment or percentage coinsurance cannot exceed 50% of the cost to the plan.<sup>8</sup>

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<sup>5</sup> Health and Safety Code, Section 1367.215

<sup>6</sup> Health and Safety Code, Section 1367(h)(1) and 1367(i)

<sup>7</sup> Health and Safety Code Section 1367, California Code of Regulations Title 28 § 1300.67.4

<sup>8</sup> California Code of Regulations, title 28, Section 1300.67.24

The CDI limits expenses paid by the insured, requiring all policies to be economically sound.<sup>9</sup> Individual policies must provide “real economic value” to the insured.<sup>10</sup>

#### *Disclosure and oversight of utilization management*

CDI-regulated insurers and DMHC regulated plans are required to file their utilization review/utilization management criteria with the DMHC or CDI and ensure that criteria are (1) developed with involvement from actively practicing health care providers; (2) consistent with sound clinical principals and processes; (3) evaluated, and updated if necessary, at least annually; and (4) if used as the basis of a decision to modify, delay, or deny services in a specified case under review, disclosed to the provider and the enrollee in that specified case.<sup>11</sup>

In addition, DMHC-regulated plans (but not CDI-regulated insurers):

- are prohibited from limiting or excluding coverage for a drug for an enrollee if the drug had previously been approved for coverage by the plan for a medical condition of the enrollee and the plan’s prescribing provider continues to prescribe the drug for the medical condition, provided that it is appropriately prescribed, and is considered safe and effective for treatment.<sup>12</sup>
- that maintain one or more drug formularies are required to 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.<sup>13</sup>

#### Other States and Federal Requirements

A law recently enacted in Louisiana (SB 421, 2010) imposes restrictions on fail-first protocols.

A majority of state Medicaid programs utilize fail-first protocols; however, CHBRP was unable to determine whether other states’ fail-first protocols are inconsistent with AB 369.

At the federal level, Part D sponsors for Medicare Prescription Drug Benefits must maintain utilization management (UM) criteria that is not “overly burdensome...[f]or example, Part D sponsors should not generally maintain prior authorization criteria that require trial and failure of more than two formulary alternatives in advance of providing access to the prescribed drug.”<sup>14</sup>

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<sup>9</sup> Insurance Code Section, 10291.5(a)(1)

<sup>10</sup> Insurance Code Section 10291.5(b)(7)(A) and 10270.95

<sup>11</sup> Health and Safety Code, Section 1374.30, 1374.4; Insurance Code Section 10123.135

<sup>12</sup> Health and Safety Code, Section 1367.22

<sup>13</sup> Health and Safety Code Sections 1367.20 and 1367.24

<sup>14</sup> Centers for Medicare and Medicaid, 2010 Call Letter for Medicare Advantage organizations, March 30, 2009.

## Medical Effectiveness

Because of the heterogeneity of causal conditions and types of pain (acute and chronic), there is no standard treatment for pain. Pain treatment varies according to type, severity, and duration of pain, as well as causal condition (if known), patient comorbidities, and other factors (e.g., medication intolerance or patient compliance). Health care providers use clinical judgment to select among various pain medications and treatments in efforts to resolve or control pain for a patient.

The use of fail-first protocols varies by plan and insurer, as well as among enrollees who have health insurance from one plan or insurer. For some enrollees, no pain medications are subject to fail-first protocols. Other enrollees, depending on the provisions of their plan contracts or insurance policies, have outpatient prescription drug benefits that subject one or more pain medications to a fail-first protocol.<sup>15</sup> Furthermore, it is possible that two enrollees with plan contracts from the same health plan (or policies from the same insurer) might have outpatient prescription drug benefits for pain medications that differ with respect to which pain medications are subject to fail-first protocols. Furthermore, not all enrollees have benefit coverage subject to any fail-first protocols for pain medications and no single pain medication appears on all fail-first protocol lists. Similarly, no particular class of drugs appears on all fail-first protocol lists. There appears to be no pattern among DMHC-regulated health plans and CDI-regulated health insurers in the use of fail-first protocols for coverage determinations regarding pain medications.

Due to this heterogeneity, CHBRP did not review effectiveness or the comparative effectiveness studies for particular pain medications. Instead, the medical effectiveness portion of this analysis considers the question: *“As methods of utilization management, do fail-first protocols for pain medications affect health outcomes, such as pain control or quality of life?”*

- CHBRP found no medical effectiveness literature addressing the direct effects of fail-first protocols on resolving or controlling pain.
  - A single small study looked at quality of life in relation to fail-first protocols and found no evidence of effect.
  - CHBRP found two studies reporting little or no effect on medical service utilization (an indirect health outcome for effectiveness of pain control) among state Medicaid populations following implementation of prior authorization protocols for nonsteroidal anti-inflammatory drugs, a class of drugs commonly used to treat pain. Study limitations include small sample size, use of weaker study methodologies, limited generalizability of study populations, and lack of direct health outcome measures.

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<sup>15</sup> The identification of medications subject to fail-first protocols and number of fail-first trials required before coverage is provided are estimates based on data submitted to CHBRP from carriers surveyed in 2010 on a similar bill (AB 1826). The plans and insurers sent complete lists of drugs on fail-first protocols. The content experts winnowed the list to identify those that would likely be prescribed for pain instead of other conditions. Because there is little likelihood that these protocols would have changed measurably within the last 12 months, CHBRP relied on this information for this analysis.

- The remaining studies of fail-first protocols focused on drug classes unrelated to pain medications and on cost-effectiveness rather than clinical endpoints. All study authors recommended that future studies of fail-first protocols include clinical and quality of life endpoints.
- CHBRP finds insufficient evidence to characterize the medical effectiveness of fail-first protocols (including those protocols that would exceed two trials of alternatives, as addressed by AB 369) for pain medications. Therefore, CHBRP concludes that the impact of AB 369 on the medical effectiveness of pain treatment is unknown. The *lack of evidence* for the effectiveness of fail-first protocols does not prove that use of such protocols leads to either positive or negative health outcomes.

### **Benefit Coverage, Utilization, and Cost Impacts**

- Of the 21.9 million Californians enrolled in DMHC-regulated plans and CDI-regulated policies, approximately 20.9 million have outpatient prescription drug benefit coverage.
- Approximately 45.5% of enrollees with an outpatient pharmacy benefit have coverage for at least one pain medication which is subject to a fail-first protocol.
- Of more than 200 prescription medications used to treat pain, 54 medications (27%) are on at least one fail-first protocol list. However, lists can vary between health plan contracts and policies (even when offered by a single health plan or health insurer).
  - Of these 54 medications, 38 appeared on only one fail-first protocol list and 16 appeared on more than one fail-first protocol list.
  - For the 16 medications that appeared on more than one fail-first protocol list, CHBRP reviewed the relevant 19 fail-first protocols on which those 16 medications appeared. There were more protocols than medications because not all plans and policies use the same protocol for a particular drug.
  - Of the 19 fail-first protocols reviewed, one requires a user to try more than two alternative medications as a condition of coverage. The other 18 fail-first protocols would be compliant with AB 369 in that they did not have requirement to try and fail more than twice.
- Because fail-first protocols can vary by plan contract or policy, as well as by health plan or insurer, and because the clinical considerations that would cause a patient to fail trials of more than two alternate medications are so complex, CHBRP lacks sufficient information to estimate the change in utilization or cost for enrollees whose prescribed medications may be subject to a fail-first protocol not compliant with AB 369. In addition, as mentioned most fail-first protocols appear to already compliant with AB 369 in that they do not have requirements to try and fail more than twice.

- CHBRP projects no measurable impact on cost or utilization of prescription drugs as a result of AB 369 because the number of enrollees with outpatient pharmacy benefit coverage would not be changed by the bill, because the bill is not expected to result in a change in the diagnosis or treatment of pain, and because CHBRP has insufficient information to project in any change in use of pain medications due to the restrictions AB 369 would place on use of fail-first protocols.

## **Public Health Impacts**

- Pain is a prevalent condition in the U.S. population, with approximately 26% of adults experiencing chronic pain (i.e., pain lasting 6 months or longer). Pain varies widely in its presentation and duration and is caused by a wide array of known and unknown origins.
- Although there is some evidence that fail-first protocols studied for conditions other than pain can lead to lower levels of patient satisfaction, delays in receiving medications, and higher rates of unfulfilled prescriptions, this research is not generalizable to populations outside of those studied. Therefore, the impact of AB 369 on patient satisfaction, delays in receiving medication, or higher rates of unfilled prescriptions is unknown.
- CHBRP did not identify any literature that examined the relationship between fail-first protocols and gender or race/ethnicity. Therefore, the impact of AB 369 on gender and racial/ethnic disparities and the differential impacts by subpopulation on pain management is unknown.
- Pain conditions are known to be relevant factors in terms of lost productivity and associated economic loss through days missed from work, as well as reduced ability to perform tasks at work. No research was identified that assessed the impact of fail-first protocols for pain medications on measures of productivity. Therefore, the impact of AB 369 on lost productivity associated with conditions requiring the use of pain medications is unknown.

## **Potential Effects of the Federal Affordable Care Act**

The federal “Patient Protection and Affordable Care Act” (P.L.111-148) and the “Health Care and Education Reconciliation Act” (H.R.4872) were enacted in March 2010. These laws (together referred to as the “Affordable Care Act [ACA]”) are expected to dramatically affect the California health insurance market and its regulatory environment, with most changes becoming effective in 2014. How these provisions are implemented in California will largely depend on pending legal actions, funding decisions, regulations to be promulgated by federal agencies, and statutory and regulatory actions to be taken by California state government. The provisions that go into effect during these transitional years would affect the baseline, or current enrollment, expenditures, and premiums. It is important to note that CHBRP’s analysis of specific mandate bills typically address 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 this report.

### Essential health benefits offered by qualified health plans in the Exchange and potential interactions with AB 369

The ACA requires that, beginning 2014, states “make payments...to defray the cost of any additional benefits” required of Qualified Health Plans (QHPs) sold in the Exchange.<sup>16</sup> AB 369 does not require coverage of additional benefits as it specifically states, under Section (h) that “Nothing in this section shall be construed to require coverage of prescription drugs not in a [plan’s/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.”

The ACA provisions related to the Exchange are silent on step therapy and fail-first protocols. Essential health benefits (EHBs) are directed to include “Prescription drugs.”<sup>17</sup> To determine whether any additional state fiscal liability as it relates to the Exchange would be incurred under AB 369 the following factors would need to be examined:

- Determination of whether AB 369 requires “additional benefits” in the first place, given provision (h) stating that the bill does not mandate coverage of prescription drugs.
- The scope of “prescription drug” benefits in the final EHB package and whether federal guidelines or regulations will provide any guidance on the utilization management of the prescription drug benefit for QHPs to be offered in the Exchange.
- The number of enrollees in QHPs.
- The methods used to define and calculate the cost of additional benefits.

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<sup>16</sup> Affordable Care Act, Section 1311(d)(3)(B)

<sup>17</sup> Affordable Care Act, Section 1302(b)(1)(F)

## ACKNOWLEDGMENTS

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 369. In response to a request from the California Assembly Committee on Health on February 14, 2011, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute.

Stephen McCurdy, MD, MPH, and Dominique Ritley, MPH, of the University of California, Davis, and Janet Coffman, MPP, PhD, of the University of California, San Francisco, prepared the medical effectiveness analysis. Bruce Abbott, MLS, of the University of California, Davis, conducted the literature search. Todd Gilmer, PhD, of the University of California, San Diego, prepared the cost impact analysis. Sara McMenamain, PhD, of the University of California, San Diego, prepared the public health impact analysis. Susan Pantely, FSA, MAAA, of Milliman, provided actuarial analysis. John Lewis, MPA, of CHBRP staff prepared the introduction and synthesized the individual sections into a single report. A member of the CHBRP Faculty Task Force, Kathleen Johnson, PharmD, MPH, PhD, of the University of Southern California, 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 and three private universities in California. 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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