California Health Benefits Review Program

Analysis of California Senate Bill 306
Health Care: STD Testing

A Report to the 2021–2022 California State Legislature

March 31, 2021

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Key Findings

Analysis of California Senate Bill 306
Health Care: STD Testing

Summary to the 2021–2022 California State Legislature, March 31, 2021

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

SUMMARY[1]

The version of California Senate Bill 306 analyzed by CHBRP would require coverage of clinician-ordered sexually transmitted disease (STD) home test kits. In 2022, of the 21.9 million Californians enrolled in state-regulated health insurance, 100% would have insurance subject to SB 306.

Benefit Coverage: Postmandate, enrollees with coverage for STD home test kits would rise from 7% to 100%. As the mandate addresses a modality of covered tests, not coverage for a new test, it would not exceed essential health benefits (EHBs).

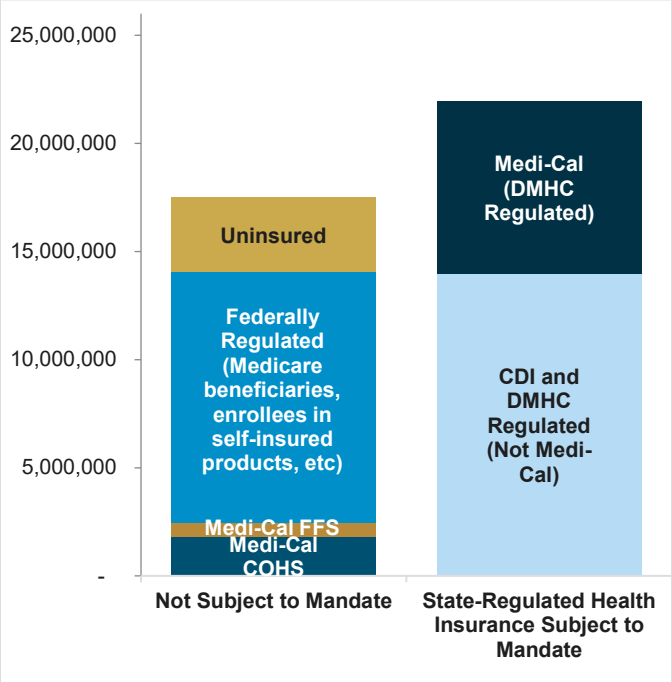
Medical Effectiveness: There is a *preponderance* of evidence that STD specimens self-collected outside the clinical setting are of equivalent effectiveness as those collected in a clinical environment. For blood and urine, there is a *preponderance* of evidence. For swabs, evidence is *clear and convincing.*

Cost and Health Impacts[2]: Changes in utilization would occur among commercial enrollees in plans and policies that generally cover out-of-network (OON) providers and among Medi-Cal beneficiaries enrolled in DMHC-regulated plans. SB 306 would result in an additional 73,225 enrollees tested and an increase in treatment for 71 with human immunodeficiency virus (HIV), 102 with hepatitis C, and 26,811 with other STDs. No initial postmandate year cost offsets or savings in other healthcare utilization would result and the total net annual expenditures would increase by $30,545,000 (0.02%). However, increased treatment leads to decreased transmission of disease and community spread, which would reduce the burden of STDs on the population as a whole.

BILL SUMMARY

SB 306 includes a benefit mandate. Section 3 and Section 7 would require coverage of STD home test kits, including the laboratory costs of processing the kit. The bill would define "home test kit" as a product approved by the federal Food and Drug Administration (FDA) for the purposes of individuals collecting specimens for STD testing remotely at a location outside of a clinical setting and ordered directly by a clinician or furnished by a standing order based on clinical guidelines and individual patient health needs. SB 306 would apply the benefit coverage of Californians enrolled in a plan or policy regulated by the California Department of Insurance (CDI) or the California Department of Managed Care (DMHC), including Medi-Cal beneficiaries enrolled in DMHC-regulated plans (see Figure A).

Figure A. Health Insurance in CA and SB 306



Source: California Health Benefits Review Program, 2021.

For this analysis, CHBRP has assumed that "approved by the FDA" would be broadly interpreted as including

[1] Refer to CHBRP's full report for full citations and references.
[2] Similar cost and health impacts could be expected for the following year, though possible changes in medical science and other aspects of health make stability of impacts less certain as time goes by.

kits that have FDA approval, have FDA clearance, and/or use the services of Clinical Laboratory Improvement Amendments (CLIA) certified laboratories (the FDA being involved in CLIA certification).

DMHC-regulated plans enrolling Medi-Cal beneficiaries are generally required to cover out-of-network (OON) STD services provided by local health department clinics, family planning clinics, or other community STD service providers. Although FamilyPACT may also cover STD testing for Medi-Cal Beneficiaries, for this analysis, CHBRP has assumed that SB 306 would require these plans to cover STD home test kids when ordered by these OON providers.

CHBRP has also assumed that SB 306 would result, among enrollees in plans and policies that generally cover OON providers, in additional covered use of STD home test kits purchased by enrollees at pharmacies or online. As the sources of such kits employ clinicians and often offer to bill the purchaser's insurance, CHBRP has assumed that SB 306 would require coverage for them as ONN providers.

Should any of these assumptions be incorrect, the impacts projected in this analysis would be smaller by orders of magnitude.

Medical Effectiveness

There is a *preponderance*[3] of evidence that specimens self-collected outside the clinical setting are of equivalent effectiveness as those collected in a clinical environment for the purposes of STD screening, though evidence related to the three basic types of specimen self-collection modalities commonly used in home-to-lab STD test kits (swabs, blood, and urine) varies. For swabs, evidence is *clear and convincing.*[4] For blood, there is a *preponderance* of evidence. For urine, evidence is *limited.*[5]

IMPACTS

Benefit Coverage, Utilization, and Cost

For this analysis, CHBRP estimates the utilization of both in-clinic STD tests and STD home test kits.

Although some in-clinic STD tests may involve clinician-collected specimens and/or on-site laboratory testing, in-clinic STD tests frequently involve self-collection of specimens (at the clinical site) that are then transported to and tested in a CLIA certified laboratory.

Most STD home test kits also involve self-collection of specimens (albeit at home) that are then transported to and tested in a CLIA certified laboratory. This process is similar to that used by at-home colorectal cancer screening kits. Currently, clinicians in the provider groups that are most likely to be in network (INN) for an enrollee (often large medical groups or clinicians attached to hospitals or other facilities) may have administrative mechanisms set up to order an at-home colorectal cancer screening test, rather than the in-clinic version of the test. However, these INN clinicians are **not** currently likely to have similar administrative paths set up to order STD home test kits, and so would be much more likely to order an in-clinic STD test. For this analysis, CHBRP has assumed that the provider situation would be unchanged for the first year postmandate, which would result in no change in utilization among enrollees accessing care through INN providers.

Some clinicians in some of the provider groups more likely to be out of network (OON) for an enrollee (often local health department clinics or family planning clinics) do have the administrative mechanisms needed to order STD home test kits, and so may order either kits or in-clinic testing. Laboratory processing of these specimens would likely also be OON. Therefore, for enrollees in plans and policies that regularly cover OON providers — and for Medi-Cal beneficiaries (whose benefit coverage must include these specific types of OON providers for STD testing and treatment) — CHBRP has projected an increase in use of STD home test kits, postmandate.

Additionally, STD home test kits are available at pharmacies and online, purchasable by an enrollee. The sources of these kits frequently employ clinicians to

[3] A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.
[4] A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.
[5] A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

initiate the laboratory test and be involved in delivering the test results. As of March 15, 2021, there are five online STD home test kit sources in California that accept private insurance. For this analysis, CHBRP has assumed that such STD home test kits, under SB 306, would be considered "clinician ordered" by an OON provider. Laboratory processing of these specimens would likely also be OON. Therefore, for enrollees in plans and policies that regularly cover OON providers - though not for Medi-Cal beneficiaries, as their coverage for STD testing and treatment is limited to specific types of OON providers - CHBRP has projected an increase in use of STD home test kits, postmandate.

There is no substantive differences in test costs by type of STD,[6] thus utilization and costs of STD tests were aggregated for all STDs but broken down for STD home test kits versus in-clinic tests in this analysis. However, in the presentation of utilization and cost of treatment of STDs, HIV, and hepatitis C treatment are shown separately as they have a different utilization pattern (chronic, lifetime use being the norm) and as they have a higher unit cost than for the treatment of other STDs.

CHBRP is unable to determine utilization of testing done for free at community public health programs. When CHBRP refers to self-pay STD test utilization throughout this analysis, some proportion of the utilization in this group may be among those who have obtained STD testing for free. Note that free STD services are typically limited to testing and likely do not apply to treatment, particularly treatment for HIV and hepatitis C, which are generally too expensive to be free.

Benefit Coverage

At baseline, 7% of enrollees in plans and policies regulated by DMHC or CDI have coverage for STD home test kits. Postmandate, 100% would. Please note: the federal cost sharing prohibition for some STD tests is applicable to INN provider services, but not to the additional OON provider services projected in this report.

Utilization

For commercial/CalPERS enrollees in plans and policies regulated by DMHC and CDI, the initial postmandate year increase in STD testing would be primarily limited to enrollees in plans and policies that generally cover OON providers. Among this group (17% of all commercial/CalPERS enrollees), SB 306 would result in 19,732 additional commercial/CalPERS enrollees being tested for STDs. Positive tests among this group would result in 46 more being treated for hepatitis C, 25 more being treated for HIV, and 6,383 more being treated for other STDs.

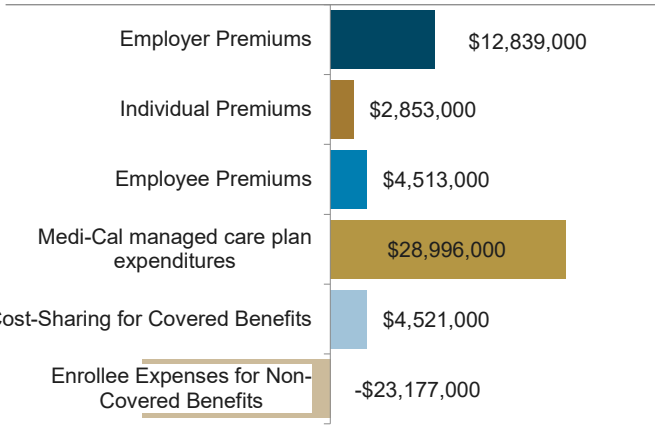
For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, no increase in INN provider ordering of home test kits is expected. However, these plans are required to cover STD testing from a limited set of OON providers (local health departments, family planning or community clinics) and some of these providers have administrative paths set up to order home test kits. Therefore, SB 306 would result in 53,492 additional Medi-Cal beneficiaries being tested for STDs. Positive tests among this group would result in 56 more being treated for hepatitis C, 47 more being treated for HIV, and 20,428 more being treated for other STDs.

No initial postmandate year cost offsets or savings in other healthcare utilization would result because of the enactment of SB 306. However, increased treatment leads to decreased transmission of disease and community spread, which would reduce the burden of STDs on the population as a whole.

Expenditures

SB 306 would increase total net annual expenditures by $30,545,000 or 0.02% for the year following implementation. This is due to an increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, offset by a decrease in enrollee expenses for covered and/or noncovered benefits; see Figure B.

Figure B. Expenditure Impacts of SB 306



Source: California Health Benefits Review Program, 2021.

[6] Kits that test for multiple STDs will appear to have higher costs because they bundle individual STD test costs.

Medi-Cal

Expenditures for enrolling Medi-Cal beneficiaries in DMHC-regulated plans would be expected to increase by $28,996,000 (0.12%).

CalPERS

Expenditures for CalPERS enrollees in DMHC-regulated plans would be expected to increase by $1,479,000 (0.03%).

Number of Uninsured in California

Because the change in average premiums does not exceed 1% for any market segment, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 306.

Essential Health Benefits and the Affordable Care Act

As SB 306 would require coverage for a particular modality of STD testing, rather than coverage for any new test, SB 306 would not exceed EHBs.

Public Health

In the first year postmandate, CHBRP estimates an additional 73,225 people would utilize at-home testing and 26,984 people would seek subsequent treatment for STDs. This includes an increase in treatment and/or follow-up services for 71 people with HIV infections, 102 people with hepatitis C infections, and 26,811 people with other STDs. This estimate is supported by a *preponderance* of evidence that at-home testing is medically effective and a projected increase in utilization (2%) of STD testing and treatment and/or follow-up services for STDs (2%), HIV (0.2%), and hepatitis C (1%).

Although a greater number of people of color are commercial/CalPERS enrollees, people of color represent a higher percentage of Medi-Cal beneficiaries and so the greater OON access for Medi-Cal beneficiaries could lead to a decrease in health disparities related to STDs for people of color.

Long-Term Impacts

Although the first-year impacts of SB 306 would be only among enrollees in plans and policies that generally cover OON providers, it is possible that in the long term there would be an upward trend in the use of STD home test kits by INN providers. The greatest barrier to wider use of STD home test kits is the lack of administrative mechanisms to order home test kits. In the future, it is possible that utilization increases by a greater degree if INN providers in managed care systems are given the opportunity to order home test kits or encouraged to do so through recommendations or financial incentives. Use of home test kits for colorectal cancer (CRC) screening offer an example of how home test kit utilization can increase over time.

The long-term public health impacts of SB 306 would include increased STD screening, a reduction in future STD transmissions (including a reduction in congenital syphilis), and an overall reduction in downstream effects such as impacts on premature death and economic loss.

While there is no estimate of the economic loss associated with STDs overall, in 2021 dollars the economic loss (both direct and indirect) associated with individual STDs are as follows. Note: enrollees in plans and policies regulated by DMCH and CDI are only 55.7% of the state population and their demographics may differ from those of the state as a whole.

- For each case of chlamydia, approximately $409 in direct and $192 in indirect costs would be avoided per case prevented among females. The total burden across California for both males and females is estimated at $90,055,446.
- For each case of gonorrhea, approximately $445 in direct and $222 in indirect costs would be avoided per case prevented among females. The total burden across California for both males and females is estimated at $24,606,153.
- For each case of syphilis, approximately $742 in direct and $145 in indirect costs would be avoided per case prevented. The total burden across California is estimated at $22,200,562.
- For each case of congenital syphilis, approximately $8,743 in direct and $78,396 in indirect costs would be avoided per case prevented. The total burden across California is estimated at $28,668,666.
- For each case of HIV, approximately $257,516 in direct and $1.1 million in indirect costs would be avoided per case prevented. The total burden across California is estimated at $180,432,263,813.

Insofar as it promotes testing, subsequent treatment, and decreased transmission of STDs, SB 306 could decrease these economic burdens as well as improve the lives of tested enrollees and their contacts.

A Report to the California State Legislature

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Health Care: STD Testing

March 31, 2021

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

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

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

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Table 1. SB 306 Impacts on Benefit Coverage, Utilization, and Cost, 2022

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	21,945,000	21,945,000	0	0%
Total enrollees with health insurance subject to SB 306	21,945,000	21,945,000	0	0%
Number of commercial/CalPERS enrollees with coverage for STD home test kits	1,569,187	21,946,000	20,376,813	
Percentage of commercial/CalPERS enrollees with coverage for STD home test kits	7%	100%	93%	
Utilization and unit cost				
STD test utilization per 1,000 enrollees:				
Home test kits				
Self-pay (b)	57.4	45.3	-12.1	-21.06%
Covered	19.1	89.1	69.9	365.55%
In-clinic tests				
Self-pay (b)	133.9	126.1	-7.8	-5.81%
Covered	554.8	522.5	-32.3	-5.81%
STD Treatment (excluding HIV & Hepatitis C)				
Self-pay (b)	83.6	77.6	-6.1	-7.27%
Covered	250.9	263.6	12.6	5.04%
HIV Treatment (monthly drug cost for antiretroviral treatment, not prevention)	27.6	27.7	0.1	0.21%
Hepatitis C Treatment (per 8-week treatment cycle)	0.52	0.52	0.0	0.90%
Average Unit Costs				
Home test kits				
Self-pay (b)	$42	$42	-	0%
Covered	$42	$42	-	0%
In-clinic tests				
Self-pay (b)	$42	$42	-	0%
Covered	$42	$42	-	0%
STD Treatment (excluding HIV and Hepatitis C)				
Self-pay (b)	$68	$68	-	0%
Covered	$68	$68	-	0%
HIV Treatment (monthly drug cost for antiretroviral treatment, not prevention)	$1,965	$1,965	-	0%
HCV Treatment (per 8-week treatment cycle)	$25,000	$25,000	-	0%

Expenditures				
Premiums (expenditures) by payer				
Private employers for group insurance	$55,036,808,000	$15,850,360,000	$2,853,000	0.02%
CalPERS HMO employer expenditures (c)	$5,765,017,000	$5,766,496,000	$1,479,000	0.03%
Medi-Cal Managed Care Plan expenditures	$24,150,529,000	$24,179,525,000	$28,996,000	0.12%
Enrollee premiums (expenditures)				
Enrollees with individually purchased insurance	$15,847,507,000	$15,850,793,000	$3,286,000	0.02%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (d)	$20,755,165,000	$20,759,678,000	$4,513,000	0.02%
Enrollee out-of-pocket expenses				
Cost sharing for covered benefits (deductibles, copayments, etc.)	$13,169,503,000	$13,174,024,000	$4,521,000	0.03%
Expenses for noncovered benefits (e) (f)	$281,450,000	$258,273,000	-$23,177,000	-8.23%
Total expenditures	$135,005,979,000	$135,036,524,000	$30,545,000	0.02%

Source: California Health Benefits Review Program, 2021.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.[7]

(b) Some portion of self-pay testing and treatments may be provided for free via community STD clinics that typically provide free testing, although treatments for HIV and HCV are generally too expensive to be free.

(c) Approximately 54.1% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

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

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

(f) Although enrollees with newly compliant benefit coverage may have paid for some tests before SB 306, CHBRP cannot estimate the frequency with which such situations may have occurred and therefore cannot estimate the related expense. Postmandate, such expenses would be eliminated, though enrollees with newly compliant benefit coverage might, postmandate, pay for some tests for which coverage is denied (through utilization management review), as some enrollees who always had compliant benefit coverage may have done and may continue to do, postmandate.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organizations; STD = sexually transmitted disease; HIV = human immunodeficiency virus

[7] For more detail, see CHBRP's *Estimates of Sources of Health Insurance in California for 2021*, a resource available at http://chbrp.org/other_publications/index.php.

POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[8] conduct an evidence-based assessment of the medical, financial, and public health impacts of SB 306 Sexually Transmitted Disease (STD) Testing.

Bill-Specific Analysis of SB 306, STD Testing

SB 306 includes benefit mandates. Section 3 and Section 7 would require coverage of home test kits for STDs, including the laboratory costs of processing the kit. The bill would define "home test kit" as a product approved by the federal Food and Drug Administration (FDA) for the purposes of individuals collecting specimens for STD testing remotely at a location outside of a clinical setting *and ordered directly by a clinician* or *furnished by a standing order* based on clinical guidelines and individual patient health needs.

The text of the mandates included in SB 306 can be found in Appendix A.

Relevant Populations

If enacted, SB 306 would apply to the health insurance of approximately 21.9 million enrollees (55.7% of all Californians). This represents 100% of the 21.9 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law, which includes health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would apply to the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies.

Analytic Approach and Key Assumptions

"FDA approval of" and "FDA clearance for" STD home test kits are not equivalent terms and rapid test kits do not need the services of laboratories certified by Clinical Laboratory Improvement Amendments (CLIA). Most kits (all but the "rapid" variety) are "home-to-lab." For these, a specimen is self-collected at home using materials and instructions provided in the kit and the kit is then mailed or otherwise transported in a prescribed manner to a laboratory or medical facility for processing and diagnosis. Most kits are cleared and have been validated using in-clinic self-collection. However, when self-collected in a setting outside of a clinic or other medical setting, home self-collection of specimens may not be covered by FDA clearance. In order for a home collection kit to be FDA approved or cleared, it would have to be established that the results of the diagnostic tests are equivalent with a self-collected sample when collected in the home (as compared to a self-collected sample obtained in a clinical environment). Establishing such equivalency can be costly and it has not been done for all available kits.

STD home test kits that are marketed directly to the consumer often refer to using "FDA-approved processes," a phrase that references use of approved laboratory processes for the processing of the specimen — not self-collection in a nonclinical setting. The source of the approval can also take more than one form. While some home-to-lab kits do list that they follow FDA-approved processes for processing and diagnosis, others note only that the labs that will be processing the specimens are certified by CLIA. CLIA is regulated and overseen by three federal agencies including the FDA, the Center for Medicaid Services (CMS), and the Centers for Disease Control and Prevention (CDC). CLIA certification is required by the FDA before a laboratory can accept any human samples for diagnostic testing.

[8] CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.

Of the STD home test kits considered in this analysis, CHBRP is aware that the HIV rapid home test kit is currently FDA approved. Rapid test kits provide diagnostic results immediately to the user, with no need to send the specimen in to a lab. FDA approval or clearance is required for rapid test kits that provide in-home diagnostics, and that are designed specifically for the consumer and not a clinical setting, as all processes are performed by the consumer.

CHBRP has made assumptions in order to analyze SB 306. The assumptions include:

- The bill specifies STD home test kits approved by the FDA. For this analysis, CHBRP has assumed that the phrase would be broadly interpreted so as to include kits that have FDA approval, have FDA clearance, and/or use the services of CLIA-certified laboratories (the FDA being involved in CLIA certification).
- As per the model two-plan contract,[9] DMHC-regulated plans enrolling Medi-Cal beneficiaries must cover out-of-network (OON) STD services provided by local health department (LHD) clinics, family planning clinics, or through other community STD service providers. Although FamilyPACT may also cover STD testing for Medi-Cal beneficiaries, for this analysis, CHBRP has assumed that SB 306 would require these plans to cover STD home test kids when those kits are ordered by clinicians associated with these OON providers.
- As further discussed in the *Benefits, Coverage, and Cost* section, CHBRP has also assumed that SB 306 would result, among enrollees in plans and policies that generally cover OON providers, additional covered use of STD home test kits purchased by enrollees at pharmacies or online.

Should any of these assumptions be incorrect, the impacts projected in this analysis would be smaller by orders of magnitude.

Interaction With Existing State and Federal Requirements

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

California Policy Landscape

California law and regulations

California has quite a number of benefit mandates that are specific to STD testing and treatment. Too complex to be briefly summarized, these laws are listed (along with related federal STD testing and treatment recommendations) in Appendix D.

As noted above, current law[10] requires and current boilerplate contract language[11] specifies that DMHC-regulated plans enrolling Medi-Cal beneficiaries cover STD services provided by OON providers at Medi-Cal's applicable fee for service rate.[12]

Similar requirements in other states

Although benefit mandate laws requiring coverage for STD testing are common, CHBRP is unaware of benefit mandates in other states that specify coverage of home test kits.

[9] See Exhibit A, Attachment 9 in the boilerplate contract, available at https://www.dhcs.ca.gov/provgovpart/Pages/MMCDBoilerplateContracts.aspx
[10] Welfare and Institutions Code 14132.07.
[11] See the Two Plan Model Boiler Plate Contract, available at https://www.dhcs.ca.gov/provgovpart/Documents/Two-PlanCCIFinalRuleBoilerplate.pdf.
[12] The same requirements are applicable to County Organized Health System (COHS) managed care programs, but COHS programs would not be subject to SB 306.

Federal Policy Landscape

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how SB 306 may interact with requirements of the ACA as presently exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[13,14]

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

Essential Health Benefits

Nongrandfathered plans and policies sold in the individual and small-group markets are required to meet a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.[15,16] CHBRP estimates that approximately 4 million Californians (10%) have insurance coverage subject to EHBs in 2021.[17]

States may require plans and policies to offer benefits that exceed EHBs.[18] However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the qualified health plan.[19,20] Health plans and policies sold outside of the health insurance marketplaces are not subject to this requirement to defray the costs. State rules related to provider types, cost sharing, or reimbursement methods would not meet the definition of state benefit mandates that could exceed EHBs.[21]

As SB 306 addresses coverage for a particular modality — home test kits — but does not require new benefit coverage, SB 306 would not appear to exceed the definition of EHBs in California.

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[13] The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories of EHBs. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.
[14] Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law.
[15] CCIIO, Information on Essential Health Benefits (EHB) Benchmark Plans. Available at: https://www.cms.gov/cciio/resources/data-resources/ehb.html.
[16] H&SC Section 1367.005; IC Section 10112.27.
[17] CHBRP, *Estimates of Sources of Health Insurance in California in 2021*. Available at: www.chbrp.org/other_publications/index.php.
[18] ACA Section 1311(d)(3).
[19] State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: https://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.
[20] However, as laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs, and there would be no requirement that the state defray the costs of those state-mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.
[21] Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.

Federally Selected Preventive Services

The ACA requires that nongrandfathered group and individual health insurance plans and policies cover certain preventive services without cost sharing when delivered by **in-network providers** and as soon as 12 months after a recommendation appears in any of a specified set of recommendation lists.[22]

STD screening recommendations that appear in one or more of these lists are presented in Appendix D.

Please note:

- This set is not as broad as the full set of STD recommendations issued by the CDC, which is presented in Appendix F.
- The cost-sharing prohibition is relevant to services from **in-network** providers, and so would not interact with the additional **out-of-network** services projected in this report as a result of SB 306.

[22] See CHBRP's resource, *Federal Preventive Services Mandate and California Mandates*, available at: www.chbrp.org/other_publications/index.php.

BACKGROUND ON SEXUALLY TRANSMITTED DISEASE(S) TESTING

As noted in the *Policy Context*, SB 306 would provide coverage for sexually transmitted disease (STD) home test kits (i.e., a product approved by the federal Food and Drug Administration (FDA) for the purposes of individuals collecting specimens for STD testing in a setting located outside of the clinical setting) either (1) directly ordered by a clinician or (2) furnished by a standing order based on clinical guidelines and individual patient health needs. Typically, the term home test kit refers to a test kit in which an individual collects a sample specimen at home and is notified of their results at the point of testing (such as the HIV rapid test) (CDC, 2020a). The term *home-to-lab test kit* refers to two processes, in which an individual (1) collects a sample specimen at home and (2) subsequently sends their sample to a laboratory for testing (CDC, 2020a). ***Note: For this analysis, the term home test kit will be inclusive of home-to-lab test kits to be consistent with the STD test kit–related language referenced in SB 306.***

It's important to note that there is some precedent for at-home testing of diseases. Innovative screening and testing for other diseases such as colorectal cancer (CRC) have been implemented in health plans nationwide (Bone et al., 2020; Jaklevic, 2021). To date, three types of CRC home screening test kits have been approved by the FDA[23] (Lieberman et al., 2016). Similar to STD home test kits, CRC home screening kits involve home collection of specimens that are mailed directly to a clinic/laboratory for subsequent testing.

This background section provides information related to STD testing as well as relevant STD screening recommendations and testing modalities to provide context for the consideration of the *Medical Effectiveness; Benefit Coverage, Utilization, and Cost Impact;* and *Public Health Impacts* sections. Various modalities of STD specimen collection as well as general STD incidence and prevalence rates are provided in this background section. Specific STD descriptions, home test kits, treatment, and related outcomes are provided in the *Medical Effectiveness* section.

Sexually Transmitted Diseases

STDs are defined as a type of disease or infection caused by a pathogen (e.g., bacterium, virus, or other microorganism) that can be transmitted or acquired via direct sexual contact from person to person (CDC, 2015). Often used interchangeably, the term sexually transmitted infection (STI) refers to an organism acquired via sexual contact, whereas STD refers to a disease state, resulting from the development of an STI (CDC, 2020b). It's important to note that not all infections present with symptoms nor evolve into a disease. For this analysis, the term STD will be used to be consistent with the STD-related language referenced in SB 306.

Obtaining testing — whether it be in clinic or at home — and treatment for STDs in a timely manner are key to limiting adverse health outcomes and to reducing the transmission of disease to noninfected partners. Based on the pathogen, STDs can be categorized into four classes of diseases: (1) bacterial, (2) viral, (3) ectoparasitic (i.e., infection caused by a parasite), and (4) protozoal. As described in the *Medical Effectiveness* section, testing and treatments vary by class of disease. Throughout this report, the term STDs will be used to refer to the STDs that have available home test kits: (1) bacterial (i.e., chlamydia, gonorrhea and syphilis), (2) viral (i.e., genital herpes simplex [HSV-1 or HSV-2], hepatitis B, hepatitis C,[24] human immunodeficiency virus [HIV], human papillomavirus [HPV]), and (3) protozoal STDs (i.e., trichomoniasis) (see Table 3 within the *Medical Effectiveness* section).

[23] FDA-approved CRC screening home test kits include guaiac fecal occult blood test (FOBT), fecal immunochemical test (FIT), and multitarget stool DNA test (FIT-DNA) (Lieberman et al., 2016).
[24] While a majority of individuals diagnosed with hepatitis C become infected through parenteral exposure (i.e., sharing of needles or other injectable equipment), it's important to note that hepatitis C can also be transmitted through sexual activity with an infected individual (CDPH, 2020a).

Based on 2018 CDC STD reporting surveillance data, California ranks among the top states for highest rates of chlamydia (13th), gonorrhea (14th), adult syphilis (3rd), and congenital syphilis (5th) among all states, with more than 327,000 combined cases in 2018 (CDC, 2019; CDPH, 2019a). In addition, there are an estimated 5,000 new cases of HIV and 35,000 new cases of hepatitis C each year in California. At any point in time, it is estimated that millions of Californians are infected with other STDs such as HPV (11 million), genital herpes simplex (2.5 million), and trichomoniasis (330,000). Detailed information related to prevalence and incidence rates can be found in Appendix E Table 14.

Prevention, Screening, and Testing for STDs

Prevention of STDs includes provision of an accurate risk assessment to assess behavioral and biological risk for acquiring or transmitting STDs (CDC, 2015). As part of the health care visit, the CDC (2015) recommends that providers routinely obtain sexual history and address risk reduction through the provision of prevention counseling. Per the United States Preventive Services Task Force, high-intensity behavioral counseling is recommended for sexually active adolescents and young adults who are at an increased risk for acquiring STDs due to a combination of factors, including behavioral, biological, and cultural reasons (CDC, 2015; CDC, 2017a).

Methods to prevent acquisition or transmission of STDs are broad and diverse and vary in efficacy. These include routine screening in populations at higher risk for STDs, pre-exposure vaccinations, abstinence, reduction in the number of concurrent sexual partners at one time, utilization of male or female condoms, male circumcision, and/or post-exposure prophylaxis (PEP) for HIV and STDs (CDC, 2015). Use of antiretroviral treatment of persons with HIV to prevent HIV infection in partners has also been demonstrated to decrease the risk of transmission (CDC, 2015).

Screening for STDs

Screening recommendations for STDs

Per the *CDC STD Treatment Guidelines* (CDC, 2015), all sexually active adults and adolescents should be screened for select STDs on an annual basis at a minimum. STD-specific screening recommendations for asymptomatic women, pregnant women, men, men who have sex with men (MSM), and persons with HIV are summarized below as well as in Appendix F Table 15.

Screening recommendations for bacterial STDs

Screening for both chlamydia and gonorrhea should be conducted at least once a year — and more frequently if at increased risk (e.g., every three to six months among MSM) — among all sexually active women, pregnant women, MSM, and persons with HIV (CDC, 2015). Specific to syphilis, all pregnant women, MSM, and persons with HIV should be screened at least annually, with increased screening among individuals who engage in high-risk behaviors (e.g., having multiple sex partners at once, partaking in inconsistent condom use, and/or having previous or coexisting STDs) (CDC, 2015).

Screening recommendations for viral STDs

Specific to genital herpes simplex, type-specific HSV serologic testing should be considered among women, men, and persons with HIV if presenting for an STD evaluation. Moreover, type-specific serologic tests may also be considered among pregnant women at risk for genital herpes simplex infection as well as MSM who may have previously undiagnosed genital tract infection (CDC, 2015). All women and men at high risk for infection as well as MSM and persons with HIV should be screened for hepatitis B. In addition, pregnant women should be screened for hepatitis B during their first prenatal visit and be retested at delivery if presenting with high risk factors (CDC, 2015). As of 2020, the CDC recommends that all adults and all pregnant women during each pregnancy be screened for hepatitis C (Schillie et al., 2020). Specific to HIV, all adults and adolescents (aged 13 to 64 years) should be screened at least once,

whereas all sexually active MSM are encouraged to be screened for HIV on an annual basis (and more frequently if at increased risk). Anyone engaging in unsafe sex or shared use of injection drug equipment should also be screened for HIV at least once a year (CDC, 2015). Women aged 21 to 29 years should be screened for cervical cancer every three years with cytology, whereas women aged 30 to 65 years should be screened for cervical cancer every three to five years with cytology along with testing for HPV. In addition, among women presenting with HIV, screening for cervical cancer should be conducted within one year of sexual activity or upon initial HIV diagnosis (CDC, 2015).

Screening recommendations for protozoal STDs

Screening for trichomoniasis should be considered for women receiving care in high prevalence settings such as STD clinics or correctional facilities as well as among women considered at high risk for infection (e.g., having multiple sex partners, a history of illicit drug use, etc.). In addition, trichomoniasis screening is recommended for women presenting with HIV at the onset of care and on a yearly basis (CDC, 2015).

Current state of screening for STDs

Despite broad recommendations for STD screening among target populations and expanded screening over the past 20 years, data indicate that there is vast room for improvement (CDC, 2019; Cuffe et al., 2016; Dailey et al., 2017; NCQA, 2021). In a national STD survey of adolescents and young adults (AYA), aged 15 to 25 years, Cuffe et al. (2016) found very few AYA received recommended screening for STDs — only 16.6% and 6.6% of females and males, respectively, had been tested within the last year. Dailey et al. (2017) found that delayed HIV diagnoses among high-risk populations (e.g., MSM, sex partners of persons with HIV infection, etc.) continued to be substantial due to missed screening opportunities. In fact, a majority of patients at high risk for HIV (>75%) reported not being offered an HIV test during their primary care visit within the last 12 months (Dailey et al., 2017). Furthermore, despite increased screening for chlamydia within commercial and Medicaid managed care plans nationwide over the past two decades — with rates increasing from 23.1% and 40.4%, respectively, in 2001 to 51.5% and 58%, respectively, in 2019 — there is a clear need for continued and expanded screening for STDs (CDC, 2019; NCQA, 2021).

STD Testing and Method of Collection of Specimen

STD testing is comprised of two processes: (1) sample specimen collection and (2) subsequent testing of the specimen. Specific to the first process, sample specimen can be collected in a clinical or home setting using various collection modalities. Once a sample specimen has been collected, testing can be conducted either (1) rapidly, in which results are provided on the spot, either at home or in clinic; or (2) in a laboratory setting.

Sample specimen collection modalities

Sample specimen collection modalities are broad and can vary by type of STD. For example, specimen collection can include serologic sampling via finger prick or venipuncture; urine sampling; and/or swabbing of various anatomical sites, including the endocervix, urethra, vagina, rectum, oral cavity, oropharynx, and/or the conjunctiva (i.e., pertaining to the eye) (Unemo et al., 2013). Sample STD specimen collection modalities per select STD are presented in Table 3 within the *Medical Effectiveness* section. Note: Certain specimen collection modalities (i.e., cervical swab, conjunctiva swab, and venipuncture) can only be performed in a clinical setting and therefore would not be available in-home test kits.

At-home specimen collection vs. in-clinic specimen collection

Specimen collection specific for STD testing can be conducted via at-home collection and/or in-clinic collection. Differences between at-home and in-clinic specimen collection procedures for STD testing may

include location of specimen collection, type of specimen collection device used, specimen transport conditions, and specimen delivery (Fajardo-Bernal et al., 2015). It's important to note that laboratory methods for testing the sample specimen, whether collected at home or in clinic, are the same. A complete list of at-home versus in-clinic specimen collection procedures specific to chlamydia and gonorrhea can be found in Table 2.

Table 2. Comparison of Specimen Collection Procedures for the Detection of Chlamydia and Gonorrhea

Specimen Collection Component	At-Home Procedures	In-Clinic Procedures
Place of specimen collection	At home	In clinic
Process for specimen collection	Self-collected	Self-collected or physician collected
Specimen collection device	Could differ	Could differ
Specimen transport conditions	Possible mailing delays, ambient temperatures	Anticipate fewer delays, with potential for cold chain transportation
Specimen delivery	Patient mails or delivers to laboratory or clinic	No involvement for patient
Specimen processing	Same	Same
Accuracy of the diagnostic test	Same	Same
Process for notifying provider of results	Same	Same
Process for notifying patient of results	Could differ	Could differ
Treatment	Same	Same
Partner management and patient follow-up	Same	Same

Source: California Health Benefits Review Program, 2021, adapted from Fajardo-Bernal et al., 2015.

At-home rapid testing vs. in-clinic rapid testing

STD testing can also be conducted via rapid testing. As there is no universally accepted definition for rapid testing, for the purpose of this analysis, rapid testing refers to a simple test that can provide rapid results to help inform patient treatment and management during the same clinical encounter (Tucker, 2013). To date, in-clinic rapid tests are available for: (1) bacterial (i.e., chlamydia, gonorrhea, and syphilis), (2) viral[25] (i.e., genital herpes simplex, hepatitis B, hepatitis C, HIV), and (3) protozoal STDs (i.e., trichomoniasis) (Tucker, 2013). Although a majority of rapid tests are available in-clinic, one at-home rapid test is available for HIV — which is the same one utilized in clinical practices (FDA, 2020; Tucker, 2013). Sample specimen collection modalities related to rapid testing also vary by STD and can include swabbing of various anatomical sites (i.e., urethra, vagina, or oral cavity) or serological sampling via finger prick.

Settings for STD Testing

In addition to accessing STD screening/testing and related services via traditional medical provider offices, Californians can also access STD screening/testing in a variety of settings throughout the state. Additional settings include: Federally Qualified Health Centers, Planned Parenthood Clinics, Local County

[25] Although an in-clinic rapid test is available for HPV, it is not currently available in the United States (Qiagen, 2021).

Public Health Departments, Rural Health Clinics, and Wellness Centers (sponsored by the AIDS Healthcare Foundation).

Clinician ordered at-home testing or specimen collection

There is very limited data on the current state of clinician-ordered at-home STD specimen collection kits (i.e., home test kits) in the United States, as the field has only recently begun to (1) consider implementation and/or (2) integrate these kits into their traditional clinical care model (Pearson et al., 2018; Peterman et al., 2018; Zigman, 2020).

Programs offering at-home specimen collection or at-home rapid tests

There are several programs that offer at-home STD specimen collection in California. For example, the Los Angeles County and Alameda County Departments of Public Health offer free at-home specimen collection tests (i.e., home test kits) for chlamydia and gonorrhea through the Don't Think, Know program (ACPHD, 2021; Don't Think, Know, 2021). All women under the age of 25 are eligible to order home test kits via phone, with delivery handled by mail (Don't Think, Know, 2021). Once in receipt, the user will send their specimen sample via mail back to the county lab, with results made available via phone or online within one week (ACPHD, 2021; Don't Think, Know, 2021). Planned Parenthood also offers a home test kits for a fee for chlamydia and gonorrhea via their mobile application, Planned Parenthood Direct, with delivery handled by mail (Planned Parenthood Direct, 2020). Once in receipt, the user will send a urine sample to the Planned Parenthood lab and will be notified of their results via mobile application (Planned Parenthood Direct, 2020). It's important to note that the Planned Parenthood Direct home test kits for gonorrhea and chlamydia are the same kits utilized within the healthcare centers (2020).

In addition, Riverside County Department of Public Health offers free, at-home HIV rapid tests through the TakeMeHome program (RCDPH, 2021). The HIV test can be ordered via the TakeMeHome website and subsequently delivered by mail (RCDPH, 2021). Once a blood sample has been collected via finger prick, results are available within 20 minutes (RCDPH, 2021).

An increasing number of online platforms offer home test kits in California — among other states — for a fee (Frederiksen et al., 2020). Although some platforms require a virtual consultation for a fee prior to the purchase of a home test kit, a majority allow individuals to purchase one without a consultation, ranging between $39 to $522 for select kits (Frederiksen et al., 2020).[26] Depending on the type of home test kit, users will collect their specimen via urine sampling, blood sampling, or swabbing and mail their sample back for testing in a laboratory (Frederiksen et al., 2020). In addition, some online platforms allow individuals to order a lab test. Once an order has been placed, the user can walk into an affiliated lab/clinic — with or without an appointment — for sample collection (Frederiksen et al., 2020). Across platforms, once the specimen has been tested by a lab, users will typically receive results via their online platform (Frederiksen et al., 2020).

Barriers to STD Testing

A number of barriers have been identified in accessing STD testing and related services, both in clinical and home settings. Summaries within each setting are provided below.

Barriers to in-clinic STD testing

A number of barriers have been identified in accessing STD testing and related services, including clinic inaccessibility; lack of knowledge and/or awareness; concerns about patient privacy and confidentiality;

[26] Although a few online platforms accept private insurance and/or Medicaid to cover the costs of a home-to-lab test kit, a majority of these programs do not accept insurance nor offer sliding fee scale options for uninsured individuals (KFF, 2020).

patient stigma and/or embarrassment; patient discomfort; patient perceptions of risk and discrimination; lack of time needed to attend appointments; as well as lack of financial resources or insurance needed to pay for related health care costs (Parrish and Kent, 2008; Paudyal et al., 2015). Furthermore, with the emergence of the COVID-19 (i.e., the coronavirus disease 2019 caused by severe acute respiratory syndrome-coronavirus-2 [SARs-CoV-2]) pandemic in early 2020, additional barriers and challenges to accessing in-clinic STD testing and related services have recently been identified (Melendez et al., 2021). As state governments implemented restrictions to slow the transmission of COVID-19 in March of 2020, access to preventive and clinical care was greatly reduced as clinics and public health departments redeployed staff and resources to respond to the COVID-19 pandemic (Melendez et al., 2021; NCSTDD, 2020a; NCSTDD, 2020b; State of California, 2020). In surveys distributed to health department STD programs and clinics in mid-March 2020 and June 2020, respectively, NCSTDD found that 83% of STD programs were deferring services; 61% were experiencing reduced provision of related services; and more than three quarters (78%) of STD programs had temporarily redeployed their workforce due to COVID-19 (Melendez et al., 2021; NCSTDD, 2020a; NCSTDD, 2020b).

Barriers to clinician ordered at-home testing or specimen collection

As noted in the *Policy Context*, SB 306 provides coverage for home test kits ordered by a clinician or provided via standing order (i.e., a preauthorized clinical order with specific instructions from a clinician to administer a home-test kit based on clinical guidelines and individual patient health needs). Several studies identified barriers to at-home testing or specimen collection. In a study examining local health department approaches and challenges to implementing the use of home test kits, Zigman (2020) identified several barriers to implementation. Despite local health departments (LHD) across the nation understanding the need to implement innovative STD testing strategies that also reduce stigma related to seeking testing and treatment, lack of funding mechanisms to support the provision of home-to-lab testing (i.e., inability to purchase sufficient test kits and required development of eligibility criteria), administrative roadblocks (i.e., difficulty in establishing order mechanisms for home-to-lab testing, insufficient staffing capacity, and low organizational buy-in), and limited validation of STD home-to-lab test kits by public health laboratories were cited as leading barriers to LHD implementation (Zigman, 2020).

Disparities[27] and Social Determinants of Health[28] in STDs

Per statute, CHBRP includes discussion of disparities and social determinants of health (SDoH) as it relates to STDs and testing for STDs. Disparities are noticeable and preventable differences between groups of people. SDoH include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography, etc.).

CHBRP found literature identifying disparities and SDoH in STDs by race/ethnicity, age, gender[29], gender identity, sexual orientation, incarceration status, socioeconomic status, and accessing testing.

[27] Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population. (Wyatt et al., 2016).
[28] CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from: CDC, 2014; Healthy People 2020, 2019). See CHBRP's SDoH white paper for further information: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.
[29] CHBRP uses the NIH distinction between "sex" and "gender:" "'Sex' refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. 'Gender' refers to socially constructed and enacted roles and behaviors which occur in a historical and cultural context and vary across societies and over time." (NIH, 2019).

Disparities and SDOH in STDs

Race or ethnicity

According to the CDC (2017b), disparities persist among racial and ethnic minorities (including Hispanic groups) related to rates of STDs compared to rates of STDs among Whites within the United States. These disparities cannot be explained by individual or behavioral differences, but rather stem from systemic, societal, and cultural barriers in accessing STD testing and related services (CDC, 2017b). It's important to note that racial/ethnic differences in STD rates may be undercounted for certain minority groups (e.g., Hispanics) as many case reports do not include racial or ethnic data (CDC, 2017b). In 2018, racial disparities were found among Blacks, Hispanics/Latinos, and Native Hawaiians and Other Pacific Islanders (not inclusive of Asians) specific to select STDs required to be reported to the CDC (i.e., chlamydia, gonorrhea, syphilis, and congenital syphilis) within the United States (CDC, 2020c; CDC, 2020d; CDC, 2020e). Similarly, racial and ethnic disparities in rates of STDs — especially among Black/African Americans and Hispanic/Latinos — have been identified in California since at least 2009 (California Health Report, 2017). Appendix G Table 16 identifies the number of new STD cases — including cases of chlamydia, gonorrhea, syphilis, and congenital syphilis — by race/ethnicity in California in 2018.

Age

In 2018, adolescents and young adults (AYA), aged 15 to 24 years, comprised one-fifth of all prevalent STD infections in the United States (equal to 12.6 million), with 45.5% (11.9 million) representing incident infections (Kreisel et al., 2021). These rates suggest that nearly half of all newly diagnosed/reported STDs are among the AYA population in the United States (Kreisel et al., 2021). In California, female AYA had the highest incidence rates of chlamydia compared to all other age groups, equal to 6,213 per 100,000 in 2018 (CDPH, 2019a). Similarly, Californian AYA accounted for the highest incidence rates of gonorrhea (834 per 100,000) compared to all other age groups in 2018 (CDPH, 2019a). Disparities persist among sexually active AYA (aged 15 to 19 years and 20 to 24 years, respectively) as these individuals may be at higher risk for STD acquisition due to a combination of factors (CDC, 2017c). High-risk factors include having more than one sexual partner at one time, having sequential sexual partnerships during a condensed period of time, opting out of or failing to use barrier protection appropriately, and facing multiple barriers to accessing primary care services (e.g., lack of access to quality STD prevention, treatment, and management; inability to pay; lack of transportation; and schedule conflicts related to clinic hours of operation and work/school schedules (CDC, 2017c).

Women and infants

Chlamydia and gonorrhea disproportionately affect women (including pregnant women), as women often present as asymptomatic during early infection, leading to the development of more serious health consequences (CDC, 2017d). If left untreated, these infections may lead to pelvic inflammatory disease, a very severe disease that can result in infertility and/or ectopic pregnancy among women (CDC, 2017d). Pregnant women[30] are at increased risk for STDs and can experience severe complications due to intrauterine (i.e., within the uterus) or perinatally transmitted (i.e., mother-to-child transmission) STDs (CDC, 2015). In 2018, the number of infants born with congenital syphilis increased 40 percent nationwide, with 25 percent of cases stemming from California (CDPH, 2021). Factors related to increased risk among pregnant women are broad and may vary by STD. For example, specific to gonorrhea among pregnant women, risk factors may include living in a high-morbidity area; prevalence of current or previous coexisting STDs; having multiple concurrent sex partners; and/or opting out of using barrier protection.

[30] CHBRP uses the term "pregnant women," but recognizes that some individuals may identify as male or nonbinary and may also have female reproductive organs.

Gender identity[31]

Transgender persons are defined as individuals who identify with a sex that varies from what they were assigned at birth given their anatomy (CDC, 2015). For example, transgender women (also referred to as trans-women or transgender male to female) identify as women despite being assigned as male at birth due their anatomy. Similarly, transgender men (also known as trans-men or transgender female to male) identify as men despite being assigned as female at birth due their anatomy. It's important to note that gender identity is separate from sexual orientation and transgender persons may use varied and fluid terminology to identify themselves throughout their life course (CDC, 2015). Among the few studies reporting on STD prevalence among transgender persons, evidence suggests that transgender women are at higher risk for STDs (such as HIV) given their diverse sexual practices and preferences (such as having sex with men, women, or both at the same time, or identifying as heterosexual, gay, lesbian, queer, or bisexual) and increased engagement in risky sexual behaviors (CDC, 2015; Operario et al., 2008).

Sexual orientation

According to the CDC (2017a), disparities exist among MSM in comparison to women and men who have sex with women. MSM are defined as a broad and diverse group of individuals who have varied sexual behaviors, identities, and individualized health care needs (CDC, 2015). Disparities among MSM reflect those observed in the general population, in which STDs disproportionately affect racial minority and Hispanic MSM as well as MSM of lower socioeconomic status, and young MSM (CDC, 2017a). Of 35,053 total reported primary and secondary syphilis cases nationwide in 2018, MSM accounted for 64.3% of reported primary and secondary syphilis cases among women or men with information specific to sex of sex partners, despite accounting for an estimated 3.8% to 6.4% of men in the U.S. population (CDC, 2019; Mauck et al., 2019). Within California, nearly 7 out of 10 early syphilis male cases were among MSM in 2018 (CDPH, 2020c). The higher burden of STDs of MSM may be indicative of having a broad and diverse sexual network; increased likelihood for substance use; increased rates of practicing unsafe sexual practices; reduced access to screening, treatment, and management; and/or having differential experiences with stigma and discrimination (CDC, 2017a).

Women who have sex with women (WSW) are a diverse group of individuals who have varied sexual identities, sexual behaviors and practices, as well as risk behaviors (CDC, 2015). According to the CDC (2015), studies have reported that some WSW, specifically adolescents and young women and women with concurrent female and male sexual partners, are at increased risk for STDs and HIV. Factors related to increased risk among WSW include having diverse sexual practices; increased risk behaviors; and opting out of using barrier protection such as gloves, condoms, and/or dental dams.

Persons in correctional facilities

Multiple studies have reported that incarcerated individuals — especially individuals aged 35 years and younger — are at high risk for STDs, including HIV and viral hepatitis (CDC, 2015). Incarcerated individuals disproportionately draw from populations with lower socioeconomic status and those living in urban areas. As reported in Hogben and Leichliter (2008), incarceration can also lead to the disruption of sexual networks and contribute to the maintenance of poverty, thereby leading to further economic disadvantage among individuals living in poverty, which is also known to be associated with STD acquisition (see SES summary below).

[31] CHBRP defines gender identity as one's internal sense of one's own gender, or the gender in which a person identifies, whether it be male, female, or nonbinary. Gender identity and sexual orientation are different facets of one's identity; an individual's gender does not determine a person's sexual orientation (i.e., a person's emotional, romantic, or sexual attraction to other people) (ACOG, 2020; CDC, 2017).

Socioeconomic status

Socioeconomic status (SES) is defined as an individual's or population's position within a social structure and is typically measured as a combination of education, income, and/or occupation (Winkleby et al., 1992). Studies have indicated an association between low SES and the acquisition of STDs (Dean and Fenton, 2010; Hogben and Leichliter, 2008). Researchers found that a lack of resources and inequality of resource distribution increased the likelihood for risky sexual behavior, lack of access to health care services, as well as increased STD rates. Moreover, poverty and lack of employment were also found to be associated with an increased likelihood for having a broader and more diverse sexual network.

Accessing STD testing and related services

Disparities in accessing STD testing and related services exist among racial/ethnic and sexual minority groups (i.e., WSW and MSM) as these populations are more likely to be uninsured compared to non-Hispanic Whites; women in different-sex relationships; or men in different-sex relationships, respectively (Berchick et al., 2019; Buchmueller and Carpenter, 2010; DHHS, 2020). Therefore, given disparities in access to health care coverage, these populations have limited access to health care services (e.g., access to STD testing) (DHHS, 2020). Identified barriers to health care access include lack of transportation and childcare, inability to take time away from work, communication and/or language barriers, discrimination, medical mistrust, and racism (DHHS, 2020).

Societal Impact of STDs in California

The presence of STDs in the United States creates a societal impact. In dollar terms, the societal impact can be both direct (medical care) and indirect (e.g., lost wages, etc.). Chesson et al. (2008) calculated the direct (i.e., average medical cost per case of select STDs) and indirect (i.e., average lost productivity costs per untreated case of select STDs) cost of STDs in 2006. Translated into 2021 dollars, they estimated that syphilis would cost $742 per case in direct costs and $145 in indirect costs which would translate into a total of $22.2 million in California. Congenital syphilis was estimated to cost $8,743 in direct costs and $78,396 in indirect costs per case for a total of $28.7 million for the 329 cases. Chlamydia is estimated to cost $90 million in both direct and indirect costs and gonorrhea is estimated to cost $24.6 million overall in California. Due to the chronic nature of HIV infection, it is estimated to cost $257,516 in direct medical costs and $1.08 million in indirect costs per case for a total cost of $180 billion in direct and indirect costs for the 135,000 individuals living with HIV in California (CDPH, 2020; Chesson et al., 2008).[32] Although the majority of HPV infections resolve on their own, those that don't result in more than 4,600 cervical cancer cases in California each year. Adjusting estimates from Max et al. (2003) for the impact of cervical cancer in California in 1998 to 2021 dollars results in an estimated $330 million in direct and indirect costs related to cervical cancer. Please note: The societal impact discussed here is relevant to a broader population than SB 306 impacts, which would affect the health insurance of a subset of Californians (see *Policy Context*). See the *Benefit Coverage, Utilization, and Cost Impacts* section for estimates of cost impacts for the specific population targeted by SB 306.

[32] Data for the indirect and direct costs per case for each disease was taken from Chesson et al. (2008) and adjusted to 2021 dollars. This figure was then applied to the number of cases presented in Appendix E Table 14 and added together to get a total combined direct and indirect costs per disease.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, SB 306 would require coverage of home test kits for sexually transmitted diseases (STDs), including the laboratory costs of processing the kit. The bill would define "home test kit" as a product approved by the federal Food and Drug Administration (FDA) for the purposes of individuals collecting specimens for STD testing outside of a clinical setting and ordered directly by a clinician or furnished by a standing order based on clinical guidelines and individual patient health needs.

As noted in the *Background* section, throughout this report the term STDs will be inclusive of the STDs that have available home-to-lab test kits: (1) bacterial (i.e., chlamydia, gonorrhea, and syphilis), (2) viral (i.e., genital herpes simplex [HSV-1 or HSV-2], hepatitis B, hepatitis C, human immunodeficiency virus [HIV], human papillomavirus [HPV]), and (3) protozoal STDs (i.e., trichomoniasis).

Research Approach and Methods

As detailed in the *Background* and *Public Health* sections of this report, the main difference between home-to-lab test kits and similar processes where the specimen (self-collected or otherwise) is collected in a clinical environment is the location of the self-collection of the specimen. When the specimen is self-collected outside of the clinical environment, the consumer depends upon written or other forms of instructions, and collection apparatus have varying degree of user-friendliness. Therefore, users do not generally have immediate and clear instructions or access to experts for questions on process and safety as they would when self-collecting in a clinical environment. Additionally, when self-collected in a clinical environment, it is generally assumed that specimens will be properly stored and transported in order to maintain maximum viability when they are processed by a laboratory (if not processed immediately on the premises). Many home-to-lab test kits have worked to address these issues by designing easy-to-use collection apparatus, providing clear instructions, and having help available in the event a consumer is encountering difficulties with the process. They also endeavor to design the return process to ensure the sample arrives at a lab as quickly as possible without being subject to undue environmental and other stresses (e.g., heat, cold, undue time lag). Once at the lab, with some exceptions, specimens self-collected at home are processed in the same way as those obtained through self- or clinician-collection. Therefore, the main factor of interest for this analysis of medical effectiveness is the equivalency of the specimens self-collected at home versus those in a clinical environment with regard to diagnostic testing.

In order to examine this question, it must first be acknowledged that not all self-collected specimens are of the same type and must therefore be addressed by modality. As shown in Table 3, there are three basic types of self-collection modalities commonly used in home-to-lab STD test kits: (1) specimens obtained using swabs, (2) blood specimens, and (3) urine specimens. As further shown in the table, swabs can be further broken down into at least six types based on what part of the body the swab is used to collect a specimen from. Although the table displays modalities that are in use for self-collection for each type of STD, it is important to note that each modality can be differentially effective across STDs with regard to screening and testing.

The following analysis will review the literature regarding the effectiveness of each of these three modalities with regard to providing a specimen of equivalent effectiveness of that collected in a clinical setting with regard to diagnostic testing for STDs.

Table 3. Sample STD Specimen Collection Modalities

STD/STI	Collection Modality						
	Blood Sample	Urine Sample	Cervical Swab	Oral (i.e., Mouth swab)	Oropharynx (i.e., Throat) Swab	Rectal Swab	Vaginal Swab
Bacterial							
Chlamydia		X	X*		X	X	X
Gonorrhea		X	X*		X	X	X
Syphilis	X						
Viral							
Genital Herpes Simplex	X						X
Hepatitis B	X						
Hepatitis C	X						
Human immunodeficiency virus (HIV)	X			X			
Human papillomavirus (HPV)		X	X*	X	X	X	X
Protozoal							
Trichomoniasis		X					X

Source: California Health Benefits Review Program, 2021, adapted from Unemo et al., 2013; Molecular Testing Labs, 2021; Nurx, 2021; OraQuick, 2021; Planned Parenthood, 2021.

Note: * Indicates specific type of specimen collection modality only available in-clinic.

Key: STD = sexually transmitted disease; STI = sexually transmitted infection.

Studies of relevant disease/condition were identified through searches of PubMed, Embase, CINAHL, and Business Source Complete. The search was limited to abstracts of studies published in English.

The search was limited to studies published from 2010 to present. CHBRP relied on a systematic review published in 2018 for findings from studies published prior to 2010. The medical effectiveness literature review returned abstracts for 248 articles, of which 45 were reviewed for inclusion in this report. A total of 14 studies were included in the medical effectiveness review, five of which were systematic reviews. The other articles were eliminated because they did not focus on self-collection of specimens, were of poor quality, or did not report findings from clinical research studies. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.[33] Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

Key Questions

1. Do specimens self-collected in the home setting by means of ***swab*** provide diagnostic results comparable to self-collected samples collected in a clinical setting?

2. Do specimens self-collected in the home setting by means of ***blood sample*** provide diagnostic results comparable to self-collected samples collected in a clinical setting?

[33] Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. For more information on CHBRP's use of grey literature, visit http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

3. Do specimens self-collected in the home setting by means of a ***urine sample*** provide diagnostic results comparable to self-collected samples collected in a clinical setting?

Outcomes Assessed

The primary outcome assessed through this analysis is equivalency or non-inferiority of self-collected specimen samples collected outside of the clinical environment versus clinician-collected specimen samples for the purposes of screening and testing for STDs. Most studies reviewed present their findings as a relative comparison of the effectiveness of the two specimen collection methods.

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of specimen self-collection outside the clinical setting as compared to self-collected or clinician-collected in a clinical setting for the use of STD/STI testing.

The following terms are used to characterize the body of evidence regarding an outcome:

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

Preponderance of evidence indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

Limited evidence indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.

Inconclusive evidence indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

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

More information is available in Appendix B.

Do Specimens Self-Collected in the Home Setting by Means of Swab Provide Diagnostic Results Comparable to Self-Collected Samples Collected in a Clinical Setting?

Home self-collection of specimens using swabs is primarily used for home-to-lab diagnostic tests for chlamydia, gonorrhea, HIV, HSV-2, HPV, and trichomoniasis. The swab modalities vary, but most often are vaginal or rectal swabs, although other modalities are used in some test kits (see Table 3).

The analysis for self-collection methods for screening for chlamydia and gonococcal infection draws primarily from two systematic reviews and meta-analyses. The first (Lunny et al., 2015) reviewed 21 studies (14 examining chlamydia, one examined gonorrhea, and six included both chlamydia and gonorrhea) that compared self- and clinician-collected specimens with regard to accuracy of screening

results. They found that for women, self-collected vaginal swabs had sufficient sensitivity and specificity to be recommended for home-based screening via self-collection.

Another systematic review and meta-analysis examining self- and clinician-collected methods for STI screening for females aged 14 to 50 years (Odesanmi et al., 2013). Three of the six trials in the analysis (Graseck et al., 2011; Jones et al., 2007; Lippman et al., 2007) included self-collected specimen quality as an outcome. The studies included a total of 2,002 subjects and examined the use of self- versus clinician-collected vaginal swabs for use in molecular diagnostic techniques (e.g., NAAT or nucleic acid amplification testing) for the diagnosis of chlamydia and gonorrhea. It was concluded that, given adequate instructions, women are able to provide a self-collected sample equally effective to that collected by clinicians for use in molecular diagnostic techniques.

For the detection of HSV-2, cervicovaginal lavage (CVL) has been a primary self-collected specimen method for women (McNicholl et al., 2017). The most common self-collection method is by self-collected vaginal swab. In a study of 67 women enrolled in a clinical trial, it was found that SCS were equally as effective for the detection of HSV-2 as CVL (McNicholl et al., 2017). In another study examining the effectiveness of self-collected samples for HSV patients, 112 participants (54% women) self-collected anogenital and oral swabs on a daily basis. It was concluded that self-collection is a reliable means of obtaining specimens for the purposes of the detection of both HSV-1 and HSV-2 (Mujugira et al., 2015).

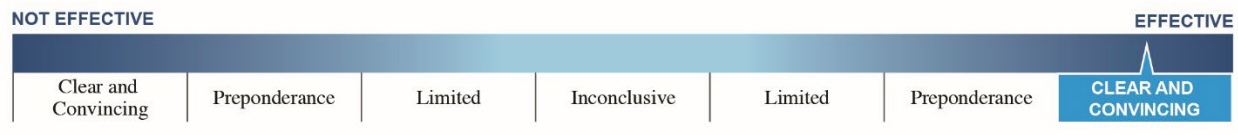
Another systematic review and meta-analysis (Arbyn et al., 2014) reviewed 36 studies covering 154,556 women who had conducted both a self-collected vaginal sample and also had a clinician-collected sample. They found that the self-collected sample overall performed slightly worse than the clinician-collected sample with regard to sensitivity and specificity for some tests, but for PCR-based HPV tests the self-collected specimens performed at an equivalent level to the clinician-collected specimens.

HIV is the one STD in this analysis for which both home-to-lab and rapid test kits are covered. Like home-to-lab kits, rapid test kits also require a self-collected specimen often collected outside of a clinical setting. However, unlike the home-to-lab kits, rapid test kits provide the user with immediate results to the diagnostic testing or screening. While ease of specimen collection, user-friendliness, and specimen viability are still concerns, the potential complications and specimen degradation due to transport are not concerns for rapid tests as the specimen is used immediately by the consumer.

There is only one FDA-approved rapid test for HIV that provides results to the consumer without sending to a lab or clinic for processing (OraQuick). This test utilizes an oral fluid sample (gum swab). In validation and approval studies, the OraQuick was tested on 4,999 individuals of unknown HIV status. Of most interest to this analysis, only 1% of the self-collected samples did not result in a valid test result. This indicates the oral swab method is highly effective with regard to providing a variable sample for rapid testing. Furthermore, the OraQuick home rapid test showed a sensitivity of 92%, indicating that 8 of 96 people who were HIV positive tested negative (false negative), and a very high specificity of 99.99%, meaning very few false positives (only 1 of 4,903) (OraQuick).

CHBRP found *clear and convincing* evidence based on four systematic reviews as well as multiple individual studies that specimens self-collected outside the clinical setting using **swabs** are of equivalent effectiveness as those collected in a clinical environment for the purposes of STD screening.

Figure 1. Medical Effectiveness of Self-Collected Specimens Collected via Swab Sample for STD Screening and Testing



Do Specimens Self-Collected in the Home Setting by Means of *Blood Sample* Provide Diagnostic Results Comparable to Self-Collected Samples Collected in a Clinical Setting?

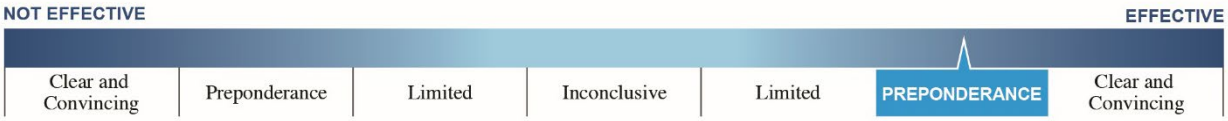
Home self-collection of specimens using blood specimens is primarily used for home-to-lab diagnostic tests for syphilis, HSV-2, hepatitis B and C, and HIV. Self-collection techniques for the screening of syphilis most often involve the collection of a blood sample known as a dried blood spot (DBS). In the DBS technique, blood is collected by means of a finger prick, which produces a drop of blood that is pressed onto a specially treated card. The card is then inserted into protective packaging and mailed back to a lab for processing. DBS techniques have the advantage of robustness against transport and environmental stressors, as well as ease of collection as compared to blood samples collected and transported as a liquid sample such as in a tube or vial. They also have been shown to provide a specimen viable for testing when self-collected in a nonclinical environment such as the home. For example, in one study, 183 men who have sex with men (MSM) were asked to self-collect a blood specimen sample using DBS cards. The investigators reported no difference in specimen quality between self- and clinician-collected specimens, and found in 91% of the cases that sufficient quantity of material was provided to perform tests for syphilis as well as HIV and hepatitis B (van Loo et al., 2017).

The self-collection of a specimen suitable for testing for hepatitis B and C can likewise be done by use of the DBS technique. In one small study of 39 patients, it was found that the self-collected DBS technique provided specimens that correlated highly with those collected by clinicians with regard to the detection of hepatitis C (Prinsenberg et al., 2020). In another study of the use of the DBS technique for self-collection of specimens for hepatitis B testing, 91% (198 of 217) of the returned samples contained sufficient materials to be tested, and the resulting tests had comparable sensitivity and specificity as seen for clinician-collected samples (van Loo et al., 2017).

However, although the DBS technique is the most widely used, some commercially available home test kits require a larger sample than that generally obtained through DBS techniques. In this case, blood is also accessed by means of finger prick, but is then collected in a blood collection tube. This type of collection has the potential limitation of inadequate sample volume. One study of a pilot home-care program found only 81% of the returned sample vials contained enough blood for processing for multiple tests including chlamydia, gonorrhoea, hepatitis B, and syphilis self-sampling (23 of 28 samples) (Leenen et al., 2020). In another larger study, 411 participants were asked to obtain a self-collected blood sample via finger prick as part of the validation and testing of a rapid test kit. The great majority of participants (99%) were able to obtain a sufficient sample of the purposes of screening (Prazuck et al., 2016).

CHBRP found a *preponderance* of evidence based on four individual studies that **blood sample** specimens self-collected outside the clinical setting are of equivalent effectiveness as those collected in a clinical environment for the purposes of STD screening.

Figure 2. Medical Effectiveness of Self-Collected Specimens Collected via Blood Sample for STD Screening and Testing



Do Specimens Self-Collected in the Home Setting by Means of a *Urine Sample* Provide Diagnostic Results Comparable to Self-Collected Samples Collected in a Clinical Setting?

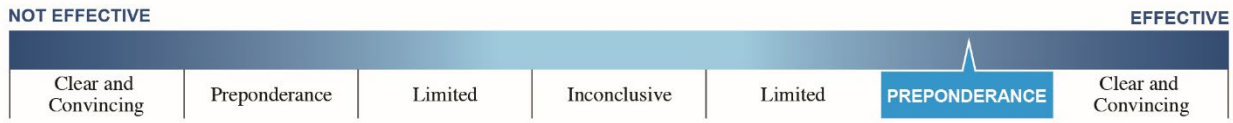
Home self-collection of urine specimens is primarily used for home-to-lab diagnostic tests for chlamydia, gonorrhea, HPV, and trichomoniasis. The urine self-collection process requires the subject to capture the first part of their urine stream in a collection cup (first capture), and then transfer the appropriate amount

into a transport tube using a provided pipette, which is then in turn placed in provided packaging for mailing.

Self-collected urine samples are often preferred by patients and have the advantage of being perceived as less invasive than some swab-based self-collected samples, and generally less aversive to patients than blood-based specimens such as finger sticks (Shafer et al., 2003). According to the 2015 CDC STD Treatment Guidelines, the two modalities (voided urine/swab) are seen as equivalent with regard to effectiveness, and equally recommended for the testing and screening of chlamydia and gonorrhea (CDC, 2015). Regardless of comparative effectiveness to other specimens collected via other modalities, the question under scrutiny for this analysis is the comparative effectiveness of self-collected urine specimens collected outside of the clinical setting as compared with those collected in a clinical setting. There are few studies that specifically compare self-collected urine samples collected outside the clinical setting to self-collected or clinician collected urine samples collected in a clinical setting. A systematic review published in 2015 reviewing studies that compared self-collected versus clinician collected samples for screening for chlamydia and gonorrhea (Lunny et al., 2015) provided the best source of such comparisons. Six studies compared self-collected urine samples to clinician-collected samples. They reported urine samples obtained through self-collection had comparably high specificity and sensitivity to clinician-collected samples for the detection of chlamydia and gonorrhea in men and chlamydia for women. They also noted the robustness of urine samples with regard to transport and storage. The fact that urine samples can be at room temperature for several days and still be viable for testing makes them good candidates for samples that must be returned to the lab by mail.

CHBRP found *a preponderance* of evidence based on one systematic review covering six studies, and current CDC Treatment Guidelines for STDs, that **urine sample** specimens self-collected outside the clinical setting are of equivalent effectiveness as those collected in a clinical environment for the purposes of STD screening.

Figure 3. Medical Effectiveness of Self-Collected Specimens Collected via Urine Sample for STD Screening and Testing

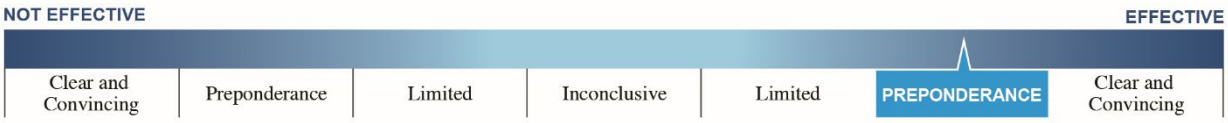


Summary of Findings

The issue of comparative effectiveness of self-collected specimens collected outside a clinical setting as compared to those collected in a clinical setting is complex and dependent upon multiple factors. Chief among these is the nature or modality of the specimen collection (swab, blood, and urine). CHBRP found abundant evidence that swab-based techniques lend themselves especially well to self-collection outside of the clinical setting and are equivalent with regard to diagnostic effectiveness to self-collected samples collected in a clinical setting. Although there were fewer studies available providing such one-to-one comparisons, CHBRP found adequate evidence that self-collected blood-based samples collected outside a clinical setting were comparably effective for diagnostic purposes as self-collected in a clinical setting. With regard to urine-based samples, CHBRP found evidence that self-collected urine samples collected outside the clinical setting were as effective for the screening and diagnosis of STDs as those collected in a clinical setting. Overall, CHBRP concludes there is a *preponderance* of evidence that self-collected specimens collected outside the clinical setting are comparably effective for the diagnosis and screening of STDs as self-collected specimens collected in a clinical setting.

CHBRP found a *preponderance* of evidence based on five systematic reviews and four individual studies that specimens self-collected outside the clinical setting are of equivalent effectiveness as those collected in a clinical environment for the purposes of STD screening.

Figure 4. Medical Effectiveness of Self-Collected Specimens Collected Outside the Clinical Setting for STD Screening and Testing



BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, Section 3 and Section 7 of SB 306 would require health plans and health policies regulated by the Department of Managed Health Care (DMHC) or the California Department of insurance (CDI) to cover home test kits for sexually transmitted diseases (STDs), including the laboratory costs of processing the kit. SB 306 defines "home test kit" as a product approved by the federal Food and Drug Administration (FDA) for the purposes of individuals collecting specimens for STD testing remotely at a location outside of a clinical setting and ordered directly by a clinician or furnished by a standing order based on clinical guidelines and individual patient health needs.

In addition to commercial enrollees, more than 50% of enrollees associated with the California Public Enrollees' Retirement System (CalPERS) and more than 70% of Medi-Cal beneficiaries are enrolled in DMHC-regulated plans.[34] As noted in the *Policy Context* section, SB 306 would impact these CalPERS enrollees' and Medi-Cal beneficiaries' benefit coverage. Thus, if enacted, SB 306 would apply to approximately 21.9 million enrollees (55.7% of all Californians), representing 100% of Californians who will have health insurance regulated by the state and potentially subject to any state health benefit mandate law. SB 306 applies to health insurance regulated by DMHC and CDI.

This section reports the potential incremental impacts of SB 306 on estimated baseline benefit coverage, utilization, and overall cost.

Approach

For this analysis, CHBRP estimates the utilization of both in-clinic STD tests and STD home test kits.

Although some in-clinic STD tests may involve clinician-collected specimens and/or on-site laboratory testing, in-clinic STD tests frequently involve self-collection of specimens (at the clinical site) that are then transported to and tested using the services of Clinical Laboratory Improvement Amendments (CLIA) certified laboratories (the FDA being involved in CLIA certification).

Most STD home test kits also involve self-collection of specimens (albeit at home) that are then transported to and tested in a CLIA certified laboratory. This process is similar to that used by at-home colorectal cancer screening kits. One STD home test kit included in this analysis, the FDA-approved rapid HIV test, is different as it offers a result immediately (no transport to a laboratory needed), somewhat like an at home pregnancy test. A review of available STD home test kits is provided in the *Medical Effectiveness* section.

Currently, clinicians in the provider groups that are most likely to be in network (INN) for an enrollee (often large medical groups or clinicians attached to hospitals or other facilities) may have access to the administrative mechanisms set up to order an at-home colorectal cancer screening test, rather than the in-clinic version of the test. However, these INN clinicians are **not** currently likely to have similar administrative paths set up to order STD home test kits, and so would be much more likely to order an in-clinic STD test.[35] For this analysis, CHBRP has assumed that the provider situation would be unchanged for the first year postmandate, which would result in no change in utilization among enrollees accessing care through INN providers.

Some clinicians in some of the provider groups that are more likely to be out-of-network (OON) for an enrollee (often local health department clinics or family planning clinics) do have the administrative mechanisms needed to order STD home test kits, and so may order kits or in-clinic testing.[36] Laboratory

[34] For more detail, see CHBRP's *Estimates of Sources of Health Insurance in California for 2021*, a resource available at http://chbrp.org/other_publications/index.php.
[35] Personal communication, E. Hook, March 2021
[36] Personal communication, E. Hook, March 2021

processing of these specimens would likely also be OON. Therefore, for enrollees in plans and policies that regularly cover OON providers — and for Medi-Cal beneficiaries (whose benefit coverage must include these specific types of OON providers for STD testing and treatment [see *Policy Context* section]) — CHBRP has projected an increase in use of STD home test kits, postmandate.

Additionally, STD home test kits are available at pharmacies and online, purchasable by an enrollee. The sources of these kits frequently employ clinicians to initiate the laboratory test and they may be involved in delivering the test results. As of March 15, 2021, there are five online STD home test kit sources in California that accept private insurance coverage (Frederiksen et al., 2020). For this analysis, CHBRP has assumed that such STD home test kits, under SB 306, would be considered "clinician ordered" by an OON provider. Laboratory processing of these specimens would likely also be OON. Therefore, for enrollees in plans and policies that regularly cover OON providers (though not for Medi-Cal beneficiaries, as their coverage for STD testing and treatment is limited to specific types of OON providers [see *Policy Context* section]), CHBRP has projected an increase in use of STD home test kits, postmandate. Additionally, CHBRP has projected a movement of some current use of these enrollee-purchased STD home test kits from "self-pay" to "covered benefit."

Several things should be noted about self-pay, for both in-clinic STD test and use of STD home test kits. Firstly, CHBRP has assumed, based on content expert advice,[37] that 25% of all STD testing is at baseline and will be postmandate done as self-pay, regardless of benefit coverage. Such choices (see *Background* section) may involve enrollee concerns about privacy. SB 306 is unlikely to alter such enrollee concerns or choices. Secondly, in some situations that CHBRP is categorizing as self-pay, the enrollee does pay for the test, but in others the test may be provided free of charge. CHBRP is unable to determine how often the latter occurs and for this analysis is referring to all tests that do not involve benefit coverage as self-pay.

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

Baseline and Postmandate Benefit Coverage

At baseline, 7% of enrollees in DMHC-regulated plans and CDI-regulated policies have coverage for STD home test kits (Table 1). Postmandate, 100% of all commercial/CalPERS enrollees would have benefit coverage for STD home test kits. However, as noted above, and discussed further below, utilization would change for only some of these enrollees.

Baseline and Postmandate Utilization

As described in more detail in Appendix C, CHBRP estimated the STD test utilization stratified by place of specimen collection (home test kit and in-clinic test). CHBRP additionally disaggregated utilization by self-pay versus use of benefit coverage.

Evidence suggests that not all who test positive for STDs go on to get treatment (Schwebke et al., 1997). Based on content expert input,[38] CHBRP has assumed that an increase of 4% in STD testing, would increase treatment for HIV by 0.4%, treatment for hepatitis C by 2.2%, and treatment for all other STDs by 3.2%. For HIV and hepatitis C, due to the lower prevalence of disease, treatment is not expected to increase to the same degree as for other STDs. Given the wider spread of HIV testing programs, the likelihood of finding a new positive due to increased testing due to this bill is smaller than that for hepatitis C, which is not as widely tested (McQuillan et al., 2021; Schillie et al., 2020).

[37] Personal communication, E. Hook, March 2021
[38] Personal communication, E. Hook, March 2021

As noted in Table 1, at baseline, the majority of STD testing occurs in-clinic (i.e., not at home) and through the use of benefit coverage, at a rate of approximately 555 tests per 1,000 enrollees per year. An additional 134 tests per 1,000 are done via self-pay. STD home test kit utilization is comparatively much smaller. At baseline, about 19 tests per 1,000 enrollees conducted using benefit coverage and additional 57 per 1,000 enrollees are done via self-pay.

As noted above, a key barrier to their utilization is the general lack of administrative mechanisms in place for INN providers to order STD home test kits for patients.

CHBRP has assumed that among enrollees in plans and policies that generally cover OON providers but do not, at baseline, cover STD home test kits, there would be a postmandate shift in STD tests with some decrease of in-clinic tests and some increase in use of STD home test kits. In addition, CHBRP expects there would be some postmandate increase in utilization of STD home test kits due to increased awareness of STD home testing as a covered benefit due to passage of SB 306 (see Appendix C for more detail).

Table 1 details the way in which STD home test kit utilization increases and shifts by disaggregating utilization rates by home test kit vs. in-clinic test and by self-pay vs. as a covered benefit. Postmandate, there would be an increase of 365% in covered STD home test utilization and a decrease of about 21% of self-pay STD home tests postmandate — a change driven by enrollees with OON coverage for STD tests. With the postmandate shift of tests towards home test kits and away from in-clinic testing, CHBRP estimates there would be a decline of about 6% of in-clinic tests paid for by self and for those covered as benefit.

Similar increases and shifts would occur for resulting STD treatment, resulting in a 5% increase as a covered benefit and a 7% decrease self-pay.

The shifts between self-pay and covered benefit and the related increases in STD home test kit utilization, would result in an overall increase of 73,225 enrollees who obtain STD testing, which is equivalent to an increase in 2% in STD testing as a whole (see Table 4 below). This figure represents postmandate testing for an additional 53,492 Medi-Cal beneficiaries and enrollees (an increase of 4%) and postmandate testing for an additional 19,732 additional commercial/CalPERS enrollees (an increase of 0.95%).

As a result of the additional tests, there would be an additional 26,811 enrollees who receive treatment for STDs (see Table 4). This figure represents an additional 20,428 Medi-Cal beneficiaries and an additional 6,383 commercial/CalPERS enrollees being treated for an STD.

Table 4. Enrollees Receiving Sexually Transmitted Disease (STD) Tests and Treatment Baseline and Postmandate

	Baseline			Postmandate			Change		
	COM	MCD	Total	COM	MCD	Total	COM	MCD	Total
STD tests	2,074,623	1,337,301	3,411,925	2,094,356	1,390,794	3,485,149	19,732	53,492	73,225
HIV drugs	25,988	11,677	37,665	26,013	11,724	37,736	25	47	71
Hepatitis C drugs	8,807	2,559	11,366	8,853	2,616	11,469	46	56	102
Other STD treatments*	838,831	638,368	1,477,199	845,214	658,796	1,504,009	6,383	20,428	26,811

Source: California Health Benefits Review Program, 2021.

*Note: *Includes related services*

Key: COM = Commercial & CalPERS enrollees in DHMC- and CDI-Regulated Plans/Policies; HIV = human immunodeficiency virus; MCD = Medi-Cal beneficiaries enrolled in DMHC-regulated plans; STD = sexually transmitted disease.

Baseline and Postmandate Per-Unit Cost

CHBRP calculated per-unit costs of STD testing and treatment using Milliman's 2018 Consolidated Health Cost Guidelines Sources Database (CHSD) and 2018 MarketScan® Commercial Claims and Encounters Database. STD testing for both home test kits and in-clinic kits are approximately $42 per test per organism/disease. Thus, STD test kits that test for multiple organisms — for example, bundled test kits that include HIV, chlamydia, gonorrhea, syphilis, trichomoniasis, and hepatitis C — will have higher costs. Tests are typically billed based on an individual test basis for these types of bundled tests.

CHBRP notes that there is no difference between costs because the laboratory costs of processing the test after specimen collection drives the bulk of the cost of testing, which does not differ for the two types of STD testing modalities and does not differ by how the test is paid for (i.e., self-pay vs. covered by insurance). For STD treatment, the baseline average cost is $68 per treatment service for all STDs excluding HIV and hepatitis C. HIV treatment averages $1,965 for a 1-month supply of antiretroviral medication used for treatment, not prophylaxis. Hepatitis C treatment for an 8-week treatment cycle averages $25,000. Per-unit costs for all STD tests and treatments would not be expected to change postmandate due to SB 306.

Baseline and Postmandate Expenditures

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

SB 306 would increase total net annual expenditures by $30,545,000 or 0.02% for the year following implementation of the mandate for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to an increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, offset by a decrease in enrollee expenses for covered and/or noncovered benefits.

Premiums

Changes in premiums as a result of SB 306 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 5, and Table 6), with health insurance that would be subject to SB 306.

CHBRP estimates that the mandate would increase premiums by about $21.46 million for all markets except for Medi-Cal Managed Care Plans. Total premiums for private employers purchasing group health insurance are estimated to increase by $11,360,000, or 0.02%. Total employer premium expenditures for CalPERS HMOs are estimated to increase by $1,479,000, or 0.03%. Changes in premiums as a result of SB 245 would vary by market segment. Note that such changes are related to the number of enrollees with health insurance that would be subject to SB 306. The greatest change in premiums as a result of SB 245 is for individual plans in the CDI-regulated market (0.08% increase) and for the small-group plans in the CDI-regulated market (0.07% increase).

Among publicly funded DMHC-regulated health plans, state premium expenditures for Medi-Cal Managed Care Plans are estimated to increase by $28,996,000, or 0.12%.

Enrollee Expenses

As previously noted, SB 306 would impact utilization among enrollees in plans and policies that generally cover OON providers. Among that group, for enrollees using STD home test kits postmandate as a covered benefit, cost sharing would be applicable. Thus, with increased utilization of STD home test kits, there is a subsequent increase in total cost sharing. This increase in cost sharing is offset by a decrease

in noncovered benefit expenses (which includes the cost of paying for STD testing completely out of pocket when no coverage is available) (see Table 1). Based primarily on the differing number of enrollees, changes in cost sharing and expenses for noncovered benefits would vary by market segment (see Table 6). The 84,859 enrollees with uncovered expenses at baseline would, as a group, receive a $23,177,000 reduction in out-of-pocket spending for covered and noncovered expenses associated with STD testing and treatment postmandate (Table 1).

As noted in the *Policy Context* section, for some commercial/CalPERS enrollees, cost sharing is not allowed for certain preventive services when performed INN, including some STD screening. Table 7 in Appendix C notes which of the STD tests (for which there a home test kit is available) are included in this cost-sharing prohibition. For this analysis, since these tests would be performed OON, CHBRP assumed cost sharing would apply to newly covered services.

Cost sharing is generally not applicable Medi-Cal beneficiaries, including those enrolled in DMHC-regulated plans. CHBRP assumes the situation would be the same for covered STD home test kits and so has estimated no cost sharing at baseline or postmandate for these beneficiaries.

Average enrollee expenses per user

SB 306 would increase utilization of STD tests (through increased use of STD home test kits) but would not alter cost sharing and CHBRP has assumed that the same cost sharing applicable to covered in-clinic tests would apply for covered STD home test kits. Thus, for enrollees with applicable cost sharing for STD tests delivered through OON providers, cost sharing would be unchanged.

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

As shown in Table 1, increased STD treatment (as a result of increased testing) is expected. Increased treatment does lead to decreased transmission of disease and community spread, which reduces the burden of STDs on the population as a whole, which may impact health and health care service utilization beyond the first postmandate year. However, among enrollees in plans and policies regulated by DMHC or CDI, CHBRP does not project any measurable cost offsets or savings in other healthcare utilization during the first postmandate year.

Postmandate Administrative Expenses and Other Expenses

Plans and insurers include a component for administration in their premiums. In general, CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies generally remain proportional to the increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. In this manner, administrative costs for additional STD treatments and laboratory processing of tests have been included in this analysis.

It is possible, however, that there may be some additional administrative costs for plans and policies covering STD home test kits when the kits are purchased by enrollees prior to a clinician order. As previously noted, some sources of enrollee-purchasable kits offer to bill an enrollee's plans or insurer, presumably by arranging for the participating laboratory (which may be OON for a particular enrollee) to do so. Such laboratory billing is common and does not include codes that indicate whether the specimen collection was done in-clinic or at home. However, the enrollee may still be expected to make an initial purchase of the kit. Such an initial purchase would be an expense that is covered under SB 306 and so plans and insurers would have to organize a means of collecting receipts and reimbursing enrollees, which is an administrative function plans and insurers are not commonly called upon to do. Therefore, although the exact increase is unknown, CHBRP would expect some extra administrative expense in covering enrollees' initial purchase cost for STD home test kits that are available at pharmacies and online.

Other Considerations for Policymakers

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

Potential Cost of Exceeding Essential Health Benefits

As explained in the *Policy Context* section, SB 306 does not appear to exceed the definition of essential health benefits (EHBs) in California.

Postmandate Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 5, and Table 6), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 306.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of SB 306.

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

CHBRP assumes that enrollees who do not have benefit coverage for STD home test kits pay for treatments/services directly (e.g., self-pay). However, in some cases, those noncovered benefits may be provided by public programs or by other, alternative sources, such as free STD clinics. CHBRP is unable to provide a quantifiable estimate of the number of enrollees who use these publicly funded free services. It is unlikely there would be a measurable shift of enrollees using free programs to using insurance coverage for STD home kits postmandate given that enrollees who use free programs even though they have insurance coverage are often motivated by the privacy of conducting testing and treatment without the involvement of their insurance plans.

Table 5. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2022

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)(f)*	*MCMC (65+) (c)(f)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,405,000	2,086,000	1,989,000	889,000	7,218,000	787,000	384,000	43,000	144,000	21,945,000
Total enrollees in plans/policies subject to SB 306	8,405,000	2,086,000	1,989,000	889,000	7,218,000	787,000	384,000	43,000	144,000	21,945,000
Premiums										
Average portion of premium paid by employer	$426.28	$374.49	$0.00	$540.40	$226.61	$478.87	$530.80	$424.26	$0.00	$84,952,354,000
Average portion of premium paid by employee	$141.02	$180.89	$624.47	$96.86	$0.00	$0.00	$186.55	$213.30	$545.57	$36,602,673,000
Total premium	**$567.30**	**$555.38**	**$624.47**	**$637.27**	**$226.61**	**$478.87**	**$717.35**	**$637.56**	**$545.57**	**$121,555,027,000**
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	$43.61	$121.70	$173.51	$50.75	$0.00	$0.00	$134.75	$197.69	$184.11	$13,169,503,000
Expenses for noncovered benefits (e)	$1.13	$1.19	$1.31	$1.13	$0.94	$0.57	$1.13	$1.21	$1.24	$281,450,000
Total expenditures	**$612.04**	**$678.26**	**$799.29**	**$689.14**	**$227.55**	**$479.45**	**$853.22**	**$836.45**	**$730.91**	**$135,005,980,000**

Source: California Health Benefits Review Program, 2021.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Approximately 54.1% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

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

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

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

(f) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

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

Table 6. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2022

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)(f)*	*MCMC (65+) (c)(f)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,405,000	2,086,000	1,989,000	889,000	7,218,000	787,000	384,000	43,000	144,000	21,945,000
Total enrollees in plans/policies subject to SB 306	8,405,000	2,086,000	1,989,000	889,000	7,218,000	787,000	384,000	43,000	144,000	21,945,000
Premiums										
Average portion of premium paid by employer	$0.0695	$0.1170	$0.0000	$0.1387	$0.3138	$0.1921	$0.2861	$0.1963	$0.0000	$41,836,000
Average portion of premium paid by employee	$0.0230	$0.0565	$0.1051	$0.0249	$0.0000	$0.0000	$0.1006	$0.0987	$0.1989	$7,365,000
Total premium	$0.0925	$0.1735	$0.1051	$0.1636	$0.3138	$0.1921	$0.3867	$0.2950	$0.1989	**$49,200,000**
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	$0.0136	$0.0526	$0.0365	$0.0242	$0.0000	$0.0000	$0.1021	$0.1157	$0.1012	$4,521,000
Expenses for noncovered benefits (e)	-$0.0546	-$0.1134	-$0.0714	-$0.0967	-$0.1141	-$0.0699	-$0.2552	-$0.2083	-$0.1542	-$23,177,000
Total expenditures	$0.0514	$0.1127	$0.0702	$0.0911	$0.1997	$0.1223	$0.2336	$0.2023	$0.1459	**$30,545,000**
Percent change										
Premiums	0.0163%	0.0312%	0.0168%	0.0257%	0.1385%	0.0401%	0.0539%	0.0463%	0.0365%	0.0405%
Total expenditures	0.0084%	0.0166%	0.0088%	0.0132%	0.0878%	0.0255%	0.0274%	0.0242%	0.0200%	0.0226%

Source: California Health Benefits Review Program, 2021.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Approximately 54.1% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

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

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

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

(f) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

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

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, SB 306 would require coverage of home test kits for sexually transmitted diseases (STDs), including the laboratory costs of processing the kit. The bill would define "home test kit" as a product approved by the federal Food and Drug Administration (FDA) for the purposes of individuals collecting specimens for STD testing remotely at a location outside of a clinical setting and ordered directly by a clinician or furnished by a standing order based on clinical guidelines and individual patient health needs.

The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate). This section estimates the short-term impact[39] of SB 306 on testing and treatment for STDs and potential reduction in disparities. See *Long-Term Impacts* for discussion of premature death and economic loss.

Estimated Public Health Outcomes

As presented in *Medical Effectiveness*, there is a *preponderance* of evidence based on multiple systematic reviews as well as individual studies that specimens collected by means of self-collection are of equivalent effectiveness as those collected by clinicians for the purposes of STD testing and treatment. Therefore, it stands to reason if more individuals are seeking at-home testing for STDs, more individuals are also likely to seek treatment when necessary.

As presented in *Benefit Coverage, Utilization, and Cost Impacts*, approximately 7% of commercial/CalPERS enrollees have coverage for STD home test kits in health plans and health policies regulated by the Department of Managed Health Care (DMHC) or the California Department of insurance (CDI) (Table 1). As SB 306 would impact the benefit coverage of all enrollees in DMHC-/CDI-regulated plans/policies, specifying that coverage for an STD home test kit is required, there would be no change for enrollees with compliant benefit coverage at baseline. However, that coverage would be locked in postmandate such that the plan/insurer could not take it away. New coverage for STD home test kits occurs postmandate only for enrollees in plans/policies currently noncompliant with SB 306. The bill affects utilization of STD tests only among enrollees with out-of-network (OON) coverage for STD testing who gain coverage for STD home test kits. Based on content expert input,[40] CHBRP assumes as a result of an increase of 4% in STD testing, subsequent service use — which includes treatment — would increase by 3.2% for STDs (excluding HIV and hepatitis C; 0.4% for HIV and 2.2% for hepatitis C). Therefore, SB 306 is expected to alter coverage for at-home STD testing for 73,225 people and treatment and/or follow-up services for approximately 26,984 people — due to a utilization increase in STD testing of 2% (see Table 1 and Table 4 within *Benefit Coverage, Utilization, and Cost Impacts*). This increase in treatment and/or follow-up services includes 71 people with HIV infections, 102 people with hepatitis C infections, and 26,811 people with other STDs.

As presented in the *Background* section, recommended testing (and subsequent treatment when necessary) for STDs relevant to this analysis promotes a reduction, elimination, and/or shortened duration of related symptoms; control in infection; suppression of viral replication; reduction in transmission of disease to a noninfected sexual partner; and/or cure rates of 92% to 100% based on the type of STD (e.g., receipt of recommended treatments for chlamydia can result in cure rates of 97% to 98%).

Furthermore, early detection and treatment of STDs are key to improving public health outcomes and related consequences. Related to a reduction in transmission of disease, in a randomized control trial conducted in a large health care organization, researchers found that screening for chlamydia among women was associated with a reduced incidence of pelvic inflammatory disease (PID) over a one-year

[39] CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.
[40] Personal communication, E. Hook, March 2021

period (Scholes et al., 1996). Given the dearth of empirical data, it stands to reason that an increase in testing for STDs would result in a reduction in adverse health outcomes (e.g., a reduction in PID among women within a one-year period). Specific to hepatitis C, Joshi (2014) determined that the early detection of hepatitis C could result in 90% to 100% of individuals successfully responding to treatment, thus preventing the progression of associated liver disease and other serious health consequences. Therefore, it stands to reason that an increase in early testing for hepatitis C would result in reduced incidence of liver disease and related comorbidities. Additionally, when assessing the impact of expanded HIV screening and antiretroviral treatment in the United States, Long et al. (2010) projected that one-time screening of low-risk individuals combined with annual screening of high-risk individuals (e.g., MSM) prevented 6.7% of the projected 1.23 million new cases to occur over 20 years among low- and high-risk groups combined. Given these national projections, it stands to reason that an increase in testing for HIV among Californians — equal to 30,453 people — would lead to a reduction in HIV transmission.

In conclusion, given the anticipated increase in STD testing utilization and subsequent treatment and/or follow-up services for STDs, there would be a decrease in short-term health outcomes per select STD.

Addressing Barriers to STD Testing Using Home Test Kits

It's important to note that at-home testing utilizing home test kits could serve as a strategy to address barriers to in-clinic STD testing as well as those brought on by the COVID-19 pandemic. In a literature review of studies evaluating at-home vs. in-clinic specimen collection specific to chlamydia and gonorrhea, researchers found that both women and men found at-home specimen collection as part of the home test kit (i.e., individual collects a sample and returns the sample via mail for testing in a laboratory) to be both feasible and acceptable (Graseck et al., 2011). In other words, prior to mass use, individuals participated in end-user testing and determined that at-home specimen collection was both feasible and an acceptable activity to conduct on their own outside of a clinic setting, indicating that others might adopt at-home specimen collection if home test kits were available to them. In a study conducted by Gaydos et al. (2006) on women's perceptions of at-home screening using home test kits for chlamydia, participants concluded that self-collected vaginal swabs were comfortable and safe, less invasive than clinician-obtained cervical samples, and that patient privacy could be maintained through the use of discreet packaging. Furthermore, Graseck et al. (2011) noted that the availability of home test kits for order via online platforms may be an ideal method to reach adolescents and young adults at high-risk — among others who may be geographically constrained — given its convenience, inherent privacy, and increased accessibility.

In the first year postmandate, CHBRP estimates an additional 73,225 people would utilize at-home testing and 26,984 people would seek treatment and/or follow-up services for STDs. This includes an increase in treatment and/or follow-up services for 71 people with HIV infections, 102 people with hepatitis C infections, and 26,811 people with other STDs. This estimate is supported by a *preponderance* of evidence that at-home testing is medically effective and an increase in utilization (2%) of STD testing and treatment and/or follow-up services for STDs (2%), HIV (0.2%), and hepatitis C (1%).

Impact on Disparities[41]

Insurance benefit mandates that bring more state-regulated plans and policies to parity may change an existing disparity. As described in the *Background* section, disparities exist by race/ethnicity, age, gender,[42] gender identity, sexual orientation, incarceration status, socioeconomic status, and access to

[41] For details about CHBRP's methodological approach to analyzing disparities, see the *Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts* document here: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

[42] CHBRP uses the NIH distinction between "sex" and "gender:" "'Sex' refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. 'Gender' refers to

STD testing. According to the CDC (2017b), disparities persist among racial and ethnic minorities (including Hispanic groups) related to rates of STDs compared to rates of STDs among Whites within the United States. Additionally, in comparison to older adults, disparities persist among sexually active adolescents (aged 15 to 19 years) and young adults (aged 20 to 24 years) as these individuals may be at higher risk for STD acquisition due to a combination of factors, including behavioral, biological, and cultural reasons (CDC, 2017c). Specific to women and infants, chlamydia and gonorrhea disproportionately affect women (and pregnant women), as women often present as asymptomatic during early infection (CDC, 2017d). Disparities also exist among men who have sex with men (MSM) in comparison to women and men who have sex with women (CDC, 2017a). Additional disparities exist among individuals who are incarcerated as well as those with low socioeconomic status (Dean and Fenton, 2010; Hogben and Leichliter, 2008). According to the Department of Health and Human Services (DHHS, 2020), disparities in access to STD testing and related services exist among racial/ethnic and sexual minorities (i.e., women who have sex with other women [WSW] and MSM) given their related disparities in access to health insurance coverage.

Addressing Disparities in STD Testing Using Home Test Kits

The use of at-home specimen collection test kits — whether it be clinician-ordered or personally ordered via online platforms — could serve as a strategy to reduce disparities and associated stigma[43] in accessing STD testing; however, it's important to note that this strategy would not serve as a panacea. Interestingly, despite innovative strategies to increase access to STD testing via online platforms, Melendez et al. (2021) noted that certain populations may continue to be inadvertently excluded such as individuals with language or literacy barriers. individuals living in poverty (and who may lack internet access), and/or transient individuals (i.e., individuals without a stable home address).

CHBRP's estimation of the impact of SB 306 on public health is primarily related to the extent to which an enrollee is able to go to an OON provider (who is more likely to be set up to order STD test kits). Per state and federal law, all Medi-Cal managed care enrollees can get reproductive and sexual health care services from OON providers. Only 17% of enrollees with private insurance subject to SB 306 have that same benefit. Therefore, as Medi-Cal beneficiaries include a larger percentage of people of color than is found in private insurance plans, CHBRP would expect to see a decrease in health disparities for some racial/ethnic groups should SB 306 become law.

Due to the higher percentage of people of color among Medi-Cal beneficiaries enrolled in DMHC-regulated plans, as compared to commercial enrollees, and due to the increased access to OON providers who could prescribe STD home test kits, SB 306 could lead to a decrease in health disparities related to STDs for people of color. The extent to which there is a decrease in disparities among any other subpopulations is unknown.

socially constructed and enacted roles and behaviors which occur in a historical and cultural context and vary across societies and over time." (NIH, 2019).

[43] Driven by medical, social, and cultural conditions, stigma has played a prominent and ongoing role in discouraging individuals from seeking STD testing and related services given its direct connection to individual health seeking behaviors as well as the control and maintenance of disease (Courtwright and Turner, 2010; Dean and Fenton, 2010; DHHS, 2020).

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of SB 306, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization Impacts

As described in the *Background* section, sexually transmitted disease (STD) home test kits have been seen as a strategy to address some of the barriers to in-clinic STD testing. As the COVID-19 pandemic propelled the use of telehealth for health services, STD home test kits were considered a potential way to continue screening and diagnostics under stay-at-home orders (Napoleon et al., 2020). While some literature exists documenting the experiences of various clinics that shifted to using STD home test kits during COVID-19 stay-at-home orders, these were all part of programs that offer free STD testing services (Carnevale et al., 2021; Melendez et al., 2021; Menza et al., 2021). Some online STD home test service companies, which largely serve individuals who self-pay for STD tests, noted increased demand at the onset of the COVID-19 pandemic (Foley, 2020). Quantitative data on utilization of STD home test kits from the various vendors who offer these kits are not available.

As shown in the sections above on the first-year impact of SB 306, CHBRP estimates an increase in STD home test kit utilization that applies to only a small subset of enrollees with out-of-network (OON) coverage who would gain coverage for these home test kits postmandate. While the short-term impacts are narrow, it is possible that in the long term there would be a more marked upward trend in the use of STD home test kits. SB 306 directly affects the benefit coverage for enrollees with OON coverage for STD tests, but it is possible that a bill of this nature has the catalyzing effect of encouraging the creation of mechanisms through which more providers can order home test kits for their patients. As noted previously, the greatest barrier to wider use of STD home test kits is largely the lack of administrative mechanisms to order home test kits. In the future, it is possible that utilization increases by a greater degree particularly if providers that are more likely to be in network are given the opportunity to order home test kits or encouraged to do so through recommendations or financial incentives.

Home test kits for colorectal cancer (CRC) screening offer an example of how home test kits utilization can increase over time (Gorin et al., 2021; Jaklevic, 2021). CRC screening tests, or fecal occult blood tests (FOBT), which involve home-based fecal collection have been listed in the United States Preventive Services Task Force's (USPSTF) CRC screening recommendations since 2016. There are currently three types of at-home CRC screening tests (Guaiac FOBT, fecal immunochemical test [FIT], and multitarget stool DNA test), all of which are approved by the federal Food and Drug Administration (FDA) — notably unlike the majority of STD home test kits which have not yet been FDA approved (see *Medical Effectiveness* for a more detailed discussion about FDA approval for STD home test kits).

As with STD home test kits, CRC home screening kits involve home collection of specimens that are mailed directly to the laboratory or to the provider who then sends the tests to the laboratory. As these tests are considered a less costly alternative to colonoscopy yet with similar clinical effectiveness, a number of health plans around the U.S. have been found to have expanded home testing programs that send CRC screening kits to enrollees who are due for CRC screening (Jaklevic, 2021). Notably, the National Committee for Quality Assurance (NCQA) began including all USPSTF-recommended screening modalities for CRC (which include home test kits as mentioned above) as part of their Healthcare Effectiveness Data and Information Set (HEDIS) measures starting in 2017, thus giving plans and insurers another incentive to use home test kits to increase CRC screening coverage (Bone et al., 2020).

In California, evidence from an integrated health care system points to how mailed FIT home test kits increased CRC screening coverage from 40% to 82% in about 1 million eligible adult enrollees (Selby et al., 2020). While STD home test kits may have a similar upward trajectory in use over time, it is possible utilization increases may be more muted than for CRC home test kits without financial incentives in place to encourage home-based STD testing.

Cost Impacts

CHBRP does not expect average unit costs of STD home test kits will change substantively in the future. Laboratory processing costs make up the bulk of the total unit costs of the tests given the hard material costs for specimen collection, such as vials and swabs, are relatively inexpensive. The laboratory processing costs may go down over time as technology improves, but it is uncertain by how much more and to what degree innovation can substantially drive costs down even further than where they already are.

Long-Term Public Health Impacts

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

In the case of SB 306, CHBRP estimates an increase in STD at-home testing of 73,225 people. This would lead to increased identification and earlier treatment and/or follow-up services for STDs (26,811 people), HIV (71 people), and hepatitis C (102 people). Therefore, the long-term public health impacts may include increased prevalence of STD screening over time, a reduction in future STD transmissions (such as a reduction in the incidence of syphilis leading to a reduction in congenital syphilis leading to a subsequent reduction in the number of overall adverse health outcomes among both mother and infant in the long term), and an overall reduction in downstream effects such as impacts on premature death and economic loss.

Impacts on Premature Death and Economic Loss

Early detection and treatment of STDs are also key to limiting long-term adverse health outcomes and related consequences such as premature death and economic loss. As the United States has the highest rates of STDs among high-income countries, the potential impact of expanded routine STD screening and subsequent treatment/control — especially among STDs that could lead to mortality — could be considerable (CDC, 1998; CDC, 2018) (see Premature Death and Economic Loss).

Premature death

Premature death is often defined as death occurring before the age of 75 years (NCI, 2019).[44] In California, it is estimated that there were nearly 5,300 years of potential life lost (YPLL) per 100,000 population each year between 2015 and 2017 (CDPH, 2019b; County Health Rankings, 2019).[45] As premature death associated with STDs can occur long after acute infection, incidence rates attributed to STD infection can be hard to estimate and/or be inaccurately reported (McElligott, 2014). For example, while syphilis can result in death, other STDs such as HPV, HIV, hepatitis B, and hepatitis C can result in death due to secondary sequelae (McElligott, 2014). Moreover, genital herpes, gonorrhea, or syphilis

[44] For more information about CHBRP's public health methodology, see http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.
[45] The overall impact of premature death due to a particular disease can be measured in years of potential life lost prior to age 75 and summed for the population (generally referred to as "YPLL") (Gardner and Sanborn, 1990).

infections may result in death due to pathogenic infection and/or from secondary sequelae (e.g., ectopic pregnancy) (McElligott, 2014). Although the aforementioned STDs can result in death, surveillance data can be inaccurate or underreported as a result of failing to record the prevalence of STD(s) on death certificates (McElligott, 2014). Mortality is a relevant outcome primarily for the following STDs: hepatitis B, hepatitis C, HIV, HPV, and congenital syphilis. The estimates of premature death due to these five STDs are provided below.

Hepatitis B

The age-adjusted mortality rate for hepatitis B in the United States was 0.43 per 100,000 persons in 2018 (CDC, 2020f). Within California, 304 deaths in 2018 were attributed to hepatitis B per the CDC WONDER online database (CDC, 2020f). While some acute hepatitis B infections can resolve on their own, others can develop into chronic infection, in which approximately 1% of reported cases across the United States can lead to liver failure and/or death (CDC, 2015).

Hepatitis C

According to the CDC WONDER online database, the age-adjusted mortality rate for hepatitis C in the United States was 3.72 per 100,000 persons in 2018 (CDC, 2020f). Within California, 2,391 deaths in 2018 were attributed to hepatitis C (CDC, 2020f). Despite some acute infections clearing on their own, most individuals diagnosed with the disease will develop chronic hepatitis C (CDC, 2015). Although individuals can live for years as asymptomatic, once symptoms appear, they are often an indicator of advanced liver disease, which can lead to liver failure and/or death (CDC, 2015).

HIV

Because HIV is known to weaken a person's immune system by progressively depleting important cells that fight disease and infection, if left untreated, individuals with HIV that progresses to AIDS can experience severe health outcomes — which can ultimately lead to mortality — with a survival rate of up to 3 years (CDC, 2015). According to the California Department of Public Health (CDPH, 2020b), the annual number of deaths of persons with HIV infection increased from 1,774 in 2014 to 1,872 in 2018 (equal to 4.7 per 100,000 population). Note: This data on deaths of persons with diagnosed HIV infection represents all causes of death and may not be related to HIV infection (CDPH, 2020b).

HPV-associated cancers

If left untreated, HPV can increase the risk for several types of cancer that can lead to mortality, such as cervical, anal, and oropharyngeal cancers, with 100%, 91%, and 70% of all cases, respectively, attributed to HPV (CDC, 2015, 2019). In 2014, 472 deaths in California were attributed to cervical cancer, a known HPV-associated cancer. Despite this, cervical cancer mortality rates have decreased rapidly due to prevention and early detection (i.e., screening via pap test or pap smear) (ACS et al., 2017). Moreover, mortality rates stabilized among women below aged 50 years as well women above aged 50 years from 2010 to 2014 (ACS at al., 2017). In 2014, 130 deaths were attributed to anal cancer, and an additional 1,027 deaths were attributed to oropharyngeal cancers (ACS et al., 2017).

Congenital syphilis

If left untreated, syphilis can result in severe health outcomes, especially among pregnant mothers; in fact, congenital syphilis can result in miscarriage; stillbirth; premature birth or low birth weight; and/or infant death shortly after birth (CDC, 2015). According to the California Department of Public Health, of the 329 cases of congenital syphilis, 19 cases resulted in still births and three cases resulted in neonatal deaths (CDPH, 2020c).

There is *clear and convincing* evidence that treatment for hepatitis B, hepatitis C, HIV, HPV, and congenital syphilis reduces the mortality rate attributed to those STDs. Therefore, it is possible that SB 306 would lead to a reduction in premature death for the 87,577 individuals who would newly get tested and treated for STDs in California, although the exact impact is unknown.

Economic loss

Economic loss associated with disease is generally presented in the literature as an estimation of the value of the YPLL in dollar amounts (i.e., valuation of a population's lost years of work over a lifetime). In addition, morbidity associated with the disease or condition of interest can also result in lost productivity by causing a worker to miss days of work due to illness or acting as a caregiver for someone else who is ill.

While there is no estimate of the economic loss associated with STDs overall, researchers have attempted to estimate the economic loss (both direct and indirect) associated with individual STDs at baseline (i.e., premandate). For example, Chesson et al. (2008) estimated the economic losses associated with chlamydia, gonorrhea, syphilis, congenital syphilis, and HIV. These estimates were comprised of direct medical costs and the indirect costs related to a reduction in productivity due to premature mortality. CHBRP translated these findings on costs per case into 2021 dollars and calculated the following California-level estimates using rates of state-wide prevalence. Note: The population subject to the mandate represents only 55.7% of the state-wide population and may not match the demographic distribution across the state.

- For each case of chlamydia, approximately $409 in direct and $192 in indirect costs would be avoided per individual case prevented among females. The total burden across California for both males and females is estimated at $90,055,446.
- For each case of gonorrhea, approximately $445 in direct and $222 in indirect costs would be avoided per individual case prevented among females. The total burden across California for both males and females is estimated at $24,606,153.
- For each case of syphilis, approximately $742 in direct and $145 in indirect costs would be avoided per individual case prevented. The total burden across California is estimated at $22,200,562.
- For each case of congenital syphilis, approximately $8,743 in direct and $78,396 in indirect costs would be avoided per individual case prevented. The total burden across California is estimated at $28,668,666.
- For each case of HIV, approximately $257,516 in direct and $1.1 million in indirect costs would be avoided per individual case prevented. The total burden across California is estimated at $180,432,263,813.

APPENDIX A TEXT OF BILL ANALYZED

On February 4, 2021, the California Senate Committee on Health asked CHBRP to analyze the benefit mandates included in Sections 3 and 7 of SB 306, as the bill was introduced on February 4, 2021.

On February 18, 2021, the Senate Health Committee asked CHBRP to analyze those benefit mandates with proposed amendments, amendments that are present in the March 9, 2021, version of the bill (available on CHBRP's website[46]).

Below are Sections 3 and 7 of SB 306, as analyzed by CHBRP.

SEC. 3.

Section 1367.32 is added to the Health and Safety Code, to read:

1367.32.

(a) Every health care service plan contract issued, amended, renewed, or delivered on or after January 1, 2022, shall provide coverage for home test kits for sexually transmitted diseases (STD), including the laboratory costs of processing the kit.

(b) For purposes of this section, "home test kit" means a product designed to allow individuals to collect specimens for STD testing remotely at a location outside of a clinical setting and that is ordered directly by a clinician or furnished by a standing order for patient use based on clinical guidelines and individual patient health needs.

SEC. 7.

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

10123.204.

(a) A health insurance policy issued, amended, renewed, or delivered on or after January 1, 2022, excluding specialized health insurance policies, shall provide coverage for home test kits for sexually transmitted diseases (STD), including the laboratory costs of processing the kit.

(b) For purposes of this section, "home test kit" means a product designed to allow individuals to collect specimens for STD testing remotely at a location outside of a clinical setting and that is ordered directly by a clinician or furnished by a standing order for patient use based on clinical guidelines and individual patient health needs.

[46] See entry for SB 306 at https://chbrp.org/completed_analyses/index.php.

APPENDIX B LITERATURE REVIEW METHODS

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

Studies of the effects of self-collection of specimens collected for the purposes of STD/STI screening and testing were identified through searches of PubMed, Embase, CINAHL, and Business Source Complete.

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

Medical Effectiveness Review

The medical effectiveness literature review returned abstracts for 248 articles, of which 45 were reviewed for inclusion in this report. A total of 14 studies were included in the medical effectiveness review, five of which were systematic reviews.

Medical Effectiveness Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach*.[47] To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

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

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

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

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

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

[47] Available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

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

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

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

Search Terms (* indicates truncation of word stem

Alphapapillomavirus	Home Test*	Self Swab*
Barrier*	Homosexuality	Self Test*
Chlamydia	Insurance Claim Review	Sexually Transmitted
Cost of Illness	Insurance Coverage	Infections
Diagnosis	Insurance, Health	Sexually Transmitted
Economic Loss	Morbidity	Diseases
Gonorrhea	Mortality	Socioeconomic Factors
Hepatitis B	Mycoplasma Genitalium	Statistics and Numerical Data
Hepatitis C	Prefer*	STDs
Herpes Genitalis	Premature Death	STIs
HIV Infections	Prior Authorization	**Syphilis**
Home Collect*	Referral and Consultation	Trichomonas Vaginitis
Home Sampl*	Self Administer*	United States
Home Screen*	Self Collect*	

(* = Truncation)

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

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc, the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.[48] Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses are available at CHBRP's website.[49]

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

As noted in the *Policy Context* section, for some enrollees — in nongrandfathered group and individual health insurance plans — there would be no cost sharing for certain preventive services, which include sexually transmitted disease (STD) screening per the Affordable Care Act (ACA). However, cost sharing is permitted for out-of-network preventive services. To determine the level of cost sharing postmandate, CHBRP adjusted cost sharing for each source of coverage using the average actuarial value for the specific source of insurance coverage.

Table 7 below notes which of the STDs (for which there a home test kit is available) are addressed in the current ACA-relevant screening recommendations for STDs — and any enrollee-specificity included in the recommendation. Please note,

- This list of tests is a subset of the recommended screening tests discussed in the *Background* and listed in Appendices D and F.
- The cost-sharing prohibition is relevant to services from **in-network** (INN) providers, and so would not interact with the additional **out-of-network** (OON) services projected in this report as a result of SB 306.

Table 7. STDs with Home Test Kits and ACA-Relevant Recommendations

	Screening (Testing) Recommendation?	Enrollee Specificity: Age/Sex/Other
Bacterial		
Chlamydial Infections[Error! Bookmark not defined.]	Yes	Sexually active women aged 24 years and younger and older women at increased risk for infection
Gonococcal Infections (Gonorrhea)[50]	Yes	Sexually active women aged 24 years and younger and older women at increased risk for infection

[48] CHBRP's authorizing statute, available at https://chbrp.org/about_chbrp/index.php, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[49] See method documents posted at http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see *2021 Cost Analyses: Data Sources, Caveats, and Assumptions*.
[50] https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/STD-Data-All-STDs-Tables.pdf

	Screening (Testing) Recommendation?	Enrollee Specificity: Age/Sex/Other
Syphilis	Yes	Pregnant women Asymptomatic non-pregnant adolescents and adults at increased risk
Viral		
Genital Herpes Simplex (HSV-2)[51]	No	n/a
Hepatitis B	Yes	Adolescents and adults at high risk for infection and all pregnant women
Hepatitis C	Yes	Adults (aged 18–79 years)
HIV	Yes	Pregnant persons, including those who present in labor or at delivery and whose HIV status is unknown Adolescents and adults aged 15 to 65 years as well as younger and older persons at increased risk
Human Papillomavirus[52]***(HPV)***	Yes	Women
Protozoal		
Trichomoniasis[53]	No	n/a

Source: California Health Benefits Review Program, 2021.

Key: ACA = Affordable Care Act; HIV = human immunodeficiency virus; STD = sexually transmitted disease.

Analysis-Specific Data Sources

Current coverage of STD home test kits for commercial enrollees was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 81% of commercial/enrollees with health insurance that can be subject to state benefit mandates. In addition, CalPERS, DHCS, and the four largest (by enrollment) DMHC-regulated plans enrolling Medi-Cal beneficiaries were queried regarding related benefit coverage.

This analysis focuses on the test and treatments for the most common STDs listed in the 2015 CDC guide (see the *Medical Effectiveness* section).

For STD testing and treatment, relevant codes from the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) and the AMA CPT® (Common Procedure Terminology) were

[51] https://www.cdc.gov/nchs/data/databriefs/db304.pdf
[52] https://gis.cdc.gov/Cancer/USCS/DataViz.html [Risk Factors: HPV-associated Cancers]; https://www.sciencedirect.com/science/article/pii/S1473309907701585?via%3Dihub#fig4
[53] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6924265/pdf/nihms-1062826.pdf

used to extract data from Milliman's proprietary 2019 Consolidated Health Cost Guidelines™ Sources Database (CHSD). The 2019 CHSD data contains proprietary historical claims experience from range of Milliman's Health Cost Guideline (HCG) data contributors. The databases contain annual enrollment and paid medical and pharmacy claims for over 72 million commercially insured individuals covered by the benefit plans of large employers, health plans, and governmental and public organizations nationwide. Medicaid members were also included in the database. Baseline cost and utilization rates per 1,000 members were calculated and used to estimate the number of STD tests, treatments, and average cost per service.

Table 9 provides procedure codes that were used to supplement the diagnosis codes for the identification of STD tests. Table 9 includes tests that are available for home testing and also those that are not yet available for home testing in order to capture the current level of STD testing for the entire population used as the basis for CHBRP's analysis. In the underlying data, CHBRP is unable to identify which tests are currently performed via home testing.

CHBRP has assumed identical unit costs between at-home testing and not-at-home testing. Unit costs are driven by a number of factors — the availability of home testing for a specific CPT code, the mix of home tests by disease, in-network (INN)/out-of-network (OON) mix, OON reimbursement policies, vendor contracting, plan reimbursement policies for direct reimbursement to members, Medi-Cal fee schedules and capitated laboratory arrangements. Furthermore, while some at-home testing may incur additional costs due to shipping, these costs may be offset by savings from not operating an office or other facility where the specimen is collected.

In addition to medical claims, CHBRP calculated the average cost for prescription medication treatment of each treatable disease from pharmacy claims in the 2019 CHSD data. Then, using the state-wide incidence rates from CHBRP's Public Health team for each disease or the utilization rate of specified drugs, CHBRP determined the total estimated prescription medication cost and utilization rate for each pharmaceutical treatment.

For STDs that require maintenance medication including HIV, HSV-2, and HPV, CHBRP estimated the total cost and utilization of medication required to treat the disease over the course of a year of treatment.

For STDs that can be cured in a course of treatment following diagnosis, CHBRP estimated the total cost and utilization of medication required to cure the disease.

CHBRP identified all individuals utilizing STD services throughout the year to establish a baseline estimate of the number of diagnosed individuals receiving such services.

For HIV medications, CHBRP calculated utilization and unit cost using Milliman's 2018 CHSD and 2018 MarketScan® Commercial Claims and Encounters Database using the same methodology described in Appendix C of CHBRP's 2020 analysis of AB 2204 (CHBRP, 2020). To identify HIV medications (antiretrovirals), CHBRP relied on Medi-Span® Therapeutic Classification System to include all medications identified in the class "Antiretrovirals." However, several medications were removed if they are commonly used to treat hepatitis B or used as PrEP/PEP for HIV.

For hepatitis C medications, CHBRP calculated baseline hepatitis C unit cost using assumptions provided by a Milliman pharmacist. Utilization of hepatitis C medications is based on CDPH 2018 reporting on the incidence of hepatitis C, adjusted for demographics and assuming that 75% of those newly diagnosed with hepatitis C would receive treatment.

The diagnosis codes associated with STD treatment covered by SB 306 are shown in Table 8.

Table 8. Diagnosis Codes for STD Services

Diagnosis Codes Used for STD Services (ICD-10)	Description
A50	Congenital syphilis
A51	Early syphilis
A52	Late syphilis
A53	Other and unspecified syphilis
A54	Gonococcal infection
A55	Chlamydial lymphogranuloma (venereum)
A56	Other sexually transmitted chlamydial diseases
A59	Trichomoniasis
A60	Anogenital herpesviral [herpes simplex] infections
A63	Other predominantly sexually transmitted diseases
A64	Unspecified sexually transmitted disease
B20	HIV
B18.0, B18.1, B19.10	Hepatitis B
B18.2	Hepatitis C
B85.3	Phthiriasis
Z11.3	STD screening
Z11.4	HIV screening
Z11.51	HPV screening

Source: California Health Benefits Review Program, 2021.

Key: HIV = human immunodeficiency virus; HPV = human papillomavirus; ICD = International Classification of Diseases; STD = sexually transmitted disease.

Table 9. Supplemental CPT/HCPCS Codes Used to Identify STD Testing

CPT/HCPCS	Description
Bacterial Vaginosis	
87210	Smear primary source with interpretation wet mount for infectious agents (e.g., saline India ink KOH preps) (Pap Smear)
Chlamydial Infections	
86631	Antibody Chlamydia
86632	Antibody Chlamydia IgM
87110	Culture chlamydia any source
87270	Infectious agent antigen detection by immunofluorescent technique Chlamydia trachomatis
87320	Infectious agent antigen detection by immunoassay technique (e.g., enzyme immunoassay [EIA] enzyme-linked immunosorbent assay [ELISA] immunochemiluminometric assay [IMCA]) qualitative or semiquantitative multiple-step method Chlamydia trachomatis

87490	Infectious agent detection by nucleic acid (DNA or RNA) Chlamydia trachomatis direct probe technique
87491	Infectious agent detection by nucleic acid (DNA or RNA) Chlamydia trachomatis amplified probe technique
87492	Infectious agent detection by nucleic acid (DNA or RNA) Chlamydia trachomatis quantification
87810	Infectious agent antigen detection by immunoassay with direct optical observation Chlamydia trachomatis
Gonococcal Infections	
87590	Infectious agent detection by nucleic acid (DNA or RNA) Neisseria gonorrhoeae direct probe technique
87591	Infectious agent detection by nucleic acid (DNA or RNA) Neisseria gonorrhoeae amplified probe technique
87592	Infectious agent detection by nucleic acid (DNA or RNA) Neisseria gonorrhoeae quantification
87850	Infectious agent antigen detection by immunoassay with direct optical observation Neisseria gonorrhoeae
Syphilis	
86592	Syphilis test non-treponemal antibody qualitative (e.g., VDRL RPR ART)
86593	Syphilis test non-treponemal antibody quantitative
86780	Antibody; Treponema pallidum
Genital Herpes Simplex	
86694	Antibody herpes simplex non-specific type test
86695	Antibody herpes simplex type 1
86696	Antibody herpes simplex type 2
Hepatitis B	
86704	Hepatitis B core antibody (HBcAb) total
86705	Hepatitis B core antibody (HBcAb) IgM antibody
86706	Hepatitis B surface antibody (HBsAb)
86707	Hepatitis Be antibody (HBeAb)
87340	Infectious agent antigen detection by immunoassay technique (e.g., enzyme immunoassay [EIA] enzyme-linked immunosorbent assay [ELISA] immunochemiluminometric assay [IMCA]) qualitative or semiquantitative multiple-step method hepatitis B surface antigen (HBsAg)
87341	Infectious agent antigen detection by immunoassay technique (e.g., enzyme immunoassay [EIA] enzyme-linked immunosorbent assay [ELISA] immunochemiluminometric assay [IMCA]) qualitative or semiquantitative multiple-step method hepatitis B surface antigen (HBsAg) neutralization
87350	Infectious agent antigen detection by immunoassay technique (e.g., enzyme immunoassay [EIA] enzyme-linked immunosorbent assay [ELISA] immunochemiluminometric assay [IMCA]) qualitative or semiquantitative multiple-step method hepatitis Be antigen (HBeAg)
87515	Infectious agent detection by nucleic acid (DNA or RNA) hepatitis B virus direct probe technique
87516	Infectious agent detection by nucleic acid (DNA or RNA) hepatitis B virus amplified probe technique
87517	Infectious agent detection by nucleic acid (DNA or RNA) hepatitis B virus quantification
87912	Infectious agent genotype analysis by nucleic acid (DNA or RNA) Hepatitis B virus

HIV	
86689	Antibody; HTLV or HIV antibody, confirmatory test (e.g., Western Blot)
86701	Antibody HIV-1
86702	Antibody HIV-2
86703	Antibody HIV-1 and HIV-2 single result
87389	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result
G0435	Infectious agent antibody detection by rapid antibody test, hiv-1 and/or hiv-2, screening
Human Papilloma Virus	
87623	Infectious agent detection by nucleic acid (DNA or RNA) Human Papillomavirus (HPV) low-risk types (e.g., 6 11 42 43 44)
87624	Infectious agent detection by nucleic acid (DNA or RNA) Human Papillomavirus (HPV) high-risk types (e.g., 16 18 31 33 35 39 45 51 52 56 58 59 68)
87625	Infectious agent detection by nucleic acid (DNA or RNA) Human Papillomavirus (HPV) types 16 and 18 only includes type 45 if performed
Scabies	
87220	Tissue examination by KOH slide of samples from skin hair or nails for fungi or ectoparasite ova or mites (e.g., scabies)
Trichomoniasis	
87660	Infectious agent detection by nucleic acid (DNA or RNA) Trichomonas vaginalis direct probe technique
87661	Infectious agent detection by nucleic acid (DNA or RNA) Trichomonas vaginalis amplified probe technique
Mycoplasma/Ureaplasma	
87109	Culture, mycoplasma, any source
87563	Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma genitalium, amplified probe technique
Hepatitis C	
86803	Hepatitis C antibody;
86804	Hepatitis C antibody; confirmatory test (e.g., immunoblot)
87520	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, direct probe technique
87521	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, amplified probe technique, includes reverse transcription when performed
87522	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, quantification, includes reverse transcription when performed
G0472	Hepatitis c antibody screening, for individual at high risk and other covered indication(s)

Source: California Health Benefits Review Program, 2021.

Key: CPT = Common Procedure Terminology; HCPCS = Healthcare Common Procedure Coding System; HIV = human immunodeficiency virus; HTLV = human T-lymphotropic virus.

STD tests included in the analysis are shown below in Table 10 along with the number of test counts found in the 2019 CHSD data and the estimated number of tests per 1,000 enrollees.

Table 10. STD Test Counts and Test Rates per 1,000 Among Enrollees in DHMC- and CDI-Regulated Plans and Policies

	Commercial & CalPERS DHMC- and CDI-Regulated Plans/Policies		DHMC-Regulated Medi-Cal Managed Care	
	Test Count in Claims Data	Test per 1,000	Test Count in Claims Data	Test per 1,000
Bacterial Vaginosis	15,976	6	10,196	14
Chlamydial Infections	206,908	78	88,790	126
Gonococcal Infections	200,654	75	86,163	122
Syphilis	116,992	44	45,260	64
Genital Herpes Simplex	41,394	16	7,912	11
Hepatitis B	132,247	50	53,394	76
HIV	125,147	47	53,191	76
Human Papillomavirus	151,632	57	20,892	30
Scabies	3,949	1	625	1
Trichomoniasis	47,138	18	12,696	18
Mycoplasma/Ureaplasma	1,984	1	39	-
Hepatitis C	92,641	35	33,713	48

Source: California Health Benefits Review Program, 2021.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HIV = human immunodeficiency virus; STD = sexually transmitted disease.

Analysis-Specific Caveats and Assumptions

- **Percent of STD tests done via STD home kits at baseline:** Home STD test kit utilization makes up 10% of all STD test utilization at baseline. Because CHBRP's data source for utilization, the 2019 CHSD data, includes data on all STD tests and does not include data specific to STD home test kits, CHBRP assumed the proportion of all STD tests are done via home test kits. The 10% assumption was chosen based on content expert consultation.[54] Further pieces of evidence helped support this assumption: (1) a national survey found 10% of obstetricians and gynecologists (OB/GYNs) surveyed reported offering STD home kits in 2020 during the COVID-19 stay-at-home restriction time period (Weigel et al., 2020) and (2) a national survey of STD clinic directors by the National Association of County and City Health Officials that found about 10% of all STD clinics offered home STD testing in 2020 (Zigman, 2020). Both of these surveys were based on reports to estimate the impact of COVID-19 on health service use. CHBRP assumes the 10% estimated in these two survey settings would be comparable to what would be found for enrollees in health plans and health policies regulated by DMHC and CDI in California. In making the assumption that 10% of all baseline STD test utilization is done via home testing, CHBRP also assumes that utilization of STD home test kits at baseline in 2022 is equivalent to that of 2020, which is likely higher than the proportion that it might have been in 2018 (the year for which claims data are available for use in this analysis). This is because the stay-at-home orders that occurred in 2020 due to COVID-19 likely increased the utilization of home test kits as

[54] Personal communication, E. Hook, March 2021

an alternative to in-clinic based testing (Carnevale et al., 2021; Melendez et al., 2021; Menza et al., 2021; Napoleon et al., 2020; Weigel et al., 2020).

- **Percent shift of baseline in-person STD testing to at-home testing due to SB 306:** Based on content expert input[55], CHBRP assumed 10% of clinical-site STD testing at baseline would shift to STD home test kit use postmandate for enrollees in health plans and health policies regulated by DMHC and CDI with OON coverage for STD testing.
- **Utilization increase of STD home test kits postmandate**: Based on content expert input[56], CHBRP assumed an increase of STD home test utilization occurs among 4% of enrollees who were getting testing at baseline. There may also be some increase in testing by partners of enrollees who use STD tests postmandate, but CHBRP assumed the overall assumed increases in utilization would be inclusive of a potential increase in utilization among partners of newly tested.
- **Increase in STD services/treatment**: Based on content expert input[57], CHBRP assumed as a result of an increase of 4% in STD testing, subsequent service use, which includes treatment, would increase by 3.2% for STDs (excluding HIV and hepatitis C, 0.4% for HIV, and 2.2% for hepatitis C. Per CHBRP's content expert, there is evidence to suggest not all who test positive for STDs go on to get treatment (Schwebke et al., 1997). For HIV and hepatitis C, due to the lower prevalence of disease, treatment is not expected to increase to the same degree as for other STDs. Given the wider spread of HIV testing programs, the likelihood of finding a new positive due to increased testing due to this bill is smaller than that for hepatitis C, which is not as widely tested (McQuillan et al., 2021; Schillie et al., 2020).
- **Self-pay assumption:** With guidance from CHBRP's content expert and staying consistent with CHBRP's analysis of AB 2204 in 2020, CHBRP assumed 25% of all STD testing and treatment is done on a self-pay basis among insured enrollees at baseline and postmandate. As described in the *Background* section, some users of STD services may not use insurance coverage when receiving STD services due to privacy concerns. These self-pay tests may be provided from STD clinics or online home test services.
- **Cost trend:** CHBRP assumed a 0% annual increase in costs over time. CHBRP has also assumed no change in the rebate for hepatitis C drugs over time.

Determining Public Demand for the Proposed Mandate

CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

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

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that in general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

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

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs

[55] Personal communication, E. Hook, March 2021
[56] Personal communication, E. Hook, March 2021
[57] Personal communication, E. Hook, March 2021

whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

Second Year Impacts on Benefit Coverage, Utilization, and Cost

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of SB 306 would have a substantially different impact on utilization of either the tests, treatments, or services for which coverage was directly addressed; the utilization of any indirectly affected utilization; or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second year impacts and determined the second year's impacts of SB 306 would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures are due to population changes between the first year postmandate and the second year postmandate.

APPENDIX D FEDERAL STD COVERAGE MANDATES

The tables in this appendix were drawn from *Federal Preventive Services Mandates and California Mandates*, a resource CHBRP maintains[58] to identify potential overlap between the federal benefit mandate requiring health insurance coverage of some preventive services and California state benefit mandates. CHBRP provides independent evidence-based analysis of health insurance benefits-related legislation at the request of the California Legislature.

Please note:

- This set is not as broad as the full set of STD recommendations issued by the CDC, which is presented in Appendix F.
- The cost-sharing prohibition is relevant to services from **in-network** (INN) providers, and so would not interact with the additional **out-of-network** (OON) services projected in this report as a result of SB 306.

Current STD screening (testing) recommendations and relevant California laws are presented in the three following tables.

[58] Available at https://chbrp.org/other_publications/index.php#revize_document_center_rz44

Table 11. Federal Health Insurance Benefit Mandates as Specified by Reference to USPSTF A and B Recommendations & Related Mandates in California State Law[59,60]

#	Federal Mandates as Specified by Reference to USPSTF					USPSTF A or B Recommendation[61]	Related Health Insurance Benefit Mandate(s) in California State Law[62]
	Condition or Disease	Test, Treatment, or Service	Specified Sex/Other[63]	Specified Age/Other[64]	Terms[65]		
1	Cervical cancer	Cytology and high-risk human papillomavirus (hrHPV) testing (cotesting) or hrHPV testing alone* *The 2018 recommendation specifies cotesting or hrHPV alone (every 5 years) as an alternative to cytology alone every 3 years	Women	30 to 65 years who want to lengthen screening interval* *Women have the option of this lengthened screening interval or the alternate recommendation above	*Without cost sharing when in network* *As soon as 12 months after recommendation release* Every 5 years	Cervical Cancer: Screening https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening (August 2018) Grade: A	Cancer screening tests: H&SC 1367.665 IC 10123.20 Cervical cancer screening: H&SC 1367.66 IC 10123.18
2	Hepatitis B virus (HBV) infection	Screening	Persons at high risk for infection	Adolescents and adults	*Without cost sharing when in network* *As soon as 12 months after recommendation release*	Hepatitis B Virus Infection: Screening, 2020 https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-b-virus-infection-screening (December 2020) Grade: B	None identified

59 For brevity, CHBRP has not listed in each row the California mandate (H&SC 1367.002 & IC 10112.2) that requires compliance with federal laws and regulations requiring coverage of preventive services without cost sharing (Affordable Care Act Section 1001, modifying Section 2713 of the Public Health Service Act).
60 CHBRP is aware that state regulation may also require benefit coverage but is focusing this resource on health insurance benefit mandate laws.
61 Unless otherwise noted, the links listed below were accessed on or before 7/22/2020.
62 Unless otherwise noted, the mandates listed below were reviewed on or before 7/22/2020.
63 "Other" is included here in order to specify pregnant or non-pregnant women.
64 "Other" is included here when more details are available about the intended group, beyond age.
65 *Italicized terms* are explicit in the federal law (Affordable Care Act Section 1001, modifying Section 2713 of the Public Health Service Act). Non-italicized terms of benefit coverage are implied by the referenced recommendation.

#	Federal Mandates as Specified by Reference to USPSTF					USPSTF A or B Recommendation[61]	Related Health Insurance Benefit Mandate(s) in California State Law[62]
	Condition or Disease	Test, Treatment, or Service	Specified Sex/Other[63]	Specified Age/Other[64]	Terms[65]		
3	Hepatitis C virus (HCV) infection	Screening		18 to 79 years	*Without cost sharing when in network* *As soon as 12 months after recommendation release*	Hepatitis C Virus Infection in Adolescents and Adults: Screening https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/hepatitis-c-screening (March 2020) Grade: B	None identified
4	Hepatitis B virus (HBV) infection	Screening	Pregnant women		*Without cost sharing when in network* *As soon as 12 months after recommendation release* At first prenatal visit	Hepatitis B Virus Infection in Pregnant Women: Screening https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/hepatitis-b-virus-infection-in-pregnant-women-screening (July 2019) Grade: A	Maternity services: IC 10123.865 IC 10123.866
5	Human immuno-deficiency virus (HIV)	Screening	Pregnant persons, including those who present in labor or at delivery and whose HIV status is unknown		*Without cost sharing when in network* *As soon as 12 months after recommendation release*	Human Immunodeficiency Virus (HIV) Infection: Screening https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening (June 2019) Grade: A	Maternity services: IC 10123.865 IC 10123.866 HIV testing: H&SC 1367.46 IC 10123.91

#	Federal Mandates as Specified by Reference to USPSTF					USPSTF A or B Recommendation[61]	Related Health Insurance Benefit Mandate(s) in California State Law[62]
	Condition or Disease	Test, Treatment, or Service	Specified Sex/Other[63]	Specified Age/Other[64]	Terms[65]		
6	Syphilis infection	Early screening	Pregnant women		*Without cost sharing when in network* *As soon as 12 months after recommendation release*	Syphilis Infection in Pregnant Women: Screening https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/syphilis-infection-in-pregnancy-screening (September 2018) Grade: A	Maternity services: IC 10123.865 IC 10123.866
7	Chlamydial infection (Topic is in the process of being updated)	Screening	Sexually active women	24 and younger and older women at increased risk for infection	*Without cost sharing when in network* *As soon as 12 months after recommendation release*	Chlamydia and Gonorrhea: Screening https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/chlamydia-and-gonorrhea-screening (September 2014) Grade: B	Maternity services: IC 10123.865 IC 10123.866 Comprehensive preventive care for children aged 16 years or younger: H&SC 1367.35 IC 10123.5 Comprehensive preventive care for children aged 17 and 18 years: H&SC 1367.3 IC 10123.55

#	Federal Mandates as Specified by Reference to USPSTF					USPSTF A or B Recommendation[61]	Related Health Insurance Benefit Mandate(s) in California State Law[62]
	Condition or Disease	Test, Treatment, or Service	Specified Sex/Other[63]	Specified Age/Other[64]	Terms[65]		
8	Gonorrhea (Topic is in the process of being updated)	Screening	Sexually active women	24 and younger and older women at increased risk of infection	*Without cost sharing when in network* *As soon as 12 months after recommendation release*	Chlamydia and Gonorrhea: Screening https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/chlamydia-and-gonorrhea-screening (September 2014) Grade: B	Maternity services: IC 10123.865 IC 10123.866 Comprehensive preventive care for children aged 16 years or younger: H&SC 1367.35 IC 10123.5 Comprehensive preventive care for children aged 17 and 18 years: H&SC 1367.3 IC 10123.55
9	Human immuno-deficiency virus (HIV)	Screening		Adolescents and adults aged 15 to 65 as well as younger and older persons at increased risk	*Without cost sharing when in network* *As soon as 12 months after recommendation release*	Human Immunodeficiency Virus (HIV) Infection: Screening https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening (June 2019) Grade: A	HIV testing: H&SC 1367.46 IC 10123.91 Comprehensive preventive care for children aged 17 and 18 years: H&SC 1367.3 IC 10123.55

#	Federal Mandates as Specified by Reference to USPSTF					USPSTF A or B Recommendation[61]	Related Health Insurance Benefit Mandate(s) in California State Law[62]
	Condition or Disease	Test, Treatment, or Service	Specified Sex/Other[63]	Specified Age/Other[64]	Terms[65]		
10	Syphilis infection	Screening		Asymptomatic non-pregnant adolescents and adults at increased risk	*Without cost sharing when in network* *As soon as 12 months after recommendation release*	Syphilis Infection in Nonpregnant Adults and Adolescents: Screening https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/syphilis-infection-in-nonpregnant-adults-and-adolescents (June 2016) Grade: A	Comprehensive preventive care for children aged 16 years or younger: H&SC 1367.35 IC 10123.5 Comprehensive preventive care for children aged 17 and 18 years: H&SC 1367.3 IC 10123.55

Source: Adapted from CHBRP resource *Federal Preventive Services Mandate and California Mandates*.[66]

Key: USPSTF = United States Preventive Services Task Force.

[66] Available at https://chbrp.org/other_publications/index.php.

Table 12. Federal Health Insurance Benefit Mandates as Specified by Reference to HRSA-Supported Health Plan Coverage Guidelines for Women's Preventive Services & Related Mandates in California State Law[67,68]

#	Federal Mandates as Specified by Reference to HRSA-Supported Guidelines					HRSA-Supported Health Plan Coverage Guidelines for Women's Preventive Services[69]	Related Health Insurance Benefit Mandate(s) in California State Law[70]
	Condition or Disease	Test, Treatment, or Service	Specified Sex/Other[71]	Specified Age/Other[72]	Terms[73]		
1	Human immuno-deficiency virus (HIV)	Prevention education and risk assessment	Adolescent and adult women		*Without cost sharing when in network* *As soon as 12 months after recommendation release* Annually	Screening for Human Immunodeficiency Virus Infection https://www.hrsa.gov/womens-guidelines-2019	HIV testing: H&SC 1367.46 IC 10123.91

[67] For brevity, CHBRP has not listed in each row the California mandate (H&SC 1367.002 & IC 10112.2) that requires compliance with federal laws and regulations requiring coverage of preventive services without cost sharing (Affordable Care Act Section 1001, modifying Section 2713 of the Public Health Service Act).
[68] CHBRP is aware that state regulation may require benefit coverage but is focusing this resource on health insurance benefit mandate laws.
[69] Unless otherwise noted, the links listed below were accessed on or before 7/22/2020.
[70] Unless otherwise noted, the mandates listed below were reviewed on or before 7/22/2020.
[71] "Other" is included here in order to specify pregnant or non-pregnant women.
[72] "Other" is included here when more details are available about the intended group, beyond age.
[73] *Italicized terms* are explicit in the federal law (Affordable Care Act Section 1001, modifying Section 2713 of the Public Health Service Act). Non-italicized terms of benefit coverage are implied by the referenced recommendation.

#	Federal Mandates as Specified by Reference to HRSA-Supported Guidelines					HRSA-Supported Health Plan Coverage Guidelines for Women's Preventive Services[69]	Related Health Insurance Benefit Mandate(s) in California State Law[70]
	Condition or Disease	Test, Treatment, or Service	Specified Sex/Other[71]	Specified Age/Other[72]	Terms[73]		
2	Human immuno-deficiency virus (HIV)	Screening	Adolescent and adult women, women with an increased risk of HIV infection, pregnant women		*Without cost sharing when in network* *As soon as 12 months after recommendation release* All women should be tested for HIV at least once during their lifetime Screening annually or more often may be appropriate for women with an increased risk of HIV infection All pregnant women upon initiation of prenatal care with retesting based on risk factors	Screening for Human Immunodeficiency Virus Infection https://www.hrsa.gov/womens-guidelines-2019	HIV testing: H&SC 1367.46 IC 10123.91

Source: Adapted from CHBRP resource *Federal Preventive Services Mandate and California Mandates*.[74]

Key: HRSA = Health Resources and Services Administration.

[74] Available at https://chbrp.org/other_publications/index.php.

Table 13. Federal Health Insurance Benefit Mandates as Specified by Reference to HRSA-Supported Comprehensive Guidelines for Infants, Children, and Adolescents[75] & Related Mandates in California State Law[76,77]

#	Federal Mandates as Specified by Reference to HRSA-Supported Guidelines					HRSA-Supported Comprehensive Guidelines for Infants, Children, and Adolescents[78]	Related Health Insurance Benefit Mandate(s) in California State Law[79]
	Condition or Disease	Test, Treatment, or Service	Specified Sex/Other	Specified Age/Other	Terms[80]		
1	Wellness	Screening (many, which includes autism screening); for full list, see *Bright Futures* schedule (see link in this row, next to last column) includes HIV and STD screening for adolescents (aged 11-21)		21 and younger, with varied ages for varied screenings; for full list, see *Bright Futures* schedule (see link in this row, next to last column)	*Without cost sharing when in network* *As soon as 12 months after recommendation release* Health benefit coverage requirements vary by screening and also vary by age– for full list, see *Bright Futures* schedule (see link in this row, next to last column)	Recommendations for Preventive Pediatric Health Care Bright Futures/American Academy of Pediatrics https://www.aap.org/en-us/Documents/periodicity_schedule.pdf (March 2020)	Comprehensive preventive care for children aged 16 years or younger:[81] H&SC 1367.35 IC 10123.5 Comprehensive preventive care for children aged 17 and 18 years: H&SC 1367.3 IC 10123.55

Source: Adapted from CHBRP resource *Federal Preventive Services Mandate and California Mandates*.[82]

Key: HRSA = Health Resources and Services Administration.

[75] Affordable Care Act Section 1001, modifying Section 2713 of the Public Health Service Act.
[76] For brevity, CHBRP has not listed in each row the California mandate (H&SC 1367.002 & IC 10112.2) that requires compliance with federal laws and regulations requiring coverage of preventive services without cost sharing (Affordable Care Act Section 1001, modifying Section 2713 of the Public Health Service Act).
[77] CHBRP is aware that state regulation may require benefit coverage but is focusing this resource on health insurance benefit mandate laws.
[78] Unless otherwise noted, the links listed below were accessed on or before 7/22/2020.
[79] Unless otherwise noted, the mandates listed below were reviewed on or before 7/22/2020.
[80] *Italicized terms* are explicit in the federal law (Affordable Care Act Section 1001, modifying Section 2713 of the Public Health Service Act). Non-italicized terms of benefit coverage are implied by the referenced recommendation.
[81] This statute references a similar but older (1987) set of American Academy of Pediatrics recommendations.
[82] Available at https://chbrp.org/other_publications/index.php.

APPENDIX E STD PREVALENCE AND INCIDENCE IN THE UNITED STATES AND IN CALIFORNIA

In 2018, there was an estimated 67.6 million prevalence of STDs — inclusive of eight STDs: chlamydia, gonorrhea, syphilis, genital herpes simplex, hepatitis B, HIV, HPV, and trichomoniasis — among persons living in the United States (Kreisel et al., 2021). Of the 67.6 million prevalent STDs in 2018, 26.2 million were incident STDs (Kreisel et al., 2021).

The following table identifies the prevalence or incidence rates for STDs within California in 2018. Four STDs are required to be reported to the CDC by state public health departments: chlamydia, gonorrhea, syphilis, and chancroid (CDC, 2019). As chancroid is extremely rare with only three documented cases in 2018 — one stemming from California — it was excluded from the table below (CDC, 2019). Note: All other STDs listed below are not required to be reported either at the state or federal level and the prevalence rates were gathered from a variety of sources.

Table 14. Prevalence or Incidence of Selected STDs in California, 2018

	Incidence Rate (Unless Otherwise Specified)	Number of Cases
Bacterial	**Rate (per 100,000 population)**	**Cases**
Chlamydia (a)	583.0 per 100,000	232,181
Gonorrhea (a)	199.4 per 100,000	79,397
Syphilis (all stages) (a)**	63.6 per 100,000	25,344
Congenital	68.2 per 100,000 live births	329
Viral		
Genital herpes simplex (b)	5,410 per 100,000*	2,513,970*
Chronic hepatitis B* (c)**	24.8 per 100,000	9,778
Chronic hepatitis C (d)	89 per 100,000	35,488
Human immunodeficiency virus (HIV) (e)	11.9 per 100,000	4,747
Human papillomavirus (HPV) (f)	27,122 per 100,000*	10,799,238*
HPV-associated cancer (g)	10.8 per 100,000	4643
Protozoal		
Trichomoniasis (j)	830 per 100,000	330,330

Sources: California Health Benefits Review Program, 2020 adapted from (a) CDPH, 2019a; (b) McQuillan et al., 2018; (c) CDPH, 2018; (d) CDPH, 2020a; (e) CDPH, 2020b; (f) McQuillan et al., 2017; (g) U.S. Cancer Statistics Working Group, 2019; and (j) Flagg et al., 2019.

Notes:

*Indicates prevalence rate and estimated total number infected in 2018.
**Incidence rate for syphilis (all stages) is inclusive of congenital syphilis.
***Incidence rate and case numbers represent 2016 data as 2018 data has not been published.

Key: STDs = sexually transmitted diseases.

APPENDIX F STD SCREENING RECOMMENDATIONS

The table in this appendix were drawn from the *Centers for Disease Control and Prevention (CDC). Sexually Transmitted Diseases Treatment Guidelines* (CDC 2015).

Please note:

- This set is broader as the set presented in Appendix D.
- This set of recommendations does not affect cost sharing.

Table 15. STD Screening Recommendations and Considerations

STD	Women	Pregnant Women	Men	MSM	Persons with HIV
Bacterial					
Chlamydia	Sexually active women under aged 25 years Sexually active women aged 25 years and older if at increased risk Retest approx. 3 months after treatment	Under aged 25 years Aged 25 years and older if at increased risk Under aged 25 years or at risk, retest during the 3rd trimester Those with infection should have test-of-cure 3-4 weeks after treatment and retest within 3 months	Consider screening young men in high prevalence clinical settings or in populations with high burden of infection (e.g., MSM)	At least annually at sites of contact (urethra, rectum) Every 3-6 months if at increased risk	Sexually active individuals, screen at first HIV evaluation and at least annually thereafter More frequent screening depending on individual risk behaviors
Gonorrhea	Sexually active women under aged 25 years Sexually active women aged 25 years and older if at increased risk Retest approx. 3 months after treatment	Under aged 25 years Retest approx. 3 months after treatment	-	At least annually at sites of contact (urethra, rectum) Every 3-6 months if at increased risk	Sexually active individuals, screen at first HIV evaluation and at least annually thereafter More frequent screening depending on individual risk behaviors
Syphilis	-	All pregnant women at the first prenatal visit	-	At least annually at sites of contact	Sexually active individuals, screen at first HIV evaluation

		Retest early in 3rd trimester and at delivery if at high risk		(urethra, rectum) Every 3-6 months if at increased risk	and at least annually thereafter More frequent screening depending on individual risk behaviors
Viral					
Genital Herpes	Consider type-specific HSV serologic testing for women presenting for STD evaluation (esp. for women with multiple sex partners)	-	Consider type-specific HSV serologic testing for men presenting for STD evaluation (esp. for MSM)	Consider type-specific serologic tests for MSM with previously undiagnosed genital tract infection	Consider type-specific HSV serologic testing for those presenting for STD evaluation (esp. for people with multiple sex partners), persons with HIV infection, and MSM at increased risk for HIV acquisition
Hepatitis B	Women at increased risk	Test for HBsAg at first prenatal visit of each pregnancy regardless of prior testing Retest at delivery if at high risk	Men at increased risk	All MSM should be tested for HBsAg	Test for HBsAg and anti-HBc and/or anti-HBs
Hepatitis C	At least once in a lifetime for all women 18 years old and older	During each pregnancy	At least once in a lifetime for all men 18 years old and older	At least once in a lifetime for all MSM 18 years old and older	At least once in a lifetime for all persons with HIV 18 years old and older
HIV	All women aged 13-64 (opt-out) All women who seek evaluation and treatment for STDs	Should be screened at first prenatal visit (opt-out) Retest in 3rd trimester if at high risk	All men aged 13-64 (opt-out) All men who seek evaluation and treatment for STDs	At least annually for sexually active MSM if HIV status is unknown or negative and the patient or his sex partner(s) have had more than one sex partner	-

				since most recent HIV test	
Cervical Cancer/HPV	Women aged 21-29 years every 3 years with cytology Women aged 30-65 years every 3 years with cytology, or every 5 years with a combination of cytology and HPV testing	Same as non-pregnant women	-	-	Women should be screened within 1 year of sexual activity or initial HIV diagnosis using conventional or liquid-based cytology; testing should be repeated 6 months later
Protozoal					
Trichomoniasis	Consider for women receiving care in high-prevalence settings and those at high risk	-	-	-	Recommended for sexually active women at entry to care and at least annually thereafter

Source: California Health Benefits Review Program, 2021 adapted from CDC, 2015.

Key: anti-HBc = previous or ongoing hepatitis B infection, anti-HBs = hepatitis B vaccine or previous recovery, HBsAg = hepatitis B surface antigen, HPV = human papillomavirus, HSV = herpes simplex virus, MSM = men who have sex with men, STD = sexually transmitted disease.

APPENDIX G STD CASES BY RACE AND ETHNICITY IN CALIFORNIA 2018

Racial and ethnic disparities in rates of STDs — especially among Black/African Americans and Hispanic/Latinos — have been identified in California since at least 2009 (California Health Report, 2017). Table 1 identifies the number of new STD cases — including cases of chlamydia, gonorrhea, syphilis, and congenital syphilis — by race/ethnicity in California in 2018.

Table 16. Select STD Cases by Race/Ethnicity in California, 2018

	Chlamydia			Gonorrhea			Syphilis			Congenital Syphilis
Race/Ethnicity	**Total Cases**	**Percentage of Female Cases**	**Percentage of Male Cases**	**Total Cases**	**Percentage of Female Cases**	**Percentage of Male Cases**	**Total Cases**	**Percentage of Female Cases**	**Percentage of Male Cases**	**Maternal Cases**
Asian/Pacific Islander	9,410	59%	41%	2,961	24%	76%	--	--	--	12
Black/African American	22,908	56%	43%	12,954	36%	62%	2,017	17%	83%	68
Hispanic/Latinos	54,326	62%	34%	20,553	35%	65%	6,151	14%	86%	155
White	33,206	54%	46%	17,337	30%	70%	4,589	16%	84%	84
Other/Unknown*	112,331	63%	37%	25,952	34%	66%	2,611	12%	88%	10

Sources: California Health Benefits Review Program, 2020 adapted from CDPH, 2019a.

Note: Percentage of male and female cases may not add to 100% due to small percentage of cases where gender was not specified.

*American Indian/Alaska Native and Multirace are included in Other/Unknown (as well as Asian/Pacific Island with respect to Syphilis)

Key: STD = sexually transmitted disease.

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CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

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

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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

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