

**OFFICE OF PHARMACY AFFAIRS (OPA)
340B PROGRAM REGISTRATION FOR CRITICAL ACCESS HOSPITALS**

To meet the eligibility requirements for a critical access hospital to participate and be listed as an eligible covered entity under Section 340B(a)(4)(N) of the Public Health Service Act, this registration form must be completed and submitted according to the established deadlines that are published on the OPA website (www.hrsa.gov/opa).

A completed registration package must include:

- (1) Basic registration information and compliance certification form;
- (2) A copy of Worksheet S-2 to demonstrate ownership type, and depending upon type the additional documentation described in II, D, below).

All documentation described in 1-2 above constitutes a complete registration package. The entire package must be submitted on the same day to be considered complete. Incomplete packages will not be processed.

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

- Entity is a Critical Access Hospital defined by section 1820(c)(2) of the Social Security Act, and this status is recognized by CMS.

A. Medicare Cost Reporting Period: __ / __ / ____ – __ / __ / ____
Filing Date: __ / __ / ____

B. Has the provider changed ownership during or since the end of the above cost reporting period?

- Yes Effective date of ownership change: __ / __ / ____
 No

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

- | | |
|--|---|
| <input type="checkbox"/> 1 – Voluntary Nonprofit, Church | <input type="checkbox"/> 8 – Governmental, City-County |
| <input type="checkbox"/> 2 – Voluntary Nonprofit, Other | <input type="checkbox"/> 9 – Governmental, County |
| <input type="checkbox"/> 3 – Proprietary, Individual | <input type="checkbox"/> 10 – Governmental, State |
| <input type="checkbox"/> 4 – Proprietary, Corporation | <input type="checkbox"/> 11 – Governmental, Hospital District |
| <input type="checkbox"/> 5 – Proprietary, Partnership | <input type="checkbox"/> 12 – Governmental, City |
| <input type="checkbox"/> 6 – Proprietary, Other | <input type="checkbox"/> 13 – Governmental, Other |
| <input type="checkbox"/> 7 – Government, Federal | |

D. Hospital Classification

- Owned or Operated by State or Local Government
- Private, Non-Profit Hospital with State/Local Government Contract

Contract start date: __ / __ / ____

Contract end date: __ / __ / ____

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

Warning: The hospital must identify a government official that will be able to certify that the hospital organization is owned or operated by a unit of state or local government, or that the hospital organization has a valid contract to provide health care services to low income individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the State plan of Title XIX of the Social Security act, as appropriate.

The specified official will receive an e-mail from HRSA's Office of Pharmacy Affairs requesting this certification; he or she must respond with the next five calendar days. **If the government official does not confirm the hospital's status by the deadline, the registration will be deleted. It is the hospital's responsibility to ensure that the government official's email address is correct, and that he or she is available to respond within 5 calendar days.**

Name: _____ Title: _____

Government Organization: _____

Phone: _____ Ext.: _____

E-mail: _____

- Public or Private Non-Profit Hospital Formally Granted Governmental Powers, submit the following:

1. *The identity of the government entity granting the governmental power to the hospital;*
2. *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*
3. *A copy of an official document issued by the government to the hospital that reflects the formal granting of governmental power.*



III. 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.

IV. Orphan Drug Exclusion

340B hospitals subject to the orphan drug exclusion (i.e., critical access hospitals, sole community hospitals, and rural referral centers) are responsible for ensuring that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the Federal Food, Drug, and Cosmetic Act.

Please choose one of the following:

- The hospital will purchase orphan drugs under the 340B Program and maintain auditable records to demonstrate compliance with the orphan drug exclusion.
- The hospital cannot or does not wish to maintain auditable records regarding compliance with the orphan drug exclusion and will purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used. Only Cancer Hospitals cannot use a GPO to purchase orphan drugs.

V. 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: _____

VI. 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 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.

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 that may be helpful in reviewing this registration for 340B eligibility:

Signature of Authorizing Official:

Date:

Rockville, Maryland, 20857.