

Date of Hearing: July 6, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

Evan Low, Chair

SB 306 (Pan) – As Amended June 23, 2021

**SENATE VOTE:** 31-7

**SUBJECT:** Sexually transmitted disease: testing

**SUMMARY:** Authorizes a pharmacist to dispense a drug to treat a sexually 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.” Provides pharmacists and health care providers immunity from civil, criminal, or administrative penalties when prescribing, dispensing, or furnishing, or rendering EPT. Requires health care professionals providing prenatal care or attending a birthing patient to provide syphilis screening and testing, as specified. Permits an HIV counselor to perform STD testing. Requires health care service plans and health insurance policies to provide coverage for home test kits for STD.

**EXISTING LAW:**

- 1) Establishes the Pharmacy Law, which governs the practice of the pharmacy profession in California. (Business and Professions Code (BPC) Section 4000 et seq.)
- 2) Prohibits a pharmacist from dispensing any prescription drug unless the container meets specified state and federal requirements and is correctly labeled with, among other items, the name of the patient or patients, the directions for the use of the drug, the condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription. (BPC Section 4076)
- 3) Permits a physician and surgeon who diagnoses a sexually transmitted chlamydia, gonorrhea, or other sexually transmitted infection in an individual patient to prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to that patient’s sexual partner or partners without examination of that patient’s partner or partners. (Health and Safety Code (HSC) Section 120582(a))
- 4) Permits nurse practitioners, certified nurse-midwives, and physician assistants to dispense, furnish, or otherwise provide prescription antibiotic drugs to the sexual partner or partners of a patient with a diagnosed sexually transmitted chlamydia, gonorrhea, or other sexually transmitted infection without examination of the patient’s sexual partner or partners. (HSC Section 120582(b))
- 5) Requires every licensed physician and surgeon engaged in prenatal care or attending at the time of delivery to obtain a blood specimen of the woman at the time of the first professional visit or within 10 days thereafter. (HSC Section 120685)
- 6) Authorizes an HIV counselor who meets specified requirements to perform any human immunodeficiency virus (HIV), hepatitis C virus (HCV) or combination HIV/HCV test that

is classified as waived under the federal Clinical Laboratory Improvement Act (CLIA). (HSC Section 120917(a))

- 7) Establishes the Department of Managed Health Care to regulate health plans and the California Department of Insurance to regulate health insurers. Requires health plans and health insurers providing health coverage in the individual and small group markets to cover, at a minimum, essential health benefits, as specified in federal and state law. (HSC Section 1341 et seq. and Insurance Code Section 10403 et seq.)
- 8) Establishes the Family Planning, Access, Care, and Treatment (Family PACT) program to provide “comprehensive clinical family planning services” to individuals who meet specified income requirements. (Welfare and Institutions Code Section 14105.181)

**THIS BILL:**

- 1) Names the existing practice of prescribing, dispensing, furnishing, or otherwise providing prescription antibiotic drugs to a patients’ sexual partner or partners without examination of that patient’s partner or partners as “expedited partner therapy”, or EPT.
- 2) Authorizes a pharmacist to dispense a prescription drug and 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) States that if a health care provider is unable to obtain the name of a patient’s sexual partner for a drug prescribed to treat an STD, the prescription shall include the words “expedited partner therapy” or the letters “EPT.”
- 4) Declares that a pharmacists prescribing, dispensing, furnishing or rendering EPT shall not be liable nor subject to civil, criminal, or administrative action, sanction, or penalty for rendering EPT, except in cases of intentional misconduct, gross negligence, or wanton or reckless activity.
- 5) Declares that a health care provider will not be liable in a medical malpractice action or professional disciplinary action for the use of EPT, except in cases of intentional misconduct, gross negligence, or wanton or reckless activity.
- 6) Requires a pharmacist providing EPT to provide written notification describing the right of an individual who receives EPT to consult with a pharmacist about the medication dispensed and additional information regarding possible drug interactions.
- 7) States that nurse practitioners, certified nurse-midwives, and physician assistants may include EPT in their practice.
- 8) Mandates every 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 California Department of Public Health (CDPH).

- 9) Clarifies that a local health jurisdiction may provide additional recommendations or guidelines for syphilis screening and testing, and that a health care professional may follow the syphilis screening and testing recommendations or guidelines issued by local health authorities, as long as, at minimum, the health care professional complies with the testing and screening requirements established by this bill.
- 10) Authorizes an HIV counselor to perform CLIA-waived (rapid) STD testing.
- 11) Mandates HIV counselors performing any rapid HIV, HCV, or other STD testing to additionally complete a training course that has been approved by the Office of AIDS.
- 12) Prohibits HIV counselors from administering a rapid HIV, HCV, or STD test until they demonstrate proficiency in administering the test.
- 13) Requires HIV counselors certified prior to January 1, 2022, who will administer rapid STD tests, to obtain the necessary training. Prohibits HIV counselors from performing rapid STD tests until after completing the required training, unless they are also certified as a limited phlebotomist technician.
- 14) Defines a home test kit as 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.
- 15) 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.
- 16) 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.
- 17) Specifies that commercial health care plans are required to cover home test kits for STDs when ordered for an enrollee by an in-network provider. Further states that for Medi-Cal beneficiaries, these services shall be covered when ordered by an enrolled Medi-Cal provider.
- 18) Expands the scope of benefits in Medi-Cal and Family PACT 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.
- 19) Makes various findings and declarations regarding the impact of STDs on California communities, the health care costs associated with STDs, and the need for California to take

a comprehensive and robust approach to strengthen public health infrastructure to ensure access to STD coverage and care.

**FISCAL EFFECT:** According to the Senate Committee on Appropriations:

- California Department of Public Health Office of AIDS reports costs of \$382,000 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 CLIA-waived STI tests, including for herpes simplex virus and trichomonas.
- The Department of Managed Health Care estimates the total cost of this bill to be approximately \$126,000 MCF and 0.6 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
- Medi-Cal & Family PACT reimbursement subject to appropriation. Unknown, potentially in the tens of millions General Fund and federal match
- Medi-Cal & Family Pact home tests & related costs of \$30 million.

**COMMENTS:**

**Purpose.** This bill is sponsored by **APLA Health, Black Women for Wellness Action Project, Essential Access Health, Fresno Barrios Unidos, Los Angeles LGBT Center, and the San Francisco AIDS Foundation.** 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.”

**Background.**

*Sexually Transmitted Diseases.* STDs are diseases or infections caused by bacteria, viruses, or parasites that are generally acquired through sexual contact. There are approximately dozens of STDs, including chlamydia, gonorrhea and syphilis. STDs may cause mild and severe symptoms, and can lead to severe health consequences if left untreated. STDs can increase the risk of HIV infection, cause chronic illness, infertility, or lead to pregnancy or newborn complications. In some circumstances, STDs do not show symptoms, and it is possible to be infected without knowing it – highlighting the importance of performing routine STD testing. It is also possible to contract an STD nonsexually, including from-mother-to-infant during pregnancy, childbirth, blood transfusions, or shared needles.

In April 2019, the Centers for Disease Control and Prevention (CDC) published data indicating that the annual cases of STDs in the United States continued to climb in 2019, reaching an all-time high for the sixth consecutive year. Among the findings, the CDC reported a nearly 30% increase in STDs between 2015 and 2019, and 2.5 million cases of chlamydia, gonorrhea and syphilis. The CDC notes that the sharpest increase was in cases of syphilis among newborns, which nearly quadrupled between 2015 and 2019.

In line with this national trend, California has also experienced a severe increase in STD infections. 2018 data from the California Department of Public Health shows a 45 percent increase in certain STDs over the last 5 years – including the largest increase in stillbirths related to congenital syphilis since 1995.

As the bill author notes, “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 – 24 years old. African Americans are 500% more likely to contract gonorrhea and chlamydia than their white counterparts. These disparities are expected to worsen during 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.”

In terms of U.S. health care costs, the CDC estimated that in 2018, chlamydia, gonorrhea, and syphilis combined accounted for \$1.1 billion in direct medical costs, and that care for young people (ages 15-24) accounted for about 60% of these costs. New HIV infections cost \$13.7 billion in direct lifetime medical costs, new HPV infections cost \$755 million in direct lifetime medical costs, and all other STIs cost \$1.4 billion in direct lifetime medical costs.

*Expedited Partner Therapy.* EPT is broadly defined as the clinical practice of treating the sex partner of a patient diagnosed with an STD by providing prescription medication to the patient to take to their partner or partners, without the health care provider first examining the partner. Although it is generally preferable that partners seek full clinical evaluation and treatment in a health care setting, EPT can be an effective method to treat a patient’s partner if they are unable or unwilling to obtain medical care. But CDC evidence also suggests that EPT can decrease reinfection rates when compared with standard partner referrals for examination and treatment.

California law currently permits the practice of EPT: a physician and surgeon who diagnoses a sexually transmitted chlamydia, gonorrhea, or other sexually transmitted infection as determined by CDPH in an individual patient may prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to that patient's sexual partner or partners without examination of that patient's partner or partners. In addition, nurse practitioners, certified nurse-midwives, and physician assistants may dispense, furnish, or otherwise provide prescription antibiotic drugs to the sexual partner or partners of a patient with a diagnosed STD without examination of the patient's sexual partner or partners.

According to the bill's sponsors, several challenges have been identified in delivering EPT to patients. For example, pharmacists do not have the ability to provide prescription antibiotic drugs to the sexual partner or partners of a patient without their names clearly identified on the prescription label. To address this barrier, this bill authorizes a pharmacist to dispense a prescription drug according to existing law and label the drug without the name of an individual if the prescription includes the words "expedited partner therapy" or the letters "EPT." To align this practice across the health care delivery system, SB 306 states that if a health care provider is unable to obtain the name of a patient's sexual partner for a drug intended for EPT use, the prescription must include the words "expedited partner therapy" or the letters "EPT." In addition, the bill requires a pharmacist to give written notification describing the right of an individual receiving EPT to consult with a pharmacist about the medication dispensed and additional information regarding possible drug interactions.

This bill also provides legal protections and immunity for health care providers providing EPT. SB 306 specifically prohibits civil, criminal, administrative action, sanction, or penalty against a pharmacist providing EPT, and protects health care providers from liability in a medical malpractice action or professional disciplinary action for the provider's use of EPT. SB 306 clarifies that this immunity is not absolute, and does not apply in cases of intentional misconduct, gross negligence, or wanton or reckless activity.

*HIV Counselors.* Existing law permits an HIV counselor who meets specified requirements to conduct rapid HIV and HCV testing. According to the author, HIV counselors, which are trained professionals working with California's most vulnerable populations, can provide rapid testing for HIV and hepatitis, but are not authorized to perform rapid tests for other common STDs. This bill would authorize an HIV counselor to perform specified STD tests, if the HIV counselor meets all existing statutory requirements and completes a training course that has been approved by the Office of AIDS.

*Congenital Syphilis Screening.* Congenital syphilis (CS) is a disease that occurs when a mother with syphilis passes the infection on to her baby during pregnancy. The CDC notes that CS can cause miscarriage, stillbirth, prematurity, low birth weight, or death shortly after birth. In 2018, CDPH reported a 900% increase in CS in California from 2012. As a result, California STD screening recommendations are aligning with national guidelines, which recommend all pregnant patients to receive syphilis screening at the first prenatal visit, with additional screening in the third trimester and at delivery of those with identified risk, including in communities and populations with high syphilis prevalence.

SB 306 codifies those recommendations, and requires every licensed 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 CDPH guidelines. The bill also clarifies that this provision does not limit a local health jurisdiction to provide additional recommendations or guidelines for syphilis screening and testing, as long as the minimum testing and screening requirements established by the bill are complied with.

*STD Home Test Kits.* This bill requires every health plan contract and specific 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. The California Health Benefits Review Program notes in its analysis that currently, an estimated 7% of enrollees in regulated health plans and policies have coverage for STD home test kits.

### **Prior Related Legislation.**

*AB 2280 (Leno, Chapter 771, Statutes of 2006)* – Extended existing law that permits a physician or nurse practitioner, who diagnoses a sexually transmitted chlamydia infection, to prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to that patient's sexual partner or partners without examination of that patient's partner or partners, to cover gonorrhea or other sexually transmitted disease infection, as determined by the CDPH.

### **ARGUMENTS IN SUPPORT:**

Supporters note that this measure seeks to address the alarming rise of sexually transmitted infection rates in California – which has been exacerbated by the COVID-19 pandemic – by expanding access to STI prevention, testing and treatment statewide. Supporters argue that California must invest in strengthening our public health infrastructure and expanding access to STD services to communities most impacted by the STD crisis.

### **ARGUMENTS IN OPPOSITION:**

**The California Association of Health Plans, the Association of California Life and Health Insurance Companies, and America's Health Insurance Plans** collectively write in opposition: “[SB 306] will increase costs, reduce choice and competition, and further incent some employers and individuals to avoid state regulation by seeking alternative coverage options [...] Large employers, unions, small businesses and hard-working families value their ability to shop for the right health plan – at the right price – that best fits their needs. Benefit mandates impose a one-size-fits-all approach to medical care and benefit design driven by the legislature, rather than consumer choice. [SB 306] will lead to higher premiums, harming affordability and access for small businesses and individual market consumers.”

**The California Chamber of Commerce** writes in opposition: [SB 306] would require health care service plans to provide coverage for home test kits for sexually transmitted diseases as well as their associated laboratory processing costs. This mandate will cause health care premiums to rise for employers and employees in order to cover the cost of the coverage. California businesses have suffered staggering financial setbacks as a result of the COVID-19 pandemic and this bill will only add to that struggle by piling another expense onto employers who are trying to rebuild.”

**REGISTERED SUPPORT:**

Access Reproductive Justice  
Access Support Network  
AIDS Healthcare Foundation  
Alliance of Californians for Community Empowerment Action  
American Academy of Pediatrics, California  
APLA Health  
Bienestar Human Services  
Biocom California  
Black Women for Wellness Action Project  
Buen Vecino  
Business & Professional Women of Nevada County  
California Academy of Family Physicians  
California Academy of Physician Assistants  
California Association for Nurse Practitioners  
California Black Health Network  
California Hepatitis Alliance  
California Latinas for Reproductive Justice  
California LGBTQ Health and Human Services Network  
California Life Sciences  
California Nurse-midwives Association  
California Pharmacists Association  
California Physicians Alliance  
California Society of Health-System Pharmacists  
California State Board of Pharmacy  
California Women's Law Center  
CaliforniaHealth+ Advocates  
Citizens for Choice  
Community Clinic Association of Los Angeles County  
County Health Executives Association of California  
Courage California  
Desert AIDS Project  
Desert Aids Project D/b/a DAP Health  
End Hep C SF  
End the Epidemics: Californians Mobilizing to End HIV, Viral Hepatitis, STIs, and Overdose  
Essential Access Health  
Fresno Barrios Unidos  
Harm Reduction Coalition  
Harm Reduction Services  
HIVE  
Los Angeles LGBT Center  
NARAL Pro-choice California  
National Health Law Program  
Plan C  
Planned Parenthood Affiliates of California  
Religious Coalition for Reproductive Choice California



San Francisco AIDS Foundation  
Team Lily  
The Los Angeles Trust for Children's Health  
The Source LGBT+ Center  
The Women's Foundation of California  
Via Care Community Health Center  
Western Center on Law & Poverty.  
Women's Foundation California

**REGISTERED OPPOSITION:**

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

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