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CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

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

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



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 by statute (California Health and Safety Code, Section 127660, et seq). 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; or (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.

A small 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, as well as Loma Linda University, the University of Southern California, and Stanford University, 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, and 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 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 a small annual assessment on health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available at the CHBRP Web site, www.chbrp.org.

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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PREFACE

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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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.¹ 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.² 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)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 insurers⁴, 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.

¹ CHBRP's authorizing statute is available at http://www.chbrp.org/documents/authorizing_statute.pdf

² CHBRP's estimates are available at http://www.chbrp.org/documents/insur_source_est_2011.pdf

³ 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.

⁴ 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.⁵ 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.⁶ Copayments, deductibles, and other limitations cannot render the benefit illusory.⁷ For outpatient prescription drug benefits, copayment or percentage coinsurance cannot exceed 50% of the cost to the plan.⁸

⁵ Health and Safety Code, Section 1367.215

⁶ Health and Safety Code, Section 1367(h)(1) and 1367(i)

⁷ Health and Safety Code Section 1367, California Code of Regulations Title 28 § 1300.67.4

⁸ 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.⁹ Individual policies must provide “real economic value” to the insured.¹⁰

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.¹¹

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.¹²
- 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.¹³

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.”¹⁴

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

⁹ Insurance Code Section, 10291.5(a)(1)

¹⁰ Insurance Code Section 10291.5(b)(7)(A) and 10270.95

¹¹ Health and Safety Code, Section 1374.30, 1374.4; Insurance Code Section 10123.135

¹² Health and Safety Code, Section 1367.22

¹³ Health and Safety Code Sections 1367.20 and 1367.24

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

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.¹⁵ 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.
 - 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.

¹⁵ 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.

- 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.¹⁶ AB 369

¹⁶ Affordable Care Act, Section 1311(d)(3)(B)

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.”¹⁷ 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.

¹⁷ Affordable Care Act, Section 1302(b)(1)(F)

INTRODUCTION

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. AB 369 would allow the use of fail-first protocols, or step therapy, as a method of utilization management for pain medications. AB 369 would require plan regulated by the Department of Managed Health Care (DMHC) and policies regulated by the California Department of Insurance (CDI) to cover the medication initially prescribed for the treatment of pain, or its generic equivalent, after a trial of no more than two prescription medications. AB 369 would also place restrictions on health plans and insurers in terms of the utilization management tools they can impose on prescribing providers. 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.¹⁸ 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)¹⁹ regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers²⁰, 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 would potentially affect the health insurance of the approximately 20.9 million Californians already with benefit coverage (56%).

Analysis of AB 369

The full text of AB 369 can be found in Appendix A.

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

¹⁸ CHBRP's estimates are available at http://www.chbrp.org/documents/insur_source_est_2011.pdf

¹⁹ 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.

²⁰ 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.

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.

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 to be as 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 patterns; rather, AB 369 would affect the criteria used by health plans and health insurers for making coverage determinations for prescribed medications.

Although it would enact a health insurance benefit mandate for DMHC-regulated plans and CDI-regulated policies, AB 369 would not require health plans or policies to provide coverage for prescription drugs not 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.

Analytic approach and key assumptions

CHBRP has made two assumptions to produce this analysis within the required 60-day time frame.

First, this analysis assumes AB 369 affects only coverage from health plans and policies that provide an outpatient pharmacy benefit. Prescription medications may be covered through an enrollee’s medical benefits or through an outpatient pharmacy benefit if the enrollee’s plan contract or policy includes an outpatient pharmacy benefit. Medications used during an inpatient hospital stay are generally covered by an enrollee’s medical benefit. Similarly, medications used during a visit to a provider’s office—like many injected and intravenous pain medications—may be covered by an enrollee’s medical benefit. However, because fail-first protocols generally are not used as methods of utilization management for medications covered through a medical benefit, this analysis is focused on pain medications covered through outpatient pharmacy benefits.

Secondly, the analysis assumes coverage is to be provided for the prescription medication initially prescribed once enrollees have completed trials of two alternate medications. The

analysis does not, however, assume coverage is to be provided for any or all prescriptions after the third prescription.

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.²¹ No current California mandate prohibits the use of fail-first protocols as a criterion 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.²² Copayments, deductibles, and other limitations cannot render the benefit illusory.²³ For outpatient prescription drug benefits, copayment or percentage coinsurance cannot exceed 50% of the cost to the plan.²⁴

The CDI limits expenses paid by the insured, requiring all to be economically sound.²⁵ Individual policies must provide “real economic value” to the insured.²⁶

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.²⁷

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 previously had 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

²¹ Health and Safety Code, Section 1367.215

²² Health and Safety Code, Section 1367(h)(1) and 1367(i)

²³ Health and Safety Code Section 1367, California Code of Regulations Title 28 § 1300.67.4

²⁴ California Code of Regulations, title 28, Section 1300.67.24

²⁵ Insurance Code Section, 10291.5(a)(1)

²⁶ Insurance Code Section 10291.5(b)(7)(A) and 10270.95

²⁷ Health and Safety Code, Section 1374.30, 1374.4; Insurance Code Section 10123.135

medical condition, provided that it is appropriately prescribed, and is considered safe and effective for treatment.²⁸

- 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.²⁹

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 (Hoadley, 2005); 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 are 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.”³⁰

Potential Effects of 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 the transitional years (2011-2013) 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. Each of the provisions that have gone into effect by January 2011 has been considered to determine whether they may affect CHBRP's 2011 Cost and Coverage Model. There are still a number of provisions that have gone into effect for which data are not yet available. Where data allows, CHBRP has made adjustments to the Cost and Coverage model to reflect changes in enrollment and/or baseline premiums. These adjustments are discussed in further detail in Appendix D.

²⁸ Health and Safety Code, Section 1367.22

²⁹ Health and Safety Code Sections 1367.20 and 1367.24

³⁰ Centers for Medicare and Medicaid, 2010 Call Letter for Medicare Advantage organizations, March 30, 2009.

A number of ACA provisions will need regulations and further clarity. One example is the ACA's requirement for certain health insurance to cover "essential health benefits." Effective 2014, Section 1302(b) will require small group and individual health insurance, including "qualified health plans" that will be sold in the California Exchange, to cover specified categories of benefits. These essential health benefits (EHBs) are defined as 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. The Secretary of Health and Human Services is charged with defining these categories through regulation, ensuring that the EHB floor "is equal to the scope of benefits provided under a typical employer plan." In addition, the ACA would allow a state to "require that a qualified health plan offered in [the Exchange] offer benefits in addition to the essential health benefits." If the state does so, the state must make payments to defray the cost of those additionally mandated benefits, either by paying the individual directly, or by paying the qualified health plan. This ACA requirement could interact with existing and proposed California benefit mandates, especially if California decided to require qualified health plans to cover California-specific mandates, and those mandates were determined to go beyond the EHB floor. Federal regulations regarding which benefits are to be covered under these broad EHB categories and other details, such as how the subsidies for purchasers of qualified health plans are structured, are forthcoming.

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.³¹ 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. EHBs are directed to include "Prescription drugs."³² 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.

³¹ Affordable Care Act, Section 1311(d)(3)(B)

³² Affordable Care Act, Section 1302(b)(1)(F)

- The number of enrollees in QHPs.
- The methods used to define and calculate the cost of additional benefits.

Background on Condition

Prevalence of Condition

Pain is a prevalent condition in the U.S. population, with approximately 26% of adults experiencing chronic pain (APF, 2008). Pain varies widely in its presentation and is caused by a wide array of known and unknown origins. Pain also varies in its duration. It is commonly classified as acute, subacute, or chronic. Acute pain is defined as pain lasting up to 30 days, whereas chronic pain is defined as six months or longer (Thienhaus and Cole, 2002) or persisting “beyond normal tissue healing time” (IASP, 2010). Subacute pain lasts from one month up to six months (Cole, 2002). Of adults reporting pain, approximately one-third indicated that their pain lasted less than 1 month, 12% indicated that their pain lasted 1 to 3 months, 14% indicated that it lasted 3 months to 1 year, and 42% indicated that their pain has lasted more than 1 year (NCHS, 2006).

The most common underlying conditions include low back pain; migraine or severe headache; and joint pain, aching, or stiffness (APF, 2008). In 2007, 28% of adults reported experiencing any joint pain in the past 3 months, 26% reported low back pain in the past 3 months, 12% reported having a severe headache or migraine in the past 3 months, and 13% reported having a neck pain in the past 3 months (NCHS, 2009). About one-third of people who report pain indicate that their pain is “disabling,” defined as both severe and having a high impact on functions of daily life (APF, 2008).

MEDICAL EFFECTIVENESS

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 coverage for medications prescribed for the treatment of pain. AB 369 would allow the use of fail-first protocols as a method of utilization management for pain medications; however, health plans and health insurers would be required to cover the initially prescribed pain medication, or its generic equivalent, after a trial of no more than two prescription medications.

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.

Medications used to treat pain fall into several drug classes (see Appendix G), including opioids, anti-depressants, anti-epileptics, and nonsteroidal anti-inflammatory drugs (NSAIDs). These classes organize available pain medications according to mechanism of action, health condition, or chemical structure. Medications may belong to more than one class and some are available without a prescription.

Fail-First Protocols

As described in the *Introduction*, CHBRP uses the phrase “fail-first protocols” to refer to the heterogeneous group of utilization management techniques for pain medications in which certain medications for pain have to be used before other ones are approved for coverage. In order to determine which and how many medications might be subject to fail-first protocols, CHBRP requested fail-first protocol lists from the seven largest California plans and insurers.³³

Responses indicated that plans and insurers were extremely varied in their use of fail-first protocols for pain medications. For some enrollees, no pain medications were subject to fail-first protocols. Other enrollees, depending on the provisions of their plan contracts or policies, had outpatient pharmacy benefits that subjected one or more pain medications to a fail-first protocol. Furthermore, the use of fail-first protocols varies both between and within health plans and insurance policies. Even when health insurance is from a single plan or insurer, some enrollees may be subject to fail-first protocols for one or more pain medications, while others are not, depending on the details of the enrollee’s plan contract or policy. Similar variation in the use of fail-first protocols is present in a sample of Medi-Cal Managed Care Plans and health plan

³³ 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.

contracts purchased by the Managed Risk Medical Insurance Board (MRMIB) for beneficiaries of the Healthy Families Program (HFP), Access for Infants and Mothers (AIM) and the Major Risk Medical Insurance Program (MRMIP) program (see *Benefit Coverage, Utilization, and Cost Impacts* section).

Of more than 200 prescription medications used to treat pain, 54 appear on at least one fail-first protocol list that would be relevant for some portion of enrollees with health insurance subject to AB 369. However, among the 54 pain medications identified as being on at least one fail-first protocol list, there is variation:

- 16 medications are on two or more lists (but not all 16 are present on any single list).
- 38 medications are on one list (but not all 38 are on a single list).

For 16 medications that appeared on more than one list, CHBRP reviewed the relevant 19 fail-first protocols (not all plans and policies have the same protocol for a particular drug). Of the 19 protocols, one included more than two alternative trials as a condition of benefit coverage. The other 18 would be compliant with AB 369.

In the use of fail-first protocols as methods of utilization management for coverage of pain medications, there appears to be no pattern among DMHC-regulated health plans and CDI-regulated insurers. Many enrollees have pain medication coverage that is not subject to any fail-first protocol. When fail-first protocols are present, there is variation between plan contracts and policies, even when issued by a single health plan or insurer. No single pain medication appears on all fail-first protocol lists. No particular class of drugs appears on all fail-first protocol lists. Due to the heterogeneity of fail-first protocol lists (when present) among DMHC-regulated plans and CDI-regulated policies, CHBRP did not review the effectiveness or the comparative effectiveness studies for particular pain medications.

Given the heterogeneity of pain causes, interventions, and medications (that can be used with or without other treatments) and the lack of any pattern in fail-first protocols for pain medications, the medical effectiveness 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?*”

Evidence Review Results

CHBRP’s conclusions regarding the medical effectiveness of fail-first protocols for pain medications are based on the best available evidence from peer-reviewed literature. Appendix B describes the literature search specifications in detail.

The literature search yielded 204 abstracts of studies that met the search criteria. Of those, no study considered the direct effects that fail-first protocols have on ameliorating or controlling pain. The medical effectiveness team identified five literature reviews and studies (Carlton et al., 2010; Carroll, 2002; Goldman et al., 2007; McAdam-Marx et al., 2008; Nau et al., 2007) that considered a broad range of fail-first protocols for various drug classes and their effect on cost,

medical utilization, satisfaction, or quality of life. Although these studies suggested little or no effect of these protocols, most are not generalizable to the medical effectiveness question posed in this report because they consider medications unrelated to pain or they do not consider clinical health outcomes related to pain control. Rather, medication cost and utilization are the two common outcomes measured for these studies. All study authors recommended that future studies include clinical outcomes, rather than limiting analysis to cost-effectiveness and utilization, as is the case in most extant studies.

The exception to CHBRP's findings comes from three specific studies cited in the literature reviews. They focused on prior authorization requirements for the NSAID drug class in the Medicaid population (see Appendix G for complete list of prescription pain medications) and measure proxy health outcomes (i.e., indirect measures of clinical benefit). Smalley et al. (1995) found no effect of a Tennessee requirement for prior authorization of brand-name NSAIDs on increasing expenditures for "other medical services," including outpatient services and inpatient hospital admissions. This "other medical services" outcome serves as a proxy health outcome for adverse effects from the prior authorization requirement: absence of an increase in the need for "other medical services" in response to the prior authorization requirement is taken as indirect evidence that clinical harm did not result.

The observational study by Hartung et al. (2004) demonstrated no utilization changes for other pain medication classes following implementation of a prior authorization program for COX-2 inhibitors (a type of NSAID) in Oregon's Medicaid program. They report a statistically insignificant increase in musculoskeletal-related encounters in emergency departments for one subpopulation and no increase for another subpopulation.

Hartung et al. (2004) also looked for changes in utilization of gastroprotectant medications. These agents are typically prescribed to counter stomach irritation and bleeding associated more strongly with nonspecific NSAIDs than with COX-2 inhibitors. Thus, one might expect that a shift away from COX-2 inhibitors toward nonspecific NSAIDs might be accompanied by an increase in the use of these gastroprotectant agents. However, no such change in utilization was identified. (Note: More recent data suggest little difference in likelihood of gastrointestinal bleeding between COX-2 inhibitors and nonspecific NSAIDs [Siracuse and Vuchetich, 2008].)

The third prior authorization Medicaid study is a small, cross-sectional survey by Momani et al. (2002). It examined the impact of a prior authorization program for NSAIDs on quality of life among participants in the West Virginia Medicaid program. Some of the outcomes measured include mobility, physical activity, activities of daily living, GI symptoms, and pain. The policy under study prohibited authorization of a brand-name NSAID until the patient had tried and showed no benefit from two different generic NSAIDs. Completed surveys from 181 patients indicated that there was no discernible effect of this fail-first protocol on quality of life over the 8-week duration of the study.

These three Medicaid studies focus on one specific drug class (NSAIDs) and do not represent the full spectrum of pain medications subject to prior authorization. Additionally, issues with one study's sample size, weak study methodologies, limited generalizability, and lack of direct health outcome measures limit the utility of these studies for CHBRP's analysis.

In view of the paucity of relevant studies and scientific reviews, CHBRP finds insufficient evidence to characterize the medical effectiveness of fail-first protocols for pain medications (including those protocols that would be limited to no more than two trials of alternative 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 protocols leads to either positive or negative health outcomes.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

AB 369 would allow the use of fail-first protocols, as a method of utilization management for pain medications. AB 369 would require DMHC-regulated plans and CDI-regulated policies to cover the medication initially prescribed for the treatment of pain, or its generic equivalent, after a trial of no more than two prescription medications.

As described in the *Medical Effectiveness* section, 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. Of more than 200 prescription medications used to treat pain (see Appendix G), 54 medications (see Appendix F) 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 (see Table F-1). For the 16 medications that appeared on more than one fail-first protocol list, CHBRP reviewed the relevant 19 fail-first protocols (see Table F-1). 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 protocol requires trial of more than two alternative medications as a condition of coverage. The other 18 fail-first protocols would be compliant with AB 369 since they do not appear to require a user to try and fail a pain medication twice prior to approval of the prescribed medication.

Current (Baseline) Benefit Coverage, Utilization, and Costs

CHBRP annually surveys the seven largest providers of health insurance in California to estimate current prescription drug benefit coverage from an outpatient pharmacy. Responses represented 85.3% of enrollees in privately funded CDI-regulated policies and 98.0% of enrollees in privately funded DMHC-regulated plans. Combined, responses to the survey represent 95.9% of privately funded health insurance subject to regulation by the DMHC or CDI.

The identification of lists of medications subject to a fail-first protocol and the details of fail-first protocols for medications prescribed for pain (including the number of alternate medications a protocol requires be tried before coverage is provided for the initially prescribed medication) is based on data submitted to CHBRP by health plans and insurers when surveyed for a similar bill, AB 1826 (2010), and extensive analysis by content experts CHBRP recruited for that analysis. In response to CHBRP's bill-specific coverage survey for AB 1826 (2010), plans and insurers provided complete lists of drugs on fail-first protocols. Content experts then winnowed the lists to identify medications likely be prescribed for pain instead of other conditions. Because there is little likelihood that the medications on fail-first protocol lists or the relevant protocols would have changed measurably within the last 12 months, CHBRP has relied on the same information for this analysis.

A survey of DMHC-regulated plans enrolling beneficiaries of Medi-Cal, the Healthy Families Program (HFP), the Aid to Infants and Mothers (AIM) program, and the Managed Risk Medical Insurance Program (MRMIP) conducted for AB 1826 (2010), confirmed that beneficiaries of public programs may also have coverage for pain medications subject to fail-first protocols. However, as was found to be the case for privately funded health insurance, the presence of fail-first protocols and the lists of pain medications subject to fail-first protocols varied by plan contract. Again, CHBRP has relied on the same information for this analysis.

Of the 21.9 million Californians enrolled in DMHC-regulated plans and CDI-regulated policies, approximately 20.9 million have outpatient pharmacy benefit coverage. Approximately 45.5% of enrollees with an outpatient pharmacy benefit have coverage for which at least one pain medication is subject to a fail-first protocol.

Current Cost and Utilization

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 current utilization or cost for enrollees whose prescribed medications may be subject to a fail-first protocol not compliant with AB 369. However, as noted, many protocols are already compliant with AB 369. The total number of prescriptions for pain (regardless of whether those medications are subject to a fail-first protocol) is estimated to be 610 per 1,000 enrollees per year (CHBRP, 2010).

Per Unit Price

The range of average cost for a prescription of pain medications varies across drug classes as well as between generic and brand-name medications within a class. An average cost per prescription can range from \$16 to \$6,800 for a 30-day supply of the prescribed medication (CHBRP, 2010).

Current (Baseline) Premiums and Expenditures

Per member per month (PMPM) premiums for CDI-regulated policies are \$497.52 in large group plans, \$334.45 in small-group plans, and \$199.13 in individual plans. Per member per month (PMPM) premiums for DMHC-regulated plans are \$400.51 in large group plans, \$350.57 in small-group plans, and \$399.69 in individual plans.

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

CHBRP is unable to estimate relevant over-the-counter medication expenses, prescription medication expenses for enrollees with no outpatient pharmacy benefit, or prescription medication expenses for enrollees with an outpatient prescription drug benefits whose prescription would not have been covered (premandate) due to a fail-first protocol requiring more than two trials of prescription medication. It's possible that some of these expenses may be shifted to the enrollee, public programs, or to drug-assistance or charitable programs, but the extent of such as potential shift is unknown.

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.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include fail-first protocols for pain medications in their health insurance negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the Preferred Provider Organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. The CalPERS PPOs 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. In the survey, CHBRP asked carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

Based on coverage levels of self-insured plans and responses from large unions, CHBRP cannot determine whether there may be public demand for restrictions of fail-first protocols by collective bargaining agents and by self-insured plans.

Impacts of Mandated Benefit Coverage

AB 369 would not change the number of enrollees with coverage for pain medications or who are diagnosed with a condition requiring pain management or treatment.

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 filled prescriptions due to the restrictions AB 369 would place on use of fail-first protocols.

Impact on per-unit cost

Currently, pain medications are generally prescribed for persons for whom such treatment is medically necessary. Pain medications subject to a fail-first protocol requiring more than two trials of alternate medication appear to be rare and patient demand would not create price

pressure postmandate. CHBRP does not anticipate any changes to the per-unit cost of any one pain medication due to AB 369.

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

CHBRP assumes that the administrative cost proportion of premiums would be unchanged because there is no increase in coverage, utilization, or costs. However, this analysis has not addressed the possible impacts that could result from AB 369's requirements beyond the prohibition of fail-first protocols that include trial of more than two alternate medications. The stipulations AB 369 includes regarding provider determination of the length of a trial for an alternate medication and the requirement that provider chart notes and/or a provider's note on a prescription suffice as proof of completion of a fail-first protocol may have administrative and costs impacts on health plans and insurers.

Impact of the Mandate on Total Health Care Costs

Changes in total expenditures

AB 369 would not be expected to impact total health care costs for enrollees in DMHC-regulated health plans and CDI-regulated health policies.

PUBLIC HEALTH IMPACTS

Approximately 26% of the population age 20 and older report experiencing chronic pain, and 11% have experienced the same pain for a year or more (APF, 2008). Untreated severe pain limits a person's ability to function, to be productive, and engage in social interactions. There are many over-the-counter and prescription pain management medications that patients can use to reduce the severity of their pain. AB 369 would require DMHC-regulated plans and CDI-regulated policies to cover the medication initially prescribed for the treatment of pain, or its generic equivalent, after a trial of two prescription medications. This section presents the overall public health impact of passage of AB 369, followed by an analysis 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 attributable to pain.

Impact of the Proposed Mandate on the Public's Health

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP lacks sufficient information to estimate the change in utilization or cost for restricting the use of fail-first protocols as a criterion for coverage of pain medications beyond two prescription medications.

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. As described in the *Medical Effectiveness* section, literature on a broad range of fail-first protocols for various drug classes and their effect on cost, medical utilization, or quality of life were examined. No studies were identified that examine the effects that fail-first protocols for pain medications have on pain control. Three studies reported little or no effect on medical service utilization (a proxy health outcome) after NSAID prior authorization protocols were implemented by states' Medicaid agencies. Because of the limited number of studies regarding pain medications, weaker study methodologies, and lack of direct health outcome measures, CHBRP concludes that the medical effectiveness of fail-first protocols for pain medications is unknown.

The five review articles identified in the *Medical Effectiveness* section were examined for any outcomes, outside of effectiveness, that may be relevant to public health impacts (Carlton et al., 2010; Carroll, 2002; Goldman et al., 2007; McAdam-Marx et al., 2008; Nau et al., 2007). This identified two studies with results relevant to public health impacts. In Cox et al. (2004), a survey of health plan members who had filled prescriptions subject to fail-first protocols found that 44% of members received a different medication than what was originally prescribed, 15% obtained a prior authorization for the medication originally prescribed, 11% received no medication, 11% paid full price for the branded medication, 8% got an over-the-counter medication, 4% received samples from their physician, and 7% used other means to obtain coverage. In addition, of those who went through the prior authorization process to get the originally prescribed medication covered, more than half (53.6%) had to wait 5 or more days to get their medication (Cox et al., 2004). Patients who received the originally prescribed

medication were more satisfied with their medication than patients who received the medication covered by the fail-first protocol (Cox et al., 2004). Similar results were also found in Motheral et al. (2004). Although these two studies presented some evidence that fail-first protocols can lead to lower levels of patient satisfaction, delays in receiving medications, and higher rates of unfulfilled prescriptions, these studies are not generalizable to AB 369 because they were not conducted exclusively on pain medications and they had weaknesses in their study design. Therefore, the public health impact of AB 369 is unknown.

The methodology used to prepare this report did not allow CHBRP to fully review possible positive impacts AB 369 could have for some enrollees. For example, while the literature reviewed in the *Medical Effectiveness* section was insufficient to draw a conclusion as to the impact of fail-first protocols on pain management, it is possible that the restriction of fail-first protocols could lead to better pain management for some persons. The heterogeneity of fail-first protocols used in California was too great for CHBRP to review comparative-effectiveness studies for every pain medication on a fail-first protocol list. However, if there is evidence that specific pain medications are more effective in controlling pain, then some persons might have better pain control if fail-first protocols were limited.

Impact on the Health of the Community Where Gender and Racial Disparities Exist

Several competing definitions of “health disparities” exist. CHBRP relies on the following definition by Braveman (2006): 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 greater health risks than more advantaged groups.

CHBRP investigated the effect that AB 369 would have on health disparities by gender, race, and ethnicity. Evaluating the impact on racial and ethnic 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 differential insurance rates, where minorities are more likely than whites to be uninsured; however, disparities also exist within the insured population (Kirby et al., 2006; Lillie-Blanton and Hoffman, 2005). Since AB 369 would only affect the insured population, a literature review was conducted to determine whether there are gender, racial, or ethnic disparities associated with the prevalence, treatment, and outcomes for pain management outside of disparities in obtaining health insurance.

Impact on Gender Disparities

Overall, females report being in pain at higher rates than males (NCHS, 2009). Of the three health conditions that are the most common types of pain—low back pain, neck pain, and migraine or severe headache—women report these conditions at statistically significantly higher rates (NCHS, 2009). In the United States, low back pain is reported by 27% of women compared to 23% of men, and 15% of women reported neck pain compared to 11% of men (NCHS, 2010).

Most strikingly, the self-reported prevalence of migraine or severe headache is more than twice as high in women (17%) compared to of men (7%) (NCHS, 2010). This finding is consistent with other studies on severe headaches and migraines, which indicate that migraines are two to three times more prevalent among women, possibly due to hormonal differences (Breslau and Rasmussen, 2001). In California, among the non-elderly insured population, females reported higher rates of pain interfering with normal work than males (CHIS, 2001). Across the United States, women report using more prescribed narcotic medications to control their pain compared to men, with 5.3% reporting usage during the previous month compared to 3.0% of men (NCHS, 2006).

CHBRP is unable to estimate the extent to which the rate that prescriptions are subject to fail-first protocols differs by gender. In addition, CHBRP does not know the extent to which AB 369 would impact females and males differentially. Therefore, CHBRP concludes that the impact of AB 369 on gender disparities in the management of pain is unknown.

Impact on Racial/Ethnic Disparities

According to data collected as part of the National Health Interview Survey, non-Hispanic white adults reported pain more often than adults of other races and ethnicities (NCHS, 2006). Although non-Hispanic whites report that they experience pain at higher rates compared to other racial/ethnic groups, they report that pain interfered with their normal work at lower rates compared to blacks and American Indians/Alaska Natives (CHIS, 2001). Across the United States, non-Hispanic white women are almost twice as likely to report using prescribed narcotic medications to control their pain compared to women of Mexican origin (NCHS, 2006).

CHBRP is unable to estimate the extent to which the rate that prescriptions are subject to fail-first protocols differs by race or ethnicity. Therefore, CHBRP does not know the extent to which AB 369 would impact different race or ethnic groups differentially. CHBRP concludes that the impact of AB 369 on racial/ethnic disparities in the management of pain is unknown.

The Extent to Which the Proposed Service Reduces Premature Death and the Economic Loss Associated With Disease

Premature death and economic loss associated with disease are measures used by economists and public health experts to assess the impact of a condition or disease. Premature death, often defined as death before the age of 75 (Cox, 2006), can be measured in years of potential life lost (YPLL) (Cox, 2006; Gardner and Sanborn, 1990). Economic loss associated with disease is generally an estimation of the value of the YPLL in dollar amount (i.e., valuation of years of work life lost from premature death or lost productivity due to disease or condition).

Premature Death

Pain medication is not used to prolong life or prevent premature death. Therefore, CHBRP concludes that AB 369 would not affect premature death in California.

Economic Loss

In California, more than one-third of insured non-elderly adults who report experiencing pain indicated that pain interfered with their work (CHIS, 2001). Pain conditions such as low back pain and migraines have been found to be associated with high economic costs comparable to those of heart disease, depression, and diabetes (Maetzel and Li, 2002). A national survey of pain found that 13% of the workforce experienced a loss in productivity in the previous two weeks (Stewart et al., 2003). The top conditions causing lost productivity were headaches (5.4%), back pain (3.2%), arthritis pain (2.0%), and other musculoskeletal pain (2.0%) (Stewart et al., 2003). This translated into 4.6 hours per week, which was valued at \$61.2 billion in annual lost productivity. Guo et al. (1999) found back pain resulted in 4.6% of the population missing work an average of 6.8 days per person per year. In the population of people subject to state-level benefit mandates, this would translate into 5.8 million days of work missed due to back pain each year.

Despite the fact that pain conditions are a major contributor to lost productivity, no research was identified that assessed the impact of fail-first protocols for pain medications on productivity. Therefore, the impact of AB 369 on lost productivity and economic loss associated with conditions requiring the use of pain medications is unknown.

APPENDICES

Appendix A: Text of Bill Analyzed

On February 14, 2011, the Assembly Committee on Health requested that CHBRP analyze AB 369

BILL NUMBER: AB 369 INTRODUCED
BILL TEXT

INTRODUCED BY Assembly Member Huffman
(Coauthors: Assembly Members Beall and Feuer)
(Coauthor: Senator Pavley)

FEBRUARY 14, 2011

An act to add Section 1367.243 to the Health and Safety Code, and to add Section 10123.192 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 369, as introduced, Huffman. Health care coverage: prescription drugs. Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Commonly referred to as utilization review, existing law governs the procedures that apply to every health care service plan and health insurer that prospectively, retrospectively, or concurrently reviews and approves, modifies, delays, or denies, based on medical necessity, requests by providers prior to, retrospectively, or concurrent with, the provision of health care services to enrollees or insureds, as specified.

Existing law also imposes various requirements and restrictions on health care service plans and health insurers, including, among other things, requiring a health care service plan that provides prescription drug benefits to maintain an expeditious process by which prescribing providers, as described, may obtain authorization for a medically necessary nonformulary prescription drug, according to certain procedures. Existing law also requires every health care service plan that provides prescription drug benefits that maintains

one or more drug formularies to provide to members of the public, upon request, a copy of the most current list of prescription drugs on the formulary.

This bill would impose specified requirements on health care service plans or health insurers that restrict medications for the treatment of pain pursuant to step therapy or fail first protocol. The bill would authorize the duration of any step therapy or fail first protocol to be determined by the prescribing physician and would prohibit a health care service plan or health insurer from requiring that a patient try and fail on more than two pain medications before allowing the patient access to other pain medication prescribed by the physician, as specified.

Because a willful violation of the bill's provisions relative to health care service plans would be a crime, the bill would impose a state-mandated local program.

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

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

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

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1367.243 is added to the Health and Safety Code, to read:

1367.243. (a) Notwithstanding any other provision of law, a health care service plan that restricts medications for the treatment of pain pursuant to step therapy or fail first protocol shall be subject to the requirements of this section.

(b) The duration of any step therapy or fail first protocol shall be determined by the prescribing physician.

(c) The health care service plan shall not require a patient to try and fail on more than two pain medications before allowing the patient access to the pain medication, or generically equivalent drug, prescribed by the physician.

(d) Once a patient has tried and failed on two pain medications, prior authorization is no longer required and the physician may write the prescription for the appropriate pain medication. A note in the patient's chart that a patient has tried and failed on the health care service plan's step therapy or fail first protocol shall suffice as prior authorization from the plan.

(e) When the physician notes on the prescription that the health

care service plan's step therapy or fail first protocols have been met, a pharmacist may process the prescription without additional communication with the plan.

(f) For the purposes of this section, "generically equivalent drug" means drug products 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 and accepted by the federal Food and Drug Administration, as those drug products having the same chemical ingredient.

(g) 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.

(h) 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:

10123.192. (a) Notwithstanding any other provision of law, a health insurer that restricts medications for the treatment of pain pursuant to step therapy or fail first protocol shall be subject to the requirements of this section.

(b) The duration of any step therapy or fail first protocol shall be determined by the prescribing physician.

(c) The health insurer shall not require a patient to try and fail on more than two pain medications before allowing the patient access to the pain medication, or generically equivalent drug, prescribed by the physician.

(d) Once a patient has tried and failed on two pain medications, prior authorization is no longer required and the physician may write the prescription for the appropriate pain medication. A note in the patient's chart that a patient has tried and failed on the health insurer's step therapy or fail first protocol shall suffice as prior authorization from the insurer.

(e) When the physician notes on the prescription that the health insurer's step therapy or fail first protocols have been met, a pharmacist may process the prescription without additional communication with the insurer.

(f) For the purposes of this section, "generically equivalent drug" means drug products 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 and accepted by the federal Food and Drug Administration, as those drug products having the same chemical ingredient.

(g) 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.

(h) 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 by CHBRP. The literature search encompasses systematic reviews, meta-analyses, and individual studies with comparison groups (e.g., randomized controlled trials, controlled clinical trials, cohort studies, case-control studies, and observational studies) dating to 1980.

The search focuses on literature addressing (1) a broad overview of prescription pain medication classes and conditions they treat; (2) presence of a fail-first protocol compared with immediate use of prescribed pain medication (e.g., substitution of brand-name prescription pain medications with their generic or therapeutic equivalent counterpart); and, (3) provider prescribing behavior in response to fail-first protocols. For all topics, the literature review was limited to articles published in English.

A medical librarian searched the following databases and resources: CINAHL, ClinicalTrials.gov, Cochrane Library, EconLit, FDA MAUDE Database, Grey Literature Index (New York Academy of Medicine), Google and Google Scholar, Healthcare Standards (ECRI), IPA (International Pharmaceutical Abstracts), MEDLINE (PubMed, Health Services Research, and OVID), MicroMedex, Scirus, U.S. National Guideline Clearinghouse, UpToDate, and Web of Science. Web sites of government agencies were also searched.

At least two reviewers screened the title and abstract of 204 abstracts returned by the literature search to determine eligibility (i.e., study relevance to AB 369) for inclusion in the medical effectiveness review. Full-text articles were obtained, and reviewers reapplied the initial eligibility criteria.

Three studies are included in the medical effectiveness review for AB 369.

In deciding on the outcome measure of interest for AB 369, the team and the content expert consider the number of studies as well the strength of the evidence. In this report, the team uses a grading system that has the following categories:

- Research design
- Generalizability of findings

The grading system also contains an overall conclusion 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
- Insufficient evidence

The conclusion states that there is “clear and convincing” evidence that an intervention has a favorable effect on an outcome if most of the studies included in a review have strong research

designs and report statistically significant and clinically meaningful findings that favor the intervention.

The conclusion characterizes the evidence as “preponderance of evidence” that an intervention has a favorable effect if the research design is strong and outcome measured is directly relevant to AB 369. For example, for some interventions, the only evidence available is from nonrandomized studies. If most such studies that assess an outcome have statistically and clinically significant findings that are in a favorable direction and enroll populations similar to those covered by a mandate, the evidence would be classified as a “preponderance of evidence favoring the intervention.” In some cases, the preponderance of evidence may indicate that an intervention has no effect or an unfavorable effect.

The evidence is presented as “ambiguous/conflicting” if their findings vary widely with regard to the direction, statistical significance, and clinical significance/size of the effect.

The category “insufficient evidence” of an intervention’s effect is used when there is little if any evidence of an intervention’s effect.

The search terms used to locate studies relevant to the AB 369 were as follows:

MeSH Terms

drug prescriptions
insurance, pharmaceutical services
insurance claim review
labeling
managed care programs
pain
pain medication(s)
physician practice patterns
therapeutic substitution/equivalency

In addition to term searches, CHBRP staff conducted citation searches to find related articles.

Publication Types

Evaluation Studies
Meta-Analysis
Multicenter Studies
Practice Guideline
Randomized Controlled Trial
Review
Systematic Review

Keywords

Cost, generic substitution, economics, off-label use, pain, pain medication(s), physician prescribing behavior, step-therapy, therapeutic substitution/equivalency.

Appendix C: Summary Findings on Medical Effectiveness

Table C-1. Summary of Published Studies on Effectiveness of Fail-First Protocols for Prescription Pain Medications

Citation	Research Design	Outcomes Measured for an NSAID Prior Authorization Protocol	Population Studied	Results Relevant to AB 369	Generalizability
Hartung et al., 2004	Observational (retrospective interrupted time-series analysis)	<ul style="list-style-type: none"> • Prescription drug expenditures • Medical claims 	Oregon Medicaid enrollees	Statistically insignificant increase in medical claims in entire study population and no increase in claims from a study subpopulation of previous NSAID users	Somewhat generalizable. (Limitations on generalizability relate to the greater diversity of CA populations affected by AB 369.)
Momani et al., 2002	Cross-sectional survey	Brand vs. generic NSAID health-related quality of life outcomes: mobility, physical activity, dexterity, activities of daily living, household activities, anxiety, depression, pain, social activity, and GI symptoms	West Virginia Medicaid enrollees	No difference in Health-related Quality of Life (HRQoL) for generic or brand NSAID users	Somewhat generalizable. (Limitations on generalizability relate to the greater diversity of CA populations affected by AB 369.)
Smalley et al., 1995	Retrospective claims data analysis	<ul style="list-style-type: none"> • Pharmacotherapy costs • Outpatient Services for routine visits, physical medicine, or radiologic exams of hip or knee • Emergency department visits coded as musculoskeletal disorder • Inpatient admissions for musculoskeletal disorder surgery for hip, knee, or elbow replacement 	Tennessee Medicaid enrollees	<ul style="list-style-type: none"> • No significant change in outpatient service expenditures • No significant change in inpatient admission expenditures 	Somewhat generalizable. (Limitations on generalizability relate to the greater diversity of CA populations affected by AB 369.)

Source: California Health Benefits Review Program, 2011

Note: NSAID=nonsteroidal anti-inflammatory drug.

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

This appendix describes data sources, 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 Web site at <http://www.chbrp.org/costimpact.html>.

The cost analysis in this report was prepared by the members of cost team, which consists of CHBRP task force members and contributors from the University of California, San Diego, and the University of California, Los Angeles, as well as the contracted actuarial firm, Milliman, Inc. (Milliman). Milliman provides data and analyses per the provisions of CHBRP's authorizing legislation.

Data Sources

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

Health insurance

1. The latest (2009) California Health Interview Survey (CHIS), which is used to estimate health insurance for California's population and distribution by payor (i.e., employment-based, individually purchased, or publicly financed). The biennial CHIS is the largest state health survey conducted in the United States, collecting information from approximately 50,000 households. More information on CHIS is available at <http://www.chis.ucla.edu>.
2. The latest (2010) California Employer Health Benefits Survey is used to estimate:
 - size of firm,
 - percentage of firms that are purchased/underwritten (versus self-insured),
 - premiums for health care service plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs] and Point of Service Plans [POS]),
 - premiums for health insurance policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service plans [FFS]), and
 - premiums for high deductible health plans (HDHPs) for the California population with employment-based health insurance.
 - 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: <http://www.chcf.org/publications/2010/12/california-employer-health-benefits-survey>.

3. 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 <http://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, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed healthcare plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP’s utilization and cost estimates draw on other data, including the following:
 - The MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
 - 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.
 - 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.
 - These data are reviewed for applicability by an extended group of experts within Milliman but are not audited externally.
4. An annual survey by CHBRP of 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 PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC- or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in plans or policies offered by these seven firms represents an estimated 93.7% of the persons with health insurance subject to state mandates. This figure represents an estimated 94.4% of enrollees in full service (non-specialty) DMHC-regulated health plans and an estimated 90.1% of enrollees in full service (non-specialty) CDI-regulated policies.³⁴

Publicly funded insurance subject to state benefit mandates

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

³⁴ CHBRP analysis of the share of enrollees included in CHBRP’s Bill-Specific Coverage Survey of the major carriers in the state is based on “CDI Licenses with HMSR Covered Lives Greater than 100,000” as part of the Accident and Health Covered Lives Data Call, December 31, 2009, by the California Department of Insurance, Statistical Analysis Division, data retrieved from the Department of Managed Health Care’s interactive Web site “Health Plan Financial Summary Report,” July-September 2010, and CHBRP’s Annual Enrollment and Premium Survey.

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 (EOCs) documents publicly available at <http://www.calpers.ca.gov>.

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 CHIS and data maintained by the Department of Health Care Services (DHCS). DHCS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the current scope of benefits. CHBRP assesses enrollment information online at http://www.dhcs.ca.gov/dataandstats/statistics/Pages/RASS_General_Medi_Cal_Enrollment.aspx.
7. Enrollment data for other public programs—Healthy Families Program (HFP), Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (MRMIP)—are estimated based on CHIS and data maintained by the Managed Risk Medical Insurance Board (MRMIB). The basic minimum scope of benefits offered by participating health plans under these programs must comply with all requirements for DMHC-regulated health plans, and thus these plans are affected by state-level benefit mandates. CHBRP does not include enrollment in the Post-MRMIP Guaranteed-Issue Coverage Products as these persons are already included in the enrollment for individual market health insurance offered by DMHC-regulated plans or CDI-regulated insurers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at <http://www.mrmib.ca.gov/>. Average statewide premium information is provided to CHBRP by MRMIB staff.

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.

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 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 one 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 recent 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, while Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and 0.84 percentage point decrease in the number of insured, respectively. The price elasticity of demand for insurance can be calculated from these studies in the following way. First, take the average percentage point decrease in the number of insured reported in these studies in response to a 1% increase in premiums (about -0.088), divided by the average percentage of insured persons (about 80%), multiplied by 100%, i.e., ($\{-0.088/80\} \times 100 = -0.11$). This elasticity converts the *percentage point* decrease in the number of insured into a *percentage* decrease in the number of insured persons for every 1% increase in premiums. 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 point of service [POS] plans—and non-HMO—including PPO and fee for service [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%.

Potential Effects of the Federal Affordable Care Act

As discussed in the *Introduction*, there are a number of the ACA provisions that have already gone into or will go into effect over the next three years. Some of these provisions affect the baseline or current enrollment, expenditures, and premiums. This subsection discusses adjustments made to the 2011 Cost and Coverage Model to account for the potential impacts of the ACA that have gone into effect by January 2011. It is important to emphasize 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 the *Benefit Coverage, Utilization, and Cost Impacts* section of this report.

CHBRP reviewed the ACA provisions and determined whether and how these provisions might affect:

1. The number of covered lives in California, and specifically the makeup of the population with health insurance subject to state mandates
2. Baseline premiums and expenditures for health insurance subject to state mandates, and
3. Benefits required to be covered in various health insurance plans subject to state mandates

There are still a number of provisions that have gone into effect for which data are not yet available. Where data allows, CHBRP has made adjustments to the 2011 Cost and Coverage model to reflect changes in enrollment and/or baseline premiums and these are discussed here.

Coverage for adult children

PPACA Section 2714, modified by HR 4872, Section 2301, requires coverage for adult children up to age 26 as dependants to primary subscribers on all individual and group policies, effective September 23, 2010. California's recently enacted law, SB 1088 (2010) implements this provision. This could potentially affect both premiums and enrollment in 2011. According to the California Health Interview Survey (CHIS) approximately 22% of Californians aged 19-25 (1,063,000) were estimated to be uninsured at some point in 2009. As a result of the ACA, many of these young adults will likely gain access to health insurance through a parent. This dynamic may diminish the number of uninsured and may also shift some young adults from the individually purchased health insurance market into the group market. The Departments of Treasury, Labor, and Health and Human Services estimate, for 2011, the number of young adults newly covered by his/her parent's plan would be about 0.78 to 2.12 million (using high and low take-up rate assumptions, respectively). Of these young adults, about 0.2 to 1.64 million would have previously been uninsured. The corresponding incremental cost impact to group insurance policies is estimated to be a premium increase of 0.5% to 1.2%. Based on the responses to the Annual Enrollment and Premium survey, there has been an increase of 1% to 1.5% in enrollment for the 19-25 year olds and the increase varies depending on whether the parents were enrolled in the large group, small group or individual markets. Based on analysis of the estimates from the Departments of Treasury, Labor and Health and Human Services as well as CHIS 2009 data, approximately 25% of the increase in enrollment represents a shift from the individual market and approximately 75% were previously uninsured. CHBRP took these estimates into account and adjusted underlying population data since source data did not reflect the effects of this provision, because shift in populations were expected to be significant, and to account for potential lags in enrollment (e.g., due to awareness).

Minimum Medical Loss Ratio requirement

PPACA Section 2718 requires health plans offering health insurance in group and individual markets to report to the Secretary of Health and Human Services the amount of premium revenue spent on clinical services, activities to improve quality, and other non-claim costs. Beginning in 2011, large group plans that spend less than 85% of premium revenue and small group/individual market plans that spend less than 80% of premium revenue on clinical services and quality must provide rebates to enrollees. According to the Interim Final Rule (45 CFR Part 158), "Issuers will provide rebates to enrollees when their spending for the benefit of policyholders on reimbursement for clinical services and quality improvement activities, in relation to the premiums charged, is less than the MLR standards established pursuant to the statute."³⁵ The requirement to report medical loss ratio is effective for the 2010 plan year, while the requirement to provide rebates is effective January 1, 2011. The MLR requirement, along with the rebate payment requirement, will affect premiums for 2011, but the effects are unknown and data are not yet available. There is potential for substantial impact on markets with higher administrative costs, including the small and individual group markets. Responses to CHBRP's Annual Enrollment and Premiums Survey indicate that carriers intend to be in compliance with these requirements. For those that may not be in compliance, the requirement to pay rebates is intended to align the MLR retrospectively.

³⁵ Department of Health and Human Services, *Interim Final Rule: Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act*. 45 CFR Part 158. December 1, 2010.

Therefore for modeling purposes, CHBRP has adjusted administrative and profit loads to reflect MLRs that would be in compliance with this provision.

Pre-Existing Condition Insurance Plan (PCIP)

PPACA Section 1101 establishes a temporary high-risk pool for individuals with pre-existing medical conditions, effective 90 days following enactment until January 1, 2014. In 2010, California enacted AB 1887 and SB 227, providing for the establishment of the California Pre-Existing Condition Insurance Plan (PCIP) to be administered by the Managed Risk Medical Insurance Board (MRMIB) and federally funded per Section 1101. MRMIB has projected average enrollment of 23,100 until the end of 2013, when the program will expire. As of December 2010, there were approximately 1,100 subscribers.³⁶ The California PCIP is not subject to state benefit mandates,³⁷ and therefore this change does not directly affect CHBRP's Cost and Coverage Model. CHBRP has revised its annual update of *Estimates of the Sources of Health Insurance in California*.³⁸ to reflect that a slight increase in the number of those who are insured under other public programs that are not subject to state-level mandates.

Prohibition of pre-existing condition exclusion for children

PPACA Sections 1201& 10103(e): Prohibits pre-existing condition exclusions for children. This provision was effective upon enactment). California's recently enacted law, AB 2244 (2010) implements this provision. AB 2244 also prohibits carriers that sell individual plans or policies from refusing to sell or renew policies to children with pre-existing conditions. Carriers that do not offer new plans for children are prohibited from offering for sale new individual plans in California for five years.³⁹ This provision could have had significant premium effects, especially for the DMHC- and CDI-regulated individual markets. The premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision.

Prohibition of lifetime limits and annual benefit limit changes

PPACA Section 2711 prohibits individual and group health plans from placing lifetime limits on the dollar value of coverage, effective September 23, 2010. Plans may only impose annual limits on coverage and these annual limits may be no less than \$750,000 for "essential health benefits." The minimum annual limit will increase to \$1.25 million on Sept. 23, 2011, and to \$2 million Sept. 23, 2012. Earlier in 2010, CHBRP conducted an analysis of SB 890 which sought to prohibit lifetime and annual limits for "basic health care services" covered by CDI-regulated policies. CHBRP's indicated that DMHC-regulated plans were generally prohibited from having annual or lifetime limits. The analysis also indicated that less than 1% of CDI-regulated policies in the state had annual benefit limits and of those, the average annual benefit limit was approximately \$70,000 for the group market and \$100,000 for the individual market. Almost all CDI-regulated policies had lifetime limits in place and the average lifetime limits was \$5 million. After the effective date

³⁶ Enrollment report presented at the Managed Risk Medical Insurance Board Meeting, January 19, 2010. Available at: http://www.mrmib.ca.gov/MRMIB/Agenda_Minutes_011911/Agenda_Item_9.a_PCIP_Board_Report_for_Dec_2010_FINAL.pdf

³⁷ Correspondence with John Symkowitz, Legislative Coordinator, MRMIB, October 19, 2010.

³⁸ See: http://www.chbrp.org/documents/insur_source_est_2010.pdf

³⁹ See enacted language at: http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab_2201-2250/ab_2244_bill_20100930_chaptered.pdf

of the PPACA Section 2711, removal of these limits may have had an effect on premiums. As mentioned, premium information is included in the responses to CHBRP's Annual Enrollment and Premium Survey. Thus the underlying data used in CHBRP annual model updates captured the effects of this provision to remove lifetime limits and to increase annual limits for those limited number of policies that had annual limits that fell below \$750,000.

Medi-Cal Managed Care Enrollment: Seniors and Persons with Disabilities

While the PPACA allows states the option to expand coverage to those not currently eligible for Medicaid (Medi-Cal in California), large scale expansions are not expected to be seen during 2011. However, as a result of the 2010-2011 California Budget Agreement, there are expected to be shifts in coverage for seniors and persons with disabilities. Specifically, "Seniors and persons with disabilities who reside in certain counties which have managed care plans, and who are not also eligible to enroll in Medicare, will be required to enroll in a managed care plan under a phased-in process."⁴⁰ The Medi-Cal Managed Care enrollment in CHBRP's 2011 Cost and Coverage Model has been adjusted to reflect this change. Baseline premium rates have also been adjusted to reflect an increase in the number of seniors and persons with disabilities in Medi-Cal Managed Care. Information from DHCS indicate these changes will go into effect July 1, 2011, and would affect approximately 427,000 Medi-Cal beneficiaries.⁴¹ CHBRP used data from DHCS to adjust enrollment in Medi-Cal Managed Care, and to adjust premiums to account for the change in acuity in the underlying populations.⁴²

Bill Specific Caveats and Assumptions

Unit Price

In the estimate of pain prescriptions per 1,000 enrollees, generic and brand-name FDA-approved medications commonly used in the treatment of pain were included. Medications used for multiple purposes were included if greater than 15% prescriptions were for the treatment of pain. The estimated percentage of prescriptions for pain treatment was based on content expert opinion.

⁴⁰ Taylor, M. Legislative Analyst, *The Budget Package 2010-11 California Spending Plan*. LAO: November, 2010. Available at: http://www.lao.ca.gov/reports/2010/bud/spend_plan/spend_plan_110510.pdf

⁴¹ Data from the Department of Health Care Services, Medi-Cal Managed Care Division. Received January 14, 2011.

⁴² See the study conducted for DHCS by Mercer on this topic: Mercer, *Medi-Cal Acuity Study: Seniors and Persons with Disabilities*. September 28, 2010. Available at: http://www.dhcs.ca.gov/provgovpart/Documents/Waiver%20Renewal/SPD_Study_092810.pdf

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 following information was submitted by the Office of Assemblymember Jared Huffman in March, 2011:

Fact Sheet AB 369 – IMPROVING PATIENT CARE

STEP THERAPY LAWS IN OTHER STATES

Submitted information is available upon request.

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

Appendix F: Prescription Pain Medications on Fail-First Protocol Lists

Prescription pain medications subject to fail-first protocols were identified by CHBRP for its analysis of AB 1826 (2010). The following medications were on one fail-first protocol list (but not necessarily the same list):

- Amrix
(Cyclobenzaprine)
- Avinza
(Morphine)
- Cocet
(Acetaminophen / Codeine)
- Combunox
(Ibuprofen/Oxycodone)
- Cymbalta
(Duloxetine)
- Darvon
(Propoxyphene)
- Daypro
(Oxaprozin)
- Duragesic
(Fentanyl)
- Effexor
(Venlafaxine)
- Fexmid
(Cyclobenzaprine)
- Flector Patch
(Diclofenac)
- Ibudone (Ibuprofen/
hydrocodone)
- Kadian (Morphine)
- Levo Dromoran
(Levorphanol)
- Liquicet
(Acetaminophen / Hydrocodone)
- Lodine
(Etodolac)
- Maxidone
(Acetaminophen / Hydrocodone)
- Mobic
(Meloxicam)
- Naprelan
(Naproxen)
- Oruvail
(Ketoprofen)
- Percocet
(Acetaminophen / Oxycodone)
- Perlox
(Acetaminophen /Oxycodone)
- Ponstel
(Mefenamic Acid)
- Primalev
(Acetaminophen /Oxycodone)
- Relafen
(Nabumetone)
- Roxicet
(Acetaminophen /Oxycodone)
- Skelaxin
(Metaxalone)
- Stadol
(Butorphanol)
- Subutex
(Buprenorphine)
- Tolmetin
(Tolectin)
- Toradol
(Ketorolac)
- Treximet
(Sumatriptan / Naproxen)
- Ultracet
(Tramadol/ Acetaminophen)
- Ultram
(Tramadol)
- Voltaren XL
(Diclofenac)
- Xodol
(Acetaminophen / Hydrocodone)
- Xolox
(Acetaminophen / Oxycodone)
- Zydone
(Acetaminophen / Hydrocodone)

Table F-1. Prescription Pain Medications on More Than One Fail-First Protocol List (but not necessarily the same lists)

Pain Medications (by brand name and generic name)	Drug Class	Examples of Fail-First Protocols Affected by AB 369
Actiq (fentanyl)	Synthetic opioid	<ul style="list-style-type: none"> Failed adequate trial of 2 weeks of single or combination pain medication containing an immediate-release acting opioid (e.g., Dilaudid, Roxanol, Opana, Combunox Percocet)
Arthortec (diclofenac/misoprostol)	NSAID	<ul style="list-style-type: none"> Failed adequate trial of 2 weeks each of at least two preferred NSAIDs (or salicylates)
Celebrex (celecoxib)	NSAID	<ul style="list-style-type: none"> Two nonsteroidal anti-inflammatory drugs (NSAIDs) or salicylates within 180 days (resulting in failure due to non-GI-related intolerance or inadequate pain control) Documented use of an H2 receptor antagonist or a proton pump inhibitor due to history of significant GI disease OR NSAID GI adverse effects necessitating discontinuation of NSAID therapy
Embeda (morphine/naltrexone)	Combination opioid/ opioid antagonist	<ul style="list-style-type: none"> Documented trial of 2 days of preferred generic morphine SR
Fentora (fentanyl)	Synthetic opioid	<ul style="list-style-type: none"> Failed adequate trial of 1 week of two preferred analgesics, one of which is generic fentanyl transmucosal lozenge, OR at least 8mg of oral hydromorphone daily OR at least 25mcg/hr transdermal fentanyl OR an equianalgesic dose of another opioid for 1 week or longer
Lidoderm (lidocaine)	Anesthetic	<ul style="list-style-type: none"> Treatment failure of 2 formulary alternatives for neuropathic pain
Lyrica (pregabalin)	Anti-epileptic (Membrane- stabilizing agent)	<ul style="list-style-type: none"> 180 days FDA-approved drug for diabetic peripheral neuropathy OR tried Cymbalta (duloxetine Hcl), carbamazepine, tricyclic antidepressants, gabapentin, trazodone, or lidocaine patch (Lidoderm), OR insufficient response to two formulary alternatives for neuropathic pain
Magnacet (APAP/oxycodone)	Semi-synthetic opioid	<ul style="list-style-type: none"> Failure of adequate clinical trial of 2 days of preferred generic alternative (i.e., generic Percocet, Endocet, Roxicet, or Tylox)
Nucynta (tapentadol)	Synthetic opioid	<ul style="list-style-type: none"> Documented trial of 2 days of preferred generic morphine or oxycodone immediate-release; OR failure of two formulary narcotics and tramadol (Ultram)
Onsolis film (fentanyl)	Synthetic opioid	<ul style="list-style-type: none"> Documented trial 1 week of preferred generic fentanyl transmucosal lozenge

Table F-1. Prescription Pain Medications on More Than One Fail-First Protocol List (but not necessarily the same lists) (Cont'd)

Pain Medications (by brand name and generic name)	Drug Class	Examples of Fail-First Protocols Affected by AB 369
Opana (oxymorphone)	Semi-synthetic opioid	<ul style="list-style-type: none"> • Treatment failure or intolerance to immediate release morphine, immediate release oxycodone, and immediate release hydromorphone • Failure of adequate clinical trial of two days of preferred generic alternative
Oxycontin (oxycodone)	Semi-synthetic opioid	<ul style="list-style-type: none"> • Other pain regimens have been inadequate
Ryzolt (tramadol)	Opioid agonist	<ul style="list-style-type: none"> • Documented trial of 2 days of preferred generic tramadol alternative • Must use tramodal immediate release tablets
Savella (milnacipran)	Serotonin/Norepinephrine Reuptake Inhibitors	<ul style="list-style-type: none"> • Insufficient response, intolerable side effect(s) or contraindication to the use of two of the following agents: antidepressants, tramadol, Lyrica, gabapentin, or cyclobenzaprine; OR failure of Cymbalta
Voltaren gel (diclofenac)	NSAID	<ul style="list-style-type: none"> • Documented trial of 2 weeks on 1 preferred generic NSAID
Zipsor (diclofenac)	NSAID	<ul style="list-style-type: none"> • Must have failed diclofenac sodium (Voltaren)

Source: California Health Benefits Review Program, 2010

Note: Fail-first protocols generally permit exceptions for intolerable side effects or contraindications.

Appendix G: Prescription Pain Medications by Drug Class

Table G-1. Prescription Pain Medications by Drug Class

Generic Name	Brand Name(s)	FDA-Approved Indication(s)	Pain-Related Non FDA-Approved Use(s)	DEA Schedule (2-5)	Available Therapeutic Equivalent
Opiates					
Codeine		Mild pain, Moderate pain	Arthralgia, Bone pain, Dental pain, Headache, Migraine, Myalgia	2	
Acetaminophen /Codeine	Tylenol #2, 3, 4; Cocet	Mild pain, Moderate pain	Arthralgia, Bone pain, Dental pain, Headache, Migraine, Myalgia	3	
Morphine	Kadian, MS Contin, MSIR, Roxanol, Avinza ¹	Moderate pain, Severe pain	Arthralgia, Bone pain, Dental pain, Headache, Migraine, Myalgia	2	Morphine sulfate extended release (e.g., generic Kadian or MS Contin)
Semi-synthetic Opioids					
Acetaminophen /Hydrocodone	Vicodin, Norco, Lortab, Lorcet, Liquicet, Maxidone, Xodol, Zydone	Moderate pain	Arthralgia, Bone pain, Dental pain, Headache, Migraine, Myalgia	3	
Ibuprofen/Hydrocodone	Vicoprofen, Ibudone	Arthralgia, Moderate pain, Myalgia	Bone pain, Dental pain,	3	
Hydromorphone	Dilaudid	Moderate pain, Severe pain	Arthralgia, Bone pain, Dental pain, Headache, Migraine, Myalgia,	2	
Oxycodone	OxyContin, OxyIR, Roxicodone	Moderate pain, Severe pain	Arthralgia, Bone pain, Dental pain, Diabetic neuropathy, Headache, Migraine, Myalgia, Neuropathic pain, Postherpetic neuralgia	2	
Acetaminophen /Oxycodone	Percocet, Endocet, Roxicet, Magnacet, Perloxx, Primalev, Roxicet, Xolox	Moderate pain	Arthralgia, Bone pain, Dental pain, Headache, Migraine, Myalgia	2	

Table G-1. Prescription Pain Medications by Drug Class (Cont'd)

Generic Name	Brand Name(s)	FDA-Approved Indication(s)	Pain-Related Non FDA-Approved Use(s)	DEA Schedule (2-5)	Available Therapeutic Equivalent
Aspirin/Oxycodone	Percodan, Endodan	Moderate pain	Arthralgia, Bone pain, Dental pain, Headache, Migraine, Myalgia	2	
Ibuprofen/Oxycodone	Combunox	Moderate pain, Severe pain	Arthralgia, Bone pain, Dental pain, Headache, Migraine, Myalgia	2	
Oxymorphone	Opana ¹ , Opana SR ¹	Moderate pain, Severe pain		2	Oxycodone (generic Oxy IR or Oxycontin)
Synthetic Opioids					
Fentanyl	Actiq, Duragesic, Fentora ¹ , Onsolis ¹	Moderate pain, Severe pain		2	Generic Actiq lozenge
Levorphanol	Levo-Dromoran	Moderate pain, Severe pain		2	
Meperidine	Demerol	Moderate pain, Severe pain	Headache, Migraine	2	
Methadone	Methadose	Severe pain	Bone pain, Neuropathic pain	2	
Tapentadol	Nucynta ¹	Moderate pain, Severe pain		2	Another short-acting opioid
Opioid Agonists					
Propoxyphene	Darvon	Mild pain, Moderate pain	Arthralgia, Bone pain, Dental pain, Headache, Migraine, Myalgia	4	
Propoxyphene/Acetaminophen	Darvocet-N, N-50, N-100	Mild pain, Moderate pain	Arthralgia, Bone pain, Dental pain, Headache, Migraine, Myalgia	4	
Tramadol	Ultram, Ultram ER, Ryzolt ¹ ,	Moderate pain	Arthralgia, Bone pain, Dental pain, Headache, Myalgia, Neuropathic pain, Osteoarthritis, Postoperative shivering, Restless legs syndrome	Non-controlled	Tramadol extended release (i.e., generic Ultram ER)
Tramadol/Acetaminophen	Ultracet	Moderate pain	Arthralgia, Bone pain, Dental pain, Headache, Myalgia, Osteoarthritis	Non-controlled	

Table G-1. Prescription Pain Medications by Drug Class (Cont'd)

Generic Name	Brand Name(s)	FDA-Approved Indication(s)	Pain-Related Non FDA-Approved Use(s)	DEA Schedule (2-5)	Available Therapeutic Equivalent
Mixed Opioid Agonist/Antagonist					
Buprenorphine	Subutex	Moderate pain, Severe pain		3	
Buprenorphine/Naloxone	Suboxone ¹	Moderate pain, Severe pain		3	
Butorphanol	Stadol NS	Moderate pain, Severe pain	Headache, Migraine,	4	
Combination Opioid/Opioid Antagonist					
Morphine/Naltrexone	Embeda ¹	Moderate pain, Severe pain		2	
Anti-epileptic drugs (AEDs)/ Membrane-Stabilizing Agents					
Carbamazepine	Tegretol, Carbatrol, Equetro	Neuropathic pain, Trigeminal neuralgia, Seizures, Bipolar disorder	Diabetic neuropathy, Postherpetic neuralgia	Non-controlled	
Oxcarbazepine	Trileptal	Seizures	Diabetic neuropathy, Neuropathic pain, Postherpetic neuralgia, Trigeminal neuralgia	Non-controlled	
Gabapentin	Neurontin	Postherpetic neuralgia, seizures	Neuropathic pain, Diabetic neuropathy	Non-controlled	
Phenytoin	Dilantin	Seizures	Diabetic neuropathy, Neuropathic pain	Non-controlled	
Pregabalin	Lyrica ¹	Diabetic neuropathy, Fibromyalgia, Neuropathic pain, Postherpetic neuralgia, Seizures	Moderate pain	5	Gabapentin
Topiramate	Topamax	Migraine prophylaxis, seizures	Diabetic neuropathy, Neuropathic pain	Non-controlled	
Tiagabine	Gabitril ¹	Seizures	Neuropathic pain	Non-controlled	
Divalproex	Depakote	Migraine prophylaxis, Bipolar disorder, seizures		Non-controlled	
Tricyclic Antidepressants (TCAs)					
Amitriptyline	Elavil	Depression	Diabetic neuropathy, Fibromyalgia, Migraine prophylaxis, Neuropathic pain, Postherpetic neuralgia	Non-controlled	

Table G-1. Prescription Pain Medications by Drug Class (Cont'd)

Generic Name	Brand Name(s)	FDA-Approved Indication(s)	Pain-Related Non FDA-Approved Use(s)	DEA Schedule (2-5)	Available Therapeutic Equivalent
Desipramine	Norpramin	Depression	Diabetic neuropathy, Neuropathic pain, Postherpetic neuralgia	Non-controlled	
Imipramine	Tofranil	Depression	Diabetic neuropathy, Neuropathic pain, Postherpetic neuralgia	Non-controlled	
Nortriptyline	Pamelor	Depression	Diabetic neuropathy, Neuropathic pain, Postherpetic neuralgia	Non-controlled	
Dopamine/Norepinephrine Reuptake Inhibitor					
Bupropion	Wellbutrin, Aplenzin ¹	Depression	Diabetic neuropathy, Neuropathic pain, Postherpetic neuralgia	Non-controlled	Generic Wellbutrin
Serotonin/Norepinephrine Reuptake Inhibitors (SNRIs)					
Duloxetine	Cymbalta ¹	Diabetic neuropathy, Fibromyalgia, Depression	Neuropathic pain	Non-controlled	Milnacipran
Venlafaxine	Effexor, Effexor XR	Depression, Anxiety	Diabetic neuropathy, Fibromyalgia, Headache, Neuropathic pain	Non-controlled	
Desvenlafaxine	Pristiq ¹	Depression	neuropathic pain	Non-controlled	Generic Effexor XR
Milnacipran	Savella ¹	Fibromyalgia		Non-controlled	Duloxetine
Muscle Relaxants					
Baclofen	Lioresal	Muscle spasm	Neuropathic pain, Trigeminal neuralgia	Non-controlled	
Carisoprodol	Soma	Muscle spasm		Non-controlled	
Aspirin/Carisoprodol	Soma Compound	Moderate pain, Muscle spasm		Non-controlled	
Chlorzoxazone	Parafon Forte	Muscle spasm		Non-controlled	
Cyclobenzaprine	Flexeril, Fexmid ¹ , Amrix ¹	Muscle spasm	Fibromyalgia	Non-controlled	

Table G-1. Prescription Pain Medications by Drug Class (Cont'd)

Generic Name	Brand Name(s)	FDA-Approved Indication(s)	Pain-Related Non FDA-Approved Use(s)	DEA Schedule (2-5)	Available Therapeutic Equivalent
Diazepam	Valium	Muscle spasm, anxiety			
Metaxalone	Skelaxin	Muscle spasm		Non-controlled	
Methocarbamol	Robaxin	Muscle spasm		Non-controlled	
Non-steroidal Anti-inflammatory Drugs (NSAIDs)					
Celecoxib	Celebrex ¹	Ankylosing spondylitis, Bone pain, Dental pain, Dysmenorrhea, Headache, Juvenile rheumatoid arthritis, Moderate pain, Osteoarthritis, Rheumatoid arthritis, Severe pain		Non-controlled	Meloxicam
Diclofenac	Cataflam, Voltaren, Zipsor ¹	Ankylosing spondylitis, Dysmenorrhea, Mild pain, Moderate pain, Osteoarthritis, Rheumatoid arthritis	Arthralgia, Bone pain, Headache, Migraine, Myalgia	Non-controlled	
Diclofenac	Flector Patch ¹	Acute mild pain or moderate pain due to minor strains, sprains, and contusions		Non-controlled	
Diclofenac	Voltaren Gel ¹	Osteoarthritis	Myalgia	Non-controlled	
Diclofenac/Misoprostol	Arthrotec ¹	Osteoarthritis, rheumatoid arthritis		Non-controlled	
Diflunisal	Dolobid	Mild pain, Moderate pain, Osteoarthritis, Rheumatoid arthritis	Arthralgia, Bone pain, Dental pain, Dysmenorrhea, Headache, Migraine, Myalgia	Non-controlled	

Table G-1. Prescription Pain Medications by Drug Class (Cont'd)

Generic Name	Brand Name(s)	FDA-Approved Indication(s)	Pain-Related Non FDA-Approved Use(s)	DEA Schedule (2-5)	Available Therapeutic Equivalent
Etodolac	Lodine	Arthralgia, Bone pain, Dental pain, Juvenile rheumatoid arthritis, Mild pain, Moderate pain, Myalgia, Osteoarthritis, Rheumatoid arthritis		Non-controlled	
Ibuprofen	Motrin, Advil	Arthralgia, Dental pain, Dysmenorrhea, Headache, Juvenile rheumatoid arthritis, Migraine, Mild pain, Moderate pain, Myalgia, Osteoarthritis, Rheumatoid arthritis	Ankylosing spondylitis Bone pain, Gouty arthritis Psoriatic arthritis	Non-controlled	
Indomethacin	Indocin	Ankylosing spondylitis, Arthralgia, Gouty arthritis, Moderate pain, Myalgia, Osteoarthritis, Rheumatoid arthritis, Severe pain, Tendonitis	Bone pain, Headache, Juvenile rheumatoid arthritis	Non-controlled	
Ketoprofen	Orudis, Oruvail	Arthralgia, Dental pain, Dysmenorrhea, Headache, Mild pain, Moderate pain, Myalgia, Osteoarthritis, Rheumatoid arthritis	Ankylosing spondylitis, Bone pain, Gouty arthritis	Non-controlled	
Ketorolac	Toradol	Arthralgia, Moderate pain, Myalgia	Bone pain, Dental pain, Headache, Migraine	Non-controlled	
Meloxicam	Mobic	Juvenile rheumatoid arthritis, Osteoarthritis, Rheumatoid arthritis	Mild pain, Moderate pain	Non-controlled	
Mefenamic Acid	Ponstel	Dysmenorrhea, mild pain, moderate pain	Migraine	Non-controlled	
Nabumetone	Relafen	Osteoarthritis, Rheumatoid arthritis	Ankylosing spondylitis, Bone pain, Moderate pain	Non-controlled	

Table G-1. Prescription Pain Medications by Drug Class (Cont'd)

Generic Name	Brand Name(s)	FDA-Approved Indication(s)	Pain-Related Non FDA-Approved Use(s)	DEA Schedule (2-5)	Available Therapeutic Equivalent
Naproxen	Naprosyn, Anaprox, Aleve, Naprelan	Ankylosing spondylitis, Arthralgia, Bursitis, Dental pain, Dysmenorrhea, Headache, Juvenile rheumatoid arthritis, Mild pain, Moderate pain, Myalgia, Osteoarthritis, Rheumatoid arthritis, Tendonitis	Bone pain, Gouty arthritis, Migraine	Non-controlled	
Oxaprozin	Daypro	Juvenile rheumatoid arthritis, Moderate pain, Osteoarthritis, Rheumatoid arthritis	Arthralgia, Bone pain, Myalgia	Non-controlled	
Sulindac	Clinoril	Ankylosing spondylitis, Bursitis, Gouty arthritis, Osteoarthritis, Rheumatoid arthritis, Tendonitis	Arthralgia, Bone pain, Headache, Juvenile rheumatoid arthritis, Migraine, Moderate pain, Myalgia	Non-controlled	
Tolectin	Tolmetin	Rheumatoid arthritis, juvenile rheumatoid arthritis/juvenile idiopathic arthritis, or osteoarthritis		Non-controlled	
Corticosteroids					
Dexamethasone	Decadron	Ankylosing spondylitis, Gouty arthritis, Headache, Juvenile rheumatoid arthritis, Osteoarthritis, Severe pain	Bone pain, Carpal tunnel syndrome	Non-controlled	
Prednisone	Deltasone	Ankylosing spondylitis, Gouty arthritis, Juvenile rheumatoid arthritis, Osteoarthritis, Severe pain	Bone pain	Non-controlled	
Methylprednisolone	Medrol	Ankylosing spondylitis, Gouty arthritis, Juvenile rheumatoid arthritis, Osteoarthritis, Severe pain	Bone pain	Non-controlled	
Barbiturates					
Acetaminophen /Butalbital/Caffeine	Fioricet	Headache	Migraine	Non-controlled	

Table G-1. Prescription Pain Medications by Drug Class (Cont'd)

Generic Name	Brand Name(s)	FDA-Approved Indication(s)	Pain-Related Non FDA-Approved Use(s)	DEA Schedule (2-5)	Available Therapeutic Equivalent
Acetaminophen/ Butalbital/Caffeine/Codeine	Fioricet w/Codeine	Headache	Migraine, Mild pain, Moderate pain	3	
Aspirin/Butalbital/Caffeine	Fiorinal	Headache	Migraine, Mild pain, Moderate pain	Non-controlled	
Aspirin/Butalbital/Caffeine/Codeine	Fiorinal w/Codeine, Ascomp w/Codeine	Headache	Migraine, Mild pain, Moderate pain	3	
Centrally Acting alpha-2 Agonist					
Clonidine	Catapres, Catapres TTS	Severe pain, Hypertension	Diabetic neuropathy, Neuropathic pain	Non-controlled	
NMDA Receptor Antagonists					
Ketamine	Ketalar	Anesthesia	Complex Regional Pain Syndrome	3	
Memantine	Namenda ¹	Dementia	Complex Regional Pain Syndrome	Non-controlled	
Amantadine	Symmetrel	Influenza, Parkinson's Disease	Complex Regional Pain Syndrome	Non-controlled	
Dextromethorphan		Cough	Complex Regional Pain Syndrome	Non-controlled	
Dopamine Agonists					
Ropinerole	Requip, Requip XL	Parkinson's Disease, Restless legs syndrome	Fibromyalgia	Non-controlled	
Pramipexole	Mirapex, Mirapex ER	Parkinson's Disease, Restless legs syndrome	Fibromyalgia	Non-controlled	
5HT-1B/1D Agonists (Triptans)					
Naratriptan	Amerge ¹	Migraine		Non-controlled	Sumatriptan
Almotriptan	Axert ¹	Migraine		Non-controlled	Sumatriptan
Frovatriptan	Frova ¹	Migraine		Non-controlled	Sumatriptan

Table G-1. Prescription Pain Medications by Drug Class (Cont'd)

Generic Name	Brand Name(s)	FDA-Approved Indication(s)	Pain-Related Non FDA-Approved Use(s)	DEA Schedule (2-5)	Available Therapeutic Equivalent
Sumatriptan	Imitrex	Migraine, Cluster headache		Non-controlled	
Rizatriptan	Maxalt ¹	Migraine		Non-controlled	Sumatriptan
Eletriptan	Relpax ¹	Migraine		Non-controlled	Sumatriptan
Zolmitriptan	Zomig ¹	Migraine		Non-controlled	Sumatriptan
Sumatriptan / Naproxen	Treximet ¹	Migraine		Non-controlled	
Ergot Alkaloids					
Ergotamine/Caffeine	Cafergot	Headache, Migraine		Non-controlled	
Dihydroergotamine	Migranal Nasal ¹	Headache, Migraine		Non-controlled	
Anesthetic					
Lidocaine	Lidoderm Patch ¹	Neuropathic pain, Post-herpetic neuralgia		Non-controlled	
Bisphosphonates					
Alendronate/Vitamin D	Fosamax-D	Osteoporosis	Complex Regional Pain Syndrome	Non-controlled	
Risedronate/Ca	Actonel Ca	Osteoporosis	Complex Regional Pain Syndrome	Non-controlled	
Alendronate	Fosamax	Osteoporosis	Complex Regional Pain Syndrome	Non-controlled	
Risedronate	Actonel	Osteoporosis	Complex Regional Pain Syndrome	Non-controlled	
Ibandronate	Boniva	Osteoporosis	Complex Regional Pain Syndrome	Non-controlled	

Source: California Health Benefits Review Program, 2011.

Note: Table developed by Content Expert, Melissa Durham, PharmD.

¹ No generic available

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A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses 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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