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Title

Analysis of California Assembly Bill 374: Step Therapy Coverage

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Analysis of California Assembly Bill AB 374 Step Therapy Coverage

A Report to the 2015–2016 California State Legislature

April 21, 2015



Key Findings:

Analysis of California Assembly Bill AB 374 Step Therapy Coverage

Summary to the 2015–2016 California State Legislature, April 2015



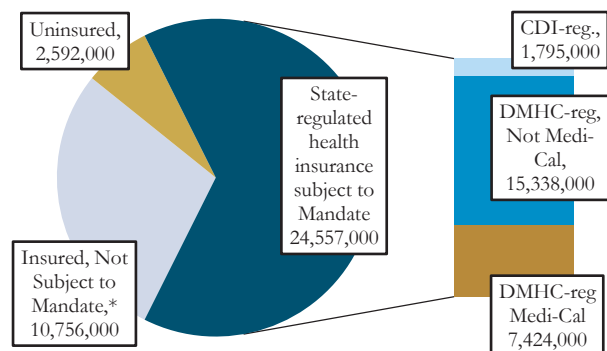
BACKGROUND

Step therapy protocols (STPs), which are also known as “fail first” protocols, are utilization management techniques applied to an enrollee’s outpatient prescription drug (OPD) benefit. When a drug subject to an STP is prescribed, the STP offers drug coverage, but requires that the enrollee try and fail one or more alternatives before coverage becomes available for the initially prescribed drug. STPs are frequently applied to expensive drugs, requiring use of less expensive substitutes. STP overrides may be requested. STP override requests generally require the prescriber to submit documentation as to why the override is justified.

BILL SUMMARY

In 2016, as noted in Figure 1, AB 374 would apply to the health insurance of 24.6 million Californians (all enrollees with health insurance potentially subject to state-level benefit mandates).

Figure 1. Health Insurance in CA and AB 374



*Federally regulated health insurance, such as Medicare, veterans, or self-insured plans.

Source: California Health Benefit Review Program, 2015.

AB 374 would require DMHC-regulated health plans and CDI-regulated policies that include both an outpatient

AT A GLANCE

Assembly Bill AB 374 (introduced February 2015) would require compliant override procedures when step therapy protocols (STPs) are applicable to an outpatient prescription drug (OPD) benefit.

- **Enrollees covered.** In 2016, approximately 24.6 million Californians will have state-regulated health insurance subject to AB 374.
- **EHBs.** AB 374 would not exceed EHBs, because the mandate is applicable to particular terms or conditions but does not require new benefit coverage.
- **Medical effectiveness.** CHBRP found insufficient evidence to conclude whether STP overrides affect health outcomes. The absence of evidence is not evidence of no effect.
- **Benefit coverage.** The terms and conditions of 27% of enrollees would change to become fully compliant with AB 374’s override approval criteria.
- **Utilization.** Filled prescriptions would be unchanged, although use of initially prescribed drugs would increase and use of STP-required drugs would decrease. The change would affect expenditures because initially prescribed drugs are frequently more expensive than STP-required drugs.
- **Impact on expenditures.** CHBRP estimates that premium impacts related to an increase in approved override requests would be 0.008%.
- **Public Health.** Because there is insufficient evidence to link approved overrides and health outcomes, the public health impact is unknown. Note: insufficient evidence is not evidence of no effect.

prescription drug (OPD) benefit and step therapy protocols (STPs) to grant step therapy overrides in five circumstances. The override is to be granted when the prescriber documents any/all of the following: that the STP-required drug 1) is contraindicated or likely to cause an adverse reaction (mental or physical harm) in the patient, 2) is expected to be ineffective due to the patient’s mental or physical characteristics, 3) is not medically appropriate, 4) is not FDA approved as a treatment for the patient’s condition; that 5) the patient is stable on the initially prescribed drug. AB 374 makes one broad exception in regard to these criteria, as AB 374 would not prohibit STPs from requiring use of an AB rated generic¹ before covering the initially prescribed drug. AB 374 also specifies that it would not affect cost-sharing terms and conditions.

IMPACT OF AB 374

CHBRP has found a wide variation in the presence of STPs for Californians enrolled in state-regulated health insurance. Not all enrollees have an OPD benefit and the presence of STPs varies. Approximately 3.0% of enrollees have no OPD benefit and 34.4% have an OPD benefit that is not subject to any STPs. Among the remaining 62.6% of enrollees, an OPD benefit is present and the number of drugs subject to STPs varies widely, from two to more than 100.

All enrollees with an OPD benefit subject to STPs have an override procedure. Postmandate, the terms of the override procedures would change for approximately 27% enrollees. Postmandate, AB 374 would alter the override criteria for some enrollees with an OPD benefit subject to STPs. AB 374 would require override approval when the prescriber documents that the STP-required drug is not medically appropriate. Currently, the override process might consider listing of the STP-required drug as proof of the drug being medically appropriate, but AB 734 would focus the request on prescriber documentation regarding medical appropriateness. The result would be an increase in approved override requests. Post mandate, AB 374

¹ The FDA considers category “A” drug products to be therapeutically equivalent to other pharmaceutically equivalent products and subcategory “AB” drug products to be those for which actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence. See FDA website www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm accessed on February 27, 2015.

would also prohibit consideration of information other than FDA approval when a prescriber requests an override and documents that the STP-required drug is not FDA-approved for the enrollee’s condition. Currently, the override process may consider other information (such as research literature indicating a common, safe and effective off-label use of the STP-required drug), but AB 374 would focus the request on FDA-approval. The result would be an increase in approved override requests.

CHBRP has assumed that the total number of filled prescriptions would not change, postmandate, because STPs offer coverage for an alternate drug. However, postmandate, STP overrides will increase from 8.7 per 1,000 enrollees to 9.0. CHBRP has assumed that additional approved override requests would decrease use of the STP-required drug, which is generally a less expensive drug and increase use of the initially prescribed drug (both drugs being in the same drug class). Expenditure impacts would be as indicated in Figure 2.

Figure 2. Expenditure Impacts of AB 374

Employer premium expenditures	\$5,013,000
Individual premium expenditures	\$2,948,000
Employee premium expenditures	\$1,260,000
Out-of-pocket expenses for covered benefits	\$1,614,000
Enrollee expenses for noncovered benefits	\$0
Net Change	\$10,835,000

MEDICAL EFFECTIVENESS AND PUBLIC HEALTH IMPACTS

CHBRP finds insufficient evidence to conclude that use of STPs or override protocols as described in AB 374 would change health outcomes. Therefore, the public health impact in the first year, postmandate, is unknown. Please note that the absence of evidence is not “evidence of no effect.” It is possible that an impact—positive or negative—could result, but current evidence is insufficient to provide an estimate.

A Report to the California State Legislature

Analysis of California Assembly Bill AB 374 Step Therapy Coverage

April 21, 2015

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ABOUT CHBRP

The California Health Benefits Review Program (CHBRP) was established in 2002 to provide the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates and repeals, per its authorizing statute. The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff in the University of California's Office of the President supports a task force of faculty and research staff from several campuses of the University of California to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact, and content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, as well as all CHBRP reports and publications, is available at www.chbrp.org.

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Table 1. AB 374 Impacts on Benefit Coverage, Utilization, and Cost, 2015

	Premandate	Postmandate	Increase/ Decrease	Change Postmandate
Benefit coverage				
Total enrollees with health insurance subject to state benefit mandates (a)	24,557,000	24,557,000	0%	0%
Total enrollees with health insurance subject to AB 374	24,557,000	24,557,000	0%	0%
Number of enrollees with an outpatient prescription drug benefit compliant with AB 374	17,804,667	24,557,000	6,752,333	38%
Percentage of enrollees with coverage for outpatient prescription drug benefit compliant with AB 374	73%	100%	27%	38%
Utilization and cost				
Annual step therapy overrides granted per 1,000 enrollees	8.7	9.0	0.3	4%
Average per-unit cost of initially-prescribed drug subject to STP	\$481.47	\$481.47	\$0.00	0%
Expenditures				
<u>Premium expenditures by payer</u>				
Private Employers for group insurance	\$58,393,205,000	\$58,396,934,000	\$3,729,000	0.0064%
CalPERS HMO employer expenditures (b)	\$4,391,552,000	\$4,391,867,000	\$315,000	0.0072%
Medi-Cal managed care plan expenditures	\$17,667,731,000	\$17,668,700,000	\$969,000	0.0055%
Enrollees for individually purchased insurance	\$21,319,735,000	\$21,322,683,000	\$2,948,000	0.0138%
Individually purchased—outside exchange	\$8,581,274,000	\$8,582,312,000	\$1,038,000	0.0121%
Individually purchased—Covered California	\$12,738,461,000	\$12,740,371,000	\$1,910,000	0.0150%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (a)	\$18,703,917,000	\$18,705,177,000	\$1,260,000	0.0067%
<u>Enrollee expenses (d)</u>				
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$15,510,004,000	\$15,511,618,000	\$1,614,000	0.0104%
Total expenditures	\$135,986,144,000	\$135,996,979,000	\$10,835,000	0.0080%

Source: California Health Benefits Review Program, 2015.

Notes: (a) This population includes persons with privately funded (including Covered California) and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans) health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employer-sponsored health insurance.

(b) Of the increase in CalPERS employer expenditures, about 55.4% or \$174,510, would be state expenditures for CalPERS members who are state employees, state retirees, or their dependents. This percentage reflects the share of enrollees in CalPERS HMOs as of September 30, 2013. CHBRP assumes the same ratio in 2015.

(c) Enrollee premium expenditures include contributions to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care.

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

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

POLICY CONTEXT

The California Assembly Committee on Health has requested² that the California Health Benefits Review Program (CHBRP)³ conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 374, a bill that would establish requirements around override procedures for step therapy protocols applicable to outpatient prescription drug coverage.

It is important to note that CHBRP's analysis of proposal benefit mandate bills typically address the incremental effects of the proposed bills—specifically, how the proposed legislation would impact benefit coverage, utilization, costs, and public health. CHBRP's estimates of these incremental effects are presented in this report.⁴

If enacted, AB 374 would affect the health insurance of approximately 24.6 million enrollees (65% all Californians). This represents 100% of the 24.6 million Californians who will have health insurance regulated by the state⁵ that may be subject to any state health benefit mandate law.^{6,7} Specifically, the Department of Managed Health Care (DMHC) regulated plans and/or the California Department of Insurance (CDI) regulated policies, would be subject to AB 374.

Bill-Specific Analysis of AB 374 Step Therapy Coverage

The coverage enrollees have for outpatient prescription drugs (OPDs) may be subject to step therapy protocols (STPs). When a drug subject to an STP is prescribed, the STP offers drug coverage, but requires that the enrollee try and fail (one or more alternatives before coverage becomes available for the initially prescribed drug). Override procedures allow the prescriber to request an exemption from the STP for a particular patient. AB 374 would require that overrides be granted by the enrollee's plan or insurer when the prescriber documents specified situations.

Bill Language

AB 374 would require DMHC-regulated health plans and CDI-regulated policies that include both an outpatient prescription drug (OPD) benefit and step therapy protocols (STPs) to grant step therapy overrides in five circumstances. The override is to be granted when the prescriber documents any/all of the following: that the STP-required drug 1) is contraindicated or likely to cause an adverse reaction (mental or physical harm) in the patient; 2) is expected to be ineffective due to the patient's mental or physical characteristics; 3) is not medically appropriate; 4) is not FDA approved as a treatment for the patient's condition; that 5) the patient is stable on the initially prescribed drug. AB 374 make one broad exception in regard to these criteria, as AB 374 would not prohibit STPs from requiring use of an AB rate

² February 23, 2015, available at www.chbrp.org.

³ CHBRP is authorized to review legislation affecting health insurance regulated by the state. CHBRP's authorizing statute is available at www.chbrp.org/docs/authorizing_statute.pdf.

⁴ For CHBRP's technical approach to developing estimates, please see Appendix C.

⁵ State benefit mandates apply to a subset of health insurance in California, those regulated by one of California's two health insurance regulators: the California Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI).

⁶ CHBRP's estimates of the source of health insurance available at: www.chbrp.org/other_publications/index.php.

⁷ Of the rest of the state's population, a portion will be uninsured (and therefore will have no health insurance subject to any benefit mandate), and another portion will have health insurance subject to other state laws or only to federal laws.

generic⁸ before covering the initially prescribed drug. AB 374 would not affect cost-sharing terms and condition and that it would not require coverage of drugs not on the plan/policy formulary.

The full text of AB 374 can be found in Appendix A.

Interaction With Existing Requirements

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

State Requirements

California law and regulations

DMHC-regulated plans are required to respond to authorization requests, such as authorization for a step therapy override, within 2 business days.⁹

CDI-regulated insurers are request to respond to urgent authorization requests within 72 hours and to other requests within five business days.¹⁰

CHBRP is aware of a number of current health insurance benefit mandates that might interact with compliance to AB 374, although none would do so directly. Examples are listed by Health and Safety Code (H&S), with Insurance Code (IC) when applicable:

- *H&S1367.21/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.* Mandate to cover prescription drugs if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition.
- *H&S 1367.22; prescription drug benefits; medically appropriate alternatives.* Mandate to covers prescription drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition.
- *H&S 1367.24; authorization for nonformulary prescription drugs.* Mandate to review coverage for nonformulary drugs.

⁸ The FDA considers category “A” drug products to be therapeutically equivalent to other pharmaceutically equivalent products and subcategory “AB” drug products to be those for which actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence. See FDA website www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm. Accessed February 27, 2015.

⁹ H&S Code 1367.241(a) and 1367.241 (b).

¹⁰ Insurance Code 10123.135(h).

Similar requirements in other states

Five states, Connecticut, Kentucky, Louisiana, Maryland, and Mississippi, have legislation limiting use of step therapy protocols for all or specific drugs.

CHBRP is unaware of a state that places requirements on STP override procedures, as AB 374 would do.

Federal Requirements

Affordable Care Act

The Affordable Care Act (ACA) has profoundly impacted health insurance, its financing, and regulation in California. As of January 2014, an expansion of the Medi-Cal program, California's Medicaid program,¹¹ and the availability of subsidized and unsubsidized health insurance purchased through Covered California,¹² the state's health insurance marketplace,¹³ significantly increased the number of people with health insurance in California.

A number of ACA provisions could interact with a mandate's requirements in general?, including the requirement for certain health insurance to cover "essential health benefits" (EHBs),¹⁴ have the potential to or do interact with state benefit mandates.

Essential health benefits

State health insurance marketplaces, such as Covered California, are responsible for certifying and selling qualified health plans (QHPs) in the small-group and individual markets.¹⁵ Health insurance offered in Covered California is required to at least meet the minimum standard of benefits as defined by the ACA as essential health benefits (EHBs), and available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.^{16,17}

States may require such QHPs to offer benefits that exceed EHBs.¹⁸ However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the

¹¹ The Medicaid expansion, which California will pursue, is to 133% of the federal poverty level (FPL)—138% with a 5% income disregard.

¹² The California Health Benefits Exchange (Covered California) Authorizing Statute is available here: www.healthexchange.ca.gov/Documents/California%20Codes%20Governing%20the%20Health%20Benefit%20Exchange.pdf.

¹³ The ACA requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces.

¹⁴ The ACA requires nongrandfathered small-group and individual market health insurance—including, but not limited to, QHPs sold in Covered California—to cover 10 specified categories of essential health benefits (EHBs). Resources on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.

¹⁵ Effective 2017, states may allow large-group purchasing through health insurance marketplaces, which may make some large-group plans and policies subject to the requirement to cover EHBs [ACA Section 1312(f)(2)(B)].

¹⁶ H&SC Section 1367.005; IC Section 10112.27.

¹⁷ The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs by selecting one of a set of specified benchmark plan options. HHS Notice of Benefit and Payment Parameters for 2016. Final Rule. Federal Register, Vol. 80, No. 39. February 27, 2015. Available at: www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf.

¹⁸ ACA Section 1311(d)(3).

purchaser directly or by paying the QHP.¹⁹ On the other hand, “state rules related to provider types, cost-sharing, or reimbursement methods” would *not meet* the definition of state benefit mandates that could exceed EHBs.²⁰

AB 374 and EHBs

AB 374’s requirements regarding step therapy protocol overrides would alter the terms and conditions of benefit coverage, but would not alter benefit coverage requirements. Therefore, AB 374 would not exceed EHBs, and therefore would not trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in qualified health plans (QHPs)²¹ in Covered California.

¹⁹ As laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the a state’s EHBs and there would be no requirement that the state defray the costs of those state mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost. Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

²⁰ Essential Health Benefits. Final Rule. A state’s health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.

²¹ In California, QHPs are nongrandfathered small-group and individual market DMHC-regulated plans and CDI-regulated policies sold in Covered California, the state’s online marketplace.

BACKGROUND ON STEP THERAPY PROTOCOLS AND OVERRIDES

This section provides context for the consideration of the impacts of AB 374 by defining step therapy protocols (STP) and STP override procedures.

Step Therapy Protocols (STPs)

Step therapy or “fail-first” protocols are one of several utilization management techniques²² applied to prescription drugs on health plan and insurer formularies²³ to control costs and manage safety. Only prescription drugs listed on the formulary are covered by insurance.²⁴ STPs, when implemented by a payer (i.e., commercial health plan or insurer, Medicare, Medicaid or self-insured employer) require an enrollee to try and fail one or more STP-required drugs prior to receiving coverage for the initially prescribed drug. According to the Pharmacy Benefits Management Institute, step therapy protocols usually recommend starting with a drug that is less expensive and/or has more “post-marketing safety experience” (PBMI, 2015). Additionally, STPs sometimes require starting with a less potent drug or dosage, perhaps with fewer side effects, and graduating to more potent drugs as necessary (e.g., from prescription Motrin to Oxycontin to treat pain).

Generally, more expensive drugs are used when the patient fails to respond to the STP-required drug (PBMI, 2015). In many instances, the first step of the STP requires use of a generic drug before “stepping up” to the more costly drug. AB 374 would not alter STPs that require a patient to try an AB-rated generic equivalent drug²⁵ prior to covering the initially prescribed drug.

Patients may learn that an initially prescribed drug is subject to a STP through a process called “step edit” or “online edit” wherein a prescription drug is electronically reviewed at the point-of-service (pharmacy) when submitted for payment authorization. The step-edit determines in real time whether a patient already used the STP-required drug and so is eligible for coverage for the initially-prescribed medication. If coverage for the initially prescribed drug is declined under the STP, a pharmacist may substitute the AB-rated generic equivalent, if appropriate.²⁶ Alternatively, the prescriber may either reissue the prescription for the STP-required drug or appeal the decision directly to the health plan or insurer (requesting approval for a STP override). A patient always has the option to purchase the initially-prescribed drug by paying the full cost out of pocket.

²² Other utilization management strategies used by insurance carriers to manage the cost or safety of prescription drugs include: prior authorization (which requires provider documentation of medical need for approval of coverage for some prescription drugs, treatments, or services); age limits; quantity limits; gender limits; copayments/coinsurance; and prescription drug tiers (which increase enrollee contributions for more costly prescription drugs classified in higher tiers).

²³ A formulary is an insurance carrier’s list of preferred drugs that are covered by the plan or policy, usually with some form of enrollee cost-sharing.

²⁴ Unless an exception is granted via prior authorization (another utilization management method).

²⁵ The FDA considers category “A” drug products to be therapeutically equivalent to other pharmaceutically equivalent products and subcategory “AB” drug products to be those for which actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence. See FDA website www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm. Accessed February 27, 2015.

²⁶ California Business & Professions Code, Chapter 9, Division 2, Regulation 4073.

Several examples of STPs are listed, below. include a requirement for a patient with:

- An enrollee with rheumatoid arthritis initially prescribed Actemra might be required, by an STP to try and fail on Humira, Enbrel (branded drugs), methotrexate, hydroxychloroquine or sulfasalazine before accessing coverage for Actemra.
- An enrollee with constipation initially prescribed Amitiza might be required, by an STP, to try and fail an over-the-counter laxative before accessing coverage for Amitiza.
- An enrollee with multiple sclerosis initially prescribed Aubagio might be required, by an STP, to try and fail Copaxone or Rebif (branded drugs) before accessing coverage for Aubagio.

Step Therapy Override Procedure

Step therapy overrides follow a procedure by which a prescriber submits clinical documentation to the health plan or insurer documenting why an enrollee should be allowed should skip one or more of an STP's steps. Reasons prescribers use to justify such an STP override include:

- the enrollee has already tried STP-required drug(s) unsuccessfully, or
- the STP-required drug is contraindicated for that enrollee due to drug-drug interactions, drug-disease interactions, or drug allergy or intolerance.

Step therapy override requests may take several days to be reviewed by the health plan or insurer.^{27,28}

Enrollees whose STP override requests are denied may purchase the initially-prescribed drug by paying out of pocket the full retail price or may purchase the STP-required drug and only pay the insurer's required co-pay/co-insurance. If the carrier grants the STP override, the enrollee will pay the designated copayment/coinsurance for that prescription.

²⁷ DMHC-regulated plans are required to respond issue authorization determinations within 2 business days. H&S Code 1367.241(a) and 1367.241 (b).

²⁸ CDI-regulated insurers are required to issue nonurgent authorization determinations within 5 business days. Urgent determinations must be made within 72 hours or less. Insurance Code 10123.135(h).

MEDICAL EFFECTIVENESS

Research Approach and Methods

Analytic Approach

As discussed in the *Policy Context* section, AB 374 would require DMHC-regulated health plans and CDI-regulated policies that include both an outpatient prescription drug (OPD) benefit and step therapy protocols (STP) to grant step therapy overrides in five circumstances. The medical effectiveness review assesses evidence regarding the following two topics:

- 1) The impact of STP on health outcomes. In particular, the review focuses on whether there is evidence that STPs have adverse effects on health outcomes; and
- 2) The impact of override procedures on health outcomes.

Studies of STPs and override procedures for drugs were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, and Business Source Complete. The following Web sites were also searched: the Agency for Healthcare Research and Quality, International Network of Agencies for Health Technology Assessment, National Health Service Centre for Reviews and Dissemination, National Institute for Health and Clinical Excellence, and the Scottish Intercollegiate Guideline Network. Because CHBRP medical effectiveness review had previously conducted thorough literature searches on STPs in 2013 for AB 899, the search was limited to studies published from January 2013 to present. The literature search on override procedures included abstracts of studies published in English from January 2005 to present. Of the 248 articles found in the literature review, 14 were reviewed for potential inclusion in this report on AB 374, and 2 studies were included in the medical effectiveness review for this report. The medical effectiveness review also presents findings from the 13 studies that were previously identified in the 2013 CHBRP AB 899 report.

Methodological Considerations

Of the peer-reviewed studies CHBRP identified on the impact of STPs, none were randomized controlled trials (RCTs), which are considered the “gold standard” of research. Most were nonrandomized studies with comparison groups that compared persons whose health plan or health insurance policy had a STP to persons whose health plan or health insurance policy did not implement STPs. In some studies, persons in the intervention group (i.e., persons with health insurance subject to the STP) and the comparison group did not have similar demographic and socio-economic characteristics prior to implementation of the STP (see, for example, Suehs et al., 2013). Although the authors of some studies attempted to use statistical methods to adjust for differences between the groups prior to the intervention, findings from some of the studies may have been affected by these differences. Seven of the 15 studies were wholly or partially funded by pharmaceutical companies. A systematic review of studies of the impact of industry sponsorship on research findings concluded that sponsorship of studies of drugs or medical devices by manufacturers is associated with results and conclusions that are more favorable to their products (Lundh et al., 2012). Sponsorship may also affect findings from studies of STPs aimed at reducing use of a manufacturer’s products.

Outcomes Assessed of Included Studies

Step Therapy Protocols

CHBRP identified only one study on the impact of STPs on health outcomes. Momani and colleagues (2002) evaluated the impact of a STP for non-steroidal anti-inflammatory drugs (NSAIDs) implemented by West Virginia's Medicaid program on health-related quality of life among persons with chronic pain (Momani et al., 2002).

Given the limited evidence on effects of STP on health outcomes, CHBRP reviewed studies that assess the effects of STP and override procedures on utilization of drugs (e.g., number of prescriptions dispensed and days' supply of drugs²⁹) and other medical services (e.g., emergency department visits). Some enrollees who are subject to STP may not obtain prescriptions for their medication or may delay or discontinue treatment. Treatment may not be initiated because an enrollee may decide not to fill the prescription, or because the enrollee's pharmacist and/or physician does not obtain authorization for the initially prescribed medication. If STPs are associated with a lower rates of treatment, this protocol may be associated with poorer health outcomes. Granting an override request may mitigate these adverse outcomes whereby enrollees would be authorized to access to the initially prescribed medication.

Override Procedures

CHBRP found no studies on the impact of override procedures on health outcomes or on utilization of prescription drugs.

Overall Study Findings

Impact of Step Therapy Protocols

- One study that directly examine the impact of STPs on a health outcome found that STPs for NSAIDs had no statistically significant effect on quality of life among persons with chronic pain. CHBRP concludes that there is *insufficient evidence* to determine whether STPs directly affect health outcomes. The absence of evidence is not evidence of no effect. It is an indication that the impact of STPs on health outcomes is unknown.
- Findings from studies of the impact of STPs on rates of initiation, continuation, and day supply of drugs are *ambiguous*.
- Finding from studies on the impact of STP on rates of hospital admission, emergency department visits, and outpatient visits are *ambiguous* across classes of drugs..

Impact of Override Procedures

- CHBRP found no studies on the impact of step therapy overrides. Due to insufficient evidence, CHBRP concludes that impact of override procedures is unknown. The absence of evidence is not evidence of no effect. It is an indication that the impact of step therapy overrides is unknown.

²⁹ Days' supply measures the number of days or percentage of days within a specified time period for which doses of a drug have been dispensed. For drugs prescribed for daily use, researchers often use days' supply as a proxy for adherence to recommended treatment.

Figure 3. Summary of Medical Effectiveness Findings

Treatment	Conclusion
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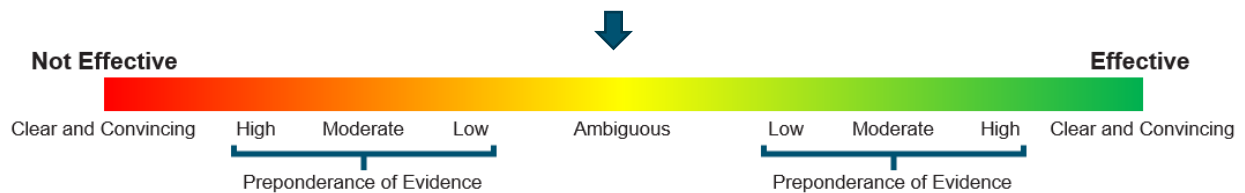
Step Therapy Protocols -- Health Outcomes

There is insufficient evidence to determine whether Step Therapy Protocols (STP) directly affect health outcomes. The absence of evidence is not evidence of no effect. It is an indication that the impact of step therapy is unknown.

Treatment	Conclusion
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Step Therapy Protocols—Initiation, continuation, and day supply of drugs

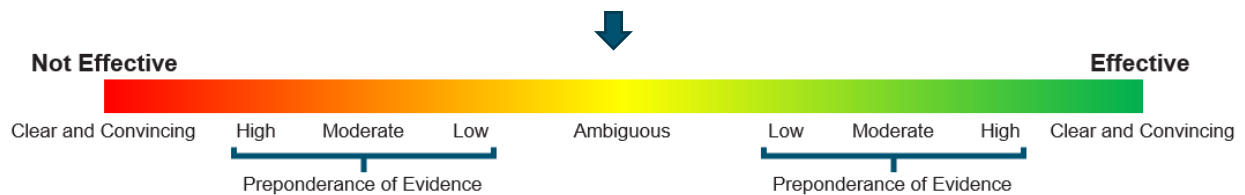
Findings from studies of the impact of STPs on rates of initiation, continuation, and day supply of drugs are ambiguous.



Treatment	Conclusion
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Step Therapy Protocols—Health Services Utilization

Findings from studies on the impact of STP on hospital admission, emergency department visits, and outpatient visits are ambiguous.



Treatment

Conclusion

Override Procedures

There is insufficient evidence to determine whether override procedures directly affect health outcomes and utilization of drugs or health services. The absence of evidence is not evidence of no effect. It is an indication that the impact of step therapy is unknown.

Characteristics of Included Studies

CHBRP identified 15 studies of the impact of STPs. The studies CHBRP identified addressed STPs for the following drug classes: antidepressants, antihypertensives, antipsychotics and anticonvulsants, nonsteroidal anti-inflammatory drugs (NSAIDs) to reduce inflammation or pain, and proton pump inhibitors to reduce stomach acidity (PPIs). No studies were found that addressed STP or override procedures across all drug classes.

Eight of the 15 studies examined the impact of STPs on persons with private health insurance (Cox et al., 2004; Dunn et al., 2006; Mark et al., 2009, 2010; Motheral et al., 2004; Suehs et al., 2013; Udall et al., 2013; Yokoyama et al., 2007). Seven studies (nine articles) assessed effects on persons enrolled in Medicaid (Delate et al., 2005; Farley et al., 2008; Hartung et al., 2004; Law et al., 2008; Lu et al., 2010; Momani et al., 2002; Smalley et al., 1995; Soumerai et al., 2008; Zhang et al., 2009).

CHBRP found no studies on the impact of override procedures on health outcomes or utilization of drugs.

Studies on the Impact of STPs

Effects on Health Status

There is insufficient evidence to determine whether step therapy protocols directly affect health outcomes. The absence of evidence is not evidence of no effect. It is an indication that the impact of step therapy protocols on health outcomes is unknown. CHBRP identified only one study on the impact of STPs on health outcomes. Momani and colleagues (2002) evaluated the impact of a STP for NSAIDs implemented by West Virginia’s Medicaid program on health-related quality of life among persons with chronic pain. Under this protocol, patients could not obtain coverage for a prescription for a brand-name NSAID unless they had tried at least two classes of generic NSAIDs for at least 2 weeks and failed to attain desired outcomes. Surveys were distributed to Medicaid enrollees under age 65 who had osteoarthritis, rheumatoid arthritis, spondylitis, or chronic pain syndromes. Responses from persons who received prescriptions for generic NSAIDs were compared to persons who received prescriptions for brand-name NSAIDs. The study found no differences between the two groups in any of the domains of health-related quality of life measured, including mobility, walking and bending, hand and finger functioning, tension, and ability to perform self-care and engage in household and social activities.

Effects on Utilization of Initially Prescribed Drug

Evidence suggests that STPs are associated with a decrease in initially prescribed drug use and increase in STP-required drug use. Studies of step therapy protocols that assessed their impact on use of prescription drugs subject to these protocols found that use of these drugs decreased after the STPs were implemented (Delate et al., 2005; Dunn et al., 2006; Farley et al., 2008; Hartung et al., 2004; Law et al., 2008; Mark et al., 2010; Smalley et al., 1995; Soumerai et al., 2008; Suehs et al., 2013; Udall et al., 2013; Yokoyama et al., 2007; Zhang et al., 2009). This finding is not surprising because STPs create financial incentives for enrollees to switch to the plans' authorized prescription medication.

Effects on Initiation, Continuation, and Day Supply of Prescription Medication

Antipsychotic drugs: Studies of the impact of STPs on antipsychotic drugs found higher rates of not initiating, discontinuing, or gaps in antipsychotic drug use in Maine's Medicaid program. The strongest evidence comes from studies that examine the effects of a step therapy protocol implemented by Maine's Medicaid program (Lu et al., 2010) that use an interrupted time series with comparison group design. In 2003, Maine implemented a STP for antipsychotic drugs. Enrollees with bipolar disorder who had not been prescribed an antipsychotic drug previously could not receive coverage for Abilify (aripiprazole) or Zyprexa (olanzapine) unless they had previously tried and failed treatment with Risperdal (risperidone) and either Seroquel (quetiapine) or Geodon (ziprasidone).³⁰ The authors reported that there was a 32% decrease in starting an antipsychotic drug among persons with bipolar disorder 4 months after the STP was instituted.

Two studies have examined the impact of the STP implemented by Maine's Medicaid program on discontinuation of antipsychotic drugs (Soumerai et al., 2008; Zhang et al., 2009). Zhang and colleagues reported that following the implementation of the STP, Maine Medicaid enrollees with bipolar disorder were 2.28 times more likely to discontinue antipsychotic drugs after 30 or more days of treatment than their counterparts in New Hampshire. Similar effects were found for discontinuation after 50 or more days or 250 or more days of treatment. Soumerai and colleagues (2008) investigated the effect of the STP on gaps, switching or augmentation of drugs for Medicaid enrollees with schizophrenia. They found that Maine enrollees with schizophrenia were 1.94 times more likely to experience one of these circumstances.

Although this study did not directly investigate effects on health outcomes, it is plausible that lower rates of initiation and continuation of drugs or gaps in drug use could have adversely affected the mental health of persons with bipolar disorder or schizophrenia because discontinuing drugs for these conditions may exacerbate symptoms.

Antihypertensive drugs: One study found that STPs are associated with higher rates of discontinuing antihypertensive drugs. Mark and colleagues (2009) evaluated a STP for antihypertensive drugs. They examined STPs instituted by two employers that required employees and dependents with hypertension who received coverage through the employers to use certain (first-line or preferred) angiotensin-converting enzyme inhibitors (ACE inhibitors) or angiotensin receptor blocker (ARB) for a specified period of time before using another (second-line) ACE inhibitor or ARB. The authors found that following implementation of the STP, the rate of discontinuation of antihypertensive drugs was larger in the STP group than in the comparison group. Discontinuing antihypertensive drugs may lead to adverse outcomes unless a person can control his or her blood pressure through diet and exercise alone.

³⁰ Persons previously prescribed Abilify or Zyprexa were grandfathered (i.e., not subject to the step therapy protocol).

If not treated, hypertension increases a person's risk of having a stroke or developing heart disease.

Findings regarding effects of days' supply of antihypertensive drugs are ambiguous. Two studies on the impact of STPs on days' supply of antihypertensive drugs reached opposite conclusions. One study found that STP had a small and statistically significant difference in days' supply of antihypertensive drugs (Yokoyama et al., 2007), whereas the other found no difference between persons who were and were not subject to a STP (Mark et al., 2009).

Antidepressant drugs: Findings from two studies of STPs for antidepressant drugs suggest that STPs do not affect the days' supply of drugs dispensed to persons with private insurance (Dunn et al., 2006; Mark et al., 2010).

CHBRP medical effectiveness also reviewed two studies that distributed surveys to enrollees whose physicians prescribed antidepressants, NSAIDs, or PPIs that were subject to STPs. The quality of these studies is low; response rates were 23% and 33% respectively, and sample sizes were small. Motheral and colleagues (2004) reported that 23% of enrollees who were prescribed a drug subject to a STP obtained coverage for the initially prescribed drug and that 29% received a different drug covered by their health plan. Sixteen percent paid out of pocket for the initially prescribed drug. Five percent used an over-the-counter drug in the same therapeutic class. Overall, 17% did not obtain any drug. Cox and colleagues (2004) reported that 10% of enrollees subject to a step therapy protocol for NSAIDs and 13% of enrollees subject to a STP for PPIs did not obtain any drug. The implications of Motheral and colleagues' and Cox and colleagues' studies are further limited, however, because NSAIDs and PPIs are used for a wide range of conditions, some of which can be treated effectively without drugs.

Effects of STPs on Utilization of Other Medical Care

Findings from studies of the impact of STPs on rates of hospital admissions, emergency department visits, and outpatient visits are ambiguous across classes of drugs. Eight studies evaluated the effects of STPs on use of medical services other than drugs. Five of these studies assessed the impact of utilization of medical services for conditions related to the prescription medication that was subject to STPs (Delate et al., 2005; Farley et al., 2008; Mark et al., 2010; Suehs et al., 2013; Udall et al., 2013). Of these five studies, four were retrospective in study design while one study (Delate et al., 2005) implemented an interrupted time-series analyses. Findings from these studies are inconsistent. Udall and colleagues (2013) and Suehs and colleagues (2013) reported on the effects of STP for anticonvulsant medication on outpatient visits among members of a commercial health plan. Among the plan's commercial population aged 18 to 65, the STP for anticonvulsant was associated with an increase in outpatient visits (Udall et al., 2013) while among the plan's Medicare Advantage Prescription Drug members, the STP for anticonvulsant found no difference in outpatient visits (Suehs et al., 2013). Mark and colleagues (2010) reported that a STP for antidepressants was associated with greater numbers of office visits, emergency department (ED) visits, and hospitalizations for mental health conditions. Farley and colleagues (2008) found that a STP for antipsychotics implemented by Georgia's Medicaid program was associated with a decrease in outpatient visits.³¹ Delate and colleagues (2005) found that a Medicaid program's STP for proton pump inhibitors had no effect on expenditures for office visits, ED visits, and hospitalizations for gastrointestinal conditions.

Five studies assessed the impact of STPs on use of medical services for any medical conditions. A study of a STP for antihypertensive drugs reported that the STP was associated with increases in office visits, ED visits, and hospitalizations for all causes (Mark et al., 2009). Two studies of the impact of STPs for NSAIDs on all-cause expenditures for office visits, ED visits, and hospitalizations reached an opposite conclusions (Hartung et al., 2004; Smalley et al., 1995). Hartung and colleagues (2004) found an

³¹ Farley et al., 2008, found that expenditures for outpatient visits increased despite the decrease in the number of outpatient visits and suggested that providers may have been reimbursed more per visit.

increase in expenditures for ED visits and Smalley and colleagues (1995) found no difference in utilization of office visits, ED visits, and hospitalizations. Two studies of a STP for anticonvulsant medication reported that the STP was associated with an increase in physical therapy visits (Suehs et al., 2013; Udall et al., 2013).

Studies on the Impact of Step Therapy Overrides

CHBRP found no studies on the impact of step therapy overrides; therefore, CHBRP concludes that impact of override procedures is unknown. The absence of evidence is not evidence of no effect. It is an indication that the impacts of step therapy overrides is unknown.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

AB 374 would require DMHC-regulated health plans and CDI-regulated policies that include both an outpatient prescription drug (OPD) benefit and step therapy protocols (STPs) to grant step therapy overrides in five circumstances. The override is to be granted when the prescriber documents any/all of the following: that the STP-required drug 1) is contraindicated or likely to cause an adverse reaction (mental or physical harm) in the patient, 2) is expected to be ineffective due to the patient's mental or physical characteristics, 3) is not medically appropriate, 4) is not FDA approved as a treatment for the patient's condition; that 5) the patient is stable on the initially prescribed drug. AB 374 make one broad exception in regard to these criteria, as AB 374 would not prohibit STPs from requiring use of an AB rate generic³² before covering the initially prescribed drug. AB 374 would not affect cost-sharing terms and condition and that it would not require coverage of drugs not on the plan/policy formulary.

CHBRP assessed coverage, utilization, and cost impacts of AB 374. CHBRP assumed that the total number of prescriptions written and filled will remain constant, pre- and post-mandate.³³ This assumption additionally holds as the literature suggested that STP might affect overall prescribing, but AB 374 does not eliminate STP where it already exists. As an approach for this report, CHBRP focuses the analysis on STP that discourage use of the more expensive drug before trying the less expensive alternative (see *Background* for greater detail). CHBRP assumes that where STP exists, an override would move a patient from the on-average less expensive STP-required drug in the same drug class to the generally more expensive initially prescribed drug. It is important also to note that AB 374 does not require DMHC-regulated plans or CDI-regulated policies to either offer an outpatient prescription drug (OPD) benefit, nor does AB 374 prohibit STPs. Rather, for those enrollees with DMHC-regulated plans or CDI-regulated policies that already have both drug coverage and STP in place, AB 374 would require that the step therapy override procedures be present and that override requests be granted when specified criteria are met and documented by the prescriber.

This section reports the potential incremental impact of AB 374 on estimated baseline benefit coverage, utilization, and overall cost. For further details on the underlying data sources and methods, please see Appendix C.

Benefit Coverage

Premandate (Baseline) Benefit Coverage

Current benefit coverage was determined by a survey of the seven largest providers of health insurance in California. Responses to this survey represent:

- 91.59% of enrollees in the privately funded, DMHC-regulated market,
- 64.59% of enrollees in the CDI-regulated market; and
- 87.30% of enrollees in the privately funded market subject to state mandates.

³² The FDA considers category "A" drug products to be therapeutically equivalent to other pharmaceutically equivalent products and subcategory "AB" drug products to be those for which actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence. See FDA website www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm. Accessed on February 27, 2015.

³³ Personal communication with content expert Debbie Stern on March 12, 2015.

Enrollees and outpatient prescription drug benefits, with and without step therapy protocols

As noted in Table 2, not all enrollees have an OPD benefit and the presence of STPs varies. Approximately 3.0% of enrollees have no OPD benefit and 34.4% have an OPD benefit that is not subject to any STPs. Among the remaining 62.6% of enrollees, an OPD benefit is present and the number of drugs subject to STPs varies widely, from two to more than 100. CHBRP assumes that all enrollees in with an OPD benefit subject to STPs are able to request an override.

Table 2. Outpatient Prescription Drug Benefits and Step Therapy Protocols by Percent of Enrollees

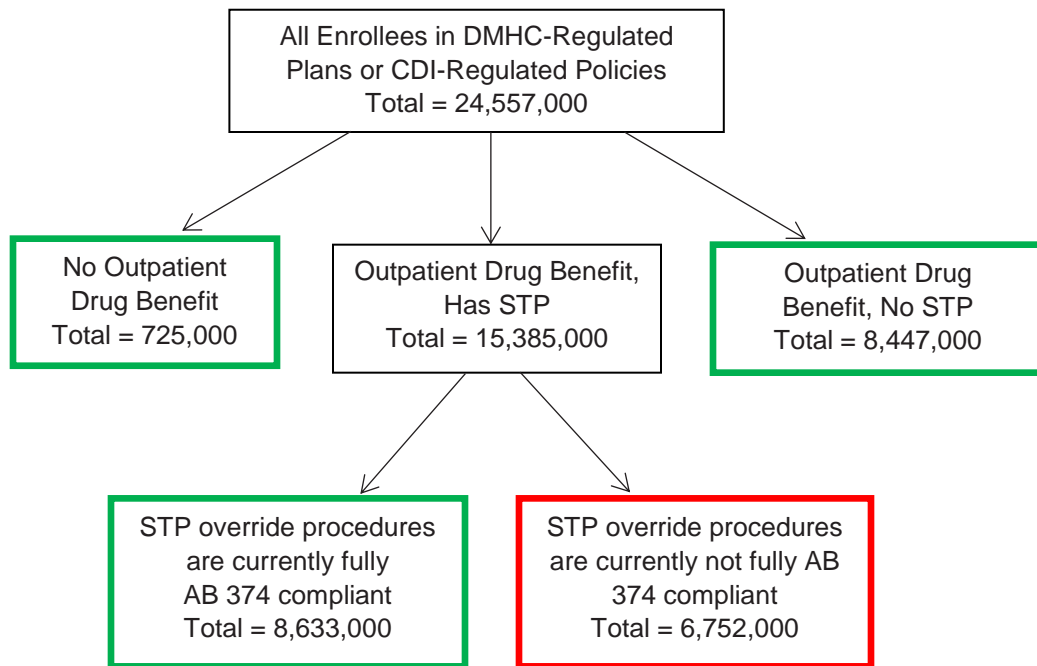
Outpatient Prescription Drug (OPD) Benefit	% of All Enrollees
Enrollees with no OPD	3.0%
Enrollees with OPD—no drug subject to STP	34.4%
Enrollees with OPD—unknown number of drugs subject to STP	19.2%
Enrollees with OPD—2–20 drugs subject to STP	21.4%
Enrollees with OPD—21–100 drugs subject to STP	5.5%
Enrollees with OPD—more than 100 drugs subject to STP	16.5%
Total enrollees in all DMHC-regulated plans or CDI-regulated policies	100.0%

Source: CHBRP, 2015.

Key: OPD = outpatient prescription drug; STP = step therapy protocol.

As noted in Figure 4, benefit coverage is fully compliant with AB 374 if: (1) there is no OPD benefit; (2) the OPD benefit is not subject to STPs; or (3) there is an OPD benefit subject to STPs and the override procedures include all five criteria specified by AB 374.

Figure 4. Baseline Enrollee Benefit Coverage and AB 374 Compliance



Note: numbers in the figure may not add to totals due to rounding.

CHBRP found that all enrollees in DMHC-regulated plans or CDI-regulated policies with OPD benefits subject to STPs have override procedures. However, not all override procedures are fully compliant with the five criteria specified by AB 374 (see Table 3).

Table 3. Premandate Override Criteria Compliance for Enrollees With an Outpatient Prescription Drug Benefit Subject to Step Therapy Protocols

AB 374 Criteria for Granting STP Override Request	Premandate % Enrollees (With OPD Coverage Subject to STPs) With AB 374–Compliant Override Criteria	Premandate % Enrollees (With OPD Coverage Subject to STPs) With AB 374–Non-Compliant Override Criteria
STP-required drug indicated by the protocol is contraindicated or likely to cause an adverse reaction (mental or physical harm) in the patient.	100.0%	100.0%
STP-required drug is expected to be ineffective due to the patient’s mental or physical characteristics.	100.0%	100.0%
STP-required drug is not medically appropriate.	82.8%	17.2%
STP-required drug is not FDA approved as a treatment for the patient’s condition.	44.4%	55.6%
The patient is stable on the initially prescribed drug.	100.0%	100.0%

Source: CHBRP, 2015.

Key: OPD = outpatient prescription drug; STP = step therapy protocol.

Postmandate Benefit Coverage

Following the enactment of AB 374, 100% of enrollees with coverage subject to AB 374 would have fully compliant coverage, with all five criteria for STP overrides included in their DMHC-regulated plans or CDI-regulated policies. Changes in benefit coverage would be as follows:

- Postmandate, AB 374 would alter the override criteria for 17.2% of enrollees with an OPD benefit subject to STPs, requiring override approval when the prescriber documents that the STP-required drug is not medically appropriate. Currently, the override process might consider listing of the STP-required drug as proof of the drug being medically appropriate, but AB 374 would focus the request on prescriber documentation regarding medical appropriateness. The result would be an increase in approved override requests.
- Postmandate, AB 374 would alter the override criteria for 55.6% of enrollees with an OPD benefit subject to STPs, prohibiting consideration of information other than FDA approval when a prescriber requests an override and documents that the STP-required drug is not FDA-approved for the enrollee's condition. Currently, the override process may consider other information (such as research literature indicating a common, safe and effective off-label use of the STP-required drug), but AB 374 would focus the request on FDA-approval. The result would be an increase in approved override requests.

Utilization

Premandate (Baseline) Utilization

Premandate, CHBRP estimates that 8.7 step therapy overrides were granted per 1,000 enrollees in DMHC-regulated plans or CDI-regulated policies (see Table 1). This number is an average over the entire insured population.

Postmandate Utilization

Postmandate, CHBRP estimates that the number of step therapy overrides per 1,000 enrollees in DMHC-regulated plans or CDI-regulated policies will increase to an average of 9.0 (see Table 1) for an increase of 0.31 step therapy overrides per 1,000 enrollees, in the year following implementation of AB 374. CHBRP estimates that the increase in approved postmandate override requests will be approximately 4% of the total number of override requests granted premandate, as enrollees with newly mandate-compliant coverage will increase their use of STP override procedures to match the same rate as enrollees who already had mandate-compliant coverage during the pre-mandate period.

Impact on access and health treatment/service availability

Postmandate, CHBRP estimates that there will be no impact on the availability of drugs (in all drug classes). STP and override procedures already exist in the pre-mandate marketplace, and the potential increase for any one particular drug from granting STP override requests due to AB 374 is too small to be measureable, particularly because the new utilization under AB 374 is spread across every drug class subject to an STP.

Per-Unit Cost

Premandate (Baseline) and Postmandate Per-Unit Cost

CHBRP estimates that the premandate and postmandate average per-unit cost of the initially prescribed drug when a STP override is granted will remain the same, as there will be no measureable change in the overall utilization of any specific drug. CHBRP assumes that the increase in granting STP override requests will not affect existing contracts between carriers and providers, or cost-sharing in any existing DMHC-regulated plans or CDI-regulated policies.

Premiums and Expenditures

Premandate (Baseline) Premiums and Expenditures

Table 4 presents per member per month (PMPM) premandate estimates for premiums and expenditures by market segment for DMHC-regulated plans and CDI-regulated policies.

PMPM by market segment is as follows for DMHC-regulated plans and CDI-regulated policies, respectively:

- Large group: \$537.63 and \$646.64.
- Small group: \$451.81 and \$558.76.
- Individual market: \$422.03 and \$334.65.

Total current annual expenditures for all DMHC-regulated plans and CDI-regulated policies is \$135,986,114,000.

Postmandate Expenditures

Changes in total expenditures

AB 374 would increase total net annual expenditures by \$10,835,000 or 0.0080% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a \$9,221,000 increase in total health insurance premiums paid by employers and enrollees for the additional STP overrides granted under AB 374, added to an increase in enrollee out-of-pocket expenditures for covered benefits (\$1,614,000), for an overall net change of \$10,835,000.

Postmandate premium expenditures and PMPM amounts per category of payer

Increases in insurance premiums as a result of AB 374 would vary by market segment. Note that the total population in Table 5, reflects the full 24,557,000 million enrollees in DMHC-regulated plans and CDI-regulated policies subject to AB 374.

In DMHC-regulated plans, CHBRP estimates that premium increases would range from \$0.03 (large group) to \$0.07 (individual) PMPM. In CDI-regulated policies, estimated premium increases range from \$0.06 (large group and individual) to \$0.13 (small group) PMPM.

Among publicly funded DMHC-regulated health plans, CHBRP estimates that CalPERS HMO premiums will increase by \$0.04 PMPM. CHBRP estimates that the Medi-Cal managed care plans will have premium increases of \$0.01 PMPM.

Average enrollee expenses for covered benefits would increase, ranging from no increase for Medi-Cal beneficiaries enrolled in DMHC-regulated managed care plans to \$0.02 for persons enrolled in CDI-regulated small group policies. The increase is due to cost-sharing and copays associated with moving to the higher cost drug when an override is granted.

Potential cost offsets or savings in the first 12 months after enactment

There is insufficient evidence in the literature to support the claim that increasing the number of granted STP override requests would increase either adherence to drugs or better health outcomes (see the *Medical Effectiveness* section). Therefore, CHBRP estimates that there will be no cost offsets in the first 12 months if AB 374 is enacted.

Postmandate administrative expenses and other expenses

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

Related Considerations for Policymakers

Cost of Exceeding Essential Health Benefits

Coverage for additional criteria to grant STP override requests under AB 374 are only requirements on the terms and conditions for existing benefits, and so would not trigger the requirement to cover mandates that exceed EHBs, and the state would not need to defray the costs.

Postmandate Changes in Uninsured and Public Program Enrollment

Changes in the number of uninsured persons

CHBRP estimates premium increases of less than 1% for each market segment; this premium increase would not have a measurable impact on the number of persons who are uninsured. CHBRP does not anticipate loss of health insurance, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of health insurance, changes in employer contribution rates, changes in take-up of health insurance by employees, or purchase of individual market policies, due to the small size of the increase in premiums after the mandate.

Changes in public program enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs or on utilization of covered benefits in the publicly funded insurance market.

How Lack of Coverage Results in Cost Shifts to Other Payers

CHBRP estimates no cost shifts to other payers due to post-mandate compliance with AB 374, though enrollee expenses for covered benefits will increase for enrollees receiving additional override approvals (see Table 1). This is because, when granted, STP override requests can result in increased cost-sharing for the patients, who may face higher copayments or co-insurance for the initially prescribed drug. Patients who had previously paid out-of-pocket for an initially prescribed drug and who would be granted a postmandate override request may see a decrease in expenses for non-covered benefits. Because CHBRP has no data on the frequency with which patients chose, premandate, to pay out-of-pocket in such circumstances, no estimate of the decrease can be calculated.

Table 4. Baseline (Premandate) Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2015

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (d)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (e)	8,651,000	2,094,000	3,757,000	836,000	6,891,000	533,000	534,000	690,000	571,000	24,557,000
Total enrollees in plans/policies subject to AB 374	8,651,000	2,094,000	3,757,000	836,000	6,891,000	533,000	534,000	690,000	571,000	24,557,000
Premium costs										
Average portion of premium paid by employer	\$423.58	\$304.59	\$0.00	\$437.75	\$179.24	\$445.00	\$511.84	\$421.06	\$0.00	\$80,452,488,000
Average portion of premium paid by employee	\$114.05	\$147.22	\$422.03	\$109.44	\$0.76	\$0.00	\$134.80	\$137.71	\$334.65	\$40,023,653,000
Total premium	\$537.63	\$451.81	\$422.03	\$547.19	\$180.00	\$445.00	\$646.64	\$558.76	\$334.65	\$120,476,140,000
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$36.95	\$89.15	\$141.84	\$29.78	\$0.00	\$0.00	\$99.91	\$166.51	\$105.38	\$15,510,004,000
Total expenditures	\$574.58	\$540.97	\$563.87	\$576.98	\$180.00	\$445.00	\$746.55	\$725.28	\$440.03	\$135,986,144,000

Source: California Health Benefits Review Program, 2015.

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

(b) As of September 30, 2013, 57.5%, or 462,580 CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2015.

(c) Includes children formerly in Health Families, which was moved into Medi-Cal Managed Care in 2013 as part of the 2012-13 state budget.

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

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

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

Table 5. Postmandate Impacts of the Mandate on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2015

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (d)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (e)	8,651,000	2,094,000	3,757,000	836,000	6,891,000	533,000	534,000	690,000	571,000	24,557,000
Total enrollees in plans/policies subject to AB 374	8,651,000	2,094,000	3,757,000	836,000	6,891,000	533,000	534,000	690,000	571,000	24,557,000
Premium costs										
Average portion of premium paid by employer	\$0.02	\$0.03	\$0.00	\$0.03	\$0.01	\$0.01	\$0.04	\$0.08	\$0.00	\$5,014,000
Average portion of premium paid by employee	\$0.01	\$0.01	\$0.06	\$0.01	\$0.00	\$0.00	\$0.01	\$0.03	\$0.05	\$4,207,000
Total premium	\$0.03	\$0.04	\$0.06	\$0.04	\$0.01	\$0.01	\$0.05	\$0.11	\$0.05	\$9,221,000
Enrollee expenses										
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$0.01	\$0.01	\$0.01	\$0.01	\$0.00	\$0.00	\$0.01	\$0.02	\$0.01	\$1,614,000
Total expenditures	\$0.03	\$0.04	\$0.07	\$0.04	\$0.01	\$0.01	\$0.06	\$0.13	\$0.06	\$10,835,000
Postmandate percent change										
Percent change insured premiums	0.0049%	0.0083%	0.0138%	0.0072%	0.0061%	0.0025%	0.0080%	0.0193%	0.0143%	0.0077%
Percent change total expenditures	0.0056%	0.0082%	0.0123%	0.0078%	0.0061%	0.0025%	0.0083%	0.0177%	0.0129%	0.0080%

Source: California Health Benefits Review Program, 2015.

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

(b) As of September 30, 2013, 57.5%, or 462,580 CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2015.

(c) Includes children formerly in Health Families, which was moved into Medi-Cal Managed Care in 2013 as part of the 2012-13 state budget.

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

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

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

PUBLIC HEALTH IMPACTS

The public health impact analysis includes estimates on mandate-relevant health outcomes, potential treatment harms, gender and racial disparities, financial burden, premature death, and economic loss in the short and long term. This section estimates the short-term public health impact³⁴ of AB 374 on step therapy protocols (STP) and override procedures. See the *Long-Term Impacts* section on page 27 for a discussion of health impacts, premature death, and economic loss beyond the first 12 months of the bill implementation.

Estimated Public Health Outcomes

As presented in the *Medical Effectiveness* section, CHBRP finds insufficient evidence of harms or benefits due to STP or override procedures on health outcomes or use of medical services. The absence of evidence is not evidence of no effect. If a STP is associated with a lower rate of initiation, delay, or discontinuation of treatment, the protocol might be associated with worse health outcomes unless patients have access to other equally effective treatments. Conversely, use of STPs might improve health outcomes by ensuring compliance with clinical protocols, enforcing documentation of correct diagnoses, and/or supporting the use of safer prescription drugs.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP estimates AB 374 would produce a small increase in the number of STP overrides/1,000 enrollees granted postmandate, (0.3 overrides per 1,000 enrollees) or about 7,532 extra overrides granted in the first year.

CHBRP finds insufficient evidence of the effect of STPs or override procedures on health outcomes. Therefore, the public health impact in the first year, postmandate, is unknown. Please note that the absence of evidence is not “evidence of no effect.” It is possible that an impact—positive or negative—could result, but current evidence is insufficient to inform an estimate.

Impact on Gender and Racial Disparities

The extent to which AB 374 would have an impact on possible racial or ethnic disparities is unknown due to a lack of evidence in disparities in use of step therapy protocols or override procedures as well as insufficient evidence of the health effects of STPs.

Estimated Impact on Financial Burden

When possible, CHBRP estimates the marginal impact of mandates on financial burden, defined as uncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (e.g., deductibles, copayments, and co-insurance).

The *Benefit Coverage, Utilization, and Cost* section estimates that AB 374 would result in an additional 7,532 STP overrides in the first year post-mandate. This would increase net out-of-pocket costs by about \$1,614,000 for the newly covered enrollees who obtain an STP override (Table 1). Some of the newly covered enrollees might see a decrease in out-of-pocket expenditures by avoiding

³⁴ CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

copayments/coinsurance for one or more prescription drugs on which they would have failed to respond to, but as a whole, CHBRP estimates an increase. This increased cost may seem counterintuitive, but generally (and as reflected in CHBRP's cost model), STPs identify lower-cost drugs as the preferred prescription. Prescription drugs in the upper tiers of the formulary have higher copayments/coinsurance associated with them. If patients skip the lower-cost, STP-required drugs, where they may have found success, they will continue to pay more for the initially-prescribed drug in the higher-cost tier.

In the first year postmandate, CHBRP estimates that AB 374 would modify coverage and increase the net financial burden by approximately \$1,614,000 for enrollees who are granted an additional 7,532 step therapy overrides.

LONG-TERM IMPACT OF AB 374

In this section, the California Health Benefits Review Program (CHBRP) estimates the long-term impact of AB 374, defined as impacts occurring beyond the first 12 months of implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization Impacts

In the 12 months following enactment, CHBRP estimates that utilization will increase from 8.7 step therapy overrides per 1,000 enrollees to 9 overrides per 1,000. In later years, the rate is likely to remain the same, as override requests require effort on the part of patient and prescriber. However, whether the percent of enrollees with an outpatient prescription drug (OPD) benefit subject to step therapy protocols (STPs) will remain constant is unknown. An increasing number of enrollees with an OPD benefit subject to STPs could result in an increased total number of approved override requests.

Cost Impacts

As there is no literature that specifically focuses on the cost-effectiveness of step therapy overrides, CHBRP cannot estimate the long-term impact of this particular piece of step therapy protocols.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments) while other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects of a proposed mandate (beyond CHBRP's 12-month analytic timeframe) to capture possible impacts to the public's health that would be attributable to the mandate, including impacts on premature death and economic loss.

In the case of AB 374, there is insufficient evidence of the medical effectiveness of STPs or override procedures; therefore the long-term public health impacts (including for premature death and economic loss) are unknown. In the future, CHBRP would expect enrollees' who are granted STP overrides to continue to pay additional out-of-pocket expenses for the initially-prescribed drugs, which are generally more costly than STP-required drugs.

APPENDIX A TEXT OF BILL ANALYZED

On February 23, 2015 California Assembly Committee on Health requested that CHBRP analyze AB 374.

AMENDED IN ASSEMBLY MARCH 2, 2015
California legislature—2015–16 regular session
ASSEMBLY BILL No. 374
Introduced by Assembly Member Nazarian
February 17, 2015

An act to add Section 1367.244 to the Health and Safety Code, and to add Section 10123.197 to the Insurance Code, relating to health care coverage.

Legislative Counsel's Digest: AB 374, as amended, Nazarian. Health care coverage: prescription drugs. 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 that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law imposes various requirements and restrictions on health care service plans and health insurers, including, among other things, requiring a health care service plan that provides prescription drug benefits to maintain an expeditious process by which prescribing providers, as described, may obtain authorization for a medically necessary nonformulary prescription drug, according to certain procedures. This bill would prohibit a health care service plan or health insurer that provides medication pursuant to a step therapy or first-fail fail-first requirement from applying that requirement to a patient who has made a step therapy override determination request if, in the professional judgment of the prescribing physician, the step therapy or first-fail 98 fail-first requirement would be medically inappropriate for that patient for specified reasons. Because a willful violation of these 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. The Legislature finds and declares all of the following:

- (a) Health care service plans and health insurers are increasingly making use of step therapy or fail-first protocols, hereafter referred to as step therapy protocol, under which patients are required to try one or more prescription drugs before coverage is provided for a drug selected by the patient's health care provider.
- (b) Step therapy protocols, when they are based on well-developed scientific standards and administered in a flexible manner that takes into account the individual needs of patients, can play an important role in controlling health care costs.
- (c) In some cases, requiring a patient to follow a step therapy protocol may have adverse and even dangerous consequences for the patient who may either not realize a benefit from taking a prescription drug or may suffer harm from taking an inappropriate drug.
- (d) It is imperative that step therapy protocols preserve the health care provider's right to make treatment decisions in the best interest of the patient.
- (e) Therefore, the Legislature declares it a matter of public interest that it require health care service plans and health insurers to base step therapy protocols on appropriate clinical practice guidelines developed by professional medical societies with expertise in the condition or conditions under consideration, that patients be exempt from step therapy protocols when inappropriate or otherwise not in

the best interest of the patients, and that patients have access to a fair, transparent, and independent process for requesting an exception to a step therapy protocol when appropriate.

SEC. 2. Section 1367.244 is added to the Health and Safety line 8 Code, to read:

1367.244. (a) A health care service plan that provides coverage for medications pursuant to a step therapy or fail-first protocol shall not apply that requirement to a patient who has made a step therapy override determination request if, in the professional judgment of the prescribing physician, the step therapy or first-fail fail-first requirement would be medically inappropriate for that patient for any of the reasons specified in subdivision (b).

(b) A step therapy override determination request by a patient with adequate supporting rationale and documentation from the prescribing physician shall be expeditiously granted by the plan if any of the following apply:

(1) The prescription drug required by the plan is contraindicated or will likely cause an adverse reaction by, or physical or mental harm to, the patient.

(2) The prescription drug required by the plan is expected to be ineffective based on the known relevant physical or mental characteristics of the patient and the known characteristics of the prescription drug regimen.

(3) The prescription drug required by the plan is not in the best interest of the patient, based on medical appropriateness.

(4) The patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration.

(5) The prescription drug required by the plan has not been approved by the federal Food and Drug Administration for the patient's condition.

(c) Upon the granting of a step therapy override determination, the health care service plan shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider, provided such prescription drug is a covered prescription drug under that policy or contract.

(d) For purposes of this section, "step therapy override determination" means a determination as to whether a step therapy protocol should apply in a particular patient's situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug.

(e) This section does not prevent a health care service plan from requiring a patient to try an AB-rated generic equivalent drug prior to providing coverage for the equivalent branded prescription drug. This section does not prevent a health care provider from prescribing a prescription drug that is determined to be medically appropriate.

SEC. 3. Section 10123.197 is added to the Health and Safety line 13 Insurance Code, to read: line 14 10123.197.

(a) A health insurer that provides coverage for medications pursuant to a step therapy or first-fail fail-first protocol line shall not apply that requirement to a patient who has made a step therapy override determination request if, in the professional judgment of the prescribing physician, the step therapy or first-fail fail-first requirement would be medically inappropriate for that patient for any of the reasons specified in subdivision (b).

(b) A step therapy override determination request by a patient with adequate supporting rationale and documentation from the prescribing physician shall be expeditiously granted by the plan if any of the following apply:

(1) The prescription drug required by the plan is contraindicated or will likely cause an adverse reaction by, or physical or mental harm to, the patient.

(2) The prescription drug required by the plan is expected to be ineffective based on the known relevant physical or mental characteristics of the patient and the known characteristics of the prescription drug regimen.

(3) The prescription drug required by the plan is not in the best interest of the patient, based on medical appropriateness.

(4) The patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration.

(5) The prescription drug required by the plan has not been approved by the federal Food and Drug Administration for the patient's condition.

(c) Upon the granting of a step therapy override determination, the health care service plan shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider, provided such prescription drug is a covered prescription drug under that policy or contract.

(d) For purposes of this section, "step therapy override determination" means a determination as to whether a step therapy protocol should apply in a particular patient's situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug.

(e) This section does not prevent a health insurer from requiring a patient to try an AB-rated generic equivalent drug prior to providing coverage for the equivalent branded prescription drug. This section does not prevent a health care provider from prescribing a prescription drug that is determined to be medically appropriate.

Sec 4. 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 SB 374, a bill that would prohibit all DMHC-regulated health plan contracts and all CDI regulated policies from applying STPs if the protocol would be medically inappropriate. The bill would require carriers to expeditiously grant a step therapy override when the prescribing physician provides adequate supporting rationale and documentation that the prescription drug required by the plan is medical inappropriate or otherwise not in the best interest of the patient. CHBRP uses the term “override procedure” to refer to the process in which a plan limits the STP in favor of immediate coverage of the health care provider’s select prescription medication. CHBRP uses the term “STP” to refer to utilization management strategy where alternative drugs must be tried before coverage for the prescribed medication is approved.

The medical effectiveness review does not address the effectiveness of prescription drugs because it is not feasible for CHBRP to review the literature on effectiveness of all drugs subject to override procedures or STPs within the 60-day timeframe allotted for this analysis. In addition, the Food and Drug Administration assesses the effectiveness of all drugs available in the United States and sets forth approved uses for them. Moreover, AB 374 does not mandate that DMHC-regulated plans and CDI-regulated policies provide coverage for prescription drugs but instead establishes terms and conditions for coverage. For these reasons, the medical effectiveness review assesses evidence regarding the following two topics:

- 1) The impact of STPs on use of health services and health outcomes. In particular, the review focuses on whether there is evidence that STPs have adverse effects on health outcomes and use of beneficial health care services; and,
- 2) The impact of override procedures on use of health services and health outcomes.

CHBRP’s medical effectiveness review for a previous bill on step therapy, AB 889, focused on the impact of STPs for prescription drugs in 2013. The literature search for STPs was limited to abstracts of studies published in English from January 2013 to present. For the analysis of AB 374, CHBRP expanded the literature review to include controlled studies of override procedures. The literature search on override procedures included abstracts of studies published in English from January 2005 to present. Studies of and STPs and override procedures for prescription drugs were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, and Business Source Complete. Of the 248 articles found in the literature review, 14 were reviewed for potential inclusion in this report on AB 374, and 2 studies were included in the medical effectiveness review for this report. The medical effectiveness review also presents findings from the 13 studies that were previously identified in the 2013 CHBRP AB 899 report.

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

Two reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

Of the 248 articles found in the literature review, 14 were reviewed for potential inclusion in this report on AB 374, and 2 studies were included in the medical effectiveness review for this report. The medical effectiveness review also presents findings from the 13 studies that were previously identified in the 2013 CHBRP AB 899 report.

Evidence Grading System

In making a “call” for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP’s *Medical Effectiveness Analysis Research Approach*.³⁵ To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

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

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

- Clear and convincing evidence;
- Preponderance of evidence;
- Ambiguous/conflicting evidence; and
- Insufficient evidence.

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective. This can be further subdivided into preponderance of evidence from high-quality studies and preponderance of evidence from low-quality studies.

A grade of *ambiguous/conflicting evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

³⁵ Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

Search Terms

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

Major MeSH terms used to search PubMed

- Step Therapy

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

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

APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

This appendix describes data sources, estimation methodology, as well as general and mandate-specific caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP website at: www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm, Milliman, Inc.³⁶

Data Sources

This subsection discusses the variety of data sources CHBRP uses. Key sources and data items are listed below, in Table 6.

Table 6. Data for 2016 Projections

Data Source	Items
California DHCS administrative data for the Medi-Cal program, data available as of end of December 2014	Distribution of enrollees by managed care or FFS distribution by age: 0–17; 18–64; 65+ Medi-Cal Managed Care premiums
California Department of Managed Health Care (DMHC) data from the interactive website “Health Plan Financial Summary Report,” August–October, 2014	Distribution of DMHC-regulated plans by market segment*
California Department of Insurance (CDI) Statistical Analysis Division data; data as of December 31, 2013	Distribution of CDI-regulated policies by market segment
California Health Benefits Review Program (CHBRP) Annual Enrollment and Premium Survey of California’s largest (by enrollment) health care service plans and health insurers; data as of September 30, 2014; responders’ data represent approximately 97.3% of persons not associated with CalPERS or Medi-Cal with health insurance subject to state mandates—98.0% of full-service (nonspecialty) DMHC-regulated plan enrollees and 97.0% of full-service (nonspecialty) CDI-regulated policy enrollees.	Enrollment by: <ul style="list-style-type: none"> • Size of firm (2–50 as small group and 51+ as large group) • DMHC vs. CDI regulated • Grandfathered vs. nongrandfathered Premiums for individual policies by: <ul style="list-style-type: none"> • DMHC vs. CDI regulated • Grandfathered vs. nongrandfathered

³⁶ CHBRP’s authorizing legislation requires that CHBRP use a certified actuary or “other person with relevant knowledge and expertise” to determine financial impact (www.chbrp.org/docs/authorizing_statute.pdf).

Data Source	Items
California Employer Health Benefits Survey, 2014 (conducted by NORC and funded by CHCF)	Enrollment by HMO/POS, PPO/indemnity self-insured, fully insured, Premiums (not self-insured) by: <ul style="list-style-type: none"> • Size of firm (3–25 as small group and 25+ as large group) • Family vs. single • HMO/POS vs. PPO/indemnity vs. HDHP employer vs. employer premium share
California Health Interview Survey (CHIS) 2012/2013/T7 (“T7” representing the first 6 months of 2014)	Uninsured, age: 65+ Medi-Cal (non-Medicare), age: 65+ Other public, age: 65+ Employer-sponsored insurance, age: 65+
California Public Employees’ Retirement System (CalPERS) data, enrollment as of October 1, 2014	CalPERS HMO and PPO enrollment <ul style="list-style-type: none"> • Age: 0–17; 18–64; 65+ HMO premiums
California Simulation of Insurance Markets (CalSIM) Version 1.9.1 (projections for 2016)	Uninsured, age: 0–17; 18–64 Medi-Cal (non-Medicare) (a), age: 0–17; 18–64 Other public (b), age: 0–64 Individual market, age: 0–17; 18–64 Small group, age: 0–17; 18–64 Large group, age: 0–17; 18–64
Centers for Medicare & Medicaid (CMS) administrative data for the Medicare program, annually (if available) as of end of September	HMO vs. FFS distribution for those 65+ (noninstitutionalized)
Milliman estimate	Medical trend influencing annual premium increases

Notes: (*) CHBRP assumes DMHC-regulated PPO group enrollees and POS enrollees are in the large-group segment.

Key: CDI = California Department of Insurance; CHCF = California HealthCare Foundation; CHIS = California Health Interview Survey; CMS = Centers for Medicare & Medicaid Services; DHCS = Department of Health Care Services; DMHC = Department of Managed Health Care; FFS = fee-for-service; HMO = health maintenance organization; NORC = National Opinion Research Center; POS = point of service; PPO = preferred provider organization.

Further discussion of external and internal data follows.

Internal data

1. CHBRP’s Annual Enrollment and Premium Survey collects data from the seven largest providers of health insurance in California (including Aetna, Anthem Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and United Healthcare/PacifiCare) to obtain estimates of enrollment not associated with CalPERS or Medi-Cal by purchaser (i.e., large and small group and individual), state regulator (DMHC or CDI), grandfathered and nongrandfathered status, and average premiums. CalSIM and market trends were applied to project 2016 health insurance enrollment in DMHC-regulated plans and CDI-regulated policies.
2. CHBRP’s other surveys of the largest plans/insurers collect information on benefit coverage relevant to proposed benefit mandates CHBRP has been asked to analyze. In each report,

CHBRP indicates the proportion of enrollees—statewide and by market segment—represented by responses to CHBRP’s bill-specific coverage surveys. The proportions are derived from data provided by CDI and DMHC.

3. External sources.
4. California Department of Health Care Services (DHCS) data are used to estimate enrollment in Medi-Cal Managed Care (beneficiaries enrolled in Two-Plan Model, Geographic Managed Care, and County Operated Health System plans), which may be subject to state benefit mandates, as well as enrollment in Medi-Cal Fee For Service (FFS), which is not. The data are available at: www.dhcs.ca.gov/dataandstats/statistics/Pages/Monthly_Trend_Report.aspx. Medi-Cal enrollment is projected to 2016 based on CalSIM’s estimate of the continuing impact of the Medi-Cal expansion implemented in 2014.
5. California Employer Health Benefits Survey data are used to make a number of estimates, including: premiums for employment-based enrollment in DMHC-regulated health care service plans (primarily health maintenance organizations [HMOs] and point of service [POS] plans) and premiums for employment-based enrollment in CDI-regulated health insurance policies regulated by the (primarily preferred provider organizations [PPOs]). Premiums for fee-for-service (FFS) policies are no longer available due to scarcity of these policies in California. 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. More information on the CHCF/NORC data is available at: www.chcf.org/publications/2014/01/employer-health-benefits.
6. California Health Interview Survey (CHIS) data are used to estimate the number of Californians aged 65 and older, and the number of Californians dually eligible for both Medi-Cal and Medicare coverage. CHIS data are also used to determine the number of Californians with incomes below 400% of the federal poverty level. CHIS is a continuous survey that provides detailed information on demographics, health insurance coverage, health status, and access to care. More information on CHIS is available at: www.chis.ucla.edu.
7. California Public Employees Retirement System (CalPERS) data are used to estimate premiums and enrollment in DMHC-regulated plans, which may be subject to state benefit mandates, as well as enrollment in CalPERS’ self-insured plans, which is not. CalPERS does not currently offer enrollment in CDI-regulated policies. Data are provided for DMHC-regulated plans enrolling non-Medicare beneficiaries. In addition, CHBRP obtains information on current scope of benefits from evidence of coverage (EOC) documents publicly available at: www.calpers.ca.gov. CHBRP assumes CalPERS’s enrollment in 2016 will not be affected by continuing shifts in the health insurance market as a result of the ACA.
8. California Simulation of Insurance Markets (CalSIM) estimates are used to project health insurance status of Californians aged 64 and under. CalSIM is a microsimulation model that projects the effects of the Affordable Care Act on firms and individuals. More information on CalSIM is available at: <http://healthpolicy.ucla.edu/programs/health-economics/projects/CalSIM/Pages/default.aspx>.
9. 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. Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed health care plans, generally those

characterized as PPO plans. More information on the Milliman HCGs is available at: <http://us.milliman.com/Solutions/Products/Resources/Health-Cost-Guidelines/Health-Cost-Guidelines---Commercial/>.

10. The MarketScan databases, which reflect the health care claims experience of employees and dependents covered by the health benefit programs of large employers. These claims data are collected from insurance companies, Blue Cross Blue Shield plans, and third party administrators. These data represent the medical experience of insured employees and their dependents for active employees, early retirees, individuals with COBRA continuation coverage, and Medicare-eligible retirees with employer-provided Medicare Supplemental plans. No Medicaid or Workers Compensation data are included.
11. Ingenix MDR Charge Payment System, which includes information about professional fees paid for health care services, based upon claims from commercial insurance companies, HMOs, and self-insured health plans.

Projecting 2016

This subsection discusses adjustments made to CHBRP's Cost and Coverage Model to project 2016, the period when mandates proposed in 2015 would, if enacted, generally take effect. It is important to emphasize that CHBRP's analysis of specific mandate bills typically addresses the incremental effects of a mandate—specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, *holding all other factors constant*. CHBRP's estimates of these incremental effects are presented in the *Benefit Coverage, Utilization, and Cost Impacts* section of this report.

Baseline premium rate development methodology

The key components of the baseline model for utilization and expenditures are estimates of the per member per month (PMPM) values for each of the following:

- Insurance premiums PMPM;
- Gross claims costs PMPM;
- Member cost sharing PMPM; and
- Health care costs paid by the health plan or insurer.

For each market segment, we first obtained an estimate of the insurance premium PMPM by taking the 2014 reported premium from the abovementioned data sources and trending that value to 2016. CHBRP uses trend rates published in the Milliman HCGs to estimate the health care costs for each market segment in 2016.

The large-group market segments for each regulator (CDI and DMHC) are split into grandfathered and nongrandfathered status. For the small-group and individual markets, further splits are made to indicate association with Covered California, the state's health insurance marketplace. Doing so allows CHBRP to separately calculate the impact of ACA and of specific mandates, both of which may apply differently among these subgroups. The premium rate data received from the CHCF/NORC California Employer Health Benefits survey did not split the premiums based on grandfathered or exchange status. However, CHBRP's Annual Enrollment and Premium (AEP) survey asked California's largest health care service plans and health insurers to provide their average premium rates separately for grandfathered and nongrandfathered plans. The ratios from the CHBRP survey data were then applied to the CHCF/NORC aggregate premium rates for large and small group, to estimate premium rates for grandfathered and

nongrandfathered plans that were consistent with the NORC results. For the individual market, the premium rates received from CHBRP's AEP survey were used directly.

The remaining three values were then estimated by the following formulas:

- Health care costs paid by the health plan = insurance premiums PMPM × (1 – profit/administration load);
- Gross claims costs PMPM = health care costs paid by the health plan ÷ percentage paid by health plan; and
- Member cost sharing PMPM = gross claims costs × (1 – percentage paid by health plan).

In the above formulas, the quantity “profit/administration load” is the assumed percentage of a typical premium that is allocated to the health plan/insurer's administration and profit. These values vary by insurance category, and under the ACA, are limited by the minimum medical loss ratio requirement. CHBRP estimated these values based on actuarial expertise at Milliman, and their associated expertise in health care.

In the above formulas, the quantity “percentage paid by health plan” is the assumed percentage of gross health care costs that are paid by the health plan, as opposed to the amount paid by member cost sharing (deductibles, copays, etc.). In ACA terminology, this quantity is known as the plan's “actuarial value.” These values vary by insurance category. For each insurance category, Milliman estimated the member cost sharing for the average or typical plan in that category. Milliman then priced these plans using the Milliman Health Cost Guidelines to estimate the percentage of gross health care costs that are paid by the carrier.

General Caveats and Assumptions

This subsection discusses the general caveats and assumptions relevant to all CHBRP reports. The projected costs are estimates of 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 the premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.

- When cost savings are estimated, they reflect savings realized for 1 year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts, please see: www.chbrp.org/analysis_methodology/docs/longterm_impacts08.pdf.
- Several studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew et al., 2005; Glied and Jack, 2003; Hadley, 2006). Chernew et al. (2005) estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, whereas Hadley (2006) and Glied and Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and a 0.84 percentage point decrease in the number of insured, respectively. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the simplifying assumption that the elasticity is the same across different types of markets. For more information on CHBRP's criteria for estimating impacts on the uninsured, please see *Criteria and Methods for Estimating the Impact of Mandates on the Number of Individuals Who Become Uninsured in Response to Premium Increases*, available at: 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 estimates 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 benefits: To help offset the premium increase resulting from a mandate, deductibles or copayments may be increased. Such changes would have a direct impact on the distribution of costs between health plans/insurers and enrollees, and may also result in utilization reductions (i.e., high levels of 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, persons or employer groups who had previously foregone health insurance may elect, postmandate, to enroll in a health plan or policy because they perceive that it is now to their economic benefit to do so.
- Medical management: Health plans/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/policy types that previously had the least effective medical management (i.e., PPO plans).
- Geographic and delivery systems variation: Variation exists in existing utilization and costs, and in the impact of the mandate, by geographic area and by delivery system models. Even within the health insurance plan/policy types CHBRP modeled (HMO, including HMO and POS plans, and non-HMO, including PPO and FFS policies), there are likely variations in utilization and costs. 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/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 impacts, CHBRP typically assumes that plans and policies subject to the mandate will be in compliance with the benefit coverage requirements of the bill. Therefore, the typical postmandate coverage rates for persons enrolled in health insurance plans/policies subject to the mandate are assumed to be 100%.

Analysis Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions relevant to specifically to an analysis of AB 374.

CHBRP relied on the content expert to categorize drugs reported as being subject to Step Therapy Protocols (STP) by therapeutic class, and to identify those drugs for which no AB Generic substitute exists and for which alternative dosage forms or strengths are not available outside the STP. CHBRP estimated the utilization per 1,000 enrollees and average allowed charge for the drugs identified from the Milliman Consolidated Health Cost Guidelines Sources Database (2012). CHBRP estimated the utilization and average allowed charges for alternative treatments within the same therapeutic class from the Milliman 2014 Commercial Health Cost Guidelines. All utilization rates and allowed charges were trended to 2016 levels.

Insofar as CHBRP recognizes the prevalence of STPs requiring multiple drugs prior to access to the initially prescribed drug, this analysis assumed that granted overrides replace an average of 1.5 STP-required prescription fills with an equal number of prescription fills of the initially prescribed drug.

Approximately 73% of enrollees have AB 374-compliant benefit coverage (either no drugs subject to STP or all mandated override provisions are already in place). The rest of the enrollees have access to one or more of the mandated override provisions.

CHBRP estimates that an expansion of override protocols will increase utilization of drugs subject to STP by approximately 4%.

CHBRP assumes that there will be no increase or decrease in overall utilization of prescription drugs due to AB 374. The change in utilization is entirely due to moving from one particular drug to another within the same classification. CHBRP further assumed that enrollees subject to STP were equally likely to be granted an override request, regardless of how many drugs in a plan were subject to STP.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits AB 374 would mandate. Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- Considers the bargaining history of organized labor; and
- Compares the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not generally include issues related to the terms and conditions of outpatient pharmacy benefits in their health insurance negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

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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 of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

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