National Coalition of STD Directors

INJECTABLE SYPHILIS TREATMENT DELIVERY

Considerations for STD Programs

This document provides technical assistance and best practice recommendations to Sexually Transmitted Disease (STD) programs funded by CDC-PS19-1901, as authorized by Section 318 of the Public Health Service Act and are therefore eligible to participate in the 340B Drug Pricing Program. This guidance is written based on the best understanding of NCSD and its contractors. Covered entities should refer to the 340B statute, HRSA published guidance, 340B Drug Pricing Program Frequently Asked Questions, and HRSA policy releases for additional guidance. Covered entities should also use their own judgment and legal counsel to assist in ensuring compliance with 340B program requirements. The materials herein do not constitute, and should not be treated as, professional advice regarding compliance with laws or regulations. This is not a legal document and should not be used to substitute the 340B statute, 340B program regulations, HRSA published guidance, HRSA policy releases, and other relevant resources. Liability for compliance with 340B program requirements resides solely with the covered entity.

INTRODUCTION

Syphilis is a disease of considerable public health importance with serious health effects if left untreated. Syphilis can be detrimental to cardiovascular and neurological health, increases HIV transmission risk, and can lead to adverse pregnancy outcomes including stillbirth and congenital syphilis (CDC, Syphilis, 2022). STD public health programs stand on the frontlines in the fight against the syphilis epidemic, as rates continue to increase, providing partner services, surveillance, case management, and appropriate treatment. However, since 2020, STD programs have experienced reduced clinic capacity as a result of the COVID-19 and mpox communicable disease outbreaks. STD programs have diverted their already limited funds and staff to these public health emergencies to provide disease intervention expertise, clinical support, and other resources. Although this assistance is vital to addressing emerging outbreaks, it also reduces the capacity of STD programs to address STD prevention. State and local STD programs are now relying on primary health care providers to diagnose and treat syphilis more than ever. Public health partnerships and cost-effective strategies for syphilis treatment should be considered.

Although syphilis screening is mandated by state laws and also recommended by the CDC, the logistics of ensuring patients receive appropriate and timely syphilis treatment vary across jurisdictions and STD programs. Ensuring timely treatment of syphilis infection is critical to preventing the adverse outcomes of syphilis infection. If health care providers are not able to provide appropriate and timely treatment, Injectable Syphilis Treatment Delivery[1](ISTD) may be an option. Through ISTD programs, the state or local health department STD program purchases medication and provides the medication directly to the diagnosing provider to treat a patient's syphilis infection when the patient cannot afford the cost of the antibiotic or the provider is unable to obtain the medication to provide timely treatment to the patient.

Through injectable syphilis treatment delivery programs, state or local health department STD programs purchase medication and provide it directly to a diagnosing provider to treat a patient's syphilis infection to ensure the accessibility of timely and appropriate treatment.

When health care providers partner with public health to ensure patients receive adequate and timely syphilis treatment, patients may experience fewer barriers to treatment and loss to follow-up may be reduced. This partnership also saves time and money, preserving valuable STD program resources and increasing STD clinical capacity. STD programs can purchase the medication using the 340B Drug Pricing Program, which greatly reduces the cost of the medication, maximizes federal funding and helps STD programs meet the demands of increasing syphilis cases.

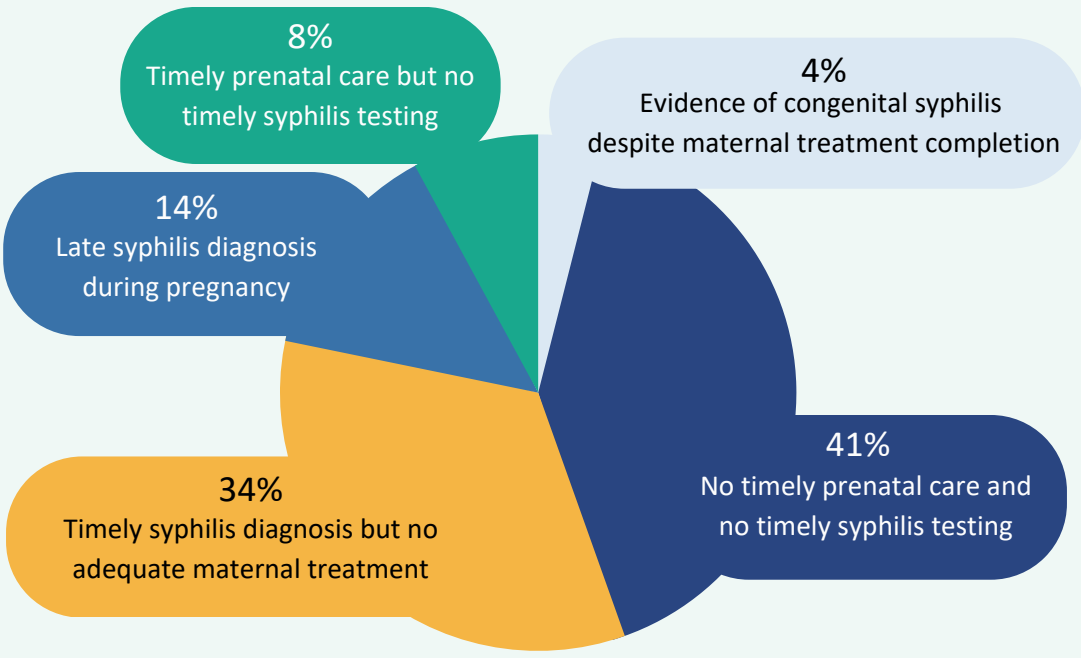
[1] Pfizer is the sole manufacturer of Benzathine penicillin G with FDA approval in the United States, which is distributed under the trademarked name Bicillin® L-A. To align with STD program language, the term Bicillin is used throughout this document in reference to benzathine penicillin G.

THE STATE OF SYPHILIS

According to the U.S. Centers for Disease Control and Prevention (CDC), the number of total syphilis cases reported in the United States has increased 74% since 2017 and the rate of primary and secondary syphilis among women more than doubled between 2017 and 2021. Alarmingly, rates of congenital syphilis have also increased 203% since 2017. In 2021, data indicated that a total of 2,855 cases of congenital syphilis were reported in the United States, including 220 stillbirths and infant deaths (CDC, Congenital Syphilis, 2021). Although the majority of congenital syphilis cases were reported from a few states, almost all jurisdictions (46 states and the District of Columbia) reported at least one case of congenital syphilis in 2021, up from just 37 jurisdictions in 2020 (CDC, STD Surveillance, 2021).

MISSED OPPORTUNITIES FOR PREVENTING CONGENITAL SYPHILIS IN 2021

Data from 2021 indicates that the most common missed opportunities for preventing congenital syphilis includes no timely prenatal care and no timely syphilis testing, and not having adequate maternal treatment despite receiving a syphilis diagnosis. Reducing barriers to prenatal care, syphilis testing, and adequate syphilis treatment for pregnant people and their partners can prevent congenital syphilis cases.



A national congenital syphilis prevention strategy requires prioritizing interventions to address the root causes of missed opportunities while maximizing the impact of finite resources. These interventions should include access to timely and appropriate syphilis treatment, which requires collaboration among public health authorities, health care providers, and policymakers. (CDC, MMWR, 2020).

ROLE OF STD PROGRAMS & HEALTH CARE PROVIDERS IN SYPHILIS SCREENING & TREATMENT

Syphilis screening, treatment, disease intervention, and surveillance are core STD program functions, with most states having statutory and regulatory language requiring these activities. Forty-four states have laws requiring syphilis testing of pregnant women (CDC, Statutory and Regulatory Language Regarding Prenatal Syphilis Screenings in the United States, 2021). In addition to individual state statutes and regulations, CDC Sexually Transmitted Infection (STI) Screening Recommendations recommend that all health care providers complete a sexual history for their patients, screen asymptomatic adults who are at an increased risk for syphilis infection as well as all pregnant people during their first prenatal visit and again in the third trimester if there is risk (CDC, STI Treatment Guidelines, 2021).

STD programs not only serve as the public health authority for syphilis control but also as the safety net for syphilis treatment.

CDC suggests that health care providers contact their state or local health department if they have challenges obtaining syphilis treatment (CDC, What Healthcare Providers Can Do, 2022). Storage requirements and the high cost of the medication mean non-health department providers frequently do not routinely stock syphilis treatment in their offices, requiring a referral to an STD clinic for treatment. Many other scenarios may prevent timely and appropriate syphilis treatment in-office as well. Ensuring timely treatment of syphilis infection is critical to preventing the adverse outcomes of syphilis infection. However, when referral for treatment occurs, continuity of care is interrupted and opportunity for loss of follow-up is introduced. Patients who are unable to receive treatment administered by their primary health care provider may experience additional barriers to receiving treatment. With patients, health care providers, legislatures and the community all relying on state and local health department STD programs to facilitate the treatment of syphilis, public health partnerships and cost-effective strategies for syphilis treatment should be considered.

POTENTIAL BARRIERS TO TREATMENT:

- Limited clinic capacity
- Unavailability of appointments
- Additional clinic fees
- Fear and stigma of being in an STD clinic
- Lack of transportation
- Access to childcare services

SYPHILIS TREATMENT DELIVERY AS STD PROGRAM PRACTICE

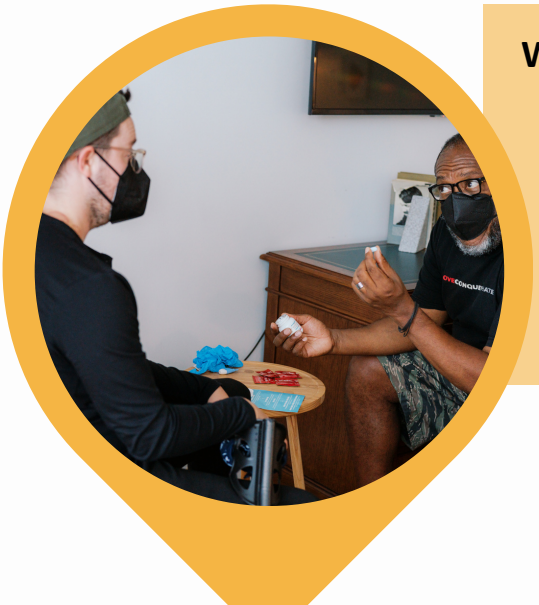
While syphilis screening is mandated by state laws and recommended by the CDC, the logistics of ensuring patients receive appropriate and timely treatment vary across jurisdictions and STD programs. When health care providers are not able to provide appropriate and timely treatment and/or they request treatment support from public health, ISTD may be an option. Injectable Syphilis Treatment Delivery is the practice of state or local health department STD programs purchasing medication and providing this medication directly to the diagnosing provider to treat the patient's syphilis infection when the provider is otherwise unable to administer appropriate and timely treatment to the patient.

When health care providers partner with public health to ensure patients receive adequate and timely syphilis treatment:

- **Patients may experience fewer barriers.**
- **Loss to follow-up may be reduced.**
- **Saves time and money, preserving valuable STD program resources and increasing STD clinic capacity.**

When STD programs purchase medication for ISTD, utilizing the 340B Drug Pricing Program greatly reduces the cost of the medication, maximizing federal funding and helping STD programs meet the demands of increasing syphilis cases.

The practice of ISTD is outlined in the CDC Notice of Funding Opportunity: PS19-1901 Strengthening STD Prevention and Control for Health Departments (STD PCHD) clarifying that funding can be used to purchase and dispense Benzathine penicillin G to uninsured and underinsured patients and their sex partners whose clinical service providers are not able to administer timely treatment (page 15). See the chart on page 8 for more information.



WHAT IS ISTD?

Injectable Syphilis Treatment Delivery is the practice of state or local health department STD programs purchasing medication and providing this medication directly to the diagnosing provider to treat the patient's syphilis infection when the provider is otherwise unable to administer appropriate and timely treatment to the patient

THE 340B DRUG PRICING PROGRAM

The 340B Program is a federal program authorized by Section 340B(a) (8) of the Public Health Service Act and enables covered entities to stretch scarce federal resources as far as possible, providing outpatient medications at significantly reduced prices. The 340B Program is administered through the Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA). Federal law defines which types of safety net programs may participate in the 340B Program, including sexually transmitted disease (STD) clinics and recipients of federal grants authorized under U.S. Public Health Services Act Section 318.

The retail cost of syphilis treatment is prohibitive for most STD programs, with prices ranging into the thousands of dollars. In contrast, the 340B Program offers a cost savings of 99.9%.

It is also important to note that there is no generic Penicillin G. Benzathine currently available on the market, limiting STD programs to purchasing this medication from one sole manufacturer.

340B ELIGIBILITY

All 59 jurisdictions funded by PS19-1901 Strengthening STD Prevention and Control for Health Departments and their sub-awardees are eligible to participate in the 340B Program as authorized by Section 318 of the Public Health Services Act. STD programs are in a unique position of protecting the health of citizens, operating with public health authority and under the direction of a medical director. Many STD programs are mandated by state law to provide syphilis control activities in their communities and assume responsibility for syphilis treatment. All 50 states require that syphilis cases be reported to state and/or local public health so that action can be taken to find and treat the patient and exposed persons (CDC, What Healthcare Providers Can Do, 2022).

340B PATIENT DEFINITION (61 FED. REG. 55156 (OCT. 24, 1996))

The 340B patient definition is set in federal statute and is the same for every 340B covered entity type. STD programs using a 340B STD designation should ensure all three components of the 340B patient definition are met for every syphilis patient that is the recipient of ISTD. The next two pages show a chart of 340B patient definition elements aligned with STD program practices.

340B Patient Definition Element	Syphilis Treatment Delivery Operational Considerations for STD Programs
The covered entity has an established relationship with the individual, such that the covered entity maintains records of the individual's health care.	**Syphilis is a reportable condition in all 50 states** in the United States, with state and local STD programs maintaining records of the individual's STD and syphilis-related health care. STD program covered entities provide case management, partner services and contact tracing, ensure timely treatment, and conduct epidemiological surveillance. It is an STD program practice to maintain patients' records indefinitely and if a patient moves, health departments communicate utilizing CDC Interstate Communications Control Records (ICCR). **The ICCR is a resource for STD programs to systematically maintain confidentiality while sharing client information between domestic jurisdictions** to conduct public health prevention activities. This includes the confidential follow-up of exposed sex partners, infected persons who need treatment or other services, and others in need of STD prevention services. Strengthening STD Prevention and Control for Health Departments (STD PCHD) CDC-PS19-1901 states that ISTD medication should be provided under medical orders of the medical director of the STD program or the health department, and medical records must be kept in the STD program for all patients treated under this order (pg 15).
The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the covered entity.	**ISTD is unique to STD programs and STD covered entity clinics.** The partnership between health care providers and STD program-covered entities falls within the "other arrangements" outlined in this component of the patient definition. The medical provider who is administering the medication to the patient diagnosed with syphilis is acting on the patient and public health's behalf, entering into an 'other arrangement' and addressing an urgent public health threat. The responsibility of **syphilis care is ultimately public health's responsibility** as outlined in state or local law.

340B Patient Definition Element	Syphilis Treatment Delivery Operational Considerations for STD Programs
The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding status has been provided to the entity.	The scope of the STD PCHD cooperative agreement (CDC-PS19-1901) is to prevent and control sexually transmitted diseases. This goal is carried out by following CDC STI screening and treatment guidelines. **Other services that are provided by the health department that are within the scope of STD PCHD and are included in the health care service or range of services from the covered entity include disease intervention services including interviews and partner elicitation, STD/HIV prevention counseling, re-engagement and linkage to care, PrEP and other referrals to preventative services.** Additional guidance regarding the health care service or range of services consistent with the cooperative agreement is provided in the PCHD notice of funding opportunity on page 15: "This funding can be used to purchase and dispense Benzathine penicillin G [Bicillin L-A] for the treatment of syphilitic infections among uninsured and underinsured patients and their sex partners whose clinical service providers are not able to administer timely treatment with Benzathine penicillin G. Providing prompt treatment to reduce the spread of syphilis in the community is a core public health function required in many states by statute or regulation (https://www.cdc.gov/publichealthgateway/publichealthservices/essentialhealthservices.html). In these critical public health situations, Benzathine penicillin G should be provided under medical orders of the medical director of the STD program or the health department. The health department physician prescribing the Benzathine penicillin G **must keep a medical record of all patients treated** under his or her orders. Upon request, the CDC may approve funding for other STD treatments to respond to local STD outbreaks or other urgent public health threats related to sexually transmitted infections."

CONSIDERATIONS FOR SYPHILIS TREATMENT DELIVERY

Health departments across the country are unique and vary in how they operationalize ISTD. Below are operational logistics that STD programs should consider when they design, implement, or improve their ISTD practices.

- STD programs should be aware of the pharmacy license(s) their health department holds and any limitations around medication distribution.
- Ensure ISTD is documented and auditable records are maintained. STD programs should use medication tracking forms and maintain comprehensive patient records. This documentation may be kept on paper, in electronic medical records, in surveillance systems, or other databases. See below for examples from STD programs, as well as the template provided by NCSD.
- 340B medication does not need to be purchased solely with PCHD funds. Once 340B eligibility is established and a covered entity is enrolled in the 340B Program, any funds can be used to purchase medication for ISDT.
- While working through administrative processes to gain access to 340B medications, STD programs may choose to pay the higher, full retail price for syphilis treatment. Medication may also be purchased through a national cooperative group purchasing organization such as the Minnesota Multistate Contracting Alliance (MMCAP). STD programs should prioritize 340B program participation over other options as the price difference has a significant impact on budgets and PCHD cooperative agreements.
- ISTD may be accomplished by in-person delivery from STD program staff, courier service, shipping (overnight or next day delivery), or local pick-up. STD programs should implement appropriate storage and handling policies and procedures when designing a delivery program.
- STD programs may want to establish memorandums of understanding or other agreements with healthcare providers who diagnose a significant amount of syphilis. Additionally, STD programs may want to discuss extending 340B eligibility to healthcare providers who are serving as STD or sexual health clinics, are the sole provider in a rural or geographically isolated area, and/or are fulfilling a public health role. STD programs can provide 340B eligibility by providing direct financial assistance or in-kind contributions using CDC-PS19-1901 funding.
- Health care providers should not bill insurance or Medicaid for the medication provided by the STD program via ISTD.
- There are multiple notice of funding opportunities (NOFOs) authorized by Section 318 of the Public Health Service Act providing additional 340B eligibility opportunities for programs including HIV Prevention, Ending the HIV Epidemic, and Viral Hepatitis NOFOs. STD covered entities participating in the 340B Program under NOFOs other than PS19-1901 may also purchase medication and treat syphilis infections.

Every 340B covered entity is responsible for their own 340B program compliance and program integrity.

INJECTABLE SYPHILIS TREATMENT DELIVERY IN ACTION

STD programs implement ISTD to reach patients who would otherwise not receive timely or appropriate treatment. This is one innovative strategy to address rising syphilis rates and reduce congenital syphilis. Below are examples of STD programs who have successfully implemented effective ISTD into their programs:

- Colorado has a Syphilis Testing & Treatment Locator dashboard which indicates providers participating in ISTD and can provide timely and appropriate syphilis testing and treatment by showing medication inventory at each location.
- Oregon issued a letter to community clinics and providers announcing Bicillin access for community partners who do not stock syphilis treatment or are otherwise unable to administer timely syphilis treatment through their local public health agencies.
- Jackson County Health & Human Services (Oregon) has information on their website on how to access no-cost injectable syphilis treatment from Jackson County Public Health including instructions for requesting the medication.
- The Louisiana HealthHub "SHP DirectRx" Benzathine Penicillin (Bicillin L-A) Delivery Program emphasizes the importance of timely and appropriate syphilis treatment and provides contact information for requesting deliveries of individual medication doses for patients free of charge.
- The Indiana Department of Health has a Provider Resource for How to Access Bicillin Syphilis Treatment which directs providers to contact a DIS to coordinate treatment for patients who are uninsured.
- Sacramento County's Bicillin Access Project was initiated in 2007 and facilitates availability and delivery of syphilis treatment to private medical providers and community health centers for treatment of confirmed syphilis-infected individuals and their partners.

Ordering & Tracking Forms

Syphilis treatment delivery should be well documented and auditable records should be maintained.
STD programs should use medication tracking forms and maintain comprehensive patient records. See below for examples of ordering and tracking forms utilized by STD programs.

- Oregon STD Program Bicillin Distribution Tracking Form (PDF)
- Canton City Public Health STI Medication Ordering Protocol from Ohio Department of Health
- State of Connecticut Department of Health STD Drug Order Form
- New Jersey Department of Health Medication Request
- Simcoe Muskoka District Health Unit (Canada) Bicillin Order Form

Standard Operating Procedures & Standing Orders

Below are examples of operating procedures and standing orders that support the operationalizing of syphilis treatment delivery in STD programs.

- Oregon Standard Operating Procedure: Local Public Health Authority Distribution of Bicillin to Community Clinics/Providers (PDF)
- Texas Health and Human Services ample STI Standing Delegation Order for Nurse Clinicians

STD PROGRAM RESOURCES

- NOFO: CDC-PS19-1901 Strengthening STD Prevention and Control for Health Departments (STD PCHD), CDC
- State Statutory and Regulatory Language Regarding Prenatal Syphilis Screenings in the United States, CDC
- Congenital Syphilis Diagnosed Beyond the Neonatal Period in the United States (2014-2018), American Academy of Pediatrics
- CDC Call to Action: Let's Work Together to Stem the Tide of Rising Syphilis in the United States
- Missed Opportunities for Prevention of Congenital Syphilis – United States, 2018, CDC
- What Healthcare Providers Can Do, CDC
- STI Treatment Guidelines Congenital Syphilis, CDC

340B PROGRAM RESOURCES

- 340B Basics and Beyond, NCSD
- 340B and Ending the Epidemics, NCSD
- 340B Drug Pricing Program, HRSA
- 340B Office of Pharmacy Affairs Information System, HRSA
- Public Health Service Act [As Amended Through PL 117–159, Enacted June 25, 2022]
- 340B section of the Public Health Service Act
- The 340B Prime Vendor Program (PVP)

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