
**SENATE COMMITTEE ON
BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT**
Senator Richard Roth, Chair
2021 - 2022 Regular

Bill No:	SB 306	Hearing Date:	April 19, 2021
Author:	Pan		
Version:	March 24, 2021		
Urgency:	No	Fiscal:	Yes
Consultant:	Dana Shaker		

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) and provides immunity from civil, criminal, or administrative penalties for an individual who prescribes, dispenses, or furnishes the drug. Requires a syphilis blood test during the third trimester of pregnancy and at delivery.

NOTE: *This measure was heard in the Senate Committee on Health on April 7, 2021 and passed on a 9-1 vote.*

Existing law:

- 1) Establishes the Pharmacy Law, which governs how pharmacists may practice in the state of California. (Business and Professions Code (BPC) §§ 4000 *et seq.*)
- 2) Establishes that the Board of Pharmacy is vested with the authority to enforce the Pharmacy Law. (BPC § 4001)
- 3) Authorizes a pharmacist to furnish the following if they notify the patient's primary care provider of the furnishing, or if the patient does not have a primary care provider, provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice (BPC § 4052) :
 - a) Emergency contraception drug therapy and self-administered hormonal contraceptives according to specified requirements.
 - b) Nicotine replacement products according to specified requirements.
 - c) Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.
 - d) HIV preexposure prophylaxis and postexposure prophylaxis, according to specified requirements.
- 4) Requires a pharmacist to dispense a prescription that meets certain labeling requirements outlined in state and federal law, including, among other information, the name of the patient or patients and the condition or purpose for which the drug

was prescribed, if the condition or purpose is indicated on the prescription. (BPC § 4076)

- 5) Permits physicians and surgeons who diagnose a sexually transmitted chlamydia, gonorrhea, or other STD as determined by the California Department of Public Health (DPH) 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"). (Health and Safety Code (HSC) §120582(a))
- 6) 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, as determined by DPH, without examination of the patient's sexual partner or partners. (HSC §120582 (b))

This bill:

- 1) Names the following, existing practice as "expedited partner therapy": where health care provider who diagnoses an STD, as specified, 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.
- 2) Requires a health care provider to include "expedited partner therapy" or "EPT" on a prescription if the practitioner is unable to obtain the name of a patient's sexual partner, and would authorize a pharmacist to dispense an expedited partner therapy prescription and label the drug without an individual's name if the prescription includes "expedited partner therapy" or "EPT."
- 3) Specifies that a health care provider is not liable in a medical malpractice action or professional disciplinary action, and that a pharmacist is not liable in a civil, criminal, or administrative action, if the health care provider's use of expedited partner therapy is in compliance with the 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 DPH 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.
- 10) Makes findings and declarations about STD rates and disparity in rates and about increases in certain STDs and the impact on public health when those are not treated, noting that California must take a comprehensive and robust approach to strengthen our public health infrastructure, ensure access to STD coverage, and care for all Californians, during the pandemic and beyond.

FISCAL EFFECT: Unknown. This bill is keyed fiscal by Legislative Counsel.

COMMENTS:

1. **Purpose.** The APLA Health, Black Women for Wellness Action Project, Essential Access Health, Fresno Barrios Unidos, the Los Angeles LGBT Center, and the San Francisco AIDS Foundation are the Co-Sponsors 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 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 Current, Broader Problem. The Author provided the following information on the current, broader problem this bill seeks to address: "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; with rates of syphilis, chlamydia, or gonorrhea is 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. The COVID-19 pandemic has exacerbated STD infection rates across the country. 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 alert from DPH about the rising number of disseminated 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. This bill takes a comprehensive approach to address California's STD crisis by expanding access to STD care in an equitable way.

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.

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 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.

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 gaps remain. For example:

- Uninsured Californians lack a pathway to STD treatment. While the Family PACT program includes STDs services as a covered benefit, it's only for patients that also seek family planning services.
- California's Expedited Partner Therapy (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.
- Existing law ensures Medi-Cal managed care enrollees can see their provider of choice for family planning services, but it should be updated to explicitly include STD services.
- HIV Counselors, trained professionals working with some of our most vulnerable populations, can provide rapid testing for HIV and hepatitis, but are disallowed from performing 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.
- During the pandemic, with undiagnosed cases of STDs rampant, access to home test kits is limited due to coverage restrictions."

STD Prescription Options. Under current law, a physician and surgeon who diagnoses a sexually transmitted chlamydia, gonorrhea, or other sexually transmitted infection, as determined by DPH, 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. 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 sexually transmitted chlamydia, gonorrhea, or other sexually transmitted infection, as determined by the California Department of Public Health (DPH) without examination of the patient's sexual partner or partners.

Under current law, pharmacists do not have the ability to 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, as determined by the DPH, without examination of the patient's sexual partner or partners. This bill would permit pharmacists to dispense a drug prescribed pursuant

to existing law described in the above paragraph. It would also permit pharmacists 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. **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 department.
4. **Comments from the Senate Committee on Judiciary.** This bill touches on various issues within the jurisdiction of the Senate Judiciary Committee, most prominently the issues of legal immunity and equal protection. With respect to the bill’s limitation on liability, the bill does not provide complete immunity for all injuries arising from medication dispensed as EPT. Instead, the bill limits pharmacist and provider civil, criminal, administrative, and other liability, in circumstances where the EPT was provided with the bill’s requirements, to cases of intentional misconduct, gross negligence, or wanton or reckless activity. These provisions thus permit a patient to pursue a lawsuit where the provision of EPT did not follow the relevant law, and where the pharmacist or provider acted particularly egregiously. In order to ensure that this limited immunity does not unintentionally prevent a patient from bringing a meritorious malpractice lawsuit unrelated to the fact that the medication was provided by EPT, the author may wish to amend the bill to include a provision clarifying that such actions are not barred by the bill’s grant of limited immunity.

With respect to the issue of equal protection, this bill expands reimbursement for certain services for Family PACT providers to patients meeting specified criteria and “who are not at risk for experiencing or causing an unintended pregnancy, and who are not in need of contraceptive services.” While it is clear that the author simply intends to expand reimbursement to persons who are not currently seeking family planning services, the phrasing of this provision could be interpreted to prohibit reimbursement for persons who are in sexual relationships that are capable of resulting in pregnancy, which in turn could result in excluding from reimbursement whole categories of persons in such relationships. The author therefore may wish to consider amending this provision to clarify that reimbursement is available for all persons regardless of their interest in, or need for, family planning services.

5. **Arguments in Support.** Generally, supporters write that SB 306 provides a strong and holistic approach to addressing California’s STD public health crisis during the COVID-19 pandemic and into the future. They argue the bill will strengthen California’s overall public health infrastructure and expand access to coverage and care for STDs to improve outcomes and create a more equitable health care system.
6. **Arguments in Opposition.** The Association of California Life & Health Insurance Companies (ACLHIC) writes in opposition that SB 306 is one of several the organization has identified this year that will “will increase costs, reduce choice and competition, and further incent some employers and individuals to avoid state

regulation by seeking alternative coverage options...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 fundamentally altered nearly every facet of everyday life for all Californians. Our member health plans, their employees or our enrollees have not been spared from the fallout of the pandemic, whether it's dealing with the monumental task of managing and mitigating the effects on the health care delivery system, to dealing with several emerging administrative and economic obstacles. This 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."

The California Chamber of Commerce writes in opposition: the "mandate [that 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] 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.

Specifically, SB 306 would require coverage of STD home test kits, including the laboratory costs of processing the kit. Under the bill, a home test kit would be defined as a product approved by the Food and Drug Administration for purposes of an individual collecting a specimen for STD testing outside of a clinical setting and ordered by a clinician."

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)
 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
 Buen Vecino

California Latinas for Reproductive Justice
California Lgbtq Health and Human Services Network
California Nurse-midwives 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
Los Angeles Lgbt Center
Los Angeles Trust for Children's Health
Naral Pro-choice California
National Health Law Program
Plan C
Religious Coalition for Reproductive Choice California
San Francisco Aids Foundation
Team Lily
The Source Lgbt+ Center
Women's Foundation of California
Via Care Community Health Center
Western Center on Law & Poverty, INC.

Opposition:

Association of California Life & Health Insurance Companies
California Chamber of Commerce

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