

OFFICE OF PHARMACY AFFAIRS (OPA)
340B PROGRAM RECERTIFICATION FOR NON-HOSPITAL (other than Federally Qualified Health Center, HEALTH CENTER PROGRAM LOOK-ALIKES and STD/TB clinics) 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: _____

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): _____

Grant Number: _____

Time period the assistance was received (applicable to RW entities): From _____ to _____

II. Medicaid Billing Information:

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:

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327. Public reporting burden for this collection of information is estimated to average .25 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N136B, Rockville, Maryland, 20857.

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