OFFICE OF PHARMACY AFFAIRS (OPA)
340B PROGRAM RECERTIFICATION FOR FREE STANDING CANCER HOSPITALS

A complete recertification 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 signed, dated, and electronically encrypted Worksheet S from the latest filed Medicare cost report;
(2) A copy of Worksheet E, Part A from the latest filed Medicare cost report (for the DSH adjustment percentage in II, A, below.);
(3) A copy of Worksheet S-2 to demonstrate ownership type, and depending upon the hospital type the additional documentation described in II, C, below).

* 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.

I. Hospital Information:

Hospital Name:

1) Has there been a change in the CMS Certification Number (CCN)?
   a) If "Yes", "You have indicated that the CCN has changed. The hospital must terminate from the 340B program and submit a new registration using the new CCN."
   b) If "No" following question:
2) Has there been a change in the hospital's classification?
   a) If "Yes", "The hospital must provide documentation to support the change as specified on the 340B Drug Pricing Program – Registration webpage."

CMS Certification Number (CCN):_____

Employer Identification Number:_____

Hospital Street Address (PO Boxes are not allowed):_____

City: _ State: ZIP: _

If address is changing:

1. Is the service remaining open at the old address?

   Yes ❒ No ❒

Hospital Billing Address (if different): _____

City:_____ State:_____ZIP:_____

Hospital Shipping Address (if different; 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

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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):

II. Eligibility Criteria

☐ **Entity is a Free Standing Cancer Hospital defined by section 1886(d)(1)(B)(v) of the Social Security Act, and this status is recognized by CMS.**

A. Disproportionate Share Adjustment Percentage:_____% based on
Medicare Cost Reporting Period: __ / __ / ____ – __ / __ / ____
Date/Time Prepared: __ / __ / ____

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

- ❒ 1 – Voluntary Nonprofit, Church
- ❒ 2 – Voluntary Nonprofit, Other
- ❒ 3 – Proprietary, Individual
- ❒ 4 – Proprietary, Corporation
- ❒ 5 – Proprietary, Partnership
- ❒ 6 – Proprietary, Other
- ❒ 7 – Government, Federal
- ❒ 8 – Governmental, City-County
- ❒ 9 – Governmental, County
- ❒ 10 – Governmental, State
- ❒ 11 – Governmental, Hospital District
- ❒ 12 – Governmental, City
- ❒ 13 – Governmental, Other

C. Hospital Classification

❒ Owned or Operated by State or Local Government
Official documentation must indicate that the hospital is owned or operated by a unit of State or Local government. More than one document may be necessary to demonstrate eligibility. Any documentation provided

should clearly state the hospital's ownership, the date the ownership was established, and the name of the hospital. Please refer to the hospital registration instructions on the Office of Pharmacy Affairs website for a description of acceptable documentation.

❒ Private, Non-Profit Hospital with State/Local Government Contract
Hospitals must be able to demonstrate through official documentation that it is both private nonprofit and that it has a contract as set forth in the statute. Please refer to the hospital registration instructions on the Office of Pharmacy Affairs website for a description of acceptable documentation.

Contract start date: MM / DD / YYYY Contract end date: MM / DD / YYYY

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

❒ A public corporation which is formally granted governmental powers by a unit of State or local government or Private Non-Profit Hospital Formally Granted Governmental Powers
Please submit the following documentation:

1. *Documents that clearly state the hospital's ownership, the date the ownership was established, and the name of the hospital. More than one document may be necessary to demonstrate eligibility;*
2. *Identity of the government entity granting the governmental powers;*
3. *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*
4. *A copy of an official document issued by the government to the hospital that reflects the formal granting of governmental power.*

Please refer to the *hospital registration instructions on the* Office of Pharmacy Affairs website for a description of acceptable documentation.

❒ Ineligible for-profit institution – **for-profit institutions are ineligible for registration**

III. 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

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. 340B **Primary** Contact and Authorizing Official Information

Covered Entity Primary Contact Name
(Must be someone employed by the Covered Entity): _____

Title: _____

Phone: _____ Ext.: _____

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.: _____

Email Address: _____

VI. Signed Agreement:

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 that:

(1) all information listed on the 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), 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) the covered entity acknowledges its responsibility to contact OPA as soon as reasonably 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.

Please provide any additional information that may be helpful in reviewing this registration for 340B eligibility:
_____
_____
_____
_____

Signature of Authorizing Official: Date:

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 .25 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 14N136B, Rockville, Maryland, 20857.