

OFFICE OF PHARMACY AFFAIRS (OPA)
340B PROGRAM REGISTRATION FOR CHILDREN'S HOSPITALS AND FREE STANDING
CANCER HOSPITALS

To meet the eligibility requirements for a children's hospital or free standing cancer hospital to participate and be listed as an eligible covered entity under Section 340B(a)(4)(M) 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) This basic registration information and compliance certification;
- (2) A copy of Worksheet E, Part A from the latest filed Medicare cost report (for the DSH adjustment percentage in II, A, below). Children's Hospitals that do not have a Worksheet E, Part A can provide Worksheet S-3 instead. Children's Hospitals that do not file a Medicare Cost report must provide a statement from a qualified independent auditor (see 74 Fed. Reg. 45206 (Sept. 9, 2009) at 45210 <http://edocket.access.gpo.gov/2009/pdf/E9-21109.pdf>);
- (3) A copy of Worksheet S-2 to demonstrate ownership type, and depending upon type the additional documentation described in II, B, below); and
- (4) Certification of non-participation in a Group Purchasing Organization.

All documentation described in 1-4 above is required to constitute 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: _____

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

A. Disproportionate Share Adjustment Percentage: _____% based on
Medicare Cost Reporting Period: ___/___ - ___/___

B. 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](http://ftp.hrsa.gov/bphc/pdf/opa/DSHGovtCert.pdf)) on the same day the registration form is submitted to the Office

of Pharmacy Affairs. Please refer to the Office of Pharmacy Affairs website for a description and examples of acceptable documentation.

c) If a Public or Private Non-Profit Hospital Formally Granted Governmental Powers, check here
(Submit supporting documentation to verify formal delegation of power to hospital by State/Local Government)
Please refer to the Office of Pharmacy Affairs website for a description and examples of acceptable documentation.

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

Will your entity bill Medicaid for drugs purchased through the 340B Drug Pricing Program?

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. 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: _____

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 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, including section 340B(a)(4)(L)(iii) – the Group Purchasing Organization prohibition - which ensures that the covered entity hospital does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement;
- (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, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity;
- (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:
