Date of Hearing: June 22, 2021

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
SB 306 (Pan) – As Amended May 25, 2021

SENATE VOTE: 31-7

SUBJECT: Sexually transmitted disease: testing.

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 the 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. Expands the scope of benefits in Medi-Cal and the Family Planning, Access, Care, and Treatment Program (FPACT) to include STD home test kits, including the laboratory costs of processing the kit, that are deemed medically necessary or appropriate and ordered directly by an enrolled Medi-Cal or FPACT clinician or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs. Specifically, **this bill**:

1) Permits a pharmacist to dispense a drug to treat an 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."

2) Prohibits a pharmacist who prescribes, dispenses, furnishes or renders EPT under 1) above from being held liable to a civil, criminal, or administrative action, sanction, or penalty, as specified, except in cases of intentional misconduct, gross negligence, or wanton or reckless activity.

3) Requires every health plan contract issued, amended, renewed or delivered on or after January 1, 2022 to provide coverage for home test kits for STD, including the laboratory costs of processing the kit, that are deemed medically necessary or appropriate to and ordered directly by a clinician or furnished through a standing order for patient use based on clinical guidelines and individual health needs.

4) Requires a health insurance policy, excluding specialized health insurance policies, issued, amended, renewed or delivered on or after January 1, 2022, to provide coverage for home test kits for STD, including the laboratory costs of processing the kit, that are deemed medically necessary or appropriate to and ordered directly by a clinician or furnished through a standing order for patient use based on clinical guidelines and individual health needs.

5) Requires a health plan to cover services specified in 3) above when ordered for an enrollee by an in-network provider, and for Medi-Cal beneficiaries, these services to be covered when ordered by an enrolled Medi-Cal provider.

6) Defines home test kit to mean a product designed, developed and federally approved to allow individuals to collect specimens for STD testing remotely at a location outside of a clinical setting.

7) 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. Makes other conforming changes.

8) Requires a health care professional engaged in providing prenatal care or attending a birthing patient at the time of delivery to provide syphilis screening and testing as outlined in the most recent guidelines published by the Department of Public Health (DPH). Provides that this does not limit a local health jurisdiction's ability to provide additional recommendations or guidelines for syphilis screening and testing, nor the ability of a health care professional to follow syphilis screening and testing recommendations or guidelines issued by local health authorities, as specified.

9) Permits an human immunodeficiency virus (HIV) counselor that meets certain requirements to perform STD test. Permits an HIV counselor to perform skin puncture for purposes of an STD test. Prohibits an HIV counselor from administering an STD test until after demonstration of proficiency in administering the test. Specifies that for an HIV counselor to make appropriate counseling and referrals to patients, the counselor to demonstrate sufficient knowledge of HIV, hepatitis C virus (HCV), and STDs. Makes other conforming changes.

10) Requires an HIV counselor who is certified prior to January 1, 2022 and who will administer rapid STD tests to obtain training, as specified. Prohibits an HIV counselor, unless also certified as a limited phlebotomist technician, from performing STD tests until after completion of training requirements.

11) Expands the training criteria for an HIV counselor to also include completion of a training course approved by the Office of AIDS.

12) Expands the scope of benefits in Medi-Cal and FPACT to include home STD test kits for STDs, including the laboratory costs of processing the kit, that are deemed medically necessary or appropriate and 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.

EXISTING LAW:

1) Establishes under federal law, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) which sets standards for privacy of individually identifiable health information and security standards for the protection of electronic protected health information, including, through regulations, that a HIPAA covered entity may not condition the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits

on the provision of an authorization, except under specified circumstances. Provides that if HIPAA's provisions conflict with state law, the provision that is most protective of patient privacy prevails.

2) Establishes the Department of Managed Health Care (DMHC) to regulate health plans and the California Department of Insurance (CDI) to regulate health insurers.

3) Establishes the federal Patient Protection and Affordable Care Act (ACA), which enacts various health care coverage market reforms including the availability of health insurance exchanges (exchanges) and new individual and small group products offered on and off the exchanges beginning 2014.

4) Requires health plans and health insurers providing health coverage in the individual and small group markets to cover, at a minimum, essential health benefits (EHBs), including the 10 EHB benefit categories in the ACA, and consistent with California's EHB benchmark plan, the Kaiser Foundation Health Plan Small Group HMO 30 plan, as specified in state law.

5) Specifies the EHBs in the following 10 categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and, pediatric services, including oral and vision care.

6) Establishes the Medi-Cal program, administered by the Department of Health Care Services (DHCS), under which qualified low-income individuals receive health care services.

7) Establishes a schedule of benefits in the Medi-Cal program, which includes outpatient services (including physician services), prescribed drugs is covered subject to the Medi-Cal List of Contract Drugs and utilization controls, and family planning services, subject to utilization controls.

8) Establishes the FPACT Program to provide "comprehensive clinical family planning services" to individuals who meet specified income requirements.

9) Defines "comprehensive clinical family planning services" to mean the process of establishing objectives for the number and spacing of children, and selecting the means by which those objectives may be achieved, including a broad range of acceptable and effective methods and services to limit or enhance fertility, including contraceptive methods, federal Food and Drug Administration (FDA) approved contraceptive drugs, devices, and supplies, natural family planning, abstinence methods, and basic, limited fertility management.

10) Requires comprehensive clinical family planning services to include, but are not limited to, preconception counseling, maternal and fetal health counseling, general reproductive health care, including diagnosis and treatment of infections and conditions, including cancer, that threaten reproductive capability, medical family planning treatment and procedures, including supplies and follow-up, and informational, counseling, and educational services. Comprehensive clinical family planning services shall not include abortion, pregnancy testing solely for the purposes of referral for abortion or services ancillary to abortions, or pregnancy care that is not incident to the diagnosis of pregnancy.

11) Requires comprehensive clinical family planning services to be subject to utilization control and to include all of the following:

    a) Family planning related services and male and female sterilization: Family planning services for men and women shall include emergency services and services for complications directly related to the contraceptive method, FDA-approved contraceptive drugs, devices, and supplies, and follow-up, consultation, and referral services, as indicated, which may require treatment authorization requests;

    b) All United States Department of Agriculture, FDA-approved contraceptive drugs, devices, and supplies that are in keeping with current standards of practice and from which the individual may choose.

    c) Culturally and linguistically appropriate health education and counseling services, including informed consent, that include all of the following:

        i) Psychosocial and medical aspects of contraception;
        ii) Sexuality;
        iii) Fertility;
        iv) Pregnancy;
        v) Parenthood;
        vi) Infertility;
        vii) Reproductive health care;
        viii) Preconception and nutrition counseling;
        ix) Prevention and treatment of sexually transmitted infection;
        x) Use of contraceptive methods, federal FDA-approved contraceptive drugs, devices, and supplies; and,
        xi) Possible contraceptive consequences and followup.

    d) Interpersonal communication and negotiation of relationships to assist individuals and couples in effective contraceptive method use and planning families;

    e) A comprehensive health history, updated at the next periodic visit (between 11 and 24 months after initial examination) that includes a complete obstetrical history, gynecological history, contraceptive history, personal medical history, health risk factors, and family health history, including genetic or hereditary conditions.

    f) A complete physical examination on initial and subsequent periodic visits; and,

    g) Services, drugs, devices, and supplies deemed by the federal Centers for Medicare and Medicaid Services to be appropriate for inclusion in the program.

FISCAL EFFECT: According to the Senate Appropriations Committee:

1) DPH Office of AIDS reports costs of $382,000 fiscal year (FY) 2021-22 and $410,000 FY 2022-2023 (General Fund) for 3.0 positions to carry out the requirements of this bill if HIV test counselors are allowed to perform all Clinical Laboratory Improvement Amendments waived sexually transmitted infection (STI) tests, including for herpes simplex virus and trichomonas.

2) DMHC estimates the total cost of this bill to be approximately $126,000 Managed Care Fund (MCF) and 0.6 personnel year (PY) in FY 2021-22, $217,000 MCF and 1.1 PYs in FY 2022-23, $126,000 MCF and 0.6 PY in FY 2023-24 and annually thereafter.

3) Medi-Cal and FPACT reimbursement subject to appropriation. Unknown, potentially in the tens of millions General Fund and federal match.

4) Medi-Cal & FPACT home tests & related costs of $30 million.

COMMENTS:

1) PURPOSE OF THIS BILL. 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.

- **BACKGROUND**. 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, U.S. health departments reported:

  - 1.8 million cases of chlamydia, an increase of nearly 20 percent since 2015;
  - 616,392 cases of gonorrhea, an increase of more than 50 percent since 2015; and,
  - 129,813 cases of syphilis (all stages), an increase of more than 70 percent since 2015.

  a) 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.

b) **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.

c) **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.

d) **Disparities and Social Determinants of Health (SDoH) in STDs.** According to CHBRP, 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. CHBRP found literature identifying disparities and SDoH in

STDs by race/ethnicity, age, gender, gender identity, sexual orientation, incarceration status, socioeconomic status, and accessing testing.

Race or ethnicity. According to the CDC, 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. CHBRP notes 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. 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. 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.

Age. In 2018, adults and young adolescents (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. These rates suggest that nearly half of all newly diagnosed/reported STDs are among the AYA population in the United States. 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. Similarly, Californian AYA accounted for the highest incidence rates of gonorrhea (834 per 100,000) compared to all other age groups in 2018. 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. 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).

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. 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. Pregnant women 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. In 2018, the number of infants born with congenital syphilis increased 40% nationwide, with 25% of cases stemming from California. 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.

Gender identity. 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.

Sexual orientation. According to the CDC, disparities exist among men who have sex with men (MSM) in comparison to women and men who have sex with women. 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. 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. Within California, nearly seven out of 10 early syphilis male cases were among MSM in 2018. 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. 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. According to the CDC, 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. Incarcerated individuals disproportionately draw from populations with lower socioeconomic status and those living in urban areas. 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 socioeconomic status summary below).

Socioeconomic status (SES). 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. Studies have indicated an association between low SES and the acquisition of STDs. 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. Therefore, given disparities in access to health care coverage, these populations have limited access to health care services (e.g., access to STD testing). 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.

e) 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.

f) FPACT. To be eligible for FPACT benefits, individuals must meet all of the following criteria:

i) Be a resident of California;
ii) Have a total taxable family income at or below 200% of the federal poverty level (at or below $24,980, for an individual in 2019);
iii) Have no other source of health care coverage for family planning services, or meet the criteria specified for eligibility with Other Health Coverage (for example, having coverage that does not cover any contraceptive methods, coverage with a high deductible the individual is unable to meet on the date of service, or limited scope Medi-Cal that does not cover family planning); and,
iv) Have a medical necessity for family planning services.

FPACT eligibility is determined at the point of service by the FPACT provider. FPACT eligibility begins on the day the client is certified by a FPACT provider as meeting the eligibility requirements and the program's Health Access Programs card is activated. FPACT clients are certified for the program for a maximum of 12 months or until the client's eligibility status changes.

The DHCS 2021-22 May Revision estimated FPACT expenditures of $371 million total funds ($282.8 million in federal funds and $88.4 million in state funds). Family planning services and testing for STIs are eligible for 90% federal financial participation (FFP). The treatment of STIs and other family planning-related services are eligible for the state's regular Medicaid FFP match rate (typically 50% federal funds, 50% state funds).

g) **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.

h) **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. SB 125 (Hernandez), Chapter 9, Statutes of 2015, added an impact assessment on EHBs, and legislation that impacts health insurance benefit designs, cost sharing, premiums, and other health insurance topics. CHBRP states the following in its analysis of this bill:

i) **Enrollees covered.** At baseline, CHBRP estimates 7% of enrollees in plans and policies regulated by DMHC or CDI have coverage for STD home test kits. Postmandate, 100% would have coverage. CHBRP notes that the federal cost sharing prohibition for some STD tests is applicable to in network provider services, but not to the additional out-of-network provider services projected in this analysis.

ii) **Impact on expenditures.** According to CHBRP, this bill 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.

(1) **Medi-Cal**. Expenditures for enrolling Medi-Cal beneficiaries in DMHC-regulated plans would be expected to increase by $28,996,000 (0.12%).
(2) **The California Public Employees' Retirement System (CalPERS)**. Expenditures for CalPERS enrollees in DMHC-regulated plans would be expected to increase by $1,479,000 (0.03%).
(3) **Number of Uninsured in California.** CHBRP expects no measurable change in the number of uninsured persons due to the enactment of this bill since the change in average premiums does not exceed 1% for any market segment.
(4) **EHBs.** As this bill provides coverage for a particular modality of STD testing, rather than coverage for any new test, this bill does not exceed EHBs.

iii) **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*. 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 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 this bill, would be considered "clinician ordered" by an out of network (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.

iv) **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), 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 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 in network 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, 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 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 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.

iv) **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.

iv) **Long-term impacts**. Although the first-year impacts of this bill 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 in network 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 in network 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 this bill 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. CHBRP notes that enrollees in plans and policies regulated by DMHC and CDI are only 55.7% of the state population and their demographics may differ from those of the state as a whole.

(1) 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.
(2) 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.
(3) 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.
(4) 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.
(5) 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, this bill could decrease these economic burdens as well as improve the lives of tested enrollees and their contacts. This bill would provide coverage for 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). 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. CHBRP notes that 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 this bill**.** CHBRP also notes that there is some precedent for at-home testing of diseases. Innovative screening and testing for other diseases such as CRC have been implemented in health plans nationwide.

To date, three types of CRC home screening test kits have been approved by the FDA. 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.

i) **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.

2) **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.

3) **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.

4) **PREVIOUS 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 SB 932.

5) **DOUBLE REFERRAL**. This bill is double referred, upon passage in this Committee, it will be referred to the Assembly Business and Professions Committee.

REGISTERED SUPPORT / OPPOSITION:

Support

AIDS Healthcare Foundation
Alliance of Californians for Community Empowerment Action
American Academy of Pediatrics, California
APLA Health
Biocom California
Black Women for Wellness Action Project
Business & Professional Women of Nevada County
California Academy of Family Physicians
California Black Health Network

California Hepatitis Alliance
California Latinas for Reproductive Justice
California Life Sciences
California Women's Law Center
CaliforniaHealth+ Advocates
Citizens for Choice
Community Clinic Association of Los Angeles County
County Health Executives Association of California
End the Epidemics: Californians Mobilizing to End HIV, Viral Hepatitis, STIS, and Overdose
Essential Access Health
Fresno Barrios Unidos
Los Angeles LGBT Center
NARAL Pro-Choice California
National Health Law Program
San Francisco AIDS Foundation
Western Center on Law & Poverty
Women's Foundation California

Opposition

America's Health Insurance Plans
Association of California Life & Health Insurance Companies
California Chamber of Commerce

Analysis Prepared by: Rosielyn Pulmano / HEALTH / (916) 319-2097