

Memorandum of Understanding (MOU)

Between

the California Department of Public Health (CDPH) Sexually Transmitted Disease (STD) Control Branch and

[Covered Entity Name]

for Participation in the 340B Drug Pricing Program as an STD Entity

I. Parties

CDPH STD Control Branch and **[Covered entity name]** are entering into this MOU to collaborate for the purpose of leveraging participation in the 340B drug pricing program to reduce the incidence of sexually transmitted infections (STI) and their sequelae.

II. Purpose

Managed by the U.S. Health and Resources Services Administration (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 U.S. Public Health Services Act Section 318.

As a recipient of the Section 318-authorized U.S. Centers for Disease Control and Prevention (CDC) [STD Prevention and Control for Health Departments \(PCHD\) grant \(PS19-1901\)](#), CDPH STD Control Branch is eligible to participate in the 340B program. CDPH is also able to confer 340B program eligibility to qualifying STD clinics and other eligible organizations who receive in-kind support purchased with CDC STD PCHD base grant funds. This MOU formalizes an agreement by which CDPH STD Control Branch confers eligibility to **[Covered entity name]** for participation in the 340B program if the terms and conditions of this MOU agreement are met.

III. Terms and Conditions

a. Responsibilities of CDPH

CDPH STD Control Branch agrees to annually provide **[Covered entity name]**, either directly or through CDPH subcontractors, a minimum of one of the following forms of in-kind support assistance, which are funded wholly or in part by the CDPH STD

Control Branch's federally funded CDC STD PCHD grant (grant number: 1H25PS005127*), to advance STI prevention, screening, and treatment goals:

- Material goods (e.g., condoms or lubricant when available),
- Chlamydia/Gonorrhea Expedited Partner Therapy Distribution Program medications, and
- Virtual or in-person training and technical assistance on topics to advance STI prevention, screening, and treatment goals (e.g., STI preventive service guidelines and best practices, participation in the 340B Program, and other STI, HIV, and viral hepatitis-related topics, as needed).

b. Responsibilities of Covered Entity

In turn, [Covered entity name] agrees to:

1. Adhere to state and federal guidelines for the prevention, screening and treatment of STIs (<https://www.cdc.gov/std/treatment>). This includes, for example, providing eligible preventive services within the scope of the CDC STD PCHD grant to establish a patient-provider relationship **prior** to treatment with 340B discounted medications. Eligible preventive services may include:
 - i. Conducting a syphilis interview (local health jurisdictions only)
 - ii. Conducting an [STI/HIV infection risk assessment](#)
 - iii. Providing [STI/HIV infection prevention counseling](#)
 - iv. Conducting [STI/HIV testing](#)
 - v. Providing another preventive service recommended in the [CDC 2021 STI Treatment Guidelines](#).

Sexual health assessments and STI preventive services **must** be documented for each patient and may be audited by HRSA.

2. Operate their STD 340B program in accordance with 340B program requirements (See <https://www.hrsa.gov/opa/program-requirements>). For example, covered entities enrolled in the 340B program can only provide 340B purchased drugs to patients who meet the program's **three-part patient definition** as defined by HRSA:
 - i. The covered entity has an established relationship with the individual, such that the covered entity maintains records of the individual's health care; *and*

* This federal grant number format is most commonly used; however, the NH25PS005127 format is also acceptable.

- ii. 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 (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; *and*
- iii. 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 [Section 318-authorized] grant funding status has been provided to the entity.

Patients **cannot** be made eligible for 340B solely by being treated with a 340B purchased drug. A covered entity must establish a relationship with the patient, by providing at least one of the preventive services in the scope of the CDC STD PCHD grant or in the [CDC 2021 STI Treatment Guidelines](#), as outlined on page 2 of this MOU, prior to treatment.

3. Maintain written 340B policies and procedures and make them available to CDPH STD Control Branch or HRSA upon request, including during a HRSA audit.
4. Maintain auditable records documenting program eligibility and compliance with [340B program requirements](#) and make them available to CDPH STD Control Branch or HRSA upon request, including during a HRSA audit. Failure to comply may make the 340B covered entity liable to manufacturers for refunds of discounts and/or cause the covered entity to be removed from the 340B Program.
5. Ensure that one provider and program administrator from each participating site that prescribes 340B medications participates in an annual virtual or in-person training offered by CDPH STD Control Branch.
6. Ensure that the covered entity's Authorizing Official understands the responsibilities outlined in this MOU.
7. Maintain a record of in-kind support received from the CDPH STD Control Branch, for a minimum of three years. CDPH STD Control Branch will have a record of in-kind material goods; however, the covered entity must maintain their own record of in-kind training or technical assistance support received. Documentation of eligible in-kind support may be requested by HRSA in the event of a 340B audit.
8. Upon request from CDPH STD Control Branch, provide a brief summary of the amount and use of 340B program cost savings to maintain, improve, or expand patient care services in line with 340B program guidelines and in support of the

goals of the CDC STD PCHD grant, including a description of how the program planning, implementation, evaluation, and reinvestment of savings promotes racial and health equity, to CDPH STD Control Branch within 30 days of request.

9. Provide immediate notification via email to CDPH STD Control Branch at std340b@cdph.ca.gov and HRSA Office of Pharmacy Affairs at apexusanswers@340bpvp.com of any changes that impact 340B eligibility or lapses in receiving in-kind support or technical assistance.
10. Provide immediate notification via email to CDPH STD Control Branch at std340b@cdph.ca.gov and submit a change request through HRSA's Office of Pharmacy Affairs Information System (OPAIS) for approval of any changes to the covered entity's Authorizing Official or Primary Contact.
11. Annually recertify eligibility for participation in the STD 340B program with HRSA and respond promptly to requests for information from CDPH STD Control Branch during the recertification period.

IV. Independence of Parties

CDPH STD Control Branch and [Covered entity name] remain separate and independent entities. Neither party is the agent of the other and neither is liable for the wrongful acts or negligence of the other in carrying out their respective responsibilities under this MOU. Neither party has the right or authority to control or direct the activities of the other or the right or ability to bind the other to any agreement with a third party or to incur any obligation or liability on behalf of the other party in carrying out their respective duties under this MOU, unless expressly authorized by this MOU. CDPH STD Control Branch and [Covered entity name] retain the authority to contract or affiliate with, or otherwise obtain services from, other parties, on either a limited or general basis.

V. General Provisions

a. Insurance. CDPH STD Control Branch and [Covered entity name] 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 MOU. Neither party will provide individual coverage for the other party's employees, with each party being responsible for coverage of its employees.

b. Financial Responsibility. Each party shall bear and be responsible solely for its own costs and expenses necessary to comply with this MOU.

c. Applicable Law. The construction, interpretation and enforcement of this MOU shall be governed by the laws of the State of California. The courts of the State of California shall have jurisdiction over any action arising out of this MOU and over the parties.

d. Entirety of Agreement. This MOU contains all the terms and conditions agreed upon by the parties regarding STD Control Branch's conferring eligibility to [Covered entity name] to participate in the 340B program and supersedes any prior negotiations, representations, and agreements relating to such subject matter, whether written or oral, between CDPH STD Control Branch and [Covered entity name] for participation in the 340B program as an STD entity by means of CDPH STD Control Branch's CDC STD PCHD grant.

e. Severability. If any provision of this MOU is held to be illegal, invalid, or unenforceable under present or future laws effective during the term hereof, such provision shall be fully severable. This MOU shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never been a part of the MOU, and the remaining provisions shall remain in full force and effect unaffected by such severance, provided that the severed provision(s) are not material to the overall purpose and operation of this MOU.

f. Third Party Beneficiary Rights. Nothing in this MOU is intended to make any person or entity who is not signatory to the agreement a third-party beneficiary of any right created by this MOU or by operation of law.

VI. Duration of Understanding

This MOU is effective upon signature by both parties and will remain in effect until the end of the CDC STD PCHD grant, January 31, 2026. This MOU must be reviewed by the Authorizing Officials from CDPH STD Control Branch and [Covered entity name] annually by April 15th in preparation for the HRSA 340B recertification process. This MOU may be amended at any time through written agreement of both parties. Either party may terminate this MOU at any time, effective immediately, by providing the other party with written notice thereof. If termination of this MOU is needed, both parties agree to provide as much advanced notice as possible.

VII. Signatures

CDPH STD Control Branch:

[Covered entity name]:

Kathleen Jacobson, MD

[Authorizing Official/Other Authorized Signatory Name]

Chief, STD Control Branch
California Department of Public Health

[Authorizing Official/Other Authorized Signatory Title]

Date:

[Organization Name]

Date: