



Office of Pharmacy Affairs
340B Database

OPA Database Guide For Public Users – Recertification

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Covered Entities Guide for Public Users

Recertifying a Covered Entity

The Office of Pharmacy Affairs (OPA) is required to recertify all participating 340B covered entities annually to ensure 340B database accuracy and promote compliance with 340B program requirements.

Authorizing Official Advance Notification

The Authorizing Official (AO) and Primary Contact (PC) receive the advanced notification email from HRSA OPA about recertification of their covered entity and the recertification period to include a start and end date. The advanced notification email notifies the AO and PC of the forthcoming requirement. User Name and Password will be distributed separately solely to the listed AO on the official recertification start date. The user name is also the batch name.

The user name and password email contain the following:

- A link to the 340B database
- Login instructions
- Instructions for completing the online recertification process (recertification user guide)
- Date the recertification is to be completed.

Note: An AO who has more than one parent covered entity will receive more than one recertification notification, each with a different user name and password. A parent hospital with associated outpatient facilities will only receive one user name and password for all covered entities/child sites.

The parent entity must be recertified first. For hospitals, the **Qualification Information** tab (QI) will auto populate all child sites after the parent has recertified.

Once AO has completed the recertification, the user name and password used to log in for an entity will no longer be active.

For batches with multiple covered entities, repeat the following steps for each entity. You must log out after each session before logging in to recertifying another entity (if you received log in information for other batches).

Logging into Recertification

When you receive the log-in recertification email from OPA, follow these login instructions:

Dear 340B Covered Entity Authorizing Official,

In order to ensure continued eligibility to participate in the 340B Program, you must electronically review and recertify the information on file in the 340B Program database for your covered entities. Please complete recertification by 11/6/2015.

It is extremely important that the 340B Program has accurate information on participating entities. Pharmaceutical manufacturers and distributors increasingly enforce the requirement for exact matches of information prior to providing access to 340B pricing. In addition, entities that lose qualifying funding or that are no longer utilizing the 340B Program must be terminated from the program (through decertification during the recertification process, or through communication with the Office of Pharmacy Affairs at any other time during the year) to ensure program integrity.

The username, password and link to your covered entity records shown below will provide you with access to your entities' data as it currently exists in the 340B Program database. Please log into the database to review, revise (if necessary) and certify entities and their associated contract pharmacies that are still participating in the 340B Program. Decertify any entities that are no longer participating in the 340B Program. After all of your entities have been reviewed, you will electronically sign and submit your certified entities and/or decertified entities.

Please note that any changes made to your entity details must be reviewed and approved by HRSA. You will receive the '340B Recertification Complete' e-mail at that time and may verify the changes through the 340B database's public search function.

Site: https://ft-reg-web01.futrend.com/OPA2014/RecertBatchDashboard.aspx?BATCH_ID=86483

Username: 010087

Password: Kd6Sz@C1

Note: Requesting that your login information be re-sent will result in assignment of a new, temporary password.

- 1) Click the URL link in the email.
- 2) When the **Welcome to OPA** login page displays, copy the user name and password from email and paste them into the user name and password fields on the login page, ensuring that there are no spaces before or after the user name or password.

HRSA Office of Pharmacy Affairs
340B Database

Home Search Register Change Request Reports/Files

Welcome to OPA

User Name: 010087

Password: ●●●●●●●●

Sign In Clear

[Forgot User ID?/Forgot Password?](#)

HRSA system users are required to comply with HRSA information technology (IT) security policies regarding the protection of HRSA information systems from misuse, abuse, loss, or unauthorized access or modification. By logging on to this system you certify that you have read, understand and agree to comply with the [Office of Pharmacy Affairs System Rules of Behavior](#).

- 3) Click the button. When the U.S. government warning pop-up window displays, click **OK**.

- 4) The **340B Database – Password Change** page requires changing your temporary password.

Change Password

Enter old password:

Enter new password:

Enter new password again:

Rules for a new password:

- Have a minimum of 8 characters
- Have at least one each of the following four character types:
 - Uppercase letters
 - Lowercase letters
 - Numbers
 - Special characters (or space): ! @ # \$ % ^ & + =

Example: Sue#Smith1

- 5) Enter a new password twice that meets the password requirements listed on the page.
- 6) Click the button.

After the password is successfully changed, an email acknowledgement is sent to the AO that the password has been updated. The log on credentials will be valid until the entity is recertified by the AO.

Recertification Batch Dashboard

The **Batch Dashboard** page displays the covered entity that will be recertified. The number of the batch you are logged into is displayed at the right side of the header bar.

[Recertification Dashboard](#) > [Initiative Dashboard](#) > [Batch Dashboard](#)

<p>Recertification Initiative Name: SCH-MLEs Batch</p> <p>Batch Name: 010061</p> <p>Start Date: 12/14/2015</p> <p>Certification Due Date: 12/16/2015</p> <p>PM/AO Name: KIM BRYANT</p> <p>PM/AO Email: ENTITY-AuthorizingOfficialEmail@futrend.com</p>	<p>Entity Type: Sole Community Hospital</p> <p>End Date: 12/16/2015</p> <p>PM/AO Phone: 256-218-3789</p>
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Covered Entities

The number of rows returned: 1 Rows/Page: 200

340B ID	Batch Name	Entity Name	Subdivision Name	Address	City	State	Zip	Status
SCH010061-00	010061	HIGHLANDS MEDICAL CENTER		380 WOODS COVE ROAD	SCOTTSBORO	AL	35788	Incomplete

1

Note: Entities will be batched according to their parent/child relationships. Entities that do not have a parent/child relationship will be batched separately (one entity per batch).

- 1) Click the parent entity's **340B ID** link.

Covered Entity Details

- 2) The **Covered Entity Details** section displays read-only data from the entity's 340B database record.

Note: The **Nature of Support** funding check boxes only appear for TB and STD entities.

Covered Entity Details [Edit](#)

340B ID: TB01199

Entity Name: BAYSTATE MEDICAL CENTER
Entity Sub-Division Name: HIGH STREET HEALTH CENTER, WESSON MEMORIAL HOSPITAL UNIT
Medicare Provider Number:

Entity Type: Tuberculosis
Employer Identification Number:
Grant Number: TB-MA

Nature of Support:

- Direct Funding (dollars received from CDC or an intermediate organization)
- In-Kind products or services (see note below; must have been purchased with section 317 funds)
- None

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.

To modify data in this section, click the [Edit](#) link. The **Sub-Division Name**, **EIN**, and **Grant Number** (and **Nature of Support** checkboxes for TB and STD entities) become editable. When finished, click [Continue](#) to save your changes or [Undo](#) to cancel them.

Covered Entity Details [Continue](#) [Undo](#)

***340B ID:** TB01199

***Entity Name:** BAYSTATE MEDICAL CENTER

Entity Sub-Division Name:

Entity Type:

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

Grant Number: (if known/applicable)

Medicare Provider Number: (only required for hospital entity types)

*** Nature of Support:**

- Direct Funding (dollars received from CDC or an intermediate organization)
- In-Kind products or services (see note below; must have been purchased with section 317 funds)
- None

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.

Covered Entity Address

- 3) The **Covered Entity Address** section displays data from the entity's 340B database record.

Covered Entity Address [Edit](#)

Street Address (PO Box Not Allowed)

140 HIGH STREET
SPRINGFIELD, MA 01105

Billing Address Same as Street Address

Billing Address

MDPH / TB CONTROL
STATE LAB
305 SOUTH STREET
JAMAICA PLAIN, MA 02130

Shipping Address Same as Street Address

Shipping Address (PO Box Not Allowed)

Shipping Address 1

BAYSTATE MEDICAL CENTER
140 HIGH STREET
SPRINGFIELD, MA 01105

To modify data in this section, click the [Edit](#) link. All address fields become editable.

Covered Entity Address [Continue](#) [Undo](#)

Street Address (PO Box Not Allowed)

*Address Line 1:

Address Line 2:

*City:

*State:

*Zip: -

Billing Address Same as Street Address [Continue](#) [Undo](#)

Billing Address

*Organization Name:

*Address Line 1:

Address Line 2:

*City:

*State:

*Zip: -

Shipping Address Same as Street Address

Shipping Address (PO Box Not Allowed) [Add](#)

New Shipping Address [Continue](#) [Undo](#)

*Organization Name:

*Address Line 1:

Address Line 2:

*City:

*State:

*Zip: -

Shipping Address 1 [Edit](#) [Delete](#)

BAYSTATE MEDICAL CENTER
140 HIGH STREET
SPRINGFIELD, MA 01105

- If the **Billing Address Same as Street Address** box is unchecked, the billing address fields allow you to edit the existing billing address or add a new one.
- If the **Shipping Address Same as Street Address** box is unchecked, an **Add** link appears to allow you to add one or more shipping addresses or edit or delete an existing shipping address. All address changes will be reviewed by OPA for consistency with shipping address requirements. **No PO boxes** can be listed except for billing addresses.

When changes to an address are complete, click **Continue** to save them or **Undo** to cancel them.

Covered Entity Date Information

- 4) The **Covered Entity Date Information** section allows you to terminate an entity or edit the termination reason, dates, and comments.

Covered Entity Date Information [Edit](#)

<p>Registration Date: 7/1/2003</p> <p>Participating Approval Date: 11/18/2004</p> <p>Termination Comments:</p>	<p>Participating Start Date: 7/1/2003</p> <p>Termination Reason:</p> <p>Termination Date:</p> <p>The date the entity became ineligible:</p> <p>Last date that 340B drugs were or will be purchased under this 340B ID:</p>
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To modify data in this section, click the **Edit** link. The termination fields become editable.

Covered Entity Date Information [Continue](#) [Undo](#)

Registration Date:	7/1/2003	
<input type="checkbox"/> Participating Approval Date	11/18/2004	
Participating Start Date:	7/1/2003	
Termination Reason:	site closure	
	<i>If none of these reasons apply, stop here and e-mail 340b.recertification@hrsa.gov for additional guidance.</i>	
Termination Date:	4/1/2015	
* The date the entity became ineligible:		
* Last date that 340B drugs were or will be purchased under this 340B ID:		
Termination Comments:	<p>Please provide a brief description of the facts surrounding the reason for termination and how the effective date was determined. This information, including relevant dates, may be made available to manufacturers and the public. If 340B drugs were purchased after losing eligibility, HRSA urges working with affected manufacturers regarding possible repayment.</p> <div style="border: 1px solid gray; height: 30px; width: 100%;"></div>	

- **Termination Reason:** Select the reason from the drop-down list.

Covered Entity Date Information Continue Undo

Registration Date: 4/2/2013

Participating Approval Date: 5/14/2013

Participating Start Date: 7/1/2013

Termination Reason: Select a Termination Reason

Termination Date:

The date the entity became ineligible:

-mail 340b.recertification@hrsa.gov for additional

- **Termination Date** – Automatically populated as the first day of the following quarter when a Termination Reason is selected (not editable).
- **Date Entity Became Ineligible:** Enter the date when the entity became ineligible for participation in the 340B Program.
- **Last Date Drugs Were/Will Be Purchased:** Enter the last date when drugs were or will be purchased under the entity’s 340B ID.
- **Termination Comments:** Enter any additional comments about the termination.

When changes are completed, click **Continue** to save them or **Undo** to cancel them.

Qualification Information (Hospitals Only)

The **Qualification Information (QI)** section only applies to hospitals. It contains required fields that must be completed before continuing with recertification. The fields that display in this section vary depending on the entity’s hospital type:

- Children’s Hospital (PED)
- Critical Access Hospital (CAH)
- Disproportionate Share Hospital (DSH)
- Free Standing Cancer Hospital (CAN)
- Rural Referral Center (RRC)
- Sole Community Hospital (SCH)

Data recorded in the QI section for the parent hospital is updated to all its child outpatient facilities when the parent is certified.

Fields in the **Qualification Information** section display as blank. They require the Authorizing Official to enter information. If the information entered does not pass validation, the system requires the authorizing official to “decertify” the CE. Decertifying the parent automatically decertifies all associated children.

Qualification Information [Edit](#)

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 Children's Hospital defined by section 1886(d)(1)(B)(iii) of the Social Security Act, and this status is recognized by CMS.

Disproportionate Share Adjustment Percentage:
Cost Reporting Period From: to
Calculation Date:
Calculation Based On: Medicare Cost Report Data
Hospital Classification: Private, Non-Profit Hospital with State/Local Govt Contract

- 5) Click the [Edit](#) link to make changes to the **Qualification Information** fields.

Qualification Information [Continue](#) [Undo](#)

From the hospital's most recently filed Medicare Cost Report, update the following:

* 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.

* **Disproportionate Share Adjustment Percentage:** 34 % (i.e., 25.75%)

* **Cost Reporting Period From:** 1/1/2014 to 12/31/2014

* **Calculation Date:** 12/16/2015

* **Hospital Classification:** Owned or Operated by State or Local Government

Contract Number or Identifier, if applicable: 1234567890

Note: [Continue](#) and [Undo](#) links appear in the upper right corner of this section. Click [Continue](#) to advance to the next section or [Undo](#) to clear your edits.

- 6) Check the box if the hospital qualifies as the specified registered entity type as defined by section CFR of the Social Security Act, and this status is recognized by CMS.
- 7) **Disproportionate Share Adjustment Percentage:** (*PED, DSH, CAN, RRC, SCH only*) – Enter the applicable percentage between 0 and 100 for the disproportionate share adjustment. This percentage must exceed a minimum percent based on the hospital entity type. A lesser percent will prompt an error message that will prevent recertification from continuing. For most hospitals this can be found on Worksheet E, part A, line 33. PED and CAN hospitals use a calculation on the S-3 or via an independent auditor.
- 8) **Cost Reporting Period:** (*PED, CAH, DSH, CAN, RRC, and SCH only*) – Enter a date range manually in mm/dd/yyyy format or by clicking the calendar icon and selecting the **From:**___ and **To:**___ dates. The **“To:”** date field must be a valid date no more than 17 months in the past (may not be a future date).

- 9) **Calculation Date:** Only applies to CAN hospitals.
- 10) **Calculation Based On:** Only applies to PED and CAN hospitals. Click the drop-down list to select.

A screenshot of a web form showing a dropdown menu for 'Calculation Based On'. The menu is open, displaying options: 'Select One', 'Official Determination from HHS Contractor', 'Medicare Cost Report Data' (highlighted in blue), 'Independent Auditor', and 'Other'. The 'Calculation Date' is set to 3/1/2011. The 'Hospital Classification' dropdown is also visible, showing 'Official Determination from HHS Contractor'.

- 11) **Hospital Classification:** Click the drop-down list to select a hospital classification.

A screenshot of a web form showing a dropdown menu for 'Hospital Classification'. The menu is open, displaying options: 'Private, Non-Profit Hospital with State/Local Govt Contract' (highlighted in blue), 'Select One', 'Owned or Operated by State or Local Government', and 'Public or Private Non-Profit Hospital Granted Governmental Powers'. Below the dropdown, a red message reads: 'You have chosen to change your listed hospital classification. Please contact 340B.recertification@hrsa.gov to determine the documentation necessary to update your covered entity profile within 5 business days.'

If you select a different classification than what is recorded for the entity, the system displays the message: “You have chosen to change your listed hospital classification. Please contact 340B.recertification@hrsa.gov to determine the documentation necessary to update your covered entity profile within 5 business days.”

Note: An email window opens for the authorizing official to notify OPA within five business days of the change in classification. Changing a covered entity’s ownership status is considered a material change reviewable by HRSA OPA to determine if there was a loss of eligibility based upon this change.

If parent entity’s eligibility for the 340B program has changed, the authorizing official must be decertified. This will cause associated hospital children to be automatically decertified. Children of non-hospitals can remain active.

All change requests are blocked from submission until a covered entity recertification is complete and reviewed by OPA. A covered entity will not be able to submit an electronic change request during this period, but a manual change request for updating and Authorizing Official may be submitted to retrieve a user name and password. Click **Forms** in the **Useful Links** on the homepage to retrieve the manual change request form and submit to HRSA OPA staff inbox, as stated on the form. If the authorizing official contact information changes, recertification confirmations will be emailed to the new authorizing official’s email addresses.

- 12) **Contract Number or Identifier:** Type the contract ID number if applicable and available.

A screenshot of a web form showing a text input field for 'Contract Number or Identifier, if applicable'. The field contains the value '1234567890'. Above it, the 'Hospital Classification' dropdown is set to 'Private, Non-Profit Hospital with State/Local Govt Contract'. Below the input field, a red message reads: 'You have chosen to change your listed hospital classification. Please contact 340B.recertification@hrsa.gov to determine the documentation necessary to update your covered entity profile within 5 business days.'

Medicaid Billing

- 13) The **Medicaid Billing** section identifies whether or not the entity will bill Medicaid for drugs purchased at 340B drug prices.

Medicaid Billing [Edit](#)

Medicaid Billing Information

Will the covered entity dispense 340B purchased drugs to Medicaid patients AND subsequently bill Medicaid for those dispensed 340B drugs? Yes No

If "Yes", please provide the entity's Medicaid Provider Number(s) (MPN) and/or National Provider Identifier(s) (NPI) for each applicable entity location that bills Medicaid for 340B drugs. If you are unsure of the entity's MPN and/or NPI, please check with your State Medicaid agency. It is important that your Medicaid billing status and appropriate provider identifier number(s) are accurate in the OPA database and align with your billing practices in order to prevent Medicaid rebates on drugs that were purchased at the 340B discounted price.

All covered entities should notify OPA prior to any change in Medicaid billing status. For more information, please visit the [HRSA website](#).

Medicaid Number(s):

Medicaid Number	State
HOS3301H	AL

NPI Number(s):

NPI Number
1023055191

To modify data in this section page, click the [Edit](#) link.

Medicaid Billing [Continue](#) [Undo](#)

Medicaid Billing Information

Will the covered entity dispense 340B purchased drugs to Medicaid patients AND subsequently bill Medicaid for those dispensed 340B drugs? Yes No

If "Yes", please provide the entity's Medicaid Provider Number(s) (MPN) and/or National Provider Identifier(s) (NPI) for each applicable entity location that bills Medicaid for 340B drugs. If you are unsure of the entity's MPN and/or NPI, please check with your State Medicaid agency. It is important that your Medicaid billing status and appropriate provider identifier number(s) are accurate in the OPA database and align with your billing practices in order to prevent Medicaid rebates on drugs that were purchased at the 340B discounted price.

All covered entities should notify OPA prior to any change in Medicaid billing status. For more information, please visit the [HRSA website](#).

Medicaid Exclusion Tutorial

Medicaid Number(s): [Add](#)

Medicaid Number	State	
<input type="text"/>	Select a State	Insert Cancel
HOS3301H	AL	Edit

NPI Number(s): [Add](#)

NPI Number		
1023055191	Edit	Delete

If the answer to the **“Will the covered entity dispense 340B purchased drugs to Medicaid patients AND subsequently bill Medicaid for those dispensed 340B drugs?”** question is **Yes**, at least one Medicaid Number and/or NPI Number must be furnished. Clicking an **Add** link allows you to add one or more Medicaid Number and/or NPI Number or edit or delete an existing Medicaid Number and/or NPI Number.

A covered entity may opt out by selecting **No**, removing all Medicaid/NPI numbers.

Note: Any changes made in this section will not be effective until the first day of the following quarter.

When changes are completed, click **Continue** to save them or **Undo** to cancel them.

Contact Information

- 14) The **Contact Information** section will appear next if you are a grantee/non-hospital covered entity. You have the ability to edit this section. If a hospital, also review the QI fields described earlier in the user guide.

Contact Information

Authorizing Official Edit

Name: Jennifer Anderson
Title: Hospital Administrator
Phone: 888-555-1212 Ext:
Fax:
Email: ENTITY-AuthorizingOfficialEmail@futrend.com

Make Primary Contact Information same as Authorizing Official

Primary Contact Edit

Name: Robby Cochran
Title: Director of Pharmacy
Phone: 888-555-2121 Ext:
Fax:
Email: ENTITY-Contact_Email@futrend.com

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 2.0 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 10C-24, Rockville, Maryland, 20857.

To modify data in this section page, click the **Edit** link.

Contact Information

Authorizing Official Continue Undo

***Name:** Jennifer Anderson
***Title:** Hospital Administrator
***Phone:** 888-555-1212 Ext:
(xxx-xxx-xxxx)
Fax:
(xxx-xxx-xxxx)
***Email:** ENTITY-AuthorizingOfficialEmail@futrend.com

Make Primary Contact Information same as Authorizing Official

Primary Contact Continue Undo

***Name:** Robby Cochran
***Title:** Director of Pharmacy
***Phone:** 888-555-2121 Ext:
(xxx-xxx-xxxx)
Fax:
(xxx-xxx-xxxx)
***Email:** ENTITY-Contact_Email@futrend.com

The primary contact should be someone employed by the Covered Entity

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 2.0 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 10C-24, Rockville, Maryland, 20857.

For either the AO or the Primary Contact information, when changes are completed, click **Continue** to save them or **Undo** to cancel them.

- 15) Click the **Update** button to complete certification of the entity. You will be asked if you are satisfied with the information for the entity. Click **OK** if you are satisfied with your edits. You will be unable to request additional changes until OPA review is complete.

Are you satisfied with the information on file for this site? After continuing, you will be unable to request additional changes until OPA review is complete.

- 16) You are returned to the **Batch Dashboard**. The entity you just certified is moved to the bottom of the list in the **Covered Entities** table with a status of "Certified"
- 17) Repeat the certification steps above until all covered entities in the batch have been recertified. When the last covered entity in the batch is certified, the system will display the **Attest and Certify** page.

Note: For multiple non-hospitals that are batched separately, you must log out after each session and log back in again to recertify another entity. Repeat the steps above for each entity.

Attest and Recertify

The **Authorized Signature** section is the final step after the parent and all child sites have been reviewed and updated.

Sole Community Hospital 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
SCH010061-00	010061	HIGHLANDS MEDICAL CENTER		380 WOODS COVE ROAD	SCOTTSBORO	AL	35788	Certified
1								

Program Manager/Authorizing Official

Name: KIM BRYANT
Title: CEO
Phone: 256-218-3789 **Ext:**
Email: ENTITY-AuthorizingOfficialEmail@futrend.com

Authorized Signature

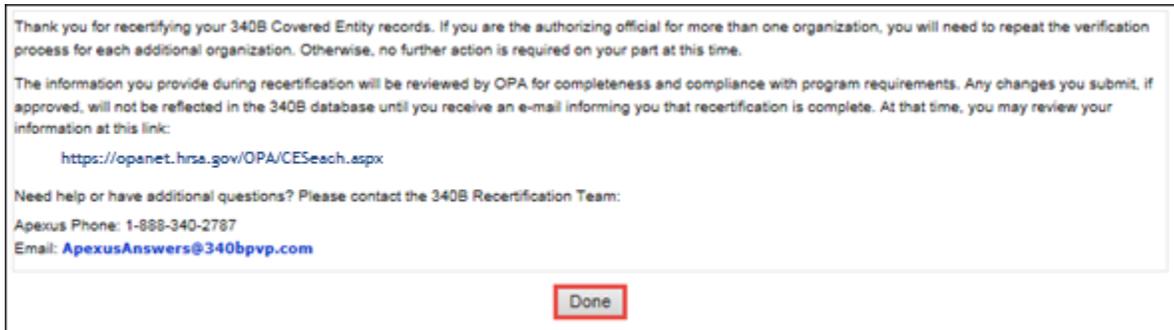
The undersigned represents and confirms that he/she is fully authorized to legally bind the covered entity and certifies that the contents of any statement made or reflected in this document are truthful and accurate. Failure to recertify may be grounds for removal from the 340B Program.

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 is complete, accurate, and correct;
- (2) the covered entity meets 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 and diversion (section 340B(a)(5)(A) and (B) of the Public Health Service Act;
- (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.

- 18) Check the box to attest that you have read and understand that you are authorized to sign for the entity and attest to the entities compliance within the 340B requirements, provided that the information listed is complete and accurate.
- 19) Click the **Attest and Recertify** button. The recertification process is now complete and the covered entity's record will be sent to HRSA OPA for review. HRSA OPA has the right to accept, reject, or accept partial updates to a covered entity's record as requested by the AO. Once this step is complete, the AO will receive an email confirmation that recertification is complete.



- 20) Click the **Done** button. You will be returned to the OPA home page for AOs.

Decertifying a Covered Entity

An Authorizing Official can request to “decertify” a covered entity, which is requesting that the entity will no longer participate in the 340B Program. If the Authorizing Official decertifies the parent hospital, associated children are automatically decertified. However, the Authorizing Official can choose to certify the parent hospital while selectively decertifying certain children.

Follow these steps to decertify an entity:

- 1) Log in using the user ID and password from the “log-in” recertification email from OPA.

The **Batch Dashboard** page for the initiative displays.

Recertification Dashboard > Initiative Dashboard > Batch Dashboard

Recertification Initiative Name: DW UI Report 12/27/2014

Batch Name: UI7893A **Entity Type:** Urban Indian

Start Date: 11/24/2014 **End Date:** 11/25/2014

Certification Due Date: 11/25/2014 **PM/AO Phone:** 928-526-2968

PM/AO Name: Linda Cowan

PM/AO Email: ENTITY-AuthorizingOfficialEmail@futrend.com

Covered Entities

The number of rows returned: 1 Rows/Page: 200

340B ID	Batch Name	Entity Name	Subdivision Name	Address	City	State	Zip	Status
UI7893A	UI7893A	NATIVE AMERICANS FOR COMMUNITY ACTION INC	FAMILY HEALTH CENTER	1500 EAST CEDAR AVE., STE 26	FLAGSTAFF	AZ	86004	Incomplete

1

- 2) Click the link in the **340B ID** column
- 3) The **Covered Entity Details** page displays. Scroll to the bottom of the page and click the **Terminate** button.

Medicaid Billing [Edit](#)

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

Contact Information

Authorizing Official [Edit](#)

Name: Linda Cowan
Title: Chief Executive Officer
Phone: 928-526-2968 **Ext:**
Email: ENTITY-AuthorizingOfficialEmail@futrend.com

Make Primary Contact Information same as Authorizing Official

Primary Contact

Name: Debra Laughlin
Title: Clinic Nurse
Phone: 928-773-1245 **Ext:** 20
Email: ENTITY-Contact_Email@futrend.com

The **Covered Entity Details** page displays validation errors for any required fields are missing information.

Errors:

- Please enter Employee Identification Number.

Covered Entity Details

***340B ID:** UI7893A [Continue](#) [Undo](#)

***Entity Name:** NATIVE AMERICANS FOR COMMUNITY ACTION INC

Entity Sub-Division Name: FAMILY HEALTH CENTER

Entity Type: Urban Indian

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

Grant Number: (if known/applicable)

Medicare Provider Number: (only required for hospital entity types)

4) Fix any validation errors and click the **Continue** link to apply your changes.

5) Click the **Terminate** button again.

The **Covered Entity Details** page prompts for any missing termination information.

Errors:

- Termination Reason is required.
- Termination Date is required.
- The date the entity became ineligible is required.
- Last date that 340B drugs were or will be purchased under this 340B ID is required.

Covered Entity Details

340B ID: UI7893A

Entity Name: NATIVE AMERICANS FOR COMMUNITY ACTION INC

Entity Sub-Division Name: FAMILY HEALTH CENTER

Medicare Provider Number:

Entity Type: Urban Indian

Employer Identification Number: 11-1111111

Grant Number:

Covered Entity Address

Street Address (PO Box Not Allowed)

1500 EAST CEDAR AVE.
STE 26
FLAGSTAFF, AZ 86004

Billing Address Same as Street Address

Shipping Address Same as Street Address

Covered Entity Date Information [Continue](#) [Undo](#)

Registration Date: 12/4/2007

Participating Approval Date: 6/20/2012

Participating Start Date: 7/1/2012

Termination Reason: site closure
If none of these reasons apply, stop here and e-mail 340b.recertification@hrsa.gov for additional guidance.

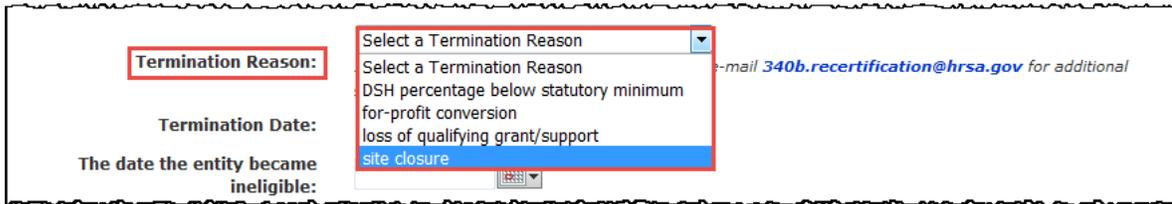
Termination Date: 11/24/2014

The date the entity became ineligible: 11/24/2014

Last date that 340B drugs were or will be purchased under this 340B ID: 11/15/2014

Termination Comments: Upon completion of this termination request, your Authorizing Official will receive an email. Please ensure that your AO reviews the email and responds to the content.

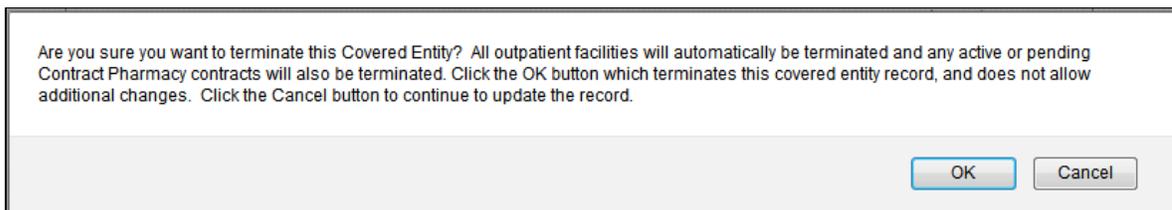
- 6) **Termination Reason:** Select the reason the entity is being decertified. If none of these reasons apply, send an email to: 340B.recertification@hrsa.gov .



The screenshot shows a web form with a dropdown menu for "Termination Reason". The dropdown is open, showing the following options: "Select a Termination Reason", "Select a Termination Reason", "DSH percentage below statutory minimum", "for-profit conversion", "loss of qualifying grant/support", and "site closure". The "site closure" option is highlighted in blue. To the right of the dropdown, there is a text prompt: "Email 340b.recertification@hrsa.gov for additional".

- 7) **Termination Date:** Enter the effective termination date manually in mm/dd/yyyy format or using the calendar icon.
- 8) **Date the entity became ineligible:** Enter in mm/dd/yyyy format or select with the calendar icon the effective date the entity is ineligible for the 340B program.
- 9) **Last date that 340B drugs were purchased:** Enter the last date drugs were purchased at 340B prices.
- 10) **Termination Comments:** Briefly describe the reason for termination and how the effective date was determined. Information entered in this section may be made available to manufacturers and the public. If 340B drugs were purchased after the entity became ineligible, affected manufacturers may be entitled to repayment.
- 11) When finished, click the **Terminate** button again.

A screen message displays a warning that if you decertify the entity, all outpatient facilities will also be decertified. If terminating any covered entity parent or child, the request will notify that there will be a termination of all contract pharmacies also.



The dialog box contains the following text: "Are you sure you want to terminate this Covered Entity? All outpatient facilities will automatically be terminated and any active or pending Contract Pharmacy contracts will also be terminated. Click the OK button which terminates this covered entity record, and does not allow additional changes. Click the Cancel button to continue to update the record." At the bottom right, there are two buttons: "OK" and "Cancel".

- 12) Click the **OK** button. The **Authorize and Submit** screen displays. You will be prompted to attest and recertify.

(Back to [Getting Started for Public Users](#))

Other Covered Entities User Guides

[Searching, Viewing, and Exporting Covered Entity Data](#)

[Registering a Covered Entity/Outpatient Facility](#)

[Submitting a Change Request](#)