

State of California—Health and Human Services Agency California Department of Public Health



At Home Testing for Sexually Transmitted Infections (STIs) Senate Bill 306 (Pan, Chapter 486, Statutes of 2021) Fact Sheet

Background

<u>Senate Bill (SB) 306</u> (Pan, Chapter 486, Statutes of 2021) became effective January 1, 2022. Among other provisions, SB 306 expands state-regulated commercial health care services plans, health insurance plans, Medi-Cal Managed Care Plans, Medi-Cal Feefor-Service, and Family Planning Access Care Treatment (Family PACT) to include the use of home test kits for sexually transmitted diseases (STDs)¹ when specified conditions are met.

Definition of a Home Test Kit²

SB 306 defines a home test kit as "a product used for a test recommended by the federal Centers for Disease Control and Prevention [CDC] guidelines or the United States Preventive Services Task Force [USPSTF] that has been Clinical Laboratory Improvement Amendments of 1988 (CLIA)-waived, U.S. Food and Drug Administration (FDA)-cleared or -approved, or developed by a laboratory in accordance with established regulations and quality standards, to allow individuals to self-collect specimens for STDs, including HIV, remotely at a location outside of a clinical setting."

Considerations for Medi-Cal Fee for Service, Medi-Cal Managed Care, and Family PACT Beneficiaries, Providers, and Health Plans

Medi-Cal and Family PACT must cover at home test kits for STDs if the tests are:

1) "deemed medically necessary or appropriate," and

² The term 'home STD test kit' is defined in the following sections of state law, organized by the departments responsible for regulating the different types of health coverage: 1) health plans regulated by Department of Managed Health Care (DMHC), at California Health and Safety Code (HSC) Section 1367.34; 2) health insurers regulated by the California Department of Insurance (CDI), at Insurance (INS) Code Section 10123.208; and 3) Medi-Cal plans overseen by the Department of Health Care Services (DHCS), at Welfare and Institutions Code [WIC] 14132(af)(1). This definition also applies to DHCS' Family Planning Access Care and Treatment (Family PACT) Program in accordance with WIC 14132(aa)(8)(G)(i) and WIC 24007.



¹ The public health field now uses the term "STIs"; SB 306 uses "STDs"—both terms are used here.

2) "ordered directly by an enrolled Medi-Cal or Family PACT clinician or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs."

In Medi-Cal and Family PACT, reimbursement shall cover any laboratory costs of processing the kit. (WIC 14132((aa)(8)(G)(i); WIC 14132(af)(1).

However, there are important requirements that have to be met before tests will be covered. Specifically, Medi-Cal and Family PACT reimbursement is "contingent upon the addition of codes specific to [at-]home [STD] test kits in the Current Procedural Terminology [CPT] or Healthcare Common Procedure Coding System [HCPCS] to comply with Health Insurance Portability and Accountability Act [HIPAA] requirements". CPT Codes are developed by the American Medical Association (AMA) and HCPCS Codes are developed by the U.S. Centers for Medicare and Medicaid Services (CMS). It is unknown if or when these specific codes will be established.

In addition, to be eligible for reimbursement in Medi-Cal or Family PACT, home STD test kits must be sent by "the enrolled Medi-Cal or Family PACT provider to a Medi-Cal enrolled laboratory with [a] fee based on the Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule." A list of enrolled Medi-Cal providers that includes clinical laboratories is available on the California Health and Human Services Open Data Portal: Profile of Enrolled Medi-Cal Fee-for-Service (FFS) Providers – Datasets. However, enrolled laboratories may not yet have reimbursement mechanisms in place for at-home STD testing until the billing codes described above have been established.

Reimbursement in Medi-Cal and for Family PACT beneficiaries will also only be covered if "any necessary federal approvals" have been obtained by the California Department of Health Care Services (DHCS).

DHCS may implement the provisions of SB 306 via "all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking any further regulatory action." See the DHCS website for Medi-Cal Managed Care All Plan Letters and Medi-Cal Provider Bulletins. Visit the Family PACT website to access news and updates and to sign up for the electronic newsletter for Family PACT providers.

Considerations for Commercial Health Insurance and Other Managed Care Plan Beneficiaries, Providers, and Payers

Health plans and health insurers, regulated respectively by the Department of Managed Health Care (DMHC)^{3,4} or the California Department of Insurance (CDI), must cover home STD test kits, including any laboratory costs of processing the kits, that are

³ To determine whether a specific health plan is licensed by DMHC, visit the DMHC website, List of All Licensed Plans at https://wpso.dmhc.ca.gov/hpsearch/viewLicensedHealthPlan.aspx. Health plan enrollees can also review their coverage documents or contact their health plan for this information.
⁴ For more information on DMHC communications to licensed health plans on SB 306-related requirements, see DMHC All Plan Letter (APL) 21-025 – Newly Enacted Statutes Impacting Health Plans

- 1) "deemed medically necessary or appropriate and ordered directly by an [in-network] clinician" (HSC 1367.34(a)(2)) (INS 10123.208), or
- 2) "furnished through a standing order for patient use based on clinical guidelines and individual patient health needs."

Health plans and insurers must cover home STD test kits and laboratory processing costs when a contract or policy is issued, amended, renewed, or delivered on or after January 1, 2022. For health insurance regulated specifically by CDI, the home STD kit coverage requirement does not apply to specialized health insurance policies that provide coverage in a single specialized area of health care, including dental-only, vision-only, and behavioral health-only policies.

Considerations for At Home STD Test Kit Providers

For more information on how to enroll as a Medi-Cal provider, visit DHCS <u>Provider Enrollment</u>. For information on how to enroll as a Medi-Cal laboratory, visit DHCS <u>Clinical Laboratory Application Information</u>.

Discussion

In response to reductions in access to STD testing and treatment during the COVID-19 pandemic, the U.S. Centers for Disease Control and Prevention (CDC) has recognized that using at home test kits to test for STDs outside of healthcare settings and clinics could be useful when in-person services are not available or feasible. Fortunately, the Affordable Care Act requires most health plans to cover preventive services with a rating of "A" or "B" from the U.S. Preventive Services Task Force (USPSTF) without cost-sharing when delivered by in-network providers. ^{5,6} USPSTF has granted A or B ratings to screening for chlamydia, gonorrhea, hepatitis B, hepatitis C, HIV, human papilloma virus, and syphilis for specified populations. ⁷ However, an analysis of SB 306 by the California Health Benefits Review Program found that many health care providers and health plans may not yet have systems in place to order or be reimbursed for home STD test kits, which could limit or delay the timely implementation of SB 306.

Some at home STD testing companies have already begun to bill insurance for their services, although Medi-Cal reimbursement may currently only cover the cost of their laboratory processing the test specimen and not the cost of the kit itself or shipping and handling until additional billing codes are established for this purpose.

⁽²⁰²¹ Legislative Session) at https://www.dmhc.ca.gov/Portals/0/Docs/OPL/APL%2021-025%20-%20Newly%20Enacted%20Statutes%20Impacting%20Health%20Plans%20(12 20 21).pdf.

⁵ Centers for Medicare & Medicaid Services: <u>Affordable Care Act Implementation FAQs – Set 12 (Feb. 20, 2013).</u>

⁶ California Health Benefits Review Program, Federal Preventive Services Mandate and Related California Mandates, (Feb. 2, 2022).

https://files4.1.revize.com/chbrpnew/Federal%20Preventive%20Services%20Mandate%20and%20California%20Mandates%20020222.pdf

⁷ U.S. Preventive Services Task Force "A and B" Recommendations, https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-and-b-recommendations

For more information on at home STD testing, ask your health plan or insurer for a list of which at home STD tests are covered under your health plan's or health insurance policy's free preventive care benefit, as well as under your in-network benefits for STD home test kits and laboratory processing (as required by SB 306).

Resources

CDC Sexually Transmitted Infections Treatment Guidelines, 2021

California Department of Public Health, STD Control Branch

FDA List of CLIA-Waived Tests

National Alliance of State and Territorial AIDS Directors: <u>Self-Testing: A Strategy to Improve Access to HIV, Viral Hepatitis, and STI Testing</u>

National Association of City and County Health Officials: <u>Billing for Clinical Services</u> Toolkit

National Coalition of STD Directors: <u>At-Home Self-Collection Lab Testing for Sexually</u> Transmitted Infections | Technical Assistance Brief