OFFICE OF PHARMACY AFFAIRS (OPA)
340B PROGRAM RECERTIFICATION FOR STD/TB ENTITIES

A completed recertification must include the following information:

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: _

If address is changing:

1. Is the service remaining open at the old address?

   Yes ❒ No ❒

2. Will this entity continue to receive federal funding that makes them eligible for the 340B Program? (for all grantees except Federally Qualified Health Centers and Health Center Program Look-Alikes)

   Yes ❒ No ❒

Billing Address (if different):_____

City:_____ State:_____ZIP: _____

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

City:_____ State:_____ZIP: _____

Is the requested shipping address location a **pharmacy** (a pharmacy prepares and dispenses drugs to patients); a **healthcare service delivery site** (a healthcare service delivery site administers/dispenses drugs to patients as part of medical encounters); or an **"other" receiving location** (an "other" receiving location does NOT administer/dispense drugs directly to patients (e.g., warehouse, loading dock, re-packager, compounding center, central fill facility, centralized distribution center, or lab/facility that prepares and ships drugs to a healthcare service delivery site))?

1. If **PHARMACY** is selected, then "Is the pharmacy owned by the covered entity (documentation to demonstrate entity ownership may include a pharmacy license and listing of the pharmacy on the covered entity's grant or Medicare Cost Report)?"
   a. If "No" is selected, then: "The pharmacy must be registered as a contract pharmacy."
   b. If "Yes" is selected, then: "List the pharmacy as a shipping address under the 340B ID that purchases the drugs."

2. If **HEALTH CARE SERVICE DELIVERY SITE** is selected, then "Is the health care service delivery site registered in OPAIS"?
   a. If "No" is selected, then: "An unregistered healthcare service delivery site may NOT be listed as a shipping address."
   b. If "Yes" is selected for any hospital or CH/FQHCLA grantee, then: "List the parent hospital, hospital child site, or grant associated site as a shipping address under the 340B ID that purchases the drugs."
   c. If "Yes" is selected for any non-CH/FQHCLA grantee, then: "Is the healthcare delivery site listed as a receiver in an OPA- approved Central Purchasing Distribution Model (CPDM)?"
      i. If "Yes" is selected, then: "List the healthcare delivery site as a shipping address under the 340B ID that purchases the drugs."

ii. If "No" is selected, then: "The healthcare delivery site must be listed as a receiver in an OPA-approved CPDM before it can be listed as a shipping address."

3. If **"OTHER' RECEIVING LOCATION** is selected, then: "Select the type of receiving location from the list below and list the location as a shipping address under the 340B ID that purchases the drugs."
   a. Select type of "other" receiving location:
      i. Warehouse
      ii. Loading dock
      iii. Re-packager
      iv. Central fill facility
      v. Centralized distribution center
      vi. Lab/facility that prepares drugs and ships them to a healthcare service delivery site
      vii. Other (please describe):

Federal Grant Number: _____

Notice of Funding Opportunity (NOFO) Number:_____

Nature of Support:

- ❒ Direct Funding (dollars received from CDC or an intermediate organization)
- ❒ "In-kind" products or services purchased with Section 318/317 funds
  - Please describe the "in-kind" support:_____
- ❒ None

Note: In-kind contributions may be 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.

Time period the 318/317 funding or in-kind support was received: From_____to_____

Please submit the following documentation:

(1) A copy of the Notice of Award from CDC that identifies the recipient (i.e., primary grantee), Federal award, and financial information, including the grant number and budget period; and
(2) For subrecipients (i.e., subgrantees), a copy of the executed written agreement (e.g., notice of subaward, or contract, MOU, MOA, etc.) with the recipient that includes the name and address of the recipient, subrecipient, subrecipient service delivery site, the grant and NOFO numbers, and the terms and conditions of support.

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

At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?
Yes ☐ No ☐

If the answer is yes, please provide the state(s) and associated billing number(s) listed on the claims to bill Medicaid fee-for-service for particular states that you plan to bill for 340B drugs in the space(s) below (this could include numbers for the state your hospital is located in and any out-of-state Medicaid agencies your hospital plans to bill for 340B drugs). All numbers you plan to use to bill Medicaid fee-for-service should be provided and may include the billing provider's national provider identifier (NPI) only, state assigned Medicaid number only, or both the NPI and state assigned Medicaid number. Do not list a state for which the covered entity will not bill Medicaid fee-for-service for drugs purchased at 340B prices.

HRSA exports the Medicaid billing information listed in this site's 340B OPAIS record to generate the quarterly Medicaid exclusion file (MEF). HRSA requires the information on the MEF be accurate and complete for every registered site in the

340B OPAIS, and that covered entities follow any additional state Medicaid requirements in order to prevent duplicate discounts.

While this site may request a change to its 340B OPAIS record at any time, the Medicaid fee-for service billing practice at this site, must match the quarterly MEF.

State	State Assigned Medicaid Number	NPI

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._____

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._____

Email Address: _____

IV. Signed Agreement:

The undersigned represents and confirms that he/she is fully authorized to legally bind the covered entity into a contract 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 OPAIS for the covered entity will be complete, accurate, and correct;
(2) the covered entity will meet all 340B Program eligibility requirements of Section 340B of the Public Health Service Act;
(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/rebates 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) 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
(6) 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.

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

_____
_____
_____
_____
_____

Signature of Authorizing Official: Date:

_____