

California Health Benefits Review Program

Analysis of California Assembly Bill (AB) 2372 HIV Specialists

A Report to the 2015–2016 California State Legislature

April 13, 2016



Key Findings:

Analysis of California Assembly Bill (AB) 2372 HIV Specialists

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

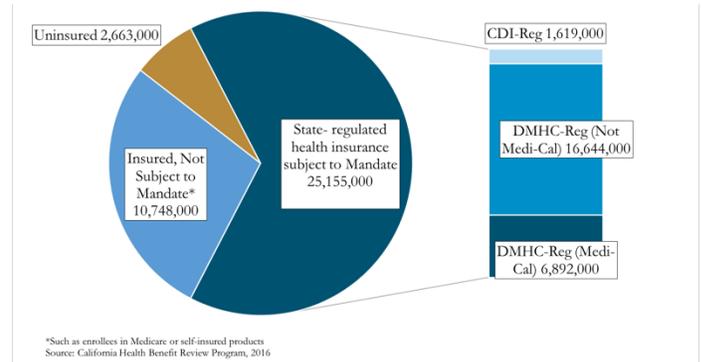


AT A GLANCE

Assembly Bill (AB) 2372 would require plans or policies to include an HIV specialist as a primary care physician (PCP), provided that they meet the plan or policy's eligibility criteria for all specialties seeking primary care physician status. The bill defines an HIV specialist as a physician or nurse practitioner who meets the criteria set forth by the American Academy of HIV Medicine (AAHVM) or the HIV Medicine Association (HIVMA), or those who are contracted to provide outpatient care under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990.

- **Analytic approach:** Based on bill language, analysis includes board-certified infectious disease providers and excludes primary care providers, who meet AB 2372 requirements premandate, including primary care and excludes HIV care.
- **Enrollees covered.** CHBRP estimates that in 2016, 25.2 million Californians have state-regulated coverage that would be subject to AB 2372.
- **Benefit coverage.** AB 2372 does not alter benefit coverage, but could increase enrollees' choice of type of PCPs who are HIV specialists.
- **Utilization.** CHBRP is unable to estimate enrollee utilization of designating an HIV specialist as a PCP.
- **Impact on expenditures.** Unknown.
- **EHBs.** AB 2372 does not expand or mandate coverage for services; the bill allows for HIV specialists to be designated as PCPs.
- **Medical effectiveness.** There is a very low preponderance of evidence from studies with weak research designs that care for non-HIV co-morbidities provided by physicians with more experience/expertise in HIV non-HIV is associated with poorer processes of care than care provided by physicians with less experience/expertise in HIV.
- **Public health.** There appear to be more than 900 HIV specialists (some of whom are AAHVM credentialed and many more who likely meet the AB 2372 specialist definition) who treat some of the 120,000 people living with HIV (PLWH) in California. However, the use of primary care services provided by HIV specialists and the resulting health outcomes for PLWH is unknown.

Figure 1. Health Insurance in California and AB 2372



A Report to the California State Legislature

Analysis of California Assembly Bill (AB) 2372
HIV Specialists

April 13, 2016

California Health Benefits Review Program
1111 Broadway, Suite 1400
Oakland, CA 94607
Tel: 510.287.3876
Fax: 510.763.4253
www.chbrp.org

REVISION HISTORY

Date	Description of Revisions
April 29, 2016	Language was added to clarify the low preponderance of evidence for medical effectiveness findings on the treatment of HIV co-morbidities.
April 29, 2016	Language was added to clarify the lack of claims data detail sufficient to determine any impact on utilization as a result of the mandate.
April 29, 2016	Language was added to clarify assumptions made in the analytical approach.

ABOUT CHBRP

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



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

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

TABLE OF CONTENTS

About CHBRP	iii
List of Tables and Figures.....	v
Policy Context	1
Bill-Specific Analysis of AB 2372, HIV Specialists	1
Background on HIV/AIDS and HIV Specialists	6
HIV/AIDS	6
Treatment of HIV/AIDS.....	6
Providers of HIV/AIDS Treatment in California	6
HIV/AIDS Incidence and Prevalence.....	7
Medical Effectiveness	10
Research Approach and Methods.....	10
Study Findings.....	11
AB 2372 Impacts on Benefit Coverage, Utilization, and Cost, 2016	Error! Bookmark not defined.
Benefit Coverage.....	13
Utilization	13
Expenditures.....	14
Estimated Public Health Impact of AB 2372	15
Appendix A Text of Bill Analyzed.....	A-1
Appendix B Literature Review Methods	B-1
References	
California Health Benefits Review Program Committees and Staff	
Acknowledgements	

LIST OF TABLES AND FIGURES

Table 1. Number of Credentialed and Non-Credentialed HIV Specialists in California, 2016	7
Table 2. Number of (Living) HIV/AIDS Cases in California, December 2013	9
Figure 1. Health Insurance in California and AB 2372.....	i
Figure 2. Non-AIDS Comorbidities Outcomes Summary	11

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)¹ conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 2372, HIV Specialists.

If enacted, AB 2372 would affect the health insurance of approximately 25.2 million enrollees (65.2% of all Californians). This represents 100% of the 25.2 million Californians who will have health insurance regulated by the state that may be subject to any state health insurance law. Specifically, health care service plans regulated by the Department of Managed Health Care (DMHC), and health insurance policies regulated by the California Department of Insurance (CDI), would be subject to AB 2372.

Bill-Specific Analysis of AB 2372, HIV Specialists

Bill Language

AB 2372 would require state-regulated health insurance plans to include an HIV specialist, as defined, as an eligible primary care physician, if they meet the plan or insurers' criteria for all specialists seeking primary care physician (PCP) status. "Primary care physician" means a physician, as defined in Section 14254 of the Welfare and Institutions Code, who has the responsibility for providing initial and primary care to patients, for maintaining the continuity of patient care, and for initiating referral for specialist care. This means providing care for the majority of health care problems, including, but not limited to, preventive services, acute and chronic conditions, and psychosocial issues. "HIV specialist" means a physician or a nurse practitioner who meets the criteria for an HIV specialist as published by the American Academy of HIV Medicine or the HIV Medicine Association, or who is contracted to provide outpatient medical care under the federal Ryan White CARE Act of 1990 (Public Law 101-381).

Key Assumptions

In this analysis, CHBRP differentiates between PCP HIV specialist and non-PCP HIV specialist. CHBRP clarifies that the "HIV specialty" designation may be obtained through a *credentialing* society or through patient care experience; it is not a formal *board-certified* specialty or subspecialty (e.g., internal medicine, infectious disease, etc.) that is recognized by the California Medical Board (or taught by medical schools).

Based on bill language parameters, this analysis:

- assumes that AB 2372 would not impact current PCPs who are also HIV specialists because they meet the bill's definition of a PCP premandate.
- assumes that AB 2372 would primarily impact board-certified infectious disease specialists who treat patients with HIV, and are not currently PCPs, but meet the bill's definition of HIV specialist.
- focuses on delivery of primary care services to people living with HIV (PLWH) rather than on delivery of HIV care because health plans already cover care for HIV provided by non-PCP HIV specialists.
- evaluates the clinical literature for evidence that non-PCP HIV specialists provided equivalent or better quality of primary care than PCP HIV specialists.

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

AB 2372 Definitions of Specialty Physician

Below are the explanations of the organizations that define HIV specialist criteria according to AB 2473. CHBRP will use the term “HIV Specialist™” to indicate those credentialed by AAHIVM and “HIV specialist” to designate any provider meeting of the three bill definitions: the published criteria established by the American Academy of HIV Medicine (AAHIVM) or the HIV Medicine Association (HIVMA); or a provider who is contracted to provide outpatient medical care under the federal Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 (Public Law 101-381).

HIV specialist certifications

AAHIVM

The Practicing HIV Specialist™ (AAHIVS)² is a trademarked credential offered by the AAHIVM to those who apply and meet the following conditions:

1. Be a licensed Physician, Nurse Practitioner, Physician Assistant, or Doctor of Pharmacology.
2. Take part in ongoing medical education programs (at least 15 CME or continuing medical education credits annually as well as complete a self-assessment examination; or complete 30 hours of CME credits and be required to participate annually in an HIV Medicine Competency Maintenance Exam).
3. Participate in, if receiving less than 30 credits of CME/year, a self-testing assessment program to measure core competencies. Substitutions acceptable: Certain training programs, HIV-specific fellowships, lecturing, and many other types of educational activity are acceptable as a substitute for actual accredited CME/CEU/CE, but explanation is required on the Credentialing application. Concise education activity summary records help facilitate the application process and may be submitted separately by mail or fax for convenience; details are provided within the online Credentialing application.
4. Have treated a minimum of at least 20 HIV patients in the past two years. Note: Providers with fewer than 20 regular HIV patients may still apply by selecting “1-19” as their patient count on the application. Once approved, the “lower-volume” applicant is then paired with a local, experienced Academy-credentialed Member as part of the Academy’s Clinical Consult Program.

AAHIVS Application Process: The applicants provide supporting documents demonstrating their education. The AAHIVM validates all submissions with a review of the application and profile, and follows up with inquiries where needed. The applicant must then sign an agreement verifying their authenticity, and agreeing to abide by the AAHIVM Code of Professional Ethics, as set forth on the AAHIVM credentialing website.

HIVMA

The organization provides a definition of specialty medical providers who manage the care of HIV-infected patients in an outpatient or clinic setting.

To be a Qualified HIV Physician³, a provider must meet three categories:

1. Patient Management: Management of at least 25 HIV-infected patients in the preceding 36 months.
2. Continuing Medical Education: At least 40 hours of HIV-related continuing medical education in the preceding 36 months, earning a minimum of 10 hours per year.

² American Academy of HIV Medicine Practicing HIV Specialist Eligibility Requirements. Downloaded from: <http://www.aahivm.org/aahivs>

³ HIV Medicine Association Qualified HIV Physician Criteria (March 2013). Available at: http://www.hivma.org/hiv_guidelines/#definition%20of%20an%20experienced%20hiv%20physician.

3. Board Certification or Significant Clinical Experience: Board certification or equivalent in one or more medical specialties or subspecialties recognized by the American Board of Medical Specialties or the American Osteopathic Association is preferred. Significant clinical and professional experience in HIV medicine, defined as a minimum of at least five years, should be considered in the absence of board certification.

Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990

The Ryan White CARE Act⁴ funds a federal program developed to assist persons living with AIDS/HIV who have no health insurance or lack financial resources to access care. The program provides grant funding to cities, states, and local community-based organizations to provide HIV care and treatment services, supporting primary medical care and support services.

Interaction with Existing Requirements

Proposed legislation can interact with state and federal requirements. When possible, CHBRP indicates possible overlaps or interactions.

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

California law and regulations

California definition of PCPs and specialists

In California, primary care physicians are defined in Sections 14254 of the Welfare and Institutions Code and Title 10, Section 2240 of the California Code of Regulations:

"Primary care physician" is a physician who has the responsibility for providing initial and primary care to patients, for maintaining the continuity of patient care, and for initiating referral for specialist care. A primary care physician shall be either a physician who has limited his or her practice of medicine to general practice or who is a board-certified or board-eligible internist, pediatrician, obstetrician-gynecologist, or family practitioner.

Specialists are defined in Section 14255 of the Welfare and Institutions Code:

"Specialist" means a physician who is board certified or board eligible in the specialty of medical care provided.

Knox-Keene Act

Health and Safety Code, Title 28, Section 1367.2 (e) requires health plans to provide accessibility to all medically necessary specialists.

Health and Safety Code Section 1351 designates specialists as allergy, anesthesiology, dermatology, cardiology and other internal medicine specialists, neonatology, neurology, oncology, ophthalmology, orthopedics, pathology, psychiatry, radiology, surgeries, otolaryngology, urology, and other designated as appropriate.

⁴ US Department of Health and Human Services. Available at: <http://hab.hrsa.gov/about/legislation.html>.

Health and Safety Code Section 1374.16 requires health plans to make standing referrals to specialists when medically necessary. Plans are not required to refer out of network, unless there is no contracting specialist in that discipline within the plan's network — in which case the plan would have to cover an out-of-network specialist referral.

Health and Safety Code Section 1374.16 specifically recognizes HIV/AIDS as a specialty as defined by the federal government or a national voluntary health organization.

Although it does not explicitly define specialist, Title 10, Section 2240 of the California Code of Regulations requires:

There are adequate full-time equivalents of primary care and specialist providers in the network accepting new patients covered by the policy to accommodate anticipated enrollment growth.

Similar requirements in other states

CHBRP is aware of two other states that have regulations regarding the definition of an HIV specialist similar to those proposed in AB 2372.

- New York law requires that managed care organizations provide treatment for those on HIV Special Needs Plans (SNPs) by HIV specialists. An HIV specialist is defined by the New York State Department of Health AIDS Institute; the result of an expert panel.⁵
- Maryland, in its administrative code, requires that health insurers cover treatment by HIV/AIDS specialists. An HIV specialist must either have an American Board of Medical Specialties certification in infectious diseases, or have performed a minimum amount of HIV care and completed an HIV education requirement, which can be filled by passing the AAHIVM credentialing exam.

Affordable Care Act

The Affordable Care Act (ACA) has impacted health insurance in California, expanding the Medi-Cal program (Medicaid in California)⁶ and making subsidized and unsubsidized health insurance available through Covered California, the state's health insurance marketplace.⁷

A number of ACA provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 2372 may interact with requirements of the ACA, including the requirement for certain health insurance to cover essential health benefits (EHBs).⁸

CHBRP is unaware of any federal laws or regulations that would interact with the provisions of AB 2372.

⁵ NY Department of Health (2009). Defining the HIV Specialist. Available at: <http://www.hivguidelines.org/wp-content/uploads/2009/06/hiv-specialist-report.pdf>

⁶ The Medi-Cal expansion is to 133% of the federal poverty level (FPL) — 138% with a 5% income disregard.

⁷ The ACA requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces.

⁸ 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.

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. Health insurance offered in Covered California is required to at least meet the minimum standard of benefits as defined by the ACA as essential health benefits (EHBs), and available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.^{9,10}

States may require such QHPs to offer benefits that exceed EHBs.¹¹ 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.^{12,13} On the other hand, "state rules related to provider types, cost sharing, or reimbursement methods" would *not meet* the definition of state benefit mandates that could exceed EHBs.¹⁴

AB 2372 and EHBs

AB 2372 allows certain physicians to be designated as primary care physicians, expanding the providers eligible to provide essential health benefits, but does not mandate coverage of additional benefits. Therefore, the provisions of AB 2372 do not appear not to exceed EHBs, and would not trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in qualified health plans (QHPs)¹⁵ in Covered California.

⁹ 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. CCIIIO, Essential Health Benefits Bulletin. Available at: cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.

¹⁰ H&SC § 1367.005; IC Section 10112.27.

¹¹ ACA § 1311(d)(3).

¹² 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/vfdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

¹³ 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 a state's EHBs and there would be no requirement that the state defray the costs of those state mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.

¹⁴ 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.

¹⁵ In California, QHPs are nongrandfathered small-group and individual market DMHC-regulated plans and CDI-regulated policies sold in Covered California, the state's health insurance marketplace.

BACKGROUND ON HIV/AIDS AND HIV SPECIALISTS

HIV/AIDS

Human immunodeficiency virus (HIV) attacks the body's immune system, specifically the CD4 cells (T cells) that fight infections, thus greatly increasing the risk of opportunistic diseases. HIV infection leads to acquired immunodeficiency syndrome (AIDS) if left untreated. Due to advances in drug treatment, HIV/AIDS has progressed from an acute illness with a high mortality rate to a manageable chronic illness where patients achieve close to normal life expectancy.

Treatment of HIV/AIDS

Proper treatment of HIV reduces viral load, increases the body's CD4 count, improves immune status, greatly reduces the risk of opportunistic diseases, improves quality of life, reduces rates of transmission, and provides near-normal life expectancy (Gallant et al., 2011). HIV/AIDS is treated with highly active anti-retroviral therapy (HAART) usually through a combination of at least three prescription medications, representing at least two different drug categories. Regimen complexity has decreased over the years, but still may present challenges to some patients. These medication regimens reduce the viral load in the blood stream, enabling the body to fend off secondary infections and diseases and reduce the risk of transmitting the virus to others. Treatment effectiveness may wane over time (due to mutations to the virus), requiring changes to the drug regimen. Other reasons for changing a treatment regimen include pregnancy or patient intolerance to side effects such as nausea, pain, fatigue, anemia, etc. Long-term effects may include insulin resistance leading to diabetes, loss of bone density, or hyperlipidemia (increases in cholesterol). Both the treatment of HIV and management of potential medication side effects require ongoing care from a health care provider (e.g., HAART therapy often has interactions with other medications that have to be considered in treatment of other chronic conditions).

As HIV has progressed to a chronic condition, people living with HIV/AIDS (PLWH) are living longer and developing other conditions common to the general population (e.g., heart disease, cancer, etc.). These non-HIV-related conditions require age- and gender-relevant preventive care and chronic care (see primary care practice guideline description in *Medical Effectiveness*) (Aberg et al., 2013; Greene et al., 2013).

Providers of HIV/AIDS Treatment in California

HIV providers may be physicians, nurse practitioners, or physician assistants and may be credentialed as an HIV Specialist™ by the American Academy of HIV Medicine. Pharmacists (who support medication adherence, identify drug interactions, and provide medication management among multiple providers) may also obtain HIV Specialist™ credentialing. (See *Policy Context* for description of credentialing). PLWH may see an HIV specialist who is in private practice, or practices at an HIV clinic, general healthcare clinic, or a community health center. Additionally, PLWH (especially those who are underinsured or uninsured, and thus not subject to AB 2372) may seek care at the clinics funded through the Ryan White CARE Act. These clinics were foundational to the control of the AIDS epidemic in the early 1990s, through their provision of HIV treatment and management. Table 1 presents the distribution of AAHIVM-credentialed HIV Specialists™ and a lower-bound estimate of non-credentialed HIV specialists in California.

Table 1. Number of Credentialed and Non-Credentialed HIV Specialists in California, 2016

Provider Type	Number of Providers
Total HIV Specialists™ (credentialed)	448
MD and DO ^a	283
By medical board certification	
Internal Medicine	96
Family Practice	89
Infectious Disease	75
Geriatrics	2
OB/GYN	2
Emergency Medicine	2
No Listing	17
Nurse Practitioner	39
Physician Assistant	18
Pharmacist	108
Non-credentialed providers listed as HIV specialists^b	+453
Total HIV Specialists in California	+900

Source: California Health Benefits Review Program, 2016.

Notes: (a) MD=258; DO=25.

(b) This count does not include HIV specialists practicing at the clinics funded by the Ryan White CARE Act. Although these clinics are not subject to AB 2372, the “specialist” definition in the bill does include providers contracted to provide care under the Ryan White CARE Act. These providers may also practice in other settings outside of the clinic and could be counted as part of the HIV specialist supply in California.

Key: MD=Doctor of Medicine; DO=Doctor of Osteopathic Medicine.

In addition to seeing an HIV specialist, PLWH may see other health care practitioners, including dentists, nurses, case managers, social workers, psychiatrists/psychologists, and medical specialists (AIDS.gov, 2016). Coordinating care among multiple providers is challenging, but necessary to improving health outcomes for PLWH; it improves medication adherence and reduces viral loads, especially for complex patients (Gallant et al., 2011).

HIV/AIDS Incidence and Prevalence

National

Nationally, the Centers for Disease Control and Prevention report that rates of diagnosis of HIV in 2014 were highest for blacks/African Americans (49.4/100,000) and lowest for whites and Asians (6.1/100,000 and 6.2/100,000, respectively). Hispanics/Latinos had a rate of 18.4/100,000 persons. Rates for persons of multiple races, Native Hawaiian/Pacific Islander, and American Indian/Alaska Native ranged between 15.4/100,000 and 9.5/100,000 (CDC, 2014). In addition to the disparate HIV incidence rates by race/ethnicity, data show that there are racial/ethnic disparities in access to physicians with HIV expertise (DHCS, 2015; Heslin et al., 2004).

California

The California Office of AIDS maintains an HIV/AIDS surveillance system that records the prevalence and incidence of HIV diagnoses and the prevalence of AIDS cases (CDPH, 2015). The most recent data available are from 2013. Differences in HIV/AIDS cases in California occur among several demographic categories including gender, race, age, and risk exposure (**Table 2**).

Table 2. Number of (Living) HIV/AIDS Cases in California, December 2013

Demographic Characteristics	Total Living HIV/AIDS Cases (n)
TOTAL	119,878¹⁶
Sex	
Men	104,796
Women	14,071
Transgender	1,011
Race/ethnicity	
White	51,651
Black	21,275
Hispanic	40,015
American Indian/Alaska Native	463
Asian	4,412
Native Hawaiian/Pacific Islander	298
Multi-race/Unknown/Other	1,764
Age (years)	
0–12	673
13–19	1,983
20–29	27,130
30–39	45,593
40–49	31,368
≥50	13,131
Risk exposure	
MSM	79,355
IDU	8,203
MSM/IDU	9,106
Hemophiliac/transfusion	440
HRH	10,893
Other/unknown	11,228
Perinatal exposure	653

Source: California Health Benefits Review Program, 2016. Adapted from California Office of AIDS, California HIV/AIDS Cases by Demographics Cumulative as of December 31, 2013, Table 2.

Key: MSM=Men who have sex with men; IDU=Injection drug use; HRH=High risk heterosexual contact.

¹⁶ CHBRP applied an average prevalence rate across all enrollees affected by the mandate, but prevalence rates could differ across enrollees by age and coverage sources.

MEDICAL EFFECTIVENESS

As discussed previously, AB 2372 would require state-regulated health insurance plans to include an HIV specialist, as defined, as an eligible primary care physician if they meet the plan or insurers' criteria for a primary care physician (PCP).

Multiple studies have found that receiving outpatient care for *HIV* from a provider with more training/expertise in HIV is associated with better outcomes for measures of HIV severity, such as plasma viral load control (Landon 2005). PLWH who treated by providers with more HIV training/expertise were more likely to be on highly active antiretroviral therapy (HAART) (Landon 2005) and on newer treatment regimens sooner (Landon 2003). *However, these studies do not address whether receiving care from an HIV specialist, as defined in the bill, is associated with better outcomes for non-HIV comorbidities.* CHBRP assumed that AB 2372 would only affect PLWH's choice of provider for non-HIV comorbidities because under current law PLWH already have access to HIV specialists for HIV/ care.

Research Approach and Methods

CHBRP assumes AB 2372 would primarily impact board-certified infectious disease specialists, who are not currently PCPs, but meet the bill's definition of HIV specialist. CHBRP searched for studies of PLWH treated by HIV specialists who are not PCPs compared to HIV specialists who are PCPs, but identified no such studies in the literature at this time. Instead, the medical effectiveness review for this bill focuses on examining physician's experience/expertise with HIV patients.

Studies of HIV specialists care were identified through searches of multiple bibliographic databases of medical, scientific, and economic literature, as well as websites maintained by organizations that produce and/or index meta-analyses and systematic reviews (see Appendix B for full list of databases and websites). The current search was limited to abstracts of peer-reviewed research studies that were published in English from 1996 to present.

Of the 110 articles found in the current literature review, 22 were reviewed for potential inclusion in this report. Studies were eliminated because they did not report findings from clinical research studies or were of poor quality. In total, 9 studies were included in the medical effectiveness review for AB 2372, based on the quality of the studies and their relevance to the specific bill language. When systematic reviews had inclusion criteria broader than the mandate of AB 2372, CHBRP summarized findings only from the relevant studies.

Methodological Considerations

Studies pertinent to AB 2372 examine primary care services provided by non-PCP HIV specialist as compared to those provided by a PCP. In the literature review for AB 2372, there are no studies that specifically address the effectiveness of primary care services for HIV patients provided by any HIV specialists, as defined in the bill language, compared to a primary care physician.

It is important to note that HIV disease does not fall under the range of any one medical specialty — physicians trained in internal medicine, family medicine, and other medical subspecialties join infectious disease specialists as HIV experts. Although many HIV experts are infectious disease physicians, not all infectious disease physicians are HIV experts. Ongoing patient management and continuing education are required for HIV expertise, regardless of specialty training (Gallant et al., 2011). While some studies may refer to HIV specialists, as defined in the bill language, it is hard to disentangle the term HIV specialist, HIV provider, HIV primary care physician, and infectious disease physician.

Outcomes Assessed

Because AB 2372 refers to primary care, including, but not limited to, preventive services, acute and chronic conditions, and psychosocial issues, CHBRP's medical effectiveness review for AB 2372 focused on non-HIV comorbidities, such as diabetes and hypertension. CHBRP searched for studies of HIV specialists who are PCPs compared to HIV specialists who are not PCPs, but identified no such studies in the literature at this time. Instead, the medical effectiveness review for this bill focuses on the impact of physician's experience/expertise with HIV patients on the care they provide for non-HIV co-morbidities.

Study Findings

Taken together, there is a very low preponderance of evidence from studies with weak research designs that indicates that primary care provided by physicians with more experience and expertise with HIV (proxy for HIV specialist) results in worse outcomes for non-HIV comorbidities such as depression, diabetes, and hypertension, than care provided by physicians with less experience/expertise in HIV. These findings are discussed in further detail in the sections that follow.

Literature on HIV Specialists

Findings for Non-AIDS comorbidities

With improved survival for PLWA, patterns of comorbidity have changed among HIV-positive patients. Cardiovascular disease, hypertension, and diabetes have become prevalent, and causes of death have shifted from opportunistic infections to end-stage liver and kidney disease and non-HIV-related malignancies (Bergersen et al., 2003; Brown et al., 2005; Hooshyar et al., 2007; Lewden et al., 2008; Palella et al., 2006; Triant et al., 2007).

CHBRP found few studies that examined non-AIDS comorbidities in patients with HIV.

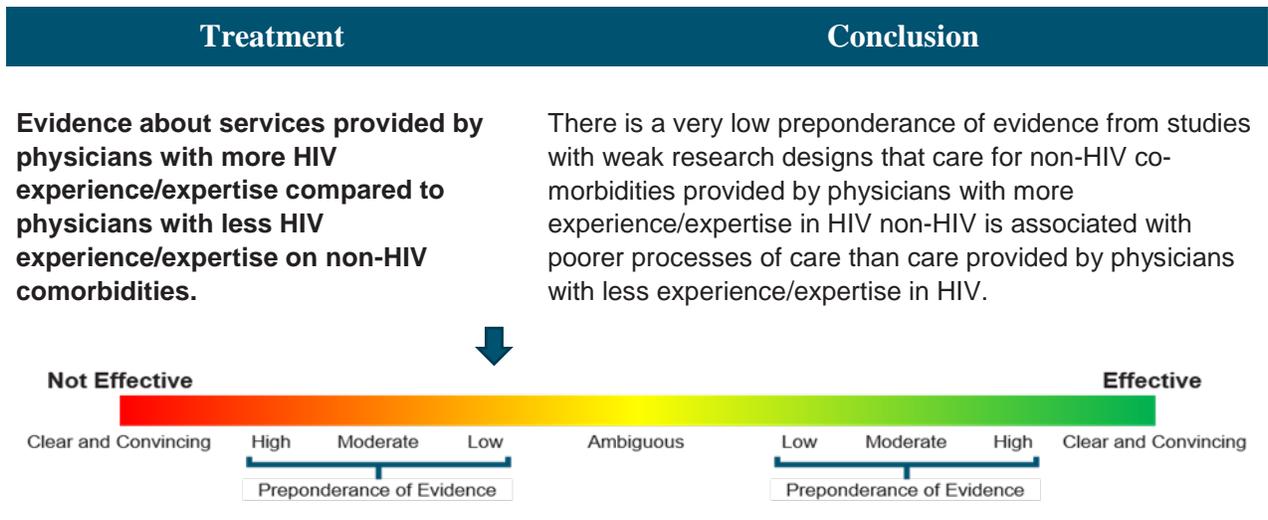
One study — a self-reported survey of 97 HIV patients and 8 providers — found that the likelihood of a patient using their HIV provider as their PCP was not associated with the number of non-AIDS medical problems ($p=0.28$), the number of non-AIDS medications ($p=0.23$), or the number of other specialists seen per year ($p=0.74$) (Cheng et al., 2014).

CHBRP found three studies that examined HIV-experienced physicians and patient comorbidities. One study, a self-reported survey, found incongruities between HIV patients' non-AIDS comorbidities and their HIV providers' comfort level in treating those diseases (Cheng et al., 2014). Other studies have shown similar results. One study examined the level of comfort by experts in HIV medicine with prescribing medications to HIV-infected patients for hyperlipidemia, diabetes, hypertension, and depression and found that infectious disease (ID)-specialists and internists practicing at HIV clinics were less comfortable than general medicine (GM) certified physicians practicing at a GM clinic with prescribing treatment for all conditions studied. For example, comfort treating HIV patients with hyperlipidemia was greater for GM-certified physicians at GM clinics than for GM-certified physicians and ID-certified physicians at ID clinics (98% vs. 73% and 71%, respectively; $P < .0001$ for trend). A similar pattern was seen for treating HIV patients with diabetes and hypertension ($P < .0001$) (Fultz et al., 2005).

Additionally, comfort with treating patients with depression was generally lower, particularly among physicians at ID clinics ($P < .0001$) (Fultz et al., 2005). A study at outpatient ID clinics at three academic medical centers, each of which serves over 1500 HIV-infected patients, reported similar findings of

physicians' discomfort with prescribing antidepressants to HIV patients and their practices regarding screening and treatment for depression. This study found that 31% of physicians reported routinely assessing all patients for depression, 13% reported following up with patients within 2 weeks of starting an antidepressant, and 36% reported systematically assessing treatment response and tolerability in adjusting treatment. Over half of providers reported not being comfortable using the full FDA-approved dosing range for antidepressants. Systematic screening for depression and best-practices depression management were uncommon (Bess et al., 2013). Cheng and colleagues (2014) also found that despite the high prevalence of depression reported by HIV patients, providers' reported a low comfort level with treating mood disorders.

Figure 2. Non-HIV Comorbidities Outcomes Summary



Source: California Health Benefits Review Program.

(AB) 2372 IMPACTS ON BENEFIT COVERAGE, UTILIZATION, AND COST, 2016

Benefit Coverage

AB 2372 does not alter the benefit coverage of 25.2 million enrollees subject to AB 2372, but enrollees could have increased choice of PCPs, as the mandate would increase the number of qualifying HIV specialist providers that could be designated as PCPs.

Key Assumptions

- CHBRP assumes AB 2372 would not impact current PCPs who are also HIV specialists. AB 2372 would impact non-PCP HIV specialists such as board certified infectious disease specialists.
- Among the HIV specialists that can be designated as PCPs as a result of AB 2372, CHBRP assumes that only HIV-positive patients would select these providers as their PCP.

Premandate (Baseline) Benefit Coverage

Currently enrollees living with HIV who are subject to AB 2732 have access to HIV specialists as defined by their plan or policy. According to the responses to the CHBRP Carrier survey, most health plans and policies allow HIV specialists to act as PCPs if the HIV specialist meets the health plan's PCP requirements. As noted in the *Policy Context* section, California law (Sections 14254 of the Welfare and Institutions Code and Title 10, Section 2240 of the California Code of Regulations) designates PCPs as either a physician who has limited his or her practice of medicine to general practice or who is a board-certified or board-eligible internist, pediatrician, obstetrician-gynecologist, or family practitioner. Based on Table 1, and focusing on credentialed HIV specialists in California, a high proportion of HIV specialists currently qualify for the PCP designation. CHBRP assumes that AB 2372 will largely impact infectious disease specialists who are not currently PCPs, but who meet the HIV specialist requirement.

Postmandate Benefit Coverage

Postmandate, CHBRP assumes that enrollees with HIV could designate infectious disease specialists, meeting the HIV specialist definition put forth in AB 2372, as their PCP. CHBRP qualitatively estimates that the impact would be minimal: according to Table 1, among credentialed HIV Specialists™ in California in 2016, there are 75 board-certified infectious disease specialists, comprising 17% of credentialed HIV Specialists™.

Utilization

CHBRP is not able to quantify the utilization impact of the proposed bill, due to limitations in health insurance claims data. "HIV specialists" are not designated in common claims data, and thus, this impacts CHBRP's ability to estimate baseline utilization. CHBRP is unable to determine whether a person living with HIV currently obtains care from an HIV specialist, and whether or not such specialist is a PCP or another board-certified specialist (such as an infectious disease specialist). Therefore, CHBRP is unable to identify whether implementation of AB 2372 would impact a shift in utilization from one provider to another, or if there would be a change in the overall volume of services provided.

Expenditures

CHBRP's expenditure analysis is informed by changes in unit costs and utilization premandate and postmandate. According to the carrier survey, when an HIV specialist serves as a PCP they are reimbursed the same as any other PCP; there is not a difference in unit cost payment or, for those health plans that pay capitation rates to providers who serve as PCPs, in the capitation payment. CHBRP therefore assumes that unit costs would not change postmandate.

A full expenditure analysis, however, is constrained by the unknowns in the utilization impact. An analysis would require a robust database that identifies primary and specialty services by provider type and whether the provider is an HIV specialist as defined by AB 2372.

While the expenditure impact is unknown, CHBRP anticipates two scenarios. First, patient cost sharing may decrease postmandate if enrollees shift to HIV specialist providers designated as PCPs, and previous preventive services delivered as a specialty visit with cost-sharing, can be billed as a preventive visit, with no cost sharing. If time and cost efficiencies are gained from consolidating HIV services with primary care resulting in fewer visits, then premiums would also be expected to decrease.

Alternatively, cost sharing may increase, particularly for patients with other chronic conditions. Increased patient cost sharing occurs if another specialist needs to be included in the treatment team, as HIV specialists may not be expert at treating all conditions that may be revealed through a primary care visit, such as diabetes, heart disease, mental health issues, and others. In this scenario, premiums may be expected to increase if the total cost of care would increase.

ESTIMATED PUBLIC HEALTH IMPACT OF AB 2372

There appear to be more than 75 non-PCP¹⁷ HIV specialists (including AAHIVM credentialed and many more who likely meet the AB 2372 specialist definition) who treat some of the PLWH with insurance subject to the mandate. However, use of primary care services provided by HIV specialists and the resulting health outcomes for non-HIV comorbidities for enrollees living with HIV is unknown. This is due to a very low preponderance of evidence indicating that care for non-HIV comorbidities provided by physicians with more experience/expertise in HIV is associated with poorer processes of care than care provided by physicians with less experience/expertise in HIV. This unknown impact conclusion extends to subpopulations of PLWH that are disproportionately affected by HIV.

¹⁷ Non-PCP HIV specialists refers to those physicians who are board certified in a particular medical subspecialty, such as infectious disease.

APPENDIX A TEXT OF BILL ANALYZED

On February 22, 2016, the California Assembly Committee on Health requested that CHBRP analyze AB 2372.

CALIFORNIA LEGISLATURE— 2015–2016 REGULAR SESSION

ASSEMBLY BILL

No. 2372

**Introduced by Assembly Member Burke
(Principal coauthor: Assembly Member Waldron)
(Principal coauthor: Senator Hertzberg)**

February 18, 2016

An act to amend Section 1367.03 of, and to add Section 1367.693 to, the Health and Safety Code, and to amend Section 10133.5 of, and to add Section 10123.833 to, the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2372, as introduced, Burke. Health care coverage: HIV Specialists.

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. A willful violation of the act is a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law requires the Department of Managed Health Care and the Insurance Commissioner to adopt regulations to ensure that enrollees and insureds have access to needed health care services in a timely manner. Existing law requires the Department of Managed Health Care to develop indicators of timeliness of access to care, including waiting times for appointments with physicians, including primary care and speciality physicians. Existing law requires the Insurance Commissioner to adopt regulations that ensure, among other things, the adequacy of the number of professional providers in relationship to the projected demands for services covered under the group policy.

This bill would define for these purposes “specialty physician” and “professional provider,” respectively, to include a physician who meets the criteria for an HIV Specialist, as specified. The bill would require a

health care service plan contract or health insurance policy that is issued, amended, or renewed on or after January 1, 2017, to include an HIV Specialist, as defined, as an eligible primary care physician, provided that he or she meets the plan's or health insurer's eligibility criteria for all specialists seeking primary care physician status. Because a willful violation of these requirements 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.

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 1367.03 of the Health and Safety Code is amended to read:
1367.03.

(a) ~~Not later than January 1, 2004, the~~ *The* department shall develop and adopt regulations to ensure that enrollees have access to needed health care services in a timely manner. In developing these regulations, the department shall develop indicators of timeliness of access to care and, in so doing, shall consider the following as indicators of timeliness of access to care:

- (1) Waiting times for appointments with physicians, including primary care and specialty physicians.
 - (2) Timeliness of care in an episode of illness, including the timeliness of referrals and obtaining other services, if needed.
 - (3) Waiting time to speak to a physician, registered nurse, or other qualified health professional acting within his or her scope of practice who is trained to screen or triage an enrollee who may need care.
- (b) In developing these standards for timeliness of access, the department shall consider the following:
- (1) Clinical appropriateness.
 - (2) The nature of the specialty.
 - (3) The urgency of care.
 - (4) The requirements of other provisions of law, including Section 1367.01 governing utilization review, that may affect timeliness of access.
- (c) The department may adopt standards other than the time elapsed between the time an enrollee seeks health care and obtains care. If the department chooses a standard other than the time elapsed between the time an enrollee first seeks health care and obtains it, the department shall demonstrate why that standard

is more appropriate. In developing these standards, the department shall consider the nature of the plan network.

(d) The department shall review and adopt standards, as needed, concerning the availability of primary care physicians, specialty physicians, hospital care, and other health care, so that consumers have timely access to care. In so doing, the department shall consider the nature of physician practices, including individual and group practices as well as the nature of the plan network. The department shall also consider various circumstances affecting the delivery of care, including urgent care, care provided on the same day, and requests for specific providers. If the department finds that health care service plans and health care providers have difficulty meeting these standards, the department may make recommendations to the Assembly Committee on Health and the Senate Committee on Insurance of the Legislature pursuant to subdivision (i).

(e) In developing standards under subdivision (a), the department shall consider requirements under federal law, requirements under other state programs, standards adopted by other states, nationally recognized accrediting organizations, and professional associations. The department shall further consider the needs of rural areas, specifically those in which health facilities are more than 30 miles apart and any requirements imposed by the State Department of Health Care Services on health care service plans that contract with the State Department of Health Care Services to provide Medi-Cal managed care.

(f) (1) Contracts between health care service plans and health care providers shall ensure compliance with the standards developed under this section. These contracts shall require reporting by health care providers to health care service plans and by health care service plans to the department to ensure compliance with the standards.

(2) Health care service plans shall report annually to the department on compliance with the standards in a manner specified by the department. The reported information shall allow consumers to compare the performance of plans and their contracting providers in complying with the standards, as well as changes in the compliance of plans with these standards.

(3) The department may develop standardized methodologies for reporting that shall be used by health care service plans to demonstrate compliance with this section and any regulations adopted pursuant to it. The methodologies shall be sufficient to determine compliance with the standards developed under this section for different networks of providers if a health care service plan uses a different network for Medi-Cal managed care products than for other products or if a health care service plan uses a different network for individual market products than for small group market products. The development and adoption of these methodologies shall not be subject to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) until January 1, 2020. The department shall consult with stakeholders in developing standardized methodologies under this paragraph.

(g) (1) When evaluating compliance with the standards, the department shall focus more upon patterns of noncompliance rather than isolated episodes of noncompliance.

(2) The director may investigate and take enforcement action against plans regarding noncompliance with the requirements of this section. Where substantial harm to an enrollee has occurred as a result of plan

noncompliance, the director may, by order, assess administrative penalties subject to appropriate notice of, and the opportunity for, a hearing in accordance with Section 1397. The plan may provide to the director, and the director may consider, information regarding the plan's overall compliance with the requirements of this section. The administrative penalties shall not be deemed an exclusive remedy available to the director. These penalties shall be paid to the Managed Care Administrative Fines and Penalties Fund and shall be used for the purposes specified in Section 1341.45. The director shall periodically evaluate grievances to determine if any audit, investigative, or enforcement actions should be undertaken by the department.

(3) The director may, after appropriate notice and opportunity for hearing in accordance with Section 1397, by order, assess administrative penalties if the director determines that a health care service plan has knowingly committed, or has performed with a frequency that indicates a general business practice, either of the following:

(A) Repeated failure to act promptly and reasonably to assure timely access to care consistent with this chapter.

(B) Repeated failure to act promptly and reasonably to require contracting providers to assure timely access that the plan is required to perform under this chapter and that have been delegated by the plan to the contracting provider when the obligation of the plan to the enrollee or subscriber is reasonably clear.

(C) The administrative penalties available to the director pursuant to this section are not exclusive, and may be sought and employed in any combination with civil, criminal, and other administrative remedies deemed warranted by the director to enforce this chapter.

(4) The administrative penalties shall be paid to the Managed Care Administrative Fines and Penalties Fund and shall be used for the purposes specified in Section 1341.45.

(h) The department shall work with the patient advocate to assure that the quality of care report card incorporates information provided pursuant to subdivision (f) regarding the degree to which health care service plans and health care providers comply with the requirements for timely access to care.

(i) The department shall annually review information regarding compliance with the standards developed under this section and shall make recommendations for changes that further protect enrollees. Commencing no later than December 1, 2015, and annually thereafter, the department shall post its final findings from the review on its Internet Web site.

(j) The department shall post on its Internet Web site any waivers or alternative standards that the department approves under this section on or after January 1, 2015.

(k) For purposes of this section, "specialty physician" includes a physician who meets the criteria for an HIV Specialist as published by the American Academy of HIV Medicine or the HIV Medicine Association, or who is contracted to provide outpatient medical care under the federal Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 (Public Law 101-381).

SEC. 2.

Section 1367.693 is added to the Health and Safety Code, immediately following Section 1367.69, to read:

1367.693.

(a) Every health care service plan contract that is issued, amended, or renewed on or after January 1, 2017, that provides hospital, medical, or surgical coverage shall include an HIV Specialist as an eligible primary care physician, provided he or she meets the health care service plan's eligibility criteria for all specialists seeking primary care physician status.

(b) For purposes of this section, "primary care physician" means a physician, as defined in Section 14254 of the Welfare and Institutions Code, who has the responsibility for providing initial and primary care to patients, for maintaining the continuity of patient care, and for initiating referral for specialist care. This means providing care for the majority of health care problems, including, but not limited to, preventive services, acute and chronic conditions, and psychosocial issues.

(c) For purposes of this section, "HIV Specialist" means a physician or a nurse practitioner who meets the criteria for an HIV Specialist as published by the American Academy of HIV Medicine or the HIV Medicine Association, or who is contracted to provide outpatient medical care under the federal Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 (Public Law 101-381).

SEC. 3.

Section 10123.833 is added to the Insurance Code, immediately following Section 10123.83, to read:
10123.833.

(a) Every health insurance policy that is issued, amended, or renewed on or after January 1, 2017, that provides hospital, medical, or surgical coverage shall include an HIV Specialist as an eligible primary care physician, provided he or she meets the health insurer's eligibility criteria for all specialists seeking primary care physician status.

(b) For purposes of this section, "primary care physician" means a physician, as defined in Section 14254 of the Welfare and Institutions Code, who has the responsibility for providing initial and primary care to patients, for maintaining the continuity of patient care, and for initiating referral for specialist care. This means providing care for the majority of health care problems, including, but not limited to, preventive services, acute and chronic conditions, and psychosocial issues.

(c) For purposes of this section, "HIV Specialist" means a physician or a nurse practitioner who meets the criteria for an HIV Specialist as published by the American Academy of HIV Medicine or the HIV Medicine Association, or who is contracted to provide outpatient medical care under the federal Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 (Public Law 101-381).

SEC. 4.

Section 10133.5 of the Insurance Code is amended to read:
10133.5.

(a) The commissioner ~~shall, on or before January 1, 2004, shall~~ promulgate regulations applicable to health insurers ~~which that~~ contract with providers for alternative rates pursuant to Section 10133 to ensure that insureds have the opportunity to access needed health care services in a timely manner.

(b) These regulations shall be designed to ~~assure~~ *ensure* accessibility of provider services in a timely manner to individuals comprising the insured or contracted group, pursuant to benefits covered under the policy or contract. The regulations shall ~~insure:~~ *ensure:*

~~1. Adequacy~~

(1) *Adequacy* of number and locations of institutional facilities and professional providers, and consultants in relationship to the size and location of the insured group and that the services offered are available at reasonable times.

~~2. Adequacy~~

(2) *Adequacy* of number of professional providers, and license classifications of such providers, in relationship to the projected demands for services covered under the group policy or plan. The department shall consider the nature of the specialty in determining the adequacy of professional providers.

~~3. The~~

(3) *The* policy or contract is not inconsistent with standards of good health care and clinically appropriate care.

~~4.~~

(4) All contracts, including contracts with providers, and other persons furnishing services, or facilities, shall be fair and reasonable.

(c) In developing standards under subdivision (a), the department shall also consider requirements under federal law; requirements under other state programs and law, including utilization review; and standards adopted by other states, national accrediting organizations, and professional associations. The department shall further consider the accessibility to provider services in rural areas.

(d) In designing the regulations, the commissioner shall consider the regulations in Title 28, of the California ~~Administrative~~ Code of Regulations, commencing with Section 1300.67.2, which are applicable to Knox-Keene plans, and all other relevant guidelines in an effort to accomplish maximum accessibility within a ~~cost-efficient~~ *cost-efficient* system of indemnification. The department shall consult with the Department of Managed Health Care concerning regulations developed by that department pursuant to Section 1367.03 of the Health and Safety Code and shall seek public input from a wide range of interested parties.

(e) Health insurers that contract for alternative rates of payment with providers shall report annually on complaints received by the insurer regarding timely access to care. The department shall review these complaints and any complaints received by the department regarding timeliness of care and shall make public this information.

(f) The department shall report to the Assembly Committee on Health and the Senate Committee on Insurance of the Legislature on March 1, 2003, and on March 1, 2004, regarding the progress towards the implementation of this section.

(g) Every three years, the commissioner shall review the latest version of the regulations adopted pursuant to subdivision (a) and shall determine if the regulations should be updated to further the intent of this section.

(h) For purposes of this section, "professional provider" includes a physician who meets the criteria for an HIV Specialist as published by the American Academy of HIV Medicine or the HIV Medicine Association, or who is contracted to provide outpatient medical care under the federal Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 (Public Law 101-381).

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 conducted for this report. A discussion of CHBRP's system for grading evidence follows, along with lists of Medical Subject Headings (MeSH) terms, keywords, and publication types.

The literature search was limited to studies published in English from 1996 to present. Studies that enrolled persons of all ages in the United States were included. The following databases of peer-reviewed literature were searched: MEDLINE (PubMed), the Cochrane Database of Systematic Reviews, the Cochrane Register of Controlled Clinical Trials, the Cumulative Index of Nursing and Allied Health Literature, EconLit, and Web of Science. In addition, websites maintained by the following organizations that index or publish systematic reviews and evidence-based guidelines were searched: American Academy of HIV Medicine, Center for Disease Control and Prevention, HIV Medicine Association, Office of AIDS, California Department of Public Health, Agency for Healthcare Research and Quality, International Network of Agencies for Health Technology Assessment, National Health Service Centre for Reviews and Dissemination, National Guidelines Clearinghouse, National Institute for Health and Clinical Excellence, World Health Organization, and the Scottish Intercollegiate Guideline Network.

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

Of 315 articles found in the literature review, 22 were reviewed for potential inclusion in this report, and a total of 9 articles were included in the medical effectiveness review for AB 2372.

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*.¹⁸ To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Consistency of findings;
- Generalizability of findings to the population whose coverage would be affected by a mandate; and
- Cumulative impact of evidence.

CHBRP uses a hierarchy to classify studies' research designs by the strength of the evidence they provide regarding a treatment's effects. CHBRP classifies research by levels I–V. Level I research includes well-implemented randomized controlled trials (RCTs) and cluster RCTs. Level II research includes RCTs and cluster RCTs with major weaknesses. Level III research consists of nonrandomized studies that include an intervention group and one or more comparison groups, time series analyses, and cross-sectional surveys. Level IV research consists of case series and case reports. Level V represents clinical/ practical guidelines based on consensus or opinion.

¹⁸ Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

CHBRP evaluates consistency of findings across three dimensions: statistical significance, direction of effect, and size of effect.

Generalizability refers to the extent to which a study's findings can be generalized to a population of interest. For CHBRP, the population of interest is the segment of California's diverse population to which a proposed mandate or repeal would apply.

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

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

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies have strong research designs, consistently find that the treatment is either effective or not effective, and have findings that are highly generalizable to the population whose coverage would be affected. This grade is assigned in cases in which it is unlikely that publication of additional studies would change CHBRP's conclusion about the effectiveness of a treatment.

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 and that the findings are generalizable to the population whose coverage would be affected. Bodies of evidence that are graded as *preponderance of evidence* are further subdivided into three categories based on the strength of their research designs: strong research designs, moderate research designs, and weak research designs.

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 with equally strong research designs 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 have weak research designs. It does not indicate that a treatment is not effective.

In addition to grading the strength of evidence regarding a treatment's effect on specific outcomes, CHBRP also assigns an overall grade to the whole body of evidence included in the medical effectiveness review. A statement of the overall grade is included in the

Medical Effectiveness section of the report. The statement is accompanied by a graphic to help readers visualize the conclusion. In the case of AB 2372, the report includes one overall grade and one figure.

Search Terms

The search terms used to locate studies relevant to AB 2372 were as follows:

MeSH terms used to search PubMed

- Acquired immunodeficiency Syndrome/epidemiology/therapy
- Antiretroviral Therapy, Highly Active
- Cardiovascular Diseases/therapy
- Chronic Disease
- Comorbidity
- Diabetes Mellitus/therapy
- Emergency Service, Hospital/statistics & numerical data/utilization
- Guideline Adherence
- Healthcare Disparities
- Health Services Needs and Demand
- Hepatitis C
- HIV infections/complications/drug therapy/epidemiology/mortality/prevention and control
- Hospitalization
- Hypertension
- Incidence
- Infectious Disease Medicine
- Lung Diseases/therapy
- Medication Adherence
- Mental Disorders/therapy
- Neoplasms/therapy
- Patient Admission/statistics & numerical data
- Patient Compliance
- Physician-Patient Relations
- Practice Patterns, Physicians
- Prevalence
- Primary Health Care
- Pulmonary Disease, Chronic Obstructive
- Mobility
- Mortality
- Quality of Health Care
- Risk Factors
- Specialization
- Treatment Outcome
- Trust
- Viral Load

Keywords used to search PubMed, Cochrane Library, Scopus and Web of Science

- “Acquired immunodeficiency syndrome”
- “Antiretroviral therapy”
- “Chronic diseases”
- “Cardiovascular Diseases”
- “Chronic Disease”
- Comorbidity
- COPD
- Depression
- Diabetes
- Disparities
- Effective
- Effectiveness
- “Emergency Service”
- “Guideline adherence”
- Hepatitis
- “HIV specialists”
- Hospitalization
- Hypertension
- “ID physicians”
- Incidence
- “Infectious disease physicians”
- “Lung Diseases”
- “Mental disorders”
- “Medication adherence”
- “Missed visits”
- Mortality
- Mobility
- Outcomes”
- “Patient Admission Rate”
- “Patient Compliance”
- PCP
- PCPs
- Prevalence
- “Primary care physicians”

- “Primary care providers”
- “Primary Health Care”
- Physician-patient relations”
- “Quality of health care”
- “Risk Factors”
- Specialization
- “Supply and demand”
- “Treatment Outcome”
- Trust
- “Viral load”

Publication types

- Clinical Trial
- Comparative Study
- Controlled Clinical Trial
- Meta-Analysis
- Practice Guideline
- Randomized Control Trial
- Systematic Reviews

REFERENCES

- Auberg JA, Gallant JE, Ghanem KG, Emmanuel P, et al., Primary care guidelines for the management of persons infected with HIV: 2013 update by the HIV medicine association of the infectious diseases society of America. *Clinical Infectious Diseases*. 2014;58(1):1-10.
- Bergersen BM, Sandvik L, Dunlop O, Birkeland K, Bruun JN. Prevalence of hypertension in HIV-positive patients on highly active antiretroviral therapy (HAART) compared with HAART-naïve and HIV-negative controls: results from a Norwegian study of 721 patients. *European Journal of Clinical Microbiology and Infectious Disease*. 2003;22:731–736.
- Bess KD, Adam J, Watt MH, et al. Providers' attitudes towards treating depression and self-reported depression treatment practices in HIV outpatient care. *AIDS Patient Care STDS*. 2013;27(3):171-180
- Brown TT, Cole SR, Li X, Kingsley LA, et al. Antiretroviral therapy and the prevalence and incidence of diabetes mellitus in the Multicenter AIDS Cohort Study. *Archives of Internal Medicine*. 2005;165:1179–1184.
- Centers for Disease Control and Prevention. HIV Surveillance Report, 2014; vol. 26. Published November 2015. Available at: <http://www.cdc.gov/hiv/library/reports/surveillance/>. Accessed March 27, 2016.
- California Department of Health Care Services (DHCS). Health Disparities in the Medi-Cal Population. Annual HIV Visit. Fall 2015. Available at: http://www.dhcs.ca.gov/dataandstats/Documents/HealthDisparities_AnnualHIVVisit.pdf. Accessed March 27, 2016
- California Department of Public Health (CDPH), Office of AIDS, California HIV/AIDS Surveillance Statistical Reports. 2015. Table 2. California HIV/AIDS Cases by Demographics Cumulative as of December 31, 2013. Available at: <https://www.cdph.ca.gov/data/statistics/Pages/OAHIVAIDSSStatistics.aspx>
- Cheng QJ, Engelage EM, Grogan TR, Currier JS, Hoffman RM. Who Provides Primary Care? An Assessment of HIV Patient and Provider Practices and Preferences. *Journal of AIDS & Clinical Research*. 2014;5(11):366.
- Fultz SL, Goulet JL, Weissman S, et al. Differences between infectious diseases-certified physicians and general medicine-certified physicians in the level of comfort with providing primary care to patients. *Clinical Infectious Diseases*. 2005;41:738–743.
- Gallant JE, Adimora AA, Carmichael JK, et al. Essential components of effective HIV care: a policy paper of the HIV Medicine Association of the Infectious Diseases Society of America and the Ryan White Medical Providers Coalition. *Clin Infect Dis*. 2011;53:1043-1050.
- Greene M, Justice AC, Lampris HW, Valcour V. Management of human immunodeficiency virus infection in advanced age. *JAMA:Journal of the American Medical Association*. 2013;309(13):1397-1405.
- Heslin KC, Andersen RM, Ettner SL, Cunningham WE. Racial and ethnic disparities in access to physicians with HIV-related expertise. *Journal of General Internal Medicine*. 2005 Mar;20(3):283-9.

- Hooshyar D, Hanson DL, Wolfe M, Selik RM, Buskin SE, McNaghten AD. Trends in perimortal conditions and mortality rates among HIV-infected patients. *AIDS*. 2007;21:2093–2100.
- Lewden C, May T, Rosenthal E, et al. Changes in causes of death among adults infected by HIV between 2000 and 2005: The Mortalité 2000 and 2005” surveys (ANRS EN19 and Mortavic). *Journal of Acquired Immune Deficiency Syndromes*. 2008;48:590–598.
- Palella FJ Jr, Baker RK, Moorman AC, et al. Mortality in the highly active antiretroviral therapy era: changing causes of death and disease in the HIV outpatient study. *Journal of Acquired Immune Deficiency Syndromes*. 2006;43:27–34.
- Triant VA, Lee H, Hadigan C, Grinspoon SK. Increased acute myocardial infarction rates and cardiovascular risk factors among patients with human immunodeficiency virus disease. *Journal of Clinical Endocrinology and Metabolism*. 2007;92:2506–2512.

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 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.

Faculty Task Force

Janet Coffman, MA, MPP, PhD, *Vice Chair for Medical Effectiveness*, University of California, San Francisco

Sara McMenamin, PhD, *Vice Chair for Medical Effectiveness and Public Health*, University of California, San Diego

Joy Melnikow, MD, MPH, *Vice Chair for Public Health*, University of California, Davis

Ninez Ponce, PhD, *Co-Vice Chair for Cost*, University of California, Los Angeles

Nadereh Pourat, PhD, *Co-Vice Chair for Cost*, University of California, Los Angeles

Susan L. Ettner, PhD, University of California, Los Angeles

Sheldon Greenfield, MD, University of California, Irvine

Sylvia Guendelman, PhD, LCSW, University of California, Berkeley

Marilyn Stebbins, PharmD, University of California, San Francisco

Task Force Contributors

Wade Aubry, MD, University of California, San Francisco

Diana Cassady, DrPH, University of California, Davis

Shana Charles, PhD, MPP, University of California, Los Angeles, and California State University, Fullerton

Shauna Durbin, MPH, University of California, Davis

Margaret Fix, MPH, University of California, San Francisco

Ronald Fong, MD, MPH, University of California, Davis

Brent Fulton, PhD, University of California, Berkeley

Erik Groessl, PhD, University of California, San Diego

Sarah Hiller, MA, University of California, San Diego

Jeffrey Hoch, PhD, University of California, Davis

Michelle Ko, MD, PhD, University of California, Los Angeles

Gerald Kominski, PhD, University of California, Los Angeles

Alicia LaFrance, MPH, MSW, University of California, San Francisco

Meghan Maiya, MA, University of California, San Diego

Ying-Ying Meng, PhD, University of California, Los Angeles
Jack Needleman, PhD, University of California, Los Angeles
Dominique Ritley, MPH, University of California, Davis
Dylan Roby, PhD, University of California, Los Angeles, and
University of Maryland, College Park
Neil Sehgal, MPH, PhD, University of California, San Francisco
Riti Shimkhada, PhD, University of California, Los Angeles
Meghan Soulsby Weyrich, MPH, University of California, Davis
Steven Tally, PhD, University of California, San Diego
Ed Yelin, PhD, Professor Emeritus, University of California, San Francisco
Byung-Kwang (BK) Yoo, MD, MS, PhD, University of California, Davis

National Advisory Council

Lauren LeRoy, PhD, Strategic Advisor, L. LeRoy Strategies, *Chair*
Stuart H. Altman, PhD, Professor of National Health Policy, Brandeis University, Waltham, MA
Deborah Chollet, PhD, Senior Fellow, Mathematica Policy Research, Washington, DC
Joseph P. Ditré Esq., Director of Enterprise and Innovation, Families USA, Washington, DC
Allen D. Feezor, Fmr. Deputy Secretary for Health Services, North Carolina Department of Health and Human Services, Raleigh, NC
Charles “Chip” Kahn, MPH, President and CEO, Federation of American Hospitals, Washington, DC
Jeffrey Lerner, PhD, President and CEO, ECRI Institute Headquarters, Plymouth Meeting, PA
Donald E. Metz, Executive Editor, *Health Affairs*, Bethesda, MD
Dolores Mitchell, Executive Director, Group Insurance Commission, Boston, MA
Marilyn Moon, PhD, Vice President and Director, Health Program, American Institutes for Research, Silver Spring, MD
Carolyn Pare, President and CEO, Minnesota Health Action Group, Bloomington, MN
Michael Pollard, JD, MPH, Senior Advisor, Policy and Regulation, Pharmaceutical Care Management Association, Washington, DC
Richard Roberts, MD, JD, Professor of Family Medicine, University of Wisconsin-Madison, Madison, WI
Prentiss Taylor, MD, Corporate Medical Director, Advocate At Work, Advocate Health Care, Chicago, IL
J. Russell Teagarden, Unaffiliated Expert in Pharmaceuticals, Danbury, CT
Alan Weil, JD, MPP, Editor-in-Chief, *Health Affairs*, Bethesda, MD

CHBRP Staff

Garen Corbett, MS, Director
John Lewis, MPA, Associate Director
Erin Shigekawa, MPH, Principal Policy Analyst
AJ Scheitler, EdD, Principal Policy Analyst
Karla Wood, Program Specialist

California Health Benefits Review Program
University of California
Office of the President
1111 Broadway, Suite 1400
Oakland, CA 94607
Tel: 510-287-3876 Fax: 510-763-4253
chbrpinfo@chbrp.org www.chbrp.org

The California Health Benefits Review Program is administered by UC Health at the University of California, Office of the President. UC Health is led by John D. Stobo, MD, Executive Vice President.

ACKNOWLEDGEMENTS

Margaret Fix, MPH, of the University of California, San Francisco, prepared the medical effectiveness analysis. Min-Lin Fang, MLIS, of the University of California, San Francisco, conducted the literature search. Dominique Ritley, MPH, of the University of California, Davis, prepared the public health impact analysis. Ninez Ponce, PhD, prepared the cost impact analysis. Sandra Hunt, MPA, of PricewaterhouseCoopers, provided actuarial analysis. Greg Melcher, PhD, of the University of California, San Francisco Medical Center, provided technical assistance with the literature review and expert input on the analytic approach. Garen Corbett, MS, and AJ Scheitler, EdD, 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, Sylvia Guendelman, PhD, LCSW, of the University of California, Berkeley, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

Please direct any questions concerning this document to:

**California Health Benefits Review Program
University of California, Office of the President
UC Health
1111 Broadway, Suite 1400
Oakland, CA 94607
Tel: 510-287-3876
Fax: 510-763-4253
www.chbrp.org**

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

Garen Corbett, MS
Director