INSTRUCTIONS FOR COMPLETING THE 340B REGISTRATION FORM

For use by any site registering as a non-hospital covered entity type (other than Consolidated Health Center, Federally Qualified Health Center Lookalike and STD/TB clinics). Specific eligibility requirements are posted on the OPA website.

An organization eligible to participate in the 340B Program must complete the registration process in order to purchase and use 340B drugs for its eligible patients. This registration must be completed and submitted according to the established deadlines that are published on the OPA website. The registration process is not complete unless all necessary supporting documentation is submitted on the same day to OPA. Once the Office of Pharmacy Affairs (OPA) receives an entity's registration and verifies that the organization is eligible, the entity may purchase 340B drugs beginning on the entity's participating start date listed on the 340B database.

The entity should ensure that all information is current and accurate on the 340B database record. It is the covered entity's responsibility to notify OPA of any changes by submitting an official 340B Program change request.

NOTE ON SHIPPING ADDRESSES – complete this section ONLY if your covered entity's 340B drugs will be shipped to an address that is different from the covered entity address. Covered entities should be aware that listing a location as a shipping address does not make that location eligible to use 340B drugs for any individuals treated there. However, do NOT use this section to provide information for a contract pharmacy arrangement. Please refer to the OPA website for instructions on registering a contract pharmacy.

Once your registration has been processed, OPA will notify you (at the e-mail address that you provide) of your covered entity's 340B Program participation start date and provide you with your 340B identification number, a unique number that OPA assigns to each covered entity. Please use this number in all correspondence to OPA. 340B identification numbers will be used by manufacturers, wholesalers, and others to search the OPA database to verify your participation in the 340B Program. It is the entity's responsibility to notify its wholesaler or manufacturer that it is registered for 340B prices when it places an order.

This registration form must be completed and submitted according to the established deadlines that are published on the OPA website (www.hrsa.gov/opa).

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OFFICE OF PHARMACY AFFAIRS
340B PROGRAM REGISTRATION FORM FOR COVERED ENTITIES

Acknowledgement of Covered Entity Participation in Outpatient Discount Drug Pricing under Section 340B of the Public Health Service Act.

I. Covered Entity Information:

Covered Entity Name: _____

Covered Entity Sub-Division Name (if applicable):_____

Employer Identification Number: _____

Street Address (PO Boxes are not allowed): _____

City:_____ State:_____ZIP: _____

Billing Address (if different):_____

City:_____ State:_____ZIP: _____

Shipping Address (if different; PO Boxes are not allowed)_____

City:_____ State:_____ZIP: _____

Entity Type (see next page for list of codes)_____

Are you attempting to reinstate under a previous 340B ID number?

- ❒ Yes 340B ID Number: _____
- ❒ No

UDS or Grant Number (if known):_____

II. Medicaid Billing Information: *You **must** answer the following question regarding Medicaid billing.*

Will the covered entity dispense 340B purchased drugs to Medicaid patients AND subsequently bill Medicaid for those dispensed 340B drugs? Yes ❒ No ❒

If "Yes", please provide the entity's Medicaid Provider Number(s) (MPN) and/or National Provider Identifier(s) (NPI) for each applicable entity location that bills Medicaid for 340B drugs. If you are unsure of the entity's MPN and/or NPI, please check with your State Medicaid agency. It is important that your Medicaid billing status and appropriate provider identifier number(s) are accurate in the OPA database and align with your billing practices in order to prevent Medicaid rebates on drugs that were purchased at the 340B discounted price.

Medicaid Provider Number(s)_____and/or_____

National Provider Identifier(s)_____and/or_____

All covered entities should notify OPA prior to any change in Medicaid billing status. For more information, please visit the HRSA website.

III. 340B Primary Contact and Authorizing Official Information:

Covered Entity Primary Contact Name
(Must be someone employed by the Covered Entity): _____

Title: _____

Phone:_____ Ext._____ Fax: _____

Email Address: _____

Covered Entity Authorizing Official
The Authorizing Official must be someone who can bind the organization into a contract, such as the President, Vice President, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, or Executive Director. Forms that are signed by an individual that OPA determines is not an acceptable representative will not be processed. If you are in doubt regarding the acceptability of a signature, please contact please contact the 340B Prime Vendor Program at 1-888-340-2787 or via email at ApexusAnswers@340bpvp.com prior to submission of your registration.

Authorizing Official Name:_____

Title: _____

Phone:_____ Ext._____ Fax: _____

Email Address: _____

IV. Signed Agreement:

The undersigned represents and confirms that he/she is fully authorized to legally bind the covered entity and certifies that the contents of any statement made or reflected in this document are truthful and accurate. The undersigned further acknowledges the 340B covered entity's responsibility to adhere to the following:

As an Authorized Official, I certify on behalf of the covered entity that:

(1) all information listed on the 340B Program database for the covered entity will be complete, accurate, and correct;
(2) the covered entity will meet all 340B Program eligibility requirements;
(3) the covered entity will comply with all requirements of Section 340B of the Public Health Service Act and any accompanying regulations including, but not limited to, the prohibition against duplicate discounts and diversion (section 340B(a)(5)(A) and (B) of the Public Health Service Act;
(4) the covered entity will maintain auditable records pertaining to compliance with the requirements described in paragraph (3) above, pursuant to section 340B(a)(5)(C) of the Public Health Service Act;
(5) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement will be performed in accordance with OPA requirements and guidelines;
(6) the covered entity acknowledges its responsibility to contact OPA as soon as possible if there is any change in 340B eligibility and/or breach by the covered entity of any of the foregoing; and
(7) the covered entity acknowledges that if there is a breach of the requirements described in paragraph (3) that the covered entity may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and, depending upon the circumstances, may be subject to removal from the list of eligible 340B entities.

In addition, I have read all applicable registration instructions and I am aware that my registration will not be reviewed if the required supporting documents are not submitted today.

Please provide any additional information or clarification that may be helpful in reviewing this registration for 340B program eligibility: _____
_____
_____

Signature of Authorizing Official: Date:

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List of Covered Entity Type Codes

Please select from the list below and enter the appropriate code(s) for your entity on the Registration Form under "Entity Type." You should enter all codes for which your organization is eligible as the scope of your grant may determine the eligibility of pharmaceuticals purchased under 340B.

Code	Program
BL	Black Lung Clinics Program
CH	Consolidated Community Health Center Cluster Program (includes Community Health Centers, Migrant Health Centers, Healthcare for the Homeless Programs, Public Housing Primary Care Programs, and School-Based Health Center (Healthy Schools, Healthy Communities) Programs
FP	Family Planning
FQHC638	Tribal Contract/Compact with IHS (P.L. 93-638)
FQHCLA	Federally Qualified Health Center Lookalike NOTE: if your organization is an FQHCLA, you MUST notify OPA if you are successful in receiving a Section 330 grant at a later date.
HM	Comprehensive Hemophilia Treatment Center
HV	Ryan White Part C
NH	Native Hawaiian Health Care Program
RWI	Ryan White Part A
RWII	Ryan White Part B
RWIID	Ryan White ADAP Rebate Option
RWIIR	Ryan White ADAP Direct Purchase
RW4	Ryan White Part D
SPNS	Special Projects of National Significance
STD	Sexually Transmitted Diseases
TB	Tuberculosis
UI	Urban Indian

This registration form must be completed and submitted according to the established deadlines that are published on the OPA website (www.hrsa.gov/opa).