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

A complete registration package must include the information noted in sections I-VI below. In addition, the hospital may be required to provide additional supporting documentation including:

1. A copy of the signed, dated, and electronically encrypted Worksheet S from the latest filed Medicare cost report. ~~Worksheet S that includes a digital encrypted signature stamp*;~~
2. A copy of Worksheet A, Worksheet C, Worksheet S-2 and Worksheet E Part A from the latest filed Medicare cost report (for the DSH adjustment percentage in II, A, below).
3. The associated trial balance. A trial balance that clearly highlights the Cost and Revenue for each child site being registered. Cost and Revenue must be unique values for every child site.

* The date and time prepared listed in the upper right corner of all worksheets must match the date and time of the digital encrypted signature stamp.

The entire registration package must be submitted on the same day to be considered complete. A registration that is submitted without any of the required documentation will be rejected.

I. HospitalInformation:

Hospital (Main Provider) Name:_____

Hospital (Main Provider) ~~Medicare Provider Number~~CMS Certification Number (CCN): _____

Hospital (Main Provider) Employer Identification Number: _____

Hospital (Main Provider) Street Address: _____

II. Hospital Outpatient Facility Information:

Please complete the following section and include all requested information. 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 outpatient facility to be registered:

Name of Facility: _____

Outpatient Employer Identification Number (if different from parent): _____

Facility CMS Certification Number (CCN)~~Medicare Provider Number~~ (if different): _____

Facility Street Address (P.O Boxes are not allowed): _____

Facility Billing Address (if different): _____

Facility Shipping Address (PO Boxes are not allowed):_____

City:_____ State:_____ZIP:_____

Is the requested shipping address location a **pharmacy** (a pharmacy prepares and dispenses drugs to patients); a **healthcare service delivery site** (a healthcare service delivery site administers/dispenses drugs to patients as part of medical encounters); or an **"other" receiving location** (an "other" receiving location does NOT administer/dispense drugs directly to patients (e.g., warehouse, loading dock, re-packager, compounding center, central fill facility, centralized distribution center, or lab/facility that prepares and ships drugs to a healthcare service delivery site))?

1) If **PHARMACY** is selected, then "Is the pharmacy owned by the covered entity (documentation to demonstrate entity ownership may include a pharmacy license and listing of the pharmacy on the covered entity's grant or Medicare Cost Report)?"
    a. If "No" is selected, then: "The pharmacy must be registered as a contract pharmacy."
    b. If "Yes" is selected, then: "List the pharmacy as a shipping address under the 340B ID that purchases the drugs."

2) If **HEALTH CARE SERVICE DELIVERY SITE** is selected, then "Is the health care service delivery site registered in OPAIS"?
    a. If "No" is selected, then: "An unregistered healthcare service delivery site may NOT be listed as a shipping address."
    b. If "Yes" is selected for any hospital or CH/FQHCLA grantee, then: "List the parent hospital, hospital child site, or grant associated site as a shipping address under the 340B ID that purchases the drugs."
    c. If "Yes" is selected for any non-CH/FQHCLA grantee, then: "Is the healthcare delivery site listed as a receiver in an OPA- approved Central Purchasing Distribution Model (CPDM)?"
        i. If "Yes" is selected, then: "List the healthcare delivery site as a shipping address under the 340B ID that purchases the drugs."
        ii. If "No" is selected, then: "The healthcare delivery site must be listed as a receiver in an OPA-approved CPDM before it can be listed as a shipping address."

3) If **"OTHER' RECEIVING LOCATION** is selected, then: "Select the type of receiving location from the list below and list the location as a shipping address under the 340B ID that purchases the drugs."
    a. Select type of "other" receiving location:
        i. Warehouse
        ii. Loading dock
        iii. Re-packager
        iv. Central fill facility
        v. Centralized distribution center
        vi. Lab/facility that prepares drugs and ships them to a healthcare service delivery site
        vii. Other (please describe):

III. Cost Center Information:

Hospitals registering outpatient facilities must identify one or more specific cost center lines that the facility being registered falls under on the organization's most recently filed Medicare cost report. In the following fields, enter the Net Expenses for Allocation for the entire line (Worksheet A, Column 7) followed by the total outpatient charges for the entire line (Worksheet C, Column 7).

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Enter expenses associated with specific clinic, service or facility being registered. The hospital must identify one or more specific cost center line for each outpatient facility that is being registered. When there is more than one clinic, service or facility rolled up to a single cost center (e.g., Line 90/Clinic) these figures will come from the corresponding trial balance. When a cost center/line only reflects a single outpatient clinic, service or facility, the expense figures will come directly from Worksheet A, Column 7 and the outpatient charges will come from Worksheet C, Column 7. These figures will be the same as those provided for the entire line -- e.g., Line 90.xx subscripts). Enter the specific cost and the specific outpatient revenue associated with the specific clinic or service being registered. These numbers are also taken from the trial balance.

Line Number/Description	Net Expenses (Worksheet A)	Outpatient Charges (Worksheet C)	Specific Service/Clinic Cost (Trial Balance)	Specific Service/Clinic Outpatient Revenue (Trial Balance)

IV. 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.

V. Statutory Prohibition on Group Purchasing Organization Participation:

Section 340B(a)(4)(L)(iii) of the Public Health Service Act, which is reiterated in the Statutory Prohibition on Group Purchasing Organization Participation Policy Release (2013-1), requires that the hospital not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. **This is a requirement for Disproportionate Share Hospitals, Children's Hospitals, and Free Standing Cancer Hospitals**.

The authorizing official must certify that this hospital will not participate in a group purchasing organization or group purchasing arrangement for covered outpatient drugs as of the date of this listing on the 340B OPAIS. If drugs are purchased using a GPO for covered outpatient drugs while participating in the 340B Program, the covered entity understands that this violates program eligibility requirements and that the covered entity is obligated to inform OPA and may be required to repay manufacturers for the 340B discount received.

☐ Yes, I confirm

☐ Not applicable

VI. Signed Agreement:

I acknowledge that I am familiar with the most recent Centers for Medicare & Medicaid Services' guidelines concerning Medicare certification of hospital components as one cost center and HRSA's guidelines for hospital outpatient facilities. Pursuant to those guidelines, I request that the attached list of qualifying outpatient facilities be added to the 340B OPAIS 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.

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 340B OPAIS 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) of the Public Health Service Act when applicable, regarding the group purchasing organization prohibition - which states 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 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);

(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) 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
(6) 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

Name & Title of Authorizing Official and Title (*please print or type)(e.g.CEO,CFO,COO)* Phone Email