

California Health Benefits Review Program

Analysis of California Senate Bill 1285 Advanced Practice Pharmacist

A Report to the 2017-2018 California State Legislature

April 17, 2018



Key Findings:

Analysis of California Senate Bill 1285 Advanced Practice Pharmacist

Summary to the 2017–2018 California State Legislature, April 17, 2018



CONTEXT

Advanced practice pharmacist (APh) licensure is relatively new in California, with the first licenses issued in 2017.¹ As of April 2018, there are 279 APh licenses in California (less than 1% of all California's pharmacists).

Working under collaborative practice agreements with physicians (CPAs), APhs may provide the following services: performance of patient assessments; ordering and interpreting all drug therapy–related tests; referring patients to other healthcare providers; participating in the evaluation and management of diseases and health conditions in collaboration with other healthcare providers; and initiating, adjusting, modifying, and discontinuing drug therapy pursuant to an order by a patient's treating prescriber and in accordance with established protocols.

Other pharmacists may also work under CPAs and may provide similar services in some settings.

Designations similar to California's APh exist in three other states: Montana, New Mexico, and North Carolina.

BILL SUMMARY

For plans regulated by the California Department of Managed Health Care (DMHC) or policies regulated by the California Department of Insurance (CDI), as well as for Medi-Cal managed care through either a DMHC-regulated plan or a County Operated Health System (COHS) program, SB 1285 would require coverage of services provided by an APh, including APh services related to comprehensive medication management (CMM).

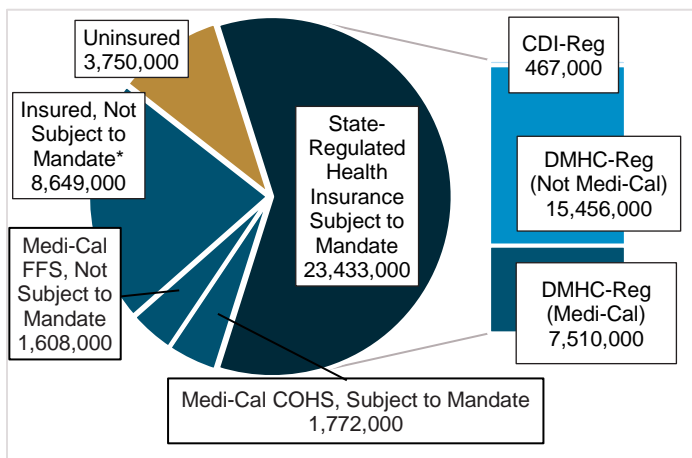
Figure 1 notes how many Californians have health insurance that would be subject to SB 1285.

AT A GLANCE

The version of California Senate Bill (SB) 1285 analyzed by CHBRP would require coverage of services provided by advanced practice pharmacists (APhs).

1. CHBRP estimates that, in 2019, 100% of the 23.4 million Californians enrolled in state-regulated health insurance, as well as the 1.8 million Medi-Cal beneficiaries enrolled in County Operated Health System (COHS) managed care will have insurance subject to SB 1285.
2. **Benefit coverage.** SB 1285 would require coverage for services delivered by APhs,
3. **Utilization & expenditures.** Due to the limited number of APhs (less than 1% of all California pharmacists) and the varied possibilities for reimbursing covered services (reimbursement, salary, etc.), the impact of SB 1285 on utilization and expenditures is unknown.
4. **Medical effectiveness.** There is limited or inconclusive evidence of effectiveness of services provided by APhs or other pharmacists working under a collaborative practice agreement with a physician.
5. **Public health.** The short-term or long-term public health impacts are unknown.

¹ Refer to CHBRP's full report for full citations and references.

Figure 1. Health Insurance in CA and SB 1285

Source: CHBRP 2018.

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

IMPACTS

Medical Effectiveness

CHBRP found limited evidence that medication adherence does not differ between persons who receive care from APhs or pharmacists with collaborative practice agreements and persons who receive usual care. There is inconclusive evidence as to whether APhs and pharmacists with collaborative practice agreements increase use of antihypertensive medications among persons with uncontrolled hypertension. With regard to clinical outcomes, there is a preponderance of evidence that receiving care from APhs or pharmacists with collaborative practice agreements is associated with better blood pressure control than persons who receive usual care. Findings for effects on control of diabetes and cholesterol are inconclusive; some studies find no difference between persons who receive care from APhs or pharmacists with collaborative practice agreements and persons who receive usual care, whereas others find that receipt of services from APhs or pharmacists with collaborative practice agreements is associated with better control of diabetes or cholesterol. Findings regarding effects on numbers of outpatient visits are inconclusive. Findings from studies that examined rates of ED visits and hospitalizations suggest that rates of ED visits and hospitalizations among persons who receive services from

an APh or a pharmacist with a collaborative practice agreement are similar to the rates of ED visits and hospitalizations among persons who received usual care. The only study that examined adverse events found no difference between persons who received services from pharmacists with collaborative practice agreements and persons who received usual care.

Benefit Coverage, Utilization, and Cost

Currently, 52% of enrollees have coverage for the services provided by an APh or a pharmacist working under a collaborative practice agreement (CPA). SB 1285 would raise the figure to 100%.

However, the means of compensation for services provided varies. CHBRP is unaware of covered APh services being discretely reimbursable, but reimbursement may be bundled with other provided services or services may be accessible through an APh's employment relationship with a licensed health facility, a physician, practice, or other employer.

Due to the limited number of APhs and the variety of possible forms of coverage compensation that would appear to be compliant with SB 1285, the impact of the mandate on utilization and expenditures is unknown.

Public Health Impacts

SB 1285 would have unknown impacts on short-term or long-term public health.

Essential Health Benefits and the Affordable Care Act

SB 1285 would not appear to interact with essential health benefits (EHBs) because it not a new benefit coverage requirement, but a requirement to cover services provided by APhs practicing in their existing professional scope. As physicians and other pharmacists with CPAs appear to already engage in these activities, SB 1285 does not appear to add to covered benefits despite adding coverage for a specific type of provider.

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California Health Benefits Review Program

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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-related legislation. The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses 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. 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.

TABLE OF CONTENTS

List of Tables and Figures.....	v
Policy Context	1
Background on Advanced Practice Pharmacists	4
Advanced Practice Pharmacists: Scope of Practice and Practice Settings	4
Medical Effectiveness	7
Research Approach and Methods.....	7
Methodological Considerations	8
Outcomes Assessed.....	13
Benefit Coverage, Utilization, and Cost Impacts.....	20
Baseline and Postmandate Benefit Coverage	20
Baseline and Postmandate Utilization.....	20
Baseline and Postmandate Per-Unit Cost.....	20
Baseline and Postmandate Expenditures	21
Other Considerations for Policymakers.....	22
Public Health Impacts	23
Long-Term Impacts	24
Appendix A Text of Bill Analyzed.....	A-1
Appendix B Literature review specifications	B-1
Appendix C Cost Impact Analysis: Data Sources, Caveats, and Assumptions.....	C-1
References	
California Health Benefits Review Program Committees and Staff	
Acknowledgements	

LIST OF TABLES AND FIGURES

Table 1. Scope of Practice for Pharmacists and Advance Practice Pharmacists in California	5
Table 2. Outline of Study Details	9
Figure 1. Medication Adherence	13
Figure 2. Use of Antihypertensive Medications.....	14
Figure 3. Diabetes	15
Figure 4. Hypertension	16
Figure 5. Cholesterol.....	17
Figure 6. Outpatient Visits.....	18
Figure 7. Emergency Department Visits	18

POLICY CONTEXT

The California Senate 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 Senate Bill (SB) 1285, Advanced Practice Pharmacists.

Bill Language

For plans regulated by the California Department of Managed Health Care (DMHC) or policies regulated by the California Department of Insurance (CDI), as well as for Medi-Cal managed care through either a DMHC-regulated plan or a County Operated Health System (COHS) program, SB 1285 would:

- Require coverage of services provided by an advanced practice pharmacist (APh) that are within their scope of practice.
- Require that these services, when delivered by an APh, be covered, potentially as discretely reimbursable services, or as capitated services, or through some other payment arrangements.
- Define comprehensive medication management (CMM) as a process of care that ensures each enrollee's/beneficiary's medications are assessed for appropriateness, effectiveness, safety (given comorbidities and other medications), and ability of the enrollee/beneficiary to take as intended.³
- Affirm CMM-related services as services that may be provided by an APh.

As defined in the California Business & Professions Code,⁴ licensed APhs have an expanded scope of practice including:

- Performance of patient assessments;
- Ordering and interpreting all drug therapy-related tests;
- Referring patients to other healthcare providers;
- Participating in the evaluation and management of diseases and health conditions in collaboration with other healthcare providers; and
- Initiating, adjusting, modifying, and discontinuing drug therapy pursuant to an order by a patient's treating prescriber and in accordance with established protocols.

The full text of SB 1285 can be found in Appendix A and a discussion of the scope of practice for all pharmacists in California, including APhs, and other pharmacists working under a collaborative practice agreement (CPAs) with physicians, can be found in the *Background* section of this report.

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

³ Please note, this is a much less robust definition of CMM than appears in another bill CHBRP analyzed in 2018, SB 1322. That report is available at http://chbrp.org/completed_analyses/index.php

⁴ Section 4052.6(a)1-5 and 4052.2(a)4,

Relevant Populations

If enacted, SB 1285 would affect the health insurance of approximately 25.2 million enrollees (64% of all Californians). This represents 100% of the 23.4 million Californians who will have health insurance regulated by DMHC or CDI. The bill would also affect the health insurance of the 1.8 million Medi-Cal beneficiaries enrolled in COHS managed care — but would not affect the health insurance of Medi-Cal beneficiaries associated with Medi-Cal fee-for-service (FFS).

Interaction with Existing Requirements

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

California Policy Landscape

CHBRP is unaware of laws or regulations relating to coverage of services provided by APhs.

Similar requirements in other states

Though a separate issue from requiring coverage for services, as SB 1285 would do, CHBRP is aware that three other states — Montana, New Mexico, and North Carolina — have APh designations, similar to California's APh licensing, that allow provision of direct patient care. However, educational requirements, service offerings, prescribing authority, and compensation vary (Giberson, 2011). Compensation for services provided in these other states may include salaries, bundled payments, or fee-for-service reimbursement available through specific programs or payers.

Collaborative practice agreements allow pharmacists to practice in partnership with physicians, health care service plans, and licensed health care facilities and settings to provide many of the services in the APh scope of practice. These agreements can lead to direct reimbursement in some states, or the ability for the supervising provider to bill for services delivered by the pharmacist operating under such an agreement.

CHBRP is aware that eight states (CO, IA, MN, MS, NM, OR, TX, and WI) provide Medicaid compensation for pharmacists (not only APhs) for medication therapy management (MTM). MTM programs are similar to CMM programs, but are often more limited in scope. Some additional state Medicaid programs compensate pharmacists for services related to preventive care (Isasi, 2015). Additionally, five states (KY, MA, MI, ND, and VA) compensate pharmacists (not only APhs) for MTM services under their state employee health programs (Isasi, 2015).

Federal Policy Landscape

Medicare Part D reimburses pharmacists (not only APhs) for MTM program services. MTM services under Medicare Part D, however, are defined narrowly to include medication review but not services such as chronic disease management, care coordination, or other follow-up care (Isasi, 2015). MTM is typically more targeted than CMM, focusing on more limited issues for only the highest-risk patients.

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 SB 1285 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 and regulations.

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}

States may require QHPs to offer benefits that exceed EHBs.⁸ However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the QHP.^{9,10} State rules related to provider types, cost-sharing, or reimbursement methods would *not meet* the definition of state benefit mandates that could exceed EHBs.¹¹

SB 1285 would not appear to interact with EHBs because it not a new benefit coverage requirement, but a requirement to cover services provided by APHs practicing in their existing professional scope. As physicians and nonAPH pharmacists with collaborative practice agreements (CPAs) appear to already engage in these activities, SB 1285 does not appear to add to the benefits covered despite adding coverage for a specific type of provider.

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 H&SC Section 1367.005; IC Section 10112.27.

⁸ ACA Section 1311(d)(3).

⁹ State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

¹⁰ However, as laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs and there would be no requirement that the state defray the costs of those state mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.

¹¹ Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.

BACKGROUND ON ADVANCED PRACTICE PHARMACISTS

As described in the *Policy Context* section, SB 1285 would mandate DMHC-regulated plans, CDI-regulated policies, and Medi-Cal managed care plans to provide coverage for services delivered by an advanced practice pharmacist (APh). This section provides a description of the requirements for the APh license, describes the uptake of the license in California, and summarizes the scope of practice and practice settings for licensed APhs, pharmacists operating under a collaborative practice agreement, and traditional pharmacists licensed in California.

Advanced Practice Pharmacists: Scope of Practice and Practice Settings

In 2013, SB 493 created the APh license.¹² An APh is a pharmacist classification that requires licensure and provides for an expanded scope of practice (California State Board of Pharmacy, 2016). APh licensure is valid for two years, coterminous with the applicant's pharmacy license. For a pharmacist to become a licensed APh in California, they must file an application with the California State Board of Pharmacy, pay a \$300 fee, hold an active pharmacy license in good standing, and fulfill two of the following three criteria: earn certification in a relevant area of practice (e.g., ambulatory care, geriatric pharmacy, and travel medicine), complete a postgraduate residency through an accredited institution that includes direct patient care services, or have provided direct patient care under a collaborative practice agreement for at least one year.¹³ A collaborative practice agreement is a framework between individual or groups of prescribers and pharmacists that defines the conditions and authorizations under which a pharmacist can initiate or modify drug therapy for patients or a patient population. Pharmacists operating outside of a licensed healthcare facility or physician practice are unable to participate in a collaborative practice agreement, but would be able to provide similar services under the APh license. Information regarding the scope of practice for pharmacists, APh, and collaborative practice agreements are presented in Table 1.

Currently, there are approximately 45,000 pharmacists licensed to practice in California (California State Board of Pharmacy, 2016). In late 2016, the California Office of Administrative Law (OAL) approved the State Board of Pharmacy's requirements for the new APh license and the first licenses were issued in February of 2017. The number of pharmacists applying for licensure as an APh has been slowly increasing since licenses were first issued. As of July 2017, there were 130 licensed APh in California, 169 as of September 2017, and as of April 2018 there were a total of 279 (CPhA, 2018; California State Board of Pharmacy, 2016).¹⁴ This represents less than 1% (0.55%) of the total population of licensed pharmacists in California.

Scope of Practice

Table 1 provides an overview of the scope of practice for pharmacists licensed to practice in California, as well as additional services that are able to be provided either by pharmacists who received additional training, an APh license, or practice under collaborative practice agreements. SB 1285 clarifies comprehensive medication management (CMM) as a service that may be provided by an APh. CMM is a process of care that ensures each patient's medications are assessed for appropriateness, effectiveness,

¹² California BPC 4052.6

¹³ California BPC 4210 and California Code of Regulations section 1730.1

¹⁴ Based upon an April 2018 search of

[http://www2.dca.ca.gov/pls/wllpub/wllqryna\\$lcev2.startup?p_qte_code=APH&p_qte_pgm_code=7200](http://www2.dca.ca.gov/pls/wllpub/wllqryna$lcev2.startup?p_qte_code=APH&p_qte_pgm_code=7200)

safety, and ability to take as intended. For an in-depth analysis of the medical effectiveness, cost, and public health impact of CMM, see CHBRP’s 2018 report on SB 1322.¹⁵

For decades, working under collaborative practice agreements, pharmacists in California have had the ability to provide additional services, but only within the context of a licensed healthcare facility, health care service plan, or physician practice (see Table 1).¹⁶ In California, the APh license allows pharmacists in other practice settings to perform the same services as pharmacists practicing under collaborative practice agreements. The APh license allows for the provision of services under collaborative practice agreements with pharmacists operating outside of a licensed healthcare facility or under supervision of a physician, for example, in a community pharmacy setting (described in more detail below).

Table 1. Scope of Practice for Pharmacists and Advance Practice Pharmacists in California

Service	All Pharmacists	Advanced Practice Pharmacists (APhs) ^(b)	Other Pharmacists with Collaborative Practice Agreements (CPAs) ^(c)
Dispense prescription medications	X	X	X
Ordering & interpreting drug-related tests			
Some tests	X		
All tests per CPA		X	X
Administer drugs and biologics	X	X	X
Perform patient assessments		X	X
Refer patients to other healthcare providers		X	X
Participate in the evaluation and management of diseases and health conditions with other healthcare providers		X	X
Initiate, adjust, modify, and discontinue drug therapy pursuant to an order by a patient’s treatment prescriber		X	X
Comprehensive medication management		X	X
Practice Setting		All	Limited to licensed facility or provider, or licensed health care service plan
With additional training, all licensed CA pharmacists are eligible to provide the following services: prescribe and dispense: emergency and hormonal contraception, ^(d) nicotine replacement therapy, ^(e) travel medications, ^(f) and naloxone, ^(g) and initiate and administer immunizations. ^(f)			

Source: California Pharmacists Association, Expanding Pharmacist Services, available at: <https://cpha.com/advocacy/provider-status/expanding-pharmacist-services/>.

Notes: (a) California Business & Professions Code (BPC) 4052. (b) California BPC 4052.6. (c) California BPC 4052.1; 4052.2. (d) California BPC 4052.3. (e) California BPC 4052.9. (f) California BPC 4052.8. (g) California BPC 4052.01.

Key: APh = advanced practice pharmacist; CPA = Collaborative practice agreement

¹⁵ Available at http://chbrp.org/completed_analyses/index.php

¹⁶ California BPC 4052.1; 4052.2

Practice Settings

Pharmacists can work in a variety of settings. The three most common practice settings for pharmacists in California are community pharmacies (37%), hospital pharmacies (27%), and physician office or outpatient setting (10.9%) (EDD, 2018). Approximately 24% of pharmacists practice in other settings such as industrial pharmacies, ambulatory care pharmacies, and regulatory pharmacies (EDD, 2018). The community pharmacy is the most common type of pharmacy (37%) and includes standalone pharmacies that are either individually owned, are part of a large retail drug store chain like CVS or Walgreens or are part of a retail chain like Target or Costco. Pharmacists working in community pharmacy settings are not permitted to work under a collaborative practice agreement and thus are limited in the types of services they can provide to patients. The second most common practice setting for pharmacists in California is the hospital setting (27%). Pharmacists working in hospitals manage the medications of patients admitted to the hospital and often work closely with other healthcare professionals to manage the medication regimen to optimize patient outcomes. It is possible for pharmacists working in hospital pharmacies, physician office, or outpatient settings to work under collaborative practice agreements depending on their specific organizational type. The APh license takes away the restrictions where a collaborative practice agreement can occur.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, SB 1285 would mandate coverage of services provided by advanced practice pharmacists (APhs). As noted in the *Background on Advanced Practice Pharmacists* section, APhs are authorized to provide the services that all pharmacists are authorized to provide as well as patient assessment; referral of patients to other providers; evaluation and management of disease; initiation, adjustment, modification, and discontinuation of medication; and comprehensive medication management (CMM). In California, pharmacists who are not APhs can provide the same services as APhs if they have a collaborative practice agreement with a physician, except if they practice in community pharmacies or in other locations outside healthcare facilities.

The medical effectiveness review summarizes findings from evidence¹⁷ on the effectiveness of APh services provided by APhs or pharmacists who have a collaborative practice agreement with a physician. Studies of pharmacists with a collaborative practice agreement are included because they are authorized to provide similar services as an APh in some settings. CHBRP believes that inferences from studies of pharmacists with collaborative practice agreements can be generalized to APhs.

The medical effectiveness review includes studies of APhs and pharmacists with collaborative practice agreements regardless of whether those services are CMM or are more narrowly focused on managing a specific disease or condition. Studies of CMM that did not indicate whether the pharmacists who provided CMM were APhs or had a collaborative practice agreement were not included. Literature on the effectiveness of CMM provided by all pharmacists regardless of whether they were APhs or had a collaborative practice agreement is reviewed in CHBRP's report on SB 1322.¹⁸

Research Approach and Methods

Studies of APhs and pharmacists working under collaborative practice agreements were identified through searches of PubMed, the Cochrane Library, Web of Science, EMBASE, and Scopus. The search was limited to abstracts of studies published in English.

The literature review returned abstracts for 239 articles, of which 14 studies met the criteria for inclusion in the medical effectiveness review for SB 1285.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature. Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

Key Questions

1. Is there evidence that services provided by APhs or by pharmacists working under collaborative practice agreements improve health outcomes?

¹⁷ Much of the discussion below is focused on reviews of available literature. However, as noted in the Medical Effectiveness (ME) approach document (available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php; see p.8), in the absence of “fully-applicable to the analysis” peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP’s hierarchy of evidence allows for the inclusion of other evidence.

¹⁸ Available at http://chbrp.org/completed_analyses/index.php

2. Is there evidence that services provided by APhs or by pharmacists working under collaborative practice agreements reduces use of non-acute outpatient visits and acute care services (e.g., emergency department visits, hospitalizations)?
3. Is there evidence that requiring reimbursement for APhs or pharmacists working under collaborative practice agreements expands utilization of their services and improves health outcomes?

Methodological Considerations

In conducting the literature search, 14 studies were determined to be relevant to SB 1285. They encompassed one study of APhs (Kislan et al., 2016) and 13 studies of pharmacists working under collaborative practice agreements (Anderegg et al., 2018; Benedict et al., 2018; Brunisholz et al., 2018; Capoccia et al., 2004; Carter et al., 2015; Heisler et al., 2012; Hunt et al., 2008; Isetts et al., 2012; Jameson and Baty, 2010; Johnson et al., 2010; Smith et al., 2016; Victor et al., 2018; Wassell et al., 2018). It should be noted that three of these studies examining collaborative practice agreements are interrelated. Anderegg et al. (2018) and Smith et al. (2016) assess outcomes for sub-populations of the larger Carter et al. (2015) study. Studies were included if the pharmacist had the authority to make changes in a patient's prescription drug regimen under the supervision of a physician and/or in accordance with a protocol. Below, Table 2 outlines study designs, the intervention(s), and study participants for each study.

Five of the studies evaluated the impact of CMM (Anderegg et al., 2018; Carter et al., 2015; Isetts et al., 2012; Smith et al., 2016; Wassell et al., 2018). Eight studies examined interventions that addressed a specific disease or condition, such as diabetes or hypertension (Brunisholz et al., 2018; Capoccia et al., 2004; Heisler et al., 2012; Hunt et al., 2008; Jameson and Baty, 2010; Johnson et al., 2010; Victor et al., 2018). One study did not specify whether the intervention was CMM or a disease-focused intervention (Kislan et al., 2016).

There are limitations among some of the studies that are important to note. Patients in the Kislan et al. (2016) study that were treated by APhs had higher hemoglobin A1c levels than patients who received care only from primary care providers. Thus, patients treated by APhs may have been sicker than patients treated solely by primary care providers, which would make it more difficult to detect the effects of the APh intervention. In Brunisholz et al. (2018), the intervention group and the control group differed; while inclusion in the intervention group required an out-of-control diagnosis for one or either of the specified conditions, inclusion in the control group only required that patients had a previous diagnosis of the condition(s). Benedict et al. (2018), Heisler et al. (2012), and Wassall et al. (2018) are limited by the fact that study participants were patients of either the VA or Kaiser Permanente, two facilities whose populations may not be representative of all persons whose coverage would be affected by SB 1285.

None of the studies CHBRP identified addressed the impact of legislation that requires reimbursement of APhs. The studies were designed only to answer the question of whether the services that the pharmacists provided improved health outcomes and/or reduced use of other health care services.

The standard by which to evaluate findings from the studies included in CHBRP's medical effectiveness review depends on the extent to which APhs serve as complements versus substitutes for other health professionals. Where APhs provide services in place of physicians or other types of health professionals, a non-inferiority standard is appropriate. In other words, if an APh provides the same service as another type of health professional, one would want to know whether APhs provide these services as effectively as the other type of health professional.

Table 2. Outline of Study Details

Study	Study Population	Comparison Group	Eligibility Criteria	Study Design	Intervention
Capoccia et al., 2004	Adults >18 years (mean age = 38 years)	Patients meeting the same eligibility criteria, but assigned to “usual care” (mean age = 39 years)	Had a new episode of depression and were also started on antidepressant medications	Prospective, randomized controlled trial (12 months)	Pharmacists collaborate with primary care providers to educate patients, initiate or adjust antidepressants, monitor patient adherence, manage adverse reactions, and prevent relapse
Hunt et al., 2008	Mean age = 68 years	Patients meeting the same eligibility criteria, but assigned to “usual care” (mean age = 68 years)	Patients of a primary care network with known hypertension and uncontrolled blood pressure	Prospective, single-blind, randomized control trial (12 months)	Pharmacy practitioners actively manage hypertension according to established collaborative treatment protocols
Jameson and Baty, 2010	Adults ≥18 years (mean age = 49 years)	Patients meeting the same eligibility criteria and who received the same outreach, but did not receive medication management, patient education, or disease control by a pharmacist (mean age = 50 years)	Diagnosed with diabetes mellitus and with a recorded HbA1c ≥9%	Prospective randomized controlled study (12 months)	Pharmacists assess patient adherence, barriers to lowering HbA1c levels, and current medication regimens; educate patients during follow-up visits and telephone calls; adjust insulin as needed
Johnson et al., 2010	Adults >18 years (mean age = 49 years)	Patients meeting the same eligibility criteria, but assigned to “usual care” (mean age = 51 years)	Diagnosed with diabetes mellitus and with a recorded HbA1c >9% and received care in safety net clinic medical homes for uninsured patients in a major city	Retrospective matched cohort study; cohort matched by referral criteria (3 years)	Pharmacists provide comprehensive pharmacy services, including medication comprehensive evaluation, medication adjustment, monitored medication adherence, patient education, and follow-up

Study	Study Population	Comparison Group	Eligibility Criteria	Study Design	Intervention
Heisler et al., 2012	Patients from 3 Veterans Affairs clinics and 2 Kaiser Permanente clinics (mean age = 65 years)	Patients meeting the same eligibility criteria, but did not receive the intervention (mean age = 65 years)	Diagnosed with diabetes mellitus and persistent hypertension (no age provided)	Prospective, multi-site randomized pragmatic controlled trial with randomization of 16 primary care teams at 5 medical centers (14 months)	Clinical Pharmacists provide Adherence and Intensification of Medications (AIM) intervention, which aims to lower blood pressure, improve refill adherence, and provide sufficient medication intensification
Isetts et al., 2012	Patients within the Fairview Health Services of Minneapolis, St. Paul Health Care System – age not reported	Patients meeting the same eligibility criteria, but assigned to “non-innovation” clinics – age not reported	No criteria mentioned aside from received care within the Fairview system	Observational, non-randomized cohort measured at 5 intervals over a 15-month period	Comprehensive face-to-face medication therapy management consultations, as well as home or telephonic visits, group visits, virtual Internet visits, and co-visits with other team providers
Carter et al., 2015	Mean age of brief intervention group = 62 years; mean age of sustained intervention group = 58 years)	Patients meeting the same eligibility criteria, but assigned to “usual care” (mean age = 62 years)	Uncontrolled blood pressure on the baseline visit, where blood pressure goals are: < 140/90 mmHg for uncomplicated hypertension, < 130/80 mmHg for patients with diabetes mellitus or chronic kidney disease	Prospective, cluster-randomized trial; brief intervention group = 9 months, sustained intervention group = 24 months	Pharmacist reviews the medical record; medication history; assesses patient knowledge of blood pressure medications, dosages and timing, and potential side effects; and other barriers to blood pressure control via phone calls and structured face-to-face visits
Kislan et al., 2016	Medicare beneficiaries that are: enrolled at the University of North Carolina Health Care and seen at one of the UNC multidisciplinary outpatient clinics	Patients meeting the same eligibility criteria, but were not managed by a Clinical Pharmacist Practitioner	Have an ICD-9 code for hypertension, diabetes mellitus, or peripheral neuropathy	Retrospective matched cohort study. Cohorts matched by age, gender, and disease state (36 months)	Cohort seen by a Clinical Pharmacist Practitioner (details of intervention not provided)

Study	Study Population	Comparison Group	Eligibility Criteria	Study Design	Intervention
Smith et al., 2016	Sub-population of Carter et al., 2015 (mean age = 63 years)	Patients meeting the same eligibility criteria, but assigned to “usual care” (mean age = 65 years)	Patients diagnosed with treatment-resistant hypertension (blood pressure uncontrolled at study entry despite taking 3 or more antihypertensive medications)	Prospective, cluster-randomized trial (pooled subjects receiving a 9 month intervention with subjects receiving a 24 month intervention)	Same as Cater et al., 2015
Anderegg et al., 2018	Sub-population of Carter et al., 2015 (mean age = 62 years)	Patients meeting the same eligibility criteria, but assigned to “usual care” (mean age = 63 years)	Patients diagnosed with diabetes mellitus, chronic kidney disease, or both	Prospective, cluster-randomized trial; brief intervention group = 9 months, sustained intervention group = 24 months	Same as Cater et al., 2015
Benedict et al., 2018	Adults aged 18-74 within the Kaiser Permanente Downey Medical Center (mean age = 55 years)	Patients receiving “usual care” (mean age = 54 years)	Patients with type II diabetes and an HbA1C \geq 8%	Retrospective cohort study; 1:1 matching	Clinical pharmacists added to health team that includes a primary care physician, nurses, and support staff; they can order labs for drug therapy monitoring and initiate, adjust, and stop medications; also address medication adherence, prescription refills, vaccinations, overdue health screenings, and reinforce patient education via telephone calls, office visits, or e-mail
Brunisholz et al., 2018	Adults \geq 18 years (mean age = 62 years) in the same healthcare system	Adults \geq 18 years from an adjacent geographic region within the same healthcare system not receiving CPSS (mean age = 61 years); previous diagnosis of hypertension or diabetes	Diagnosis of out-of-control hypertension and/or diabetes	Retrospective observational study. The intervention (CPSS) group was matched using propensity scores	Clinical Pharmacists plan therapies, adjust medications, educate patients, and schedule follow-up tests for patients in the CPSS group

Study	Study Population	Comparison Group	Eligibility Criteria	Study Design	Intervention
Victor et al., 2018	Adults 35-79 years of age (mean age = 54 years)	Customers of barbers who were trained to encourage lifestyle modification and doctor appointments; discuss the instructional information with participants (mean age = 55 years)	Non-Hispanic black men who were regular patrons of participating barbershops (≥ 1 haircut every 6 weeks for ≥ 6 months) and who had systolic blood pressure levels of 140 mmHg or higher	Cluster-randomized trial	Barbers promoted follow-up with specialty-trained pharmacists. Pharmacists met regularly with participants at the barbershops, prescribed/monitored an antihypertensive drug regimen and sent notes on progress to the participants' providers.
Wassell et al., 2018	Adults ≥ 18 years of age receiving care at to Department of Veterans Affairs community-based outpatient clinics (mean age = 66 years)	Patients receiving care by a primary care physician at the two VA outpatient clinics (mean age = 65 years)	Patients diagnosed with type II diabetes and with an HbA1c $\geq 8\%$	Retrospective chart review	Clinical pharmacist specialist initiated, adjusted, or discontinued medications following ADA and VA guidelines; in-depth dietary and exercise counseling, tobacco cessation education medical adherence, and immunization administration. After initial referral and 30 minute appointment, face-to-face appointments every 4-12 weeks

Source: California Health Benefits Review Program, 2018; Anderegg et al., 2018; Benedict et al., 2018; Brunisholz et al., 2018; Capoccia et al., 2004; Carter et al., 2015; Heisler et al., 2012; Hunt et al., 2008; Isetts et al., 2012; Jameson and Baty, 2010; Johnson et al., 2010; Kislak et al., 2016; Smith et al., 2016; Victor et al., 2018; Wassell et al., 2018.

Outcomes Assessed

The 14 articles included in CHBRP’s review assessed the following outcomes: (1) medication adherence; (2) use of antihypertensive medications; (3) clinical outcomes; (4) outpatient visits in settings other than an emergency department (ED); (5) ED visits; and (6) inpatient admissions.

Study Findings

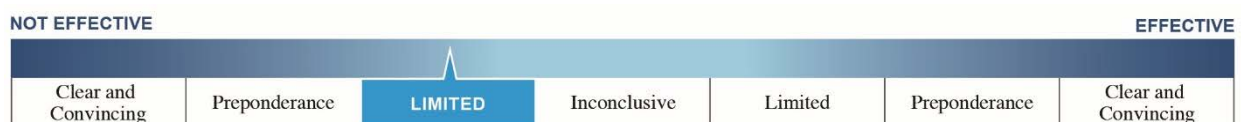
CHBRP found limited evidence that medication adherence does not differ between persons who receive care from APhs or pharmacists with collaborative practice agreements and persons who receive usual care. There is inconclusive evidence as to whether APhs and pharmacists with collaborative practice agreements increase use of antihypertensive medications among persons with uncontrolled hypertension. With regard to clinical outcomes, there is a preponderance of evidence that receiving care from APhs or pharmacists with collaborative practice agreements is associated with better blood pressure control than persons who receive usual care. Findings for effects on control of diabetes and cholesterol are inconclusive; some studies find no difference between persons who receive care from APhs or pharmacists with collaborative practice agreements and persons who receive usual care whereas others find that receipt of services from APhs or pharmacists with collaborative practice agreements is associated with better control of diabetes or cholesterol. Findings regarding effects on numbers of outpatient visits are inconclusive. Findings from studies that examined rates of ED visits and hospitalizations suggest that rates of ED visits and hospitalizations among persons who receive services from an APh or a pharmacist with a collaborative practice agreement are similar to the rates of ED visits and hospitalizations among persons who received usual care. The only study that examined adverse events found no difference between persons who received services from pharmacists with collaborative practice agreements and persons who received usual care.

Medication Adherence

Three randomized controlled trials (RCTs) of pharmacists working under collaborative practice agreements examined medication adherence; because all relied on self-reported data, they could be subject to recall bias. One RCT asked patients the number of days they took their medication in the past month (Capoccia et al., 2004), and two RCTs utilized an assessment consisting of four validated, patient self-report questions (Hunt et al., 2008; Smith et al., 2016). No statistically significant differences between intervention and control groups were found in any of the studies when data for all subjects were analyzed (Capoccia et al., 2004; Hunt et al., 2008; Smith et al., 2016). However, in one study, a greater proportion of minorities reported significantly higher medication adherence (Smith et al., 2016).

Summary of findings regarding effects on medication adherence: There is limited evidence from three RCTs that medication adherence does not differ between persons who receive services from APhs or pharmacists with collaborative practice agreements and persons who receive usual care.

Figure 1. Medication Adherence



Use of Antihypertensive Medications

Three RCTs examined patients' use of antihypertensive medication. Victor et al. (2018) found that the use of antihypertensive medications increased significantly both for the intervention and control group, but the increase was greater for the intervention group (from 53% to 63% for control group, from 55% to 100% for intervention group). Smith et al. (2016) found that there were significantly more dose increases or medication additions in the intervention group, but that the use of most antihypertensive classes remained about the same between intervention and control groups. Another study found that the number of antihypertensive medications increased significantly for both intervention and control groups (Hunt et al., 2008).

Summary of findings regarding effects on use of antihypertensive medications: There is inconclusive evidence from three RCTs as to whether APs and pharmacists who have collaborative practice agreements increase use of antihypertensive medications among persons with hypertension.

Figure 2. Use of Antihypertensive Medications



Clinical Outcomes

All studies reported results for one or multiple clinical outcomes.

Diabetes

Three retrospective studies examined achievement of diabetes-related goals. One study found that 19.37% of intervention group patients compared to 6.49% of the control group achieved the treatment goal of HbA1c <7% ($p < 0.001$), and 52.25% of intervention patients compared to 19.85% of the control group achieved an HbA1c of <8% ($p < 0.001$) during their last visit (Johnson et al., 2010). Patients in the intervention group of the Brunisholz et al. (2018) study were 57% more likely to achieve an HbA1c value of <8% ($p < 0.001$). Benedict et al. (2018) also found reductions in HbA1c among persons in the intervention group, reporting that intervention patients were more likely to achieve an HbA1c of < 8% at 3 months ($p < 0.0001$) and at 6 months ($p < 0.007$). Furthermore, the intervention group reached HbA1c goals faster than the control group after controlling for covariates. However, no significant differences were found in achieving HbA1c goals or in HbA1c reduction at 9 months or 12 months (Benedict et al., 2018). One possible explanation for this finding is that pharmacists ceased managing patients once their HbA1c value was < 8%. Improvements these patients obtained from care that pharmacists provided may have dissipated when they returned to receiving usual care from their physicians.

Five studies (two RCTs, three retrospective studies) examined diabetes-related measures and reached inconsistent conclusions about the effect of the interventions studied. In one study, HbA1c values for patients who received the intervention were significantly lower than for patients in the control group, measuring at 8.30% vs. 9.62%, respectively ($p < 0.001$) (Johnson et al., 2010). Another study found an absolute reduction in HbA1c among both the control and intervention group, but found a greater absolute reduction (1.6 percentage points) in the intervention group compared to the control group (Wassell et al., 2018). Heisler et al. (2012) and Kiskan et al. (2016) found no statistically significant difference in HbA1c values between intervention and control groups. While Jameson and Baty's (2010) RCT found no

statistically significant differences between the intervention and control groups as a whole in median HbA1c values, it did find that males in the intervention group achieved a statistically significant improvement in HbA1c levels compared to males in the control group.

One study showed improvements within diabetes care as measured by the percentage of persons who achieved benchmarks that are used to identify persons with diabetes who are receiving high-quality care (i.e., hbA1c, LDL cholesterol, blood pressure, aspirin use, and tobacco cessation). Of patients diagnosed with diabetes who received CMM, 40% achieved all five quality performance benchmarks compared to 17.5% of all patients within Minnesota (Isetts et al., 2012).

Summary of findings regarding effects on diabetes mellitus outcomes: There is inconclusive evidence from two RCTs and six observational studies regarding the impact of services provided by APhs and pharmacists with collaborative practice agreements on diabetes control.

Figure 3. Diabetes



Hypertension

Six studies (three RCTs, three retrospective studies) examined blood pressure control and reached inconsistent conclusions about the effect of the interventions studied. Blood pressure control was defined differently across studies.¹⁹ Brunisholz et al. (2018) used a measure of <140/90 mmHg to define control. Kislán et al. (2016) also used this measure as a general guideline, but primary care physicians could alter this number for each patient to reflect differences in patient age and comorbidities. Victor et al. (2018) used a measure of <130/80 mmHg to define control; Johnson et al. (2010) stated that the ADA recommends a blood pressure goal of <130/80 mmHg, but was not clear in stating that this was the goal used across all patients in the study. Two studies had blood pressure goals of <140/90 mmHg for patients with uncomplicated hypertension and <130/80 mmHg for patients with diabetes mellitus or chronic kidney disease (Anderegg et al., 2018; Carter et al., 2015).

Two studies of blood pressure control did not find statistically significant differences between intervention and control groups' ability to reach blood pressure goals (Carter et al., 2015; Kislán et al., 2016). In examining patients with diabetes mellitus and/or chronic kidney disease, Anderegg et al. (2018) studied a sub-population of the Carter et al. (2015) study found that the intervention group was able to reach significant BP control compared to the control group, suggesting that the Carter et al. (2015) intervention improved BP control for the subset of patients who had comorbid diabetes mellitus and/or chronic kidney disease. Separate from Carter et al. (2015), another study found that 63.6% of intervention patients, compared to 11.7% of control patients, reached a BP goal of <130/80 mmHg (Victor et al., 2018). In another study, participants in the intervention group were 93% more likely to achieve a blood pressure goal of <140/90 mmHg compared to the control group (p<0.001) (Brunisholz et al., 2018). Finally, another

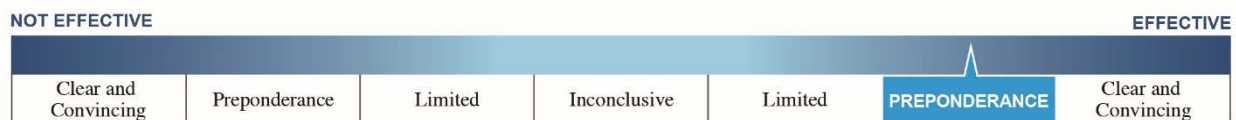
¹⁹ Note that the American College of Cardiology changed its hypertensive guidelines in 2017; some studies in this report may have used what are now considered outdated guidelines, but were the appropriate guidelines at that time. The new guidelines can be found here: http://www.onlinejacc.org/content/early/2017/11/04/j.jacc.2017.11.006?_ga=2.167254134.979805552.1523477928-1688592692.1523477928.

study found that a higher proportion of patients in the intervention group (77.94%) achieved their blood pressure goal compared to the control group (62.15%) at the last visit (Johnson et al., 2010).

Six studies (five RCTs, one retrospective matched cohort study) focused specifically on measures of mean systolic blood pressure (SBP) and/or diastolic blood pressure (DBP) and reached inconsistent conclusions about the effect of the interventions studied. Carter et al. (2015) found significant reductions in SBP and DBP in 9-month intervention groups compared to the control group; mean SBP was 6.1 mm lower and mean DBP was 2.9 mm lower across all study participants at 9 months.²⁰ Smith et al. (2016), studying the treatment-resistant hypertension sub-population of Carter et al. (2015), found that at 9 months, mean SBP was significantly lower in the intervention group compared to the control group, and DBP was similar among both groups (after adjustment). In examining patients with diabetes mellitus and/or chronic kidney disease, Anderegg et al. (2018) also studied a sub-population of the Carter et al. (2015) study. Here, the intervention group also achieved significant reductions in SBP and DBP at the 9-month mark. Separate from Carter et al. (2015), another study found that mean SBP reduction was 21.6 mmHg greater among the intervention group ($p < 0.001$) (Victor et al., 2018). Another study examined both SBP and diastolic blood pressure (DBP) and found that the intervention group had significant differences in measures for both; these differences remained significant when data were assessed by intention-to-treat analysis (Hunt et al., 2008). A retrospective study found that SBP fell significantly for intervention patients while increasing for the control group and that DBP fell significantly for intervention patients while no significant change was detected for control patients (Johnson et al., 2010). Heisler et al. (2012) found no differences between the intervention and control group (8.9 mmHg and 9.0 mmHg, respectively).

Summary of findings regarding effects on blood pressure outcomes: The preponderance of evidence from five RCTs and three observational studies indicates that services provided by APHs or pharmacists with collaborative practice agreements improve blood pressure control.

Figure 4. Hypertension



Cholesterol

Three studies investigated the impact of pharmacists with collaborative practice agreements on cholesterol. One RCT did not find any differences in LDL levels between intervention and control groups (Heisler et al., 2012). One retrospective study did not find any significant differences in total cholesterol, LDL cholesterol, or triglycerides between intervention and control groups (Wassell et al., 2018). Another retrospective study found both the intervention and control groups to have significantly lower mean LDL levels, total cholesterol (TC), and triglycerides (TG), but that there was a greater net change for LDL levels, TC, and TG for the intervention group compared to the control group (Johnson et al., 2010).

²⁰ In addition to examining SBP and DBP among intervention and control groups. Carter et al. (2015) also examined differences in SBP and DBP across race as a secondary outcome. SBP and DBP were found to be significantly lower for minority groups at 9 months with differences of 6.4 mm and 2.9 mm, respectively. While there was no evidence that changes in SBP and DPB differed among race at the 9-month mark, there was evidence that reduction in SBP and DBP differed by race over time; while the minority group sustained BP reductions at the 24-month mark, the nonminority group’s measures deteriorated.

Additionally, a significantly higher proportion of individuals reached LDL level goals in the intervention group (79.73%) compared to the control group (46.70%) at the last visit (Johnson et al., 2010).

Summary of findings regarding effects on cholesterol outcomes: There is inconclusive evidence from three studies (one RCT, two observational) as to whether receiving services from an APh or a pharmacist under a collaborative practice agreement improves cholesterol.

Figure 5. Cholesterol



Pain

One observational study with a comparison group examined pain scores. More patients in the intervention group reported lower pain scores than the control group (55.3% vs. 41.9%, respectively), but the difference was not statistically significant (Kislan et al., 2016).

Depression

One RCT examined clinically depressed patients; it found no statistically significant differences between the intervention and control groups for scores on two instruments used to assess mental health status (Capoccia et al., 2004).

Outpatient Visits

Three studies that examined outpatient visits found that patients in intervention groups had more outpatient visits compared to patients in control groups. In one study, intervention patients reported an average of 20.6 outpatient visits compared to an average of 13.2 outpatient visits for control patients ($p=0.0002$) (Kislan et al., 2016). Another study reported that the intervention group had significantly more clinic visits, where clinic visits include physician and pharmacist visits, compared to control; however, the number of physician visits was significantly lower in the intervention group ($p<0.0001$) (Hunt et al., 2008). An observational study found that intervention group patients averaged significantly more primary care, specialty care, and care manager (registered nurse) visits compared to control group patients (Brunisholz et al., 2018). This finding may be explained by differences between the intervention and comparison groups. All persons in the intervention group had uncontrolled hypertension and diabetes, whereas the comparison group included persons with a diagnosis of hypertension or diabetes regardless of whether their disease was under control.

Two studies did not find any statistically significant differences between intervention and control groups. One study observed a mean of 4.6 primary care visits in the intervention group and a mean of 4.3 primary care visits in the control group, but the difference was not statistically significant (Heisler et al., 2012). Capoccia et al. (2004) did not find any differences between intervention and control groups for visits to physicians, psychiatrists or psychologists, counselors or other mental health providers, nor alternative medicine providers.

Summary of findings regarding effects on outpatient visits: There is inconclusive evidence from three RCTs and two observational studies regarding the effect of services provided by APhs or by pharmacists under collaborative practice agreements on outpatient visits.

Figure 6. Outpatient Visits

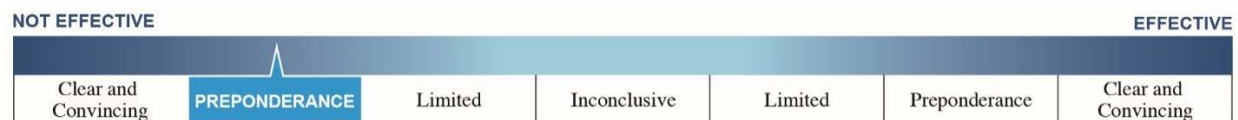


Emergency Department Visits

Four studies examined whether ED usage differed between intervention and control groups (Brunisholz et al., 2018; Capoccia et al., 2004; Heisler et al., 2012; Kislán et al., 2016). In a study of APhs, patients within the intervention group averaged fewer ED visits per patient (1.7 vs. 2.9), but this difference was not statistically significant (Kislán et al., 2016). In another study, 24% of patients in the intervention group and 23% of patients in the control group visited the ED, but results were not statistically significant ($p=0.43$) (Heisler et al., 2012). In addition, Capoccia et al. (2004) did not find any statistically significant differences of ED usage between the intervention and control group ($p=0.27$). Brunisholz et al. (2018) found that intervention patients visited the ED more than control patients (0.27 visits vs. 0.21 visits per patient-year, respectively), and these differences were statistically significant ($p=0.007$). This finding may be explained by differences between the intervention and comparison groups. All persons in the intervention group had uncontrolled hypertension and diabetes, whereas the comparison group included persons with a diagnosis of hypertension or diabetes regardless of whether their disease was under control.

Summary of findings regarding effects on ED visits: The preponderance of evidence from two RCTs and two observational studies with comparison groups indicates that persons who received services from APhs or pharmacists under collaborative practice agreements have ED visit rates similar to those of persons who do not receive such services.

Figure 7. Emergency Department Visits



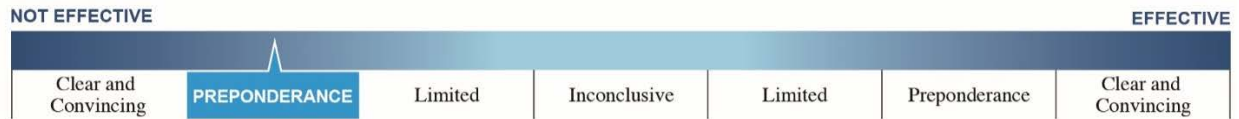
Inpatient Admissions

An observational study of APhs found that patients in the intervention group had fewer inpatient admissions compared to patients in the control group (1.4 vs. 1.8, respectively), but this difference was not statistically significant (Kislán et al., 2016). Two studies of pharmacists working under collaborative practice agreements (1 RCT and 1 observational study) found no differences in inpatient admissions between intervention and control groups (Brunisholz et al., 2018; Heisler et al., 2012).

Summary of findings regarding effects on hospitalizations: There is a preponderance of evidence from one RCT and two observational studies with comparison groups that the rate of hospitalization

among persons who receive services from APhs or by pharmacists under collaborative practice agreements is similar to the rate of hospitalization among persons who do not receive these services.

Figure 8. Inpatient Admissions



Effect of Reimbursing Advanced Practice Pharmacists

CHBRP did not identify any studies that addressed the impact of requiring health plans and health insurance policies to reimburse APhs. Thus, CHBRP concludes that there is insufficient evidence to determine whether requiring reimbursement is associated with an increase in use of the services that APhs provide or whether an increase in the provision of these services improves health outcomes or reduces use of other types of health care services. The absence of evidence is not evidence of no effect but instead indicates that there is insufficient evidence to determine whether or not an intervention has an effect.

Summary of evidence regarding reimbursement: There is insufficient evidence to assess the impact of requiring reimbursement of APhs on use of APh services and on whether increased use of these services improves health outcomes or reduces use of other types of health care services.

Figure 9. Reimbursement



BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, SB 1285 would require enrollees in DMHC-regulated health plans, including Medi-Cal managed care plans, CDI-regulated policies, and Medi-Cal COHS to have coverage for services provided by an advanced practice pharmacist (APh) and services related to comprehensive medication management (CMM) that may be provided by an APh under their current professional scope of practice.

This section reports the potential incremental impacts of SB 1285 on estimated baseline benefit coverage and explains the likelihood of utilization and cost impacts based on the proposed legislation.

Baseline and Postmandate Benefit Coverage

Currently, 52% of enrollees with health insurance that would be subject to SB 1285 have coverage for the services provided by an APh or other pharmacists working under a collaborative practice agreement (CPA) with a physician. However, benefit coverage can vary as some health insurance reimburses for CMM-services provided by a pharmacist under supervision of a physician and some health insurance provides enrollees access to pharmacists working under CPAs who are paid salaries or hourly rather than receiving reimbursement for services.

Although services by APhs and other pharmacists working under CPAs may be covered for enrollees in DMHC/CDI-regulated plans/policies and Medi-Cal COHS as reimbursable services when bundled with other provided services or delivered through an employment relationship with licensed health facilities or physician practices, CHBRP is unaware of coverage for APh services as discretely reimbursable services.

Current benefit coverage was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 58% of enrollees with private market health insurance regulated by DMHC or CDI, and 45% of enrollees in Medi-Cal managed care plans regulated by DMHC.

Baseline and Postmandate Utilization

Postmandate, all Medi-Cal beneficiaries enrolled in COHS managed care and all enrollees in plans or policies regulated by DMHC or CDI would have SB 1285 compliant benefit coverage.

Baseline and Postmandate Per-Unit Cost

Although APh licenses have been granted in the state of California as of April 2018 (less than 1% of the overall pharmacist provider population in the state),²¹ it is currently not possible to estimate the number of services provided by APhs. Despite the presence of benefit coverage for APh-equivalent services, paid claims for the services in the APh scope of practice are rare because the pharmacists are frequently paid salaries, hourly wages, or are using other payment mechanisms.

By examining MarketScan data for claims paid for medication therapy management in California and in two states with APh-equivalent laws (North Carolina and New Mexico), CHBRP evaluated the prevalence of claims for three medication therapy management (MTM) CPT codes (99605, 996060, and 99607).

²¹ From April 2018 search of [http://www2.dca.ca.gov/pls/wllpub/wllqryna\\$!ceev2.startup?p_qte_code=APH&p_qte_pgm_code=7200](http://www2.dca.ca.gov/pls/wllpub/wllqryna$!ceev2.startup?p_qte_code=APH&p_qte_pgm_code=7200)

There are very few paid claims for those CPT codes delivered by pharmacists (whether billed by a supervising physician or directly by an independent APh-equivalent pharmacist). There is less than 1 CPT code paid per 1,000 claims even in states with APh-equivalent laws, suggesting that services provided by APhs are likely paid through mechanisms other than direct reimbursement by health insurance, which make it difficult to determine the baseline use of services provided by APhs or other pharmacists operating under a CPA. In addition, SB 1285 does not require plans to contract with APh as part of their networks, making it difficult to estimate whether provider contracting (and reimbursement for services) would occur or whether benefit coverage would continue to be provided through bundled services, salaries, hourly wages, or other payment mechanisms. Currently, plans often have their own pharmacy and medication management protocols to coordinate medications and CMM-related services, making it difficult to predict and measure the outcome if a plan would abandon or enhance that service by adding separately contracted APh providers to the network.

Because of the lack of claims data available in the MarketScan claims data for APh-related or similar pharmacy services in California, SB 1285's impact on unit cost would be unknown.

Baseline and Postmandate Expenditures

As the impact on utilization and unit cost are unknown, the impact SB 1285 would have on expenditures (premiums and enrollee expense paid for covered and non-covered services) is also unknown.

Out-of-Pocket Spending for Covered and Noncovered Expenses

As the impacts of SB 1285 on utilization and unit costs are unknown, the impact on enrollee expenses for noncovered benefits are also unknown. However, it is likely that APhs currently in practice and providing services are not directly billing for services provided (given the lack of claims available in MarketScan data), so there may be little or no premandate payments by enrollees for noncovered services provided by APhs or other pharmacists working under CPAs.

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

As the impacts of SB 1285 on utilization and unit costs are unknown, there are no known cost offsets or savings in the first 12 months of enactment of SB 1285. However, at the current rate of licensing APhs, it is unlikely that the change in benefit coverage would significantly change the use of services in their scope of practice (including CMM) in the short-term.

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies would 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. In the case of SB 1285, as the impact on premiums is unknown, the impact on administrative expenses is also unknown.

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 Persons²²

No measurable change in the number of uninsured persons as a result of SB 1285 is expected.

Changes in Public Program Enrollment

No measurable impact on public program enrollment due to SB 1285 is expected.

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

No measurable impact on public program enrollment due to SB 1285 is expected.

²² 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.

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, SB 1285 would mandate DMHC-regulated plans, CDI-regulated policies, and County Organized Health System (COHS) managed care to provide coverage of services for advanced practice pharmacists (APhs). These services include comprehensive medication management; performance of patient assessments; ordering and interpreting all drug therapy-related tests; referring patients to other healthcare providers; participating in the evaluation and management of diseases and health conditions in collaboration with other healthcare providers; and initiating, adjusting, modifying, and discontinuing drug therapy pursuant to an order by a patient's treating prescriber and in accordance with established protocols.

As presented in the *Medical Effectiveness* section, evidence differs across outcomes but for the most part suggests that outcomes of care provided by APhs or other pharmacists working under a collaborative practice agreement (CPA) are similar to outcomes for persons who receive usual care. The literature review did find one exception, where outcomes related to the control of hypertension were better where services were provided by APhs or APh-equivalents. Additionally, as presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, the utilization impacts of SB 1285 are unknown. Therefore, CHBRP concludes that passage of SB 1285 would have unknown short-term public health impacts. For this reason, CHBRP also concludes that SB 1285 would have an unknown impact on disparities in health outcomes by gender, race/ethnicity, age, or sexual orientation/gender identity. It also would have an unknown impact on premature death and societal economic losses

LONG-TERM IMPACTS

There are 279 licensed APhs in California since the original law took effect in 2016. The utilization and cost impacts of SB 1285 are unknown due to the relatively small number of APhs, the lack of data on payment for and use of APh or other pharmacists working under a collaborative practice agreement (CPA), and uncertainty regarding health plans and insurers contracting with APhs in the long-term. Even if take-up of APh licensure among pharmacists increased in the future, it is unclear whether health plans and insurers will contract with APhs as participating providers or would use APhs instead of other pharmacists with CPAs. For these reasons, CHBRP would not estimate a large increase in APh services in the years immediately following 2019.

According to CHBRP's exploration of MarketScan data in states like North Carolina, where their advance practice pharmacy has been in existence since 1999, there are limited claims processed each year for medication therapy management (MTM) services provided by pharmacists under their current scope of practice. However, the review of MarketScan does not allow CHBRP to assess how many APhs or other pharmacists in with CPAs may be providing services compensated through salaries, hourly wages, bundled payments, or other means that would not result in records of reimbursement.

As the long-term impacts of SB 1285 on utilization of APh services are unknown, so, too are SB 1285's long-term public health impacts are unknown.

APPENDIX A TEXT OF BILL ANALYZED

On February 16, 2018, the California Senate Committee on Health requested that CHBRP analyze SB 1285.

SENATE BILL

No. 1285

Introduced by Senator Stone

February 16, 2018

An act to add Section 1367.44 to the Health and Safety Code, to add Section 10123.204 to the Insurance Code, and to add Section 14132.09 to the Welfare and Institutions Code, relating to health care coverage.

legislative counsel's digest

SB 1285, as introduced, Stone. Health care coverage: advanced practice pharmacist.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law establishes the Medi-Cal program, which is administered by the State Department of Health Care Services and under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid Program provisions. Under existing law, one of the methods by which Medi-Cal services are provided is pursuant to contracts with various types of managed care plans.

This bill would require coverage for services provided by an advanced practice pharmacist, as defined, performed within the scope of his or her practice, including, but not limited to, comprehensive medication management (CMM) services, as defined, in a health care service plan contract and health insurance policy, and, to the extent that federal financial participation is available, in a Medi-Cal managed care plan. Because a willful violation of that provision by a health care service

plan would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement. This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1367.44 is added to the Health and Safety
2 Code, to read:

3 1367.44. (a) Every health care service plan contract that is
4 issued, amended, or renewed on or after January 1, 2019, shall
5 provide coverage for services provided by an advanced practice
6 pharmacist, as defined in Section 4016.5 of the Business and
7 Professions Code, performed within the scope of his or her practice,
8 including, but not limited to, comprehensive medication
9 management (CMM) services.

10 (b) For purposes of this section, "comprehensive medication
11 management" means the process of care that ensures each
12 beneficiary's medications, whether they are prescription drugs and
13 biologics, over-the-counter medication, or nutritional supplements,
14 are individually assessed to determine that each medication is
15 appropriate for the beneficiary, effective for the medical condition,
16 and safe given the comorbidities and other medications being
17 taken, and that all medications are able to be taken by the patient
18 as intended.

19 (c) This section does not apply to a contract with a pharmacy
20 benefit management company or a direct contract for only
21 prescription dispensing or related services.

22 SEC. 2. Section 10123.204 is added to the Insurance Code, to
23 read:

24 10123.204. (a) Every health insurance policy that is issued,
25 amended, or renewed on or after January 1, 2019, shall provide
26 coverage for services provided by an advanced practice pharmacist,
27 as defined in Section 4016.5 of the Business and Professions Code,
28 performed within the scope of his or her practice, including, but

1 not limited to, comprehensive medication management (CMM)
2 services.

3 (b) For purposes of this section, “comprehensive medication
4 management” means the process of care that ensures each
5 beneficiary’s medications, whether they are prescription drugs and
6 biologics, over-the-counter medication, or nutritional supplements,
7 are individually assessed to determine that each medication is
8 appropriate for the beneficiary, effective for the medical condition,
9 and safe given the comorbidities and other medications being
10 taken, and that all medications are able to be taken by the patient
11 as intended.

12 (c) This section does not apply to a contract with a pharmacy
13 benefit management company or a direct contract for only
14 prescription dispensing or related services.

15 SEC. 3. Section 14132.09 is added to the Welfare and
16 Institutions Code, to read:

17 14132.09. (a) Services provided by an advanced practice
18 pharmacist, as defined in Section 4016.5 of the Business and
19 Professions Code, performed within the scope of his or her practice,
20 including, but not limited to, comprehensive medication
21 management (CMM) services, shall be a covered benefit in a
22 Medi-Cal managed care plan.

23 (b) For purposes of this section, “comprehensive medication
24 management” means the process of care that ensures each
25 beneficiary’s medications, whether they are prescription drugs and
26 biologics, over-the-counter medication, or nutritional supplements,
27 are individually assessed to determine that each medication is
28 appropriate for the beneficiary, effective for the medical condition,
29 and safe given the comorbidities and other medications being
30 taken, and that all medications are able to be taken by the patient
31 as intended.

32 (c) This section does not apply to a contract with pharmacy
33 benefit management companies or a direct contract for only
34 prescription dispensing or related services.

35 (d) This section shall be implemented only to the extent that
36 federal financial participation is available.

37 SEC. 4. No reimbursement is required by this act pursuant to
38 Section 6 of Article XIII B of the California Constitution because
39 the only costs that may be incurred by a local agency or school
40 district will be incurred because this act creates a new crime or

1 infraction, eliminates a crime or infraction, or changes the penalty
2 for a crime or infraction, within the meaning of Section 17556 of
3 the Government Code, or changes the definition of a crime within
4 the meaning of Section 6 of Article XIII B of the California
5 Constitution.

APPENDIX B LITERATURE REVIEW SPECIFICATIONS

This appendix describes methods used in the medical effectiveness literature review conducted for this report. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

Studies of the effects of cost sharing on use of oral anticancer medications were identified through searches of PubMed, the Cochrane Library, Web of Science, Scopus, and Embase. Websites maintained by the following organizations were also searched: Agency for Healthcare Research and Quality and National Guideline Clearinghouse. The search was limited to abstracts of studies published in English.

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.

The literature review returned abstracts for 239 articles, of which 14 studies met the criteria for inclusion in the medical effectiveness review for SB 1285.

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*.²³ To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

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

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

- *Clear and convincing evidence;*
- *Preponderance of evidence;*
- *Limited evidence*
- *Inconclusive evidence; and*
- *Insufficient evidence.*

²³ Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

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.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *inconclusive 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

1. Comprehensive medication management (CMM)
2. CMM AND adherence
3. CMM AND advanced practice pharmacist
4. CMM AND adverse drug interactions
5. CMM AND beneficiaries
6. CMM AND eligibility
7. CMM AND emergency department visits
8. CMM AND frequency
9. CMM AND health outcomes
10. CMM AND hospitalizations
11. CMM AND medication reconciliation
12. CMM AND provider
13. CMM AND self-management behaviors
14. CMM AND training

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, and the University of California, Davis, as well as the contracted actuarial firm PricewaterhouseCoopers (PwC).²⁴

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.²⁵

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

Analysis-Specific Caveats and Assumptions

There are no further caveats or assumptions relevant to specifically to an analysis of SB 1285.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits SB 1285 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 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.

²⁴ 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.

²⁵ See *2017 Cost Impact Analyses: Data Sources, Caveats, and Assumptions*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

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CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

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 researchers and analysts who are **Task Force 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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Janet Coffman, MA, MPP, PhD, Jacqueline Miller, BA, and Christopher Toretsky, MPH, of the University of California, San Francisco, prepared the medical effectiveness analysis. Bruce Abbott, MLS, of the University of California, Davis, conducted the literature search. Danielle Casteel, MA, and Naomi Hillery, MPH, both of the University of California, San Diego, prepared the public health impact analysis. Dylan Roby, PhD, of the University of Maryland and University of California, Los Angeles, prepared the cost impact analysis. Susan Maerki, MHSA, MAE, of PricewaterhouseCoopers, and supporting actuarial staff, provided actuarial analysis. John Lewis, MPA, of CHBRP staff prepared the Policy Context and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Marilyn Stebbins, PharmD, of the University of California, San Francisco, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request. 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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Please direct any questions concerning this document to: California Health Benefits Review Program; MC 3116; Berkeley, CA 94720-3116, info@chbrp.org, or www.chbrp.org