

MEMORANDUM OF UNDERSTANDING

Note: This information is provided by NCSD for general information purposes and does not constitute legal advice. This resource is designed to support 318 recipients and subrecipients, including, but not limited to, those receiving a grant or contract funded under the PCHD NOFO (19-1901) and the Ending the HIV Epidemic (EHE) NOFO (20-2010), in the event of a HRSA audit of 340B operations and compliance.

This Memorandum of Understanding, (the “MOU”), is entered into by and between the _____ (state/local department of health and primary grantee of Section 318 funds of the Public Health Service Act, hereafter, referred to as PRIMARY GRANTEE) and _____, (local city/county health department, juvenile detention center, local city or county correctional facility, community-based clinic, sexual health, family planning, or another essential community provider, hereafter, referred to as the SUBRECIPIENT), (collectively, the “Parties”) in the effort to outline the relationship and set out the roles and responsibilities between the Parties regarding eligibility and participation in the Health Resources and Services Administration’s (HRSA) 340B Drug Pricing Program (the “Program”) and to ensure the coordination and implementation of strategies to support the scope of [PCHD NOFO (19-1901), Ending the HIV Epidemic (EHE) NOFO (20-2010), or other qualifying Section 318 grant].

RECITALS

WHEREAS, the PRIMARY GRANTEE receives a direct grant from CDC that uses funds from Section 318 of the Public Health Service Act to be provisioned in compliance with federal and state program regulations.

WHEREAS, the SUBRECIPIENT provides services consistent with the purpose of the Section 318 grant, including but not limited to, [*describe relevant grant activities*].

WHEREAS, the SUBRECIPIENT receives from the PRIMARY GRANTEE:

- Direct financial support paid for by Section 318 funds;
- In-kind, non-cash, contributions paid for by Section 318 funds in the form of real property, equipment, supplies, and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.
[*Describe the relationship/in-kind in this section*]
- 340B medication(s) paid for by Section 318 funds and distributed through a HRSA-approved Combined Purchasing and Distribution Model.¹

¹ While this agreement is intended to define the relationship between the parties and describe the nature of support, there may be specific practices and requirements related to registration and participation in a Combined Purchasing and Distribution model, set forth by HRSA, to be approved by both Parties.

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NOW THEREFORE in consideration of the mutual promises set forth herein and other for valuable consideration, the sufficiency of which is hereby acknowledged, the Parties agree to as follows:

I. Joint Responsibilities

- A. Ensure policies and procedures align with Program guidelines and expectations of compliance; and
- B. Ensure all policies and procedures are implemented and adhered to.

For 340B Combined Purchasing and Distribution medications only:

- C. Monitor and track medications from the Combined Purchasing and Distribution Program.

II. PRIMARY GRANTEE Responsibilities

- A. Attest to HRSA the eligibility of the SUBRECIPIENT to participate in the Program;
- B. Provide to the SUBRECIPIENT the federal grant number of the award or the Notice of Funding Opportunity (NOFO) number under which it is funded for registration in the Office of Pharmacy Affairs Information System (OPAIS) database;
- C. Review, approve, and monitor SUBRECIPIENT's registration in OPAIS;
- D. May review and approve the eligibility for each SUBRECIPIENT site to participate in the Program outline in Attachment A; and
- E. Provide education concerning Program compliance to SUBRECIPIENT through initial and ongoing technical assistance, including information on how to access the Apexus PVP Program, a HRSA contractor for further education.

For 340B Combined Purchasing and Distribution medications only:

- F. Create, review, and update policies and procedures to ensure compliance with the Combined Purchasing and Distribution Program;
- G. Ensure all 340B medications provided to SUBRECIPIENT are through pre-authorized entities; and
- H. Monitor and support the SUBRECIPIENT on all compliance elements of the Program addressed in the policies and procedures outlined by the Combined Purchasing and Distribution Program.

III. SUBRECIPIENT Responsibilities

- A. Determine eligibility of participation in the Program for each site listed in Attachment A;
- B. Register as a Covered Entity in OPAIS database, maintaining registration and annual recertification for all registered sites and associated pharmacies (if applicable) using the Section 318 grant number or NOFO

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- number under which it receives funding or in-kind contributions from. The OPAIS database can be accessed at: <https://340bopais.hrsa.gov/>;
- C. On a continual basis, ensure all 340B OPAIS information is accurate and up to date;
 - D. Ensure program integrity by maintaining accurate records and documenting compliance with all Program requirements. The SUBRECIPIENT will be liable and hold the PRIMARY GRANTEE harmless for any findings of noncompliance by the SUBRECIPIENT;
 - E. Ensure all 340B medications, laboratory, and/or other in-kind services provided under this MOU are used only for qualifying patients. It is the responsibility of the SUBRECIPIENT to prevent the diversion of 340B medications to ineligible patients.
 - F. Report to HRSA and the PRIMARY GRANTEE how the SUBRECIPIENT will bill Medicaid fee-for-service drugs on the Medicaid Exclusion File, as mandated by 42 USC 256b(a)(5)(A)(i), to ensure compliance with the Duplicate Discount Prohibition requirements.
 - G. Use 340B revenue to promote the purpose of the federal section 318 grant under which it is 340B eligible;
 - H. Permit on-site or remoting audit and program monitoring visits by HRSA to ensure compliance with Program regulations; and
 - I. Notify the PRIMARY GRANTEE of any change in organizational policy relating to the distribution, storage, and dispensing of 340B medications, change in registration information, non-compliance, or discontinuation of participation in the program as soon as possible.

For 340B Combined Purchasing and Distribution medications only:

- J. Obtain medications from authorized entity designated by the PRIMARY GRANTEE;
- K. Distribute medications at no charge to eligible patients;
- L. Maintain records of each medication distributed to eligible patients. Records may be requested and audited by PRIMARY GRANTEE for on-site or remote monitoring at any time to ensure compliance. Records including, but are not limited to: billing records, medication tracking logs, and relevant patient records'
- M. Will not bill Medicaid or other payors for medications;
- N. Ensure medications are not sold or exchanged to any individual or entity; and
- O. Report waste or loss of medications or any discovered non-compliance to the PRIMARY GRANTEE as soon as possible.

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IV. Term of the MOU

This MOU begins upon the first date on which it has been executed by both Parties and ends one year thereafter. *[Or add specific dates.]*

V. Amendments

Amendments to this MOU shall be in writing and signed by the Parties.

VI. Termination of MOU

- A. **Termination by Mutual Agreement.** Either Party may terminate this MOU, or any part thereof, at any time with written notice thirty days prior to the date of termination. Upon expiration of the thirty (30) day period, the SUBRECIPIENT shall notify HRSA and be removed from the 340B Program if otherwise ineligible to participate in the Program.
- B. **Termination for Cause.** This MOU may be terminated for a material breach upon thirty (30) days written notice of such alleged material breach. Such notice shall specify in reasonable detail the nature of the breach and the actions required to cure the breach if such is curable. Termination of this MOU and suspension from the 340B Program shall occur upon the expiration of said thirty (30) day period if the conditions to resolve the material breach cannot be met.

VII. Additional Terms and Conditions

A. Confidentiality

Confidential Information: All Confidential Information (as defined below) shall be the property of the disclosing party. Each party agrees the receiving party shall (i) use at least the same degree of care to prevent unauthorized use and disclosure of disclosing party's Confidential Information as the receiving party uses concerning its own Confidential Information (but in no case less than a reasonable degree of care); (ii) use the disclosing party's Confidential Information only in the performance of the receiving party's obligations under this Agreement or for internal purposes to improve the quality of service performed under this Agreement; and (iii) except as otherwise expressly provided herein, not disclose or grant access to the disclosing party's Confidential Information to any third party, without the prior written consent of the disclosing party.

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“Confidential Information” means non-public information that the disclosing party designates as being confidential to the receiving party or which, under the circumstances surrounding disclosure ought to be treated as confidential by the receiving party, including without limitation, information received from others that the disclosing party, is obligated to treat as confidential. Confidential Information does not include information that (i) is or subsequently becomes generally available to the public other than by a breach of a confidentiality obligation; (ii) is already in the possession of receiving party prior to disclosing party’s disclosure to receiving party; (iii) is independently developed by receiving party without use or reference to the disclosing party’s Confidential Information; or (iv) becomes available to receiving party from a source other than the disclosing party other than by a breach of a confidentiality obligation.

B. Medical Records

All parties to this Agreement shall comply with all applicable state and federal laws and regulations regarding confidentiality of patient records, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the Privacy Standards (45 C.F.R. Parts 160 and 164), the Standards for Electronic Transactions (45 C.F.R. Parts 160 and 162), and the Security Standards (45 C.F.R. Part 162) (collectively, the “Standards”) promulgated or to be promulgated by the Secretary of Health and Human Services on and after the applicable effective dates specified in the Standards. Notwithstanding the foregoing, the parties shall be permitted to enter into such Business Associate Agreements as are permitted or required by HIPAA.

VIII. Entire Agreement

The Parties acknowledge that this MOU, including the incorporated attachments, is the entire agreement of the Parties and that there are no agreements or understandings, written or oral, between them with the respect to the subject matter of this MOU, other than as set forth in this MOU.

By signing below, the Parties acknowledge that they have read the MOU and agree to its terms and that the persons whose signatures appear below have the requisite authority to execute this MOU on behalf of the named party.

Signature Page follows

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PRIMARY GRANTEE

By: _____

Printed Name: _____

Title: _____

Date: _____

SUBRECIPIENT

By: _____

Printed Name: _____

Title: _____

Date: _____

**The following Attachments are attached and incorporated as part of the MOU:
Attachment A--SUBRECIPIENT's Participating Locations**

Attachments follow



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Attachment A SUBRECIPIENT's Participating Locations

Site Name	Address	City	Zip	Phone Number

