

California Health Benefits Review Program

Analysis of California Assembly Bill 1353 Drug Utilization Management Exceptions

A Report to the 2017–2018 California State Legislature

April 21, 2017



Key Findings:

Analysis of California Assembly Bill 1353 Drug Utilization Management Exceptions

Summary to the 2017–2018 California State Legislature, April 21, 2017



AT A GLANCE

The version of California Assembly Bill (AB) 1353 analyzed by CHBRP would require a compliant exceptions request process in regard to some utilization management techniques that may be applicable to an outpatient prescription drug (OPD) benefit. CHBRP estimates that, in 2018, all of the 24 million Californians enrolled in health insurance regulated by DMHC or CDI will have insurance subject to AB 1353.

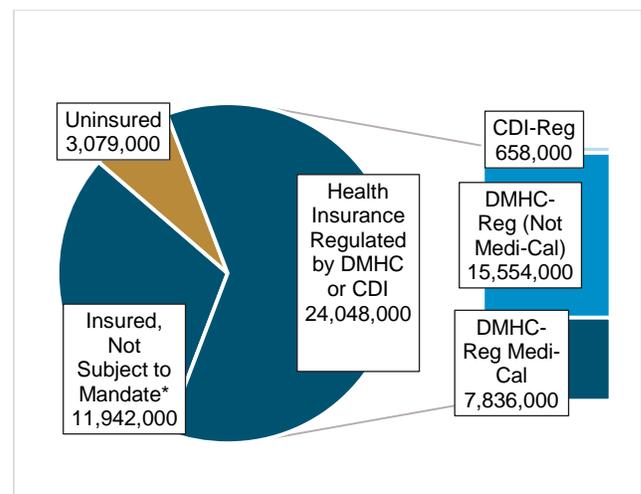
- 1. Benefit coverage.** The percentage of enrollees with fully AB 1353–compliant coverage would rise from 92% to 100%.
- 2. Utilization.** In the first year postmandate, AB 1353 would be particularly relevant among enrollees which chronic conditions switching from one health plan/policy to another. By increasing granted exception requests, AB 1353 would increase (as a percentage of drugs used) the use of more expensive drugs.
- 3. Expenditures.** Total expenditures (premiums and enrollee expenses for covered benefits) would increase by \$8,960,000 (0.0061%).
- 4. Medical effectiveness.** There is *insufficient* evidence to determine whether utilization management exceptions affect health outcomes. There is *conflicting* evidence on the impact of step therapy requirements and prior authorization requirements on health outcomes. There is a *preponderance* of evidence that generic substitutions are equivalent to the brand-name drugs with regard to medical effectiveness.
- 5. Public Health.** As evidence is insufficient or conflicting, the impact on health outcomes of the utilization changes AB 1353 would prompt are unknown.
- 6. Long term.** In the long term, as enrollees, providers, and pharmacist become aware of AB 1353, annual impacts could increase. In particular, impacts associated with Medi-Cal beneficiaries in DMHC-regulated plans could increase because other inducements (such as greater cost sharing for more expensive drugs) are less likely to be present

BILL SUMMARY

A set of current California laws, similar to what AB 153 would require, may require continued coverage of a particular drug (or a compliant exceptions request process) for most enrollees in DMHC-regulated plans and many enrollees in CDI-regulated policies.

AB 1353 would require that all DMHC-regulated plans and CDI-regulated policies that include an outpatient prescription drug (OPD) benefit have a process by which exceptions to utilization management techniques can be granted and would, in some circumstances, require that the exception be granted. AB 1353 would be relevant to the benefit coverage of some more enrollees in DMHC-regulated plans and CDI-regulated policies than is the set of current laws, but a key difference is that it would extend the possibility of a granted exception to enrollees switching from one health plan or policy to another.

Figure 1. Health Insurance in CA and AB 1353



Source: CHBRP 2017.

Notes: *Medicare beneficiaries, enrollees in self-insured products, etc.

Benefit Coverage, Utilization and Cost

For this analysis, CHBRP has focused on the impact an AB 1353 could have regarding granted exceptions to three utilization management techniques: step therapy

requirements, prior authorization requirements, and mandatory generic substitution requirements. Because AB 1353 addresses continued coverage, CHBRP has focused on use of drugs related to chronic conditions.

Benefit Coverage

At baseline, approximately 92% of enrollees have benefit coverage fully compliant with AB 1353. Noncompliance would limit granted utilization management technique exceptions for enrollees switching from one plan or policy to another Post mandate, the figure would rise to 100%.

Utilization

AB 1353 would not impact the total utilization of prescription drugs. However, CHBRP would anticipate an increased number of exception requests and an increased rate of exception approvals. The resulting increase in exemption approvals would alter the mix of average cost per prescription, from the lower cost associated with exceptions being denied toward the higher cost associated with exceptions being approved (because many exceptions would extend coverage for a more expensive drug).

Expenditures

Total expenditures (premiums and enrollee expenses for covered benefits) would increase by \$8,960,000 (0.0061%). Variation between market segments would be primarily driven by rates of enrollees switching from one health plan or policy to another - which is most common in the individual market and more common in the small group market than in the large group market or among Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Medi-Cal

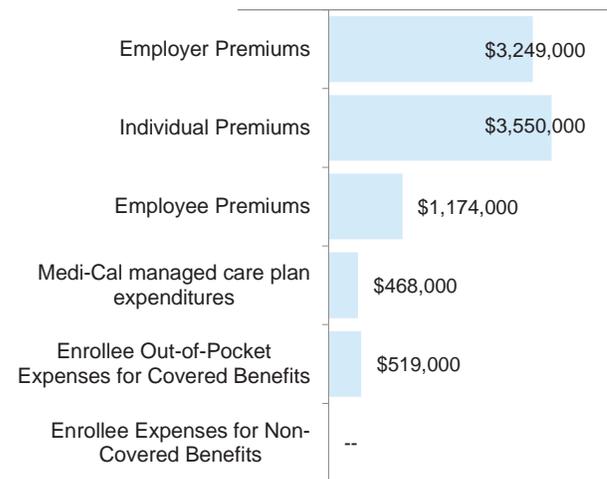
Premiums for Medi-Cal beneficiaries enrolled in DMHC-regulated plans would increase by \$468,000 (0.0017%).

CalPERS

Premium for enrollees in DMHC-regulated plans associated with CalPERS would increase by \$114,000 (0.0023%).¹

¹ Approximately 58.82% of enrollees in DMHC-regulated plans associated with were state retirees, state employees, or their

Figure 2. Expenditure Impacts of AB 1353



Source: CHBRP 2017.

Number of Uninsured in California

The projected impacts would not be expected to alter the number of uninsured Californians.

Medical Effectiveness

There is *insufficient* evidence to determine whether utilization management exceptions directly affect health outcomes.

There is *conflicting* evidence on the impact of step therapy requirements on health outcomes. There is *limited* evidence that step therapy requirements impact rates of discontinuation and interruption of drug use. There is *conflicting* evidence on the impact of step therapy requirements on hospital admissions, emergency department use, and outpatient visits.

There is *conflicting* evidence on the impact prior authorization requirements on health outcomes. There is *insufficient* evidence that prior authorization requirements affect utilization of drugs or other health services.

dependents. About a quarter of these enrollees have an OPD benefit not subject to DMHC, so CHBRP has projected no impact for those enrollees, but is aware that CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

There is a *preponderance* of evidence that generic substitutions are equivalent to the brand-name drugs with regard to medical effectiveness.

Public Health

In the first year postmandate, the public health impact of AB 1353 is unknown due to insufficient or conflicting evidence regarding the effect of prior authorization, step therapy, and generic substitution requirements on health outcomes related to discontinuities in OPD treatments for a range of illnesses and conditions. 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.

Long-Term Impacts

Although CHBRP projects that AB 1353 would cause a 5% increase in the number of exception requests in the first year, in the long run, this figure may increase as more enrollees, providers, and pharmacists become aware of the conditions under which AB 1353 would require that exceptions be granted. At baseline, it is likely that some enrollees who would be affected by AB 1353 do not file for exceptions because they are unaware that it is possible to do so or do not believe it is likely that their exception would be granted. Additionally, the current laws that are similar to what AB 1353 would require do not apply to the benefit coverage of quite as many enrollees as would AB 1353.

Utilization management exists for purposes besides controlling costs. Utilization management is also used to discourage the use of drugs with potentially dangerous side effects, or drugs that are inferior to newer drugs on the market. However, as new generic drugs and other lower cost alternatives come onto the market, AB 1353 will limit inducements to enrollees with ongoing prescriptions for higher cost drugs to switch to lower cost alternatives. This impact is likely to be most notable among Medi-Cal beneficiaries enrolled in DMHC-regulated plans, as other inducements, such as higher cost-sharing requirements for more expensive drugs, are less likely to be present.

Just as utilization impacts may increase over time, so may the cost impacts of greater utilization of more expensive drugs. As with utilization impacts, the related cost impact of AB 1353 would be likely to be greater

among Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Essential Health Benefits and the Affordable Care Act

Because AB 1353 specifies terms of existing benefit coverage, it appears that AB 1353 would not exceed essential health benefits (EHBs), and so would not trigger the ACA requirement that the state defray the cost of additional benefit coverage.

A Report to the California State Legislature

Analysis of California Assembly Bill 1353
Drug Utilization Management Exceptions

April 21, 2017

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ABOUT CHBRP

The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit bills. 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, authorizing statute, as well as all CHBRP reports and other publications, are available at www.chbrp.org.

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Table 1. AB 1353 Impacts on Benefit Coverage, Utilization, and Cost, 2018

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	24,048,000	24,048,000	0	0%
Total enrollees with health insurance subject to AB 1353	24,048,000	24,048,000	0	0%
Percentage of enrollees with health insurance subject to AB 1353	100%	100%	0	0%
Number of enrollees with OPD coverage fully compliant with AB 1353	22,133,000	24,048,000	1,915,000	9%
Percentage of enrollees with OPD coverage fully compliant with AB 1353	92%	100%	8%	9%
Utilization and unit cost				
Annual drug utilization management exception requests				
Exceptions Granted	75,000	129,000	54,000	72%
Exceptions Denied	57,000	12,000	-45,000	-79%
Annual drug utilization management exception requests per 1,000 enrollees				
Exceptions Granted	3.12	5.32	2.20	71%
Exceptions Requested	5.52	5.80	0.28	5%
Average cost per request for drugs related to chronic conditions				
...subject to step therapy	\$249	\$338	\$89	36%
...subject to prior authorization	\$307	\$361	\$54	18%
... subject to mandatory generic substitution	\$262	\$330	\$68	26%
Expenditures				
Premium expenditures by payer				
Private employers for group insurance	\$64,820,615,000	\$64,823,750,000	\$3,135,000	0.0048%
CalPERS HMO employer expenditures (c)	\$4,884,262,000	\$4,884,376,000	\$114,000	0.0023%
Medi-Cal Managed Care Plan expenditures	\$27,983,856,000	\$27,984,324,000	\$468,000	0.0017%
Enrollees for individually purchased insurance	\$14,608,214,000	\$14,611,764,000	\$3,550,000	0.0243%
Individually purchased – outside exchange	\$6,304,061,000	\$6,305,557,000	\$1,496,000	0.0237%
Individually purchased – Covered California	\$8,304,153,000	\$8,306,207,000	\$2,054,000	0.0247%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (b)	\$20,387,090,000	\$20,388,264,000	\$1,174,000	0.0058%
Enrollee expenses				
For covered benefits (deductibles, copayments, etc.)	\$13,565,623,000	\$13,566,142,000	\$519,000	0.0038%
For noncovered benefits (d) (e)	—	—	—	—

Total expenditures	\$146,249,660,000	\$146,258,620,000	\$8,960,000	0.0061%
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Source: California Health Benefits Review Program, 2017.

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) As of June 1, 2016, 58.82% of CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2018.

(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.

(e) Although enrollees with newly compliant benefit coverage may have paid for some drugs before AB 1353, CHBRP cannot estimate the frequency with which such situations may have occurred or and so cannot estimate the total expense such situations might have incurred. Postmandate, such expenses would be gone, though enrollees with newly compliant benefit coverage might, postmandate, pay for some treatments for which coverage is denied (through utilization management review), as some enrollees who always had compliant benefit coverage may have done and may continue to do, postmandate. Again, CHBRP cannot estimate the frequency with which such situations might occur, and or the total expense such situations might incur.

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

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)² conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 1353, a bill which would require that a compliant exceptions processes regarding utilization management techniques applicable to outpatient prescription drug (OPD) benefits be in place and that exceptions be granted when specified conditions are met.

If enacted, AB 1353 would affect the health insurance of approximately 24 million enrollees (62% of all Californians). This represents all Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law — health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI).

Bill-Specific Analysis

AB 1353 would require that DMHC-regulated plans and CDI-regulated policies that include an outpatient prescription drug (OPD) benefit have a process by which exceptions to utilization management protocols can be granted. The bill specifies step therapy and prior authorization requirements and indicates that the exceptions process be relevant to other utilization/medical management techniques.

AB 1353 would require that such exception processes:

- Grant the exception if:
 - The enrollee had been prescribed the drug (within 100 days) prior to enrollment in the current plan/policy **or** had previously been approved for coverage by the current plan/insurer (within 100 days);

and

 - The enrollee is medically stable, and the enrollee's provider continues (at least every 100 days) to prescribe the drug; and
- Respond within 72 hours (or 24 hours, in some cases) to the enrollee with reasons for denying the exception — or consider the exception granted and permit the exception to continue for the duration of the enrollee's relevant medical condition.

AB 1353 would also require plans and policies that include an OPD benefit to grant exceptions to utilization management protocols (including step therapy and prior authorization requirements, or other utilization/medical management techniques), any nonformulary drug that was (within 100 days) previously on formulary and prescribed to the enrollee if all of the following conditions are met:

- The enrollee was previously (within 100 days) prescribed the nonformulary drug;
- The enrollee is medically stable;
- The enrollee had previously been approved for coverage by the current plan/insurer; and
- The enrollee's provider determines that the alternative formulary drug is not medically appropriate.

² CHBRP's authorizing statute is available at <http://chbrp.org/faqs.php>.

In addition, if these conditions are met, the exemption would continue so long as the provider continues (within every 100 days) to prescribe the drug.

The full text of AB 1353 can be found in Appendix A.

CHBRP is aware of a number of current health insurance benefit mandate laws (and one relevant regulation) that include requirements similar to what AB 1353 would require. However, as noted in Table 2, differences exist.

Table 2. AB 1353 and Current California Laws*

Current Law or Regulation	AB 1353 Differences
<p><i>Health and Safety Code 1367.22; prescription drugs: coverage of previously covered drugs.</i> 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. Specifies applicability to "off-label" use of drugs only when <i>Health and Safety Code 1367.21</i> (see row below) conditions have been met.</p>	<p>AB 1353 would require compliance from all CDI-regulated policies as well as all DMHC-regulated plans. The current law addresses all DMHC-regulated plans but only addresses the subset of Small Group and Individual Market CDI-regulated policies required to cover essential health benefits (EHBs).³</p> <p>AB 1353 would require compliant exceptions request process as well as drug coverage when certain conditions are met. The current law directly requires drug coverage when certain conditions are met.</p> <p>AB 1353 would be applicable to new enrollees (or enrollees switching from one product to another) as well as continuing enrollees. The current law is applicable only to continuing enrollees.</p> <p>AB 1353 would not limit "off-label" use in the way the current law does (by reference to <i>Health and Safety Code 1367.21</i>), specifying conditions that include external authority recognition of appropriateness of off-label use).</p>
<p><i>Health and Safety 1367.21 as well as Insurance Code 10123.195; prescription drugs: off-label use.</i> Mandate to cover "off-label" uses of FDA-approved drugs — uses other than the specific FDA-approved use — when specified conditions are met.</p>	<p>See previous row.</p>

³ Insurance Code 10112.27(a)(2)(A)(iv).

Current Law or Regulation

AB 1353 Differences

Health and Safety Code 1367.24; authorization for nonformulary prescription drugs. Mandate to maintain an exceptions request process relevant to nonformulary drugs.

For individual, small group, or large group contracts, *Health and Safety Code 1367.24* includes a timeline for exceptions tied to Section 156.122 of Title 45 of the Code of Federal Regulations: no later than 72 hours following receipt of the request, and in the case of exigent circumstances, no later than 24 hours following receipt of the request. In addition, pursuant to *Health and Safety Code 1367.241* (see row below), failure to respond by the deadline is considered a granting of the request.

AB 1353 would affect CDI-regulated polices and DMHC-regulated plans. The current law addresses DMHC-regulated plans but only addresses the subset of Small Group and Individual Market CDI-regulated policies required to cover essential health benefits (EHBs).⁴

In addition, AB 1353 would apply response deadlines to Medi-Cal managed care plans. The current law exempts them from compliance to this aspect of the law.

Health and Safety Code 1367.241 as well as Insurance Code 10123.191 prior authorization request form. Mandate specifies use of a standard form and establishes a timeline for request review.

See previous row

Health and Safety Code 1367.244 as well as Insurance Code 10123.197 step therapy. Mandate establishes standard prior authorization form (see prior row) as applicable to exceptions requests regarding step therapy.

see previous row.

28 CCR 1300.6724(d): limitations. For DMHC-regulated plans, regulation prohibits step therapy from being applied to a new enrollee's coverage for continued use of a drug.

Where the current regulation and law would prohibit application of step therapy in certain circumstances, AB 1353 would establish an exceptions request process.

as well as

Insurance Code 10123.201(c)(2)(B). For CDI-regulated policies, prohibits step therapy from being applied to a new enrollee's coverage for continued use of a drug.

Source: California Health Benefits Review Program, 2017.

Note: * The current set of laws and regulations are applicable to DMHC-regulated plans and CDI-regulated policies that include and OPD benefit, as AB 1353 would be.

⁴ Insurance Code 10112.27(a)(2)(A)(iv).

Key: CCR = California Code of Regulations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; FDA = Food and Drug Administration; HMO = health maintenance organization; OPD = outpatient prescription drug.

Analytic Approach and Key Assumptions

For this analysis, CHBRP will refer to an AB 1353 compliant process and will discuss exceptions requests being granted or not. CHBRP will do so to avoid confusion. An enrollee new to a drug might file a “prior authorization request” (which would be granted or not) in connection with one of the three utilization management techniques described above, but AB 1353 is concerned with enrollees’ coverage for continued use (not new use) of a drug. CHBRP has also focused this analysis on utilization of drugs associated with chronic conditions, because longer periods of utilization would be most likely to prompt enrollees to engage the exceptions process AB 1353 would require.

The language of AB 1353 is broad, referencing any utilization management technique. For this analysis, CHBRP has focused on three “medical management” utilization management techniques that AB 1353 seems likely to impact:

- Step therapy (or “fail first”) requirements — which require that an enrollee try and fail an alternative drug before coverage for a particular drug can be accessed. These requirements are generally applicable to a list of “on formulary” drugs.
- Prior authorization requirements — which require that the enrollee’s plan or policy actively approve before coverage for a particular drug can be accessed. These requirements are generally applicable to a list of “on formulary” drugs and to all nonformulary drugs.
- Mandatory generic substitution requirements — which make coverage available only for the generic drug when a generic is available. Such requirements can be broad (applicable to all drugs for which a generic is available) or narrow (applicable only to brand name drugs listed as subject to a mandatory generic substitution requirement).

As noted in Table 2, AB 1353 is similar to a set of existing laws but is sometimes relevant to the benefit coverage of a broader set of enrollees. For this analysis, CHBRP has focused on the impact AB 1353 would have related to enrollees switching from one health plan or insurer to another, the aspect of AB 1353 that seems separate from what is required by the existing set of laws.

General Caveat for All CHBRP Analyses

It is important to note that CHBRP’s analysis of proposal benefit mandate bills address the incremental effects — 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.

Interaction With Existing Requirements

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

Federal Requirements

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 1353 may interact with requirements of the ACA as presently exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).⁵

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law.

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. QHPs are required to meet a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.^{6,7}

Because AB 1353 specifies terms of existing benefit coverage, it appears that AB 1353 would not exceed essential health benefits (EHBs), and so would not trigger the ACA requirement that the state defray the cost of additional benefit coverage.

⁵ 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 EHBs. Resources on EHBs and other ACA impacts are available on the CHBRP website: http://www.chbrp.org/other_publications/index.php.

⁶ The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options. CCIIO, Essential Health Benefits Bulletin. Available at: cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.

⁷ HEALTH AND SAFETY CODE HEALTH AND SAFETY CODE Section 1367.005; IC Section 10112.27.

BACKGROUND ON DRUG UTILIZATION MANAGEMENT TECHNIQUES

Drug Utilization Management Techniques

Drug utilization management techniques are designed to manage the cost or safety of use of outpatient prescription drugs (Happe et al., 2014). In addition to minimizing the use of more expensive prescription drugs, these techniques are also sometimes used for clinical reasons. Drug utilization management techniques may promote adherence to clinical recommendations for specific illnesses or may protect enrollees from outdated or potentially dangerous drugs (Pharmacopeia, 2000).

AB 1353 would require that exceptions to applicable OPD utilization management techniques be granted when specified conditions are met (see the *Policy Context* section for details). For this analysis, CHBRP has focused on AB 1353's likely impacts on three drug utilization management techniques (prior authorization requirements, step therapy requirements, and mandatory generic substitution requirements), which are reviewed in detail below. It is important to note that as described in the *Benefit Coverage, Utilization, and Cost Impacts* section, some enrollees are not subject to any utilization management techniques in their OPD coverage, and for those that are, that there is significant variation in terms of what types and to what extent these techniques are used (PBMI, 2016).

Prior Authorization Requirements

For some covered drugs, prior authorization policies require that clinicians document medical need before coverage for the drug is available. This may include drugs on formulary (i.e., a list of drugs that are covered by an insurer) drugs, which are noted as requiring prior authorization (Curtiss, 2005). Prior authorization requirements are also generally applicable to drugs that are not on formulary (Curtiss, 2005; Ovsag et al., 2008; PBMI, 2016). In addition to being used to manage costs, formularies may also be based on reviews of the efficacy or severity of side effects, and may be used to protect enrollees from outdated or potentially dangerous drugs (Curtiss, 2005; Ovsag et al., 2008). For drugs that have the potential for abuse, or have harmful effects if combined with other drugs or administered to a patient with a specific health condition, prior authorization can help ensure that patients receive a limited quantity of the drug, that their other medications are reviewed for interactions, or additional lab work is done to ensure the patient is healthy enough to take the medication (Curtiss, 2005).⁸

Step Therapy Requirements

For some covered drugs, step therapy requirements, sometimes known as “fail-first” protocols, may call for an enrollee to try and fail on one or more step therapy-required drugs to treat a specific condition prior to receiving coverage for the initially prescribed drug. In many instances, the first step of a step therapy requirement mandates the use of a generic drug before “stepping up” to a more costly drug (PBMI, 2015). In addition to managing the cost of more expensive drugs, step therapy is also used to promote physician and patient compliance with recommended treatment and drug safety guidelines. Step therapy requirements usually recommend starting with a drug that is less expensive and/or has more “post-marketing safety experience” (PBMI, 2015). Additionally, step therapy sometimes requires starting with a less potent drug or dosage, perhaps with fewer side effects, and graduating to more potent drugs as necessary, such as requiring the patient to use prescription Motrin (ibuprofen) for pain management before covering OxyContin (oxycodone), which has potential for misuse or abuse (Curtiss, 2005).

⁸ Personal communication ,S. Lynch, March 2017.

Mandatory Generic Substitution Requirements

If a generic formulation of a more expensive brand-name drug is available, mandatory generic substitution requirements may be used to manage the cost of these treatments. This requirement entails that enrollees will only have coverage for the generic drug if one is available, and not the brand-name drug. Exceptions to this rule may be sought by patients or physicians who wish to use a brand-name drug due to perceptions or prior experiences of greater effectiveness (Dunne and Dunne, 2015; Toverud et al., 2015).

Conditions Frequently Associated With Drug Utilization Management Techniques

The following conditions are often treated with drugs that are may be subject to prior authorization or step therapy (PBMI, 2016). This list is not all-inclusive, but representative of conditions for which drug utilization management techniques are commonly used.

- Rheumatoid arthritis/fibromyalgia;
- High cholesterol;
- Psychiatric disorders, such as attention deficit hyperactivity disorder, depression, anxiety, bipolar, schizophrenia;
- Chronic pain management, especially when treated with opioids;
- Migraines;
- Hypertension (high blood pressure) and pulmonary hypertension;
- Allergies;
- Infertility;
- Multiple sclerosis;
- Hereditary angioedema (i.e., episodes of swelling in the face, hands, upper respiratory system, and other areas of the body);
- Urinary incontinence;
- Acid reflux;
- Inflammatory bowel disease/Crohn's disease;
- Diabetes; and
- Asthma.

They include a diverse range of mostly chronic health conditions, including common conditions, such as cardiovascular disease and diabetes, pain management (particularly for conditions that are treated with medications that have a high risk of misuse or abuse), and more rare conditions such as multiple sclerosis, which are treated with specialty drugs.⁹ Mandatory generic substitution requirements may be applied for any brand-name drug, which has a generic equivalent, and thus not usually linked to any specific disease or condition.

⁹ Personal communication, S. Lynch, March 2017.

Drug Utilization Management Exception Requests

Exception Requests

Laws and regulations currently governing drug utilization management and exception requests are discussed in the *Policy Context* section. When drug utilization management techniques are used, procedures are normally included to allow an enrollee or their physician to request an exception by submitting documentation as to why the exception is necessary. Exception requests may take several days to be reviewed. If the carrier grants an exception (i.e., the exception request is approved), the enrollee will pay the designated copayment/coinsurance for their initially prescribed drug. Enrollees whose exception requests are denied may still purchase the initially prescribed drug by paying the full retail price out of pocket.

Transition Procedures

Transition procedures may be in place to provide a new enrollee or a current enrollee affected by a formulary change with a limited supply (e.g., 30 days) of their noncovered drugs to ensure continuity of treatment, and giving the enrollee and his/her physician a timeframe (e.g., 90 days) to find an equivalent covered drug or request an exception to have their nonformulary drug covered in the long term (Medicare Rights Center, 2017). However, such transition plans are temporary in nature, whereas AB 1353 could offer a means of indefinite exception, allowing an enrollee indefinite coverage for a nonformulary drug.

Prevalence of Drug Access Issues After Health Plan Switching and/or Formulary Revision in the United States

By impacting drug coverage, drug utilization management techniques may affect access to prescribed drugs among: 1) enrollees who have recently switched health plans and must participate in a drug utilization management requirement to obtain medications they are currently on; and/or 2) enrollees who must meet drug utilization management requirements to obtain coverage for a drug that was recently removed from their plan's formulary.

Health Plan Switching

General estimates on annual health plan switching are provided in the *Benefit Coverage, Utilization, and Cost Impacts* section. In terms of issues related to accessing prescription drugs after an enrollee switches health plans, one study that examined prescription drug continuity among Medicaid patients with serious mental illness (SMI) switching to Medicare Part D prescription plans in 10 states in 2006 found that 48.3% faced at least one medication access issue in the first 4 months post-switch; the majority of these access issues were attributed to drugs not being on the formulary (70.0%), mandatory generic substitution requirements (53.1%), and step therapy requirements (38.9%) (West et al., 2009). Specifically, 32.4% of California enrollees with SMI faced medication access issues, which was lower compared to 7 of 10 other states included in the study (range: 27.1% to 64.7%), suggesting that Medicare drug utilization management policies in California were less restrictive than in some other states (West et al., 2009).

Formulary Revision

Limited data suggest that formulary revisions can negatively impact current enrollees' access to prescription drugs; a survey of 428 family practice patients in Ohio found that 23% faced challenges in obtaining a new prescription or a refill of an existing prescription in the past 12 months due to formulary

changes (i.e., when a drug was removed from a formulary) (Rood et al., 2012). The most common drugs for which formulary changes had caused an access issue were antihypertensives, cholesterol-lowering drugs, and psychiatric medications (Rood et al., 2012).

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, AB 1353 would require DMHC-regulated plans and CDI-regulated policies that provide coverage for outpatient prescription drugs (OPDs) to grant, when certain conditions are met, exceptions to several utilization management techniques. For this analysis, CHBRP has focused on exceptions to three “medical management” utilization management techniques AB 1353 would be likely to impact: step therapy requirements, prior authorization requirements, and mandatory generic substitution requirements. CHBRP has also considered the AB 1353 compliant utilization management utilization management exceptions request process AB 1353 would require.

AB 1353 would likely result in more approved exceptions to drug utilization management techniques. Approved exceptions would result in continued coverage for and continued use of the drugs for which request for exceptions are submitted. This analysis will focus on the impact of step therapy requirements, prior authorization requirements, and mandatory generic substitution requirements¹⁰ on specified outcomes when no exception is granted.

Research Approach and Methods

Studies related to exception request processes and related utilization management requirements (step therapy, prior authorization, and mandatory generic substitution) were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, and Business Source Complete. The following websites 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.

The search was limited to abstracts of studies published in English. The search was limited to studies published from 2016 to the present because CHBRP had previously conducted thorough literature searches on these topics in 2015 for AB 374, and prior to that for AB 899. Of the 181 articles found in the literature review, 87 were reviewed for potential inclusion in this report on AB 1353, and a total of 21 studies were included in the medical effectiveness review for this report. The medical effectiveness review also presents findings from the 15 studies identified in other CHBRP reports.¹¹ The other articles were eliminated because they did not focus on drug utilization management techniques and/or exceptions, were of poor quality, or did not report findings from clinical research studies. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B: Literature Review Methods.

Methodological Considerations

Of the peer-reviewed studies CHBRP identified on the medical effectiveness of step therapy requirements, PAs, and generic substitution, few if any were randomized controlled trials (RCTs), which

¹⁰ The focus is generic substitution and not therapeutic interchange (or substitution). Therapeutic interchange involves the substitution of one drug for another within the same class, whereas generic substitution involves the substitution of a bio- and therapeutically equivalent product. Therapeutic interchange is far less likely to occur as a result of mandatory generic substitution requirements.

¹¹ CHBRP's 2015 report on AB 374 and 2013 report on AB 899 are available at http://chbrp.org/completed_analyses/index.php.

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 drug utilization program to persons whose health plan or health insurance policy did not. In some studies, persons in the intervention group (i.e., persons with health insurance subject to the step therapy requirements) and the comparison group did not have similar demographic and socioeconomic characteristics prior to implementation of the program (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. In addition, many studies in this area are 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 aimed at reducing use of a manufacturer’s products.

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 prior authorization requirements or step therapy requirements 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.

Potential Outcomes Assessed

Outcomes for Step Therapy Requirements

Step therapy requires an enrollee to try and fail one or more required drugs prior to receiving coverage for the initially prescribed drug. The mechanisms through which step therapy requirements could potentially impact medical effectiveness are through utilization-related outcomes such as continuity of treatment, medication adherence, drug supply, and potentially increased utilization of other medical services such as emergency care. All of these outcomes could potentially directly or indirectly be related to health status and were thus included as outcomes for this literature review.

Outcomes for Prior Authorization Requirements

Prior authorization (PA) is when documentation (of medical necessity and/or other issues) is required before coverage for a drug is made available. As this may result in the change or discontinuation of a given drug to a patient, the potential impact on medical effectiveness is similar to that of step therapy: continuity of treatment, medication adherence, drug supply, and potentially increased utilization of other medical services.

Outcomes for Mandatory Generic Substitution Requirements

Generic substitution (GS) is when coverage for generic formulations is automatically substituted for coverage for more expensive brand-name drugs. The main question of interest with regard to GS is one of efficacy. Specifically, do generic drugs have the same medical effectiveness and potential harms as their name brand counterparts? As mentioned in the introductory paragraphs of the section, generic substitution involves the substitution of a bio and therapeutically equivalent product and is the focus of this analysis. Therapeutic interchange is the substitution of one drug for another within the same class and would not likely be a focus of the exceptions proposed by AB 1353.

Study Findings

Summary of Findings and Conclusions

CHBRP found *conflicting* evidence regarding the impact of step therapy requirements on health outcomes and use of other medical care. CHBRP found limited evidence that step therapy requirements impact drug discontinuation.

CHBRP found *insufficient* and *conflicting* evidence regarding the impact of prior authorization requirements on medical effectiveness as defined by continuity of treatment, supply, and use of other medical services.

CHBRP found a *preponderance* of evidence that generic substitutions are medically equivalent to the brand-name drugs with regard to medical effectiveness.

CHBRP found *insufficient* evidence on the impact of exception request procedures for step therapy requirements, prior authorization requirements, or mandatory generic substitution requirements.

Studies on the Impact of Step Therapy Requirements

Effects on Health Outcomes

CHBRP identified only two studies examining the impact of step therapy requirements on health outcomes. In a retrospective cohort study comparing the incidence of gastrointestinal (GI) complications for patients with restricted coverage (e.g., step therapy with prior authorization restrictions) versus those with unrestricted coverage, it was found that members of the restricted group were at slightly higher risk for serious GI complications compared with the unrestricted group (Louder et al., 2011). In a retrospective study of type II diabetes patients with step therapy in a managed care population, researchers found step therapy patients had lower rates of achieving hemoglobin A1c goals as compared to those on fixed-dose combinations (Williams et al., 2012).

Summary of findings regarding impact of step therapy requirements on health outcomes.

There is *conflicting evidence* to determine whether step therapy requirements directly affect health outcomes.

Effects on Discontinuation and Interruption

Two studies have examined the impact of the step therapy requirements 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 step therapy requirement, 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 step therapy requirement 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.

Another study found that step therapy requirements are associated with higher rates of discontinuing antihypertensive drugs. Mark and colleagues (2009) evaluated a step therapy requirement for

antihypertensive drugs instituted by two employers that required employees and dependents with hypertension who received coverage through the employers to use certain (first-line) angiotensin-converting enzyme inhibitors (ACE inhibitors) or angiotensin receptor blockers (ARBs) for a specified period of time before using another (second-line) ACE inhibitor or ARB. The authors found that following implementation of the step therapy requirement, the rate of discontinuation of antihypertensive drugs was larger in the step therapy requirement group than in the comparison group.

Although these studies did not directly investigate effects on health outcomes, it is plausible that lower rates of 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. Discontinuing antihypertensive drugs may lead to adverse outcomes unless a person can control his or her blood pressure through diet and exercise alone. If not treated, hypertension increases a person's risk of having a stroke or developing heart disease.

Summary of findings regarding impact of step therapy requirements on discontinuation and interruption of drugs. There is *limited evidence* that step therapy requirements could impact discontinuation or interruption rates.

Effects of Step Therapy Requirements on Utilization of Other Medical Care

Findings from studies of the impact of step therapy requirements on rates of hospital admissions, emergency department visits, and outpatient visits are conflicting across classes of drugs. Eight studies evaluated the effects of step therapy requirements 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 step therapy requirements (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 analysis. Findings from these studies are inconsistent. Udall and colleagues (2013) and Suehs and colleagues (2013) reported on the effects of step therapy requirements for anticonvulsant medication on outpatient visits among members of a commercial health plan. Among the plan's commercial population aged 18 to 65 years, the step therapy requirement for anticonvulsants was associated with an increase in outpatient visits (Udall et al., 2013), whereas among the plan's Medicare Advantage Prescription Drug members, the step therapy requirement for anticonvulsants found no difference in outpatient visits (Suehs et al., 2013). Mark and colleagues (2010) reported that a step therapy requirement 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 step therapy requirement for antipsychotics implemented by Georgia's Medicaid program was associated with a decrease in outpatient visits.¹² Delate and colleagues (2005) found that a Medicaid program's step therapy requirement 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 step therapy requirements on use of medical services for any medical conditions. A study of a step therapy requirement for antihypertensive drugs reported that the step therapy requirement was associated with increases in office visits, ED visits, and hospitalizations for all causes (Mark et al., 2009). Two studies of the impact of step therapy requirements 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 increase in expenditures for ED visits, and Smalley and colleagues (1995) found no difference in utilization of office

¹² 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.

visits, ED visits, and hospitalizations. Two studies of a step therapy requirement for anticonvulsant medication reported that the step therapy requirement was associated with an increase in physical therapy visits (Suehs et al., 2013; Udall et al., 2013).

Summary of findings regarding impact of step therapy requirements on health services utilization.

Findings from studies on the impact of step therapy requirements on hospital admission, emergency department visits, and outpatient visits are *conflicting*.

Studies on the Impact of Step Therapy Exceptions

Summary of findings regarding the impact of exceptions to step therapy requirements.

CHBRP found no studies on the impact of step therapy exceptions; therefore, CHBRP concludes that the impact of exception requests processes is unknown. The absence of evidence is not evidence of no effect. It is an indication that the impacts of exceptions to step therapy requirements are unknown. However, it stands to reason that if a drug or therapy is continued as before due to the exception, with no interruption in service or change of drug or treatment, then the impact on medical effectiveness would be neutral (no impact) as no changes would have taken place.

Studies on the Impact of Prior Authorization Requirements

CHBRP found few relevant studies examining the impact on medical effectiveness of prior authorization requirements. However, it stands to reason that if a patient already receiving effective drug therapy has an interruption in service or supply, or must change medication due to prior authorization requirements, the same outcomes as described under step therapy requirements could potentially be experienced and disruptions in treatment continuity, such as initiation, discontinuation, or supply could occur.

The few studies found that directly assessed prior authorization requirements had conflicting results. One study examined clinical outcomes for asthma and allergic rhinitis among children and adolescent members of Oklahoma Medicaid from 2007 through 2010. When comparing data from the pre- and post-prior authorization period, they found no increases in emergency room utilization or disease-related physician office visits (Keast et al., 2014). Another study examined the implementation of a prior authorization requirement and its impact on buprenorphine users for opioid addiction with the PA requiring lower initial dosage rates. The authors reported significant relapse rates for the cohort that experienced the transition to lower dosage rates due to the prior authorization requirement (Clark et al., 2014).

Prior authorization requirements may also be enacted in order to prevent adverse events, such as drug interactions. In a quasi-experimental time-series study conducted using pharmacy claims for 1.4 million patients, Starner and colleagues (2012) examined the effect of a prior authorization requirement enacted as a safety measure in order to deny claims for drugs if they had a history of using any of a list of contraindicated drugs within the past 60 days. It was found that the prior authorization requirements significantly reduced adverse events among health plan members of type II diabetes.

Summary of findings regarding impact of prior authorization requirements. CHBRP found that findings from 3 studies on the impact of prior authorization requirements on health outcomes are *conflicting*.

Studies on the Impact of Prior Authorization Exceptions

Summary of findings regarding Impact of prior authorization exceptions. CHBRP found no studies on the impact of prior authorization exceptions; therefore, CHBRP concludes that impact of an exception procedure 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. However, it stands to reason that if a drug or therapy is continued as before due to the exception, with no interruption in service or change of drug or treatment, then the impact on medical effectiveness would be neutral (no impact) as no changes would have taken place.

Studies on the Impact of Mandatory Generic Substitution Requirements

Researchers generally find that generic substitution is not problematic with regard to effectiveness and health outcomes. A meta-analysis published in 2010 by Lewek and Kardas included 47 studies, 38 of which were RCTs. Their general conclusions were that there was no evidence of superiority of brand-name drugs versus generics. It was noted that, although the generic must contain the same active ingredient in the same quantity, the inert ingredients do not have to be the same. This can lead to differences in drug absorption and distribution. Additionally, generic drugs often are not subject to the same requirements with regard to clinical trials as was required for initial approval of the brand-name medication.

Another literature review examining generic substitution for antiepileptic drugs (Yamada and Welty, 2010), examined 20 studies covering 44,081 participants. They concluded that, in very large part the generic and name brand drugs performed at an equivalent level with regard to effectiveness and adverse events, although there were still some medical complications reported.

Summary of findings regarding Impact of generic substitution. Findings from one meta-analysis covering 47 studies including 38 RCTs and one systematic review including 20 studies found *clear and convincing evidence* that generic substitutions are equivalent to the brand-name drugs with regard to medical effectiveness.

Summary of Findings

Figure 3. Step Therapy Requirements — Health Outcomes

Conclusion

There is *conflicting evidence* on the impact of step therapy requirements on health outcomes based on two studies.

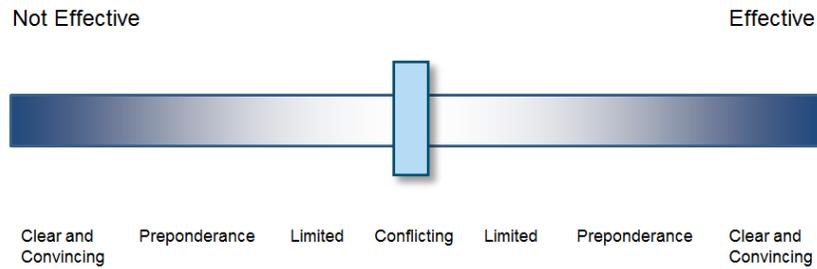


Figure 4. Step Therapy Requirements — Discontinuation and Interruption of Drugs

Conclusion

There is *limited evidence* that step therapy requirements impact rates of discontinuation and interruption of drugs based on two studies.

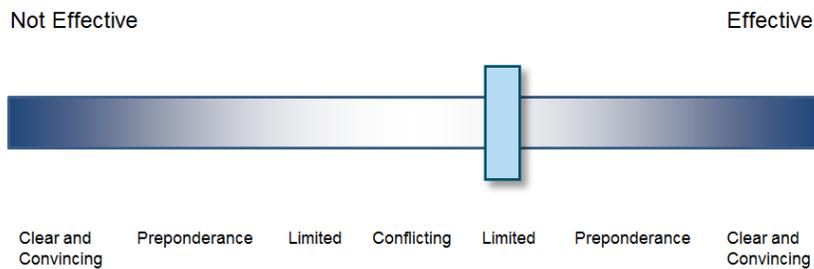


Figure 5. Step Therapy Requirements — Health Services Utilization

Conclusion

There is *conflicting evidence* on the impact of step therapy requirements on hospital admission, emergency department visits, and outpatient visits based on eight studies.

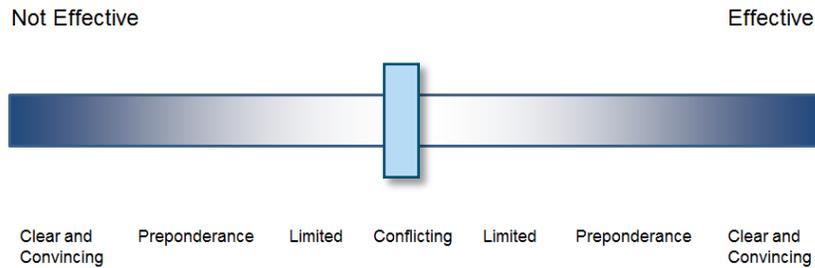


Figure 6. Exceptions to Step Therapy Requirements

Conclusion

There is *insufficient evidence* to determine whether exception procedures directly affect health outcomes and utilization or drugs or health services.

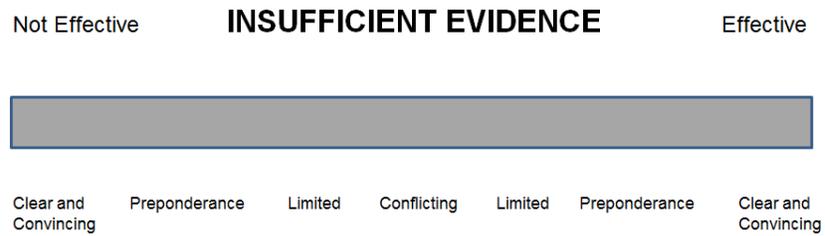


Figure 7. Prior Authorization Requirements — Health Outcomes

Conclusion

There is *conflicting evidence* on the impact of prior authorization requirements on health outcomes based on three studies.

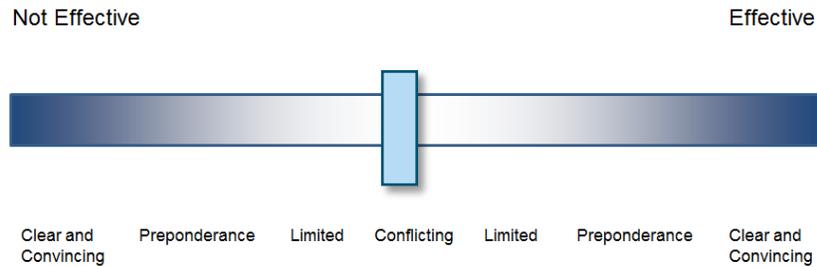


Figure 8. Exceptions to Prior Authorization Requirements

Conclusion

There is *insufficient evidence* to determine whether exceptions to prior authorization requirements directly affect health outcomes and utilization of drugs or health services.

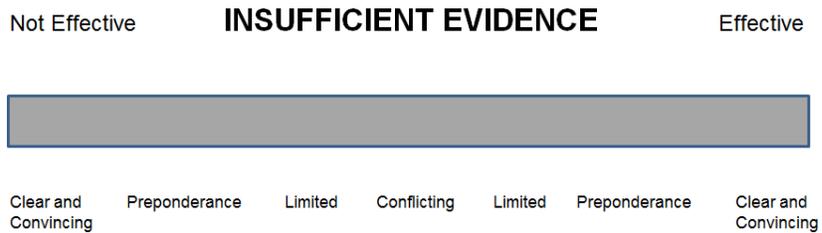
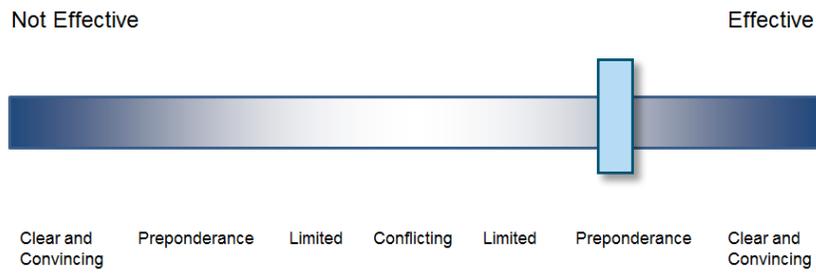


Figure 9. Mandatory Generic Substitution Requirements

Conclusion

CHBRP found a *preponderance of evidence* that generic substitutions are equivalent to the brand-name drugs with regard to medical effectiveness.



BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

This section reports the potential incremental impacts of AB 1353 on estimated baseline benefit coverage, cost, and utilization.

As noted in the *Policy Context* section, a set of current California laws may require continued coverage of a particular drug (or a compliant exceptions request process) for most enrollees in DMHC-regulated plans and many enrollees in CDI-regulated policies. AB 1353 would require that all DMHC-regulated plans and CDI-regulated policies that include an OPD benefit have a process by which exceptions to utilization management protocols can be granted. As noted in the comparison of the bill with current laws offered in Table 2, AB 1353 would be relevant to the benefit coverage of some more enrollees in DMHC-regulated plans and CDI-regulated policies than is the set of current laws. However, a key difference, and the focus of this analysis, is that AB 1353 would extend the possibility of continuing coverage for a particular drug to enrollees switching from one health plan or insurer to another.

As noted, in the *Policy Context* section, AB 1353 is broad as to which utilization management techniques would be affected. For this analysis, CHBRP has considered AB 1353's impact on three:

- Step therapy requirements;
- Prior authorization requirements; and
- Mandatory generic substitution requirements.

These utilization management techniques are further described in the *Background on Drug Utilization Management Techniques* section.

In the first year after implementation, as an addition to the existing set of similar laws, AB 1353 key impact would be related to the aspect of the bill that differs from the existing set of similar laws – it's requirement that enrollees switching to a health plan or policy that applies utilization management techniques to an OPD benefit regulated by DMHC or CDI have access to an AB 1353-compliant exceptions request process. In addition, in some circumstances, AB 1353 would require that such exceptions requests be granted. Among this group of enrollees, those using a drug related to a chronic condition would be the most likely to be affected by AB 1353, as extended use of a drug is more likely to prompt use of an AB 1353-compliant exceptions request process.

In order to quantify possible impacts of AB 1353, CHBRP identified lists of drugs used to treat chronic conditions that may be subject to a step therapy requirement, a prior authorization requirement, or a mandatory generic substitution requirement. CHBRP also estimated baseline figures for exceptions requests made and granted. CHBRP projects that AB 1353 would increase the number of requests made and would also increase the percentage of requests granted. Because the bill would compel granting exceptions under specified circumstances CHBRP has assumed that the increased success rate would encourage more enrollees to make requests.

To determine the impact on costs for increases in the number of requests made and granted, CHBRP used the lists of OPDs related to chronic conditions and potentially subject to utilization management to calculate the average cost per request for drugs related to chronic conditions when an exception is granted or not. Granted exceptions, increase the percentage of higher cost drugs used, and so increase the average cost. CHBRP calculated the per request granted or denied averages for chronic condition

drugs that may be subject to the three considered utilization management techniques. The difference in the two costs multiplied by the number of additional requests granted and weighted by the fraction of enrollees who switch carriers in a given market segment each year yields the increased costs attributable to AB 1353.

Because AB 1353 would, in the first year, primarily impact the benefit coverage of enrollees who switch to a health plan or policy not currently compliant with AB 1353, the bill's effect is proportional to the rate of switching in a given market segment (see Table 3) and weighted by the fraction of enrollees with non-compliant benefit coverage in that market segment.

Table 3. Enrollee Switching Rates by Market Segment

Market Segment	Annual Switch
Large-group market	5%
Small-group market	20%
Individual market	40%
CalPERS HMOs	5%
Medi-Cal managed care (under 65)	5%
Medi-Cal managed care (65+)	5%

Source: CHBRP, 2017, adapted from sources: (1) Covered California 2016-2022 Market Analysis and Planning (PwC, 2016); and (2) Department of Health and Human Services Consumer Decisions Regarding Health Plan Choices in the 2014 and 2015 Marketplaces (DeLeire and Marks, 2015).

For this analysis CHBRP has assumed:

1. In the first year after implementation, AB 1353 would be most relevant to the benefit coverage of enrollees switching from one plan or policy to another because existing law (for almost all enrollees DMHC-regulated plans and many enrollees in CDI-regulated policies) generally allows exceptions to utilization management techniques to be requested by continuously enrolled enrollees (see the *Policy Context* section for more details).
2. Although AB 1353 would theoretically make it easier to switch from one plan or policy to another (because drug coverage would be less likely to be interrupted by utilization management techniques), enrollee switching would not be measurably affected during the first year after implementation.
3. AB 1353 would primarily impact utilization management for OPDs that are used for chronic medical conditions. OPDs for non-chronic conditions have not been included in CHBRP's projections because patients are less likely to refill such prescriptions (or request exceptions from utilization management techniques) because the medical conditions to which they apply do not require ongoing treatment.
4. AB 1353 would result in an increase in the percentage of exceptions that are granted (as benefit coverage becomes fully compliant) from a baseline of 56% to 92%, and a small 5% increase in the number of exceptions requested (as enrollees and providers become aware of AB 1353's passage and the greater likelihood of an exceptions request being granted).
5. AB 1353 would not affect cost sharing applicable to OPDs.

For further details on the underlying data sources and methods, please see Appendix C.

Baseline and Postmandate Benefit Coverage

As noted in Appendix D, almost all enrollees in DMHC-regulated plans and CDI-regulated policies have coverage for outpatient prescription drugs (OPDs). Because AB 1353 addresses the health insurance of enrollees who have OPD coverage that is regulated by DMHC or CDI (but does not require such benefit coverage where it is not present), the benefit coverage of approximately 1.5% of enrollees in DMHC-regulated plans and CDI-regulated policies that have no coverage for outpatient prescription drugs (OPDs) and 3.2% that have OPD coverage that is not regulated by DMHC or CDI are considered compliant with AB 1353 for this analysis.

The percent of enrollees with AB 1353 compliant benefit coverage (either with no DMHC/CDI-regulated OPD benefit, with a benefit that is not subject to the listed utilization management techniques, or with an OPD benefit that complies with AB 1353's requirements) was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 94% of enrollees with privately funded health insurance that can be subject to state mandates. Queries were also sent to Medi-Cal managed care plans and CalPERS.

At baseline, 89% of enrollees have OPD coverage that is fully compliant with AB 1353. Enrollees generally had access to an exceptions request processes and could expect such requests to be granted under certain circumstances. Exceptions request processes were also generally compliant with AB 1353's conditions of response within 24 hours for emergency requests and within 72 hours otherwise. Noncompliance relates to enrollees who switch to a health plan or policy that has utilization management techniques applicable to a currently used drug. For this analysis, noncompliance with AB 1353 means that an enrollee who switches plans and has an ongoing prescription may be denied a requested exception to the utilization management techniques used by their new plan or policy even if the patient requests an exception. AB 1353 would mandate such exceptions be granted when specified conditions are met.

As there is variation by market segment in terms of enrollee switching rates (see Table 3, above), there is also considerable variation as to the presence of the various utilization management techniques (see Table 4, below). Medi-Cal beneficiaries enrolled in DMHC-regulated plans are much more likely than are other enrollees to have an OPD benefit that includes the listed techniques. As cost-sharing is less flexible for Medi-Cal beneficiaries, these techniques may be more key in efforts to influence greater use of less expensive drugs.

Table 4. Presence of Utilization Management Techniques

Utilization Management Technique	Percentage of Enrollees With an Outpatient Prescription Drug Benefit Subject to the Utilization Management Technique	
	Non-Medi-Cal enrollees in DMHC-regulated plans and enrollees in CDI-regulated policies	Medi-Cal beneficiaries enrolled in DMHC-regulated plans
Step therapy requirement	56%	99%
Pre-authorization requirement	56%	99%
Mandatory generic substitution requirement	7%	99%

Source: CHBRP, 2017.

Baseline and Postmandate Utilization

Postmandate, CHBRP projects that there will be an increase from 3.12 to 5.32 exceptions granted per 1,000 enrollees. The increase in exceptions is based on an assumption that 80% of previously denied exceptions requests would be granted, increasing the rate of exceptions granted from 59% to 92% granted postmandate. The increase is due to the fact that more of the previously denied requests that would meet the requirements for AB 1353 would be granted. CHBRP does not project 100% granting of exception because not all requests would meet AB 1353's specifications. CHBRP has assumed an increase of 5% in the total number of exception requests made because some patients may be encouraged to file exception requests if they know that their medical circumstances warrant an automatic exception.

CHBRP assumes there would be no resulting increase in the utilization of OPDs, but that additional granted requests would result in switching of use from generally less expensive OPDs to generally more expensive alternatives.

Baseline and Postmandate Per-Unit Cost

Per-unit costs are not projected to change as a result of AB 1353, but average costs are projected to increase, postmandate, because the additional granted exceptions would lead to greater use of more expensive drugs. The change is based on differences in average unit costs, weighted by utilization prevalence, between "high-cost" drugs and the "low-cost" alternative drugs utilization management techniques would encourage. Weighted by the rate of exceptions granted and the change from baseline to postmandate, the average cost per exception request (as noted in Table 1) would increase from \$249 to \$338 for chronic condition drugs subject to step therapy, from \$307 to \$361 for chronic condition drugs subject to prior authorization, and from \$262 to \$330 for chronic condition drugs subject to mandatory generic substitution. The change assumes 1.5 additional prescriptions filled per exception request as some patients would eventually move through the requirements of the relevant utilization management technique and be granted coverage for the more expensive OPD.

Baseline and Postmandate Expenditures

Table 5 and Table 6 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses).

AB 1353 would increase total net annual expenditures by \$8,960,000 or 0.0061% for enrollees with DMHC-regulated plans and CDI-regulated policies. This includes a \$519,000 increase in enrollee expenses for covered and/or noncovered benefits. The effect size of AB 1353 is limited as it is associated only with enrollees who (1) switch to a plan or policy that includes an OPD benefit subject to a relevant utilization management technique and (2) then request an exception in order to continue utilizing a chronic condition drug.

Premiums

Changes in premiums as a result of AB 1353 would vary by market segment. Because AB 1353 allows for enrollees who switch plans to continue to use OPDs prior to enrollment, the bill will have its biggest initial year impact on market segments where enrollees are more likely to switch from one plan or policy to

another. Due to varied annual enrollee switching rates (see Table 3), impacts would be greatest, as noted in Table 6, in the individual market and greater in the small group than in the large group market. , Among publicly funded DMHC-regulated health plans (i.e., Medi-Cal and CalPERS), the effect would be similar to what would be expected for the large group market.

Enrollee Expenses

As noted in Table 6, changes in total enrollee expenses for covered benefits (deductibles, copays, etc.) would vary by market segment. Such changes are related to the number of enrollees using chronic condition drugs expected to use request utilization management exceptions during the year after enactment.

CHBRP projects no change to copayments or copayment rates but does project an increase in utilization of more expensive OPDs and therefore an increase in enrollee cost sharing. It is possible that some enrollees incurred expenses related to drugs for which coverage was denied, but CHBRP cannot estimate the frequency with which such situations occur and so cannot offer a calculation of impact.

Potential Cost Offsets or Savings in the First 12 Months After Enactment

CHBRP finds insufficient evidence to determine whether AB 1353 would generate cost savings (see the *Medical Effectiveness* section for more details).

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. Carriers currently have procedures in place for responding to OPD utilization management exception requests and will be projected to see a small increase in the number of requests.

Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

Postmandate Changes in the Number of Uninsured Persons¹³

As the change in average premiums does not exceed 1% for any market segment (see Table 5), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 1353.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of AB 1353.

¹³ See also CHBRP's *Criteria and Methods for Estimating the Impact of Mandates on the Number of Uninsured*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

Cost shifting is unlikely due to the changes proposed in AB 1353. Insurance providers should bear the full cost of changes in prescription drug and other types of utilization.

Table 5. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2018

	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+) (c)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates ^(d)	9,128,000	3,163,000	2,379,000	884,000	7,192,000	644,000	276,000	145,000	237,000	24,048,000
Total enrollees in plans/policies subject to AB 1353	9,128,000	3,163,000	2,379,000	884,000	7,192,000	644,000	276,000	145,000	237,000	24,048,000
Premiums										
Average portion of premium paid by employer	\$456.42	\$324.76	\$0.00	\$460.43	\$257.00	\$751.00	\$527.06	\$433.40	\$0.00	\$97,688,732,000
Average portion of premium paid by employee	\$115.59	\$149.62	\$469.56	\$115.11	\$0.00	\$0.00	\$166.32	\$157.88	\$423.05	\$34,995,304,000
Total premium	\$572.01	\$474.38	\$469.56	\$575.54	\$257.00	\$751.00	\$693.38	\$591.28	\$423.05	\$132,684,037,000
Enrollee expenses										
for covered benefits (deductibles, copays, etc.)	\$44.11	\$103.11	\$126.07	\$31.49	\$0.00	\$0.00	\$115.39	\$166.25	\$75.74	\$13,565,623,000
Enrollee expenses for benefits not covered ^(e)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
Total expenditures	\$616.12	\$577.49	\$595.64	\$607.03	\$257.00	\$751.00	\$808.77	\$757.53	\$498.79	\$146,249,660,000

Source: California Health Benefits Review Program, 2017.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, both on Covered California and outside the health insurance marketplace.

(b) As of June 1, 2016, 58.82% of CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2018.

(c) Medi-Cal managed care plan expenditures for members over age 65 years include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) 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.

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

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

Table 6. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2018

	DMHC-Regulated Plans						CDI-Regulated Policies			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+) (c)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	9,128,000	3,163,000	2,379,000	884,000	7,192,000	644,000	276,000	145,000	237,000	24,048,000
Total enrollees in plans/policies subject to AB 1353	9,128,000	3,163,000	2,379,000	884,000	7,192,000	644,000	276,000	145,000	237,000	24,048,000
Premiums										
Average portion of premium paid by employer	\$0.0124	\$0.0425	\$0.0000	\$0.0108	\$0.0050	\$0.0050	\$0.0153	\$0.0670	\$0.0000	\$3,719,000
Average portion of premium paid by employee	\$0.0031	\$0.0196	\$0.1134	\$0.0027	\$0.0000	\$0.0000	\$0.0048	\$0.0244	\$0.1094	\$4,723,000
Total premium	\$0.0155	\$0.0620	\$0.1134	\$0.0135	\$0.0050	\$0.0050	\$0.0201	\$0.0915	\$0.1094	\$8,441,000
Enrollee expenses										
For covered benefits (deductibles, copays, etc.)	\$0.0009	\$0.0038	\$0.0073	\$0.0007	\$0.0003	\$0.0003	\$0.0012	\$0.0060	\$0.0063	\$519,000
For noncovered benefits (e)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
Total expenditures	\$0.0164	\$0.0659	\$0.1208	\$0.0143	\$0.0052	\$0.0052	\$0.0213	\$0.0975	\$0.1157	\$8,961,000
Percent change										
Premiums	0.0027%	0.0131%	0.0242%	0.0024%	0.0019%	0.0007%	0.0029%	0.0155%	0.0258%	0.0064%
Total expenditures	0.0027%	0.0114%	0.0203%	0.0024%	0.0020%	0.0007%	0.0026%	0.0129%	0.0232%	0.0061%

Source: California Health Benefits Review Program, 2017.

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

(b) As of June 1, 2016, 58.82% of CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2018.

(c) Medi-Cal managed care plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) 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.

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

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

PUBLIC HEALTH IMPACTS

AB 1353 would require that exceptions to any applicable OPD utilization management techniques be granted when specified conditions are met (see the *Policy Context* section for details).

The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate). This section estimates the short-term impact¹⁴ of AB 1353 on mandate-relevant health outcomes, racial/ethnic disparities, financial burden, and economic loss. See the *Long-Term Impacts* section for a discussion of utilization and cost impacts, health impacts, and social determinants of health.

Estimated Public Health Outcomes

Measurable health outcomes relevant to AB 1353 include those related to continuity or discontinuity of OPD treatment, adherence to treatment, and treatment efficacy for diverse diseases and conditions treated with drugs that are subject to drug utilization management techniques including prior authorization requirements, step therapy requirements, and mandatory generic substitution requirements.

As presented in the Medical Effectiveness section, CHBRP found limited, conflicting, or insufficient evidence regarding the impact of these drug utilization management techniques on continuity of and adherence to OPD treatments. One exception was that CHBRP found a preponderance of evidence that generic substitutions are medically equivalent to the brand-name drugs with regard to medical effectiveness. CHBRP found no studies on the impact of exception requests for either step therapy requirements or prior authorization requirements. The absence of evidence is not evidence of no effect. It stands to reason that if a drug utilization management technique causes a delay or discontinuation of treatment, the technique might be associated with worse health outcomes unless patients have access to other equally effective treatments. Conversely, the use of utilization management techniques 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 1353 would produce a 5% increase in the number of exceptions requested by enrollees, and a 71% increase in the number of exceptions granted postmandate, or about 54,000 total extra exceptions granted in the first year.

Although the requesting and granting of exceptions that meet the criteria specified in AB 1353 are estimated to increase, insufficient, limited, or conflicting evidence about the impact of these specific drug utilization management on continuity of treatment and health outcomes prevents CHBRP from estimating any certain public health impact. However, it stands to reason that enrollee satisfaction may improve, and for some enrollees, negative health outcomes may be avoided if they are able to more easily obtain a permanent exception to be able to continue using their OPDs.

¹⁴ CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

In the first year postmandate, the public health impact of AB 1353 is unknown despite a relatively small increase in the number of exceptions to drug utilization management techniques requested and granted due to *insufficient, limited, or conflicting evidence* regarding the effect of prior authorization and step therapy on health outcomes related to discontinuities in OPD treatments for a range of illnesses and conditions, and a preponderance of evidence that generic drugs and brand-name drugs are clinically equivalent. 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.

Health Disparities¹⁵ in the Effect of Drug Utilization Management Techniques on Access to Prescription Drugs

“Health disparity’ denotes differences, whether unjust or not. ‘Health inequity’ on the other hand, denotes differences in health [status or] outcomes that are systematic, avoidable, and unjust.” (Wyatt et al., 2016). CHBRP found literature identifying differences by age in how drug utilization management techniques may affect access to prescription drugs. No disparities were found for gender, race/ethnicity, or gender identity/sexual orientation.

A cross-sectional study found that younger family practice patients in Ohio were more likely to face problems accessing prescribed drugs due to insurance formulary changes compared to older patients after controlling for gender, self-reported health status, number of prescriptions taken, and government versus commercial insurance coverage (Rood et al., 2012). This multivariate analysis also found that having a higher number of prescriptions and having government-provided health care, the latter of which implies meeting requirements for low income individuals, were independently associated with a greater likelihood of facing medication access issues after a formulary change (Rood et al., 2012). The reason for these differences is unclear; although younger individuals with low-incomes tend to be insured by Medicaid, which has stricter drug utilization management requirements compared to commercial insurers or Medicare (West et al., 2009).

Impact on Disparities¹⁶

Insurance benefit mandates that bring all state-regulated plans and policies to parity may change an existing disparity. As described in the previous paragraph, limited evidence was found to suggest that disparities in OPD access and continuity issues due to drug utilization management techniques exist by age and by type of insurance, with younger individuals and individuals with government-provided insurance (vs. commercial insurance) facing more issues. However, due to the limited nature of this evidence of disparities, and insufficient or conflicting evidence of how these specific access issues affect health outcomes, CHBRP cannot estimate changes in disparities caused by AB1353 in the first 12 months postmandate. (For a discussion of potential impacts beyond the first 12 months of implementation, see the *Long-Term Impacts* section.)

¹⁵ Several competing definitions of “health disparities” exist. CHBRP relies on the following definition: Health disparity is defined as the difference in health outcomes between groups within a population. While the terms may seem interchangeable, “health disparity” is different from “health inequity.” “Health disparity” denotes differences, whether unjust or not. “Health inequity,” on the other hand, denotes differences in health [status or] outcomes that are systematic, avoidable, and unjust.” Wyatt et al., 2016.

¹⁶ For details about CHBRP’s methodological approach to analyzing disparities, see http://www.chbrp.org/analysis_methodology/docs/Estimating_Impacts_on_Racial_and_Ethnic_Disparities_FINAL.pdf.

The extent of disparities in age and type of insurance regarding OPD access issues due to drug utilization management techniques is unknown due to a lack of evidence. Therefore, the extent to which AB 1353 would have an impact on potential disparities is unknown.

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 coinsurance). The *Benefit Coverage, Utilization, and Cost Impacts* section estimates that AB 1353 would result in an additional 54,000 granted exceptions in the first year postmandate. Due to new coverage, CHBRP estimates that total out-of-pocket expenses for those newly covered who use the drug utilization management exceptions would increase by a maximum of \$519,000 under the new mandate (Table 1). This does not take into account that some of the newly covered enrollees might see a decrease in out-of-pocket expenditures by avoiding copayments/coinsurance for one or more prescription drugs on which they would have failed to respond to as a part of step therapy, but as a whole, CHBRP estimates an increase because this number was not able to be estimated. This increased cost may seem counterintuitive, but generally (and as reflected in CHBRP's cost model), drug utilization management techniques identify lower-cost drugs as the preferred prescription. Although AB 1353 allows exceptions for continued drug coverage in the event of a formulary revision or enrollees' switching plans or carriers, it does not dictate the cost sharing at which excepted drugs must be covered. Enrollees will have coverage for their previously prescribed OPDs, but potentially still have to pay a higher copayment or co-insurance. CHBRP estimates are based on claims data and may overestimate the cost increases for enrollees due to carriers' ability to negotiate discounted rates that are unavailable to patients and their families.

CHBRP estimates that AB 1353 would modify coverage and increase the net financial burden by \$519,000 in the first year postmandate for enrollees who are granted an additional 54,000 drug utilization management exceptions.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact¹⁷ of AB 1353, which CHBRP defines as impacts occurring beyond the first 12 months after 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

Although CHBRP projects that AB 1353 would cause a 5% increase in the number of exception requests in the first year, in the long run, this figure may increase as more enrollees, providers, and pharmacists become aware of the conditions under which AB 1353 would require that exceptions be granted. At baseline, it is likely that some enrollees who would be affected by AB 1353 do not file for exceptions because they are unaware that it is possible to do so or do not believe it is likely that their exception would be granted. Additionally, as noted in the *Policy Context* section, the current set of laws similar to what AB 1353 would require do apply to the benefit coverage of quite as many enrollees as would AB 1353. In particular, AB 1353 would create new requirements for some enrollees in CDI-regulated policies. Therefore, a somewhat larger long-term effect for enrollees in CDI-regulated policies is possible.

Utilization management exists for purposes besides controlling costs. Utilization management is also used to discourage the use of drugs with potentially dangerous side effects, or drugs that are inferior to newer drugs on the market (see the *Background on Drug Utilization Management Techniques* section for more details). However, as new generic drugs and other lower cost alternatives come onto the market, AB 1353 will limit inducements to enrollees with ongoing prescriptions for higher cost drugs to switch to lower cost alternatives. This impact is likely to be most notable among Medi-Cal beneficiaries enrolled in DMHC-regulated plans, as other inducements, such as higher cost-sharing requirements for more expensive drugs, are less likely to be present.

Cost Impacts

Just as utilization impacts may increase over time, so may the cost impacts of greater utilization of more expensive drugs. As with utilization impacts, the related cost impact of AB 1353 would be likely to be greater among Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments), whereas 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 (beyond 12 months postmandate) to the public's health that would be attributable to the mandate, including impacts on social determinants of health, premature death, and economic loss.

¹⁷ See also CHBRP's *Criteria and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

In the case of AB 1353, CHBRP estimates the increase in exemption requests would be approximately 5% per year, and would likely increase over time, especially for enrollees in CDI-regulated plans who will be most affected by this bill. The evidence for the medical effectiveness of granting exception requests to ensure continuity of treatment is insufficient or conflicting; therefore, the long-term public health impacts (including for low socioeconomic status and health literacy issues, premature death, and economic loss) are unknown, but it stands to reason that enrollee satisfaction will improve, and for some enrollees, negative health outcomes could be avoided if easing the requirements for exceptions leads more enrollees to continue OPD treatment. In the future, CHBRP would expect enrollees' who are granted drug utilization management exceptions to continue to pay additional out-of-pocket expenses for the originally prescribed drugs, which are generally more costly than the drugs that would have been required by drug utilization management techniques.

Impacts on the Social Determinants of Health¹⁸ and Disparities

Per statute, CHBRP includes discussion of social determinants of health (SDoH) that may contribute to the use of drug utilization management techniques. SDoH include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography). In the case of AB 1353, CHBRP found one study that suggested that socioeconomic status may contribute to the effects of drug utilization management techniques on access to prescription drugs. Persons on government-funded insurance plans, which may require enrollees to meet low-income requirements, were shown to be 1.9 times more likely to face issues accessing prescription drugs due to health plan formulary changes, usually removing a drug from a form (Rood et al., 2012). Persons with lower levels of education or health literacy, which would enable them to familiarize themselves their health insurance benefits, may also be at a greater disadvantage in being able to communicate with their physician to file an exception or find an appropriate covered replacement for a drug that is no longer covered, which may contribute to inconsistent adherence or discontinuation of treatment.¹⁹

Societal Burden of Drug Utilization Management Techniques on Access to Prescription Drugs in the United States

The following presents an estimated cost of the various drug utilization management techniques and any impacts they may have on access to prescription drugs in the United States and other developed countries. These costs include direct (medical care, etc.) and indirect costs (lost wages, etc.), and differ from the incremental cost estimates associated with AB 1353 that are discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section. Reviews of multiple studies have conflicting conclusions about the societal benefit or burden of how drug utilization management techniques and subsequent drug access issues affect the balance between direct medical costs borne by the health care system or the patient (e.g., prescription costs, hospitalizations, outpatient treatment) and changing patient outcomes due to treatment discontinuity. A review of 19 studies on formulary exclusions (i.e., revisions to remove a drug from a formulary) found net reductions in healthcare costs by saving on drug expenditures with minimal or no effect on patient outcomes, but a minority of these studies (21%) found that cost savings were outweighed by subsequent visits and lab work, particularly for patients who had switched to a less expensive proton-pump inhibitor for the treatment of gastrointestinal acid reflux (Chambers et al., 2016). Another review of the effect of drug utilization management techniques found similarly mixed balances between medical direct cost saving and patient outcomes such as adherence and discontinuation, with step therapy, prior authorization, and formulary restrictions having more negative effects, and quantity limits having more positive effects (Happe et al., 2014). No studies were found describing more indirect

¹⁸ For more information about SDoH, see *Incorporating Relevant Social Determinants of Health into CHBRP Benefit Mandate Analyses* available at http://www.chbrp.org/analysis_methodology/public_health_analysis.php.

¹⁹ Personal communication, S. Halini Lynch, March 2017.

impacts on quality of life, productivity, or economic loss due to maintaining or losing continuity of treatment with specific drugs due to drug utilization management techniques, formulary changes, or plan switching.

Periodically, health insurance mandates can mediate health inequities. Evidence presented in the *Background on Drug Utilization Management Techniques* section indicates that low socioeconomic status (i.e., having government-provided healthcare) is correlated with a greater likelihood of experiencing issues with continued access to OPDs due to health plan formulary changes (Rood et al., 2012). However, this one study does not provide sufficient evidence to make clear why these differences are present. More research is needed to understand if this relationship exists in a larger U.S. population, and if so, what is driving this relationship (e.g., health literacy, government insurance regulations, patient-provider communication issues, etc.).

There is a potential relationship between the SDoH of low socioeconomic status and having OPD access issues due to formulary changes, but the extent to which AB 1353 would have an impact on this relationship is unknown due to a lack of evidence on the mechanisms which would drive this difference.

APPENDIX A TEXT OF BILL ANALYZED

On March 1, 2017, the California Assembly Committee on Health requested that CHBRP analyze AB 1353. The bill language was amended on March 23, 2017 and is pasted below.

CALIFORNIA LEGISLATURE— 2017–2018 REGULAR SESSION

ASSEMBLY BILL

No. 1353

Introduced by Assembly Member Waldron

February 17, 2017

An act to add Sections 1367.245 and 1367.246 to the Health and Safety Code, and to add Sections 10123.203 and 10123.204 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 1353, as amended, Waldron. Health care coverage: prescription drugs: continuity of care. 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. Existing law makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Insurance Commissioner. Existing law requires a health care service plan contract or a health insurance policy that provides coverage for outpatient prescription drugs to cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary, and authorizes a health care service plan or health insurer to utilize formulary, prior authorization, step therapy, or other reasonable medical management practices in the provision of outpatient prescription drug coverage. Existing law requires a health care service plan health insurer that provides coverage for prescription drugs to utilize a specified uniform prior authorization form or electronic authorization process for prescription drugs that require prior authorization by the plan or health insurer, and requires the plan or health insurer to respond to those prior authorization requests within 72 hours for nonurgent requests and 24 hours if exigent circumstances, as defined, exist. Existing law authorizes a request for an exception to a health care service plan's or health insurer's step therapy process for prescription drugs to be submitted in the same manner as a request for prior authorization for prescription drugs, and requires the plan or health insurer to treat, and respond to, those exception requests in the same manner as a request for prior authorization for prescription drugs. Existing law prohibits a health care service plan contract that covers prescription drug benefits from limiting or excluding coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to

prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition.

This bill would require a health care service plan and health insurer that provides coverage for outpatient prescription drugs to establish an expeditious process, as described, by which enrollees and insureds, enrollees' and insureds' designees, or prescribing providers may request and obtain an exception to any prior authorization process or any other utilization management or medical management practices utilized by the plan or health insurer for medically necessary prescription drugs, and would require a plan or health insurer to grant an exception request under these provisions under specified circumstances to ensure continuity of care for an enrollee or insured who is medically stable and was *either* previously prescribed the prescription drug ~~either~~ *within 100 days* prior to enrollment or ~~if~~ *if, within 100 days prior to the exception request*, the prescription drug was previously approved for coverage by the plan or ~~insurer~~ *insurer for the same medical condition*. The bill would require a plan or health insurer to respond to an exception request within 72 hours, or within 24 hours if exigent circumstances exist, following receipt of the exception request. The bill would require a plan or health insurer that denies an exception request to provide the reasons for the denial in a notice provided to the enrollee or insured, as specified.

The bill would require a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2018, that provides coverage for outpatient prescription drugs to provide coverage, without imposing a prior authorization or step therapy process, or any other reasonable utilization management or medical management practices, for a medically necessary nonformulary drug ~~that was~~ *prescribed for an enrollee or insured that was, within the 100-day period immediately preceding the date of the prescription*, previously included on a formulary or formularies maintained by the plan or health insurer if specified conditions are satisfied, including that the enrollee's or insured's prescribing provider has determined that prescribing an alternative formulary prescription drug is not medically appropriate for the enrollee or insured or represents a significant health risk to the enrollee or insured.

By imposing new requirements on a health care service plan, the willful violation of which is a crime, this 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.

DIGEST KEY

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

BILL TEXT

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

SECTION 1.

Section 1367.245 is added to the Health and Safety Code, immediately following Section 1367.244, to read:

1367.245.

(a) Notwithstanding Section 1367.24, 1367.241, or any other law, a health care service plan that provides coverage for outpatient prescription drugs shall establish an expeditious process, as described in this section, by which enrollees, enrollees' designees, or prescribing providers may request and obtain an exception to any prior authorization process or any other utilization management or medical management practices utilized by the plan for medically necessary prescription drugs.

(b) A health care service plan shall grant an exception request under this section if both of the following are met:

(1) Either the enrollee was previously prescribed the prescription drug ~~prior to~~ *within 100 days prior to his or her* enrollment in the health care service plan or the prescription drug ~~had had,~~ *within 100 days prior to the exception request,* been previously approved for coverage by the plan for ~~a~~ *the same* medical condition of the enrollee.

(2) The enrollee is medically stable and the enrollee's prescribing provider ~~continues~~ *continues, at least once every 100 days from the date of the last prescription for the same drug,* to prescribe the drug for the *same* medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition.

(c) (1) A health care service plan shall respond to an exception request within 72 hours following receipt of the exception request. A plan that grants an exception request under this subdivision shall provide coverage of the prescription drug for the duration of the medical condition for which the medication was prescribed.

(2) A health care service plan shall provide that an exception request may be obtained within 24 hours if an enrollee is suffering from a health condition that may seriously jeopardize his or her life, health, or ability to regain maximum function or if an enrollee is undergoing a current course of treatment using that prescription drug. A plan that grants an exception request under this subdivision based on exigent circumstances shall provide coverage for the duration of the medical condition for which the medication was prescribed.

(d) If a health care service plan fails to respond within 72 hours, or within 24 hours if exigent circumstances exist, upon receipt of a completed exception request, the exception request shall be deemed to have been granted.

(e) A health care service plan that denies a request made pursuant to this section to obtain an exception to any prior authorization process or any other reasonable utilization management or medical management practices utilized by the plan for a medically necessary prescription drug shall provide the reasons for the denial in a notice provided to the enrollee. The notice shall indicate that the enrollee may file a grievance with the plan if the enrollee objects to the denial. The notice shall comply with subdivision (b) of Section 1368.02.

SEC. 2.

Section 1367.246 is added to the Health and Safety Code, immediately following Section 1367.245, to read:

1367.246.

Notwithstanding subdivision (c) of Section 1367.22, Section 1367.24, or any other law, a health care service plan contract issued, amended, or renewed on or after January 1, 2018, that provides coverage for outpatient prescription drugs shall provide coverage, without imposing a prior authorization or step therapy process, or any other reasonable utilization management or medical management practices, for a medically necessary nonformulary prescription drug ~~that was prescribed for an enrollee that was,~~ *within the 100-day period immediately preceding the date of the prescription,* previously included on a formulary or formularies for outpatient prescription drugs maintained by the plan if all of the following conditions are satisfied:

- (a) The enrollee ~~was~~ *was, within the immediately preceding 100 days*, previously prescribed that nonformulary prescription drug.
- (b) The enrollee is medically stable.
- (c) The drug previously had been approved for coverage by the plan for ~~a~~ *the same* medical condition of the enrollee and the enrollee's prescribing provider ~~continues~~ *continues, at least once every 100 days from the date of the last prescription for the same drug*, to prescribe the drug for the *same* medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition.
- (d) The enrollee's prescribing provider has determined that prescribing an alternative formulary prescription drug is not medically appropriate for the enrollee or represents a significant health risk to the enrollee.

SEC. 3.

Section 10123.203 is added to the Insurance Code, to read:

10123.203.

- (a) Notwithstanding Section 10123.191 or any other law, a health insurer that provides coverage for outpatient prescription drugs shall establish an expeditious process, as described in this section, by which insureds, insureds' designees, or prescribing providers may request and obtain an exception to any prior authorization process or any other utilization management or medical management practices utilized by the health insurer for medically necessary prescription drugs.
- (b) A health insurer shall grant an exception request under this section if both of the following are met:
 - (1) Either the insured was previously prescribed the prescription drug *within 100 days* prior to enrollment or the prescription drug ~~had~~ *had, within 100 days prior to the exception request*, been previously approved for coverage by the health insurer for ~~a~~ *the same* medical condition of the insured.
 - (2) The insured is medically stable and the insured's prescribing provider ~~continues~~ *continues, at least once every 100 days from the date of the last prescription for the same drug*, to prescribe the drug for the *same* medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the insured's medical condition.
- (c) (1) A health insurer shall respond to an exception request within 72 hours following receipt of the exception request. A health insurer that grants an exception request under this subdivision shall provide coverage of the prescription drug for the duration of the medical condition for which the medication was prescribed.
- (2) A health insurer shall provide that an exception request may be obtained within 24 hours if an insured is suffering from a health condition that may seriously jeopardize his or her life, health, or ability to regain maximum function or if an insured is undergoing a current course of treatment using that prescription drug. A health insurer that grants an exception request under this subdivision based on exigent circumstances shall provide coverage for the duration of the medical condition for which the medication was prescribed.
- (d) If a health insurer fails to respond within 72 hours, or within 24 hours if exigent circumstances exist, upon receipt of a completed exception request, the exception request shall be deemed to have been granted.
- (e) A health insurer that denies a request made pursuant to this section to obtain an exception to any prior authorization process or any other reasonable utilization management or medical management practices utilized by the health insurer for a medically necessary prescription drug shall provide the reasons for the denial in a notice provided to the insured. The notice shall

indicate that the insured may file a grievance with the health insurer if the insured objects to the denial.

SEC. 4.

Section 10123.204 is added to the Insurance Code, to read:

10123.204.

Notwithstanding any other law, a health insurance policy issued, amended, or renewed on or after January 1, 2018, that provides coverage for outpatient prescription drugs shall provide coverage, without imposing a prior authorization or step therapy process, or any other reasonable utilization management or medical management practices, for a medically necessary nonformulary prescription drug ~~that was~~ *prescribed for an insured that was, within the 100-day period immediately preceding the date of the prescription,* previously included on a formulary or formularies for outpatient prescription drugs maintained by the health insurer if all of the following conditions are satisfied:

- (a) The insured ~~was~~ *was, within the immediately preceding 100 days,* previously prescribed that nonformulary prescription drug.
- (b) The insured is medically stable.
- (c) The drug previously had been approved for coverage by the health insurer for ~~a the same~~ *the same* medical condition of the insured and the insured's prescribing provider ~~continues~~ *continues, at least once every 100 days from the date of the last prescription for the same drug,* to prescribe the drug for the *same* medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the insured's medical condition.
- (d) The insured's prescribing provider has determined that prescribing an alternative formulary prescription drug is not medically appropriate for the insured or represents a significant health risk to the insured.

SEC. 5.

No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

APPENDIX B LITERATURE REVIEW METHODS

Appendix B describes methods used in the medical effectiveness literature review for AB 1353, a bill that would provide exceptions to any applicable OPD utilization management techniques be granted when specified conditions are met (see the *Policy Context* section for details).

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 the relevant utilization management techniques 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.

The literature search was limited to studies published in English, for which abstracts were available, from 2015 to present.

The following databases of peer-reviewed literature were searched: MEDLINE (PubMed), Business Sources Complete, the Cochrane Library (includes Cochrane Register of Controlled Clinical Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment Database, and NHS Economic Evaluation Database, EconLit, Web of Science (includes Science Citation Index Expanded and the Social Science Citation Index), Embase, Cumulative Index of Nursing and Allied Health Literature, Pharmaceuticals – BIOSIS, Pharmaceuticals – International Pharmaceutical Abstracts (if available), and Pharmaceuticals – Micromedex (if available). In addition, websites maintained by the following organizations that index or publish systematic reviews and evidence-based guidelines were searched: National Institutes of Health, Institute for Clinical Systems Improvement, and the World Health Organization. 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. Abstracts for 181 articles were identified. 87 meta-analyses, systematic reviews, narrative reviews, RCTs, and nonrandomized studies with comparison groups were retrieved and reviewed and 21 were included in the medical effectiveness review for this 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*.²⁰ 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.

²⁰ Available at: http://www.chbrp.org/analysis_methodology/medical_effectiveness_analysis.php.

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;
- Limited evidence;
- 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.

Search Terms

The search terms used to locate studies relevant to AB 1353 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/Prior authorization and...

- Generic substitution
- Prescription drugs
- Exception
- Cost savings
- Unit cost
- Price
- Clinical care pathways
- Drug Utilization Management
- Generics
- Fail first
- Prescription drugs
- Exception
- Override
- Exemption
- Race
- Racial disparities
- Ethnicity
- Gender
- Sex differences
- Prevalence
- Incidence
- Screen
- Premature death
- Economic loss
- Morbidity
- Mortality
- Long term impacts
- Productivity and cost of illness
- Continuity of care
- Price of treatment
- Unit cost of treatment
- Cost of treatment
- Cost offset associated with treatment
- Cost savings associated with treatment
- Cost-effectiveness of treatment
- Cost-utility associated with treatment
- Utilization of treatment
- Demand for treatment
- Supply of treatment
- Price elasticity of demand for treatment

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

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, the University of California, San Francisco, and the University of California, Davis, as well as the contracted actuarial firms, PricewaterhouseCoopers (PwC).²¹

Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses are available at CHBRP's website.²²

This appendix describes any analysis-specific data sources, estimation methods, caveats and assumptions used in preparing this cost impact analysis.

Analysis-Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions relevant to specifically to an analysis of AB 1353. Baseline unit cost of drugs subject to utilization management techniques were developed based on 2014 and 2015 MarketScan commercial claims data. The drugs included in the analysis were based on lists of drugs subject to step therapy, prior authorization, and generic substitution provided by DMHC-regulated plans and CDI-regulated insurers. From those lists, CHBPR identified chronic condition drugs, as drugs used for extended periods would be most likely to be impacted by AB 1353. To determine the average unit cost, CHBRP identified "high-low" pairs of drugs -- high cost chronic condition drugs subject to utilization management and their low cost counterparts. CHBRP identified a number of high-low pairs for each category: 29 for step therapy, 42 for pre-authorization, and 542 for generic substitution. Drugs for which MarketScan utilization data did not exist for one of the "High-Low" pairs were excluded from the analysis. The drugs subject to a utilization management technique and included in the analysis are listed, below, in tables C-1, C-2, and C-3. CHBRP determined the average unit cost for each drug and calculated the weighted average unit costs by applying the utilization for the drugs subject to utilization management. As expected, MarketScan utilization for the higher costs drugs in the "High-Low" pair is typically much lower than their low-cost counterparts. Although the unit cost for each drug does not change postmandate, the average cost per unit increases postmandate, reflecting the shift toward the higher-cost drugs. CHBRP assumes that there are 1.5 scripts per exception request, regardless of whether it is approved or denied. Tables C-1 and C-2 show the list of drugs subject to step therapy and prior authorization that were analyzed.

²¹ CHBRP's authorizing statute, available at www.chbrp.org/docs/authorizing_statute.pdf, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

²² See *2017 Cost Impact Analyses: Data Sources, Caveats, and Assumptions*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

Table C-1. Chronic Condition Drugs Subject to Step Therapy Requirements

AMRIX	PRISTIQ	TIVORBEX
AZOR	PROVIGIL	TRIBENZOR
BINOSTO	ROZEREM	TYZEKA
CELEBREX	SILENOR	VASCEPA
CORLANOR	TACLONEX	VIIBRYD
FETZIMA	TEKAMLO	ZIPSOR
FORFIVO XL	TEKTURNA	ZORVOLEX
LIVALO	TEKTURNA HCT	ZYFLO
PATADAY	TEVETEN	ZYFLO CR
PAZEO	TEVETEN HCT	

Table C-2. Chronic Condition Drugs Subject to Prior Authorization Requirements

ABILIFY DISCMELT	GRALISE	RASUVO
ACIPHEX	HYSINGLA ER	RAYOS
ACTICLATE	KITABIS PAK	REVATIO
ACZONE	LAMICTAL ODT	RYTARY
APTENSIO XR	LAMISIL	SEROQUEL XR
ASTAGRAF XL	LOCOID	TOPICORT
BUNAVAIL	MESTINON	UCERIS
CADUET	MIRVASO	ULTRASAL-ER
CAMBIA	NATESTO	ULTRAVATE
CELEBREX	NEXIUM	VALCHLOR
CLARINEX	ONMEL	ZOVIRAX
CRINONE	OXTELLAR XR	ZYCLARA
DULOXETINE HCL	PENNSAID	
EDLUAR	PHENTERMINE HCL	
GIAZO	QUDEXY XR	

Table C-3. Chronic Condition Drugs Subject to Mandatory Generic Substitution Requirements

ABILIFY	ACULAR	AMARYL
ABILIFY DISCMELT	ACULAR LS	AMBIEN
ACCOLATE	ADALAT CC	AMBIEN CR
ACCUPRIL	ADIPEX-P	AMERGE
ACEON	AGGRENOX	AMICAR
ACIPHEX	AGRYLIN	ANAFRANIL
ACTIGALL	ALDACTAZIDE	ANAPROX DS
ACTIQ	ALDACTONE	ANASPAZ
ACTIVELLA	ALDARA	ANTABUSE
ACTONEL	ALORA	ANUSOL-HC
ACTOPLUS MET	ALPHAGAN P	ARAVA
ACTOS	ALTACE	ARICEPT

ARIMIDEX	CASODEX	DIBENZYLINE
ARIXTRA	CATAPRES	DIFFERIN
ARMOUR THYROID	CATAPRES-TTS	DIFLUCAN
AROMASIN	CEFTIN	DILANTIN
ARTHROTEC	CELEBREX	DILANTIN INFATABS
ASTEPRO	CELEXA	DILAUDID
ATACAND	CELLCEPT	DIOVAN
ATACAND HCT	CENTANY	DIOVAN HCT
ATELVIA	CILOXAN	DIPROLENE
ATRALIN	CLARINEX	DIPROLENE AF
ATROVENT	CLEOCIN	DITROPAN XL
AUGMENTIN	CLIMARA	DORYX
AUGMENTIN ES-600	CLOBEX	DOVONEX
AUGMENTIN XR	CLOZARIL	DRISDOL
AVALIDE	COLAZAL	DRYSOL
AVAPRO	COLESTID	DUAC
AVAR LS CLEANSER	COLESTID FLAVORED	DUETACT
AVAR-E LS	COMBIVIR	DURAGESIC
AVELOX	COMTAN	DYAZIDE
AVODART	CONDYLOX	E.E.S. GRANULES
AXERT	CORDARONE	EC-NAPROSYN
AYGESTIN	COREG	EFFEXOR XR
AZOR	CORGARD	EFUDEX
AZULFIDINE	CORTEF	ELDEPRYL
AZULFIDINE EN-TABS	COUMADIN	ELESTAT
BACTRIM	COZAAR	ELIMITE
BACTRIM DS	CUTIVATE	ELIPHOS
BACTROBAN	CYCLOGYL	ELOCON
BARACLUDE	CYMBALTA	EMLA
BENTYL	CYTOMEL	ENTOCORT EC
BENZAMYCIN	CYTOTEC	EPIVIR
BETAGAN	DANTRIUM	EPIVIR HBV
BETAPACE	DAYPRO	EPZICOM
BETAPACE AF	DDAVP	ERYGEL
BEYAZ	DEMADEX	ESGIC-PLUS
BIAXIN	DEMEROL	ESTRACE
BLEPH-10	DEPAKOTE	ESTROSTEP FE
BONIVA	DEPAKOTE ER	EVISTA
BUPAP	DEPAKOTE SPRINKLES	EVOCLIN
CADUET	DERMATOP	EVOXAC
CAFERGOT	DERMOTIC	EXALGO
CALAN SR	DESOGEN	EXELON
CARAFATE	DESOWEN	EXFORGE
CARBATROL	DESOXYN	EXFORGE HCT
CARDIZEM CD	DETROL	EXTINA
CARDIZEM LA	DETROL LA	FAMVIR
CARDURA	DEXEDRINE	FAZACLO
CARNITOR	DIABETA	FELBATOL
CARNITOR SF	DIAMOX	FELDENE

FEMARA	KENALOG	MAXALT
FEMCON FE	KEPPRA	MAXALT-MLT
FENOGLIDE	KEPPRA XR	MAXZIDE
FEXMID	KITABIS PAK	MAXZIDE-25
FIORICET	KLARON	MEDROL
FIORINAL	KLONOPIN	MEGACE ES
FLAGYL	K-PHOS NEUTRAL	MEPRON
FLOMAX	K-TAB	MESTINON
FLONASE	LAC-HYDRIN	MESTINON TIMESPAN
FML LIQUIFILM	LAMICTAL	METADATE CD
FOCALIN	LAMICTAL ODT	METHADOSE
FOCALIN XR	LAMICTAL XR	METHYLIN
FORTAMET	LAMISIL	METROCREAM
FOSAMAX	LANOXIN	METROGEL
FURADANTIN	LASIX	METROGEL-VAGINAL
GABITRIL	LESCOL	METROLOTION
GARAMYCIN	LESCOL XL	MICARDIS
GASTROCROM	LEVAQUIN	MICARDIS HCT
GEODON	LEVBID	MICROZIDE
GLUCOPHAGE	LEXAPRO	MILLIPRED
GLUCOPHAGE XR	LIDODERM	MINIVELLE
GLUCOTROL	LIPITOR	MIRALAX
GLUCOTROL XL	LITHOBID	MIRAPEX
GLUCOVANCE	LOCOID	MIRAPEX ER
GLUMETZA	LOCOID LIPOCREAM	MOBIC
GOLYTELY	LODOSYN	MONODOX
GRIFULVIN V	LOESTRIN FE 1.5/30	MS CONTIN
GRIS-PEG	LOESTRIN FE 1/20	MYAMBTOL
HALCION	LOFIBRA	MYCOBUTIN
HECTOROL	LOMOTIL	MYFORTIC
HEPSERA	LOPID	MYSOLINE
HYDREA	LOPRESSOR	NAFTIN
HYPER-SAL	LOPROX	NAMENDA
HYZAAR	LOTENSIN	NAPRELAN
IMITREX	LOTENSIN HCT	NAPROSYN
IMURAN	LOTREL	NARDIL
INDERAL LA	LOTRISONE	NASACORT ALLERGY 24HR
INSpra	LOTRONEX	NASONEX
INTERMEZZO	LOVAZA	NEORAL
INTUNIV	LOVENOX	NEOSPORIN
INVEGA	LUNESTA	NEURONTIN
IOPIDINE	LUXIQ	NEXIUM
ISOPTO CARPINE	LYSTEDA	NIASPAN
ISORDIL TITRADOSE	MACROBID	NICODERM CQ
JALYN	MACRODANTIN	NICORETTE
KADIAN	MALARONE	NITRO-DUR
KAPVAY	MARINOL	NITROSTAT
KAYEXALATE	MAVIK	
KEFLEX		

NIZORAL	PREVIDENT	SALVAX
NORINYL 1+35	PREVPAC	SANDIMMUNE
NORPACE	PRILOSEC	SANDOSTATIN
NORPRAMIN	PRINIVIL	SARAFEM
NOR-QD	PRISTIQ	SECTRAL
NORVASC	PROCARDIA	SEROQUEL
OCUFLOX	PROCARDIA XL	SEROQUEL XR
OLUX	PROCENTRA	SILVADENE
OLUX-E	PROGRAF	SINEMET
OPANA	PROMETRIUM	SINEMET CR
ORAP	PROSCAR	SINGULAIR
ORAPRED ODT	PROTONIX	SKELAXIN
ORTHO-NOVUM 7/7/7	PROTOPIC	SOLARAZE
OVACE PLUS	PROVERA	SOMA
OVACE WASH	PROVIGIL	SONATA
OVCON-35	PROZAC	SORIATANE
OVIDE	PROZAC WEEKLY	STARLIX
OXANDRIN	PULMICORT	STROMEKTOL
OXSORALEN ULTRA	QUALAQUIN	SULAR
PAMELOR	QUESTRAN	SUMADAN WASH
PAMINE	RAPAMUNE	SUMAXIN
PARLODEL	REGLAN	SUMAXIN TS
PARNATE	REMERON	SUMAXIN WASH
PATANASE	REMERON SOLTAB	SUPRAX
PATANOL	REQUIP	SYMBYAX
PAXIL	REQUIP XL	SYNALAR
PAXIL CR	RESTORIL	SYNTHROID
PENLAC NAIL LACQUER	RETIN-A	TACLONEX
PENNSAID	RETIN-A MICRO	TAPAZOLE
PEPCID	REVATIO	TARGRETIN
PERCOCET	RHINOCORT AQUA	TARKA
PERSANTINE	RILUTEK	TASMAR
PHENYTEK	RISPERDAL	TEGRETOL
PHOSLO	RISPERDAL M-TAB	TEGRETOL-XR
PLAN B ONE-STEP	RITALIN	TEMODAR
PLAQUENIL	RITALIN LA	TEMOVATE
PLAVIX	ROBAXIN	TENORETIC 100
PLETAL	ROBAXIN-750	TENORMIN
PLEXION	ROBINUL	TERAZOL 3
POLYTRIM	ROBINUL FORTE	TERAZOL 7
PONSTEL	ROCALTROL	TESSALON PERLES
POTASSIUM CHLORIDE	ROSULA	TIAZAC
PRANDIN	ROXICODONE	TIMOPTIC-XE
PRAVACHOL	RYTHMOL	TINDAMAX
PRECOSE	RYTHMOL SR	TOBRADEX
PRED FORTE	SALAGEN	TOBREX
PREVACID	SALEX	TOFRANIL

TOPAMAX	VASOTEC	YAZ
TOPICORT	VELTIN	ZANAFLEX
TOPROL XL	VERELAN	ZANTAC
TRANXENE T	VERELAN PM	ZARONTIN
TRICOR	VERIPRED 20	ZEGERID
TRIGLIDE	VFEND	ZEMPLAR
TRILEPTAL	VIBRAMYCIN	ZESTORETIC
TRILIPIX	VIDEX EC	ZESTRIL
TRIZIVIR	VIRAMUNE	ZIAC
TRUSOPT	VIRAMUNE XR	ZIAGEN
TWYNSTA	VIRASAL	ZITHROMAX
ULTRAM	VIROPTIC	ZOCOR
ULTRAM ER	VISTARIL	ZOFRAN
ULTRASAL-ER	VOLTAREN	ZOFRAN ODT
ULTRAVATE	VOLTAREN-XR	ZOLOFT
URAMAXIN	WELLBUTRIN	ZOMIG
UROCIT-K	WELLBUTRIN SR	ZONEGRAN
UROXATRAL	XALATAN	ZOVIRAX
URSO FORTE	XANAX	ZYBAN
VAGIFEM	XANAX XR	ZYLOPRIM
VALCYTE	XELODA	ZYMAXID
VALIUM	XENAZINE	ZYPREXA
VALTREX	XOPENEX	ZYPREXA ZYDIS
VANCOCIN HCL	XYLOCAINE	ZYVOX
VASERETIC	XYZAL	

The estimated number of baseline exception requests and approvals are based on responses from the carrier surveys. Carrier enrollment was used to calculate baseline exception requests per 1,000 enrollees. Exception requests were assume to be equally distributed across the three utilization management techniques. The effect of this assumption is minimal on final costs as each utilization management technique’s effect is approximately equal.

CHBRP assumes that among the enrollees switching from one health plan/insurer to another (see market segment specific switch rates in Table 3 in the *Benefit Coverage, Cost, and Utilization Impacts* section) switches plans, not all would be affected by this mandate. For example, those who are seeking exception to a drug when they did not use the exception drug when on their previous health plan should not receive an exception approval due to this mandate. CHBRP assumes that 80% of the previous denials are now approved post mandate under AB1353.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits AB 1353 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 include cost-sharing arrangements for description treatment or service. 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.

APPENDIX D OUTPATIENT PRESCRIPTION DRUG BENEFITS AND STATE-LEVEL MANDATES

As noted in Table D-1, for 2018, CHBRP estimates that approximately 1.5% of enrollees in plans regulated by the California Department of Managed Health Care (DMHC) or policies regulated by the California Department of Insurance (CDI) have no coverage for outpatient prescription drugs (OPDs) and 3.2% of these enrollees have OPD coverage that is not regulated by DMHC or CDI.

Table 7. 2018 Outpatient Prescription Drug Coverage

Enrollees in DMHC-Regulated Plans and in CDI-Regulated Policies	
Enrollee counts	
Total enrollees in plans/policies subject to state mandates (a)	24,048,000
Outpatient prescription drug (OPD) coverage	
DMHC- or CDI-regulated brand name and generic OPD coverage	95.1%
DMHC- or CDI-regulated generic only coverage	0.3%
No OPD coverage	1.5%
Other OPD coverage	3.2%

Source: California Health Benefits Review Program, 2017.

Notes: (a) 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; HMO = Health Maintenance Organization; OPD = Outpatient Prescription Drug.

Additional detail about the presence and absence of OPD coverage in various market segments is presented in the tables that follow.

Relevant State and Federal Law

- A number of overlapping state and federal laws require broad OPD coverage or coverage for particular drugs, but the requirements are not applicable to all forms of health insurance.
- Some (but not all) small-group and individual market health care service plans and health insurance policies are required to provide coverage for OPDs as part of coverage for essential health benefits (EHBs).²³
- Some (but not all) large-group, small-group, and individual market health care service plans and health insurance policies are required to provide coverage for particular drugs as part of preventive services, but not for all OPDs.²⁴

²³ California Health & Safety Code: 1367.005, 1367.006, 1367.0065; California Insurance Code: 10112.27, 10112.28, 10112.285; Federal Affordable Care Act of 2010: Section 1301, 1302, and Section 1201 modifying Section 2707 of the PHSA.

- Some state-level mandates, applicable to some or all plans and policies regulated by DMHC or CDI, require coverage for particular drugs. For example, there is a mandate that requires coverage for insulin and prescription drugs for the treatment of diabetes but does not require coverage for drugs that treat diabetes-related conditions.²⁵

However, this mix of laws does not require that all enrollees in plans and policies regulated by DMHC or CDI have an OPD benefit.

Presence or Absence of Coverage for Outpatient Prescription Drugs and Related Regulation

Coverage of OPDs was estimated through surveys and queries. For enrollees in the privately funded markets regulated by DMHC and CDI, coverage was determined by responses to a survey of the largest providers of health insurance in California. Responses to this survey represent 92.9% of enrollees in these markets. The California Public Employees' Retirement System (CalPERS) was queried regarding coverage among DMHC regulated plan enrollees associated with CalPERS. The California Department of Health Care Services (DHCS) was queried about coverage among Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

From this information, CHBRP concluded that most enrollees have coverage for OPDs through their DMHC-regulated plan or CDI-regulated policy. These enrollee's OPD coverage is generally accessed through the enrollee's "pharmacy benefit," and generally used when acquiring drugs at an outpatient pharmacy or mail order service. When OPD coverage is handled through a subcontracting pharmacy benefit management (PBM) organization, the plan or policy, licensed by DMHC or CDI, requires the subcontracting PBM to comply with relevant state-level health insurance benefit mandates.

As coverage for OPDs is not universally required, some enrollees in DMHC-regulated plans and CDI-regulated policies have no OPD coverage. Although these enrollee's health insurance cover prescription drugs delivered during a hospital (or other facility) admission and some prescription drugs that are dispensed through a clinician's office, these enrollees' health insurance would not generally help them acquire drugs intended for outpatient use. As noted above, there are some drug specific exceptions, such as insulin, but coverage would be limited to those specific outpatient drugs.

In terms of alternate regulation, some enrollees who have no OPD benefit through their DMHC-regulated plan or CDI-regulated policy still do have an OPD benefit — but have it through another source, one that is not regulated by DMHC or CDI. Such a circumstance can occur if, for example, an employer arranges for a large-group plan to exclude coverage for OPDs and then contracts separately with a PBM to administer an OPD benefit. In this example, the PBM is not a subcontractor to a plan or insurer; it is directly contracting with the employer. If the contracting PBM is not licensed by either DMHC or CDI, it is not subject to state-level health insurance benefit mandates.

²⁴ California Health & Safety Code: 1367.002; California Insurance Code: 10112.2; Federal Affordable Care Act of 2010: Section 1001 modifying Section 2713 of the PHSA.

²⁵ California Health & Safety Code: 1367.51 and California Insurance Code: 10176.61.

Table 8. 2018 Outpatient Prescription Drug Coverage in the Large-Group and Publicly Funded Markets

	DMHC-Regulated Plans					CDI-Regulated Policies	
	Privately Funded Large Group		Publicly Funded Plans			Privately Funded Large Group	
	Grand-fathered	Non-Grand-fathered	CalPERS HMOs (a)	MCMC (Under 65) (b)	MCMC (65+) (b)	Grandfathered	Non-Grand-fathered
Enrollee counts							
Total enrollees in plans/policies subject to state mandates (c)	2,363,000	6,765,000	884,000	7,192,000	644,000	57,000	219,000
Outpatient Prescription Drug (OPD) Coverage							
DMHC or CDI regulated brand name and generic OPD coverage	95.0%	89.6%	74.8%	100.0%	100.0%	80.9%	86.7%
DMHC or CDI regulated generic only coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
No OPD coverage	5.0%	2.8%	0.0%	0.0%	0.0%	19.1%	2.9%
Other OPD coverage	0.0%	7.6%	25.2%	0.0%	0.0%	0.0%	10.4%

Source: California Health Benefits Review Program, 2017.

Notes: (a) As of June 1, 2016, 58.82% of CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2018.

(b) Medi-Cal managed care plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(c) 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; COHS = County Operated Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal managed care; OPD = outpatient prescription drug.

Table 9. 2018 Outpatient Prescription Drug Coverage in the DMHC-Regulated Small-Group and Individual Markets

	Privately Funded Small Group				Privately Funded Individual			
	<i>Grand-fathered</i>	<i>Non-Grand-fathered Covered California (a)</i>	<i>Non-Grand-fathered Mirror Plans (b)</i>	<i>Other Non-Grand-fathered</i>	<i>Grand-fathered</i>	<i>Non-Grand-fathered Covered California (a)</i>	<i>Non-Grand-fathered Mirror Plans (b)</i>	<i>Other Non-Grand-fathered</i>
Enrollee counts								
Total enrollees in plans/policies subject to state mandates (c)	384,000	33,000	738,000	2,008,000	138,000	1,425,000	638,000	178,000
Outpatient prescription drug (OPD) coverage								
DMHC- or CDI-regulated brand name and generic OPD coverage	99.9%	100.0%	100.0%	100.0%	92.3%	100.0%	100.0%	100.0%
DMHC- or CDI-regulated generic only coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
No OPD coverage	0.1%	0.0%	0.0%	0.0%	7.7%	0.0%	0.0%	0.0%
Other OPD coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: California Health Benefits Review Program, 2017.

Notes: (a) The Affordable Care Act (ACA) requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces. In California, the marketplace is called "Covered California."

(b) "Mirror Plans" are qualified health plans (QHPs) available outside of Covered California.

(c) 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; COHS = County Operated Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal managed care; OPD = outpatient prescription drug.

Table 10. 2018 Outpatient Prescription Drug Coverage in CDI-Regulated Small-Group and Individual Markets

	Privately Funded Small Group				Privately Funded Individual			
	<i>Grand-fathered</i>	<i>Non-Grand-fathered Covered California (a)</i>	<i>Non-Grand-fathered Mirror Plans (b)</i>	<i>Other Non-Grand-fathered</i>	<i>Grand-fathered</i>	<i>Non-Grand-fathered Covered California (a)</i>	<i>Non-Grand-fathered Mirror Plans (b)</i>	<i>Other Non-Grand-fathered</i>
Enrollee counts								
Total enrollees in plans/policies subject to state mandates (c)	1,000	5,000	25,000	114,000	186,000	3,000	22,000	26,000
Outpatient prescription drug (OPD) coverage								
DMHC- or CDI-regulated brand name and generic OPD coverage	100.0%	100.0%	100.0%	100.0%	50.9%	100.0%	100.0%	100.0%
DMHC- or CDI-regulated generic only coverage	0.0%	0.0%	0.0%	0.0%	35.3%	0.0%	0.0%	0.0%
No OPD coverage	0.0%	0.0%	0.0%	0.0%	13.7%	0.0%	0.0%	0.0%
Other OPD coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: California Health Benefits Review Program, 2017.

Notes: (a) The Affordable Care Act (ACA) requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces. In California, the marketplace is called “Covered California.”

(b) “Mirror Plans” are qualified health plans (QHPs) available outside of Covered California.

(c) 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; COHS = County Operated Health Systems; MCMC = Medi-Cal managed care; OPD = outpatient prescription drug.

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A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, PricewaterhouseCoopers, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

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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**A small percentage of AJ Scheitler's time is available to
serve as a backup CHBRP staff resource.*

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A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP Faculty Task Force comprises rotating representatives from multiple University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis.

CHBRP staff coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature.

CHBRP is also grateful for the valuable assistance of its National Advisory Council, who provide expert reviews of draft analyses and offer general guidance on the program. CHBRP is administered by UC Health at the University of California, Office of the President, led by John D. Stobo, MD, Executive Vice President.

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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