



**OPA DATABASE GUIDE**  
**FOR**  
**PUBLIC USERS - RECERTIFICATION**

**AUGUST 2013**  
**VERSION 5.2.1**

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## CERTIFICATION

### Objectives:

- Logging In
- Navigating Dashboards
- Certifying Covered Entity
- Decertifying Covered Entity
- Authorizing Official Authorization and Submit Process
- OPA Review and Approvals

### ADVANCE NOTIFICATION

#### DETAILS

OPA Recertification is required annually for Covered Entities participating in the 340B discount drug program.

#### ***Authorizing Official (AO) Advance Notification***

- An advance notification is sent to the Authorizing Official and Primary Contact via email, which provides preliminary information about the OPA recertification process.
- An Authorizing Official is the person who represents and confirms that they are fully authorized to legally bind the covered entity into a relationship with the Federal Government and has knowledge of the practices and eligible programs at that site. For additional clarification, refer to FAQ's on page 25.
- Content displays the Initiative Start Date, which is the date the Authorizing Official will receive a follow-up email containing their login User ID and Password. Content also provides the date the Recertification is to be completed.

#### EXAMPLE

Dear 340B Covered Entity,

This is an advance reminder of the electronic recertification process required for continued participation in the 340B Drug Pricing Program administered by the Health Resources and Services Administration's Office of Pharmacy Affairs (OPA). Please read this e-mail carefully.

It is extremely important that the 340B Program database 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.

An e-mail containing a username, a password, and a link to your covered entity records will be provided to the authorizing official receiving this e-mail on the day recertification **STARTS (7/1/2013)**. This will provide access to the data for your currently active sites in the 340B Program database.

Please use this username to review, revise (if necessary), and CERTIFY entity sites that are still participating in the 340B Program. Please also DECERTIFY any entity sites that are no longer participating in the 340B Program. After all of your entity sites have been certified and/or decertified, the entity's Authorizing Official will have to electronically sign a statement certifying that the entity meets all 340B Program requirements.

Please note that any changes made to your entity details will not be reflected through the public search function until reviewed and approved by OPA.

**RECERTIFICATION MUST BE COMPLETED BY 7/31/2013.**

A user manual for recertification is available at:

<http://opanet.hrsa.gov/opa/Manuals/OPA%20Database%20Guide%20for%20Public%20Users%20-%20Recertification.pdf>

If your organization has additional eligible sites that are not yet registered in the 340B Program database, please complete the online registration forms at <http://opanet.hrsa.gov/opa/Default.aspx> during the next open registration period (the first 15 days of each calendar quarter). This activity is separate from the recertification of existing covered entity sites.

NEED HELP?

Questions regarding recertification may be directed to the 340B Prime Vendor Program at 1-888-340-2787, or by sending an e-mail to [ApexusAnswers@340bpvp.com](mailto:ApexusAnswers@340bpvp.com).

## USER ID/PASSWORD EMAIL

### DETAILS

#### 340B Recertification Email

- Authorizing Official receives a 340B Recertification Username and Password email for each batch to be certified.
- Username/Password email provides:
  - Instructions on the online recertification process
  - 340B URL link to Recertification screens (Site).
  - Log in steps to access the 340B System
  - Username and Password for authentication
- **IMPORTANT:** If you are listed as the Authorizing Official for more than one covered entity, you may receive more than one user name and password to represent each unique 340B ID.
- **IMPORTANT:** Hospitals listed, as the primary site (Parent) with associated outpatient facilities (Child) relationships will *only* receive one user name and password for all covered entities.

### EXAMPLE

Dear 340B Covered Entity Authorizing Official,

Welcome to 340B Recertification for Disproportionate Share Hospital covered entities. In order to ensure your entities' continued eligibility to participate in the 340B program managed by the Health Resources and Services Administration's Office of Pharmacy Affairs, you must electronically review and recertify the information on file in the 340B Program database for your entities. Please complete recertification by 12/31/2013.

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.

It also is essential for the database to contain accurate information about whether or not Medicaid is billed for drugs purchased at 340B prices and, if so, what Medicaid numbers or NPI numbers are used for billing. If the covered entity decides to purchase drugs for Medicaid OUTSIDE the 340B program (i.e. "carve out Medicaid from 340B"), then ALL drugs billed to that Medicaid provider number and or NPI must NOT be purchased under 340B, and those numbers should not be listed in the 340B database. If the covered entity decides to bill Medicaid FOR drugs purchased under 340B ("carve in") with a Medicaid provider number and or NPI, then ALL drugs billed to that number must be purchased under 340B, and that Medicaid provider number and or NPI must be listed in the 340B database. More information on Medicaid billing and the 340B Program is available online at <http://www.hrsa.gov/opa/programrequirements/mcicaidexclusion>. If further assistance is needed to understand this requirement, please contact the 340B Prime Vendor Program at 1-888-340-2787 or at [ApexusAnswers@340bpvp.com](mailto:ApexusAnswers@340bpvp.com).

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 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 decertified entities.

Please note that any changes made to your entity details will not be reflected through the public search function until reviewed and approved by OPA.

Site: [http://opatest.primescapesolutions.net/OPA\\_Mod\\_Test/RecertBatchDashboard.aspx?BATCH\\_ID=26126](http://opatest.primescapesolutions.net/OPA_Mod_Test/RecertBatchDashboard.aspx?BATCH_ID=26126)

Username: 060004

Password: z&4LW2n#

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

#### FIRST TIME LOG IN STEPS:

1. Log into the site with the username and password provided above. You may copy and paste the initial password from this e-mail, but please ensure that you select only the password. Users who have trouble logging in have often accidentally selected extra spaces at the beginning or end of the password.
2. Reset your password. The password must be 8 characters long and must include an uppercase letter, a lowercase letter, a number and a special characters (!, @, #, \$, %, ^, &, + or =).
3. Continue with recertification as described in the user guide linked below.

#### ADDITIONAL INFORMATION:

- A user manual for recertification is available at: <http://opanet.hrsa.gov/opa/Manuals/OPA%20Database%20Guide%20for%20Public%20Users%20-%20Recertification.pdf>
- OPA must have a street address for each covered entity site. Please provide a street address, even if your entity normally only lists a P.O. Box for a site.
- Please review all covered entity information carefully before submitting, as it will not be possible for you to revise an entity's information after submission.
- If you are missing any entities that you think you are responsible for recertifying, or there are entities in your list that you think are not your responsibility, please contact the Office of Pharmacy Affairs immediately at [340b\\_recertification@hrsa.gov](mailto:340b_recertification@hrsa.gov).
- After you complete recertification, the information you provided will undergo one or more levels of review and approval. AFTER all approvals have been received and processed, the updated information will be saved to the 340B database and you will receive e-mail confirmation that recertification is complete for your covered entities.

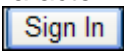
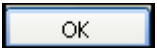
#### NEED HELP?

General questions regarding recertification may be directed to the 340B Prime Vendor Program at 1-888-340-2787, or by sending an e-mail to [ApexusAnswers@340bpvp.com](mailto:ApexusAnswers@340bpvp.com).

## LOGGING IN

### DETAILS

#### AO Logging In

1. Click on URL link (Site) and the Welcome to OPA screen displays, which is the Authentication and Authorization window.
2. Copy and paste user name from email in the User Name field. The User Name is the Batch Name.
3. Copy and paste password from the email in the Password field. Password consists of letters, numbers, and at least one special character.
4. Click the  button and the U.S. Government Warning pop-up window displays.
5. Click the  button.
6. Copy and paste password from email into the Enter old password field.
7. Enter a single new password in the Enter new password field.
8. Re-enter same new password in the Enter new password again field.
- New password must consist of the following:
  - 6 to 12 characters
  - 1 Uppercase letter
  - 1 Special Character  
@, #, %, &, \*, \$, /, ^

### EXAMPLE

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 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 decertified entities.


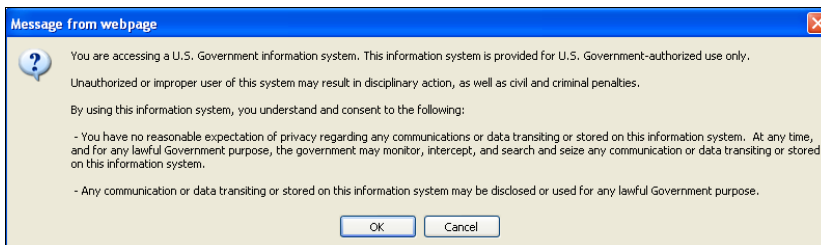
Please note that any changes made to your entity details will not be reflected through the public search function until reviewed and approved by OPA.

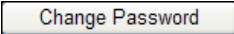


Site: [http://opatest.primescapesolutions.net/OPA\\_Mod\\_Test/RecertBatchDashboard.aspx?BATCH\\_ID=26126](http://opatest.primescapesolutions.net/OPA_Mod_Test/RecertBatchDashboard.aspx?BATCH_ID=26126)

Username: 060004

Password: z&4LW2r#

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


LOGGING IN	
DETAILS	EXAMPLE
<p>9. Click the  button; an email acknowledgement is sent to the Authorizing Official that the password has been updated.</p>	<div> <p><b>340B Database - Password Changed</b></p> <p> opastaff@hrsa.gov</p> <p>Sent: Mon 4/15/2013 9:19 AM</p> <p>To: </p> <hr/> <p>Dear Susan,</p> <p>This is an automated message sent from HRSA's 340B Drug Pricing Program database.</p> <p>Your password has been changed per your request; you may begin using the new password immediately.</p> <p>If you have any questions or if you did not request a password change, please contact the 340B Prime Vendor Program at 1-888-340-2787 or by sending an email to <a href="mailto:ApexusAnswers@340bvp.com">ApexusAnswers@340bvp.com</a>.</p> <p>Thank You!</p> </div>

## DASHBOARDS

### DETAILS

#### Navigating Dashboards

- Recertification Dashboard displays:
  - Initiative Name – link navigates to the Initiative Dashboard
  - Entity Type
  - Start Date
  - End Date
  - Number of Covered Entities in a Batch (Parent/Child)
- Initiative Dashboard displays:
  - Batch Name – link navigates to Batch Dashboard
  - Number of Entities
  - Status of Certification
- Batch Name search field is used when multiple batches are included an Initiative.
- Batch Dashboard displays:
  - 340B ID for Covered Entity – links to Covered Entity Details
  - Batch Name
  - Entity Name
  - Subdivision Name
  - Address
  - City
  - State
  - Zip
  - PM/AO Certification Status
- Click on the column headings to change the sort order of the covered entity records.

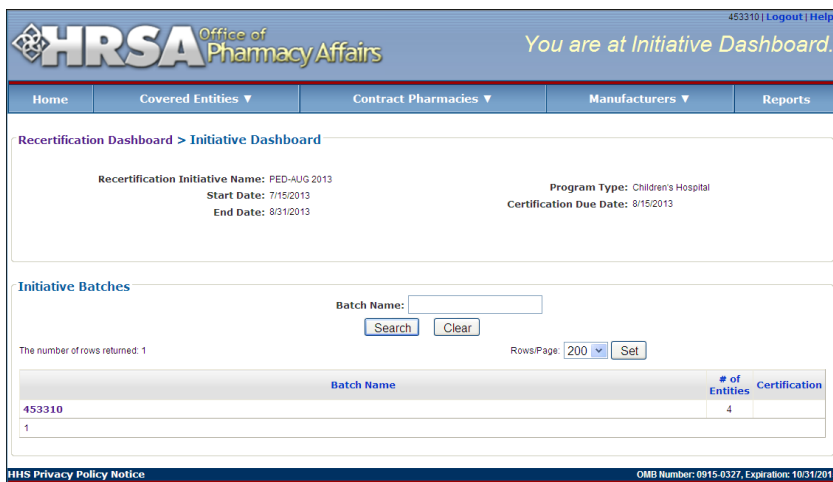
### EXAMPLE

#### Recertification Dashboard



The screenshot shows the HRSA Office of Pharmacy Affairs Recertification Dashboard. The user is logged in as 453310. The dashboard displays a table of Recertification Initiatives. The table has columns for Initiative Name, Entity Type, Start Date, End Date, and # of Batches. One initiative is listed: PED-AUG 2013, PED, 07/15/2013, 08/31/2013, 5.

#### Initiative Dashboard



The screenshot shows the HRSA Office of Pharmacy Affairs Initiative Dashboard. The user is logged in as 453310. The dashboard displays the Recertification Initiative Name: PED-AUG 2013, Start Date: 7/15/2013, End Date: 8/31/2013, and Program Type: Children's Hospital. Below the initiative details, there is a section for Initiative Batches. A search field for Batch Name is present. The table shows one batch: 453310, with 4 entities.

#### Batch Dashboard



The screenshot shows the HRSA Office of Pharmacy Affairs Batch Dashboard. The user is logged in as 453310. The dashboard displays the Recertification Initiative Name: PED-AUG 2013, Batch Name: 453310, Start Date: 7/15/2013, Certification Due Date: 8/15/2013, and Entity Type: Children's Hospital. Below the batch details, there is a section for Covered Entities. The table shows four entities with columns for 340B ID, Batch Name, Entity Name, Subdivision Name, Address, City, State, Zip, and PM/AO Certification. The entities are: PED453310-00, PED453310-01, PED453310-02, and PED453310-03, all with incomplete certification status.

**DASHBOARDS**
**DETAILS**


*To navigate from one dashboard to another, click on a dashboard name.*

**Batching Rules**

- Covered entities that have multiple entities included in a single Batch meet the following criteria.
- Hospitals** (CAN, CAH, DSH, PED, RRC, SCH) are batched by Medicare Provider Numbers. The primary covered entity (Parent) and all associated outpatient facilities (Children) that share the same Medicare Provider Number are included in the same batch.
- Grantees** (BL, CH, FP, FQHCLA, FHSC638, HM, NH, RWI, RWII, RWIID, RWIIR, HV, RW4, STD, TB, UI) are batched by 340B ID Numbers.

**AO Batch Dashboard**

- Batch Dashboard initially displays the status as "Incomplete" until each covered entity is Certified or Decertified. Once the Authorizing Official selects the applicable certification status, then the field is updated.
- Recertification is not complete until the Authorizing Official attestation language checkbox, and the Authorize and Submit button are selected; refer to page 15.

**EXAMPLE**

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

453310 | [Logout](#) | [Help](#)


You are at Batch Dashboard.

[Home](#) | [Covered Entities ▼](#) | [Contract Pharmacies ▼](#) | [Manufacturers ▼](#) | [Reports](#)

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

Recertification Initiative Name: PED-AUG 2013  
Batch Name: 453310  
Start Date: 7/15/2013  
Certification Due Date: 8/15/2013  
PM/AO Name: BOB BENNETT  
PM/AO Email: sandydee@zzz.net

Entity Type: Children's Hospital  
End Date: 8/31/2013  
PM/AO Phone: 512-324-0106

**Covered Entities**  
The number of rows returned: 4

Rows/Page: 200

340B ID	Batch Name	Entity Name	Subdivision Name	Address	City	State	Zip	PM/AO Certification
PED453310-00	453310	DELL CHILDREN'S MEDICAL CENTER		4900 MUELLER BOULEVARD	AUSTIN	TX	78723	Incomplete
PED453310-01	453310	DELL CHILDREN'S MEDICAL CENTER	CRANIOFACIAL AND RECONSTRUCTIVE PLASTIC SURGERY CENTER	1301 BARBARA JORDAN BLVD... SUITE 301	AUSTIN	TX	78723	Incomplete
PED453310-02	453310	DELL CHILDREN'S MEDICAL CENTER	CHILDREN'S BLOOD AND CANCER CENTER OF CENTRAL TEXAS	1301 BARBARA JORDAN BLVD... SUITE 401	AUSTIN	TX	78723	Incomplete
PED453310-03	453310	DELL CHILDREN'S MEDICAL CENTER	Dell Children's Neurosurgery Center of Central Texas	1301 Barbara Jordan Blvd. Ste. 307	Austin	TX	78723	Incomplete

1

HHS Privacy Policy Notice

OMB Number: 0915-0327, Expiration: 10/31/2015



## CERTIFYING COVERED ENTITY

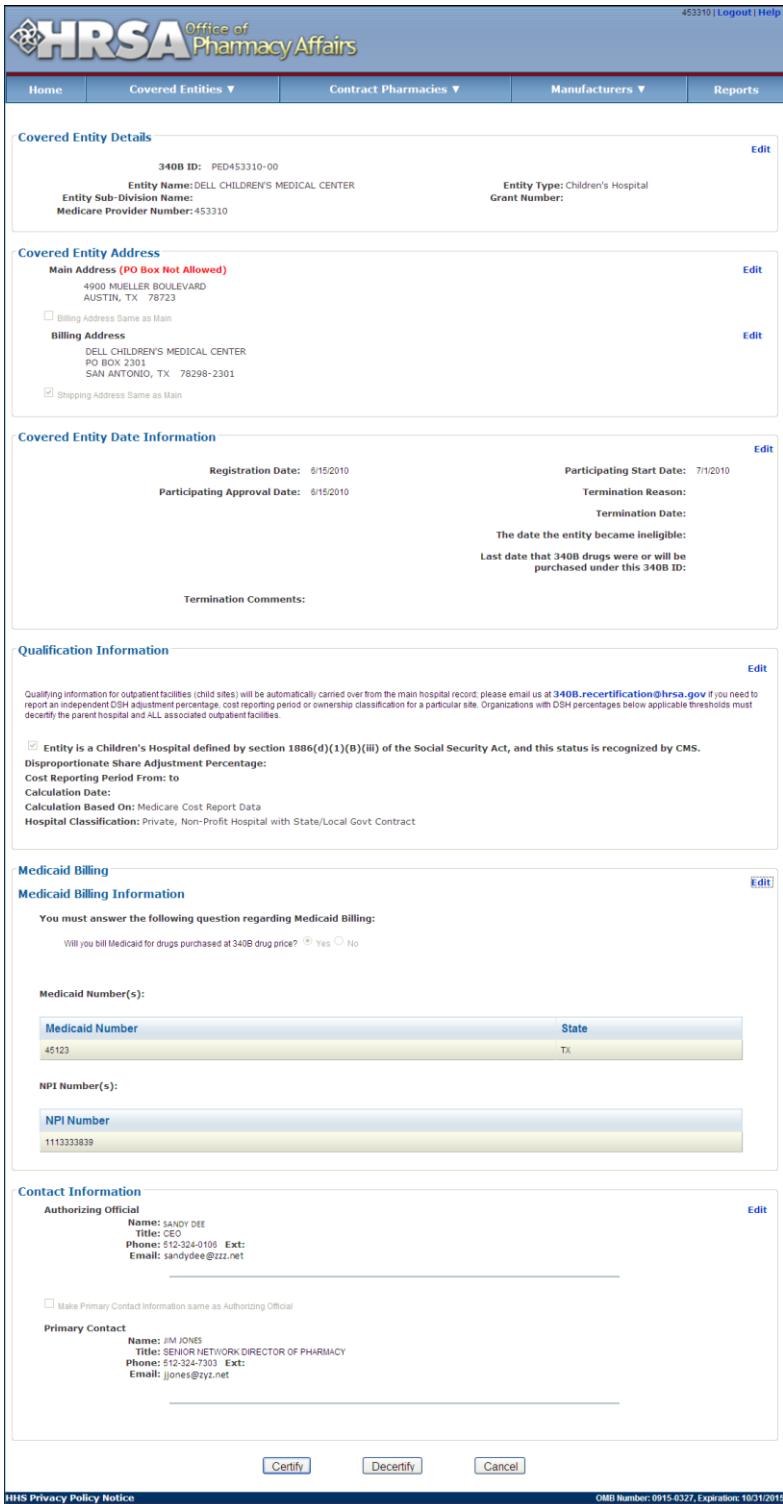
### DETAILS

#### *Certifying Covered Entity*

- Each section of the Covered Entity Details record is labeled and information can be edited or added.
- Fields that cannot be edited display as grayed-out.
- Changes to required fields that are grayed-out can be requested for change post Recertification using Change Request process.
- Change Request form is located by clicking the Forms link under Useful Links on the HRSA OPA homepage.
- Red asterisk \* displays next to required fields.
- An error message displays at the top of the screen when a field or fields are left blank or do not meet validation.
- When an error occurs, the Authorizing Official cannot advance to the next section until the error has been rectified.

### EXAMPLE

#### Covered Entity Details Record



The screenshot displays the 'Covered Entity Details Record' form within the HRSA Office of Pharmacy Affairs system. The form is organized into several sections, each with an 'Edit' link. The sections include:

- Covered Entity Details:** Displays the 340B ID (PED453310-00), Entity Name (DELL CHILDREN'S MEDICAL CENTER), Entity Sub-Division Name, Medicare Provider Number (453310), and Entity Type (Children's Hospital Grant Number).
- Covered Entity Address:** Includes Main Address (4900 MUELLER BOULEVARD, AUSTIN, TX 78723) and Billing Address (DELL CHILDREN'S MEDICAL CENTER, PO BOX 2301, SAN ANTONIO, TX 78298-2301). It also has checkboxes for 'Billing Address Same as Main' and 'Shipping Address Same as Main'.
- Covered Entity Date Information:** Shows Registration Date (8/15/2010), Participating Approval Date (8/15/2010), Participating Start Date (7/1/2010), Termination Reason, Termination Date, and a field for 'The date the entity became ineligible: Last date that 340B drugs were or will be purchased under this 340B ID:'. It also includes a 'Termination Comments' field.
- Qualification Information:** Contains a checkbox for '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.' and a 'Disproportionate Share Adjustment Percentage' field.
- Medicaid Billing:** Includes a question 'Will you bill Medicaid for drugs purchased at 340B drug price?' with 'Yes' and 'No' radio buttons. It also has fields for 'Medicaid Number(s)' and 'NPI Number(s)'.
- Contact Information:** Includes fields for 'Authorizing Official' (Name: SANDY DEE, Title: CEO, Phone: 512-324-0106, Ext: , Email: sandydee@zzz.net) and 'Primary Contact' (Name: JIM JONES, Title: SENIOR NETWORK DIRECTOR OF PHARMACY, Phone: 512-324-7503, Ext: , Email: jjones@zyz.net).

At the bottom of the form, there are buttons for 'Certify', 'Decertify', and 'Cancel'. A footer bar contains the 'HHS Privacy Policy Notice' and 'OMB Number: 0915-0327, Expiration: 10/31/2015'.

CERTIFYING COVERED ENTITY	
DETAILS	EXAMPLE
<p><b>Covered Entity Details section</b> displays important covered entity information.</p> <ul style="list-style-type: none"> <li>Site ID field is only a required field when certifying covered entity types for Consolidated Health Center Program (CH) and Federally Qualified Health Center Look Alike (FQHCLA).</li> </ul>	<div> <div> <div>Covered Entity Details</div> <div> <div>Continue</div> <div>Undo</div> </div> </div> <div> <div>*340B ID:</div> <div>PED453310-00</div> </div> <div> <div>*Entity Name:</div> <div>DELL CHILDREN'S MEDICAL CENTER</div> </div> <div> <div>Entity Sub-Division Name:</div> <div></div> </div> <div> <div>Entity Type:</div> <div>Children's Hospital</div> </div> <div> <div>Grant Number:</div> <div>(if known/applicable)</div> </div> <div> <div>Medicare Provider Number:</div> <div>453310</div> <div>(only required for hospital entity types)</div> </div> </div> <div> <div>Errors:</div> <div>Please enter Site ID.</div> </div> <div> <div>Covered Entity Details</div> <div> <div>Continue</div> <div>Undo</div> </div> </div> <div> <div>*340B ID:</div> <div>FQ45</div> </div> <div> <div>*Entity Name:</div> <div>MERCY DIAGNOSTIC TREATMENT CENTER</div> </div> <div> <div>Entity Sub-Division Name:</div> <div></div> </div> <div> <div>Entity Type:</div> <div>Federally Qualified Health Center Look-Alike</div> </div> <div> <div>Grant Number:</div> <div>LAL000069</div> <div>(if known/applicable)</div> </div> <div> <div>Medicare Provider Number:</div> <div></div> <div>(only required for hospital entity types)</div> </div> <div> <div>*Site ID:</div> <div></div> <div>*</div> </div>

Covered Entity Address

Main Address (PO Box Not Allowed)

4900 MUELLER BOULEVARD

AUSTIN, TX 78723

Billing Address Same as Main

Billing Address

DELL CHILDREN'S MEDICAL CENTER

PO BOX 2301

SAN ANTONIO, TX 78298-2301

Shipping Address Same as Main

Covered Entity Address

Continue

Undo

Main Address (PO Box Not Allowed)

\*Address Line 1:

4900 MUELLER BOULEVARD

Address Line 2:

\*City:

AUSTIN

\*State:

Texas

\*Zip:

78723

-

Billing Address Same as Main

Billing Address

Continue

Undo

\*Organization Name:

DELL CHILDREN'S MEDICAL CENTER

\*Address Line 1:

PO BOX 2301

Address Line 2:

\*City:

SAN ANTONIO

\*State:

Texas

\*Zip:

78298

-

2301

Shipping Address Same as Main

Shipping Address (PO Box Not Allowed)

Add

New Shipping Address

Continue

Undo

\*Organization Name:

Dell Children's Medical Bum Center

\*Address Line 1:

100 Main Street

Address Line 2:

\*City:

Austin

\*State:

Texas

\*Zip:

78724

-

Covered Entity Address

Main Address (PO Box Not Allowed)

4900 MUELLER BOULEVARD

AUSTIN, TX 78723

Billing Address Same as Main

Billing Address

DELL CHILDREN'S MEDICAL CENTER

PO BOX 2301

SAN ANTONIO, TX 78298-2301

Shipping Address Same as Main

Shipping Address (PO Box Not Allowed)

Shipping Address 1

Dell Children's Medical Bum Center

100 Main Street



Austin, TX 78724


Edit

Delete

CERTIFYING COVERED ENTITY	
DETAILS	EXAMPLE
<p><b>Qualification Information (QI) section</b> only pertains to Hospitals (not Grantees):</p> <ul style="list-style-type: none"> <li>– Children’s (PED)</li> <li>– Critical Access (CAH), Disproportionate Share (DSH),</li> <li>– Free Standing Cancer (CAN)</li> <li>– Rural Referral Center (RRC)</li> <li>– Sole Community (SCH)</li> <li>• QI section fields are based on the hospital type and are required fields.</li> <li>• Certain Qual Info fields display as blank, and require the Authorizing Official to enter information. Some fields must pass validation; if not, the system requires the Authorizing Official to ‘decertify’. Decertifying the Parent automatically decertifies all associated Children.</li> <li>• System requires that the primary covered entity (Parent) record be updated first. Once the Qual Info for the Parent is updated and the record is certified, then all associated Outpatient Facilities (Children) Qual Information is populated with the same data and cannot be changed.</li> <li>• <b>DSH Percentage</b> field pertains to DSH, PED, RRC, SCH, and CAN. The DSH percentage entered must pass the percentage threshold for the specific entity type in order to pass system validation.</li> </ul>	<div> <p><b>Qualification Information</b> <a href="#">Edit</a></p> <p><small>Qualifying information for outpatient facilities (child sites) will be automatically carried over from the main hospital record, please email us at <a href="mailto:3408.recertification@hrsa.gov">3408.recertification@hrsa.gov</a> 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.</small></p> <p><input checked="" type="checkbox"/> 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.</p> <p>Disproportionate Share Adjustment Percentage:</p> <p>Cost Reporting Period From: to</p> <p>Calculation Date:</p> <p>Calculation Based On: Medicare Cost Report Data</p> <p>Hospital Classification: Private, Non-Profit Hospital with State/Local Govt Contract</p> </div> <div> <p><b>Qualification Information</b> <a href="#">Continue</a> <a href="#">Undo</a></p> <p>From the hospital's most recently filed Medicare Cost Report, update the following:</p> <p>* <input checked="" type="checkbox"/> 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.</p> <p>* Disproportionate Share Adjustment Percentage: <input type="text" value=""/> % (i.e., 25.75%)</p> <p>* Cost Reporting Period From: <input type="text" value=""/> to <input type="text" value=""/></p> <p>* Calculation Date: <input type="text" value=""/></p> <p>* Calculation Based On: <input type="text" value="Medicare Cost Report Data"/></p> <p>* Hospital Classification: <input type="text" value="Private, Non-Profit Hospital with State/Local Govt Contract"/></p> </div> <div> <p><b>Qualification Information</b> <a href="#">Continue</a> <a href="#">Undo</a></p> <p>From the hospital's most recently filed Medicare Cost Report, update the following:</p> <p>* <input checked="" type="checkbox"/> 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.</p> <p>* Disproportionate Share Adjustment Percentage: <input type="text" value="20"/> % (i.e., 25.75%)</p> <p>* Cost Reporting Period From: <input type="text" value="1/1/2012"/> to <input type="text" value="12/31/2012"/></p> <p>* Calculation Date: <input type="text" value="6/15/2012"/></p> <p>* Calculation Based On: <input type="text" value="Medicare Cost Report Data"/></p> <p>* Hospital Classification: <input type="text" value="Private, Non-Profit Hospital with State/Local Govt Contract"/></p> </div>

CERTIFYING COVERED ENTITY	
DETAILS	EXAMPLE
<ul style="list-style-type: none"> <li>• <b>Cost Reporting Period</b> <b>From/To</b> field pertains to DSH, PED, CAN, RRC, and SCH. The “To” date field must be less than eighteen months from the Initiative Start Date to pass system validation.</li> <li>• When the ‘To’ date field entered is greater than the eighteen months from the Initiative Start Date, this error message displays.</li> <li>• <b>Calculation Date</b> field pertains to PED and CAN and must be an accurate date.</li> <li>• Detailed error messages display at the top of the Covered Entity screen when Qual Info does not meet system validation.</li> <li>• <b>Hospital Classification</b> field change requires the Authorizing Official to contact OPA. When selecting a different hospital classification, text displays below the field with a hyperlink. Click the link and an email window opens with the appropriate email address.</li> </ul>	<div> <p><b>Errors:</b> The attempted Cost Reporting Period Information entered exceeds the 18-month allowable timeframe from 7/15/2013. If the dates entered do not meet the specified criteria, you will need to communicate with <a href="mailto:340B.recertification@hrsa.gov">340B.recertification@hrsa.gov</a> for further instructions.</p> </div> <div> <p><b>Errors:</b> DSH percentage does not meet threshold of greater than 11.75 percent. If a DSH percentage remains below threshold, covered entity must be Decertified.</p> </div> <div> <p><b>*Hospital Classification:</b> <span>Owned or Operated by State or Local Government</span></p> <p>You have chosen to change your listed hospital classification. Please contact <a href="mailto:340B.recertification@hrsa.gov">340B.recertification@hrsa.gov</a> to determine the documentation necessary to update your covered entity profile within 5 business days.</p> </div> <div> <p>To: <a href="mailto:340B.recertification@hrsa.gov">340B.recertification@hrsa.gov</a></p> <p>Cc:</p> <p>Subject:</p> <p>Send</p> </div>

CERTIFYING COVERED ENTITY	
DETAILS	EXAMPLE
<p><b>Medicaid Billing section</b> allows Authorizing Official to add new Medicaid and/or NPI information or updating existing information.</p> <ul style="list-style-type: none"> <li>Select the  radio button next to "Yes" and the section opens.</li> <li>Select the  radio button next to "No" removes any existing Medicaid and NPI numbers from the section, or leaves the section closed.</li> <li><b>Add</b> button opens Medicaid and NPI Number sections.</li> <li><b>Insert</b> button inserts data to field.</li> <li><b>Cancel</b> button cancels data entered.</li> <li><b>Edit</b> button allows applicable field to be edited.</li> <li><b>Delete</b> button deletes applicable Medicaid Number or NPI number.</li> </ul>	<div> <div> Medicaid Billing Information Continue Undo </div> <div> You must answer the following question regarding Medicaid Billing: </div> <div> Will you bill Medicaid for drugs purchased at 340B drug price? <input type="radio"/> Yes <input checked="" type="radio"/> No </div> </div> <div> <div> <div> Medicaid Number State </div> <div> 45123 Texas </div> <div> Insert Cancel </div> </div> <div> <div> NPI Number </div> <div> 1113339393 </div> <div> Insert Cancel </div> </div> </div>

CERTIFYING COVERED ENTITY	
DETAILS	EXAMPLE
<ul style="list-style-type: none"> <li>• <b>Orphan Drug section</b> only pertains to covered entity types CAH, CAN, RRC, and SCH.</li> <li>• Orphan Drug is a required field and must be completed for a primary hospital and all associated outpatient facilities that are being certified.</li> <li>• Orphan Drug field is not required when covered entities are being decertified.</li> <li>• Select the applicable  radio button to confirm:             <ul style="list-style-type: none"> <li>– Hospital will purchase orphan drugs under 340B Program and maintain auditable records to demonstrate compliance with the orphan drug exclusion.</li> <li><b>or</b></li> <li>– Hospital cannot or does not wish to maintain auditable records regarding compliance with the orphan drug 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.</li> </ul> </li> </ul>	<div> <p><b>Orphan Drug Exclusion</b></p> <p>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 525 of the Federal Food, Drug, and Cosmetic Act. Please choose one of the following:</p> <p><input type="radio"/> The hospital will purchase orphan drugs under the 340B Program and maintain auditable records to demonstrate compliance with the orphan drug exclusion.</p> <p><input type="radio"/> 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.</p> <p><small>Note: Any change to your selection will be effective on the first day of the quarter following approval by OPA.</small></p> </div>

CERTIFYING COVERED ENTITY	
DETAILS	EXAMPLE
<p><b>Contact Information</b> section provides ability to change information for Authorizing Official and Primary Contact.</p> <p><b>IMPORTANT:</b> When changing the Authorizing Official contact information, all recertification confirmations will be emailed to the 'new' and 'previous' Authorizing Official's email address.</p> <p><b>Date Information</b> section is <i>only</i> applicable when a covered entity is being "Decertified".</p> <ul style="list-style-type: none"> <li>Refer to page 17 to review "Decertifying" a covered entity.</li> </ul>	<div> <div> <b>Contact Information</b> <a>Edit</a> </div> <div> <p><b>Authorizing Official</b></p> <p>Name: BOB BENNETT  Title: CEO  Phone: 512-324-0106 Ext:  Email: sandydee@zzz.net</p> <hr/> <p><input type="checkbox"/> Make Primary Contact Information same as Authorizing Official</p> <p><b>Primary Contact</b></p> <p>Name: SHEWAN AZIZ  Title: SENIOR NETWORK DIRECTOR OF PHARMACY  Phone: 512-324-7303 Ext:  Email: sazziz@zzz.net</p> </div> </div> <div> <div> <b>Covered Entity Date Information</b> <a>Continue</a> <a>Undo</a> </div> <div> <p>Registration Date: 6/15/2010 <a>edit</a></p> <p><input type="checkbox"/> Participating Approval Date: 6/15/2010</p> <p>Participating Start Date: 7/1/2010 <a>edit</a></p> <p>Termination Reason: Select a Termination Reason <a>▼</a></p> <p>Termination Date: <a>edit</a></p> <p>The date the entity became ineligible: <a>edit</a></p> <p>Last date that 340B drugs were or will be purchased under this 340B ID: <a>edit</a></p> <p>Termination Comments: <a>edit</a></p> </div> </div>

## CERTIFYING COVERED ENTITY

### DETAILS

1. Click on applicable 340B ID link for a covered entity and the Covered Entity Detail record displays.

### EXAMPLE



**Recertification Dashboard > Initiative Dashboard > Batch Dashboard**

Recertification Initiative Name: PED-AUG 2013  
 Batch Name: 453310  
 Start Date: 8/1/2013  
 Certification Due Date: 8/20/2013  
 PM/AO Name: SANDY DEE  
 PM/AO Email: sandydee@zzz.net

Entity Type: Children's Hospital  
 End Date: 8/31/2013  
 PM/AO Phone: 512-324-9106

**Covered Entities**

The number of rows returned: 4

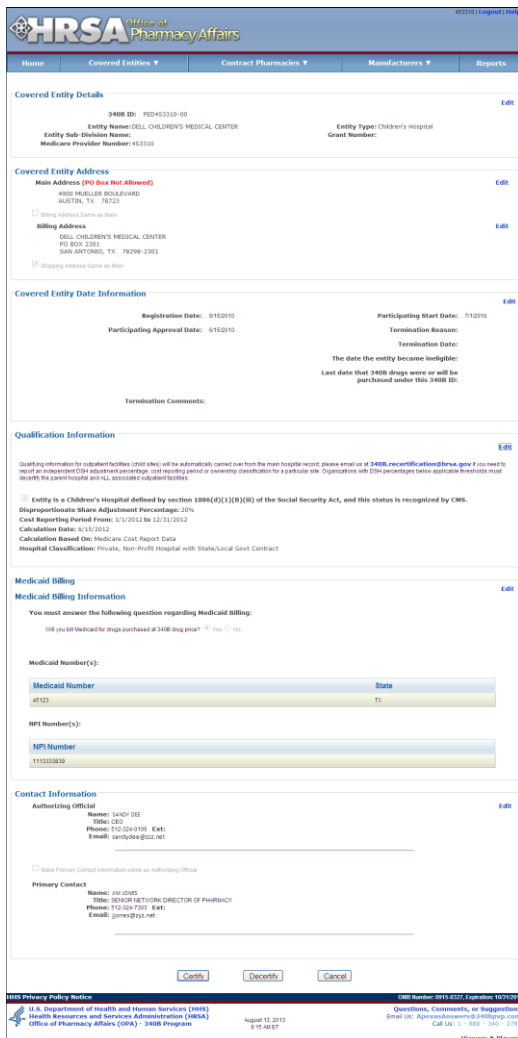
340B ID	Batch Name	Entity Name	Subdivision Name	Address	City	State	Zip	PM/AO Certification
PED453310-01	453310	DELL CHILDREN'S MEDICAL CENTER	CRAIWOFFACIAL AND RECONSTRUCTIVE PLASTIC SURGERY CENTER	1301 BARBARA JORDAN BLVD., SUITE 301	AUSTIN	TX	78723	Incomplete
PED453310-02	453310	DELL CHILDREN'S MEDICAL CENTER	CHILDREN'S BLOOD AND CANCER CENTER OF CENTRAL TEXAS	1301 BARBARA JORDAN BLVD., SUITE 401	AUSTIN	TX	78723	Incomplete
PED453310-03	453310	DELL CHILDREN'S MEDICAL CENTER	Dell Children's Neurosurgery Center of Central Texas	1301 Barbara Jordan Blvd. Ste. 307	Austin	TX	78723	Incomplete
PED453310-00	453310	DELL CHILDREN'S MEDICAL CENTER		4900 MUELLER BOULEVARD	AUSTIN	TX	78723	Certified

HRSA Privacy Policy Notice

2. Review covered entity record.
3. Enter data in blank fields or edit existing information.



*Reference pages 7 through 13 for details on editing each section.*



**Covered Entity Details**

340B ID: PED453310-00  
 Entity Name: DELL CHILDREN'S MEDICAL CENTER  
 Entity Sub-division Name: CHILDREN'S BLOOD AND CANCER CENTER OF CENTRAL TEXAS  
 Medicare Provider Number: 453310  
 Entity Type: Children's Hospital  
 Grant Number:

**Covered Entity Address**

Main Address (PO Box Not Allowed)  
 4900 MUELLER BOULEVARD  
 AUSTIN, TX 78723

Billing Address  
 DELL CHILDREN'S MEDICAL CENTER  
 PO BOX 2383  
 SAN ANTONIO, TX 78298-2383

**Covered Entity Date Information**

Registration Date: 8/1/2010  
 Participating Approval Date: 8/1/2010  
 Participating Start Date: 7/1/2010  
 Termination Reason:  
 The date the entity became ineligible:  
 Last date that 340B drugs were or will be purchased under this 340B ID:  
 Termination Comments:

**Qualification Information**

Qualifying information for subsequent facilities (child sites) will be automatically carried over from the main hospital record. Please email us at [340B.recertification@hhsa.gov](mailto:340B.recertification@hhsa.gov) if you need to report an independent COA adjustment percentage, and reporting period or submitting identification for purchase site. Organizations with COA percentages below applicable thresholds must identify the parent hospital and all associated subsequent facilities.

☒ Entity is a Children's Hospital defined by section 1886(d)(1)(D)(ii) of the Social Security Act, and this status is recognized by CMS.  
 Disproportionate Share Adjustment Percentage: 20%  
 Cost Reporting Period From: 1/1/2012 To: 12/31/2012  
 Calculation Date: 8/15/2012  
 Calculation Based On: Medicare Cost Report Data  
 Hospital Classification: Private, Non-Profit Hospital with State/Local Govt Contract

**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

Medicaid Number(s):  
 Medicaid Number: 453310 State: TX

NPI Number(s):  
 NPI Number: 152333839

**Contact Information**

Authorizing Official  
 Name: SANDY DEE  
 Title: CEO  
 Phone: 512-324-9106 Ext: 441  
 Email: sandydee@zzz.net

Primary Contact  
 Name: JAY JONES  
 Title: SENIOR NETWORK DIRECTOR OF PHARMACY  
 Phone: 512-324-7559 Ext: 8441  
 Email: jones@zzz.net

Buttons:

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4. Click the **Certify** button at the bottom of screen and a pop-up message displays.

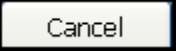




*For batches with multiple covered entities, repeat the same steps for each covered entity.*


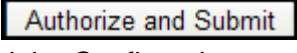
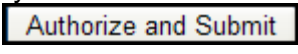


## CERTIFYING COVERED ENTITY

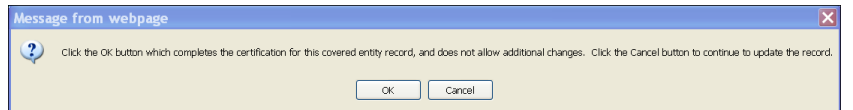
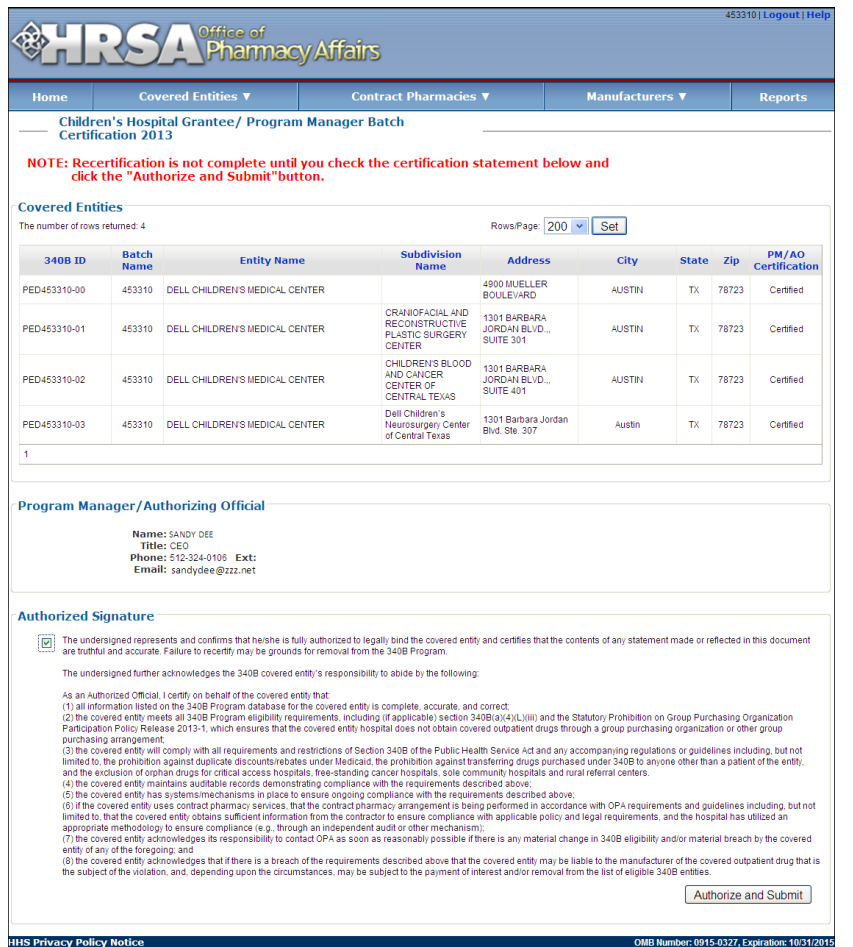
### DETAILS

- When attempting to update an outpatient facility (Child) record prior to the primary record, *only* the  button displays. Message states, "You must update the primary record prior to certifying or decertifying an outpatient facility."
- Click the  button and the Authorize and Submit screen displays.
- Click the  button to remain on the CE Details record.

### Authorize and Submit

- Authorize and Submit screen displays when all covered entities in a batch have been certified/decertified.
- After reviewing, carefully read the Authorizing Official Attestation language in the Authorized Signature section.
- Click the  checkbox in the Authorized Signature section.
- Click the  button and the Confirmation screen displays.
- Information entered or modified is not committed to the 340B system until the  button is performed. Once the button is clicked, the information is updated to the permanent record.

### EXAMPLE

**Children's Hospital Grantee / Program Manager Batch Certification 2013**

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

**Covered Entities**  
The number of rows returned: 4

340B ID	Batch Name	Entity Name	Subdivision Name	Address	City	State	Zip	PM/AO Certification
PED453310-00	453310	DELL CHILDREN'S MEDICAL CENTER		4800 MUELLER BOULEVARD	AUSTIN	TX	78723	Certified
PED453310-01	453310	DELL CHILDREN'S MEDICAL CENTER	ORANIOFACIAL AND RECONSTRUCTIVE PLASTIC SURGERY CENTER	1301 BARBARA JORDAN BLVD., SUITE 301	AUSTIN	TX	78723	Certified
PED453310-02	453310	DELL CHILDREN'S MEDICAL CENTER	CHILDREN'S BLOOD AND CANCER CENTER OF CENTRAL TEXAS	1301 BARBARA JORDAN BLVD., SUITE 401	AUSTIN	TX	78723	Certified
PED453310-03	453310	DELL CHILDREN'S MEDICAL CENTER	Dell Children's Neurosurgery Center of Central Texas	1301 Barbara Jordan Blvd. Ste. 307	Austin	TX	78723	Certified

**Program Manager/Authorizing Official**

Name: SANDY DEE  
Title: CEO  
Phone: 512-324-0106 Ext:  
Email: sandydee@tzz.net

**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 all 340B Program eligibility requirements, including (if applicable) section 340B(a)(4)(L)(iii) and the Statutory Prohibition on Group Purchasing Organization Participation Policy Release 2013-1, which ensures 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 and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity, 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 demonstrating compliance with the requirements described above;
- (5) the covered entity has systems/mechanisms in place to ensure ongoing compliance with the requirements described above;
- (6) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement is being performed in accordance with OPA requirements and guidelines including, but not limited to, that the covered entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the hospital has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism);
- (7) the covered entity acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material change in 340B eligibility and/or material breach by the covered entity of any of the foregoing; and
- (8) the covered entity acknowledges that if there is a breach of the requirements described above 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 the payment of interest and/or removal from the list of eligible 340B entities.

**Authorize and Submit**


HHS Privacy Policy Notice OMB Number: 0915-0327, Expiration: 10/31/2015

## CERTIFYING COVERED ENTITY

### DETAILS

4. Click the **Done** button and the 340B HRSA OPA homepage displays.
  - Authorizing Official and Primary Contact receive this notification.
5. Click on the Logout button at the top right of the screen to exit the system.
  - **IMPORTANT:** You can continue to log in with your User Name and Password to view when HRSA OPA has completed approval of your entities Recertification.
  - Once OPA has completed verification, your login credentials will no longer be active and this screen displays. Refer to page 23 to view the changes on the History tab.
  - When changes are made to the covered entity record during certification and approved by OPA, the Authorizing Official will receive a 340B database modification email with the changes listed with before and after values.

### EXAMPLE



453310 | Logout | Help

**HRSA** Office of Pharmacy Affairs

Home Covered Entities ▼ Contract Pharmacies ▼ Manufacturers ▼ Reports

Thank you for recertifying your 340B Covered Entity records. If you are the authorizing official for more than one organization, you will need to repeat the verification process for each additional organization. Otherwise, no further action is required on your part at this time.

The information you provide during recertification will be reviewed by OPA for completeness and compliance with program requirements. Any changes you submit, if approved, will not be reflected in the 340B database until you receive an e-mail informing you that recertification is complete. At that time, you may review your information at this link:

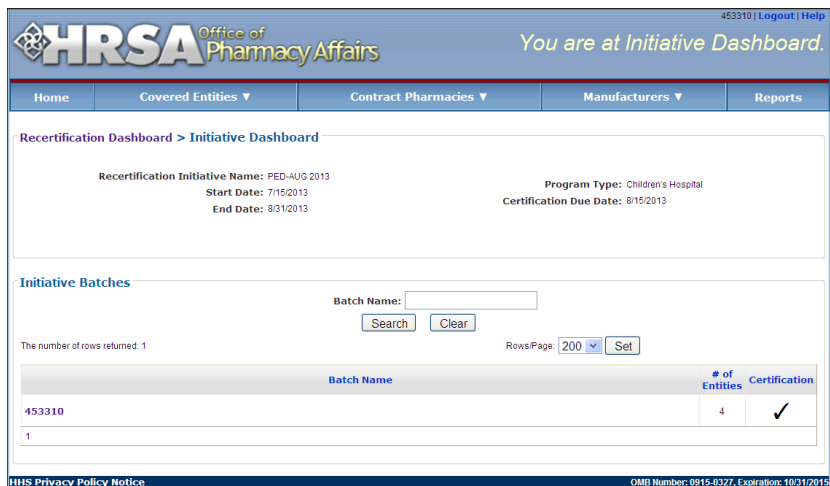
<http://opanet.hrsa.gov/OPA/CESearch.aspx>

Need help or have additional questions? Please contact the 340B Recertification Team:

Apexus Phone: 1-888-340-2787  
Email: [340B.recertification@hrsa.gov](mailto:340B.recertification@hrsa.gov)

Done

HHS Privacy Policy Notice OMB Number: 0915-0327, Expiration: 10/31/2015



453310 | Logout | Help

**HRSA** Office of Pharmacy Affairs

You are at Initiative Dashboard.

Home Covered Entities ▼ Contract Pharmacies ▼ Manufacturers ▼ Reports

Recertification Dashboard > Initiative Dashboard

Recertification Initiative Name: PED-AUG 2013  
Start Date: 7/15/2013  
End Date: 8/31/2013

Program Type: Children's Hospital  
Certification Due Date: 8/15/2013

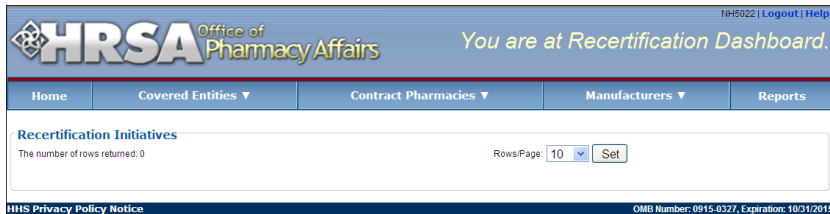
Initiative Batches

Batch Name:   
Search Clear

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

Batch Name	# of Entities	Certification
453310	4	✓

HHS Privacy Policy Notice OMB Number: 0915-0327, Expiration: 10/31/2015



NH5022 | Logout | Help

**HRSA** Office of Pharmacy Affairs

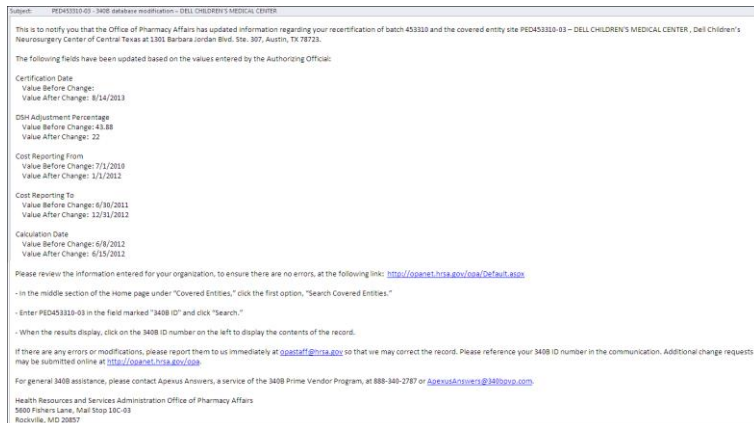
You are at Recertification Dashboard.

Home Covered Entities ▼ Contract Pharmacies ▼ Manufacturers ▼ Reports

Recertification Initiatives

The number of rows returned: 0 Rows/Page: 10 Set

HHS Privacy Policy Notice OMB Number: 0915-0327, Expiration: 10/31/2015



Subject: PED453310-03 - 340B database modification - DELL CHILDREN'S MEDICAL CENTER

This is to notify you that the Office of Pharmacy Affairs has updated information regarding your recertification of batch 453310 and the covered entity site PED453310-03 - DELL CHILDREN'S MEDICAL CENTER, Dell Children's Neurosurgery Center of Central Texas at 1301 Barbara Jordan Blvd, Ste. 307, Austin, TX 78723.

The following fields have been updated based on the values entered by the Authorizing Official:

Certification Date:  
Value Before Change: 8/14/2013  
Value After Change: 8/14/2013

DSM Adjustment Percentage  
Value Before Change: 43.88  
Value After Change: 22

Cost Reporting From  
Value Before Change: 7/1/2010  
Value After Change: 1/1/2012

Cost Reporting To  
Value Before Change: 6/30/2011  
Value After Change: 12/31/2012

Calculation Date  
Value Before Change: 6/8/2012  
Value After Change: 6/15/2012

Please review the information entered for your organization, to ensure there are no errors, at the following link: <http://opanet.hrsa.gov/opa/Default.aspx>

- In the middle section of the Home page under "Covered Entities," click the first option, "Search Covered Entities."

- Enter PED453310-03 in the field marked "340B ID" and click "Search."

- When the results display, click on the 340B ID number on the left to display the contents of the record.

If there are any errors or modifications, please report them to us immediately at [opanet@hrsa.gov](mailto:opanet@hrsa.gov) so that we may correct the record. Please reference your 340B ID number in the communication. Additional change requests may be submitted online at <http://opanet.hrsa.gov/opa>

For general 340B assistance, please contact Apexus Answers, a service of the 340B Prime Vendor Program, at 888-340-2787 or [ApexusAnswers@340b.gov](mailto:ApexusAnswers@340b.gov)

Health Resources and Services Administration Office of Pharmacy Affairs  
3800 Pihlers Lane, Mail Stop 19C-03  
Rockville, MD 20857

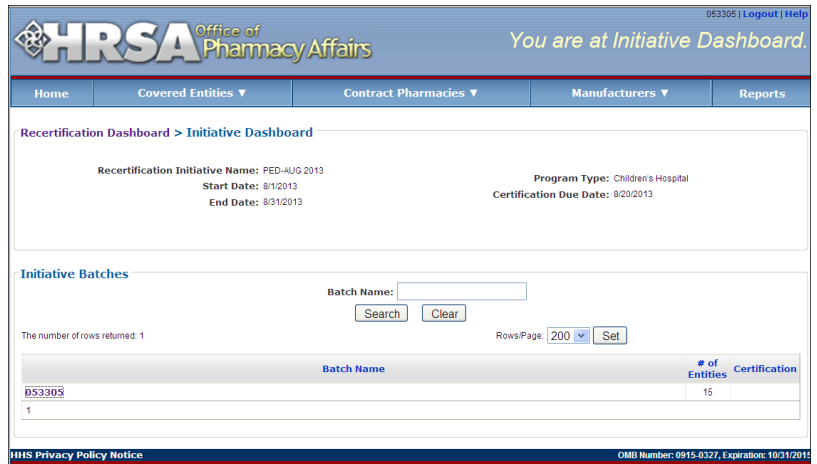
## DECERTIFYING COVERED ENTITY

### DETAILS

#### Decertifying Covered Entity

- Authorizing Official can request to 'decertify' a covered entity, which is requesting that the entity will no longer participate in the 340B Program.
  - For Hospitals, when the primary covered entity (Parent) is decertified, then the system automatically decertifies all the associated outpatient facilities (Children).
  - Primary hospital (Parent) can be certified, and the Authorizing Official can select to decertify applicable outpatient facilities (Children).
1. Click on Batch Name link on the Batch Dashboard and the Batch Dashboard displays.
  2. Click on applicable 340B ID link and the Covered Entity Details record displays.

### EXAMPLE



**HRSA Office of Pharmacy Affairs** You are at Initiative Dashboard.

Home Covered Entities ▼ Contract Pharmacies ▼ Manufacturers ▼ Reports

Recertification Dashboard > Initiative Dashboard

Recertification Initiative Name: PED-AUG 2013  
 Start Date: 8/1/2013  
 End Date: 8/31/2013

Program Type: Children's Hospital  
 Certification Due Date: 8/20/2013

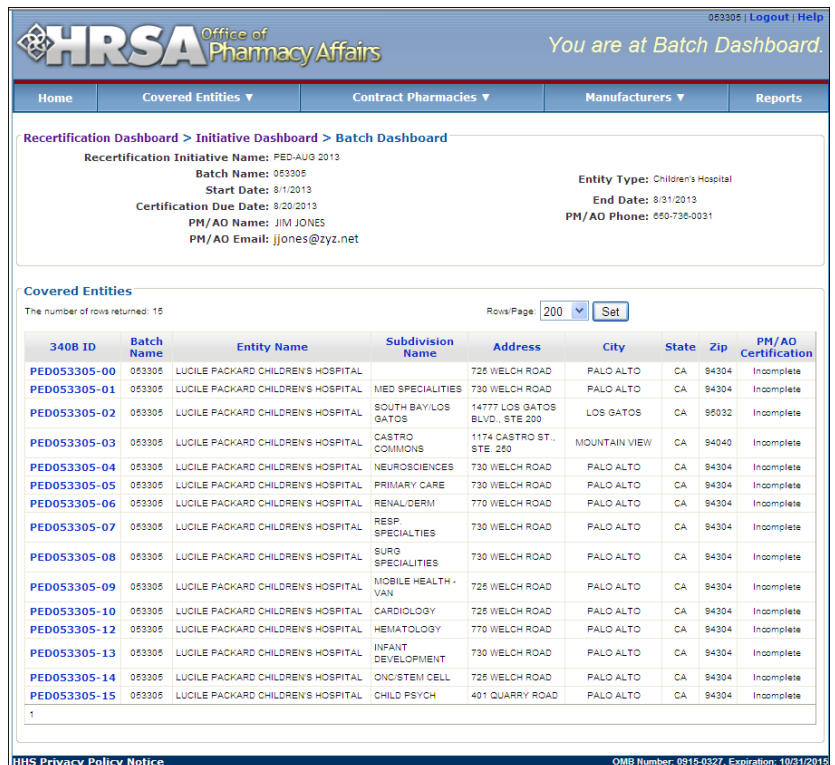
Initiative Batches

Batch Name:  Search Clear

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

Batch Name	# of Entities	Certification
<a href="#">B53305</a>	15	

HHS Privacy Policy Notice OMB Number: 0915-0327, Expiration: 10/31/2015



**HRSA Office of Pharmacy Affairs** You are at Batch Dashboard.

Home Covered Entities ▼ Contract Pharmacies ▼ Manufacturers ▼ Reports

Recertification Dashboard > Initiative Dashboard > Batch Dashboard

Recertification Initiative Name: PED-AUG 2013  
 Batch Name: B53305  
 Start Date: 8/1/2013  
 Certification Due Date: 8/20/2013

Entity Type: Children's Hospital  
 End Date: 8/31/2013  
 PM/AO Name: JIM JONES  
 PM/AO Phone: 850-736-0031  
 PM/AO Email: jjones@zyz.net

Covered Entities

The number of rows returned: 15 Rows/Page: 200 Set

340B ID	Batch Name	Entity Name	Subdivision Name	Address	City	State	Zip	PM/AO Certification
PED053305-00	053305	LUCILE PACKARD CHILDREN'S HOSPITAL		725 WELCH ROAD	PALO ALTO	CA	94304	Incomplete
PED053305-01	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	MED SPECIALITIES	730 WELCH ROAD	PALO ALTO	CA	94304	Incomplete
PED053305-02	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	SOUTH BAY/LOS GATOS	14777 LOS GATOS BLVD., STE 200	LOS GATOS	CA	95032	Incomplete
PED053305-03	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	CASTRO COMMONS	1174 CASTRO ST., STE. 200	MOUNTAIN VIEW	CA	94040	Incomplete
PED053305-04	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	NEUROSCIENCES	730 WELCH ROAD	PALO ALTO	CA	94304	Incomplete
PED053305-05	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	PRIMARY CARE	730 WELCH ROAD	PALO ALTO	CA	94304	Incomplete
PED053305-06	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	RENAL/DERM	770 WELCH ROAD	PALO ALTO	CA	94304	Incomplete
PED053305-07	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	RESP. SPECIALTIES	730 WELCH ROAD	PALO ALTO	CA	94304	Incomplete
PED053305-08	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	SURG. SPECIALTIES	730 WELCH ROAD	PALO ALTO	CA	94304	Incomplete
PED053305-09	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	MOBILE HEALTH - VAN	725 WELCH ROAD	PALO ALTO	CA	94304	Incomplete
PED053305-10	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	CARDIOLOGY	725 WELCH ROAD	PALO ALTO	CA	94304	Incomplete
PED053305-12	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	HEMATOLOGY	770 WELCH ROAD	PALO ALTO	CA	94304	Incomplete
PED053305-13	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	INFANT DEVELOPMENT	730 WELCH ROAD	PALO ALTO	CA	94304	Incomplete
PED053305-14	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	ONC/STEM CELL	725 WELCH ROAD	PALO ALTO	CA	94304	Incomplete
PED053305-15	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	CHILD PSYCH	401 QUARRY ROAD	PALO ALTO	CA	94304	Incomplete

HHS Privacy Policy Notice OMB Number: 0915-0327, Expiration: 10/31/2015

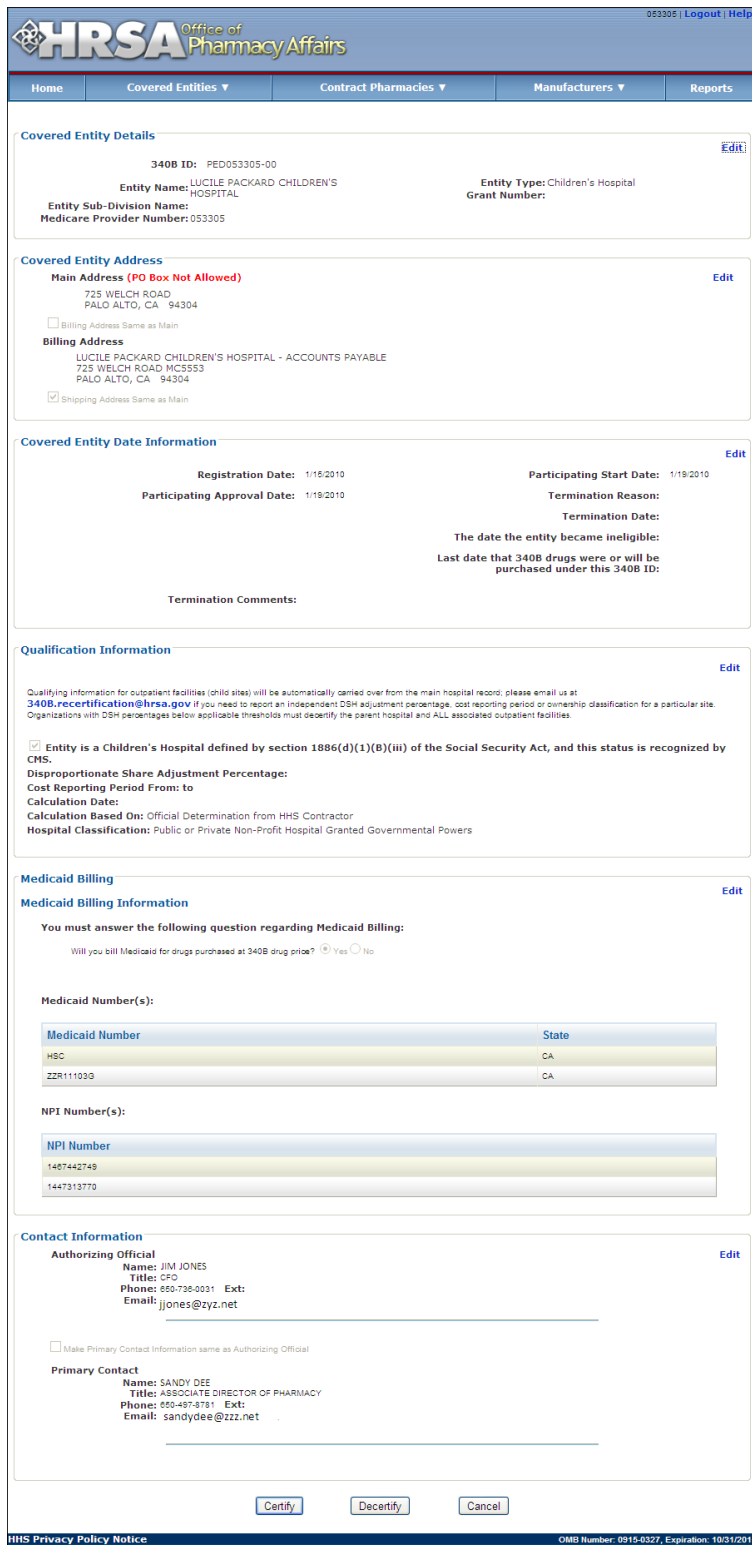
## DECERTIFYING COVERED ENTITY

### DETAILS

- Click the **Edit** button for the Covered Entity Date Information section to update Termination fields.

**Exception:** Qualification Information fields for hospitals become optional **only** when a covered entity is decertified.

### EXAMPLE



353305 | Logout | Help

Home Covered Entities ▼ Contract Pharmacies ▼ Manufacturers ▼ Reports

**Covered Entity Details** [Edit](#)

340B ID: PED053305-00

Entity Name: LUCILE PACKARD CHILDREN'S HOSPITAL Entity Type: Children's Hospital

Entity Sub-Division Name: HOSPITAL Grant Number:

Medicare Provider Number: 053305

**Covered Entity Address** [Edit](#)

Main Address (PO Box Not Allowed)

725 WELCH ROAD  
PALO ALTO, CA 94304

☐ Billing Address Same as Main

Billing Address

LUCILE PACKARD CHILDREN'S HOSPITAL - ACCOUNTS PAYABLE  
725 WELCH ROAD MC5553  
PALO ALTO, CA 94304

☒ Shipping Address Same as Main

**Covered Entity Date Information** [Edit](#)

Registration Date: 1/15/2010 Participating Start Date: 1/19/2010

Participating Approval Date: 1/19/2010 Termination Reason:

Termination Date:

The date the entity became ineligible:  
Last date that 340B drugs were or will be purchased under this 340B ID:

Termination Comments:

**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: Official Determination from HHS Contractor

Hospital Classification: Public or Private Non-Profit Hospital Granted Governmental Powers

**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

Medicaid Number(s):

Medicaid Number	State
HSC	CA
ZZR111030	CA

NPI Number(s):

NPI Number
1467442749
1447313770

**Contact Information** [Edit](#)

Authorizing Official

Name: JIM JONES  
Title: CFO  
Phone: 855-736-0031 Ext:  
Email: jjones@zyz.net

☐ Make Primary Contact Information same as Authorizing Official

Primary Contact

Name: SANDY DEE  
Title: ASSOCIATE DIRECTOR OF PHARMACY  
Phone: 855-457-8781 Ext:  
Email: sandydee@zzz.net

[Certify](#) [Decertify](#) [Cancel](#)

HRSA Privacy Policy Notice OMB Number: 0915-0327, Expiration: 10/31/2015

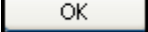
DECERTIFYING COVERED ENTITY	
DETAILS	EXAMPLE
<p>4. Select a reason from the Termination Reason drop-down list, a required field.</p> <div data-bbox="203 443 639 602"> <p>Select a Termination Reason</p> <ul style="list-style-type: none"> <li>site closure</li> <li>DSH percentage below statutory minimum</li> <li>loss of qualifying grant</li> <li>for-profit conversion</li> <li>voluntary withdrawal</li> </ul> </div> <ul style="list-style-type: none"> <li>If none of these Termination Reasons meets your request, send an email to: 340B.recertification@hrsa.gov.</li> <li>Termination Reason instructions: <ul style="list-style-type: none"> <li>If DSH percentage is below the allowable threshold, the Authorizing Official must select, '<i>DSH percentage below statutory limit</i>' as the reason. If not this error message displays.</li> </ul> </li> <li>System auto-populates the following fields to the first date of the next quarter, which cannot be edited: <ul style="list-style-type: none"> <li>Termination Date</li> <li>The date the entity became ineligible</li> <li>Last date that 340B drugs were or will be purchased under this 340B ID</li> </ul> </li> <li>System auto-populates the Termination Comments, but the field allows additional comments to be added.</li> </ul> <p>5. Click the <b>Continue</b> button to close the section.</p> <p>6. Click the <b>Decertify</b> button and a warning message displays pertaining to terminating outpatient facilities and active and pending Contract Pharmacy contracts.</p>	<div data-bbox="685 340 1505 707"> <p>Covered Entity Date Information <span>Continue Undo</span></p> <p>Registration Date: 1/15/2010</p> <p><input type="checkbox"/> Participating Approval Date: 1/19/2010</p> <p>Participating Start Date: 1/19/2010</p> <p>Termination Reason: Select a 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> <p>Termination Comments: </p> </div> <div data-bbox="685 852 1505 907"> <p>Errors:</p> <p>For Termination Reason, select 'reported DSH percentage below statutory minimum' because the DSH percentage reported does not meet the specified threshold.</p> </div> <div data-bbox="677 1094 1513 1442"> <p>Covered Entity Date Information <span>Continue Undo</span></p> <p>Registration Date: 1/15/2010</p> <p><input type="checkbox"/> Participating Approval Date: 1/19/2010</p> <p>Participating Start Date: 1/19/2010</p> <p>Termination Reason: voluntary withdrawal</p> <p>Termination Date: 10/1/2013</p> <p>The date the entity became ineligible: 10/1/2013</p> <p>Last date that 340B drugs were or will be purchased under this 340B ID: 10/1/2013</p> <p>Termination Comments: Upon completion of this termination process, your authorizing official(AO) will receive an email, please ensure that your AO reviews the email and respond to the content.</p> </div> <div data-bbox="677 1696 1533 1795"> <p>Message from webpage</p> <p>Are you sure you want to decertify this Covered Entity? All outpatient facilities will automatically be decertified and any active or pending Contract Pharmacy contracts will also be terminated. Click the OK button which decertifies this covered entity record, and does not allow additional changes. Click the Cancel button to continue to update the record.</p> <p>OK Cancel</p> </div>

## DECERTIFYING COVERED ENTITY

### DETAILS


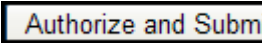


**An error message displays if the Certify button is selected when a Termination Reason displays.**

- Click the  button and the Authorize and Submit screen displays.
- Authorize and Submit screen displays once all covered entities in a batch have been certified/decertified in a batch.




**For this example, the primary covered entity (Parent) was decertified; the system automatically decertified all the outpatient facilities (Children).**

- Click the  checkbox in the Authorized Signature section.
- Click the  button and the Confirmation screen displays.

### EXAMPLE

**Errors:**  
**CE cannot be Certified with a Termination Reason.**


063306 | [Logout](#) | [Help](#)

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[Contract Pharmacies ▼](#)
[Manufacturers ▼](#)
[Reports](#)

**Children's Hospital Grantee/ Program Manager Batch**  
**Certification 2013**

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

**Covered Entities**  
The number of rows returned: 15
Rows/Page:

340B ID	Batch Name	Entity Name	Subdivision Name	Address	City	State	Zip	PM/AO Certification
PED053305-00	053305	LUCILE PACKARD CHILDREN'S HOSPITAL		725 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-01	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	MED SPECIALTIES	730 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-02	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	SOUTH BAYLOS GATOS	14777 LOS GATOS BLVD., STE 200	LOS GATOS	CA	95032	Decertified
PED053305-03	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	CASTRO COMMONS	1174 CASTRO ST., STE. 250	MOUNTAIN VIEW	CA	94040	Decertified
PED053305-04	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	NEUROSCIENCES	730 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-05	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	PRIMARY CARE	730 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-06	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	RENAL/DERM	770 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-07	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	RESP. SPECIALTIES	730 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-08	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	SURG. SPECIALTIES	730 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-09	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	MOBILE HEALTH-VAN	725 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-10	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	CARDIOLOGY	725 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-12	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	HEMATOLOGY	770 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-13	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	INFANT DEVELOPMENT	730 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-14	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	ONCO/STEM CELL	725 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-15	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	CHILD PSYCH	401 QUARRY ROAD	PALO ALTO	CA	94304	Decertified

**Program Manager/Authorizing Official**  
**Name:** JIM JONES  
**Title:** CFO  
**Phone:** 650-735-0031 **Ext:**  
**Email:** jjones@zyz.net

**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 all 340B Program eligibility requirements, including (if applicable) section 340B(a)(4)(L)(iii) and the Statutory Prohibition on Group Purchasing Organization Participation Policy Release 2013-1, which ensures 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 and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity, 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 demonstrating compliance with the requirements described above;  
 (5) the covered entity has systems/mechanisms in place to ensure ongoing compliance with the requirements described above;  
 (6) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement is being performed in accordance with OPA requirements and guidelines including, but not limited to, that the covered entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the hospital has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism);  
 (7) the covered entity acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material change in 340B eligibility and/or material breach by the covered entity of any of the foregoing; and  
 (8) the covered entity acknowledges that if there is a breach of the requirements described above 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 the payment of interest and/or removal from the list of eligible 340B entities.




## DECERTIFYING COVERED ENTITY

### DETAILS

10. Click the **Done** button and the 340B HRSA OPA homepage displays.

- Authorizing Official can view the Batch Dashboard, which displays the AO Certification status as "Decertified".

### EXAMPLE


523300 | [Logout](#) | [Help](#)

[Home](#)
[Covered Entities ▼](#)
[Contract Pharmacies ▼](#)
[Manufacturers ▼](#)
[Reports](#)

Thank you for recertifying your 340B Covered Entity records. If you are the authorizing official for more than one organization, you will need to repeat the verification process for each additional organization. Otherwise, no further action is required on your part at this time.

The information you provide during recertification will be reviewed by OPA for completeness and compliance with program requirements. Any changes you submit, if approved, will not be reflected in the 340B database until you receive an e-mail informing you that recertification is complete. At that time, you may review your information at this link:


<http://opanet.hrsa.gov/OPA/CESearch.aspx>

Need help or have additional questions? Please contact the 340B Recertification Team:

Apexus Phone: 1-888-340-2787  
Email: [340B.recertification@hrsa.gov](mailto:340B.recertification@hrsa.gov)

**Done**

HHS Privacy Policy Notice
OMB Number: 0915-0327, Expiration: 10/31/2015


053305 | [Logout](#) | [Help](#)

You are at Batch Dashboard.

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[Covered Entities ▼](#)
[Contract Pharmacies ▼](#)
[Manufacturers ▼](#)
[Reports](#)

Recertification Dashboard > Initiative Dashboard > Batch Dashboard

Recertification Initiative Name: PED-AUG 2013

Batch Name: 053305

Start Date: 8/1/2013

Certification Due Date: 8/20/2013

PM/AO Name: JIM JONES

PM/AO Email: [jjones@xyz.net](mailto:jjones@xyz.net)

Entity Type: Children's Hospital

End Date: 8/31/2013

PM/AO Phone: 650-736-0031

**Covered Entities**

The number of rows returned: 15


Rows/Page:

340B ID	Batch Name	Entity Name	Subdivision Name	Address	City	State	Zip	PM/AO Certification
PED053305-00	053305	LUCILE PACKARD CHILDREN'S HOSPITAL		725 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-01	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	MED SPECIALTIES	730 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-02	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	SOUTH BAYLOS GATOS	14777 LOS GATOS BLVD, STE 200	LOS GATOS	CA	95032	Decertified
PED053305-03	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	CASTRO COMMONS	1174 CASTRO ST., STE. 250	MOUNTAIN VIEW	CA	94040	Decertified
PED053305-04	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	NEUROSCIENCES	730 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-05	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	PRIMARY CARE	730 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-06	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	RENALDERM	770 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-07	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	RESP. SPECIALTIES	730 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-08	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	SURO SPECIALTIES	730 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-09	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	MOBILE HEALTH-VAN	725 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-10	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	CARDIOLOGY	725 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-12	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	HEMATOLOGY	770 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-13	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	INFANT DEVELOPMENT	730 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-14	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	ONCOSTEM CELL	725 WELCH ROAD	PALO ALTO	CA	94304	Decertified
PED053305-15	053305	LUCILE PACKARD CHILDREN'S HOSPITAL	CHILD PSYCH	401 QUARRY ROAD	PALO ALTO	CA	94304	Decertified

1

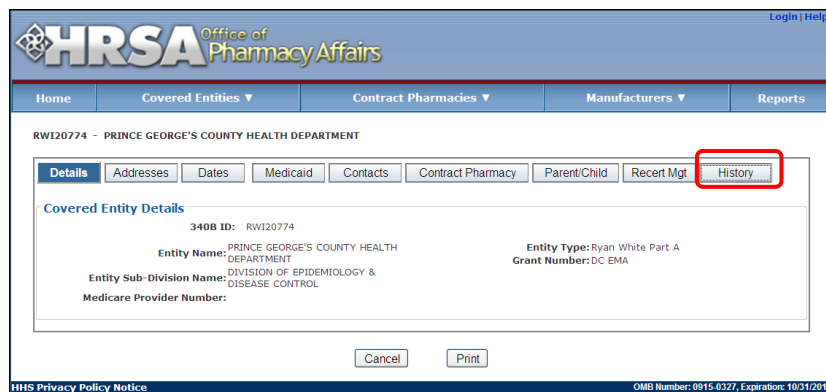
HHS Privacy Policy Notice
OMB Number: 0915-0327, Expiration: 10/31/2015

**LOGGING OUT**
**DETAILS**
**AO Logging Out**

- When logging out, Authorizing Official must completely log-out of the session because the system retains their login information. This is important when receiving multiple emails for different covered entities. Each session must be completely closed prior to opening a new session.
- Click on **Logout** in the upper right of the OPA 340B homepage. The session remains open.
  - Click on  located at top of browser window screen and the session is closed.
  - Once all covered entities (single or multiple) are “certified” or “decertified”, the Authorizing Official cannot access the Recertify Covered Entities link on the HRSA OPA home page to view.

**Viewing Recertification Info**

- Authorizing Official can view the history of changes during recertification by searching for the covered entity using the Search Covered Entities link and entering criteria.
- History tab on the Covered Entity Details screen provides view of recertification history.

**EXAMPLE**


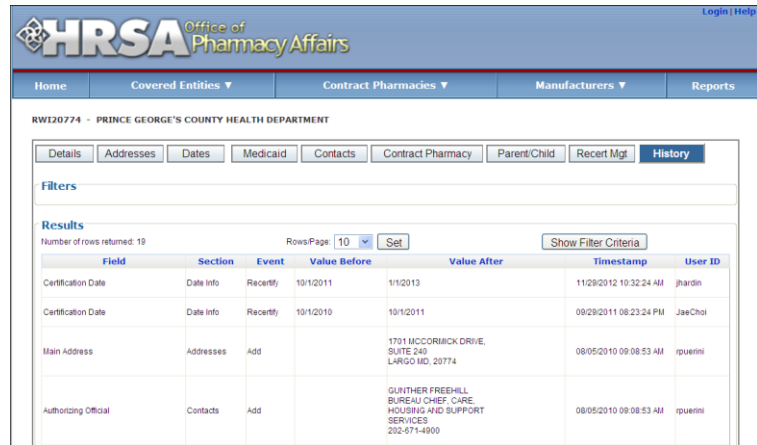


## RECERTIFICATION HISTORY

### DETAILS

- History provides details including field name, section, event, values before and after, timestamp of change and person who made the change.

### EXAMPLE



Field	Section	Event	Value Before	Value After	Timestamp	User ID
Certification Date	Date Info	Recertify	10/1/2011	1/1/2013	11/29/2012 10:32:24 AM	jhardin
Certification Date	Date Info	Recertify	10/1/2010	10/1/2011	09/29/2011 08:23:24 PM	JaeChoi
Main Address	Addresses	Add		1701 MCCORMICK DRIVE, SUITE 240 LARGO MD, 20774	08/05/2010 09:08:53 AM	rpuerini
Authorizing Official	Contacts	Add		GUNTHER FREEHILL BUREAU CHIEF, CARE HOUSING AND SUPPORT SERVICES 202-671-4900	08/05/2010 09:08:53 AM	rpuerini

### OPA Review and Approval

- OPA review can include the following:
  - Accept and approve all or partial proposed changes
  - Revise proposed changes all or partial proposed changes
  - Reject proposed changes all or partial change

### Confirmation

Dear 340B Covered Entity Authorizing Official,

Thank you for completing recertification of your 340B covered entity site(s). No further action is required on your part at this time.

You may now review your entities' information at this link - <http://opanet.hrsa.gov/OPA/CESearch.aspx>.

If you find any errors or have any additional changes to names, addresses, contact information and/or Medicaid billing details, please submit an online 340B Change Request (<http://opanet.hrsa.gov/OPA/CRPublicSearch.aspx>). Please note that paper change request forms (<http://www.hrsa.gov/opa/programrequirements/forms/index.html>) are still required for entity termination requests, changes to Authorizing Officials and/or changes to contract pharmacy relationships.

#### NEED HELP?

Questions regarding recertification may be directed to the 340B Prime Vendor Program at 1-888-340-2787, or by sending an e-mail to [ApexusAnswers@340Bpvp.com](mailto:ApexusAnswers@340Bpvp.com).

### Termination Confirmation

This is to notify you that the Office of Pharmacy Affairs (OPA) has terminated the participation of METRO PUBLIC HEALTH DEPARTMENT, LENTZ HEALTH CENTER located at 311 23RD AVENUE NORTH, NASHVILLE, TN 37203 as a FP covered entity in the 340B Program. The effective date is 7/1/2013. This site was terminated due to termination for cause.

You may view the details of this termination action at the following link: <http://opanet.hrsa.gov/opa/Default.aspx>

- In the middle section of the Homepage under "Covered Entities," click the first option, "Search Covered Entities".

- Enter FP372035 in the field marked "340B ID" and click "Search".

- When the results display, click on the 340B ID number on the left to display the contents of the record.

If you have any questions, please contact us at [opastaff@hrsa.gov](mailto:opastaff@hrsa.gov).

Office of Pharmacy Affairs  
5600 Fishers Lane, Mail Stop 10C-03  
Rockville, MD 20857  
1-800-628-6297

- An email notification is sent to the Authorizing Official once the OPA Reviewer completes review and approves and/or decertifies all Covered Entities in a batch.

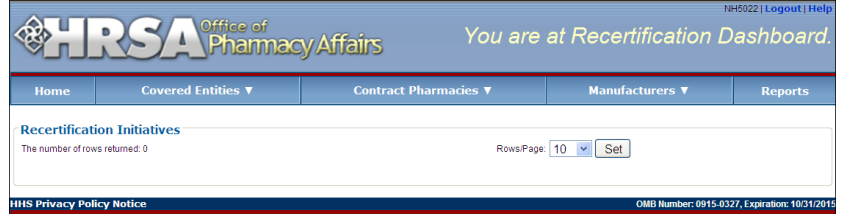
**IMPORTANT:** If the Authorizing Official contact information is updated during certification, the recertification confirmation will be emailed to the "new" Authorizing Official's email address.

## CERTIFICATIONS

### DETAILS

- **IMPORTANT:** You can continue to login with your User Name and Password to view if HRSA OPA has completed their verification of your entities Recertification. However, once OPA has completed their verification your login credentials will no longer be active, and this screen displays. Refer to page **23** to view the History tab.
- Your user name and password are only active for 90 days during Recertification, and will be deactivated on day 91. Each year during Recertification, you will receive a new user name and password.
- All other changes to the covered entity record need to be submitted via the Change Request process at: <http://opanet.hrsa.gov/OPA/CRPpublicSearch.aspx>.

### EXAMPLE



The screenshot shows the HRSA Office of Pharmacy Affairs Recertification Dashboard. The header includes the HRSA logo and the text "You are at Recertification Dashboard." with a user ID "NH5022" and links for "Logout" and "Help". A navigation bar contains tabs for "Home", "Covered Entities", "Contract Pharmacies", "Manufacturers", and "Reports". The main content area is titled "Recertification Initiatives" and shows "The number of rows returned: 0". There is a "Rows/Page" dropdown set to "10" and a "Set" button. The footer includes the "HHS Privacy Policy Notice" and "OMB Number: 0915-0327, Expiration: 10/31/2015".

## HRSA OPA FREQUENTLY ASKED QUESTIONS

### FAQs

**1. Where do I go for more information on the 340B Program and recertification?**

Please direct inquiries to Prime Vendor Program at 888-340-2787 or visit the 340B web page at: <http://www.hrsa.gov/opa/index.html>.

**2. Am I required to fill out a change request form for recertification if my covered entity has no necessary changes to be made in the 340B database prior to recertification?**

No change request form will be required

**3. My covered entity submitted a change request form; does this mean we are recertified?**

No - a change request form only updates the covered entity's information in the 340B database. Recertification is a separate process that will require the covered entity's Authorizing Official to update covered entity information if necessary and certify to compliance with program requirements during a specified time period. The hospital's Authorizing Official is responsible for ensuring program compliance for the covered entity. Recertification will cover the organization (parent) and all registered outpatient/sub-grantee (child) sites in the program database. OPA, however strongly recommends that you update the database using the change request form prior to recertification to ensure a smooth recertification process. It is the covered entity's responsibility to keep all information in the 340B Program database up to date at all times. The program database is the sole source for covered entity and manufacturer information.

**4. During recertification, will the Authorizing Official and Primary Contact receive emails?**

The Authorizing Official and Primary Contact will receive an email from OPA with the date that recertification will begin, advanced notifications, and for all webinar and training events. On the recertification start date, only the Authorizing Official will receive the required User name and Password to perform recertification.

**5. Who can or should be listed as the Authorizing Official?**

Each entity type runs their 340B programs slightly different based upon several factors of grantee status/sub-grantees/Federal funding distribution. The Authorizing Official is someone who represents and confirms that they are fully authorized to legally bind the covered entity into a relationship with the Federal Government and has knowledge of the practices and eligible programs at that site. This would be the person responsible and whom the Federal Government would reach out to for requests of compliance, integrity evaluations, and audits. So for many entities this is the grantee of record or the Clinic Director based upon Federal funding streams. For hospitals it is required that someone of the CEO/CFO/COO/President/Vice President level perform this role.

**FAQs**
**6. I was told that we cannot list our in-house pharmacy as a child site. Is that correct?**

Pharmacies are not eligible 340B covered entities and therefore, should not be listed as a child site with a 340B ID in the database. If the site is only a pharmacy and is listed as a covered entity with a 340B ID, this pharmacy must be terminated from the database. It should then be determined whether it is appropriate for the pharmacy to be added as a “ship to” address for the actual covered entity in the database.

If the pharmacy is located within an offsite outpatient facility that also provides healthcare services and provides 340B drugs to its patients, the outpatient facility must be registered as a child site with the pharmacy listed as a “ship to” of that outpatient facility. When a pharmacy is supporting multiple child sites of a parent entity, the pharmacy should be listed as a “ship to” address under the parent’s 340B ID.

**7. Is my Covered Entity required to submit our Medicaid/NPI number to the database?**

If a covered entity bills 340B drugs to Medicaid it must provide that Medicaid billing number to the Office of Pharmacy Affairs to ensure against duplicate discounts. For further clarification on whether to submit your Medicaid/NPI number please review the Medicaid Exclusion Tutorial at:

<http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html>

If a child site bills under a different Medicaid Provider Number or NPI than the parent site, those need to be appropriately listed with the child sites.

**ACRONYMS**

**HRSA** – U.S. Department of Health and Human Services

**OPA** – Office of Pharmacy Affairs

**Authorizing Official** – The Authorizing Official is someone who represents and confirms that they are fully authorized to legally bind the covered entity into a relationship with the Federal Government and has knowledge of the practices and eligible programs at that site. An Authorizing Official may be the President, Chief Executive Officer, Chief Operating Officer, or Chief Financial Officer.

**Parent** – Primary covered entity.

**Child** – Outpatient facility or another covered entity associated with a “Parent”

**Batch** – For Recertification, the batch is the 340B ID of Parent and Child or common associated numbers, such as grant or Medicare Provider numbers.

**Dashboard** – References screens in the system that allows user to follow status of recertification progress.

**Covered Entity Acronym List** – Go to HRSA OPA homepage to view a list of all covered entity acronyms at <http://opanet.hrsa.gov/opa/CoveredEntityAcronyms.aspx>.