

OFFICE OF PHARMACY AFFAIRS (OPA)
340B REGISTRATION FORM FOR OUTPATIENT FACILITIES USING MEDICARE COST REPORT

I. Hospital Information:

Hospital (Main Provider) Name: _____

Hospital (Main Provider) Medicare Provider Number: _____

Hospital (Main Provider) Employer Identification Number: _____

Hospital (Main Provider) Street Address: _____

II. Hospital Outpatient Facilities Information:

Please complete Section IV and list outpatient facilities and all requested information. List only those outpatient facilities that will participate in the 340B Drug Pricing Program. This registration form and supporting documentation must be completed and submitted according to the established deadlines that are published on the OPA website (www.hrsa.gov/opa). The registration process is not complete unless the registration form has been completed in its entirety (all requested information is filled in on the form) and all required supporting documentation is submitted on the same day to OPA. **Incomplete packages will not be processed.**

Indicate the following regarding the list from Section IV of outpatient facilities:

Attached is a copy of Worksheets A and C from the latest filed Medicare Cost Report Documentation to track or break down outpatient facility clinic costs associated with reimbursable cost centers listed on Worksheets A and C

Yes No
 Yes No

III. Authorized Signature:

I acknowledge that I am familiar with the Center for Medicare & Medicaid Services' guidelines concerning Medicare certification of hospital components as one cost center and HRSA's final guidelines for hospital outpatient facilities (59 Fed. Reg. 47884 (Sept. 19, 1994)). Pursuant to those guidelines, I request that the attached list of qualifying outpatient facilities be added to the database of 340B covered entities. I have examined the list and certify that each outpatient facility is reimbursable on the covered entity's most recently filed Medicare cost report and is an integral part of the aforementioned hospital under the Medicare provider number listed above. I further acknowledge that the main provider hospital is in compliance with 340B published guidelines and regulations.

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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 burden is estimated to average 0.5 hours per respondent, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, 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 14-33, Rockville, Maryland 20857.

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, including section 340B(a)(4)(L)(iii) when applicable – 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

Name & Title of Authorizing Official and Title

Phone

Email

(please print or type)(e.g.CEO,CFO,COO)

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IV. List of Outpatient Facilities:

NAME OF FACILITY & FACILITY'S MEDICARE PROVIDER NUMBER/NPI (If Applicable)	STREET ADDRESS BILLING ADDRESS (if different) SHIPPING ADDRESS (if different)	340B CONTACT (Name, Title, Phone Number, Email Address)	If facility bills Medicaid for 340B drugs subject to a rebate, then you must submit all such MEDICAID PROVIDER NUMBER(S)

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