INSTRUCTIONS FOR COMPLETING THE 340B REGISTRATION FORM

(for use by Black Lung Clinics, Consolidated Health Center Programs, Family Planning entities authorized under Title X, Federally Qualified Health Center Look-alikes, FQHC638, Comprehensive Hemophilia Treatment Centers, Native Hawaiian Health Care Programs, Ryan White Programs, Sexually Transmitted Disease entities authorized by Section 318, Tuberculosis entities authorized by Section 317,and Urban Indian Programs – specific eligibility requirements are posted on the OPA website)

While an organization may be eligible to participate in the 340B Program by virtue of its status (i.e., receiving a grant from an eligible program), it must notify the Office of Pharmacy Affairs (OPA) of its intention to participate by completing and submitting a signed original of the "340B Program Registration Form for Covered Entities." Once the OPA receives, verifies, and processes this information, the entity will be eligible to purchase pharmaceuticals at the 340B price beginning the next calendar quarter. If your organization has been awarded a qualifying grant recently, you may want to include a copy of your Notice of Grant Award to expedite the processing of your form.

This registration form must be completed and submitted according to the established deadlines that are published on the OPA website (www.hrsa.gov/opa). The registration process is not complete unless the registration form has been completed in its entirety (all requested information is filled in on the form) and all required supporting documentation is submitted on the same day to OPA. **Incomplete packages will not be processed.**

NOTE ON SIGNATURES – the Registration Form must be signed by the Authorizing Official of the covered entity. The authorizing official may be the President, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, or Program 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 OPA prior to submission of your registration form. Please include the title, telephone number, and e-mail address of the individual who is signing.

NOTE ON SHIPPING ADDRESSES – complete this section ONLY if your pharmaceuticals will be shipped to an address that is different from the covered entity address. However, do NOT use this section to provide information for a contracted pharmacy arrangement. Use the form found at this link for contracted pharmacy information.

Accurate information on the entity should always be reflected on the OPA website. It is the covered entity's responsibility to notify OPA of any changes in writing by submitting the official 340B Program change request found at this link.

Once your form has been processed, the OPA will notify you (at the e-mail address that you provide on the Program Registration Form) of your effective date in the 340B Program 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. This is the number 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 tell its wholesaler or manufacturer that it is registered for 340B prices when it places an order. You may view the information for your entity on the OPA website by entering the 340B ID number in the field labeled "340B ID. Entities will not see their 340B identification number in the database immediately after approval. Approved 340B identification numbers will appear in the database at the start of the upcoming quarter.

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: _____

Employer Identification Number: _____

Street Address: _____

City:_____ State:_____ZIP: _____

Billing Address (if different):_____

City:_____ State:_____ZIP: _____

Shipping Address (if different):_____

City:_____ State:_____ZIP: _____

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

UDS or Grant Number:_____

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

Will you bill Medicaid for drugs purchased through the 340B Drug Pricing Program? Yes ☐ No ☐

If "Yes," please provide the Pharmacy/Clinic Medicaid Provider Number(s) and/or National Provider Identifier(s) (NPI) (*please include the number(s) and State*):

Medicaid Provider Number(s)_____and/or_____

National Provider Identifier(s)_____and/or_____

If you bill Medicaid for pharmaceuticals that may be subject to a payment of a Medicaid rebate to a state, you must submit to OPA the pharmacy Medicaid number and/or clinic Medicaid number and/or NPI which is used to bill Medicaid for outpatient drugs. If you are unsure of your pharmacy Medicaid number and/or NPI, please check with your State Medicaid agency. It is important that your Medicaid billing status in our database is accurate to prevent Medicaid rebates on drugs that were sold to a covered entity at a discounted price. If you bill at an all-inclusive rate, which includes pharmaceuticals, or if you do not bill Medicaid, state N/A (Not Applicable) which is entered in our database. You should notify OPA prior to any change in your Medicaid billing status. For more information, go to: http://www.hrsa.gov/opa/medicaidexclusion.htm

III. Designated 340B Contact and Authorizing Official Information:

340B Contact Name: _____

Title: _____

Phone: _____ Ext._____ Fax: _____

Email Address: _____

Covered Entity Authorizing Official (Must be authorized to legally bind covered entity (e.g., CEO, CFO, COO)) 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 abide by 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 and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity;
(4) the covered entity will maintain auditable records demonstrating compliance with the requirements described in paragraph (3) above;
(5) the covered entity has systems/mechanisms in place to ensure ongoing compliance with the requirements described in (3) above;
(6) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement will be performed in accordance with OPA requirements and guidelines including, but not limited to, that the covered entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the covered entity has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism);
(7) the covered entity acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material change in 340B eligibility and/or material breach by the covered entity of any of the foregoing; and
(8) 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 the payment of interest and/or removal from the list of eligible 340B entities.

Signature of Authorizing Official: Date:

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)
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
UI	Urban Indian