Injectable Syphilis Treatment Delivery Agreement Between

San Bernardino County Department of Public Health

and [ENTER NAME] (Requesting Provider)

Background

Syphilis remains one of the most widespread sexually transmitted diseases (STDs), with its prevalence steadily increasing in recent years. Although syphilis is a treatable condition, the associated treatment can pose a significant financial burden for both patients and healthcare providers. To address barriers to accessing care, local health departments partner with both brick-and-mortar and mobile healthcare providers to increase access to syphilis treatment by using "Injectable Syphilis Treatment Delivery."

The National Coalition of STD Directors and STD programs nationwide define "Injectable Syphilis Treatment Delivery" as the practice where state or local health departments purchase injectable Syphilis treatment and provide this medication for syphilis treatment to patients of the local health jurisdiction (LHJ) when the diagnosing provider is unable to administer timely treatment, or the patient is unable to afford treatment due to financial burden and/or high insurance costs. When an LHJ becomes aware of a syphilis patient who may not receive prompt treatment, the LHJ can quickly establish an LHJ-patient relationship and then supply the medication to the diagnosing provider to treat the LHJ's patient in a timely manner and prevent further transmission of syphilis. LHJs can purchase the medication using benefits of the 340B Drug Discount Program, which greatly reduces the cost of medication and helps maximize federal funding.

For Injectable Syphilis Treatment Delivery, establishing comprehensive policies, procedures, and tracking methods is critically important. This is because the 340B program mandates meticulous monitoring of each medication unit, from the point of purchase through to the point of administration to the patient. Well established policies and procedures can help ensure passage of a Health Resources and Services Administration (HRSA) audit of LHJ's 340B program.

Purpose

Managed by the HRSA Office of Pharmacy Affairs, the purpose of the 340B drug pricing program ("340B") is to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Section 340B(a)(4) of the Public Health Service Act specifies which covered entities are eligible to participate in 340B, including STD clinics and recipients of federal grants authorized under the Public Health Services Act Section 318. This Agreement establishes an understanding between the San Bernardino County Department of Public Health (DPH) and the requesting healthcare provider [ENTER ENTITY NAME] (Requesting Provider) when the need to treat a patient who has tested positive for syphilis arises.

I. Parties

_____ (referred to as "Requesting Provider") and San Bernardino County, by and through DPH are entering into this Agreement to participate in the Injectable Syphilis Treatment Delivery Program. Through this program, DPH will deliver injectable Syphilis treatment free of charge to the Requesting Provider located within San Bernardino County. This assists with the treatment of patients who require medication for the treatment of syphilis.

II. Terms and Conditions

A. Responsibilities of DPH

DPH will deliver Bicillin-LA an injectable Syphilis treatment free of charge to the Requesting Provider to treat patients and their partners diagnosed with syphilis. This effort aims to ensure adequate treatment is available, while also providing education and conducting sexual history investigations to help prevent further disease transmission. To maintain compliance with local and state regulations, DPH will perform the following for all patients:

- 1. Ensure an agreement is established with Provider.
- 2. Provide an "Acknowledgment of Receipt of Medication" for each treatment delivery made to the Requesting Provider.
- 3. Conduct a syphilis interview with the patient.
- 4. Conduct an STI/HIV Infection Risk Assessment.
- 5. Provide STI/HIV Infection Prevention Counseling.
- 6. Coordinate the care of the patient through treatment plan follow-up.

 Sexual health assessments and STI investigative and preventative services <u>must</u> be documented for each patient who receives the administered Syphilis treatment and may be audited by the California Department of Public Health (CDPH) and HRSA.

B. Responsibilities of the Requesting Provider

The Requesting Provider must:

- 1. Adhere to state and federal guidelines for the prevention, screening and treatment of STIs, including but not limited to the <u>CDC STI Treatment Guidelines</u>.
- Submit a request to DPH for Bicillin-LA as needed for patient treatment. At the time of the request, provide DPH with the treatment plan or visit notes and Requesting Provider's order for therapy for all patients requiring treatment.
- 3. Administer the delivered Bicillin-LA promptly and before the noted expiration date.
- 4. Maintain all delivered Bicillin-LA in accordance with the temperature control guidelines.
- Use the provided medication only on the patient(s) that it was intended for.
- 6. Not charge the patient(s) or a third party a fee for the Bicillin-LA being delivered by the DPH.
- 7. Thoroughly document the following in the patients' health records:
 - Accurate details of any observed signs and symptoms related to the positive STI diagnosis,
 - ii. Medication name, strength, dose, route and administration dates for each injectable Syphilis treatment dose, and
 - iii. Name of ordering provider.
- 8. Notify DPH if a patient misses their treatment appointment so that the delivered Bicillin-LA can be retrieved.

- i. The medication may not be reassigned to another patient without prior notification and approval from DPH, and only if the new patient has been assigned to a CDI by DPH as part of an investigation case.
- 9. Furnish DPH with all requested medical records related to the patient's positive STI diagnosis to allow DPH to thoroughly investigate the patient's sexual health history and provide education on their diagnosis and prevention methods for reinfection.

III. Fiscal Provisions

This Agreement is non-financial and no Party will receive remuneration hereunder. In the event the state or federal funding used to fund this Agreement is no longer available, DPH may terminate this Agreement immediately.

IV. Breach and Termination

The failure of the Requesting Provider to comply with or fulfill any of the responsibilities above may result in immediate termination of this Agreement, at the sole discretion of DPH. Prior to termination, DPH will provide written notice of the breach and the effective termination date.

V. Duration of Agreement

This Agreement is effective upon signature by both parties and will remain in effect for one year from the signature date. The Agreement may be terminated earlier by either Party upon 30 days' written notice. Upon termination of the Agreement, the Requesting Provider must retain the patient's information as described in Article II., Section B. above according to the applicable timeframes established by law and provide such records to DPH upon request.

VI. Indemnification

Requesting Provider agrees to indemnify, defend (with counsel reasonably approved by County) and hold harmless the County and its authorized officers, employees, agents and volunteers from any and all claims, actions, losses, damages and/or liability arising out of this Agreement, including the acts, errors or omissions of any person and for any costs or expenses incurred by the County on account of any claim except where such indemnification is prohibited by law. This indemnification provision shall apply regardless of the existence or degree of fault of indemnities. Requesting Provider's indemnification obligation applies to the County's "active" as well as "passive" negligence but does not apply to the County's "sole negligence" or "willful misconduct" within the meaning of Civil Code section 2782.

VII. Confidentiality

Pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act, regulations have been promulgated governing the privacy of individually identifiable health information. Requesting Provider acknowledges that it is a covered entity and subject to the requirements of HIPAA and HITECH, and their implementing regulations. Requesting Provider agrees to fully comply with the terms of HIPAA and HITECH, and regulations promulgated thereunder, and to ensure any subcontractors utilized to fulfill services pursuant to this Agreement comply with said provisions. Requesting Provider further

agrees to comply with the requirements of all other applicable federal and state laws that pertain to the protection of health information.

VIII. Insurance requirements

DH and Requesting Provider represent and warrant that each party hereunder is covered by either a self-insured policy, professional liability insurance policy (malpractice, errors, and omissions), or general liability policy that provides sufficient coverage against professional liabilities that may arise from acts or omissions in connection with or related to this agreement. Both parties are solely responsible for maintaining insurance coverage for its own employees.

IX. General Terms

A. Venue

The parties acknowledge and agree that this Agreement was entered into and intended to be performed in San Bernardino County, California. The parties agree that the venue of any action or claim brought by any party to this Agreement will be the Superior Court of California, San Bernardino County, San Bernardino District. Each party hereby waives any law or rule of the court, which would allow them to request or demand a change of venue. If any action or claim concerning this Agreement is brought by any third party and filed in another venue, the parties hereto agree to use their best efforts to obtain a change of venue to the Superior Court of California, San Bernardino County, San Bernardino District.

B. Relationship of the Parties

Nothing contained in this Agreement shall be construed as creating a joint venture, partnership, or employment arrangement between the Parties hereto, nor shall either Party have the right, power or authority to create an obligation or duty, expressed or implied, on behalf of the other Party hereto.

C. Records

Requesting Provider shall maintain all records and books pertaining to the delivery of services under this Agreement and demonstrate accountability for contract performance. All records shall be complete and current and comply with all Agreement requirements. Failure to maintain acceptable records shall be considered grounds for withholding of payments for invoices submitted and/or termination of the Agreement.

All records relating to the Requesting Provider's personnel, consultants, subcontractors, Services/Scope of Work and expenses pertaining to this Agreement shall be kept in a generally acceptable accounting format. Records should include primary source documents. Fiscal records shall be kept in accordance with Generally Accepted Accounting Principles and must account for all funds, tangible assets, revenue and expenditures. Fiscal records must comply with the appropriate Office of Management and Budget (OMB) Circulars, which state the administrative requirements, cost principles and other standards for accountancy.

D. Licenses, Permits and/or Certifications

Requesting Provider shall ensure that it has all necessary licenses, permits and/or certifications required by the laws of Federal, State, County, and municipal laws, ordinances, rules and regulations. Requesting Provider shall maintain these licenses, permits and/or certifications in effect for the duration of this Agreement. Contractor will notify County immediately of loss or suspension of any such licenses, permits and/or certifications. Failure to maintain a required license, permit and/or certification may result in immediate termination of this Agreement.

E. Debarment and Suspension

Requesting Provider certifies that neither it nor its principals or subcontractors is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency. (See the following United States General Services Administration's System for Award Management website https://www.sam.gov). Requesting Provider further certifies that if it or any of its subcontractors are business entities that must be registered with the California Secretary of State, they are registered and in good standing with the Secretary of State.

F. Change of Address

Requesting Provider shall notify the County in writing of any change in mailing address within ten (10) business days of the change.

G. Contract Assignability

Without the prior written consent of the County, the Agreement is not assignable by Requesting Provider either in whole or in part.

H. Electronic Signatures

This Agreement may be executed in any number of counterparts, each of which so executed shall be deemed to be an original, and such counterparts shall together constitute one and the same Agreement. The parties shall be entitled to sign and transmit an electronic signature of this Agreement (whether by facsimile, PDF or other mail transmission), which signature shall be binding on the party whose name is contained therein. Each party providing an electronic signature agrees to promptly execute and deliver to the other party an original signed Agreement upon request.

IN WITNESS WHEREOF, the San Bernardino County and the Requesting Provider have each caused this Agreement to be subscribed by its respective duly authorized officers, on its behalf.

Requesting Provider (print name):	
Title:	
License Number:	
NPI:	
Requesting Provider Signature:	
Date:	
DPH Representative (print name):	
Title:	
DPH Representative Signature:	
Date:	
Approved as to Legal Form	
Adam Ebright, Deputy County Counsel	
Date:	