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) Worksheet S-2 to demonstrate ownership type (Proprietary hospitals must provide additional documentation to demonstrate non-profit status such as IRS documentation), and depending upon type the additional documentation described in II, B, below); and

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.

This information is collected during the online 340B registration process
FOR REFERENCE ONLY
http://opanet.hrsa.gov/opa/

I. Hospital Information:

Hospital Name: _____

Medicare Provider Number: _____

Employer Identification Number: _____

Hospital Street Address: _____

City: _____ State: _____ ZIP: _____

Hospital Billing Address (if different): _____

City: _____ State: _____ ZIP: _____

Hospital Shipping Address (if different): _____

City: _____ State: _____ ZIP: _____

II. Eligibility Criteria

Type of Hospital

a) If Owned or Operated by State or Local Government, check here ❒
(Submit supporting documentation to verify State/Local Government ownership or operation) Please refer to the Office of Pharmacy Affairs website for a description and examples of acceptable documentation.

b) If a Private, Non-Profit Hospital with State/Local Government Contract, check here ❒
(You must complete and attach State/Local Government Certification form (ftp://ftp.hrsa.gov/bphc/pdf/opa/DSHGovtCert.pdf) on the same day the registration form is submitted to the Office of Pharmacy Affairs.

c) If a Public or Private Non-Profit Hospital Formally Granted Governmental Powers, check here ❒ and 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: *You **must** answer the following question regarding Medicaid billing.*

Will your entity bill Medicaid for drugs purchased at 340B drug prices?
Yes ❒ No ❒

If "Yes," please provide the Pharmacy/Clinic Medicaid Provider Number(s) and/or National Provider Identifier(s) (NPI) used to bill Medicaid for 340B drugs (*please include the number(s) and State*):

Medicaid Provider Number(s) _____ and/or_____

National Provider Identifier(s) _____and/or_____

If your entity bills Medicaid for 340B drugs that may be subject to a payment of a Medicaid rebate to a state, you must submit to OPA the pharmacy/clinic Medicaid number and/or NPI which is used to bill Medicaid for outpatient drugs. If you are unsure of your Medicaid billing number and/or NPI, please check with your State Medicaid agency. It is important that your Medicaid billing status is accurate in the 340B database Medicaid Exclusion File to prevent Medicaid rebates on drugs that were purchased under the 340B Drug Pricing Program and to ensure that the state Medicaid Agency has accurate information for those drugs not purchased under the 340B Program. You must notify OPA prior to any change in your Medicaid billing status.

For more information, go to: http://www.hrsa.gov/opa/medicaidexclusion.htm

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.

V. 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: _____

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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 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, the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity, 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 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 hospital 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:

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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 2.0 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 10-29, Rockville, Maryland, 20857.