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).

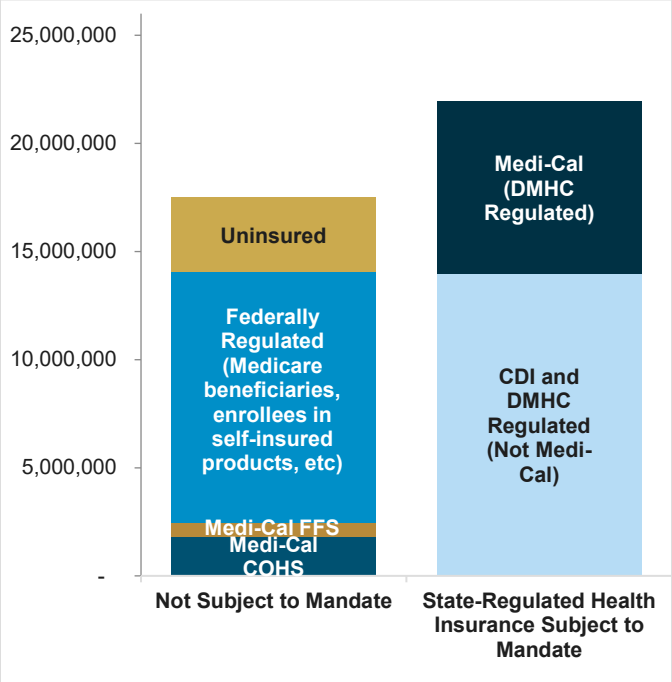
Medical Effectiveness: There is a *preponderance* of evidence that STD specimens self-collected outside the clinical setting are of equivalent effectiveness as those collected in a clinical environment. For blood and urine, there is a *preponderance* of evidence. For swabs, evidence is *clear and convincing.*

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.

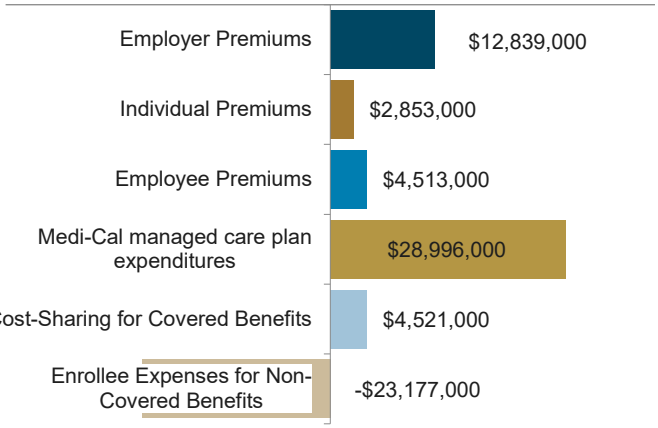
For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, no increase in INN provider ordering of home test kits is expected. However, these plans are required to cover STD testing from a limited set of OON providers (local health departments, family planning or community clinics) and some of these 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.