SENATE COMMITTEE ON HEALTH
Senator Dr. Richard Pan, Chair

BILL NO: SB 306
AUTHOR: Pan
VERSION: March 24, 2021
HEARING DATE: April 7, 2021
CONSULTANT: Melanie Moreno

SUBJECT: Sexually transmitted disease: testing

SUMMARY: Permits pharmacists to dispense a drug, without the name of an individual for whom the drug is intended, when prescribed for the sexual partner of someone who has been diagnosed with a sexually transmitted disease (STD). Prohibits health care providers who prescribe, dispense, or furnish such a drug from being subject to, civil, criminal, or administrative penalties, as specified. Requires a syphilis blood test, during the third trimester of pregnancy and at delivery, as specified. Requires public and commercial health coverage of home STD test kits. Requires Family PACT reimbursement for STD services provided to patients who are not at risk for experiencing or causing an unintended pregnancy, and who are not in need of contraceptive services. Adds rapid STD tests to existing law which permits HIV counselors to perform rapid HIV and hepatitis C tests.

Existing law:

1) Permits physicians, nurse practitioners, certified nurse-midwives, and physician assistants who diagnose a sexually transmitted chlamydia, gonorrhea, or other STD to prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to that patient's sexual partner or partners without examination of that patient's partners (referred to as "expedited partner therapy" or "EPT"). [HSC §120582]

2) Requires physicians and or other persons engaged in prenatal care of a pregnant woman, or attending the woman at the time of delivery, to obtain or cause to be obtained a syphilis blood test at the time of the first professional visit or within ten days. [HSC §120685]

3) Establishes the Department of Managed Health Care (DMHC) to regulate health plans under the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act); and the California Department of Insurance (CDI) to regulate health and other insurance. [HSC §1340, et seq., INS §106, et seq.]

4) Establishes the Department of Health Care Services (DHCS) to administer the Medi-Cal program, which provides medical coverage to low income persons, and the Family PACT program, which provides comprehensive clinical family planning services to low income persons. [WIC §14000, et seq., WIC §14132, et seq.]

5) Establishes the State-Only Family Planning Program to provide family planning services for men and women, including emergency and complication services directly related to the contraceptive method and follow-up, and consultation and referral services. [WIC §24007]

6) Permits HIV counselors to perform HIV, hepatitis C virus (HCV), or combination HIV/HCV tests that are waived under the federal Clinical Laboratory Improvement Act (CLIA) under certain circumstances, including if they are working under the direction of a physician and are trained in accordance with specified state and federal guidelines. Requires these HIV

counselors to be either trained by California Department of Public Health's (CDPH's) Office of AIDS (OA) and working in an HIV counseling and testing site funded by CDPH through a local health department (LHD), or to be working in an HIV counseling and testing site that utilizes HIV counseling staff who are trained by the OA and are approved by an LHD. [HSC §120917]

This bill:

1) Requires health care providers who prescribe, dispense, or otherwise furnish EPT, and are unable to obtain the name of a patient's sexual partner, to include the words "expedited partner therapy" or the letters "EPT" on the prescription.

2) Permits pharmacists to dispense a drug prescribed under EPT and to label the drug without the name of an individual for whom the drug is intended, if the prescription includes the words "expedited partner therapy" or the letters "EPT."

3) Prohibits a pharmacist or other health care provider who prescribes, dispenses, furnishes, or otherwise renders EPT, from being liable in, or subject to, a civil, criminal, or administrative action, sanction, or penalty for rendering EPT, if the use of EPT is in compliance with this bill and existing law, except in cases of intentional misconduct, gross negligence, or wanton or reckless activity.

4) Requires physicians or other persons engaged in prenatal care of a pregnant woman to obtain a syphilis blood test during the third trimester of pregnancy (in addition to at the time of the first visit). Requires health care providers attending a woman at the time of delivery to ensure that a syphilis blood test is done at the time of delivery, unless the patient's chart shows a negative syphilis screen in the third trimester.

5) Requires Family PACT, the State-Only Family Planning Program, Medi-Cal, and commercial health plans and health insurers to cover home STD test kits, including the laboratory costs of processing the kit. Defines "home STD test kit" as a product designed to allow individuals to collect specimens for STD testing remotely at a location outside of a clinical setting and ordered directly by a clinician or furnished under a standing order based on clinical guidelines and individual patient health needs.

6) Requires reimbursement for STD services under the Family PACT program, subject to an appropriation by the Legislature and any potential draw down of federal matching funds, as specified, to uninsured, income-eligible patients or patients with health care coverage who have confidentiality concerns, who are not at risk for experiencing or causing an unintended pregnancy, and who are not in need of contraceptive services. Requires these office visits, including in person and visits through telehealth, to be reimbursed at the same rate as those office visits for any other Family PACT visit.

7) Adds CLIA-waived (rapid) STD tests to existing law which permits HIV counselors to perform rapid HIV/HCV tests. Requires HIV counselors that perform any of these tests to complete an HIV counseling training course that has been approved by CDPH OA. Prohibits HIV counselors from administering a rapid HIV, HCV, or STD test until they demonstrate proficiency in administering the test.

8) Requires HIV counselors to demonstrate sufficient knowledge of HIV, HCV, and STDs to provide appropriate counseling and referrals to patients. Requires HIV counselors certified

prior to January 1, 2022, who will administer rapid STD tests, to obtain training described in 7) above. Prohibits HIV counselors from performing rapid STD tests until after completing the required training, unless they are also certified as a limited phlebotomist technician.

9) Makes other technical, clarifying changes to existing law.

FISCAL EFFECT: This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) *Author's statement.* According to the author, California has taken a robust approach to expanding access to health care. However, the state has lagged in enacting comprehensive policies to increase access to STD screening and treatment, and uninsured Californians lack a pathway to STD treatment. For example, while the Family PACT program includes STD services as a covered benefit, it's only for patients that are seeking family planning services. California's EPT statute, the first in the nation, permits health care providers to treat the sex partners of patients diagnosed with STDs by providing prescriptions or medications to the patient to take to his/her partner *without the health care provider first examining the partner*. However, our EPT statute is underutilized because it lacks liability protections for providers who might otherwise be interested in integrating the evidence-based practice into their service delivery. HIV Counselors, trained professionals working with some of our most vulnerable populations, can provide rapid testing for HIV and hepatitis, but cannot perform rapid tests for other common STDs. Current law requires congenital syphilis screening in the first trimester of pregnancy, but without additional screening requirements, far too many cases go undetected. Finally, during the pandemic, with undiagnosed cases of STDs rampant, access to home test kits, which would detect undiagnosed STDs, is limited due to coverage restrictions. The COVID-19 pandemic has exacerbated STD infection rates across the country, and this bill takes a comprehensive approach to address California's STD crisis by expanding access to STD care in an equitable way.

2) *Background*. The Centers for Disease Control and Prevention (CDC) estimates that one in five people in the U.S. have an STD. In 2018, nearly 68 million STD infections were reported nationwide, and rates of syphilis, chlamydia, or gonorrhea are up 40% since 2013. California had the second highest syphilis rates in the nation in 2018. Between 2008 and 2018, the syphilis rate among women of reproductive age increased by 743%. In 2018, more than 329 babies were born with congenital syphilis in California and there were 20 stillbirths associated with the disease. Last year, the CDC announced that a new, antibiotic-resistant strain of gonorrhea began to spread across the country amidst the COVID-19 crisis. A December 2020 CDPH alert about the rising number of gonococcal infections warned of a severe complication of untreated gonorrhea that spreads across the body through the bloodstream. The CDC estimates that untreated STDs cause at least 24,000 women in the U.S. each year to become infertile. Untreated syphilis can also lead to negative maternal child health outcomes, including infant deaths. The CDC estimates that of pregnant women who acquire syphilis up to four years before delivery, 80% will transmit the infection to the fetus, and 40% may result in stillbirth or death.

3) *Inequities persist*. The STD crisis affects communities across the state, but California youth, people of color, and gay, bisexual, and transgender people are disproportionately impacted. Statewide data indicate over half of all STDs in the state are experienced among California youth ages 15 to 24 years old. African Americans are 500% more likely to contract gonorrhea and chlamydia than their white counterparts. These disparities are expected to

worsen as a result of the COVID-19 pandemic. CDC studies suggest a range of factors may contribute to rising STD rates, including inequitable access to health care and culturally competent medical services, race, poverty, stigma, discrimination, and drug use.

According to a California Health Benefits Review Program (CHBRP) analysis of this bill, 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. A national STD survey of youth (ages 15 to 25) years found very few received recommended screening for STDs — only 16.6% of females and 6.6% of males had been tested within the last year. A 2017 study found that delayed HIV diagnoses among high-risk populations (e.g., men who have sex with men (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.

4) *Costs of the STD crisis*. The CDC estimates that STD infections acquired in 2018 totaled nearly $16 billion in direct lifetime medical costs nationwide. Chlamydia, gonorrhea, and syphilis accounted for more than $1 billion of the total cost. Sexually acquired HIV and human papilloma virus (HPV) were the costliest due to lifetime treatment for HIV at $13.7 billion and treatment for HPV-related cancers at $755 million. Approximately $1 billion is spent annually in California on health costs associated with STDs.

5) *Congenital syphilis*. According to a July 2020 article in Health Affairs, as the health care system responds to COVID-19 cases across the country, a June 2020 CDC analysis reminds us that there's another, often overlooked, epidemic that doesn't show signs of slowing down: STDs. The most unexpected finding is the alarming rise in congenital syphilis, which occurs when the infection is passed from mother to baby during pregnancy. Recent data show that cases of congenital syphilis increased 40% between 2017 and 2018, from 24 to 33 cases per 100,000 live births. While these increases are being seen across the country, the western and southern regions of the U.S. have been hit particularly hard. According to a 2019 California HealthCare Foundation report, Texas, Nevada, Louisiana, Arizona, and California had the highest rates of congenital syphilis in 2018. According to CDPH, in California in 2018, 329 babies with congenital syphilis were reported, representing a 900% increase from 2012. According to the 2020 CDC analysis, half of the cases of congenital syphilis occur due to gaps in testing and treatment during prenatal care. The CDC recommends testing for syphilis for all pregnant women in the first prenatal visit and re-testing in the third trimester for women who are at high risk for syphilis, who live in areas with high numbers of syphilis cases, and/or who were not previously tested, or had a positive test in the first trimester. CDPH guidance on syphilis testing states:

   a) All pregnant patients should be screened for syphilis at least twice during pregnancy: once at either confirmation of pregnancy or at the first prenatal encounter (ideally during the first trimester) – and again during the third trimester (ideally between 28–32 weeks' gestation), regardless of whether such testing was performed or offered during the first two trimesters;
   b) Patients should be screened for syphilis at delivery, except those at low risk who have a documented negative screen in the third trimester;
   c) Emergency department (ED) providers in local health jurisdictions with high congenital syphilis morbidity should consider confirming the syphilis status of all pregnant patients

prior to discharge, either via documented test results in pregnancy, or a syphilis test in the ED if documentation is unavailable;

d) All people who are or could become pregnant entering an adult correctional facility located in a local health jurisdiction with high congenital syphilis morbidity should be screened for syphilis at intake, or as close to intake as feasible;

e) All sexually active people who could become pregnant should receive at least one lifetime screen for syphilis, with additional screening for those at increased risk; and,

f) All sexually active people who could become pregnant should be screened for syphilis at the time of each HIV test.

6) *EPT*. According to the CDC, effective clinical management of patients with treatable STDs requires treatment of the patients' current sex partners to prevent reinfection and curtail further transmission. The standard approach to partner treatment includes clinical evaluation in a health care setting, with partner notification by the presenting patient, by the provider, or by both. Provider-assisted referral for follow-up care is considered the optimal strategy for partner treatment, but is not always feasible. The CDC states that EPT is a useful option to facilitate partner treatment, particularly for treatment of male partners of women with chlamydial infection or gonorrhea. According to a May 2020 analysis, EPT is explicitly permitted in 45 states, is potentially allowable in four states (Alabama, Kansas, Oklahoma, and South Dakota), and prohibited in South Carolina.

7) *Home STD kits*. According to the CHBRP report of this bill, most home STD kits are "home-to-lab," except for CLIA-waived, rapid tests. For non-rapid tests, a specimen is self-collected at home using materials and instructions provided in the kit and the kit is then mailed to a laboratory or medical facility for processing and diagnosis. When self-collected in a setting outside of a medical setting, collection of specimens may not be covered by Federal Drug Administration (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 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 state 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.

8) *CHBRP analysis*. AB 1996 (Thomson, Chapter 795, Statutes of 2002) requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996, and reviewed the mandate to cover home STD kits under this bill. Key findings include:

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

b) *Medical effectiveness:* There is a preponderance 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. For blood, there is a preponderance of evidence. For urine, evidence is limited.

c) *Public health:* In the first year post-mandate, 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 HCV (1%).

d) *Utilization:* For commercial/CalPERS enrollees in plans and policies, the initial post-mandate year increase in STD testing would be primarily limited to enrollees in plans and policies that generally cover out-of-network providers. Among this group (17% of all commercial/CalPERS enrollees), this bill 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 HCV, 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 in-network provider ordering of home test kits is expected. However, these plans are required to cover STD testing from a limited set of out-of-network 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, this bill 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 HCV, 47 more being treated for HIV, and 20,428 more being treated for other STDs. No initial post-mandate year cost offsets or savings in other healthcare utilization would result because of this bill. 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.

e) *Expenditures:* This bill would increase total net annual expenditures by $30,545,000 or 0.02% for the year following implementation (a range of approximately $.09 per member per month to $.38 per member per month). 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.

9) *Triple referral.* This bill has been triple referred. Should it pass out of this committee, it will be referred to the Senate Committee on Business, Profession and Economic Development.

10) *Prior legislation.* SB 855 (Pan of 2020) would have permitted the Family PACT program to offer covered benefits to income-eligible patients, even if contraception is not discussed during the patient encounter, updated California's EPT statute to include provider liability protections used in other states, and clarified that Medi-Cal managed care enrollees can obtain STD services from their provider of choice. *SB 855 was not heard in the Senate Business, Professions, and Economic Development Committee.*

SB 932 (Wiener of 2020) would have added rapid STD tests to existing law which permits HIV counselors to perform rapid HIV/HCV tests. *These provisions were amended out of the bill.*

11) *Support*. The sponsors of this bill write that the STD epidemic requires a bold response and that California must take a comprehensive and robust approach to strengthening our public health infrastructure and expanding access to STD coverage and care to communities most impacted by the STD crisis. Supporters state that the COVID-19 pandemic has exacerbated STD rates in California and across the country that were already skyrocketing to epidemic proportions prior to the public health emergency. Nearly 340,000 Californians were infected with syphilis, chlamydia, or gonorrhea in 2018 – up 40% since 2013. In 2016 alone, gonorrhea rates increased by double digits in the following counties: Sacramento 50%, Los Angeles 27%, San Diego 35.5%, San Francisco 18%, and Kings 41%. Untreated STDs can lead to serious long-term health consequences, including infertility, blindness in the case of gonorrhea, cervical cancer related to human papilloma virus (HPV) infections, and negative maternal and child health outcomes. STDs also increase both the transmission and acquisition of HIV.

12) *Opposition*. America's Health Insurance Plans, the Association of California Life and Health Insurance Companies, and the California Association of Health Plans, writing in opposition to a number of mandate bills, state that California has been a national leader in maintaining a stable market despite rising costs and uncertainty at the federal level over the individual and employer market. The COVID-19 pandemic has forced us all to re-evaluate our priorities this year, focusing on the critical issues necessary to address this pandemic. Now is not the time to inhibit competition with proscriptive mandates that reduce choice and increase costs. In the face of this continued uncertainty and efforts to fragment the market and promote less comprehensive coverage, California needs to protect the coverage gains we've made and stay focused on the stability and long-term affordability of our health care system. Benefit mandates impose a one-size-fits-all approach to medical care and benefit design driven by the legislature, rather than consumer choice. These bills will lead to higher premiums, harming affordability and access for small businesses and individual market consumers. State mandates increase costs of coverage – especially for families who buy coverage without subsidies, small business owners who cannot or do not wish to self-insure, and California taxpayers who foot the bill for the state's share of those mandates.

SUPPORT AND OPPOSITION:

Support: APLA Health (co-sponsor)
Black Women for Wellness Action Project (co-sponsor)
Essential Access Health (co-sponsor)
Fresno Barrios Unidos (co-sponsor)
Los Angeles LGBT Center (co-sponsor)
San Francisco AIDS Foundation (co-sponsor)
ACCE Action
Access Reproductive Justice
Access Support Network
AIDS Healthcare Foundation
American Academy of Pediatrics, California
American Nurses Association California
Bienestar Human Services
Business & Professional Women of Nevada County

California Latinas for Reproductive Justice
California LGBTQ Health and Human Services Network
California Nurse-Midwives Association
California Pharmacists Association
California Physicians Alliance
California Society of Health-System Pharmacists
California Women's Law Center
CaliforniaHealth+ Advocates
Citizens for Choice
County Health Executives Association of California
Courage California
Desert AIDS Project
End HEP C SF
Harm Reduction Coalition
Harm Reduction Services
HIVE
MPact/Fijate Bien Program
NARAL Pro-Choice California
Sacramento LGBT Community Center
Team Lily
The Los Angeles Trust for Children's Health
The Women's Foundation California
Via Care Community Health Center
Western Center on Law & Poverty, Inc.
One Individual

Oppose: America's Health Insurance Plans
Association of California Life and Health Insurance Companies
California Association of Health Plans

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