



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 1826: Pain Prescriptions

A Report to the 2009-2010 California Legislature
April 16, 2010

CHBRP 10-03



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 2009-2010 California State Legislature

Analysis of Assembly Bill 1826: Pain Prescriptions

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill (AB) 1826 (Huffman) Pain Prescriptions. In response to a request from the California Assembly Committee on Health on February 12, 2010, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the program's authorizing statute. Joy Melnikow, MD, MPH, Stephen McCurdy, MD, MPH, and Dominique Ritley, MPH, all of the University of California, Davis, prepared the medical effectiveness analysis. Bruce Abbott, MLS, of the University of California, Davis, conducted the literature search. Helen Halpin, ScM, PhD, Sara McMenamin, PhD, and Nicole Bellows, PhD, all of the University of California, Berkeley, and Alexis Muñoz, MPH, of the University of California, San Diego, prepared the public health impact analysis. Ying-Ying Meng, DrPH, and Lori Uyeno, MD, both of the University of California, Los Angeles, prepared the cost impact analysis. Jay Ripps, FSA, MAAA, and Susan Pantely, FSA, MAAA, of Milliman, provided actuarial analysis. Melissa Durham, PharmD, of the University of Southern California, and Debbie Stern, RPh, of Rxperts, provided technical assistance with the literature review and expert input on the analytic approach. John Lewis, MPA, and Susan Philip, MPP, both of CHBRP staff, prepared the background section and synthesized the individual sections into a single report. Sarah Ordódy provided editing services. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and 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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Susan Philip, MPP
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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 1826

The California Senate Committee on Health requested on February 12, 2010, 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) 1826, a bill that would impose a health benefit mandate. AB 1826 would prohibit the use of fail-first protocols as methods of utilization management for pain medications covered through an outpatient pharmacy benefit by a health care service plan or health insurer subject to regulation by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) unless the health insurance is purchased by the California Public Employees' Retirement System (CalPERS).

On March 23, 2010, the federal government enacted the federal "Patient Protection and Affordable Care Act" (P.L.111-148), which was amended by the "Health Care and Education Reconciliation Act" (H.R.4872) that the President signed into law on March 30, 2010. These laws (referred to as P.L. 111-148) came into effect after CHBRP received a request for analysis for AB 1826. There are provisions in P.L.111-148 that go into effect by 2014 and beyond that would dramatically affect the California health insurance market and its regulatory environment. For example, the law would establish state-based health insurance exchanges, with minimum benefit standards, for the small group and individual markets. How these provisions are implemented in California would largely depend on regulations to be promulgated by federal agencies, and statutory and regulatory actions to be undertaken by the California state government.

There are also provisions in P.L.111-148 that go into effect within the short term or within 6 months of enactment that would expand the number of Californians obtaining health insurance and their sources of health insurance. For example, one provision would allow children to enroll onto their parent's health plan or policy until they turn 26 years of age (effective 6 months following enactment). This may decrease the number of uninsured and/or potentially shift those enrolled with individually purchased insurance to group purchased insurance. These and other short term provisions would affect CHBRP's baseline estimates of the number and source of health insurance for Californians in 2010. Given the uncertainty surrounding implementation of these provisions and given that P.L.111-148 was only recently enacted, the potential effects of these short-term provisions are not taken into account in the baseline estimates presented in this report. 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 state mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP's estimates of these marginal effects continue to be relevant for the 12 months that would follow implementation of the mandate.

Approximately 19.5 million Californians (51%) have health insurance that may be subject to a health benefit mandate law passed at the state level (CHBRP, 2010). Of the rest of the population, a portion is uninsured, and therefore not affected by health insurance benefit mandate

laws. Others have health insurance not subject to health insurance benefit mandate laws. Uniquely, California has a bifurcated system of regulation for health insurance subject to state level benefit mandate law. The California Department of Managed Health Care (DMHC)¹ regulates health care service plans that offer coverage for benefits to their enrollees through health care service plan contracts. The California Department of Insurance (CDI) regulates health insurers² that offer coverage for benefits to their enrollees through health insurance policies.

AB 1826 would place requirements on DMHC-regulated health plan contracts and CDI-regulated policies—unless purchased by the California Public Employees’ Retirement System (CalPERS). Therefore, approximately 18.7 million Californians (49%) have health insurance that would be subject to this mandate.

AB 1826 would mandate that plans and policies providing outpatient pharmacy benefits provide coverage for medication prescribed by a participating licensed health care professional for the treatment of pain “without first requiring the subscriber or enrollee to use an alternative prescription or over-the-counter product.”

Throughout this report, CHBRP uses the phrase “fail-first protocols” to reference the heterogeneous group of utilization management techniques that would be prohibited by AB 1826 for pain 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.³

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* 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 step-therapy 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 plan contract or policy or appeal the decision. Alternatively, the patient may purchase the prescription at full-cost. A fail-first protocol may also be the basis for part or all of a *pre-certification* or *prior authorization* protocol, which may also require the prescriber to confirm to the plan or insurer that an alternate medication or medications have been unsuccessfully tried by the patient before the prescriber’s preferred medication is covered. 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

¹ The DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.

² 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.

³ Personal communication with content experts M. Durham and D. Stern.

medical problem or diagnosis or confirmation that the patient meets other criteria such as age or specified comorbidities. Some, but not all, *generic or therapeutic substitution* protocols may be subject to AB 1826. AB 1826 would not affect a formulary that includes only a generic medication and not its brand-name equivalent. However, AB 1826 would prohibit generic substitution when used as part of a fail-first protocol that explicitly requires the use of a generic before another medication (e.g., a specific brand-name version of the generic medication) within the formulary is covered.

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 consumed during an inpatient hospital stay are generally covered by an enrollee's medical benefit. Similarly, medications consumed during a visit to a provider's office—like many injected and intravenous anticancer 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.

This analysis assumes that AB 1826 would not increase the number of enrollees with an outpatient pharmacy benefit. All health insurance regulated by the DMHC or CDI must cover prescription medications delivered during a hospital stay. Therefore, the language of the bill, which addresses plans and policies covering prescription medications, could be interpreted as requiring all plans and all policies (even those without an outpatient pharmacy benefit) to cover prescribed pain medication (effectively expanding coverage for pain medications). However, regulators are likely to consider legislative intent when interpreting a mandate,⁴ and such an expansion of benefit coverage is not the intent according to the preamble provided by the Legislative Counsel's Office included in the introduced version of AB 1826.

Therefore, CHBRP's analysis assumes that the bill would prohibit only fail-first protocols as a method of utilization management, but would not expand coverage for pain medications or require coverage of medications not in the plan's or insurer's existing drug formulary. However, it should be noted that the language of the bill is not clear on this point.

It is important to note that physicians and other providers would not be subject to AB 1826. The bill, as a health insurance benefit mandate, would affect health plans and health insurers, not providers. Although providers, independent of plan/policy protocols, may direct a patient to try any number of alternate medications before prescribing a particular pain medication, provider prescribing practice would not be subject to the bill's mandate.

No current California mandate requires an outpatient pharmacy benefit to cover prescription medications. No current California mandate prohibits use of fail-first protocols with prescription medications.

CHBRP found no mandates current in other states prohibiting the use of fail-first protocols with prescription medications.

⁴ Personal communication with S. Lowenstein, DMHC.

Medical Effectiveness

Because of the heterogeneity of causal conditions and types of pain (acute and chronic), there is no standard treatment for pain. Pain treatment varies according to type, severity, and duration of pain, as well as the 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 individual patients.

As described in the introduction, CHBRP uses the phrase “fail-first protocols” to reference a heterogeneous group of utilization management techniques that would be prohibited by AB 1826 for pain medications. 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 pharmacy benefits that make coverage for between 1 and 38 pain medications subject to fail-first protocols.⁵ It is possible that two enrollees with plan contracts from a single health plan (or policies from a single insurer) might not have outpatient pharmacy benefits for pain medications that are subject to the same list of fail-first protocols—or one of them might not be subject to any list at all.

Of more than 200 prescription medications used to treat pain, 54 are subject to fail-first protocols for at least some portion of enrollees with health insurance subject to AB 1826 whose health insurance includes an outpatient pharmacy benefit. However, among the 54 medications identified, there is variation in frequency of medications subject to fail-first protocols: two medications are present on four fail-first protocol lists; two medications are present on three lists, 12 medications are on two lists (but not all 12 are present on a single list), and each of the remaining 38 medications is on one list.

In the use of fail-first protocols as methods of utilization management for coverage of pain medications through outpatient pharmacy benefits, there appears to be no pattern among DMHC-regulated health plans and CDI-regulated insurers. Not all enrollees have benefit coverage subject to fail-first protocols for pain medications. 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 this heterogeneity, CHBRP did not review comparative-effectiveness studies for particular pain medications.

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?*”

⁵ The carrier-submitted fail-first protocol lists were not always limited to pain medications. Each submission was reviewed by the pharmacist content expert, Melissa Durham, PharmD, and culled as appropriate. The list was further reviewed and culled to ensure the medication was subject to the fail-first protocols protocol addressed in AB 1826. A second request asked carriers to clarify ambiguous language and to verify the accuracy of the reviewed and culled list. Clarified responses were incorporated accordingly into the fail-first protocol lists.

- 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 non-steroidal 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.

- CHBRP finds insufficient evidence to characterize the medical effectiveness of fail-first protocols for pain medications. Therefore, CHBRP concludes that the impact of AB 1826 on the medical effectiveness of pain treatment is unknown. The lack of evidence for the effectiveness of fail-first protocols is not evidence that these protocols produce either positive or negative health outcomes.

Utilization, Cost, and Benefit Coverage Impacts

Table 1 summarizes the estimated benefit coverage, utilization, and cost impacts of AB 1826.

This analysis is focused on pain medications covered through an outpatient pharmacy benefit. Although pain medications can be covered through a medical benefit (as is the case, for example, during a hospital admission), the fail-first protocols prohibited by AB 1826 generally affect coverage of pain medications when coverage is provided through an outpatient pharmacy benefit.

In Table 1 and throughout this report, the terms “cost” and “costs per prescription” are used. Cost is the total of amount paid by health plans/insurers and enrollees, unless otherwise noted in the text. Cost per prescription is the average cost for a 30-day supply of the prescribed medication, as paid by the health plan or insurer and the enrollee (through any applicable cost sharing).

Due to the heterogeneity of fail-first protocol lists, a select set of brand-name pain medications present on at least one list was generated for use in the cost and utilization analysis. Cost is not the only possible cause for a medication to be on a fail-first protocol list. However, the cost analysis focused on the select set of brand name medications that make up 84% of the total cost of pain medications that appear on at least one fail-first protocol list.

Outpatient Pharmacy Benefit Coverage

Not all enrollees subject to AB 1826 have an outpatient pharmacy benefit. Of those who do, not all have outpatient pharmacy benefit coverage for pain medications that is subject to any fail-first protocol. Among enrollees whose benefit coverage is subject to one or more fail-first protocols, there is a great deal of variation, depending on the provisions of the enrollee's plan contract or policy, as to which or how many pain medications are on a fail-first protocol list. Benefit coverage is described below.

- 18,667,000 enrollees in DMHC-regulated health plans or CDI-regulated policies have health insurance subject to AB 1826.
 - 18,146,000 (97.2%) enrollees have outpatient pharmacy benefit coverage. Benefit coverage details for these enrollees is as described below:
 - 8,258,000 (45.5%) have benefit coverage subject to fail-first protocols for one or more pain medications.
 - 8,950,000 (49.3%) have benefit coverage not subject to fail-first protocols and so would not be affected the mandate.
 - 417,000 (2.2%) have generic-only outpatient pharmacy benefit coverage and would not be affected by the mandate because generic medications are not generally present on fail-first protocol lists.⁶
 - 521,000 (2.8%) enrollees do not have outpatient pharmacy benefit coverage and so would not be affected by AB 1826.

Utilization

- Prescriptions for identified FDA-approved medications commonly used for pain (generic and brand-name) are estimated to be 610 per 1,000 enrollees per year. AB 1826 is not expected to measurably affect this number because outpatient pharmacy benefit coverage is not expanded by this mandate and the mandate is not expected to result in an increase in diagnosis or treatment of pain.
- AB 1826 is expected to affect the percentage make up of filled pain prescriptions in terms of generic versus brand name medications. Premandate, generic pain medications are estimated to be 88% of all filled pain prescriptions and brand-names about 12%. Postmandate, the percentage of generic medications would decrease and there would be an increase in the percentage of brand-name medications previously subjected to fail-first protocols. Pain medications formerly on fail-first protocol lists, predominantly brand name medications, would become a greater percentage of filled prescriptions and there would be a concomitant decrease in prescriptions for the alternative medications the protocols had indicated should be tried first.

⁶ Personal communication with content experts M. Durham and D. Stern.

- The cost and utilization analysis focuses on a select set of brand-name medications in order to assess the cost impacts of AB 1826, but the impact of the mandate would be similar for other pain medications that had previously been on a fail-first protocol list.

Costs

- Total annual expenditures are estimated to increase by \$27.7 million or 0.0363% due to increases in premiums and enrollee out-of-pocket expenditures resulting from the increase in the average cost per prescription for pain medications. The restriction of fail-first protocols is expected to increase the number of more expensive brand-name pain medications as a percentage of all prescriptions for pain. Premandate, it is estimated that brand-name medications are only 12% of all pain prescriptions but make up 54.5% of total cost. These percentages are expected to increase postmandate.
- The average cost per prescription associated with the select set of pain medications on at least one fail-first protocol list is projected to increase \$30 or 14% due to the higher percentage of more expensive, brand-name pain prescriptions being filled. The premandate average includes a blend of the select set of brand name pain medications and their generic alternatives. The postmandate average reflects the select set alone. Therefore, the postmandate increase in average cost per prescription reflects the decrease in generic and increase in brand-name medications. The per-unit cost of the medications themselves is not expected to increase.
- Enrollee out-of-pocket expenses for covered benefits are expected to increase by \$3.19 million or 0.0535 % due to the increased use of the select set of brand-name pain medications, many of which are subject to higher cost sharing requirements than are their alternatives that a fail-first protocol would have indicated.
- AB 1826 is estimated to increase insurance premiums. The distribution of the impact on premiums is as follows:
 - Total premiums for private employers purchasing group health insurance are estimated to increase by \$9.33 million, or 0.0214%.
 - Enrollee contributions toward premiums for group insurance regulated by the DMHC or CDI are estimated to increase by \$2.97 million, or 0.0232%.
 - Total premiums for purchasers of individual market health insurance are estimated to increase by \$2.04 million, or 0.0340%.
 - Total employer premium expenditures for CalPERS HMOs would not increase, because AB 1826 exempts CalPERS from the mandate.
- State expenditures for Medi-Cal HMOs are estimated to increase by \$8.12 million or 0.2023%.
- State expenditures for the Healthy Families Program, the Aid to Infants and Mothers (AIM) program, and the Major Risk Medical Insurance Program (MRMIP) are estimated to increase by \$2.10 million or 0.2310 %.

Impact on the Number of Uninsured Persons

- CHBRP estimates no measurable impact of the mandate on the number of uninsured persons.

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 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 public health impact of AB 1826 is unknown.
- CHBRP did not identify any literature that examined the relationship between fail-first protocols and gender or race/ethnicity. In addition, CHBRP does not know the extent to which AB 1826 would impact people of different genders or racial/ethnic groups differentially. Therefore, the impact of AB 1826 on gender and racial/ethnic disparities in 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 1826 on lost productivity and economic loss associated with conditions requiring the use of pain medications is unknown.

Table 1. AB 1826 Impacts on Benefit Coverage, Utilization, and Cost, 2010

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	19,487,000	19,487,000	0	0%
Total enrollees with health insurance subject to AB 1826	18,667,000	18,667,000	0	0%
Percentage of enrollees with outpatient pharmacy benefit	97.2%	97.2%	0.0%	0%
Percentage of enrollees with outpatient pharmacy benefit coverage subject to fail-first protocols	45.5%	-	45.5%	-100%
Percentage of enrollees with outpatient pharmacy benefit coverage NOT subject to fail-first protocols	49.3%	97.2%	49.3%	103%
Percentage of enrollees with generic-only outpatient pharmacy coverage (not affected by fail-first protocols)	2.2%	2.2%	0.0%	0%
Percentage of enrollees with NO outpatient pharmacy benefit (not affected by fail-first protocols)	2.8%	2.8%	0.0%	0%
Number of enrollees with outpatient medication coverage	18,146,000	18,146,000	0	0%
Number of enrollees with outpatient benefit coverage subject to fail-first protocols	8,258,000	-	8,258,000	-100%
Number of enrollees with outpatient benefit coverage NOT subject to fail-first protocols	8,950,000	18,146,000	9,196,000	103%
Number of enrollees with generic-only outpatient pharmacy benefit coverage	417,000	417,000	0	0%
Number of enrollees with NO outpatient pharmacy benefit coverage	521,000	521,000	0	0%
Utilization and Cost				
Number of pain prescriptions per 1,000 enrollees per year	610	610	0	0%
Average cost per prescription associated with a select set of brand name prescription medications on at least one fail-first protocol list (c)	\$215	\$244	\$30	14%

Table 1. AB 1826 Impacts on Benefit Coverage, Utilization, and Cost, 2010 (Cont'd)

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Expenditures				
Premium expenditures by private employers for group insurance	\$43,519,324,000	\$43,528,652,000	\$9,328,000	0.0214%
Premium expenditures for individually purchased insurance	\$5,992,795,000	\$5,994,830,000	\$2,035,000	0.0340%
Premium expenditures by persons with group insurance, CalPERS HMOs, Healthy Families Program, AIM or MRMIP (b)	\$12,820,614,000	\$12,823,585,000	\$2,971,000	0.0232%
CalPERS HMO employer expenditures (d)	\$3,267,842,000	\$3,267,842,000	\$0	0.0000%
Medi-Cal HMOs state expenditures	\$4,015,596,000	\$4,023,718,000	\$8,122,000	0.2023%
Healthy Families Program state expenditures (e)	\$910,306,000	\$912,409,000	\$2,103,000	0.2310%
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$5,961,186,000	\$5,964,374,000	\$3,188,000	0.0535%
Enrollee expenses for noncovered benefits (f)		-	-	-
Total Annual Expenditures	\$76,487,663,000	\$76,515,410,000	\$27,747,000	0.0363%

Source: California Health Benefits Review Program, 2010.

Notes: (a) This population includes persons enrolled in privately funded (group and individual) and publicly funded (e.g., CalPERS HMOs, Medi-Cal HMOs, Healthy Families Program, AIM, MRMIP) health insurance plans/policies regulated by the DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance.

(b) Premium expenditures by individuals include employee contributions to employer-sponsored health insurance and beneficiary contributions to public insurance.

(c) The premandate average includes a blend of the select set of brand name pain medications and their generic alternatives. The postmandate average reflects the select set alone. Therefore, the postmandate increase in average cost per prescription reflects the decrease in generic and increase in brand-name medications. The per-unit cost of the medications themselves is not expected to increase.

(d) AB 1826 exempts CalPERS from the mandate. Were CalPERS to be subject to the mandate, about 58% of the identified CalPERS expenditures would be for CalPERS HMO enrollees who are state employees.

(e) Healthy Families Program state expenditures include expenditures for 7,000 enrollees covered by the Major Risk Medical Insurance Program (MRMIP) and 7,000 enrollees covered by the Access for Infants and Mothers (AIM) program.

(f) 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 pharmacy benefits whose prescription would not have been covered (premandate) due to a fail-first protocol.

Key: AIM=Access for Infants and Mothers; CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

INTRODUCTION

The California Senate Committee on Health requested on February 12, 2010, 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) 1826, 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.

Potential Effects of Health Care Reform

On March 23, 2010, the federal government enacted the federal "Patient Protection and Affordable Care Act" (P.L.111-148), which was further amended by the "Health Care and Education Reconciliation Act" (H.R.4872) that the President signed into law on March 30, 2010. These laws (referred to as "P.L.111-148") came into effect after CHBRP received a request for analysis for AB 1826.

There are provisions in P.L.111-148 that go into effect by 2014 and beyond that would dramatically affect the California health insurance market and its regulatory environment. These major long-term provisions of P.L.111-148 would require that most U.S. citizens and qualified legal residents have health insurance and that large employers offer health insurance coverage or a tax-free credit to their employees. It would establish state-based health insurance exchanges, with minimum benefit standards, for the small group and individual markets. Subsidies for low-income individuals would be available to purchase into the exchanges. How these provisions are implemented in California would largely depend on regulations to be promulgated by federal agencies, and statutory and regulatory actions to be undertaken by the California state government.

There are also short-term provisions in P.L.111-148 that go into effect within 6 months or less of enactment that would expand the number of Californians obtaining health insurance and their sources of health insurance. For example:

- Children and young adults up to 26 years of age would be allowed to enroll onto their parent's health plan or policy (effective 6 months following enactment). This provision may decrease the number of uninsured and/or potentially shift those enrolled with individually purchased insurance to group purchased insurance.
- A temporary high-risk pool for those with pre-existing conditions would be established (effective 90 days following enactment). How California chooses to implement this provision would have implications for health insurance coverage for those high-risk individuals who are currently without health insurance and/or are in California's Major Risk Medical Insurance Program (MRMIP).

These and other short term provisions would affect CHBRP's baseline estimates of the number of insured and sources of health insurance for Californians and corresponding total costs for

2010. Given the uncertainty surrounding implementation of these provisions and given that P.L.111-148 was only recently enacted, the potential effects of these short-term provisions are not taken into account in the baseline estimates presented in this report. 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 state mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. CHBRP’s estimates of these marginal effects continue to be relevant for the 12 months that would follow implementation of the mandate.

Approximately 19.5 million Californians (51%) have health insurance that may be subject to a health benefit mandate law passed at the state level (CHBRP, 2010). Of the rest of the population, a portion is uninsured, and therefore not affected by health insurance benefit mandate laws. Others have health insurance not subject to health insurance benefit mandate laws. Uniquely, California has a bifurcated system of regulation for health insurance subject to state-level benefit mandate laws. The California Department of Managed Health Care (DMHC)⁷ regulates health care service plans that offer coverage for benefits to their enrollees through health care service plan contracts. The California Department of Insurance (CDI) regulates health insurers⁸ that offer coverage for benefits to their enrollees through health insurance policies.

AB 1826 would place requirements on DMHC-regulated health plan contracts and CDI-regulated policies—unless purchased by the California Public Employees’ Retirement System (CalPERS). Therefore, approximately 18.7 million Californians (49%) have health insurance that would be subject to this mandate.

Bill Language

The full text of AB 1826 can be found in *Appendix A* of this report.

AB 1826 would mandate that plans and policies providing outpatient pharmacy benefits provide coverage for medication prescribed by a participating licensed health care professional for the treatment of pain “without first requiring the subscriber or enrollee to use an alternative prescription or over-the-counter product.”

Throughout this report, CHBRP uses the phrase “fail-first protocols” to reference the heterogeneous group of utilization management techniques that would be prohibited by AB 1826 for pain 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

⁷ The DMHC was established in 2000 to enforce the Knox-Keene Health Care Service Plan of 1975; see Health and Safety Code, Section 1340.

⁸ 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.

and insurers to implement fail-first protocols.⁹ 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* 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 plan contract or policy or appeal the decision. Alternatively, the patient may purchase the prescription at full cost. A fail-first protocol may also be the basis for part or all of a *pre-certification* or *prior authorization* protocol, which may also require the prescriber to confirm to the plan or insurer that an alternate medication or medications have been unsuccessfully tried by the patient before the prescriber's preferred medication is covered. 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. Some, but not all, *generic or therapeutic substitution* protocols may be subject to AB 1826. AB 1826 would not affect a formulary decision to cover only a generic medication and not its brand-name equivalent. However, AB 1826 would prohibit generic substitution if used as part of a fail-first protocol that explicitly requires the use of a generic before another medication (e.g., a specific brand-name version of the generic medication) within the formulary is covered.

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 (McDonald, 2008). Medications consumed during an inpatient hospital stay are generally covered by an enrollee's medical benefit. Similarly, medications consumed during a visit to a provider's office—like many injected and intravenous anticancer medications—may be covered through an enrollee's medical benefit. However, because fail-first protocols are generally 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.

This analysis assumes that AB 1826 would not increase the number of enrollees with an outpatient pharmacy benefit. All health insurance regulated by the DMHC or CDI must cover prescription medications delivered during a hospital stay. Therefore, the language of the bill, which addresses plans and policies covering prescription medications, could be interpreted as requiring all plans and all policies (even those without an outpatient pharmacy benefit) to cover prescribed pain medication (effectively expanding coverage for pain medications). However, regulators are likely to consider legislative intent when interpreting a mandate,¹⁰ and such an expansion of coverage is not the intent according to the preamble provided by the Legislative Counsel's Office included in the introduced version of AB 1826. Therefore, CHBRP's analysis assumes that the bill would prohibit only fail-first protocols as a method of utilization management, but would not expand coverage for pain medications or require coverage of

⁹ Personal communication with content experts M. Durham and D. Stern.

¹⁰ Personal communication with S. Lowenstein, DMHC.

medications not in the plan's or insurer's existing drug formulary. However, it should be noted that the language of the bill is not clear on this point.

Analytic Approach and Key Assumptions

AB 1826 would prohibit DMHC-regulated plans and CDI-regulated policies (excepting those purchased by CalPERS) from using fail-first protocols as methods of utilization management for prescribed pain medications. However, this analysis assumes that plans or policies that use formularies to limit coverage to generic medications will not be affected by AB 1826 because CHBRP found no evidence that they require the use of an alternative medication (other generic or over-the-counter medication) before covering the initially prescribed generic medication.

It is important to note that physicians and other providers would not be subject to AB 1826. The bill, as a health insurance benefit mandate, would affect health plans and health insurers, not providers. Although providers, independent of plan/policy protocols, may direct a patient to try any number of alternate medications before prescribing a particular pain medication, provider prescribing practice would not be subject to the bill's mandate.

Existing California Requirements

No current California mandate requires an outpatient pharmacy benefit to cover prescription medications.

No current California mandate prohibits use of fail-first protocols with prescription medications.

However, there are a number of health insurance benefit mandates that might interact with AB 1826. The relevant mandates are listed by Health and Safety Code (H&S), with Insurance Code (IC):

H&S 1367.21/IC10123.195 prescription drugs: off-label use

Mandate to cover "off-label" uses of FDA-approved drugs—uses other than the specific FDA-approved use—in life-threatening situations and in cases of chronic and seriously debilitating conditions, when a set of specified provisions regarding evidence are met.

H&S 1367.22 prescription drugs: coverage of previously covered drugs; medically appropriate alternatives

Mandate to cover prescription drugs if the drug previously has 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 the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition.

H&S 1367.6/IC 10123.8 breast cancer benefits

Mandate to provide coverage for breast cancer screening, diagnosis, and treatment of enrollee's medical condition.

H&S 1367.24 authorization for nonformulary prescription drugs

Mandate to review coverage for nonformulary drugs.

Requirements in other States

CHBRP found no evidence of mandates current in other states prohibiting the use of fail-first protocols with prescription medications (BCBSA, 2009).

Background of the Disease or 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 one 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 1826 would prohibit DMHC-regulated plans and CDI-regulated policies (unless purchased by CalPERS) from using fail-first protocols as methods of utilization management.

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 the 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 individual patients.

Medications used to treat pain fall into several drug classes (see *Appendix G*), such as opioids, anti-depressants, anti-epileptics, and non-steroidal 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.

Fail-First Protocols

As described in the *Introduction*, CHBRP uses the phrase “fail-first protocols” to reference a heterogeneous group of utilization management techniques that would be prohibited by AB 1826 for prescription pain medications. In order to determine which and how many medications might be subject to fail-first protocols, CHBRP requested a fail-first protocol list from the seven largest California plans and insurers. 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 made between 1 and 38 pain medications subject to fail-first protocols.¹¹ The use of fail-first protocols varies both between and within health plans and insurance policies. Thus, even within the same plan or policy, some enrollees may be subject to fail-first protocols, while others are not. Similar variation of fail-first protocols is present in a sample of Medi-Cal HMOs and health plan contracts purchased by MRMIB for beneficiaries of Healthy Families, AIM and MRMIP programs (see *Utilization, Cost, and Benefit Coverage Impacts* section).

Of more than 200 prescription medications used to treat pain, 54 are subject to fail-first protocols for at least some portion of enrollees with health insurance subject to AB 1826 whose health insurance includes an outpatient pharmacy benefit (see *Appendix F*). However, among the 54 medications identified, there is variation in frequency of medications subject to fail-first protocols:

- Two medications are present on four fail-first protocol lists.
- Two medications are present on three lists.

¹¹ The submitted fail-first protocol lists were not always limited to pain medications. Each submission was reviewed by the pharmacist content expert, Melissa Durham, Pharm.D., and culled as appropriate. The list was further reviewed and culled to ensure the drug was subject to the fail-first protocols addressed in AB 1826. A second request asked respondents to clarify ambiguous language and to verify the accuracy of the reviewed and culled list. Clarification responses were incorporated accordingly into the fail-first protocol lists.

- 12 medications are on two lists (but not all 12 are present on a single list).
- Each of the remaining 38 medications is on one list.

In the use of fail-first protocols as methods of utilization management for coverage of pain medications through outpatient pharmacy benefits, there appears to be no pattern among DMHC-regulated health plans and CDI-regulated insurers (see *Appendix F*). 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 contract 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 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 considers 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 consider 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 suggest 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 focus 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) find 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) demonstrates 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 examines 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, use of weaker 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 subject to AB 1826. The lack of evidence for the effectiveness of fail-first protocols is not evidence that these protocols produce either positive or negative health outcomes.

UTILIZATION, COST, AND BENEFIT COVERAGE IMPACTS

Health plan contracts regulated by DMHC and health insurance policies regulated by CDI—unless purchased by CalPERS—would be subject to AB 1826. AB 1826 would prohibit the use of fail-first protocols in the coverage of pain medications.

This analysis is focused on pain medications covered through an outpatient pharmacy benefit. Although pain medications can be covered through a medical benefit (as is the case, for example, during a hospital admission), the fail-first protocols prohibited by AB 1826 generally affect coverage of pain medications when coverage is provided through an outpatient pharmacy benefit. However, the mandate would not affect generic-only outpatient pharmacy benefit coverage because generic and over-the-counter pain medications are not generally subject to fail-first protocols. The mandate would not change or expand the medications covered by a generic-only policy or plan and would therefore not affect enrollees covered by such policies/plans.

For the cost, utilization, and benefit coverage portion of this analysis, the following factors were identified: the percentage of enrollees with and without an outpatient pharmacy benefit; the percentage of enrollees with and without outpatient pharmacy benefit coverage for pain medications subject to fail-first protocols; variations between fail-first protocol lists for pain medications; and fail-first protocols for a select set of pain medications. Fail first protocols were found to vary. As described in the *Medical Effectiveness* section, 54 pain medications were identified as being on at least one list.

In Table 1 and throughout this report, the terms “cost” and “costs per prescription” are used. Cost is the total of amount paid by health plans/insurers and enrollees, unless otherwise noted in the text. Cost per prescription is the average cost for a 30-day supply of the prescribed medication, as paid by the health plan or insurer and the enrollee (through any applicable cost sharing).

Due to the heterogeneity of fail-first protocol lists, a select set of brand-name pain medications present on at least one list was generated for use in the cost and utilization analysis. Cost is not the only possible cause for a medication to be on a fail-first protocol list. However, the cost analysis focused on the select set of brand name medications that make up 84% of the total cost of pain medications that appear on at least one fail-first protocol list. For further details on the underlying data sources, methods, and assumptions, see *Appendix D*.

This section will present the current (baseline) costs, utilization, and benefit coverage, then detail the estimated impacts of AB 1826.

Present Baseline Cost and Benefit Coverage

Current Coverage of the Mandated Benefit

CHBRP surveyed the seven largest providers of health insurance in California to estimate current benefit coverage. Responses represented 82.37% of enrollees in privately funded CDI-regulated

policies and 92.03% of enrollees in privately funded DMHC-regulated plans. Combined, responses to the survey represent 90.45% of privately funded health insurance subject to regulation by the DMHC or CDI.

To determine whether enrollees in DMHC-regulated health plan contracts and CDI-regulated policies have pain medication coverage through outpatient pharmacy benefits that is subject to fail-first protocols, CHBRP included relevant questions in the survey. In the survey, CHBRP requested percentages of enrollees with outpatient pharmacy benefits (brand-name and generic or generic only), lists of medications subject to fail-first protocols, and percentages of enrollees with outpatient pharmacy benefits that would be subject to the fail-first protocol lists. As described in the *Medical Effectiveness* section, the resulting analysis of the fail-first protocol lists indicated a great deal of variation as to which and how many medications might be on such a list. The analysis also indicated that not all enrollees have outpatient pharmacy benefits and of those who do, not all have benefit coverage that is subject to any fail-first protocol for pain medications.

Table 2. Current Coverage of Outpatient Pharmacy Benefits by Market Segment, California, 2010

	No Outpatient Pharmacy Benefit	Outpatient Pharmacy Benefit for Brand and Generic Medications	Outpatient Pharmacy Benefit for Only Generic Medications
DMHC-regulated plans, privately funded (a)			
Large group	3.7%	96.3%	0.0%
Small group	0.0%	100.0%	0.0%
Individual	0.0%	100.0%	0.0%
All	2.8%	97.2%	0.0%
CDI-regulated policies (a)			
Large group	1.8%	98.2%	0.0%
Small group	0.2%	89.2%	10.6%
Individual	11.8%	58.2%	30.0%
All	6.0%	75.4%	18.6%
DMHC-regulated plans, Publicly funded			
CalPERS HMOs (b)	N/A	N/A	N/A
Medi-Cal HMOs	0.0%	100.0%	0.0%
Healthy Families/MRMIP/AIM	0.0%	100.0%	0.0%
Total	2.7%	94.9%	2.4%

Source: California Health Benefits Review Program, 2010

Note: Percentages may not perfectly match Table 1 due to rounding.

(a) The population includes employees and dependents covered by employer-sponsored insurance

(b) SB 961 exempts CalPERS.

Key: AIM=Access for Infants and Mothers; CalPERS=California Public Employees' Retirement System; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; MRMIP=Major Risk Medical Insurance Program; N/A=not applicable.

Not all enrollees subject to AB 1826 have an outpatient pharmacy benefit (Table 2). Of those who do, not all have outpatient pharmacy benefit coverage for pain medications that is subject to any fail-first protocol. Among enrollees whose benefit coverage is subject to one or more fail-first protocols, there is a great deal of variation, depending on the provisions of the enrollee's plan contract or policy, as to which or how many pain medications are on a fail-first protocol list. Benefit coverage is described below.

- 18,667,000 enrollees in DMHC-regulated health plans or CDI-regulated policies have health insurance subject to AB 1826.
 - 18,146,000 (97.2%) enrollees have outpatient pharmacy benefit coverage. Benefit coverage details for these enrollees is as described below:
 - 8,258,000 (45.5%) have benefit coverage subject to fail-first protocols for one or more pain medications.
 - 8,950,000 (49.3%) have benefit coverage not subject to fail-first protocols and so would not be affected the mandate.
 - 417,000 (2.2%) have generic-only outpatient pharmacy benefit coverage and would not be affected by the mandate because generic medications are not generally present on fail-first protocol lists.¹²
 - 521,000 (2.8%) enrollees do not have outpatient pharmacy benefit coverage and so would not be affected by AB 1826.

Inquiries made to the California Department of Health Care Services (DHCS) and the Managed Risk Medical Insurance Board (MRMIB) confirmed that beneficiaries of public programs enrolled in DMHC-regulated health plans may also have coverage for pain medications subject to fail-first protocols. However, CHBRP's survey of several DMHC-regulated plans into which they might be enrolled revealed variation. CHBRP was able to confirm that a portion of beneficiaries of Medi-Cal (Medi-Cal HMO enrollees) and MRMIB (enrollees in Healthy Families Program, AIM, and MRMIP) have outpatient pharmacy benefits for pain medication subject to some 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 varied by plan.

Current Utilization Levels and Costs of the Mandated Benefit

Current utilization levels

Current utilization of prescription pain medication was estimated by determining the number of prescriptions filled based on pharmacy claims data for 2009 and trended for 2010. The number of prescriptions for pain is estimated to be 610 per 1,000 enrollees per year. Of these, 88% are prescriptions for generic pain medications, and 12% are prescriptions for brand-name pain medications. In the estimate of pain prescriptions per 1000 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 >15% prescriptions were for the treatment of pain. The estimated percentage of prescriptions for pain treatment was based on content expert opinion.

¹² Personal communication with content experts M. Durham and D. Stern.

Unit price

The average unit price is represented by the average cost per prescription for pain medication (30-day supply).

The estimate of the average cost per prescription for pain medication was based on CHBRP's select set of brand-name pain medications on at least one fail-first protocol list. The premandate average cost included a blend of these brand-name pain medications and their generic alternatives. The average postmandate cost per prescription reflects a decrease in generic pain medication prescriptions and an increase in fill rate for (the usually more expensive brand-name) pain medications that would have been on a fail-first protocol list. The average cost per prescription associated with the select set of brand-name pain medications on at least one fail-first protocol list is \$215. This includes average cost to health plan or insurer and average enrollee cost share.

The range of average cost for a prescription of the select set 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. Any applicable enrollee cost share would vary by the provisions of the enrollee's plan or policy.

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 enrollee costs for noncovered benefits and cannot address the sources of such payments.

Public Demand for Benefit Coverage

As a way to determine whether public demand exists for the proposed mandate (based on criteria specified under CHBRP's authorizing statute), CHBRP reports on the extent to which collective bargaining entities negotiate for, and the extent to which self-insured plans (which are not regulated by the DMHC or CDI and so not subject to state-level mandates) currently have, coverage for the benefits specified under the proposed mandate.

Currently, the largest public self-insured plans are the PPO plans offered by CalPERS. These plans provide coverage and benefits similar to those offered in the group health insurance market subject to the mandate.

To further investigate public demand, CHBRP also utilized the mandate-specific health plan and insurer survey to ask carriers administering plans or policies for other (non-CalPERS) self-insured group health insurance programs whether the relevant coverage and benefits differed from what is offered in the commercial markets. The responding carriers indicated that there were no substantive differences, again suggesting that the market is meeting public demand.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include prohibitions of fail-first protocol lists for pain medications in their health insurance policy negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.¹³

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

Impacts of Mandated Benefit Coverage

AB 1826 would not change the number of enrollees with coverage for pain medications. For enrollees with a premandate outpatient pharmacy benefit, AB 1826 would prohibit use of fail-first protocols as methods of utilization management for pain medications.

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

Impact on supply and on the health benefit

The mandate's prohibition of fail-first protocols for pain medications is projected to increase utilization of more expensive brand-name medications. The mandate may have some impact on supply of brand-name pain medications as use of generics decreases and demand for brand-name pain medications increase. CHBRP is unable to quantify that impact.

Impact on per-unit cost

The average cost per prescription associated with the select set of pain medications on at least one fail-first protocol list is projected to increase \$30 or 14% due to the higher percentage of more expensive, brand-name pain prescriptions being filled. The premandate average includes a blend of the select set of brand name pain medications and their generic alternatives. The postmandate average reflects the select set alone. Therefore, the postmandate increase in average cost per prescription reflects the decrease in generic and increase in brand-name medications. The per-unit cost of the medications themselves is not expected to increase. Thus, an overall increase in average cost per prescription for a pain medication is estimated. In the short-term, CHBRP does not estimate an increase in the per-unit costs of any individual pain medication.

¹³ Personal communication with the California Labor Federation and member organizations, January 2009.

How Would Utilization Change As a Result of the Mandate?

Overall utilization of prescription pain medications is not projected to measurably change as a result of the mandate. A shift from generic to more expensive brand-name pain medications is anticipated because the mandate would allow patients to go directly to more expensive, brand-name pain medications, if prescribed. This assumption is based on literature on NSAIDs showing that the implementation of fail-first protocols as methods of utilization management resulted in decreased use of brand-name medications and increased use of less expensive generics (Hartung, 2004; Motheral, 2004). The converse—elimination of fail-first protocols resulting in increased use—is presumed to be true. Therefore, AB 1826 is expected to affect the percentage make up of filled pain prescriptions in terms of generic versus brand name medications. Premandate, generic pain medications are estimated to be 88% of all filled pain prescriptions and brand-names about 12%. Postmandate, the percentage of generic medications would decrease and there would be an increase in the percentage of brand-name medications previously subjected to fail-first protocols. Pain medications formerly on fail-first protocol lists, predominantly brand name medications, would become a greater percentage of filled prescriptions and there would be a concomitant decrease in prescriptions for the alternative medications the protocols had indicated should be tried first.

In order to determine the cost impacts of AB 1826, CHBRP analyzed a select set of brand-name pain medications that were on at least one fail-first protocol list and were determined to have a significant cost impact. However, an increase in utilization of all pain medications previously on a fail-first protocol would be expected.

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

CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there would be a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost proportion of premiums would be unchanged. All health plans and insurers include a component for administration and profit in their premiums. CHBRP estimates that the increase in administrative costs of CDI-regulated policies and DMHC-regulated plans would remain proportional to the increase in premiums.

Impact of the Mandate on Total Health Care Costs

Changes in total expenditures

The mandate would increase average per unit cost for a prescription for pain medications due to higher-cost brand-name medications representing a greater percentage of prescriptions for pain. This increase in cost would result in an increase in total expenditures, including higher premiums as well as an overall increase in out-of-pocket expenditures (through cost-sharing for brand-name medications) for enrollees.

CHBRP estimates total net expenditures (including premiums and out-of-pocket expenses) for prescriptions for pain medications would increase by \$27.7 million or 0.0363 % due to AB 1826 (Table 1). AB 1826 is expected to increase premiums for both employer and employee, out-of-pocket expenses for covered benefits, and state expenditures for public programs including Medi-Cal.

- Total premiums for private employers are expected to increase by \$9.33 million or 0.0214%.
- Premiums for individually purchased insurance are expected to increase by \$2.04 million or 0.0340%.
- Enrollee out-of-pocket expenses for covered benefits are also estimated to increase by \$3.19 million or 0.0535%.
- Medi-Cal HMO expenditures are estimated to increase by \$8.12 million or 0.2023% and state expenditures for Healthy Families, AIM, and MRMIP are estimated to increase by \$2.10 million or 0.2310%. This is an increase of \$0.24 PMPM for Medi-Cal HMO and Healthy Families, AIM, and MRMIP (Table 4).

Offsets

No offsetting savings are projected. No literature or evidence for savings by offsetting other services such as adjuvant pain therapies or services, physician visits, emergency room visits, or hospitalizations related to fail-first protocols for pain medications were identified. Therefore, none are projected.

Impact on long-term costs

Longer-term cost impacts of the mandate are unknown but likely to increase over time as newer, more costly brand-name medications for the treatment of pain are introduced into the market.

Impacts for Each Category of Payer Resulting from the Benefit Mandate

Changes in expenditures and PMPM amounts by payer category

Total expenditures are expected to increase 0.0363% due to the mandate. The increase in expenditures for public programs for enrollees in Medi-Cal HMOs and for beneficiaries of Healthy Families, AIM, and MRMIP reflects currently more intensive use of fail-first protocols that is assumed for health plans serving these enrollees. This assumption is supported by published literature (Wallack, 2004) and by content expert opinion.¹⁴

Total expected expenditure increases by market segment are as follows:

- 0.0216% in large group market DMHC-regulated plans
- 0.0217% in large group market CDI-regulated policies

¹⁴ Personal communication with content expert M. Durham.

- 0.0325% in small group market DMHC-regulated plans
- 0.0385% in small group market CDI-regulated policies
- 0.0231% in individual market DMHC-regulated plans
- 0.0452% in individual market CDI-regulated policies
- Publicly funded health insurance subject to AB 1826:
 - 0.2146% in under 65 Medi-Cal HMOs
 - 0.1087% in 65 and over Medi-Cal HMOs
 - 0.2277% in Healthy Families, AIM, and MRMIP

The expected increases in expenditures per member per month (PMPM) by market segment are as follows:

- \$0.08 PMPM in large-group market DMHC-regulated plans
- \$0.11 PMPM in large-group marked CDI-regulated policies
- \$0.11 PMPM in small-group market DMHC-regulated plans
- \$0.17 PMPM in small-group market CDI-regulated policies
- \$0.10 PMPM in individual market DMHC-regulated plans
- \$0.10 PMPM in individual market CDI-regulated policies
- Publicly funded health insurance subject to AB 1826¹⁵:
 - \$0.24 PMPM in under 65 Medi-Cal DMHC-regulated HMOs
 - \$0.24 PMPM in 65 and over Medi-Cal DMHC-regulated HMOs
 - \$0.24 PMPM in Healthy Families, AIM, MRMIP
- Insurance purchased by California Public Employees' Retirement System with public funds (CalPERS HMOs) is not affected by this mandate

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

CHBRP estimates premium increases of less than 1% for enrollees with health insurance subject to AB 1826. CHBRP does not anticipate loss of health insurance, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of health insurance, changes in employer contribution rates, changes in take-up of health insurance by employees, or purchase of individual market plans and policies, due to the small size of the increase in premiums after

¹⁵ The publicly funded health insurance expenditures PMPM are estimations that were based on private insurer fail-first protocols and extrapolated to the public programs.

the mandate. This premium increase is not estimated to have a measurable impact on the number of persons who are uninsured.

Impact on Access and Health Service Availability

CHBRP expects that this mandate would have no measurable impact on access to or availability of pain medications. Some enrollees may have easier access to certain prescribed pain medications due to removing the fail-first requirements. However, the increase in out-of-pocket expenses for brand-name medications may moderate this effect.

Table 3. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2010

	DMHC-Regulated							CDI-Regulated			Total Annual
	Privately Funded			CalPERS HMOs (b)	Medi-Cal HMOs		Healthy Families Program HMOs (d)	Privately Funded			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65		Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to state Mandates (a)	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Total enrollees in plans/policies subject to AB 1826	9,445,000	2,394,000	785,000	0	175,000	2,616,000	814,000	324,000	935,000	1,179,000	18,667,000
Average portion of premium paid by Employer	\$290.96	\$223.84	\$0.00	\$332.10	\$223.00	\$113.00	\$93.19	\$346.40	\$246.40	\$0.00	\$51,713,067,000
Average portion of premium paid by Employee	\$72.11	\$92.31	\$364.68	\$58.61	\$0.00	\$0.00	\$11.78	\$105.37	\$79.68	\$180.77	\$18,813,408,000
Total Premium	\$363.07	\$316.14	\$364.68	\$390.70	\$223.00	\$113.00	\$104.97	\$451.77	\$326.08	\$180.77	\$70,526,476,000
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$19.77	\$25.74	\$64.43	\$20.15	\$0.00	\$0.00	\$1.52	\$58.78	\$116.51	\$44.19	\$5,961,186,000
Enrollee expenses for benefits not covered (e)	-	-	-	-	-	-	-	-	-	-	-
Total Expenditures	\$382.84	\$341.88	\$429.11	\$410.85	\$223.00	\$113.00	\$106.50	\$510.56	\$442.59	\$224.96	\$76,487,662,000

Source: California Health Benefits Review Program, 2010.

Note: (a) This population includes persons insured with private funds (group and individual) and insured with public funds (e.g., CalPERS HMOs, Medi-Cal HMOs, Healthy Families Program, AIM, MRMIP) enrolled in health plans or policies regulated by the DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance. (b) AB 1826 exempts CalPERS. (c) Medi-Cal HMO state expenditures for enrollees over 65 years of age include those who also have Medicare coverage. (d) Healthy Families Program state expenditures include expenditures for MRMIP and AIM. (e) 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 pharmacy benefits whose prescription would not have been covered (premandate) due to a fail-first protocol.

Key: AIM=Access for Infants and Mothers; CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

Table 4. Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2010

	DMHC-Regulated							CDI-Regulated			Total Annual
	Privately Funded			CalPERS HMOs (b)	Medi-Cal HMOs		Healthy Families Program HMOs (d)	Privately Funded			
	Large Group	Small Group	Individual		65 and Over (c)	Under 65		Large Group	Small Group	Individual	
Total enrollees in plans/policies subject to State Mandates (a)	9,445,000	2,394,000	785,000	820,000	175,000	2,616,000	814,000	324,000	935,000	1,179,000	19,487,000
Total enrollees in plans/policies subject to AB 1826	9,445,000	2,394,000	785,000	0	175,000	2,616,000	814,000	324,000	935,000	1,179,000	18,667,000
Average portion of premium paid by Employer	\$0.0534	\$0.0635	\$0.0000	\$0.0000	\$0.2425	\$0.2425	\$0.2153	\$0.0743	\$0.1041	\$0.0000	\$19,553,000
Average portion of premium paid by Employee	\$0.0132	\$0.0258	\$0.0843	\$0.0000	\$0.0000	\$0.0000	\$0.0272	\$0.0226	\$0.0336	\$0.0877	\$5,006,000
Total Premium	\$0.0666	\$0.0893	\$0.0843	\$0.0000	\$0.2425	\$0.2425	\$0.2425	\$0.0969	\$0.1377	\$0.0877	\$24,559,000
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$0.0160	\$0.0217	\$0.0148	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0139	\$0.0325	\$0.0138	\$3,188,000
Enrollee expenses for benefits not covered (e)	-	-	-	-	-	-	-	-	-	-	-
Total Expenditures	\$0.0825	\$0.1111	\$0.0991	\$0.0000	\$0.2425	\$0.2425	\$0.2425	\$0.1108	\$0.1702	\$0.1016	\$27,747,000
Percentage Impact of Mandate											
Insured Premiums	0.0183%	0.0283%	0.0231%	0.0000%	0.1087%	0.2146%	0.2310%	0.0214%	0.0422%	0.0485%	0.0348%
Total Expenditures	0.0216%	0.0325%	0.0231%	0.0000%	0.1087%	0.2146%	0.2277%	0.0217%	0.0385%	0.0452%	0.0363%

Source: California Health Benefits Review Program, 2010.

Note: (a) This population includes persons insured with private funds (group and individual) and insured with public funds (e.g., CalPERS HMOs, Medi-Cal HMOs, Healthy Families Program, AIM, MRMIP) enrolled in health plans or policies regulated by the DMHC or CDI. This population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance. (b) AB 1826 exempts CalPERS. (c) Medi-Cal HMO state expenditures for enrollees over 65 years of age include those who also have Medicare coverage. (d) Healthy Families Program state expenditures include expenditures for MRMIP and AIM. (e) 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 pharmacy benefits whose prescription would not have been covered (premandate) due to a fail-first protocol.

Key: AIM=Access for Infants and Mothers; CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care.

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 1826 would prohibit health insurance plans or policies from using a fail-first protocol before authorizing coverage of prescribed pain medications. This section presents the overall public health impact of passage of AB 1826, 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

CHBRP estimates that each year there are 502,000 prescriptions for pain medications subjected to fail-first protocols that would be affected by AB 1826. CHBRP estimates that generic pain medications represent 88% of all pain prescriptions filled and brand-name medications make up about 12%. As presented in the *Utilization, Cost, and Benefit Coverage Impacts* section, AB 1826 is expected to increase utilization of more costly brand-name pain medications because it is assumed that the mandate would prevent any requirement for a trial of less expensive, alternative pain medications first and allow patients to go directly to more expensive, brand-name 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 state 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 1826 because they were not conducted exclusively on pain medications and they had weaknesses in their study design. Therefore, the public health impact of AB 1826 is unknown.

The methodology used to prepare this report did not allow CHBRP to fully review possible positive impacts AB 1826 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 elimination 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, there could be evidence that specific pain medications are more effective in controlling pain, and that some persons might have better pain control, were fail-first protocols removed.

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 1826 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 1826 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 U.S., 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, 2009). 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, 2009). 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). Not surprisingly, 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 1826 would impact females and males differentially. Therefore, CHBRP concludes that the impact of AB 1826 on gender disparities in 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 1826 would impact different race or ethnic groups differentially. CHBRP concludes that the impact of AB 1826 on racial/ethnic disparities in 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 1826 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 AB 1826 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 1826 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 12, 2010, the Assembly Committee on Health requested CHBRP to analyze the following submitted text for AB 1826. Below is the bill as introduced. Following is the text of the bill as will be amended as indicated by the Bill Author.

ASSEMBLY BILL No. 1826

Introduced by Assembly Member Huffman

(Coauthor: Senator Price)

February 11, 2010

An act to add Section 1367.225 to the Health and Safety Code, and to add Section 10123.197 to the Insurance Code, relating to health care coverage.

AB 1826, as introduced, Huffman. Health care coverage: prescriptions.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act's requirements a crime. Existing law provides for the regulation of health insurers by the Department of Insurance.

Existing law requires a health care service plan contract or a health insurance policy that covers prescription drug benefits to provide specified coverage to subscribers, enrollees, and insureds.

This bill would prohibit a health care service plan or a health insurer covering prescription drug benefits from requiring a subscriber, enrollee, or insured who has been prescribed a product for the treatment of pain by his or her health care provider to use a different specified product prior to authorizing coverage of the product prescribed by the health care provider.

Because a willful violation of the bill's requirements with respect 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 1367.225 is added to the Health and Safety Code, to read:

1367.225. (a) No health care service plan that covers prescription drug benefits shall require a subscriber or enrollee who has been prescribed a product for the treatment of pain by his or her health care provider to use an alternative prescription or an over-the-counter product prior to authorizing coverage of the product prescribed by the health care provider.

(b) 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 set forth to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.

SEC. 2. Section 10123.197 is added to the Insurance Code, to read:

10123.197. (a) No health insurer that covers prescription drug benefits shall require an insured who has been prescribed a product for the treatment of pain by his or her health care provider to use an alternative prescription or an over-the-counter product prior to authorizing coverage of the product prescribed by the health care provider.

(b) This section does not prohibit a health insurance policy from charging an insured 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 set forth to the insured pursuant to the disclosure provisions of Section 10603.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIIB 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.

AB 1826 – Amended Text, submitted to CHBRP on February 19, 2010.

SECTION 1. Section 1367.225 is added to the Health and Safety Code, to read:

1367.225. (a) ~~No~~ Every health care service plan that covers prescription drug benefits shall ~~require~~ *provide coverage for a subscriber or enrollee who has been* drug that has been prescribed ~~a product~~ *by a participating licensed health care professional* for the treatment of pain ~~by his or her health care provider~~ *without first requiring the subscriber or enrollee to use an alternative prescription or an over-the-counter product prior to authorizing coverage of the product prescribed by the health care provider.*

(b) 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 set forth to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.

(c) This section shall not apply to a policy of health insurance purchased by the Board of Administration of the Public Employees' Retirement System pursuant to the Public Employees' Medical and Hospital Care Act (commencing with Section 22750) of Division 5 of Title 2 of the Government Code.

SEC. 2. Section 10123.197 is added to the Insurance Code, to read:

10123.197. (a) ~~No~~ Every health insurer that covers prescription drug benefits shall ~~require~~ *provide coverage for a drug that an insured who has been prescribed a product by a participating licensed health care professional* for the treatment of pain ~~by his or her health care provider~~ *without first requiring the insured to use an alternative prescription or an over-the-counter product prior to authorizing coverage of the product prescribed by the health care provider.*

(b) This section does not prohibit a health insurance policy from charging an insured 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 set forth to the insured pursuant to the disclosure provisions of Section 10603.

(c) This section shall not apply to a policy of health insurance purchased by the Board of Administration of the Public Employees' Retirement System pursuant to the Public Employees' Medical and Hospital Care Act (commencing with Section 22750) of Division 5 of Title 2 of the Government 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 for AB 1826. 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, US 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 1826) 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 1826.

In deciding on the outcome measure of interest for AB 1826, 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 1826. 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 1826 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 1826	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 1826.)
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 1826.)
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 1826.)

Source: California Health Benefits Review Program, 2010.

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/analysis_methodology/cost_impact_analysis.php.

The cost analysis in this report was prepared by the Cost Team, which consists of CHBRP task force members and staff, specifically from the University of California, Los Angeles, and Milliman Inc. (Milliman). Milliman is an actuarial firm that 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 (2007) California Health Interview Survey (CHIS), which is used to estimate health insurance for California's population and distribution by payer (i.e., employment-based, individually purchased, or publicly financed). The biannual CHIS is the largest state health survey conducted in the United States, collecting information from over approximately 53,000 households. More information on CHIS is available at www.chis.ucla.edu. The population estimates for both adults and children from 2007 were adjusted to reflect the following trends as of 2009 from the data sources listed: (1) the increase in the total non-institutionalized population in California, from the California Department of Finance; (2) the decrease in privately funded health insurance (both group- and individual-level), from the CHBRP Annual Premium and Enrollment Survey; and (3) the increase in all types of publicly funded insurance, from enrollment data available from the Centers for Medicare & Medicaid Services, the California Medical Statistics Section, and the Managed Risk Medical Insurance Board. The residual population after accounting for these trends was assumed to be uninsured.
2. The latest (2009) 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/topics/healthinsurance/index.cfm?itemID=133543>.
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 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 enrollees. 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 enrollees of self-insured and insured group health plans.
 - An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2008 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2007 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 95.9% of the persons with privately funded health insurance subject to state mandates. This figure represents 98.0% of enrollees in full service (non-specialty), privately funded DMHC-regulated health plan contracts and 85.3% of enrollees in full service (non-specialty), privately funded CDI-regulated policies.

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 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 www.calpers.ca.gov.
6. Enrollment in Medi-Cal Managed Care (DMHC-regulated health 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/BeneficiaryDataFiles.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 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://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.
- 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. 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://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

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%.

Bill Analysis-Specific Caveats and Assumptions

The following is a description of the methodology used in analyzing the cost impact of AB 1826.

The analysis is focused on pain medications covered through an outpatient pharmacy benefit. Although pain medications can be covered through a medical benefit (as is the case, for example during a hospital admission), the fail-first protocols that would be prohibited by AB 1826 generally affect coverage of pain medications when coverage is provided through an outpatient pharmacy benefit.

No measurable increase in utilization of pain medications is projected, but medications formerly on fail-first protocol lists would become a greater percentage of filled prescriptions and there would be a concomitant decrease in prescriptions for the generic or alternative medications the protocols had indicated should be tried first.

CHBRP performed this analysis for each response to CHBRP's carrier survey before aggregating the results to provide statewide estimates. This approach was necessary due to the heterogeneity of the responses, which indicated that enrollees in privately funded DMHC-regulated plans or CDI-regulated policies have outpatient pharmacy benefit coverage for pain medications that is highly variable, in terms of whether the benefit coverage is subject to fail-first protocols. Responses indicated that some enrollees have benefit coverage not subject to any fail-first protocol and that the variation was on a plan contract by plan contract or policy by policy basis. Among enrollees with benefit coverage subject to one or more fail-first protocols, variation was also present.

1. Identification of Pain Medications on Fail-First Protocol Lists: Based on responses to the carrier survey and content expert opinion, a list of approximately 54 pain medications on at least one fail-first protocol list was compiled. For medications used for pain and for purposes other than control or amelioration of pain (e.g. antidepressants), content expert opinion was used to establish percentage use for pain. Any medication with >15% prescriptions for the treatment of pain was included.
2. Average Cost Per Prescription: The number of prescriptions for pain was estimated from the list of 54 brand-name medications. For medications that are prescribed for pain and for purposes other than pain management (e.g. depressions), CHBRP multiplied the prescription number by the expected percentage of prescriptions for pain (e.g. 15%) based on content expert opinion. CHBRP determined average costs per prescription from 2009 MedStat claims data for California. CHBRP trended the average costs per prescription to 2010 using a 3% annual trend based on the list of 54 brand-name medications subjected to fail-first protocols as described above. 12 brand-name medications were identified that made up 84% of the total prescription cost and 78% of number of prescriptions for all the brand-name prescriptions identified as subject to fail-first protocols. The select set of 12 prescription medications (Table D-1), due to their likely impact on cost, were used to calculate cost and utilization estimates. The other medications on one or more fail-first protocol lists, due to their low cost per prescription

or low utilization, were expected to have minimal impact and were not included in the cost and utilization calculations.

3. Postmandate Utilization of Pain Medications: For the select set of medications CHBRP determined postmandate utilization rates (prescriptions per 1,000 enrollees) by using Milliman's 2009 Prescription Drug Rating Model¹⁶, based on a loosely managed health plan (i.e., little or no utilization management, including no fail-first requirements). CHBRP trended the utilization rates to 2010 using a 5% annual trend rate and adjusted for area (California). For medications that are prescribed for pain and for purposes other than pain management, CHBRP multiplied the utilization rates by the expected percentage of prescriptions for pain (e.g., 15%) based on content expert opinion.
4. Postmandate PMPM Costs: Using the average costs per prescription from 2. and the utilization rates from 3., CHBRP calculated the postmandate per member per month (PMPM) costs. These PMPM costs are based on utilization rates and average cost per prescription representative of programs with no fail-first protocols.
5. Fail-First Protocol Estimation of Utilization Shift Alternative/Generic and Brand-Names: Based on assumptions drawn from maximum prescription fill rates for medications with generics of the same class (i.e., 50%) and failure rates of fail-first medications without generics of the same class (Milliman's Formulary Analysis Tool), CHBRP reduced the utilization rates of the select set of prescription medications to reflect use of the fail-first protocols. The reduction in utilization of these prescription medications was assumed to result in an increase in the required alternative or generic pain medication required prior to medications on fail-first protocol lists.
6. Premandate PMPM Costs: Using the utilization rates from 3. and the average costs per prescription from 2., CHBRP calculated the PMPM costs including the effects of fail-first protocols (premandate PMPM costs).
7. Change to PMPM Costs Due to AB 1826: The difference between 4. and 6. as CHBRP's estimate of the expected increase in PMPM costs due to AB 1826.
8. Adjustment for PMPM Costs Based on Carrier Enrollee Number and Outpatient Pharmacy Benefit Coverage Subject to Fail-First Protocols: CHBRP weighted the carrier-specific increases in PMPM cost by number of enrollees with outpatient pharmacy benefits subjected to fail-first protocols to produce the average aggregate increases in PMPM by market segment for the private sector programs. If carriers had no enrollees or only a percentage of enrollees with outpatient pharmacy benefits subjected to fail-first protocols, this was adjusted for in the PMPM costs.
9. Cost Model Assumptions Specific for Public Purchasers: For Medi-Cal HMOs and the MRMIB programs (AIM, Healthy Families), CHBRP surveyed the DMHC-regulated

¹⁶ The Prescription Drug Rating Model is claim data from contributors to Milliman's Health Cost Guidelines database and MedStat; MediSpan is used help determine Brand/Generic, Therapy Class, Maintenance, and other classifications.

health plans that have the largest share of Medi-Cal HMO enrollees and MRMIB program beneficiaries as enrollees. Responses indicated that enrollees in publicly funded DMHC-regulated plans have outpatient pharmacy benefit coverage for pain medications that is highly variable, in terms of whether the benefit coverage is subject to fail-first protocols. Responses indicated that some enrollees have benefit coverage not subject to any fail-first protocol and that the variation was on a plan contract by plan contract or policy by policy basis. Among enrollees with benefit coverage subject to one or more fail-first protocols, variation was also present. Due to lack of pharmacy claims data specific to the Medi-Cal HMO enrollees and MRMIB plan enrollees and a paucity of information on formulary or fail-first protocol lists, specific assumptions were made to estimate the impact of AB 1826 on these public purchasers of DHMC-regulated health insurance. For health plans that responded no outpatient pharmacy benefit subjected to fail-first protocols, we assumed no change. For carriers that responded some pain medications subject to fail-first, we used the highest change in expenditures of the private sector health plans/insurers. The reasoning for this was based on information that the public programs are considered to apply very stringent fail-first protocols (Wallack, 2004; content expert opinion). For carriers that responded *all* pain medications were subject to fail-first protocols, we modeled *all* 12 representative brand-name medications subject to fail-first protocols (based on private insurer responses) adjusting for the respective public purchasers number of affected enrollees.

Table D-1. Select Set of Prescription Medications Present on at Least One List of Fail-First Protocol List (a)

Prescription Medication (Brand name/generic)	Annual Cost(b)	Number of Prescriptions per 1,000 enrollees per year
OXYCONTIN/oxycodone	\$3,915,000	6.4
CYMBALTA/duloxetine	\$1,412,000	17.4
LYRICA/pregabalin	\$914,000	6.0
CELEBREX/celecoxib	\$825,000	6.1
FENTORA/fentanyl	\$459,000	0.2
EFFEXOR XR/venlafaxine	\$432,000	19.3
DURAGESIC/fentanyl	\$336,000	0.4
KADIAN/morphine	\$318,000	0.7
AVINZA/morphine	\$258,000	0.7
ARTHROTEC 75/diclofenac/misoprostol	\$45,000	0.4
ARTHROTEC 50/diclofenac/misoprostol	\$22,000	0.1
EFFEXOR/venlafaxine	\$1,000	0.05

(a) Based on MedStat 2009 data, adjusted to 2010

(b) Cost is to carrier and patient for covered medications.

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. For more on the processes for submitting information to CHBRP for review and consideration please visit:

http://www.chbrp.org/recent_requests/index.php.

The following information was submitted by the Office of Assembly Member Jared Huffman in March, 2010.

American Pain Foundation. *Access to Pain Care: Key Messages*. September, 2009. Available at: <http://www.painfoundation.org/take-action/popan/documents/talking-points-pain-care-advocacy.pdf>. Accessed on March 22, 2010.

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Women in Pain. *Stop the Practice of Step Therapy—Fail First By Insurers*. Petition at the 2nd Annual Women in Pain Conference. September 18, 2009.

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

Each of the following prescription pain 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)

The following table includes prescription pain medications on more than one fail-first protocol list (but not necessarily the same lists).

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 Prohibited by AB 1826
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 Non-Steroidal 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 Prohibited by AB 1826
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 contra-indication to the use of two of the following agents: anti-depressants, 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, 2010..

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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