

**Covered Entity Details**

|                                  |  |
|----------------------------------|--|
| <b>340B ID:</b>                  | <b>Entity Type:</b>                    |
| <b>Entity Name:</b>              | <b>Employer Identification Number:</b> |
| <b>Entity Sub-Division Name:</b> | <b>Grant Number:</b>                   |
| <b>Medicare Provider Number:</b> |  |

**Covered Entity Address**

Street Address (PO Box Not Allowed)

[Continue](#) [Undo](#)

\*Address Line 1:

Address Line 2:

\*City:

\*State:

\*Zip:  -

Billing Address Same as Street Address

Billing Address

[Continue](#) [Undo](#)

\*Organization Name:

\*Address Line 1:

Address Line 2:

\*City:

\*State:

\*Zip:  -

Shipping Address Same as Street Address

Shipping Address (PO Box Not Allowed)

[Add](#)

**Covered Entity Date Information**

|                                     |  |
|-------------------------------------|--|
| <b>Registration Date:</b>           | <b>Participating Start Date:</b>   |
| <b>Participating Approval Date:</b> | <b>Termination Reason:</b>   |
|                                     | <b>Termination Date:</b>   |
|                                     | <b>The date the entity became ineligible:</b>                                  |
|                                     | <b>Last date that 340B drugs were or will be purchased under this 340B ID:</b> |
| <b>Termination Comments:</b>        |  |

**Qualification Information**

Qualifying information for outpatient facilities (child sites) will be automatically carried over from the main hospital record; please email us at **340B.recertification@hrsa.gov** if you need to report an independent DSH adjustment percentage, cost reporting period or ownership classification for a particular site. Organizations with DSH percentages below applicable thresholds must decertify the parent hospital and ALL associated outpatient facilities.

**Entity is a Critical Access Hospital defined by section 1820(c)(2) of the Social Security Act, and this status is recognized by CMS.**

**Hospital Classification:**

**Medicaid Billing**

**Medicaid Billing Information**

**You must answer the following question regarding Medicaid Billing:**

Will you bill Medicaid for drugs purchased at 340B drug price?  Yes  No

**Orphan Drug Exclusion**

340B hospitals subject to the orphan drug exclusion (i.e., critical access hospitals, free-standing cancer hospitals, sole community hospitals and rural referral centers) are responsible for ensuring that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the Federal Food, Drug, and Cosmetic Act. Please choose one of the following:

- The hospital will purchase orphan drugs under the 340B Program and maintain auditable records to demonstrate compliance with the orphan drug exclusion.
- The hospital cannot or does not wish to maintain auditable records regarding compliance with the orphan drugs exclusion and will purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used and will not use a Group Purchasing Organization (GPO) to purchase those drugs if the hospital is a free-standing cancer hospital.

Note: Any change to your selection will be effective on the first day of the quarter following approval by OPA.

**Contact Information**

**Authorizing Official**

**Name:**  
**Title:**  
**Phone:**    **Ext:**  
**Email:**

Make Primary Contact Information same as Authorizing Official

**Primary Contact**

**Name:**  
**Title:**  
**Phone:**    **Ext:**  
**Email:**

**Black Lung Clinics Program Grantee/ Program Manager  
Batch Certification 2015**

**NOTE: Recertification is not complete until you check the certification statement below and click the "Attest and Recertify" button.**

**Covered Entities**

The number of rows returned: 1

Rows/Page: 200

| 340B ID | Batch Name | Entity Name | Subdivision Name | Address | City | State | Zip | Status |
|---------|------------|-------------|------------------|---------|------|-------|-----|--------|
| 1       |            |             |                  |         |      |       |     |        |

**Program Manager/Authorizing Official**

**Name:**  
**Title:**  
**Phone:**      **Ext:**  
**Email:**

**Authorized Signature**

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. Failure to recertify may be grounds for removal from the 340B Program.

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 meets all 340B Program eligibility requirements;
- (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 maintains 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) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement will be performed in accordance with OPA requirements and guidelines;
- (6) 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
- (7) 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.