OFFICE OF PHARMACY AFFAIRS (OPA)
340B PROGRAM COVERED ENTITY CHANGE REQUEST FORM

Note: The Authorizing Official represents the covered entity and must be fully authorized to legally bind the covered entity. The Authorizing Official is usually the CEO/CFO/COO/President/Vice President or equivalent.

I. Covered Entity Details

Entity Name:

Hospitals:

1) Has there been a change in the ~~Medicare Provider Number (MPN)?~~CMS Certification Number (CCN)?
   a) If "Yes", "You have indicated that the ~~MPN~~ CCN has changed. The hospital must terminate from the 340B program and submit a new registration using the new CCN~~MPN.~~"
   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."
   a)

Entity Sub-Division Name:_____

Employer Identification Number (EIN): (Enter the registrant's EIN if a sub-grantee/sub-recipient)

As assigned by the IRS

_____

Grant Number:

For Urban Indian (UI) and FQHC638 add field:
Tribal Agreement #:
Select: Title I or Title V

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Site ID: _____

Nature Of Support (for STD/TB only)

- ❒ Direct Funding (dollars received from CDC or an intermediate organization)
- ❒ In-Kind products or services (see note below; must have been purchased with section 318 funds)
- ❒ None

Time period section 318 funding or in-kind support was received

From Date To Date

- ❒ Valid until no longer receiving

Note: In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the

project or program.

Time period the assistance was received (applicable to RW-, FP entities): From _____ to _____

Please submit the following documentation:

(1) A copy of the Notice of Award from CDC that identifies the recipient (i.e., primary grantee), Federal award, and financial information, including the grant number and budget period; and

(2) For subrecipients (i.e., subgrantees), a copy of the executed written agreement (e.g., notice of subaward, or contract, MOU, MOA, etc.) with the recipient that includes the name and address of the recipient, subrecipient, subrecipient service delivery site, the grant and NOFO numbers, and the terms and conditions of support.

Street Address

Address Line 1: _____

Address Line 2 (Optional):_____Suite (Optional): _____

City:_____ State:_____ Zip:_____

If address is changing:

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

   Yes ❒ No ❒

2. Will this entity continue to receive federal funding that makes them eligible for the 340B Program? (for all grantees except Federally Qualified Health Centers and Health Center Program Look-Alikes)

   Yes ❒ No ❒

**PO Boxes Not Allowed

Billing Address

❒ Billing Address is same as Street Address
Address Line 1: _____

Address Line 2 (Optional):_____Suite (Optional): _____

City:_____ State:_____ Zip:_____

Shipping Addresses

❒ Shipping Address is same as Street Address
Address Line 1: _____

Address Line 2 (Optional):_____Suite (Optional): _____

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):

II. Contact Information

Authorizing Official

Email: _____ Name: _____

Title: _____

Organization: _____

Phone: _____ Ext.:_____

E-mail: _____

Primary Contact

Email: _____ Name: _____

Title: _____

Organization: _____

Phone: _____ Ext.:_____

E-mail: _____

~~II.~~III. Eligibility Criteria (Hospitals Only)

❒ **Entity is a Disproportionate Share Hospital defined by section 1886(d)(1)(B) of the Social Security Act, and this status is recognized by CMS.**

Select One:

❒ Entity is a Rural Referral Center defined by section 1886(d)(5)(C)(i) of the Social Security Act, and this status is recognized by CMS.

- Is this facility classified as a referral center (Worksheet S-2, Line 116)
  - Y
  - N
    - If No: "Please attach CMS Rural Referral Center (RRC) approval letter."

❒ Entity is a Sole Community Hospital defined by section 1886(d)(5)(C)(iii) of the Social Security Act, and this status is recognized by CMS.

- If this is a sole community hospital (SCH), enter the number of periods SCH status in effect in the cost reporting period (Worksheet S-2, Line 35)
  - [Enter number]
    - If "0": "Please attach CMS Sole Community Hospital (SCH) approval letter"

A. Disproportionate Share Adjustment Percentage:_____% based on
Medicare Cost Reporting Period: MM / DD / YYYY – MM / DD / YYYY
~~Filing Date:~~ Date/Time Prepared: MM / DD / YYYY

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

❒ 0 – Undetermined
❒ 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.~~IV. Medicaid Billing Information

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	Medicaid Number	NPI

Authorizing Official Signature

By signing, I represent and confirm that I am fully authorized to bind the covered entity and certify that the contents of any statement made or reflected in this document are truthful and accurate. The covered entity will comply with all of the requirements and restrictions of section 340B of the Public Health Service Act, including, but not limited to, the prohibitions on duplicate discounts and drug diversion.

Submission Comment

Please provide any additional information that may be helpful in reviewing this change request:

❒ By checking this box, I confirm that I have read the above statements and fully understand my obligations.