SENATE THIRD READING SB 306 (Pan) As Amended August 30, 2021 Majority vote

# SUMMARY

Permits a pharmacist to dispense a drug to treat sexually a transmitted disease (STD) without the name of an individual for whom a drug is intended if the prescription includes the words "expedited partner therapy" or the letters "EPT." Requires every health care service plan (health plan) contract or health insurance policy issued, amended, renewed or delivered on or after January 1, 2022 to provide coverage for home test kits for STD, including any laboratory costs of processing the kit, that are deemed medically necessary or appropriate and ordered directly by a clinician or furnished through a standing order for patient use based on clinical guidelines and individual health needs. Permits a human immunodeficiency virus (HIV) counselor that meets certain requirements to perform STD test. Clarifies that the practice of a physician and surgeon prescribing, dispensing, furnishing, or providing prescription antibiotic drugs to a patient's sexual partner/s without examination of the partner/s is referred to as EPT. Requires a prescription to include the words EPT if a health care provider is unable to obtain the name of a patient's sexual partner for a drug prescribed for STDs. Prohibits a health care provider from being held liable in medical malpractice action or professional disciplinary action if the use of EPT is in compliance with this bill, except in cases of misconduct, gross negligence, or wanton or reckless activity. Expands the scope of benefits in Medi-Cal to include STD home test kits, including any laboratory costs for processing the kit, that are deemed medically necessary or appropriate and ordered directly by an enrolled Medi-Cal or the Family Planning, Access, Care, and Treatment Program (FPACT) clinician or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs. Defines home test kit to mean a product that has been Food and Drug Administration (FDA)-waived, -cleared, - approved, or developed by a laboratory in accordance with established regulations and quality standards, to allow individuals to collect specimens or test, or both collect specimens and test, for STDs, including HIV, remotely at a location outside of a clinical setting.

# **COMMENTS**

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. Often used interchangeably, the term STI refers to an organism acquired via sexual contact, whereas STD refers to a disease state, resulting from the development of an STI. 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. According to a 2021 report from the Centers for Disease Control and Prevention (CDC), in 2019, United States health departments reported: 1.8 million cases of chlamydia, an increase of nearly 20% since 2015; 616,392 cases of gonorrhea, an increase of more than 50% since 2015; and, 129,813 cases of syphilis (all stages), an increase of more than 70% since 2015.

*Screening for STDs.* According to the California Health Benefits Review Program (CHBRP), prevention of STDs includes provision of an accurate risk assessment to assess behavioral and biological risk for acquiring or transmitting STDs. As part of the health care visit, the CDC

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. 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 for HIV and STDs. Use of antiretroviral treatment of persons with HIV to prevent HIV infection in partners has also been demonstrated to decrease the risk of transmission.

Barriers to STD Testing. A number of barriers to STD testing and related services both in clinical and home settings. For example in the clinical setting, the barriers include clinic inaccessibility; lack of knowledge and/or awareness; concerns about patient privacy and confidentiality; 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. Furthermore, with the emergence of the COVID-19 pandemic in early 2020, additional barriers and challenges to accessing in-clinic STD testing and related services have recently been identified. 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. Several studies identified barriers to at-home testing or specimen collection. 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.

*Home testing programs.* LHDs with programs that offer at-home STD specimen include Los Angeles County and Alameda County Departments of Public Health offer free-at-home test kits for chlamydia and gonorrhea through the Don't Think, Know program. Women under the age of 25 are eligible to order home test kits via phone, with delivery handled by mail. The recipient then send their sample via mail back to the county lab, with results made available via phone or online within one week. Under Planned Parenthood Direct, Planned Parenthood offers a home test kits for a fee for chlamydia and gonorrhea via their mobile application. 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 home test kits for gonorrhea and chlamydia are the same kits utilized within the healthcare centers.

*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.). CHBRP cited a study that 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. 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 another study 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.

*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.

# 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 FPACT 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.

#### **Arguments in Support**

Numerous supporters and the sponsors, APLA Health, Black Women for Wellness Action Project, Essential Access, Fresno Barrios Unidos, Los Angeles LGBT Center and the San Francisco AIDS Foundation, state that this bill is a robust approach to addressing California's STI public health crisis during the COVID-19 pandemic and beyond. This bill aims to strengthen our state's public health infrastructure and expand access to STI coverage and care to improve health outcomes and create a more equitable health system. They conclude that California must take a comprehensive and robust approach to strengthening our public health infrastructure and expanding access to STI coverage and care to communities most impacted by the STI crisis.

#### **Arguments in Opposition**

The America's Health Insurance Plans, Association of California Life and Health Insurance Companies and the California Chamber of Commerce state that this bill will lead to higher premiums, harming affordability and access for small businesses and individual market consumers.

The Department of Finance (DOF) is opposed to this bill because it results in significant General Fund impacts not included in the 2021 Budget Act. DOF states given the recent budget investments, proposals and legislation focused on STD prevention and treatment, a comprehensive approach should be undertaken through the budget process to identify where any gaps exist, and to consider the most appropriate use of resources to address STD prevention, testing and treatment.

# **FISCAL COMMENTS**

According to the Assembly Appropriations Committee, amendments recently take significantly narrow this bill, reducing costs. Estimates for the remaining provisions are uncertain but could range from several hundred thousand dollars to more than \$1 million (50% state General Fund and 50% federal funds).

# VOTES

#### **SENATE FLOOR: 31-7-2**

YES: Allen, Archuleta, Atkins, Becker, Bradford, Caballero, Cortese, Dodd, Durazo, Eggman, Glazer, Gonzalez, Hertzberg, Hueso, Hurtado, Kamlager, Laird, Leyva, Limón, McGuire, Min, Newman, Pan, Portantino, Roth, Rubio, Skinner, Stern, Umberg, Wieckowski, Wiener NO: Bates, Borgeas, Dahle, Grove, Jones, Ochoa Bogh, Wilk ABS, ABST OR NV: Melendez, Nielsen

#### **ASM HEALTH: 12-2-1**

YES: Wood, Aguiar-Curry, Eduardo Garcia, Burke, Carrillo, Maienschein, McCarty, Nazarian, Luz Rivas, Rodriguez, Santiago, Waldron
NO: Bigelow, Flora
ABS, ABST OR NV: Mayes

#### ASM BUSINESS AND PROFESSIONS: 16-2-1

YES: Low, Berman, Bloom, Chiu, Cunningham, Fong, Gipson, Grayson, Holden, Irwin, McCarty, Medina, Mullin, Salas, Ting, Akilah Weber
NO: Flora, Megan Dahle
ABS, ABST OR NV: Chen

# **ASM APPROPRIATIONS: 13-3-0**

**YES:** Lorena Gonzalez, Bryan, Calderon, Carrillo, Chau, Fong, Gabriel, Eduardo Garcia, Levine, Quirk, Robert Rivas, Akilah Weber, Kalra **NO:** Bigelow, Megan Dahle, Davies

# UPDATED

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CONSULTANT: Rosielyn Pulmano / HEALTH / (916) 319-2097

FN: 0001349