



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 1894: HIV Testing

A Report to the 2007-2008 California Legislature
April 7, 2008

CHBRP 08-04



The California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analyses of the medical, financial, and public health impacts of proposed health insurance benefit mandates and proposed repeals of health insurance benefit mandates. In 2002, CHBRP was established to implement the provisions of Assembly Bill 1996 (California Health and Safety Code, Section 127660, et seq.) and was reauthorized by Senate Bill 1704 in 2006 (Chapter 684, Statutes of 2006). The statute defines a health insurance benefit mandate as a requirement that a health insurer or managed care health plan (1) permit covered individuals to obtain health care treatment or services from a particular type of health care provider; (2) offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition; or (3) offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.

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Analysis of Assembly Bill 1894 HIV Testing

April 7, 2008

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of AB 1894, a bill to mandate the coverage of HIV and AIDS testing, regardless of whether testing is related to a primary diagnosis. In response to a request from the California Assembly Committee on Health on February 6, 2008, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as chaptered in Section 127600, et seq. of the California Health and Safety Code.

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CHBRP gratefully acknowledges all of these contributions but assumes full responsibility for all of the report and its contents. Please direct any questions concerning this report to:

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 1894: HIV Testing

The California Assembly Committee on Health requested on February 6, 2008, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 1894. In response to this request, CHBRP undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as codified in Section 127600, et seq. of the California Health and Safety Code. According to the bill author, the AB 1894 will be amended to reflect the language submitted to CHBRP for analysis, as show in Appendix A of this report. Henceforth, whenever this report refers to “AB 1894” it is referring to the amended version of the bill presented for analysis.

AB 1894 requires health care service plans regulated by the Department of Managed Health Care (DMHC) and group insurance policies regulated by the California Department of Insurance (CDI) to provide coverage for the testing for human immunodeficiency virus (HIV) antibodies and acquired immune deficiency syndrome (AIDS), regardless of whether the testing is related to a primary diagnosis. Although a variety of HIV and AIDS tests exist, this report focuses on the use of HIV testing as a screening tool used to identify new cases among asymptomatic individuals (or individuals receiving care for symptoms unrelated to HIV).

AB 1894 allows CDI-regulated plans discretion in contracting with testing providers but is makes no similar provision for DMHC-regulated plans. Assuming the difference in statutory treatment is purposeful, CHBRP interprets AB 1894 as requiring DMHC-regulated plans (but not CDI-regulated policies) to provide coverage for HIV testing in out-of-network emergency settings even if the test is not related to the emergency episode.

AB 1894 includes mandates beyond CHBRP’s purview. This report analyzes the benefit mandate provisions of the bill, as per the provisions of CHBRP’s authorizing statute, SB 1704. Specifically, this report focuses on the provisions requiring DMHC-regulated health care plan service contracts and CDI-regulated health insurance policies regulated to cover HIV and/or AIDS testing, regardless of primary diagnosis. The bill’s additional requirements would be placed on health care facilities, which are beyond CHBRP’s statutory charge for analysis. Although a variety of HIV and AIDS tests exist, this report focuses on the use of HIV testing as a screening tool used to identify new cases among asymptomatic individuals (or individuals receiving care for symptoms unrelated to HIV).

Currently, DMHC-regulated health care service plans regulated are required to provide diagnostic services as part of the minimum “basic health care services” benefit.¹ CDI-regulated health insurance products have no statutory minimum services, except specific mandated benefits. Nonetheless, health insurance products generally cover physician and hospital services and medical tests.

¹ California Health and Safety Code, Section 1345 and Section 1300.67 of the California Code of Regulations, Title 28.

Although not related to the benefit mandate contained in AB 1894, there are likely to be increases in HIV screening in the near future. Current national guidelines for HIV screening are broadening the population for whom screening is recommended. The US Preventive Services Task Force (USPSTF) and the Centers for Disease Control and Prevention (CDC) both support testing for all pregnant women and testing for adults and adolescents considered to be at risk for HIV. However, the CDC has recently recommended the screening for all adolescents and adults, regardless of perceived risk. Regardless of AB 1894's benefit mandate, the change in CDC recommendations may influence provider behavior and, therefore, utilization.

Medical Effectiveness

- Although no studies have directly assessed whether testing asymptomatic persons for HIV decreases morbidity and mortality, there is substantial indirect evidence that screening for HIV is effective.
- There is a preponderance of evidence from multiple studies that tests for HIV are highly accurate (i.e., have high sensitivity and specificity). The studies also showed that:
 - Rapid tests for HIV are almost as accurate as standard tests, and
 - The speed at which rapid test results are available over standard tests can increase the number of persons who can be referred for treatment when they test positive.
- There is clear and convincing evidence from multiple controlled studies that the following treatments for HIV reduce the risk of clinical progression, opportunistic infection, and death:
 - Highly active antiretroviral therapy (HAART) for most patients with CD4 T-cell counts below 350 cells/mm³;
 - Prophylaxis for pneumocystis carinii pneumonia, tuberculosis, and mycobacterium avium-intracellulare complex and possibly cytomegalovirus; and
 - Vaccination against hepatitis B and influenza.
- A preponderance of evidence suggests that delivering infants born to HIV-positive mothers by elective cesarean section instead of vaginally and choosing formula feeding over breastfeeding reduces the risk of HIV transmission from mother to infant.
- There is also evidence from studies of self-report of behavior that persons who are aware that they are HIV-positive are less likely to engage in unprotected intercourse.
- Acceptance rates for HIV testing among asymptomatic persons vary widely and are:
 - Generally lower in settings in which the prevalence of HIV is low, and
 - Generally higher among pregnant women when screening is offered on an “opt-out” basis, and when rapid tests are offered instead of standard tests.
- The rates at which persons obtain the results of HIV testing vary widely, as do the rates at which persons with HIV receive treatment.

Utilization, Cost, and Coverage Impacts

- The number of individuals who are covered for HIV testing is expected to remain the same after enactment of AB 1894. However, since AB 1894 mandates coverage of HIV testing “regardless of primary diagnosis, there would be some expansion of coverage, postmandate.
 - Disregarding primary diagnosis would require DMHC-regulated plans and CDI-regulated policies to cover HIV testing for asymptomatic and persons for whom exposure is uncertain. It would also require plans and policies to cover testing done by an in-network emergency or urgent care service provider, even if the testing were unrelated to the emergency or urgent care episode.
 - As discussed above, CHBRP also assumes that AB 1894 (because it addresses CDI-regulated policies but is silent towards DMHC-regulated plans) would mandate coverage by DMHC-regulated plans for HIV testing provided by out-of-network emergency care providers, even if the testing was unrelated to the emergency episode.
- While there is some limited expansion in coverage is assumed CHBRP estimates that there would not be an overall effect on utilization of the HIV test. Instead, CHBRP estimates a shift in who pays for the HIV testing. Postmandate, testing currently paid for out-of-pocket or paid by other sources is expected to be paid for by insurance. CHBRP estimates that the shift would increase the rate of covered HIV testing by 0.8 tests per 1,000 members per year, or by 3%.
- CHBRP’s assumption of no utilization increase is supported by three factors: (1) AB 1894 would not increase the number of members who have coverage for HIV/AIDS testing; (2) physician testing practices are unlikely to change, since the barriers to HIV/AIDS testing at the physician level are unlikely to be removed after the mandate; and (3) patient requests for testing covered by insurance would remain low due to patient concerns about confidentiality and fear of job or insurance discrimination.
- Total net annual expenditures are estimated to increase by \$554,000 annually, or 0.0007%, mainly due to the administrative costs associated with the implementation of AB 1894, and costs that would be absorbed by insurance for tests previously not covered.
- The mandate is estimated to increase health insurance premiums by about \$512,000. For affected markets, premiums are expected to increase by 0.0007%. Increases as measured by per member per month (PMPM) payments are estimated to be less than 1 cent (\$0.0019), ranging from \$0.0017 PMPM in the small-group CDI-regulated market to \$0.0029 PMPM in the individual DMHC-regulated market. CHBRP estimates no cost impacts to Medi-Cal managed care and the Healthy Families programs. .
- CHBRP estimates that per-unit cost of HIV testing (\$27.46) would remain the same after the enactment of AB 1894. At present, CHBRP estimates that, for a typical insured population, HIV tests have a total PMPM cost of about \$0.06.
- Long-term impacts: Recent studies demonstrate that voluntary HIV testing as a screening tool is cost-effective even in health care settings in which HIV prevalence is low. CDC

revised their recommendations in September 2006 to urge providers to include HIV testing as a routine part of their patients' health care. It is possible that this mandate may increase physicians' awareness and adoption of the CDC guidelines, leading to an increase in utilization. CHBRP did not make this assumption in analyzing the impact of AB 1894 because the bill does not require the adoption of CDC guidelines. However, *Appendix E* presents an alternative scenario in which utilization would increase to conform to CDC guidelines. If this were to occur, CHBRP estimates that total expenditures would increase by about \$10,151,000 or 0.0128% in the first year after the implementation.

Public Health Impacts

- It is estimated that AB 1894 would not stimulate an increase in HIV testing in the population defined in the bill. Because the covered population remains the same and the mandate is unlikely to alter practice patterns and utilization of HIV testing, no impact on overall public health is anticipated in the short term.
- There are significant racial/ethnic and gender differences in risk for HIV and AIDS. Men are infected with HIV at a rate 10 times that of women, and the AIDS incidence rates for blacks are almost four times greater than for Hispanic or whites. Disparities are evident even within high-risk groups. For example, men who have sex with men represent over two-thirds of cumulative HIV/AIDS cases, and the second largest high-risk group— injection drug users— represent about one-tenth of those cases. It is unlikely that AB 1894 would alter coverage, practice patterns, or utilization of HIV testing in communities affected by the bill. Therefore, no public health impact on gender or racial/ethnic disparities is anticipated.
- Mortality rates due to HIV/AIDS have decreased markedly since the early 1990s. This decrease is attributable to the diagnosis and early treatment interventions for HIV/AIDS. Identifying HIV-positive persons before they exhibit symptoms helps to prolong their productive life by providing treatment at the most clinically opportune time; however, no change in test utilization is anticipated. Accordingly, no resultant reductions in death or economic loss are anticipated.
- Based on the findings stated above, no long-term public health impacts are anticipated. However, due to the CDC's revised guidelines issued in 2006, it is possible that practitioners may start to offer routine HIV testing to adolescents and adults in all health care settings. It is possible that this mandate could increase practitioners' awareness of the CDC guidelines, but because AB 1894 does not require plans and carriers to adopt CDC guidelines, CHBRP did not make this assumption. However, CHBRP offers an alternative scenario (*Appendix E*) that assesses the long-term impact on public health due to increased testing utilization (as conforms to CDC guidelines).

Table 1. Summary of Coverage, Utilization, and Cost Impacts of AB 1894

| | Before Mandate | After Mandate | Increase/ Decrease | Change After Mandate |
|---|-------------------------|-------------------------|-----------------------|----------------------------|
| Coverage | | | | |
| Number of individuals subject to the mandate | 22,190,000 | 22,190,000 | 0 | 0% |
| Percentage of individuals with coverage | 100.0% | 100.0% | 0.0% | 0% |
| Number of individuals with coverage | 22,190,000 | 22,190,000 | - | 0% |
| Utilization and cost | | | | |
| Annual covered utilization per 1,000 members | 27.4 | 28.2 | 0.8 | 3% |
| Average per unit cost | \$27.46 | \$27.46 | - | 0% |
| Expenditures | | | | |
| Premium expenditures by private employers for group insurance | \$47,088,966,000 | \$47,089,306,000 | \$340,000 | 0.0007% |
| Premium expenditures for individually purchased insurance | \$6,158,288,000 | \$6,158,355,000 | \$67,000 | 0.0011% |
| Premium expenditures by individuals with group insurance, CalPERS, Healthy Families, AIM or MRMIP | \$12,819,308,000 | \$12,819,398,000 | \$90,000 | 0.0007% |
| CalPERS employer expenditures | \$2,942,984,000 | \$2,942,999,000 | \$15,000 | 0.0005% |
| Medi-Cal state expenditures (a) | \$4,044,192,000 | \$4,044,192,000 | \$0 | 0.0000% |
| Healthy Families state expenditures | \$644,074,000 | \$644,074,000 | \$0 | 0.0000% |
| Individual out-of-pocket expenditures (deductibles, copayments, etc.) | \$5,602,060,000 | \$5,602,102,000 | \$42,000 | 0.0007% |
| Out-of-pocket expenditures for non-covered services | \$0 | \$0 | \$0 | 0.0000% |
| Total annual expenditures | \$79,299,872,000 | \$79,300,426,000 | \$554,000 | 0.0007% |

Source: California Health Benefits Review Program, 2008.

Notes: The population includes employees and dependents covered by employer-sponsored insurance (including CalPERS), individually purchased insurance, and public health insurance provided by a health plan subject to the requirements of the Knox-Keene Health Care Service Plan Act of 1975. All population figures include enrollees aged 0-64 years and enrollees 65 years or older covered by employer-sponsored insurance. Premium expenditures by individuals include employee contributions to employer-sponsored health insurance and member contributions to public health insurance. (a) Medi-Cal state expenditures for members under 65 years of age include expenditures for Major Risk Medical Insurance Program (MRMIP) and Access for Infants and Mothers (AIM) program. years of age include expenditures for Major Risk Medical Insurance Program (MRMIP) and Access for Infants and Mothers (AIM) program.

Key: CalPERS = California Public Employees' Retirement System.

INTRODUCTION

Assembly Bill (AB) 1894 requires health care service plans regulated by the Department of Managed Health Care (DMHC) and group insurance policies regulated by the California Department of Insurance (CDI) to cover testing for human immunodeficiency virus (HIV) antibodies and acquired immune deficiency syndrome (AIDS), regardless of whether the testing is related to a primary diagnosis.

The California Health Benefits Review Program (CHBRP) undertook this analysis in response to a request from the California Assembly Committee on Health on February 6, 2008. AB 1894 was introduced by Assemblymember Krekorian on February 7, 2008. According to the bill author, the AB 1894 will be amended to reflect the language submitted to CHBRP for analysis, as shown in Appendix A of this report. Henceforth, whenever this report refers to “AB 1894” it is referring to the amended version of the bill presented for analysis.

SB 1704, CHBRP’s authorizing legislation defines a benefit mandate bill as “a proposed statute that requires a health care service plan or a health insurer, or both, to ...offer or provide coverage for the screening, diagnosis or treatment of a particular disease or condition.” Thus, the portion of the population directly affected by a benefit mandate bill are those enrolled in health insurance products offered by health care service plans or health insurers. As a benefit mandate bill, AB 1894 affects statutory requirements on insurance coverage that can be influenced by California law. Specifically, AB 1894 would affect the markets regulated by DMHC and CDI, including large- and small-group and individual market policies. The bill does not exempt CalPERS or Medi-Cal Managed Care, Healthy Families, or other publicly funded insurance and would affect members enrolled in these programs through its impact on the DMHC-regulated plans. AB 1894 would not directly affect populations that are enrolled in health insurance products not subject to California benefit mandates, such as those enrolled in Medicare Advantage or in self-insured plans (both of which are exempted by Federal laws) or those who are uninsured. Please see *Appendix D* for a detailed description of the cost impact portion of this analysis.

The remainder of this introduction focuses on details of the bill language, summarizes background information on HIV testing as a screening tool, mentions relevant law in California and in other states, lists key assumptions of the analytic approach, and provides information about the current status of HIV testing in California.

Bill Language and Key Assumptions

The full text of AB 1894 and the amended language submitted to CHBRP by the bill author’s office can be found in *Appendix A*. This report focuses on the amended language, which the Author intends to introduce.

Several terms or phrases in AB 1894 are ambiguous, often due to the differences in legal and medical terminology, and the specific nature of potential regulation is not always clear. However, the scope and intent of a bill must be defined to conduct an analysis. This report assumes the interpretations listed in this section. CHBRP’s interpretations are based on conversation with bill author staff; discussions with regulatory agencies, including the DMHC;

and reasonable legal and layperson interpretation of the bill language. In addition, CHBRP makes assumptions for the purposes of analysis since the scope and intent of a bill must be defined in order to conduct an analysis.

Testing or screening

The phrase “testing for HIV and AIDS” as written in the bill has some ambiguity due to the differences in legal and medical terminology. Although a variety of HIV and AIDS tests exist, this report focuses on the use of HIV testing as a screening tool used to identify new cases among asymptomatic individuals (or individuals receiving care for symptoms unrelated to HIV). Diagnostic tests (generally performed after an initial diagnosis as guides to treatment) are broadly covered and not a source of disagreement among national guidelines.

Facilities mandate

AB 1894 includes mandates that are beyond CHBRP’s purview. This report analyzes the benefit mandate provisions of the bill, as per the provisions of CHBRP’s authorizing statute, SB 1704. Specifically, this report focuses on the provisions requiring health care plan service contracts (regulated by the DMHC) and health insurance policies (regulated by the CDI) to cover HIV and/or AIDS testing, regardless of primary diagnosis.

AB 1894 also requires facilities, including hospitals and clinics, to offer tests when providing service. Although this portion of the bill is beyond CHBRP’s purview, initial consideration was given to the facilities mandate as a factor that could affect benefits utilization. However, when asked to review the bill language, the California Department of Health Care Services (DHCS) Office of Licensing and Certification stated that the requirement in AB 1894 on health facilities is not placed in Chapter 2 of the Health and Safety Code, and so is not a condition of licensure. Therefore, the California Department of Public Health (CDPH) would not be involved in enforcing a facility’s compliance with this provision.² As the key regulatory body’s view is that the mandate would be unenforceable, the facilities mandate language has not been considered in this analysis.

DMHC coverage for out-of-network HIV Testing

AB 1894 allows CDI-regulated plans discretion in contracting with testing providers but is makes no similar provision for DMHC-regulated plans. Assuming the difference in statutory treatment is purposeful, CHBRP interprets AB 1894 as requiring DMHC-regulated plans (but not CDI-regulated policies) to provide coverage for HIV testing in out-of-network emergency settings even if the test is not related to the emergency episode.

Existing California Requirements

Existing legislation requires all health care service plans regulated by the DMHC to provide diagnostic services as part of the minimum “basic health care services” benefit.³ Health insurance products regulated by the CDI have no statutory minimum services, except specific

²Personal communication, Jennifer Simoes, California Department of Public Health, March 2008.

³ California Health and Safety Code, Section 1345 and Section 1300.67 of the California Code of Regulations, Title 28.

mandated benefits. Nonetheless, health insurance products generally cover physician and hospital services and medical tests.

Although there are a variety of laws related to both HIV and AIDS in many states, CHBRP's research located no states that specify HIV testing as a mandated benefit.

Background of Disease

HIV is an infectious disease that is spread through contact with the bodily fluids of persons infected with the disease. Today most persons contract HIV through sexual contact or by sharing needles used to inject drugs.⁴ When HIV was first identified in the early 1980s, most persons with the virus progressed rapidly to AIDS and death. Since that time, the development of antiretroviral medications has dramatically altered the course of illness in most persons with HIV. The current standard of care, a combination of three or more antiretroviral drugs known as highly active antiretroviral therapy (HAART) and prophylaxis for opportunistic infections, has led to substantial reductions in morbidity and mortality from HIV and AIDS (Branson et al., 2006). The majority of persons with HIV who receive treatment now live for many years following their diagnosis.

In 2004, almost 40% of persons who tested positive for HIV were unaware of their infections until shortly before they were diagnosed with AIDS (Branson et al., 2006). Treatment is less likely to be effective once a person has AIDS, because antiretroviral medications work primarily by slowing the progression of disease. Once a person has AIDS, the course of the disease is more difficult to reverse (Chou et al., 2005a).

Based on national estimates from 2003, there are approximately 1,000,000 persons in the U.S. infected with HIV, of whom approximately one-quarter (180,000-280,000) are thought to be unaware of their infection. Approximately 400,000 of those infected with HIV have AIDS (Chou and Huffman, 2007). California contributes 14% of cumulative AIDS cases in the U.S., second only to New York (SFAF, 2008).

Statewide incidence rates for HIV and for AIDS are not publicly available for California, and the number of cases is underrepresented due to a new name-based reporting method adopted by California in 2006. The CDPH Office of AIDS anticipates its reporting system will account for all cases by 2010. The San Francisco AIDS Foundation estimates 6,700-9,000 new infections occur annually in California (SFAF, 2006).

Population at risk

HIV is a fragile virus and cannot live long outside the body. As a result, the virus is not transmitted through day-to-day activities such as shaking hands, hugging, or a casual kiss. HIV is primarily found in the blood, semen, or vaginal fluid of an infected person.

⁴When HIV was first identified in the early 1980s, a number of persons were infected through blood transfusions. Since that time, extensive efforts have been implemented to screen all blood donors for HIV. Although HIV can still be transmitted through transfusion, such cases are now rare in the United States (Branson et al., 2006).

According to the CDC (CDC, 2006), individuals may be at increased risk for HIV infection if they:

- have unprotected vaginal, anal, or oral sex (sex without condoms);
- use injected drugs or steroids, during which equipment and blood were shared with others;
- exchange sex for drugs or money;
- receive a diagnosis of (or have been treated for) hepatitis, tuberculosis, or a sexually transmitted disease such as syphilis;
- received a blood transfusion or clotting factor during 1978-1985;
- have unprotected sex with someone who has any of the previously listed risk factors; or
- are men who have sex with men (with multiple partners or with anonymous partners).

Pregnant women are another subpopulation that receives attention in the public health realm, due to the risk of transmission from mother to child. Studies have shown that anti-retroviral treatment, elective cesarean deliveries, and abstention from breastfeeding reduce the perinatal transmission rate by 14% to 25% (USPSTF, 2007).

Transmission

Marks et al. (2005) estimate that 25% of HIV-positive persons unaware of their status contribute between 54% and 70% of sexually transmitted infections. One study indicated that the HIV transmission rate is up to 3.5 times higher for those undiagnosed than for those who are aware of their positive status (Marks et al., 2005). Moreover, Marks et al. (2005) found that those aware of their HIV-positive status were 68% less likely to engage in unprotected intercourse with uninfected partners when compared with persons unaware of their positive status, thereby bolstering the view that screening plays an integral role in reducing transmission rates and curtailing the HIV/AIDS epidemic.

Types of HIV tests

Most HIV tests look for the HIV antibodies rather than HIV itself. There are tests for HIV's genetic material, but these are not in widespread use. The most common HIV tests use blood to detect HIV infection. Tests using saliva or urine are also available. Some tests take a few days for results, but rapid HIV tests can give results in about 20 minutes. All positive HIV tests must be followed up by another test to confirm the positive result. Results of this confirmatory test can take from a few days to a few weeks.

Throughout this report, the phrase “HIV testing” indicates the use of two HIV tests (initial and confirmatory) as the means of obtaining an initial diagnosis.

The enzyme immunoassay (EIA) used on blood drawn from a vein is the most common test used to look for antibodies to HIV. A positive (reactive) EIA must be used with a follow-up (confirmatory) test such as the Western blot to make a positive diagnosis. There are EIA tests that use other body fluids to look for antibodies to HIV. These include oral fluid tests and urine tests. Oral fluid tests use oral fluid (not saliva) collected from the mouth using a special collection device. A follow-up Western blot test uses the same oral fluid sample. Urine tests have

somewhat less sensitivity and specificity (accuracy) than that of blood and oral fluid tests. They also require a follow-up Western blot test using the same urine sample.

A rapid HIV test produces results in approximately 20 minutes. Rapid tests use oral fluid or blood from a vein or finger stick to look for the presence of antibodies to HIV. As is true in all HIV testing, a reactive rapid HIV test result must be confirmed with a follow-up confirmatory test such as the Western blot to make a positive diagnosis.

Many places offer HIV testing, including health departments, doctors' offices, hospitals, and sites specifically set up to provide HIV testing.

HIV Testing as a Means of Screening

HIV testing can be used for a variety of purposes. As a screening tool, HIV testing is used with asymptomatic individuals in order to find previously undetected cases of HIV infection. After an initial diagnosis, HIV tests can also be used as confirmatory tests or as monitoring tests that help determine the most appropriate course of treatment.

Considerable discussion in the public health community concerns the proper populations to be screened and the frequency of screening. The U.S. Preventive Services Task Force (USPSTF) recommends testing only those persons at high risk for HIV infection, including those populations among whom HIV prevalence is determined to be at >0.1% of the population (USPSTF, 2007). The CDC, in contrast, recommends screening all patients utilizing the health care system—regardless of the reason for seeking care and regardless of perceived HIV risk-group status—as the most effective approach to protecting public health (CDC, 2006). For those at lowest risk, a one-time test is recommended. Those who exhibit high-risk behaviors should be tested annually.

As a matter of context, it is helpful to know that in California, 52% of the insured population answered yes to the survey question “Have you *ever* been tested for HIV/AIDS?” (CHIS, 2005). However, the survey did not differentiate between high-risk persons (for whom testing is recommended annually) or those persons who used insurance or other means of payment (out-of-pocket or anonymous test sites) for testing.

HIV Testing for screening purposes can be conducted in a variety of health care settings. In a presentation at the 9th Annual Ryan White CARE Act Clinical Update conference, Robert Janssen noted that, nationally, 44% of HIV testing was performed by a private doctor or HMO and yielded 17% positive test rate. Hospital emergency departments and outpatient clinics performed 22% of HIV testing and yielded a 27% positive test rate. Public community clinics performed 9% of HIV testing and yielded a 21% positive test rate (Janssen, 2007).

MEDICAL EFFECTIVENESS

As noted in the *Introduction*, AB 1894 would require health plans to cover testing for HIV and AIDS, regardless of whether the purpose of testing is to diagnose persons with symptoms consistent with HIV or AIDS or to screen asymptomatic persons for the disease. Analyses of the effectiveness of screening tests for diseases and conditions are more complicated than analyses of the effectiveness of treatments. Analyses of screening tests must evaluate their accuracy, the public's willingness to be screened, the rates at which persons screened obtain test results and treatment, the harms of screening, and the impact of early detection and treatment on morbidity and mortality. For HIV and other communicable diseases, analyses must also consider whether testing leads persons who test positive to refrain from behaviors that can lead to transmission of the disease. In many cases, few studies have been published that directly assess the impact of screening on morbidity, mortality, or disease transmission.

Literature Review Methods

For AB 1894, the review of the medical literature focused on the effectiveness of testing asymptomatic persons for HIV. Studies of initial tests for HIV and tests used to confirm findings from initial tests were reviewed. The effectiveness of HIV testing to monitor the progress of treatment for HIV or AIDS was not examined. Literature regarding tests used to diagnose opportunistic infections associated with AIDS was not included.

CHBRP relied heavily on two systematic reviews of the literature on testing asymptomatic persons for HIV and on treatment for HIV that the Oregon Evidence-based Practice Center prepared for the USPSTF in 2005 (Chou et al., 2005a; Chou et al., 2005b). Those systematic reviews synthesized literature on HIV testing and treatment published prior to July 2004. CHBRP augmented these systematic reviews with a search of literature published in English from July 2004 to present.

The following databases of peer-reviewed literature were searched: PubMed (MEDLINE and other PubMed records), the Cochrane Database of Systematic Reviews, the Cumulative Index of Nursing and Allied Health Literature, Global Health, Web of Science, and EconLit. Two databases for clinicians—the American College of Physicians' Physician's Information and Education Resource and DynaMed—were also searched. In addition, the Health Technology Assessments Database produced by the Centre for Reviews and Dissemination, and the National Guideline Clearinghouse, funded by the Agency for Healthcare Research and Quality, were searched.

Fourteen pertinent studies were identified, retrieved, and reviewed. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure are presented in *Appendix B: Literature Review Methods*.

Outcomes Assessed

The outcomes assessed varied across the dimensions of HIV testing examined. For studies of the accuracy of the tests, the sensitivity and specificity of tests were evaluated. *Sensitivity* refers to

the ability of a test to accurately identify persons who *have* a disease or condition. *Specificity* refers to a test's ability to accurately identify persons who *do not have* a disease or condition. Positive predictive value and negative predictive value were also examined.

For studies of the effectiveness of treatments, the outcomes assessed were clinical progression of HIV, risk of opportunistic infection (e.g., pneumocystis pneumonia, tuberculosis), death, and transmission of HIV to other persons. The impact of testing asymptomatic persons for HIV on transmission was also evaluated by analyzing self-reported data regarding behaviors associated with transmission.

Rates of action were used to investigate the impact of HIV testing on diagnosis and treatment. The rate at which asymptomatic persons offered HIV testing agreed to be tested was examined, along with the rate at which persons received the results, and the rate at which persons who tested positive obtained treatment.

Study Findings

Accuracy of Screening Tests for HIV

There are two major types of tests for HIV. The first tests developed for HIV, typically referred to as standard or conventional HIV tests, involve analysis of blood samples in medical laboratories. Results of these tests are available within several days to several weeks. One important limitation of standard HIV tests is that they are not able to detect HIV infection in recently infected persons who have not yet seroconverted. New tests are being developed to address this limitation (Chou et al., 2005a).

A systematic review of studies of standard tests for HIV found that these tests are highly accurate. Studies conducted since 1989 report that standard HIV tests have a sensitivity of 99.7% or greater and a specificity of 98.5% or greater (Chou et al., 2005a).

In recent years, the Food and Drug Administration (FDA) has approved four rapid HIV tests that use blood or oral fluids. Two of these rapid tests, OraQuick and Uni-Gold, have received FDA waivers that allow testing sites and health care facilities to analyze samples onsite instead of sending them to a medical laboratory. Results of these two rapid tests can be provided in 10 to 30 minutes, enabling persons whose test results are negative for HIV to receive reassurance quickly. Specimens from persons who test positive on rapid tests are retested with standard tests before a definitive diagnosis is made (Chou et al., 2005a).

Studies of rapid HIV tests indicate that they are as accurate as standard HIV tests in correctly identifying persons who do not have HIV and are almost as accurate in correctly identifying persons who have HIV. Two systematic reviews of studies of the accuracy of the OraQuick and Uni-Gold rapid HIV tests that use blood specimens reported that sensitivities ranged from 86% to 100% and specificities were greater than 99% (Chou et al., 2005a; Pai et al., 2007). One of these systematic reviews found that studies of rapid HIV tests using oral specimens reported sensitivities ranging from 75% to 100% and specificities greater than 99.8% (Pai et al., 2007). An analysis of post-marketing surveillance data on the OraQuick rapid tests for blood and oral specimens reported equally high specificities (Weslowski et al., 2006). In all studies, the accuracy of rapid HIV tests was compared to that of standard HIV tests.

The FDA has also approved a standard HIV test using oral fluid, a urine test, and a home collection kit for obtaining blood or oral specimens for laboratory testing. A systematic review found that oral fluid tests have sensitivities and specificities of greater than 99% (Chou et al., 2005a). Urine tests for HIV are less accurate than both standard and rapid tests using blood or oral fluids and are not widely used. The home collection kit has a sensitivity and specificity similar to standard HIV tests, because medical laboratories use standard HIV tests to analyze specimens that persons collect in their homes (Chou et al., 2005a).

Findings from studies of the accuracy of HIV tests indicate that there is a preponderance of evidence that standard HIV tests are highly accurate. There is also a preponderance of evidence that rapid HIV tests alone are highly accurate for identifying persons who do not have HIV and are highly accurate for identifying persons who have HIV if findings are corroborated by standard HIV tests.

Effectiveness of Treatments for HIV

Two systematic reviews have synthesized findings from studies of the effectiveness of treatments for HIV and interventions to prevent persons with HIV from acquiring opportunistic infections that can further compromise their immune systems and from transmitting HIV to other persons. One systematic review examined literature on adolescents and adults who are not pregnant (Chou et al., 2005a). The other systematic review focused on pregnant women due to the unique risk of vertical transmission of HIV from mothers to children in this population (Chou et al., 2005b).

Treatment for HIV

As noted previously, HAART, a regimen of three or more antiretroviral drugs, is the standard treatment regimen for HIV,⁵ particularly in the United States and other developed countries. Most studies of HAART have compared it with one- or two-drug regimens that were previously used to treat HIV.

A systematic review identified 54 randomized controlled trials (RCTs) that compared HAART with one- or two-drug regimens administered to persons with HIV who had little or no previous exposure to antiretroviral medication and 14 RCTs that enrolled persons who had previously taken antiretroviral medication. All of these RCTs found that HAART was associated with a statistically significant decrease in the risk of clinical progression of HIV and death. The results of nonrandomized studies that examined the use of HAART outside clinical trials also suggest that HAART is superior to one- or two-drug regimens in slowing both the clinical progression of HIV and the incidence of opportunistic infections (Chou et al., 2005a).

Furthermore, there is clear and convincing evidence that initiating HAART before symptoms of HIV/AIDS appear is associated with better health outcomes. Studies of the benefit of early treatment usually examine the effectiveness of prescribing HAART to HIV-positive persons with higher versus lower CD4 T-cell counts. T-cells are a type of white blood cells (lymphocytes) that

⁵ HAART is also used to treat persons with AIDS. However, because the intent of AB 1894 is to increase the number of asymptomatic persons tested for HIV, the literature review was limited to studies of the effectiveness of HAART for treatment of persons who have HIV but have not developed AIDS.

are part of the immune system (i.e., help the body to fight disease and harmful substances). Persons who do not have HIV typically have CD4 T-cell counts greater than 600 cells/mm³. There is strong and consistent evidence that providing HAART to asymptomatic persons with HIV who have a CD4 count below 200 cells/mm³ reduces the risk of disease progression and increases survival (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2008). Studies have also assessed the impact of providing HAART to asymptomatic persons with HIV who have a CD4 count between 200 and 500 cells/mm³. Several large, longitudinal nonrandomized studies with comparison groups have reported that initiating HAART at a CD4 count between 200 and 350 cells/mm³ was associated with lower risks of developing AIDS and death than delaying initiation of HAART until the CD4 count falls below 200 cells/mm³ (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2008). In contrast, most studies of the use of HAART among persons with CD4 counts above 350 cells/mm³ have found no difference between initiating HAART at CD4 counts of 350 cells/mm³ and above, and initiating it at CD4 counts between 200 and 350 cells/mm³ (Chou et al., 2005a).

There is clear and convincing evidence that HAART reduces the risk of clinical progression of HIV and death, and that initiating HAART before a person with HIV becomes symptomatic is associated with better outcomes.

Prevention of opportunistic infections

Although HAART reduces the risk of opportunistic infections among persons with HIV, prophylaxis and vaccination against these infections continues to be an important part of treatment for persons with advanced disease.

A systematic review found multiple studies of the effectiveness of prophylaxis against opportunistic infections. The authors identified two systematic reviews that reported that persons with HIV who obtained prophylaxes for pneumocystis carinii pneumonia (PCP) were less likely to acquire this infection and that the difference was statistically significant. Another systematic review was found that prophylaxis for tuberculosis (TB) was associated with statistically significant reduction in the risk of acquiring TB and the risk of death. Six studies of prophylaxis for mycobacterium avium-intracellulare complex (MAC) found that prophylaxis was associated with a statistically significant reduction in the risk of acquiring this disease. Three studies suggest that prophylaxis may also be effective for cytomegalovirus (CMV), although the evidence is not as strong as the evidence for prophylaxis of PCP, TB, and MAC (Chou et al., 2005a).

Studies have also investigated the impact of vaccination against opportunistic infections. A systematic review identified one RCT on the effectiveness of influenza vaccination. This study found that persons who were vaccinated for influenza had lower risks of respiratory symptoms and laboratory-confirmed symptomatic influenza during the three months following vaccination, and that these differences were statistically significant. This systematic review also located a longitudinal, nonrandomized study of the impact of the hepatitis B vaccine on incidence of acute hepatitis B infection. This study found that vaccination was associated with a statistically significant reduction in the risk of acute hepatitis B infection. Findings from studies of pneumococcal vaccination have been less consistent. An RCT conducted in Uganda found that vaccination was associated with elevated risk of all-cause pneumonia, whereas nonrandomized

studies with comparison groups conducted in the United States have reported that vaccination reduced the risk of pneumonia. In addition, the Ugandan RCT found that despite the increased risk of pneumococcal disease, vaccination conferred a long-term survival advantage (Chou et al., 2005a).

A preponderance of evidence suggests that prophylaxis and vaccination against opportunistic infections reduces the risk that persons with HIV will contract these infectious diseases.

Prevention of HIV transmission

Studies have examined whether HAART lowers the risk of horizontal transmission of HIV to sexual partners or to other injection drug users with whom a person shares needles. HAART may lower rates of horizontal transmission of HIV by suppressing viral load and, thus, the risk of transmitting genital fluids containing HIV (Chou et al., 2005a). On the other hand, taking HAART may create a false sense of security which may lead persons with HIV to take fewer precautions to prevent horizontal transmission of HIV, such as using condoms and clean needles and reducing the number of sexual partners (Chou et al., 2005a). One major limitation of all studies of the behavior of persons who are HIV-positive is that they rely on self-reported data (Chou and Huffman, 2007). Social desirability bias may lead some persons with HIV to underreport the extent to which they engage in behaviors associated with transmission of HIV.

A systematic review identified one meta-analysis on the relationship between use of HAART and engaging in unprotected intercourse. The meta-analysis found that use of HAART was not associated with the likelihood of engaging in unprotected intercourse (Chou et al., 2005a). However, a recent study of injection drug users taking HAART reported that improvement in CD4 count was associated with a greater risk of engaging in unprotected intercourse but not with greater risk of sharing needles (Chou et al., 2005a).

Current guidelines recommend prescription of HAART to persons who have CD4 counts at or below 350 cells/mm³ (Sanders et al., 2005). Among persons who have HIV but have higher CD4 counts, reduction in high-risk behaviors is the only means for reducing the risk of horizontal transmission of HIV.

One systematic review identified a meta-analysis that synthesized studies of rates of unprotected intercourse among HIV-positive persons. The studies included in the meta-analysis investigated whether persons who were HIV-positive and knew their HIV status were less likely to engage in unprotected intercourse than those who did not know they were HIV-positive. The rate of unprotected intercourse with persons who were HIV-negative was 68% lower among persons who knew they were HIV-positive (Marks et al., 2005, as cited in Chou and Huffman, 2007).

Reducing horizontal transmission of HIV depends upon both receiving treatment for HIV and decreasing behaviors associated with transmission. There is some evidence that persons who know that they are HIV-positive are less likely to engage in unprotected intercourse. The available evidence also suggests that using HAART does not increase rates of unprotected intercourse.

Much of the literature on the effectiveness of interventions to prevent the transmission of HIV has focused on prevention of vertical transmission of HIV from pregnant women to newborns. A systematic review identified a previous systematic review of seven RCTs that compared pregnant women who were prescribed the antiretroviral drug zidovudine to pregnant women who received a placebo. The authors reported that pregnant women who took zidovudine had lower odds of transmitting HIV to their infants and that the difference was statistically significant. Zidovudine has also been associated with decreased risk of stillbirth and infant mortality (Chou et al., 2005b). In the United States, regimens of multiple antiretroviral drugs have replaced zidovudine as the standard treatment for pregnant women with HIV. A systematic review identified one nonrandomized study with a comparison group that compared the use of HAART to no use of antiretroviral medication. The authors found that HAART was associated with a statistically significant reduction in the odds of mother-to-child transmission of HIV. Other nonrandomized studies with comparison groups have reported that antiretroviral regimens with more drugs are superior to regimens with fewer drugs (Chou et al., 2005b).

There is some evidence that early detection of HIV infection and initiation of antiretroviral therapy reduces the risk of mother-to-child transmission. A systematic review identified one RCT that found that initiating antiretroviral therapy during the 28th week of pregnancy and providing six weeks of prophylaxis to infants was more effective than initiating antiretroviral therapy during the 35th week and providing three days of prophylaxis to infants (Chou et al., 2005b). However, even late initiation of antiretroviral therapy can reduce mother-to-child transmission. The systematic review found three RCTs that reported that pregnant women who received antiretroviral therapy from the 36th week of pregnancy onward were less likely to transmit HIV to their infants than pregnant women who received a placebo (Chou et al., 2005b).

Studies have also examined the effectiveness of elective cesarean section for preventing mother-to-child transmission of HIV. Performing an elective cesarean section reduces contact between a fetus and a mother's infected bodily fluids. A systematic review identified one well-implemented nonrandomized study with a comparison group that was conducted on this topic since HAART became the standard of care for antiretroviral treatment. The authors reported that women who had elective cesarean sections were less likely to transmit HIV to their newborns and that the difference was statistically significant for women who had not taken HAART or who were not candidates for HAART due to undetectable viremia (Chou et al., 2005b).

In addition, studies have investigated the impact of feeding infants born to mothers with HIV with formula instead of breastfeeding them. A systematic review found that meta-analyses have consistently reported that women with HIV who breastfeed their infants are more likely to transmit HIV to their infants than those who used formula and that the differences are statistically significant. Although most studies of breastfeeding have been conducted in developing countries, a nonrandomized study carried out in Italy found that the relationship between breastfeeding and HIV transmission persisted even when use of antiretroviral therapy was taken into account (Chou et al., 2005b).

There is clear and convincing evidence that antiretroviral therapy reduces the risk of mother-to-child transmission for HIV and that multiple-drug regimens are more effective than zidovudine alone. There is also evidence that performing elective cesarean section and avoiding breastfeeding also reduce the risk of mother-to-child transmission.

Harms of Screening

Few studies have examined the potential harms of receiving false-positive results of HIV tests. A systematic review found only one study of the harms of false-positive tests. That study reported that persons who had false-positive results on rapid HIV tests unnecessarily received antiretroviral therapy in less than 1% of cases (Chou et al., 2005a). The very low rate of unnecessary treatment reflects the high accuracy of HIV tests and the performance of repeat testing to confirm the diagnosis of HIV and determine whether a person has a viral load or CD4 count that is sufficiently low to meet guidelines for prescription of antiretroviral therapy.

Studies have examined the potential harms associated with true positive tests for HIV (i.e., correct diagnosis). A systematic review found one study of persons recently infected with HIV that reported that 4% of participants had lost a job due to their HIV status, 1% had been asked to move by a landlord, and 1% had been assaulted (Chou et al., 2005a). Studies have also found that persons who have HIV frequently encounter violence, but these studies do not have comparison groups, which prevents the authors from ascertaining whether persons with HIV are more likely to encounter violence than other persons with similar demographic and socio-economic characteristics (Chou et al., 2005a). Although earlier studies found that persons with HIV had an increased risk of suicide, studies conducted since the development of HAART have found no association between having HIV and risk of suicide (Chou et al., 2005a). In addition, the harms that do occur to persons with HIV must be weighed against the clear and convincing evidence that treatment for HIV reduces morbidity and mortality and decreases transmission of HIV to others.

The only study that has assessed the potential harms of false-positive results on HIV tests found that very few persons received unnecessary antiretroviral therapy.

Acceptance Rates for HIV Testing Among Asymptomatic Persons

To be effective, screening tests must be widely accepted by the population at risk for a disease or condition. It is insufficient to know that a test is accurate and that treatment is associated with better health outcomes and reduces transmission of the disease or condition. A substantial proportion of the population at risk has to take a test in order for substantial numbers of cases of the disease or condition to be diagnosed or treated.

Five systematic reviews synthesized findings from studies of acceptance rates for HIV testing among asymptomatic persons published through 2006 (Chou et al., 2005a; Chou et al., 2005b; Chou and Huffman, 2007; Pai et al., 2007; Roberts et al., 2007). Eight additional studies of acceptance rates for HIV testing were published subsequently to the studies included in these syntheses (Brown et al., 2007; Campos-Outcalt et al., 2006; Lyons et al., 2005; Lyss et al., 2007; Mehta et al., 2006; Silva et al., 2007; Walensky et al., 2005a; Yudin et al., 2007). Acceptance rates varied widely across studies, ranging from 10% to 100%.

The rate of receipt of testing is associated with several factors. In general, persons in settings in which the prevalence of HIV was low were less likely to agree to be tested (Chou et al., 2005a). Conversely, pregnant women were more likely than other populations to agree to HIV testing when offered (Pai et al., 2007; Roberts et al., 2007). Persons who were referred for testing by their health care providers were also more willing to be tested than those who were approached by outreach workers (Lyss et al., 2007). Acceptance rates for newer forms of HIV tests (e.g., rapid tests, oral specimen tests, home collection kits) were also generally higher than acceptance rates for standard tests (Chou et al., 2005a).

Policies for offering HIV testing also affect acceptance rates. Traditionally, testing was offered on an “opt-in” basis, which requires that a provider obtain informed consent specifically for HIV testing. In 2006, the Centers for Disease Control and Prevention issued a new guideline for HIV screening that recommends that screening be provided to all persons on an “opt-out” basis. Under “opt-out” screening, persons are told that they will be given an HIV test unless they object. For example, a person undergoing blood testing for multiple diseases and conditions may be told that the HIV test will be one of tests performed unless the person does not wish to be tested for HIV. Studies that have compared acceptance rates for “opt-in” and “opt-out” screening for HIV have reported that “opt-out” screening is associated with higher rates of test acceptance. Among studies of pregnant women, acceptance rates for “opt-out” testing ranged from 71% to 98% versus 25% to 83% for “opt-in” screening (Chou et al., 2005b; Yudin et al., 2007). One study that compared acceptance rates among non-pregnant adolescents and adults reported a test acceptance rate of 65% for “opt-out” screening versus an acceptance rate of 35% for “opt-in” screening (Chou et al., 2005a). A subsequent systematic review of studies of both pregnant and non-pregnant persons reported similar findings (Roberts et al., 2007).

There is a preponderance of evidence that acceptance rates for HIV testing among asymptomatic persons vary widely. Persons in low-prevalence settings are less likely to agree to be tested. Factors associated with higher acceptance rates for HIV testing include being pregnant, referral by one’s health care provider, use of newer testing technologies, and adoption of an “opt-out” screening policy.

Rates of Obtaining Results of HIV Tests

The rate at which persons obtain results of HIV tests is another important factor that affects the effectiveness of screening for HIV. Unless persons with HIV obtain their test results, they will not know that they need treatment. Three systematic reviews have synthesized findings from studies of the rate at which persons obtain test results. Most of these studies were conducted in the United States. Rates of receiving results of HIV tests ranged from 27% to 100% (Chou et al., 2005a; Chou et al., 2005b; Roberts et al., 2007). Pregnant women appear more likely than other populations to receive HIV test results. Studies of pregnant women uniformly reported that over 90% of participants obtained their results (Chou et al., 2005b). Studies that examined rapid HIV tests generally reported higher rates of receipt of test results than studies of standard tests (Chou et al., 2005a), most likely because results of rapid tests are available within 10 to 30 minutes.⁶ In

⁶ These studies did not examine the rate at which persons with positive results for rapid HIV tests obtain results for standard HIV tests administered to confirm the initial results. Such persons may have a stronger incentive to obtain results for confirmatory standard tests than persons who initially undergo a standard HIV test.

contrast, results of standard HIV tests are not available for days or weeks and persons must often make a second visit to the testing site to obtain results (Roberts et al., 2007).

There is a preponderance of evidence that rates of receipt of results for HIV tests vary widely, but are generally higher for rapid tests than for standard tests.

Rates of Obtaining Treatment for HIV

In order for HIV testing for screening purposes to improve health outcomes and reduce transmission of the disease, persons who know that they have HIV must receive treatment promptly. Some studies have investigated the receipt of any medical care whereas others have examined receipt of specific treatments. A systematic review identified one analysis of data from 1996 that reported that 36% to 63% of HIV-positive persons received care from a provider other than an emergency department at least once every six months (Chou et al., 2005a). Two systematic reviews have synthesized findings from studies that address receipt of antiretroviral therapy for HIV. Rates of receipt of antiretroviral therapy in accordance with guidelines prevailing at the time a study was conducted ranged from 53% to over 90% (Chou et al., 2005a; Chou et al., 2005b). As with receipt of test results, pregnant women were more likely to obtain antiretroviral therapy than other populations. One systematic review identified one survey of rates of receipt of prophylaxis for opportunistic infections. Among the opportunistic infections studied, rates of receipt of prophylaxis ranged from a low of 62% for MAC to a high of 93% for PCP (Chou et al., 2005a). Another systematic review found that studies of rates of providing elective cesarean section to HIV-positive pregnant women reported rates that ranged from 37% to 50% (Chou et al., 2005b). No studies of receipt of vaccines for opportunistic infections were identified.

There is a preponderance of evidence that rates of receipt of antiretroviral therapy vary widely and tend to be highest among pregnant women. Rates of receipt of prophylaxis for opportunistic infections and receipt of elective cesarean section by pregnant women also vary.

Summary of Findings

- Although no studies have directly assessed whether testing asymptomatic persons for HIV decreases morbidity and mortality, there is substantial indirect evidence that screening is effective.
- There is a preponderance of evidence from multiple studies that tests for HIV are highly accurate (i.e., have high sensitivity and specificity).
 - Rapid tests are almost as accurate as standard tests.
 - Results for rapid tests are available much more quickly than results of standard tests, which can increase the number of persons who learn their test results and can be referred for treatment if they test positive.

- There is clear and convincing evidence from multiple controlled studies that the following treatments for HIV reduce the risk of clinical progression, opportunistic infection, and death:
 - HAART for most patients with CD4 counts below 350 cells/mm³;
 - Prophylaxis for pneumocystis carinii pneumonia, tuberculosis, and mycobacterium avium-intracellulare complex and possibly cytomegalovirus; and
 - Vaccination against hepatitis B and influenza.
- A preponderance of evidence suggests that delivering infants born to HIV-positive mothers by elective cesarean section instead of vaginally, and formula-feeding rather than breastfeeding reduces the risk of HIV transmission from mothers to infants.
- There is also evidence from studies of self-report of behavior that persons who are aware that they are HIV-positive are less likely to engage in unprotected intercourse.
- Acceptance rates for HIV testing among asymptomatic persons vary widely and are:
 - Generally lower in settings in which the prevalence of HIV is low; and
 - Generally higher among pregnant women, when screening is offered on an “opt-out” basis, and when rapid tests are offered instead of standard tests.
- The rates at which persons obtain the results of HIV tests vary widely, as do the rates at which persons with HIV receive treatment.

UTILIZATION, COST, AND COVERAGE IMPACTS

Present Baseline Cost and Coverage

This section details the estimated impacts on utilization, cost, and coverage of AB 1894. A discussion of the current or baseline levels precedes presentation of the impact estimates.

Current Coverage of Mandated Benefit

AB 1894 would require all group or individual plans and policies to provide coverage for the testing for HIV and AIDS, regardless of whether the testing is related to a primary diagnosis. The current practice of health plans and insurance carriers is to provide coverage for HIV testing either: (1) as determined medically necessary by a plan provider; (2) in accordance with recommendations from the USPSTF; or (3) in accordance with recommendations from the CDC.

There are 22,190,000 individuals in California under age 65 with HIV testing coverage in group and individual insurance plans or policies who would be affected by the mandate (Table 1).

CHBRP surveyed the seven largest health plans and insurers in California regarding their coverage and benefit levels for HIV testing. CHBRP determined that members could fall into one of four different categories for HIV testing:

- covered as determined medically necessary;
- covered under the USPSTF recommendations;
- covered under the CDC recommendations; and
- no coverage.

Six of the seven health plans and insurers responded to the survey representing approximately 82.6% of the privately insured enrollees in the CDI-regulated market and approximately 93.9% of the DMHC-regulated market.⁷ DMHC-regulated plans represent about 89.6% of the privately insured market in California, while CDI-regulated plans represent 10.4%. CHBRP's methods of calculating enrollment in private and public programs that would be affected by the mandate are described in Appendix D.

Using the responses of the six carriers that replied to the survey, CHBRP determined that all individuals have some coverage for HIV testing (Table 2). On an average, most individuals (65%) have coverage for HIV testing as determined medically necessary by a plan provider, some individuals (30%) have coverage under the USPSTF recommendations, and a few individuals (5%) have coverage under the CDC recommendations.

⁷ CHBRP analysis of the share of insured members included in CHBRP's survey of the major carriers in the state is based on "CDI Licenses with HMSR Covered Lives Greater than 100,000" as part of the Accident and Health Covered Lives Data Call, December 31, 2006 by the California Department of Insurance, Statistical Analysis Division and data retrieved from The Department of Managed Health Care's interactive web site "Health Plan Financial Summary Report," December, 2007.

Table 2. Member Coverage of HIV Testing Benefits by Market Segment, California, 2008

| Premandate Coverage | | No Coverage | Medically Necessary | USPSTF | CDC | Total |
|---------------------|-------------|-------------|---------------------|--------|-----|-------|
| DMHC | Large Group | 0% | 66% | 31% | 3% | 100% |
| | Small Group | 0% | 65% | 33% | 2% | 100% |
| | Individual | 0% | 77% | 23% | 0% | 100% |
| CDI | Large Group | 0% | 53% | 19% | 27% | 100% |
| | Small Group | 0% | 55% | 37% | 9% | 100% |
| | Individual | 0% | 65% | 30% | 5% | 100% |
| Average | | 0% | 65% | 30% | 5% | 100% |

Source: California Health Benefits Review Program, 2008.

Note: Figures may exceed 100% due to rounding error.

Some of the CalPERS members have coverage for HIV testing as determined medically necessary by a plan provider. Medi-Cal and Healthy Families beneficiaries have coverage under the USPSTF recommendations.

Current Utilization Levels and Costs of the Mandated Benefit

CHBRP estimates that the HIV Testing rate is 27.4 per 1,000 members annually and average cost for HIV testing is \$27.46. The estimates are based on Milliman’s 2006 Health Cost Guidelines (HCGs) claims database. The unit cost for HIV testing is consistent with other reports containing market prevailing prices for both conventional and rapid HIV tests (Ekwueme et al., 2003; Greenwald et al., 2006) (Table 1). CHBRP estimates that for a typical insured population, HIV testing has a total PMPM cost of \$0.06. This is the total amount paid for testing services, excluding the pre- and post-test counseling costs.

The Extent to Which Costs Resulting from Lack of Coverage Are Shifted to Other Payers, Including Both Public and Private Entities

Costs incurred by publicly funded HIV testing programs could remain the same as a result of the concerns of confidentiality and insurability. For instance, people may still go to publicly funded free testing sites for HIV testing even if they have coverage. These sites provide free confidential testing, which usually eases the concerns about potential consequences a positive result could have on insurability. CHBRP recognizes that there may be some current shift in costs from the carriers to public testing programs, but it was not possible to quantify this effect since the insurance status data are not collected through the publicly funded programs.

Public Demand for Coverage

As a way to determine whether public demand exists for the proposed mandate (based on criteria specified under SB 1704 [2007]), CHBRP is to report on the extent to which collective bargaining entities negotiate for, and the extent to which self-insured plans currently have, coverage for the benefits specified under the proposed mandate. Currently, the largest public self-insured plans are those preferred provider organization (PPO) plans offered by CalPERS. These plans provide coverage similar to that of the privately self-insured plans. CalPERS PPO plans are administered by Blue Cross. The plans cover screening and diagnostic tests that are

medically necessary as defined by Blue Cross of California's Medical Policy. Based on conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost-sharing arrangements in their health insurance policy negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and coinsurance levels.⁸

Impacts of Mandated Coverage

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

Impact on per-unit cost

CHBRP estimates that the per-unit cost of HIV testing (\$27.46) would remain the same after the enactment of AB 1894. At present, CHBRP estimates that, for a typical insured population, HIV testing has a total PMPM cost of about \$0.06. CHBRP does not anticipate a price increase in the overall market (Table 1).

Postmandate coverage

As mentioned, CHBRP estimates that all 22, 190,000 enrollees in group and individuals plans affected by AB 1894 currently have coverage for HIV testing. The *number* of individuals who are covered for HIV testing is expected to remain the same after enactment of AB 1894.

Coverage for HIV testing services after the mandate could still fall into the following categories:

- covered as determined medically necessary;
- covered under USPSTF recommendations; and
- covered under CDC recommendations.

The number of individuals who are covered for HIV testing is expected to remain the same after enactment of AB 1894. However, since AB 1894 mandates coverage of HIV testing "regardless of primary diagnosis, there would be some expansion of coverage, postmandate.

Disregarding primary diagnosis would require DMHC-regulated plans and CDI-regulated policies to cover HIV testing for asymptomatic and persons for whom exposure is uncertain. It would also require plans and policies to cover testing done by an in-network emergency or urgent care service provider, even if the testing were unrelated to the emergency or urgent care episode.

As discussed in this report's introduction, CHBRP also assumes that AB 1894 (because it addresses CDI-regulated policies but is silent towards DMHC-regulated plans) would mandate coverage by DMHC-regulated plans for HIV testing provided by out-of-network emergency care providers, even if the testing was unrelated to the emergency episode.

⁸ Personal communication with the California Labor Federation and member organizations on January 29, 2007.

How Will Utilization Change as a Result of the Mandate?

While there is some limited expansion in coverage is assumed CHBRP estimates that there would not be an overall effect on utilization of the HIV test. Instead, CHBRP estimates a shift in who pays for the HIV testing. Postmandate, testing currently paid for out-of-pocket or paid by other sources is expected to be paid for by insurance. CHBRP estimates that the shift would increase the rate of covered HIV testing by 0.8 tests per 1,000 members per year, or by 3%.

CHBRP's assumption of no utilization increase is supported by the following evidence:

- **No increase in the number of newly covered members:** AB 1894 would not increase the number of members who have coverage for HIV testing since all insurance currently covers at least HIV testing deemed to be medically necessary.
- **Test offering practices are unlikely to change:** Physician HIV testing practices are unlikely to change, because there is a lack of compelling evidence that the barriers to HIV testing at the provider levels would be removed after the mandate (Rodnick, 2007). Previous studies showed that insufficient time, lack of knowledge/training, lack of patient acceptance, competing priorities, and inadequate reimbursement were the major barriers to offer HIV testing (Burke et al., 2007).
- **Acceptance of testing would remain low:** Previous studies show that people in low prevalence populations appear to have low acceptance of HIV testing (see "Acceptance Rates for HIV Testing Among Asymptomatic Persons" in the *Medical Effectiveness* section). Among populations at high risk for HIV infection, the most frequently mentioned barriers would remain, such as fear of finding out the results, not being ready to deal with a positive result, fear of social discrimination, concerns about named reporting, fear of job or insurance discrimination, and inconvenience (Spielberg et al., 2003).

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

Health care plans include a component for administration and profit in their premiums. In estimating the impact of this mandate on premiums, actuarial analysis assumes that health plans would apply their existing administration and profit loads to the increase in health care costs produced by the mandate. Therefore, although there may be administrative costs associated with the mandate, administrative costs as a portion of premium would likely not change. For example, health plans and insurers may implement administrative changes as to how the HIV testing is covered—regardless of whether the testing is related to a primary diagnosis. In addition, AB 1894 would require the plans and insurers to notify members and applicants of their HIV testing coverage changes. These administrative changes would be absorbed in the standard administrative cost load associated with premiums.

Impact of the Mandate on Total Health Care Costs

CHBRP estimates that total net expenditures (including total premiums and out-of-pocket expenditures) for HIV testing are estimated to increase by 0.0007% as a result of AB 1894 (Table 4).

Costs or Savings for Each Category of Insurer Resulting from the Benefit Mandate

The impact on total expenditures varies by market segment:

- 0.0008% for the large-group HMO/POS market;
- 0.0004% for the large-group PPO/FFS market;
- 0.0007% for the small-group HMO/POS market;
- 0.0005% for the small-group PPO/FFS market;
- 0.0010% for the individual HMO/POS market; and
- 0.0014% for the individual PPO/FFS market.

These percentage increases result in a \$554,000 annual increase in total health care costs in California. For affected markets, premiums are expected to increase by 0.0007%, or \$0.0019 PMPM. The increases in premiums vary by market segment:

- \$0.0022 PMPM in the large-group DMHC-regulated market;
- \$0.0018 PMPM in the large-group CDI-regulated market;
- \$0.0023 PMPM in the small-group DMHC-regulated market;
- \$0.0017 PMPM in the small-group CDI-regulated market;
- \$0.0029 PMPM in the individual DMHC-regulated market; and
- \$0.0023 PMPM in the individual CDI-regulated market.

MediCal and Healthy Families currently provide coverage for HIV testing that is aligned with the mandated benefit required under AB 1894. Therefore, MediCal and Healthy Families programs are expected to face no impact if AB 1894 were to be enacted.

Impact on Long-Term Costs

Recent studies demonstrate that voluntary HIV testing as a means of screening is cost-effective even in health care settings in which HIV prevalence is low (Paltiel et al., 2005; Paltiel et al., 2006; Walensky et al., 2005b). In populations for which prevalence of undiagnosed HIV is $\geq 0.1\%$, HIV screening is as cost-effective as other established screening programs for chronic diseases (e.g., hypertension, colon cancer, and breast cancer) (Paltiel et al., 2005; Sanders et al., 2005). Because of the substantial survival advantage resulting from earlier diagnosis of HIV infection when therapy can be initiated before severe immunologic compromise occurs, screening reaches conventional benchmarks for cost-effectiveness even before including the important public health benefit from reduced transmission to sex partners (Sanders et al., 2005). CHBRP does not anticipate that AB 1894 has any impacts on long-term costs only if CDC guidelines are adopted as discussed below.

Potential impacts of adopting CDC guidelines over the long-term: alternative scenario analysis

Based on these findings and changing HIV epidemiology, the CDC revised their recommendations in September 2006 and urges providers to include HIV testing as a routine part of health care (Branson et al., 2006). The recommendations are still relatively new. It is possible that this mandate may increase physicians' awareness and adoption of the CDC guidelines,

leading to an increase in utilization. Based on expert clinical input and existence of many barriers to implement universal HIV testing (Rodnick, 2007), CHBRP did not make this assumption in analyzing the impact of AB 1894 because the bill does not require the adoption of CDC guidelines; however, *Appendix E* presents an alternative scenario in which utilization would increase to conform to CDC guidelines. If this were to occur, CHBRP estimates that total expenditures would increase by about \$10,151,000 or 0.0128% in the first year after the implementation.

Impact on Access and Health Service Availability

CHBRP expects that there would be minimal impacts on the access and availability of HIV testing as a result of AB 1894 because either utilization or coverage is projected to have a very small change. To the extent that AB 1894 requires providing coverage for HIV testing regardless of whether the testing is related to a primary diagnosis, access could be improved for the individuals who seek HIV testing.

Table 3. Baseline (Premandate) Per Member Per Month Premium and Expenditures by Insurance Plan Type, California, 2008

| | Large Group | | Small Group | | Individual | | CalPERS | Medi-Cal | | Healthy Families | Total Annual |
|--|----------------|---------------|----------------|---------------|----------------|---------------|----------|--------------------------|-----------------------|------------------|------------------|
| | DMHC-Regulated | CDI-Regulated | DMHC-Regulated | CDI-Regulated | DMHC-Regulated | CDI-Regulated | HMO (a) | Managed Care 65 and Over | Managed Care Under 65 | Managed Care | |
| Population Currently Covered | 11,721,000 | 342,000 | 3,256,000 | 728,000 | 1,299,000 | 812,000 | 815,000 | 172,000 | 2,532,000 | 685,000 | 22,362,000 |
| Average Portion of Premium Paid by Employer | \$238.92 | \$315.18 | \$245.82 | \$296.00 | \$0.00 | \$0.00 | \$300.92 | \$181.00 | \$120.01 | \$78.35 | \$54,695,911,000 |
| Average Portion of Premium Paid by Employee | \$54.60 | \$86.99 | \$93.75 | \$62.26 | \$294.46 | \$160.95 | \$53.10 | \$0.00 | \$0.80 | \$6.81 | \$19,001,902,000 |
| Total Premium | \$293.53 | \$402.17 | \$339.57 | \$358.26 | \$294.46 | \$160.95 | \$354.02 | \$181.00 | \$120.81 | \$85.17 | \$73,697,813,000 |
| Member expenses for covered benefits (Deductibles, copays, etc.) | \$15.78 | \$45.50 | \$24.95 | \$95.56 | \$50.61 | \$39.36 | \$18.26 | \$0.00 | \$0.56 | \$2.32 | \$5,602,060,000 |
| Member expenses for benefits not covered | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0 |
| Total Expenditures | \$309.30 | \$447.67 | \$364.52 | \$453.82 | \$345.07 | \$200.31 | \$372.28 | \$181.00 | \$121.36 | \$87.49 | \$79,299,873,000 |

Source: California Health Benefits Review Program, 2008.

Note: The population includes individuals and dependents in California who have private insurance (group and individual) or public insurance (e.g., CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) under health plans or policies regulated by the DMHC or the CDI. All population figures include enrollees aged 0-64 years and enrollees 65 years or older covered by employment-based coverage.

Key: CalPERS = California Public Employees' Retirement System; HMO = health maintenance organization and point of service plans.

(a) Of these CalPERS members, about 60% or 489,000 are state employees whose cost is borne by the General Fund.

Table 4. Postmandate Impacts on Per Member Per Month and Total Expenditures by Insurance Plan Type, California, 2008

| | Large Group | | Small Group | | Individual | | CalPERS | Medi-Cal | | Healthy Families | Total Annual |
|--|----------------|---------------|----------------|---------------|----------------|---------------|----------|--------------------------|-----------------------|------------------|--------------|
| | DMHC-Regulated | CDI-Regulated | DMHC-Regulated | CDI-Regulated | DMHC-Regulated | CDI-Regulated | HMO (a) | Managed Care 65 and Over | Managed Care Under 65 | Managed Care | |
| Population Covered | 11,721,000 | 342,000 | 3,256,000 | 728,000 | 1,299,000 | 812,000 | 815,000 | 172,000 | 2,532,000 | 685,000 | 22,362,000 |
| Average Portion of Premium Paid by Employer | \$0.0018 | \$0.0014 | \$0.0017 | \$0.0014 | \$0.0000 | \$0.0000 | \$0.0016 | \$0.0000 | \$0.0000 | \$0.0000 | \$355,000 |
| Average Portion of Premium Paid by Employee | \$0.0004 | \$0.0004 | \$0.0006 | \$0.0003 | \$0.0029 | \$0.0023 | \$0.0003 | \$0.0000 | \$0.0000 | \$0.0000 | \$156,000 |
| Total Premium | \$0.0022 | \$0.0018 | \$0.0023 | \$0.0017 | \$0.0029 | \$0.0023 | \$0.0018 | \$0.0000 | \$0.0000 | \$0.0000 | \$512,000 |
| Member expenses for covered benefits (Deductibles, copays, etc.) | \$0.0001 | \$0.0002 | \$0.0002 | \$0.0004 | \$0.0005 | \$0.0006 | \$0.0001 | \$0.0000 | \$0.0000 | \$0.0000 | \$42,000 |
| Member expenses for benefits not covered | \$0.0000 | \$0.0000 | \$0.0000 | \$0.0000 | \$0.0000 | \$0.0000 | \$0.0000 | \$0.0000 | \$0.0000 | \$0.0000 | \$0 |
| Total Expenditures | \$0.0024 | \$0.0020 | \$0.0025 | \$0.0021 | \$0.0034 | \$0.0028 | \$0.0019 | \$0.0000 | \$0.0000 | \$0.0000 | \$554,000 |
| Percentage Impact of Mandate | | | | | | | | | | | |
| Insured Premiums | 0.0008% | 0.0004% | 0.0007% | 0.0005% | 0.0010% | 0.0014% | 0.0005% | 0.0000% | 0.0000% | 0.0000% | 0.0007% |
| Total Expenditures | 0.0008% | 0.0004% | 0.0007% | 0.0005% | 0.0010% | 0.0014% | 0.0005% | 0.0000% | 0.0000% | 0.0000% | 0.0007% |

Source: California Health Benefits Review Program, 2008.

Note: The population includes individuals and dependents in California who have private insurance (group and individual) or public insurance (e.g, CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) under health plans or policies regulated by the DMHC or the CDI. All population figures include enrollees aged 0-64 years and enrollees 65 years or older covered by employment-based coverage.

Key: CalPERS = California Public Employees' Retirement System; HMO = health maintenance organization and point of service plans.

(a) Of these CalPERS members, about 60% or 489,000 are state employees whose cost is borne by the General Fund.

PUBLIC HEALTH IMPACTS

Impact of the Proposed Mandate on the Public's Health

AB 1894 intends to increase routine HIV testing in the insured population in order to inform seropositive persons of their status so that they may receive treatment, alter risk behaviors, and thereby reduce HIV transmission rates. The proposed bill also seeks to increase access to HIV testing by requiring all health facilities to offer “opt-out” HIV testing to patients. However, the impact of the facilities mandate contained in AB 1894 would be negligible due to lack of regulatory jurisdiction.⁹ This mandate would not directly change health care practitioner behavior, although the 2006 CDC guidelines could influence health care practitioners to routinely offer HIV testing to a larger population.

The CHBRP analysis of AB 1894 finds that this bill provides negligible or no net benefit to public health because health plans and insurance carriers already cover HIV tests as a matter of standard practice (see *Utilization, Cost, and Coverage Impacts* section), the insured population covered by this mandate would remain the same. Should HIV testing rates increase in California, CHBRP would attribute that increase to the CDC's updated screening guideline rather than directly to AB 1894.

Therefore, CHBRP estimates that this mandate would not stimulate an increase in HIV testing in the population covered by AB 1894. Because the bill mandate is unlikely to alter coverage, practice patterns, or utilization of HIV testing in communities affected by the bill, no impact on public health is anticipated.

Impact on the Health of the Community Where Gender and Racial Disparities Exist

Reflective of the nation, California's overall prevalence and incidence rates vary greatly between subpopulations, including those defined by sex, ethnicity, and high-risk behaviors.

Sex

National data show that men are at markedly increased risk for HIV compared to women. Among blacks, the risk for males is 131.6/10⁵-y compared to 67.0/10⁵-y among females—a nearly two-fold increase in risk. A more pronounced pattern is seen among whites, where the risk among males is nearly six-fold that of women (18.7/10⁵-y vs. 3.2/10⁵-y) (CDC, 2004). In California, men represent 90% of the cumulative HIV/AIDS cases (Table 5).

Ethnicity

There are marked ethnic differences in risk for HIV and progression to AIDS. For example, Table 5 shows California's estimated AIDS incidence rates for blacks are almost four times greater than for Hispanic or whites and almost ten times greater than for Native Americans and

⁹ Personal communication, Jennifer Simoes, Department of Public Health, March 2008.

Asian/Pacific Islanders¹⁰. Despite their relatively lower risk for AIDS compared to other ethnic groups, whites represent 55.9% of cases in California. Hispanics represent 23.1% of cases, and blacks 17.8%. Other ethnic groups represent a combined total of fewer than 5% of cases (CDPH-OA, 2008).

Risk Groups

The primary risk groups for HIV are men who have sex with men (MSM) and injection drug users (IDU). California data show that MSM represent over two-thirds (67.0%) of cumulative HIV/AIDS cases. IDUs represent almost 10% of cumulative HIV/AIDS cases. The subpopulation of MSM/IDU contribute 9.0% of cumulative HIV/AIDS cases. The remaining risk groups (associated with hemophilia, transfusions, and pediatric cases) contribute a combined total of less than 15% of cumulative HIV/AIDS cases in California (CDPH-OA, 2008) (Table 5).

Because the AB 1894 mandate is unlikely to alter coverage, practice patterns and utilization of HIV testing in communities affected by the bill, no impact on gender or racial/ethnic disparities is anticipated.

¹⁰ Personal communication, Matt Facer, California DPH-OA, March 2008.

Table 5. Epidemiologic Overview of Cumulative HIV/AIDS Cases and AIDS Incidence¹¹

| Characteristic | Cumulative HIV/AIDS cases (CA, 2007)¹ [n (%)] | AIDS Incidence² (CA, 2006) [n/10⁵-y] | Comment |
|-------------------------------------|---|---|---|
| Total cases | 172,298 (100) | | |
| Deceased | 85,249 (49.5) | | |
| Sex | | | |
| Male | 155,085 (90.0) | - | CDPH does not publish incidence rates for HIV or AIDS by gender |
| Female | 16,114 (9.4) | - | |
| Transgender | 1,099 (0.6) | - | |
| Race/ethnicity | | | |
| White | 94,618 (54.9) | 8.80 | CDPH provided AIDS incidence rates by race/ethnicity through a special data request |
| Black | 30,807 (17.9) | 30.75 | |
| Hispanic | 40,925 (23.8) | 8.81 | |
| Asian/Pacific Islander | 4,414 (2.6) | 3.47 | |
| American Indian/Alaskan Native | 803 (0.5) | 4.73 | |
| Multirace | 463 (0.3) | - | |
| Other/Unknown | 268 (0.2) | - | |
| Risk group | | | |
| MSM ³ | 115,511 (67.0) | - | CDPH does not publish incidence rates for HIV or AIDS by risk group |
| IDU ⁴ | 17,041 (9.9) | - | |
| MSM ³ & IDU ⁴ | 15,538 (9.0) | - | |
| Hemophiliac/Transfusion | 2,391 (1.4) | - | |
| Heterosexual contact | 11,219 (6.5) | - | |
| Pediatric | 1,049 (0.6) | - | |
| Other | 9,549 (5.5) | - | |

Source: California Health Benefits Review Program, 2008.

¹California Department of Public Health (CDHP),

(<http://www.dhs.ca.gov/aids/Statistics/pdf/Stats2007/Dec07HIVMerged.pdf>). AIDS cases are cumulative from 1983, whereas HIV cases without AIDS are current from April 2006 due to California's name-based reporting system begun in 2006. Therefore, this number represents an undercount of HIV cases.

²Personal communication, California Department of Public Health, Office of AIDS, Epidemiology Section, March 2008).

³Men who have sex with men

⁴Injection drug user

Extent to Which the Proposed Service Reduces Premature Death and the Economic Loss Associated with Disease

Since the 1980s, the diagnosis and treatment of HIV infection have increased an HIV-positive person's average life expectancy from 4 years to 24.2 years from diagnosis (Shackman et al., 2006). HIV/AIDS was the leading cause of death in the United States in 1994 for adults aged 25-44 years. With the introduction of pharmaceutical treatments, the mortality rate dropped by 50% in 1996 and by another 20% in 1998. These decreases in mortality rates did not extend to all

¹¹ Statewide HIV/AIDS incidence rates are not publicly available for California. However, through a CHBRP data request, the CDPH-OA's epidemiology section generated estimated AIDS incidence rates as shown in Table 5. As stated in the *Introduction*, these reported rates underrepresent the true incidence.

demographic groups equally. For example, mortality rates for whites decreased by 20% while blacks experienced a 2% decrease during the same time period. Nationally, the mortality rate decreased from 51,000 deaths in 1995 to 16,000 deaths in 2002 (SFAF, 2008).

Mortality rates have leveled out since 2002 and researchers are finding that HIV/AIDS mortality is changing significantly since the epidemic first began. During the last several years, due to increased life expectancy, the number of persons dying from diseases prevalent in the general population, such as heart disease and stroke, has increased (SFAF, 2008).

The number of studies addressing both direct and indirect economic loss associated with HIV/AIDS is sparse. Hutchison et al. identified two published studies that included indirect costs in their analysis, and both were conducted early in the AIDS epidemic (1986 and 1987) (Hutchinson et al., 2006). Hutchinson et al. calculated both the direct and indirect costs of new HIV infections in the U.S. using 2002 data. Their estimated total cost to the U.S. was \$36.4 billion with 81% of the total cost attributable to mortality-related productivity loss (\$29.7 billion) and the remaining 19% related to direct medical costs (\$6.7 billion). The authors estimated that the average productivity loss per case was \$742,100. They also found racial and ethnic disparities related to HIV/AIDS and economic loss: productivity losses were lowest for whites (\$661,100) and highest for Hispanics (\$838,000). No information was found regarding California's economic burden associated with HIV/AIDS.

CHBRP estimates that AB 1894 would not change utilization of testing, population covered, or practice patterns. Accordingly, no additional case findings would occur and therefore, no resultant reduction in death or economic loss would occur.

Long-Term Public Health Impacts

A review of the literature indicates that there are public health benefits to be realized from an increase in routine HIV testing. The primary benefit occurs through a reduction in HIV transmission rate. Sanders et al. (2005) found that HIV transmission rates, with the use of HIV testing, decreased by approximately 20% due to risk behavior modification through counseling and decreased viral load due to anti-retroviral treatments as compared with no testing. From a population perspective, any reduction in transmission rates results in a lower incidence of HIV. Another public health benefit resulting from routine HIV testing is increased life expectancy. Sanders et al. (2005) suggest that routine HIV testing in populations with a 0.1% HIV prevalence is cost effective and yields 5.48 days in increased life expectancy.

Because CHBRP estimates that AB 1894 would not change utilization of testing, population covered or practice patterns, no long-term public health impacts are anticipated.

Potential impacts of adopting CDC guidelines over the long-term: alternative scenario analysis

The CDC revised its HIV testing guidelines in 2006 to recommend that voluntary "opt-out" HIV testing become part of routine care administered to adults, adolescents, and pregnant women in all health care settings (Branson, 2006). The primary objectives of the revised guidelines are to increase HIV screening of patients, foster earlier detection of HIV infection, and to enroll those persons identified with HIV into clinical and prevention services (CDC, 2006). These guidelines

expand the target population beyond the guidelines issued by the USPSTF (which reflect the CDC's previous guidelines) to focus on persons at high risk for HIV and pregnant women.

Should the CDC guidelines become universally accepted in the future, and practitioners increase HIV testing as part of routine care administered in physician offices, emergency departments and health clinics, there would be a significant increase in testing utilization. *Appendix E* presents an alternative scenario in which utilization would increase to conform to the 2006 CDC guidelines. If this were to occur, CHBRP estimated that testing utilization would increase by 50%, in part, due to practice pattern changes. The overall result of such an assumption is that the public health impact is estimated to be 777 additional cases of HIV diagnosed annually.

APPENDICES

Appendix A: Text of Bill Analyzed

After introduction, the author's office submitted amended text for AB 1894 to CHBRP. At the author's request, CHBRP has focused this report on the amended language. Below is the text as introduced. Following is the amended language.

BILL NUMBER: AB 1894 INTRODUCED
BILL TEXT

INTRODUCED BY Assembly Member Krekorian

FEBRUARY 7, 2008

An act to add Sections 1367.46 and 120897 to the Health and Safety Code, to add Section 10123.91 to the Insurance Code, and to add Section 14132.33 to the Welfare and Institutions Code, relating to HIV testing.

LEGISLATIVE COUNSEL'S DIGEST

AB 1894, as introduced, Krekorian. HIV testing.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the regulation of health care service plans by the Department of Managed Health Care. Existing law requires a health care service plan to provide specified coverage to its enrollees and subscribers. Existing law provides that a willful violation of the act is a crime.

Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health insurance policy to provide specified coverage to insureds.

This bill would require health care service plans and health insurers, on or after January 1, 2009, to offer testing for human immunodeficiency virus (HIV) antibodies and for acquired immune deficiency syndrome (AIDS) regardless of whether the testing is related to a primary diagnosis.

Because this bill would place additional requirements on health care service plans, the violation of which would be a crime, the bill would impose a state-mandated local program.

Under existing law, the State Department of Public Health is responsible for the licensure and regulation of health facilities, including general acute care hospitals, as defined, and health clinics.

This bill would require every general acute care hospital or health clinic that provides emergency medical care to offer patients testing for the HIV antibodies and for AIDS regardless of whether the testing is related to a primary diagnosis.

Existing law, the Medi-Cal Act, establishes the Medi-Cal program to provide health care benefits and services to low-income persons who meet specified eligibility criteria.

This bill would include testing for HIV antibodies and for AIDS as a covered service within the Medi-Cal program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

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

SECTION 1. Section 1367.46 is added to the Health and Safety Code, to read:

1367.46. Every individual or group health care service plan contract that is issued, amended, or renewed on or after January 1, 2009, that covers hospital, medical, or surgery expenses shall provide coverage for the testing for human immunodeficiency virus (HIV) antibodies and for acquired immune deficiency syndrome (AIDS) regardless of whether the testing is related to a primary diagnosis.

SEC. 2. Section 120897 is added to the Health and Safety Code, to read:

120897. Every general acute care hospital or health clinic that provides emergency medical care shall offer patients testing for the human immunodeficiency virus (HIV) antibodies and for acquired immune deficiency syndrome (AIDS), regardless of whether the testing is related to a primary diagnosis.

SEC. 3. Section 10123.91 is added to the Insurance Code, to read:

10123.91. (a) On or after January 1, 2009, every insurer that issues, amends, or renews an individual or group policy of health insurance that covers hospital, medical, or surgical expenses shall offer coverage for the testing for human immunodeficiency virus (HIV) antibodies and for acquired immune deficiency syndrome (AIDS) regardless of whether the testing is related to a primary diagnosis.

(b) It shall remain within the sole discretion of the health insurer as to the provider of the testing with which it chooses to contract. Reimbursement shall be provided according to the respective

principles and policies of the health insurer.

SEC. 4. Section 14132.33 is added to the Welfare and Institutions Code, to read:

14132.33. The testing of human immunodeficiency virus (HIV) antibodies and for acquired immune deficiency syndrome (AIDS) regardless of whether the testing is related to a primary diagnosis is a covered service under this chapter.

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.

AB 1894 – Amended Text, submitted to CHBRP on February 15, 2008.

SECTION 1. Section 1367.46 is added to the Health and Safety Code, to read:

1367.46. Every individual or group health care service plan contract that is issued, amended, or renewed on or after January 1, 2009, that covers hospital, medical, or surgery expenses shall provide coverage for the testing for human immunodeficiency virus (HIV) antibodies and for acquired immune deficiency syndrome (AIDS) regardless of whether the testing is related to a primary diagnosis.

SEC. 2. Section 120897 is added to the Health and Safety Code, to read:

120897. Every general acute care hospital ~~or health clinic~~ that provides emergency medical care or health clinic shall offer patients *no more frequently than every six months* testing for the human immunodeficiency virus (HIV) antibodies and for acquired immune deficiency syndrome (AIDS), regardless of whether the testing is related to a primary diagnosis.

SEC. 3. Section 10123.91 is added to the Insurance Code, to read:

10123.91. (a) On or after January 1, 2009, every insurer that issues, amends, or renews an individual or group policy of health insurance that covers hospital, medical, or surgical expenses shall ~~offer~~ provide coverage for the testing for human immunodeficiency virus (HIV) antibodies and for acquired immune deficiency syndrome (AIDS) regardless of whether the testing is related to a primary diagnosis.

(b) It shall remain within the sole discretion of the health insurer as to the provider of the testing with which it chooses to contract. Reimbursement shall be provided according to the respective principles and policies of the health insurer.

~~SEC. 4. Section 14132.33 is added to the Welfare and Institutions Code, to read:~~

~~14132.33. The testing of human immunodeficiency virus (HIV) antibodies and for acquired immune deficiency syndrome (AIDS) regardless of whether the testing is related to a primary diagnosis is a covered service under this chapter.~~

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school

district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Appendix B: Literature Review Methods

Appendix B describes methods used in the medical effectiveness literature review for AB 1894, a bill that would require health plans to provide coverage for testing for the human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS), regardless of whether the purpose of testing is to determine a primary diagnosis.

The literature review focused on studies regarding testing asymptomatic persons for HIV infection, because health plans already cover HIV tests administered to persons with symptoms that may indicate HIV infection. To identify pertinent literature, a medical librarian performed a search of studies that addressed topics pertinent to the assessment of the effectiveness of HIV testing. These topics included the accuracy of HIV tests; acceptance rates for testing; rates at which persons with HIV receive treatment; and the effects of treatment on morbidity, mortality, and transmission of HIV. The search was limited to publications in English. Additional searches were performed for the cost and public health analyses to retrieve studies regarding the cost and cost-effectiveness of testing asymptomatic persons for HIV infection; economic loss associated with HIV and AIDS; and racial/ethnic and gender disparities in the incidence and prevalence of HIV, testing for HIV, and receipt of treatment.

During the initial stage of the literature search, CHBRP identified two systematic reviews on testing asymptomatic persons for HIV infection that were produced by the Oregon Evidence-based Practice Center for the United States Preventive Services Task Force (Chou et al., 2005a; Chou et al., 2005b). CHBRP determined that these systematic reviews were of high quality and decided to rely on them for information regarding findings from studies published through the end date for the literature searches conducted for them (June 2004). The parameters of the literature search were refined to limit the search to literature published from July 2004 to present.

The following databases that index peer-reviewed literature were searched: PubMed (MEDLINE and other PubMed records), the Web of Science (Science Citation Index and Social Science Citation Index), the Cochrane Library (including the Cochrane Database of Systematic Reviews and the Cochrane Register of Controlled Clinical Trials), Global Health, EconLit. The National Guideline Clearinghouse database of clinical practice guidelines was also searched, along with the Health Technology Assessments Database, which is produced by the Centre for Reviews and Dissemination using information obtained from organizations that issue health technology assessments.

The literature search yielded a total of 325 abstracts regarding topics related to HIV testing for asymptomatic persons. At least two reviewers screened the title and abstract of each citation returned by the literature search to determine eligibility for inclusion. The reviewers obtained the full text of articles that appeared to be eligible for inclusion in the review and reapplied the initial eligibility criteria. Twelve studies met the inclusion criteria and were included in the medical effectiveness review (in addition to the two systematic reviews).

In making a “call” for each outcome measure, the team and the content expert consider the number of studies as well the strength of the evidence. 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
- Generalizability of findings

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

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

The conclusion states that there is “clear and convincing” evidence that an intervention has a favorable effect on an outcome if multiple well-implemented randomized controlled trials (RCTs) were conducted and if these studies report statistically significant and clinically meaningful findings that favor the intervention.

The conclusion characterizes the evidence as “preponderance of evidence” that an intervention has a favorable effect if most but not all five criteria are met. For example, for some interventions the only evidence available is from nonrandomized studies or from a few RCTs with small sample sizes and weak research designs. If most such studies that assess an outcome have statistically and clinically significant findings that are in a favorable direction and enroll populations similar to those covered by a mandate, the evidence would be classified as a “preponderance of evidence favoring the intervention.” In some cases, the preponderance of evidence may indicate that an intervention has no effect or has an unfavorable effect.

The evidence is presented as “ambiguous/conflicting” if studies’ findings vary widely with regard to the direction, statistical significance, and clinical significance/size of the effect.

The category “insufficient evidence” of an intervention’s effect is used where there is little if any evidence of an intervention’s effect.

Search Terms

The use of Major Subject Heading (MeSH) terms and keywords to retrieve studies pertinent to the analysis of AB 1894. Searches using the term “HIV testing” were combined other terms as follows to obtain titles and abstracts for studies that addressed different aspects of HIV testing.

("hiv infections/diagnosis"[Mesh Terms] OR "hiv infections/prevention and control"[Mesh Terms]) AND ("enzyme-linked immunosorbent assay"[MeSH Terms] OR "blotting, western"[MeSH Terms] OR "aids serodiagnosis"[MeSH Terms] OR "mandatory testing"[MeSH Terms] OR "mass screening"[MeSH Terms] OR "hiv antibody test "[All Fields] OR "hiv antibody testing "[All Fields]) OR ("hiv test* "[All Fields]) AND ("humans"[MeSH Terms] AND English[lang])

AND systematic[sb]

diagnosis (broad)

AND (sensitiv*[Title/Abstract] OR sensitivity and specificity[MeSH Terms] OR diagnos*[Title/Abstract] OR diagnosis[MeSH:noexp] OR diagnostic *[MeSH:noexp] OR diagnosis,differential[MeSH:noexp] OR diagnosis[Subheading:noexp])

clinical prediction guide (broad)

AND (predict*[tiab] OR predictive value of tests[mh] OR scor*[tiab] OR observ*[tiab] OR observer variation[mh])

costs

AND (cost[tiab] OR costs[tiab] OR costs and cost analysis[mh] OR ec[sh])

economics

AND (costs[tiab] OR cost effective[tiab] OR economic[tiab])

Appendix C: Summary Findings on Medical Effectiveness

Appendix C describes the meta-analyses, systematic reviews, and individual studies on HIV testing that were analyzed by the medical effectiveness team. Table C-1 presents information regarding the type of study, topic studied, population of the study, and the location at which a study was conducted. Tables C-2-a through C-2-f list studies that assessed topics pertinent to the evaluation of the effectiveness of screening for HIV.

Table C-1. Summary of Published Studies on Effectiveness of HIV Testing

| Citation | Type of Trial | Topics | Population Studied | Location |
|------------------------|-------------------|--|---|----------|
| Chou et al., 2005a | Systematic review | 1. Accuracy of FDA-approved HIV tests 2. Harms of HIV screening 3. Acceptability of HIV screening 4. Proportions of HIV-positive persons receiving interventions for which they meet criteria 5. Effectiveness of interventions for persons who are HIV-positive | General adult and adolescent population – Excluded studies that only included overtly symptomatic or end-stage patients | N/A |
| Chou et al., 2005b | Systematic review | 1. Accuracy of FDA-approved HIV tests 2. Harms of HIV screening 3. Acceptability of HIV screening 4. Proportions of HIV-positive persons receiving interventions for which they meet criteria 5. Effectiveness of interventions for persons who are HIV-positive | Pregnant women including adolescents. Includes women with unsuspected HIV infection and those previously identified as having HIV infection | N/A |
| Chou and Huffman, 2007 | Systematic review | 1. Acceptability of HIV screening 2. Proportions of HIV-positive persons receiving interventions for which they meet criteria | Non-pregnant adults and adolescents in lower prevalence settings | N/A |
| Pai et al., 2007 | Meta-analysis | Accuracy of rapid tests and acceptance rates of rapid tests | Pregnant women in antenatal clinics and delivery rooms located in hospitals or referral centers | N/A |
| Roberts et al., 2007 | Systematic review | 1. Proportions of persons taking HIV rapid test and receiving interventions | Studies of individuals who use a HIV rapid test | N/A |

Table C-1. Summary of Published Studies on Effectiveness of HIV testing (cont'd)

| Citation | Type of Trial | Topics | Population Studied | Location |
|-----------------------------|----------------------|---|---|--|
| Wesolowski et al., 2006 | Surveillance data | Accuracy of OraQuick whole blood and oral fluid tests | Persons who received care from health departments | Chicago, New York, San Francisco, AZ, DE, FL, IN, LA, MA, MI, MT, NE, NJ, NY, NC, UT, WI |
| Brown et al., 2007 | Cross-sectional | Rates of acceptance of HIV testing when offered | Persons presenting at Emergency Department (ED) | Washington, DC |
| Campos-Outcalt et al., 2006 | Cross-sectional | Rates of acceptance of HIV testing when offered | Persons presenting at ED who were not HIV-positive and who had not received a HIV test in the previous 3 months; persons presenting at urban STD clinic | Phoenix, AZ |
| Lyons et al., 2005 | Cross-sectional | Rates of acceptance of HIV testing when offered | Persons aged 18 and over who presented at ED teaching hospital | Urban Midwest |
| Lyss et al., 2007 | Cross-sectional | Rates of acceptance of HIV testing when offered | Persons presenting at urban ED aged 18 to 54 years without known HIV infection and who had not been tested within 3 months | Chicago, IL |
| Mehta et al., 2006 | Cross-sectional | Rates of acceptance of HIV testing when offered | Persons presenting at ED who were not HIV-positive and who had not received a HIV test in the previous 1 month; patients who presented to the ED solely seeking HIV testing were excluded | Boston, MA |
| Silva et al., 2007 | Cross-sectional | Rates of acceptance of HIV testing when offered | Persons presenting at Emergency Department (ED) who were not HIV-positive and who had not been tested within 3 months | Chicago, IL |

Table C-1. Summary of Published Studies on Effectiveness of HIV testing (cont'd)

| Citation | Type of Trial | Topics | Population Studied | Location |
|------------------------|----------------------|---|--|-----------------|
| Walensky et al., 2005a | Cross-sectional | Rates of acceptance of HIV testing when offered | Persons presenting at urgent care center in 3 urban not-for-profit hospitals, and 1 urban public authority hospital; all persons presenting to the hospitals for any reason were offered testing | Urban, MA |
| Yudin et al., 2007 | Prospective study | Rates of acceptance of HIV testing when offered | Women presenting at their first prenatal visit at a women's clinic in a hospital | Toronto, Canada |

Table C-2-a. Summary of Evidence Regarding HIV Testing – Accuracy of HIV Tests

| Citation | Research Design ¹² | Type of Test | Delivery | Statistical Significance | Direction of Effect | Size of Effect |
|--------------------|--|---|---|--|--|--|
| Chou et al., 2005a | Systematic review of 26 studies | 1. Standard Tests ¹³ – reactive Enzyme Immunoassay (EIA) and Western Blot (WB) or immunoflourescent assay (IFA) | 1. Whole blood laboratory testing – Confirmatory testing of positive EIA results with Western blot is required | 1. N/A – studies of test accuracy | 1. N/A – studies of test accuracy | 1. Studies conducted since 1989 report sensitivities greater than 99.7% and specificities ranging from 98.5% to 99.8%; rates of indeterminate Western blot range between 4% to 20% ¹⁴ |
| | Level I-II: 3 of 6 Level III-IV: 3 of 6 | 2. Rapid Tests a. OraQuick | 2a. Whole blood and oral fluid tests – testing at point of care and results available in 10-30 minutes | 2a. N/A – studies of test accuracy | 2a. N/A – studies of test accuracy | 2a. Sensitivities ranging from 96% to 100% and specificities greater than 99.9%; positive predictive value (PPV) of 90% and negative predictive value (NPV) of 100% |
| | Level I-II: 0 of 3 Level III-IV: 3 of 3 Level I-II: 0 of 3 Level III-IV: 3 of 3 | b. Uni-Gold c. Reveal | 2b. Whole blood tests – testing at point of care and results available in 10-30 minutes 2c. Laboratory testing | 2b. N/A – studies of test accuracy 2c. N/A – studies of test accuracy | 2b. N/A – studies of test accuracy 2c. N/A – studies of test accuracy | 2b. Sensitivities ranging from 94% to 100% and specificities greater than 99% 2c. Sensitivities ranging from 94% to 100% and specificities greater than 99% |

¹² Level I = Well-implemented RCTs and cluster RCTs; Level II = RCTs and cluster RCTs with major weaknesses; Level III = Nonrandomized studies that include an intervention group and one or more comparison group, time series analyses, and cross-sectional surveys; Level IV = Case series and case reports; Level V = Clinical/practice guidelines based on consensus or opinion.

¹³ Standard testing (also know as conventional testing) is not able to detect recently infected persons who have not yet seroconverted.

¹⁴ Rates vary according to the immunoblot used, the prevalence of HIV-1 infection, and interpretive criteria used. Reasons for an indeterminate Western blot include overlapping autoimmune disorders or blood test taken during early seroconversion. Indeterminate tests require further evaluation.

Table C-2-a. Summary of Evidence Regarding HIV Testing – Accuracy of HIV Tests (cont'd)

| Citation | Research Design | Type of Test | Delivery | Statistical Significance | Direction of Effect | Size of Effect |
|----------------------------|--|--|---|--|---|---|
| | Level I-II: 2 of 2 Level III-IV: 0 of 2 | 3. Oral Fluid Epitope OraSure | 3. Laboratory testing | 3. N/A – studies of test accuracy | 3. N/A – studies of test accuracy | 3. Sensitivities and specificities greater than 99%. PPV of 93.4% and NPV of 99.9% |
| | Level I-IV: 4 of 4 | 4. Urine Tests | 4. Laboratory testing | 4. N/A – studies of test accuracy | 4. N/A – studies of test accuracy | 4. Sensitivities and specificities are generally lower than standard testing |
| | Level I-II: 1 of 1 Level III-IV: 0 of 1 | 5. Home Sampling Tests – Home Access kit | 5. Home collection sample sent for laboratory testing; uses finger stick blood spot samples and oral fluid specimens | 5. N/A – studies of test accuracy | 5. N/A – studies of test accuracy | 5a. 100% sensitivity and specificity |
| Pai et al., 2007 | Systematic review of Level III-IV studies | 6. Rapid Test a. blood based tests b. oral fluid tests | 6a-b. Pregnant women in antenatal clinics and delivery rooms located in hospitals or referral centers | 6a-b. N/A – studies of test accuracy | 6a-b. N/A – studies of test accuracy | 6a. Sensitivity range 86.4- 100% and specificity range 99.5-100% 6b. Oral fluid tests: sensitivity range 75-100% and specificity range 99.9- 100% |
| Wesolowski et al., 2006 | Surveillance data | 7. OraQuick tests a. OraQuick whole blood b. OraQuick oral fluid | 7a-b. OraQuick tests were conducted: 30% at counseling and testing sites; 29% at STD clinics; 18% at correctional facilities | 7a-b. N/A – studies of test accuracy | 7a-b. N/A – studies of test accuracy | 7a. Specificity of 99.98% and PPV of 99.2% 7b. Specificity of 99.89% and PPV of 90.0% |

Table C-2-b. Summary of Evidence Regarding HIV Testing – Acceptability of Testing

| Citation | Research Design | Outcome | Population Studied | Statistical Significance | Direction of Effect | Size of Effect |
|--------------------|--|--|--|--|------------------------------|--|
| Chou et al., 2005a | Systematic review of 62 Level III-IV studies | <p>1a. Acceptance rates of voluntary routine HIV/AIDS testing in the U.S.</p> <p>1b. Acceptance rates of sex partners of newly diagnosed HIV-infected persons</p> <p>1c. Acceptance rates with “opt-out” testing</p> <p>1d. Newer testing method</p> | 1. Adults and adolescents – specific characteristics vary across the studies included in the systematic review | 1. N/A – all subjects offered HIV test | 1. N/A – no comparison group | <p>1a. Acceptance rates varied widely within and between similar settings (range 10% to 97%); in general, low prevalence settings seem to be associated with lower acceptance</p> <p>1b. 44% to 89%</p> <p>1c. Rates increase from 35% to 65% in one study</p> <p>1d. Preference for newer screening methods (rapid tests, non-invasive sample, home-based collection, on-site testing.) that may increase rates</p> |

Table C-2-b. Summary of Evidence Regarding HIV Testing – Acceptability of Testing (cont’d)

| Citation | Research Design | Outcome | Population Studied | Statistical Significance | Direction of Effect | Size of Effect |
|------------------------|--|--|---|---|--|---|
| Chou et al., 2005b | Systematic review of cohort and cross-sectional studies | <p>2a. Acceptance rates among pregnant women</p> <p>2b. Acceptance rates between an “opt-out” program compared to an “out-in” program among pregnant women.</p> <p>2c. Acceptance rates of rapid tests in labor and delivery units</p> | 2. Pregnant women – specific characteristics vary across the studies included in the systematic review | 2. N/A – all subjects offered HIV test | 2. N/A – no comparison group | <p>2a. Rates range from 23% to 100%.</p> <p>2b. Range of 71% to 98% compared to 25%-83%.</p> <p>2c. Rate of 84%</p> |
| Chou and Huffman, 2007 | <p>Systematic review</p> <p>3a. description of research designs</p> <p>3b. 1 RCT</p> | <p>3a. Acceptance rates</p> <p>3b. Acceptance rates of rapid tests vs. standard tests</p> | <p>3a. Voluntary HIV tests in high-prevalence urgent care centers</p> <p>3b. Inpatient and outpatient clients</p> | <p>3a. N/A – all subjects offered HIV test</p> <p>3b. Statistically significant</p> | <p>3a. N/A – no comparison group</p> <p>3b. Favors rapid tests</p> | <p>3a. 33% accepted testing</p> <p>3b. Rates for rapid testing (59%) were higher than for standard testing (41%) (p=0.07)</p> |

Table C-2-b. Summary of Evidence Regarding HIV Testing – Acceptability of Testing (cont’d)

| Citation | Research Design | Outcome | Population Studied | Statistical Significance | Direction of Effect | Size of Effect |
|-----------------------------|---|---------------------|--|--|------------------------------|---|
| Roberts et al., 2007 | Systematic review of peer-reviewed studies – no description of research designs | 4. Acceptance rates | 4. Varies across the studies included in the systematic review | 4. N/A – all subjects offered HIV test | 4. N/A – no comparison group | 4. Ranges of acceptance of rapid test vary from 14%-98%: among pregnant women, rates range from 74% to 86%; among individuals in health care facilities, rates range from 29% to 93%; at STD clinics, rates range from 65% to 69%; in other community, setting rate range from 14% to 46% |
| Brown et al., 2007 | Cross-sectional | 5. Acceptance rates | 5. Ambulatory patients and those arriving by ambulance were informed of an OraQuick rapid test and an “opt-out” option. | 5. N/A – all subjects offered HIV test | 5. N/A – no comparison group | 5. 60% accepted the HIV test |
| Campos-Outcalt et al., 2006 | Cross-sectional | 6. Acceptance rates | 6. Patients were informed of HIV testing as an “opt-out” option. Used standard test. | 6. N/A – all subjects offered HIV test | 6. N/A – no comparison group | 6. 68% of patients accepted HIV test |
| Lyons et al., 2005 | Cross-sectional | 7. Acceptance rates | 7. Persons were offered a standard HIV test | 7. N/A – all subjects offered HIV test | 7. N/A – no comparison group | 7. 64% accepted HIV test |
| Lyss et al., 2007 | Cross-sectional | 8. Acceptance rates | 8a. Patients who were screened by staff were offered a rapid test 8b. Patients who were referred by their providers were offered a rapid test | 8. N/A – all subjects offered HIV test | 8. N/A – no comparison group | 8a. 58% accepted HIV test 8b. 95% accepted HIV test |

Table C-2-b. Summary of Evidence Regarding HIV Testing – Acceptability of Testing (cont’d)

| Citation | Research Design | Outcome | Population Studied | Statistical Significance | Direction of Effect | Size of Effect |
|------------------------|------------------------|----------------------|---|---|-------------------------------|-------------------------------|
| Mehta at al., 2006 | Cross-sectional | 9. Acceptance rates | 9. Persons were offered a standard HIV test | 9. N/A – all subjects offered HIV test | 9. N/A – no comparison group | 9. 45% accepted the HIV test |
| Silva et al., 2007 | Cross-sectional | 10. Acceptance rates | 10. Persons who visited the ED were offered a rapid HIV blood test | 10. N/A – all subjects offered HIV test | 10. N/A – no comparison group | 10. 48% accepted testing. |
| Walensky et al., 2005a | Cross-sectional | 11. Acceptance rates | 11. Persons presenting were offered an OraSure that uses a check swab. This is not a rapid test | 11. N/A – all subjects offered HIV test | 11. N/A – no comparison group | 11. 37% accepted testing. |
| Yudin at al., 2007 | Prospective study | 12. Acceptance rates | 12. Pregnant women were offered a HIV test and an “opt-out” option | 12. N/A – all subjects offered HIV test | 12. N/A – no comparison group | 12. 93% accepted the HIV test |

Table C-2-c. Summary of Evidence Regarding HIV Testing – Harms of Testing

| Citation | Research Design | Outcome | Design/Description | Statistical Significance | Direction of Effect | Size of Effect |
|--------------------|--|--|---|------------------------------|------------------------------|---|
| Chou et al., 2005a | Systematic review – Level I-II: 1 of 1 Level III-IV: 0 of 1 | 1. Harms of false-positive tests | 1. OraQuick Rapid blood false-positive rate | 1. N/A – no comparison group | 1. N/A – no comparison group | 1. Resulted in unnecessary antiretroviral therapy in less than 1% |
| | Systematic review of Level I-IV studies: 3 of 3 | 2. Harms of true positive tests a. Stigmatizing attitudes | 2a. Self-reported harms | 2. N/A – no comparison group | 2. N/A – no comparison group | 2a. Report fears of rejection, abandonment, verbal abuse, and physical assault. In a study of persons recently diagnosed with HIV, 4% reported losing a job because of their HIV status, 1% had been asked to move by a landlord, and 1% had been assaulted |
| | Systematic review of Level I-IV studies: 9 of 9 | 2b. Affective and adjustment disorders, including suicide | 2b. Self-reported harms (studies conducted since the introduction of HAART) ¹⁵ | | | 2b. In the post-HAART era, there is no evidence of suicide risk |
| | Systematic review of Level III-IV studies: 8 of 8 | 2c. Intimate partner or other violence | 2c. Self-reported harms (studies conducted since the introduction of HAART) | | | 2c. Violence occurs at a high frequency in HIV-infected persons, but studies had no control group |
| | Systematic review of Level I-IV studies: 3 of 3 | 2d. Close relationships | 2d. Self-reported partnership dissolution | | | 2d. No effect |

¹⁵ HAART = highly active antiretroviral therapy, a combination of antiretroviral medications that is the standard treatment for HIV.

Table C-2-d. Summary of Evidence Regarding HIV Testing – Proportion of HIV-Positive Persons Receiving Interventions for Which They Meet Criteria

| Citation | Research Design | Outcome | Study Description | Statistical Significance | Direction of Effect | Size of Effect |
|--------------------|---|--|---|------------------------------|------------------------------|--|
| Chou et al., 2005a | Systematic review of Level III-IV studies | 1a. Do not obtain results 1b. Receive care 1c. Receive antiretroviral treatment 1d. Receive HAART 1e. Receive prophylaxis | 1a-c. Observational, cohort and cross-sectional studies 1d. 4 survey studies 1e. 1 survey study | 1. N/A – no comparison group | 1. N/A – no comparison group | 1a. Range from 38% to 58% 1b. Receiving medical care at least once every six months ranges from 36% to 63%. 1c. Range from 53% to 85% 1d. Range from 57% to 79% 1e. 93% received PCP ¹⁶ prophylaxis, 62% MAC ¹⁷ prophylaxis, and 73% toxoplasmosis prophylaxis |
| Chou et al., 2005b | Systematic review of Level III-IV | 2a. Receive results 2b. Receive antiretroviral treatment to reduce mother-to-child transmission 2c. Receive elective cesarean section to reduce mother-to-child transmission | 2a-c. Observational, cohort and cross-sectional studies | 2. N/A – no comparison group | 2. N/A – no comparison group | 2a. Over 90% of pregnant women returned for results 2b. Over 90% receive antiretrovirals and 58%-80% received combination regimens 2c. Range is 37% to 50% |

¹⁶ Pneumocystis carinii pneumonia (PCP)

¹⁷ Mycobacterium avium-intracellulare complex (MAC)

Table C-2-d. Summary of Evidence Regarding HIV Testing – Proportion of HIV-Positive Persons Receiving Interventions for Which They Meet Criteria (cont’d.)

| Citation | Research Design | Outcome | Study Description | Statistical Significance | Direction of Effect | Size of Effect |
|----------------------|--|---|--|------------------------------|------------------------------|--|
| Roberts et al., 2007 | Systematic review – research designs not described | 3a. Receive results (rapid tests) 3b. Receiving medical care | 3a. Peer review studies – no description on designs 3b. One study of an STD clinic in Chicago | 3. N/A – no comparison group | 3. N/A – no comparison group | 3a. In health care settings, rates range from 89 to 100%, except for one study (27%); in alternative/community setting rates are greater than 98% 3b. 100% who tested positive went to first clinic appointment |

Table C-2-e. Summary of Evidence Summary of Evidence Regarding HIV Testing – Reduction of Risk Behaviors

| Citation | Research Design | Outcome | Study Description | Statistical Significance | Direction of Effect | Size of Effect |
|------------------------|--|---|------------------------|-------------------------------|---|--|
| Chou and Huffman, 2007 | 1a. Systematic review of 4 Level III studies | 1a. Rates of unprotected intercourse among HIV-positive persons who were aware of HIV status versus those not aware of their status | 1a. Self-reported data | 1a. Statistically significant | 1a. Lower for persons aware of HIV status | 1a. Rate of unprotected intercourse was 53% lower among those aware of their HIV status |
| | 1b. 23 Level III studies | 1b. Rates of unprotected intercourse among HIV-positive, HIV-negative, and untested persons | 1b. Self-reported data | 1b. Not stated | 1b. Not stated | 1b. Reductions in unprotected intercourse were greatest for HIV-positive persons compared to HIV-negative and untested persons |

Table C-2-f. Summary of Evidence Regarding HIV Testing – Effectiveness of Interventions for Persons Who Are HIV-Positive

| Citation | Research Design | Outcome | Study Description | Statistical Significance | Direction of Effect | Size of Effect |
|--------------------|---|---|--|-------------------------------|-----------------------|---|
| Chou et al., 2005a | Systematic review of studies of adults and adolescents who are not pregnant | 1.HAART on clinical progression and death | 1a. 54 RCTs compare HAART to two drug therapy and less-intensive regimes | 1a. Statistically significant | 1a. Favors HAART | 1a. OR= .62 (95% CI 0.51-0.70) |
| | | | 1b. 10 cohort studies compare HAART to alternate regimes | 1b. Statistically significant | 1b. Favors HAART | 1b. Found marked decreases using HAART |
| | | 2. Prophylaxis on clinical outcomes: 2a. PCP | 2a. 2 systematic reviews on prophylaxis and PCP | 2a. Statistically significant | 2a. Favor prophylaxis | 2a.RR=0.39 (95% CI 0.27-0.55) |
| | | 2b. Tuberculosis and death | 2b. Systematic review on prophylaxis and tuberculosis | 2b. Statistically significant | 2b. Favor prophylaxis | 2b. Reduced TB risk by 60% to 86% and death by 21%-23% |
| | | 2c. MAC | 2c. 6 trials on prophylaxis on MAC and death | 2c. Statistically significant | 2c. Favor prophylaxis | 2c. Effective in preventing MAC and may be associated with mortality benefit HR around 0.75 |
| | | 2d. CMV ¹⁸ | 2d. 3 trials on prophylaxis on CMV | 2d. Statistically significant | 2d. Favor prophylaxis | 2d. May prevent invasive CMV-disease |

¹⁸ Cytomegalovirus (CMV)

Table C-2-f. Summary of Evidence Regarding HIV Testing – Effectiveness of Interventions for Persons Who Are HIV-Positive (cont'd)

| Citation | Research Design | Outcome | Study Description | Statistical Significance | Direction of Effect | Size of Effect |
|----------|-----------------|--|---|-------------------------------|------------------------|--|
| | | 3. Vaccines on clinical outcomes 3a. Pneumococcal | 3a. RCT conducted in Uganda pneumococcal vaccination vs. control | 3a. Statistically significant | 3a. Mixed | 3a. Intervention group was association with increased risk of all-cause pneumonia. HR 1.89, (95% CI 1.1-3.2), but long term survival advantage 0.84 (95% CI 0.7-1.0) |
| | | 3b. Influenza | 3b. RCT on influenza vaccination vs. control on risk for respiratory symptomatic illness | 3b. Statistically significant | 3b. Favors vaccination | 3b. 29% vs. 49% (p=0.04) |
| | | 3c. Hepatitis B vaccines on clinical outcomes | 3c. Longitudinal study of hepatitis B virus vaccine on incidence of acute hepatitis B virus infection | 3c. Statistically significant | 3c. Favors vaccination | 3c. RR=0.6 (95% CI 0.4-0.9) |

Table C-2-f. Summary of Evidence Regarding HIV Testing – Effectiveness of Interventions for Persons Who Are HIV-Positive (cont'd)

| Citation | Research Design | Outcome | Study Description | Statistical Significance | Direction of Effect | Size of Effect |
|--------------------|--|---|---|---|--------------------------------|--|
| Chou et al., 2005b | Systematic review of Level I-III studies of pregnant women | 4. Antiretroviral to prevent mother-to-child transmission | 4a. RCT | 4a. Statistically significant | 4a. Favors treatment | 4a. Decreased transmission from 25% to 8% compared to placebo. |
| | | 4a. 3-part zidovudine prophylaxis | | | | |
| | | 4b. Any zidovudine prophylaxis | 4b. RCT | 4b. Statistically significant | 4b. Favors treatment | 4b. Decreased transmission OR=0.46 (95% CI=0.35-0.60) |
| | | 4c. Zidovudine on infant death | 4c. RCT | 4c. Statistically significant | 4c. Favors treatment | 4c. Decreased infant death OR=0.57 (95% CI=0.38-0.85) |
| | | 4d. Antiretroviral regimes with two or more drugs vs. zidovudine alone | 4d. Observational studies | 4d. Statistically significant in 2 of 3 studies | 4d. Favors multi-drug regimens | 4d. Antiretroviral regimes with more drugs were superior to fewer drugs. |
| | | 4e. HAART vs. no antiretroviral | 4e. Good observational study | 4e. Statistically significant | 4e. Favors HAART | 4e. OR=0.13 (95% CI 0.06-0.27) |
| | | 5. Scheduling elective cesarean section to prevent mother-to-child transmission (i.e., avoiding vaginal delivery) | 5. Nonrandomized study with comparison group conducted in HAART era | 5. Statistically significant ¹⁹ | 5. Favors cesarean section | 5. OR = 0.33 (95% CI = 0.11-0.94) |

¹⁹ Statistically significant for all women enrolled in the trial but not statistically significant for women who also received HAART.

Table C-2-f. Summary of Evidence Regarding HIV Testing – Effectiveness of Interventions for Persons Who Are HIV-positive (cont'd)

| Citation | Research Design | Outcome | Study Description | Statistical Significance | Direction of Effect | Size of Effect |
|----------|-----------------|---|--|-------------------------------|---------------------|--|
| | | 6. Avoidance of breastfeeding to prevent mother-to-child transmission (i.e., using formula) | 6a. Two meta-analyses | 6a. Statistically significant | 6a. Favors formula | 6a. Breastfeeding was associated with an increased rate of vertical transmission of 14% to 16% |
| | | | 6b. Nonrandomized study with comparison group ²⁰ | 6b. Statistically significant | 6b. Favors formula | 6b. Breastfeeding increased rates of transmission OR = 10.2 (95% CI 2.7-38.1) |
| | | | 6c. RCT in Africa comparing breastfeeding to formula ²¹ | 6c. Statistically significant | 6c. Favors formula | 6c. Transmission rate for breastfeeding was 37% and 21% for formula |

Notes: RR = Risk Ratio, OR= Odds Ratio, HR=Hazard Ratio, CI = Confidence Interval

²⁰ Controlled for receipt of antiretroviral therapy by some women in the study.

²¹ Women enrolled in the study did not receive antiretroviral therapy.

Appendix D: Cost Impact Analysis: Data Sources, Caveats, and Assumptions

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

The cost analysis in this report was prepared by the Cost Team, which consists of CHBRP task force members and staff, specifically from the University of California, Los Angeles, and Milliman Inc. (Milliman). Milliman is an actuarial firm, and it provides data and analyses per the provisions of CHBRP authorizing legislation.

Data Sources

In preparing cost estimates, the Cost Team relies on a variety of data sources as described below.

Private Health Insurance

1. The latest (2005) California Health Interview Survey (CHIS), which is used to estimate insurance coverage for California's population and distribution by payer (i.e., employment-based, privately purchased, or publicly financed). The biannual CHIS is the largest state health survey conducted in the United States, collecting information from over 40,000 households. More information on CHIS is available at www.chis.ucla.edu/
2. The latest (2007) California Employer Health Benefits Survey is used to estimate:
 - size of firm,
 - percentage of firms that are purchased/underwritten (versus self-insured),
 - premiums for plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs]),
 - premiums for policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs]), and
 - premiums for high-deductible health plans (HDHPs) for the California population covered under employment-based health insurance.

This annual survey is released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. Information on the CHCF/NORC data is available at: www.chcf.org/topics/healthinsurance/index.cfm?itemID=133543.

3. Milliman data sources are relied on to estimate the premium impact of mandates. Milliman's projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States. See www.milliman.com/expertise/healthcare/products-tools/milliman-care-

[guidelines/index.php](#). Most of the data sources underlying the HCGs are claims databases from commercial health insurance plans. The data are supplied by health insurance companies, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed healthcare plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following:

- The MEDSTAT MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
- An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2006 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2005 experience.
- Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.

These data are reviewed for applicability by an extended group of experts within Milliman but are not audited externally.

4. An annual survey by CHBRP of the seven largest providers of health insurance in California (Aetna, Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) was completed to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC- or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. A separate survey was completed to ascertain levels of premandate coverage for services outlined in the mandate. Of the seven providers, six responded to the survey regarding premandate coverage levels. Enrollment in these six firms represents 94% of privately insured enrollees in full-service health plans regulated by the DMHC and 83% of those privately insured by comprehensive health insurance products regulated by the CDI.

Public Health Insurance

5. Premiums and enrollment in DMHC- and CDI-regulated plans by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their family members who receive their benefits through CalPERS. Enrollment information is provided for fully funded, Knox-Keene licensed health care service plans covering non-Medicare beneficiaries—which is about 75% of CalPERS total enrollment. CalPERS self-funded plans—approximately 25% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from health plans' evidence of coverage (EOCs) publicly available at www.calpers.ca.gov.
6. Enrollment in Medi-Cal Managed Care (Knox-Keene licensed plans regulated by DMHC) is estimated based on CHIS and data maintained by the Department of Health

Care Services (DHCS). DHCS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the current scope of benefits. CHBRP assesses enrollment information available online at www.dhs.ca.gov/admin/ffdmb/mcss/RequestedData/Beneficiary%20files.htm.

7. Enrollment data for other public programs—Healthy Families, Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (MRMIP)—are estimated based on CHIS and data maintained by the Major Risk Medical Insurance Board (MRMIB). The basic minimum scope of benefits offered by participating plans under these programs must comply with all requirements of the Knox-Keene Act, and thus these plans are affected by changes in coverage for Knox-Keene licensed plans. CHBRP does not include enrollment in the Post-MRMIB Guaranteed-Issue Coverage Products as these individuals are already included in the enrollment for individual health insurance products offered by private carriers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at www.mrmib.ca.gov/. Average statewide premium information is provided to CHBRP by MRMIB staff.

General Caveats and Assumptions

The projected cost estimates are estimates of the costs that would result if a certain set of assumptions were exactly realized. Actual costs will differ from these estimates for a wide variety of reasons, including:

- Prevalence of mandated benefits before and after the mandate may be different from CHBRP assumptions.
- Utilization of mandated services before and after the mandate may be different from CHBRP assumptions.
- Random fluctuations in the utilization and cost of health care services may occur.

Additional assumptions that underlie the cost estimates presented in this report are:

- Cost impacts are shown only for people with insurance and only for the first year after enactment of the proposed mandate.
- The projections do not include people covered under self-insured employer plans because those plans are not subject to state-mandated minimum benefit requirements.
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for one year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more

information on CHBRP's criteria for estimating long-term impacts please see:
http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php

- Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the plan types CHBRP modeled (HMO—including HMO and point of service (POS) plans—and non-HMO—including PPO and fee for service (FFS) policies), there are likely variations in utilization and costs by these plan types. Utilization also differs within California due to differences in the health status of the local commercial population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between health plans and providers. Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, CHBRP has estimated the impact on a statewide level.

Appendix E: Potential Impacts of Adapting CDC Guidelines over the Long-Term: Alternative Scenario Analysis

Bill Analysis–Specific Caveats and Assumptions

It is possible that this mandate may increase healthcare providers' awareness and adoption of the CDC guidelines, leading to an increase in utilization. Based on expert clinical input and the existence of many barriers to implement universal HIV testing (Rodnick, 2007), CHBRP did not make this assumption for AB 1894. However, CHBRP completed additional analyses to present an alternative scenario in which utilization would increase to conform to CDC guidelines. If this were to occur, CHBRP estimates that the utilization would increase by 50%, in part due to practice pattern changes. The overall result of such an assumption is that healthcare expenditures are estimated to increase by about \$10,151,000, or 0.0128%, versus CHBRP's estimated AB 1894 impact of an increase of \$554,000, or 0.0007%. If such a change did occur, it is questionable whether the change could be attributed largely to AB 1894, which is CHBRP's reason for not using this assumption in its estimated impact analysis.

Public Health Impact: Alternative Utilization Scenario

Assuming the same scenario presented above (where CDC guidelines are adopted and HIV testing utilization increases by 50%), the public health impact is estimated to be 777 additional cases of HIV diagnosed annually. The public health analysis assumes that a 50% increase of the baseline 27 tests/1,000 members would yield an additional 14 tests/1,000 members annually or an additional 310,660 tests per year. CHBRP calculated a rough estimate of the general population prevalence and applied this 0.25% prevalence rate to the 310,660 additional tests. Identifying these additional HIV-positive persons would likely help reduce the rate of transmission and increase anti-retroviral treatment, which could help reduce lost productivity and improve mortality rates. It is likely that a reduction in HIV infection rates would occur over the long term, however an exact number is difficult to estimate with precision.

(The estimated California HIV prevalence [0.25%] is based upon the number of known living HIV/AIDS cases living in the state at the end of 2007 expressed as a fraction of the state's population. It is likely that this underestimates the prevalence in California, as it is based only on *known* cases. In the absence of any direct information on the prevalence of HIV in the covered population, we employ this state-based estimate. However, the true prevalence among covered members may be greater or less than this estimate.)

27 tests/1,000 members baseline (per Milliman)

14 additional tests/1,000 members (assumes 50% increase in screening)

14/1,000 members *22,190,000= 310,660 additional tests (occurring in the baseline population of 22,190,000 members)

Rough estimate of California HIV Prevalence: 87,049 living HIV/AIDS cases (CDPH-OA, 2008)/34,457,549 persons (based on 2006 census estimate)=0.25% prevalence

0.25%*310,660=777 additional cases of HIV diagnosed annually

Appendix F: Information Submitted by Outside Parties

In accordance with CHBRP policy to analyze information submitted by outside parties during the first two weeks of the CHBRP review, the following parties chose to submit information.

No information was submitted directly by interested parties for this analysis.

For information on the processes for submitting information to CHBRP for review and consideration please visit http://www.chbrp.org/recent_requests/index.php.

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California Health Benefits Review Program Committees and Staff

A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses and three private universities in California. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis. The CHBRP **staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature. The level of involvement of members of the CHBRP Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others.

As required by the CHBRP authorizing legislation, UC contracts with a certified actuary, Milliman Inc. (Milliman), to assist in assessing the financial impact of each benefit mandate bill. Milliman also helped with the initial development of CHBRP methods for assessing that impact.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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