OFFICE OF PHARMACY AFFAIRS (OPA)
340B PROGRAM RECERTIFICATION FOR RURAL REFERRAL CENTERS AND SOLE COMMUNITY HOSPITALS

A completed recertification package must include:
(1) The following recertification information and compliance certification, and the following documents if the hospital is alerted;
(2) A copy of Worksheet S that is signed and dated from the latest filed Medicare cost report;
(3) A copy of Worksheet E, Part A from the latest filed Medicare cost report (for the DSH adjustment percentage in II, A, below.);
(4) A copy of Worksheet S-2 to demonstrate ownership type, and depending upon the hospital type the additional documentation described in II, C, below.

I. Hospital Information:

Hospital Name: _____

Medicare Provider Number:_____

Employer Identification Number:_____

Hospital Street Address (PO Boxes are not allowed):_____

City:_____ State:_____ZIP:_____

Hospital Billing Address (if different): _____

City:_____ State:_____ZIP:_____

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

City:_____ State:_____ZIP:_____

II. Eligibility Criteria

Select One:

- ❒ Entity is a Rural Referral Center defined by section 1886(d)(5)(C)(i) of the Social Security Act, and this status is recognized by CMS.
- ❒ Entity is a Sole Community Hospital defined by section 1886(d)(5)(C)(iii) of the Social Security Act, and this status is recognized by CMS.

A. Disproportionate Share Adjustment Percentage:_____% based on
Medicare Cost Reporting Period: __ / __ / ____ – __ / __ / ____
Filing Date: __ / __ / ____

B. Type of Control (as filed on cost report Worksheet S-2, Line 21)

- ❒ 1 – Voluntary Nonprofit, Church
- ❒ 2 – Voluntary Nonprofit, Other
- ❒ 3 – Proprietary, Individual
- ❒ 8 – Governmental, City-County
- ❒ 9 – Governmental, County
- ❒ 10 – Governmental, State

- ❒ 4 – Proprietary, Corporation
- ❒ 5 – Proprietary, Partnership
- ❒ 6 – Proprietary, Other
- ❒ 7 – Government, Federal
- ❒ 11 – Governmental, Hospital District
- ❒ 12 – Governmental, City
- ❒ 13 – Governmental, Other

C. Hospital Classification

❒ Owned or Operated by State or Local Government
Official documentation must indicate that the hospital is owned or operated by a unit of State or Local government. More than one document may be necessary to demonstrate eligibility. Any documentation provided should clearly state the hospital's ownership, the date the ownership was established, and the name of the hospital. Please refer to the hospital registration instructions on the Office of Pharmacy Affairs website for a description of acceptable documentation.

❒ Private, Non-Profit Hospital with State/Local Government Contract
Hospitals must be able to demonstrate through official documentation that it is both private nonprofit and that it has a contract as set forth in the statute. Please refer to the hospital registration instructions on the Office of Pharmacy Affairs website for a description of acceptable documentation.

Contract start date: MM / DD / YYYY Contract end date: MM / DD / YYYY

❒ Check here if the entity's contract is valid until cancelled.

❒ A public corporation which is formally granted governmental powers by a unit of State or local government or Private Non-Profit Hospital Formally Granted Governmental Powers
Please submit the following documentation:

1. *Documents that clearly state the hospital's ownership, the date the ownership was established, and the name of the hospital. More than one document may be necessary to demonstrate eligibility;*
2. *Identity of the government entity granting the governmental powers;*
3. *A description of the governmental power that has been granted to the hospital and a brief explanation as to why the power is considered to be governmental; and*
4. *A copy of an official document issued by the government to the hospital that reflects the formal granting of governmental power.*

Please refer to the *hospital registration instructions on the* Office of Pharmacy Affairs website for a description of acceptable documentation.

❒ Ineligible for-profit institution – **for-profit institutions are ineligible for registration**

D. Government Official who can certify the hospital's classification

Name: _____Title:_____

Government Organization:_____

Phone: _____Ext.:_____

E-mail:_____

III. 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.

IV. 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, 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 the 340B Prime

Vendor Program at 1-888-340-2787 or via email at ApexusAnswers@340bpvp.com prior to submission of your registration.

Covered Entity Authorizing Official Name: _____

Title: _____

Phone: _____ Ext.:_____ Fax:_____

Email Address: _____

V. 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 and its outpatient facilities 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/rebates and diversion (section 340B(a)(5)(A) and (B) of the Public Health Service Act), and the exclusion of orphan drugs for critical access hospitals, free- standing cancer hospitals, sole community hospitals and rural referral centers.
(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.

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_____
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Signature of Authorizing Official: Date:

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