

Office of Pharmacy Affairs Website

STD, TB, FP, RWI & RWII Recertification & Revalidation Manual

PDF Version
Updated 10.5.2007

Important Notice:

The information contained in this manual ONLY pertains to the recertification and revalidation of the following entity types:
STD, TB, FP, Ryan White I and Ryan White II.



Entity Recertification/Revalidation Instructions

Introduction

These instructions are provided for Grantees to complete the annual recertification/revalidation process for their funded 340B Covered Entities.

In an effort to maintain current and accurate information, the recertification/revalidation process allows Grantees to update their 340B Covered Entities using the HRSA OPA website at <https://opanel.hrsa.gov/opa/certification/Login.aspx> with the logins provided.

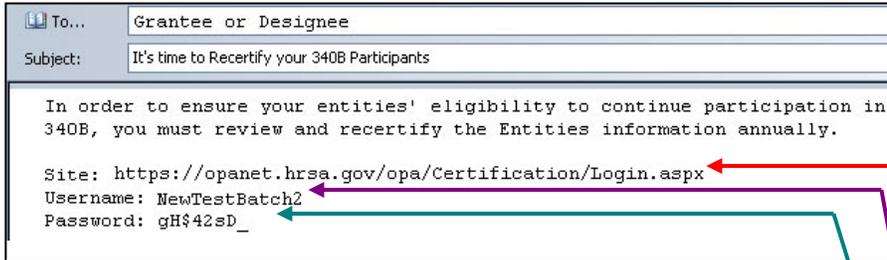
Grantees or Covered Entities may request special interim updates and recertification/revalidation as needed from HRSA OPA and PSSC Staff.

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Beginning the Recertification Process

Receive Email notification



To... Grantee or Designee
Subject: It's time to Recertify your 340B Participants

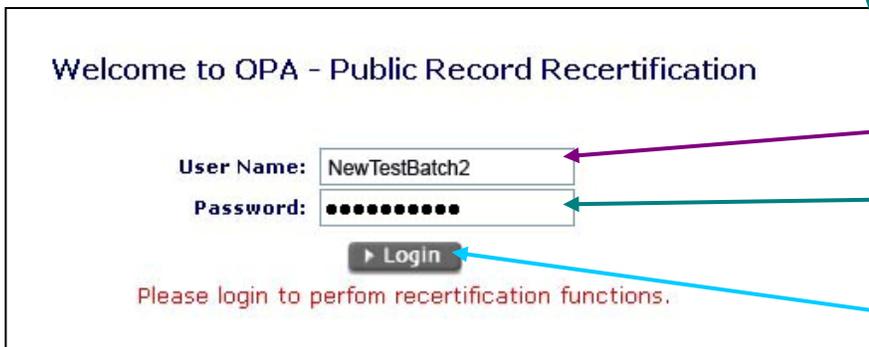
In order to ensure your entities' eligibility to continue participation in 340B, you must review and recertify the Entities information annually.

Site: <https://opanet.hrsa.gov/opa/Certification/Login.aspx>
Username: NewTestBatch2
Password: gH\$42sD_

Step 1. Receive E-mail notification

- Open E-mail
- Click on Link to the login screen <https://opanet.hrsa.gov/opa/Certification/Login.aspx>

Login to OPA Website



Welcome to OPA - Public Record Recertification

User Name: NewTestBatch2
Password: ●●●●●●●●

Please login to perform recertification functions.

Step 2. Login using temporary password provided in e-mail

- Enter Username from E-mail into the User Name box
- Copy and paste the temporary Password from E-mail into the Password box
- Click the Login button to go to the screen to change your password

Change Password



Welcome to OPA - Public Record Recertification

New Password:
New Password Confirm:

This is your first time logging in. Please change your temporary password.

Step 3. Change temporary password

- Enter a new password
- Enter new password again to confirm it
- New password must:
 - Contain 6-12 characters
 - Include alpha-numeric characters: **a b c... 1 2 3...**
 - Include a special character from this list: **@ # \$ % ^ & * /**
- Click the Change Password button
- A notification message will display regarding an activation E-mail that will be sent



Home Covered Entity Contracted Pharmacy Manufacturer Reports

3/6/2006 8:51:01 AM

Welcome to OPA - Public Record Recertification

You will now receive an email containing a website link that will activate your account. Please log in at your earliest convenience.

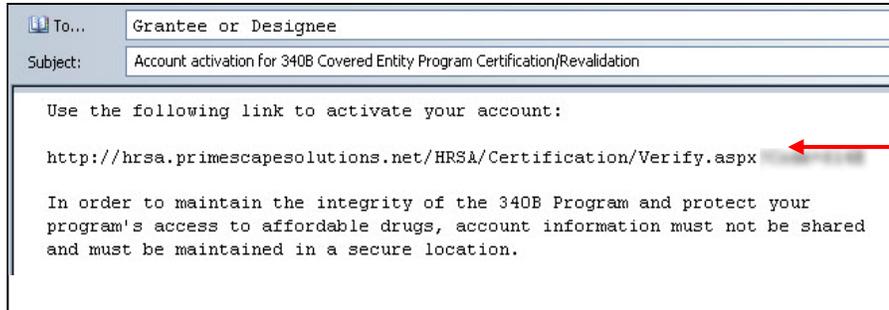
We strongly recommend using Microsoft Internet Explorer 6.0.

Do not save passwords for this application.
To ensure application security, you will be frequently asked to change passwords.

Do not enable the "remember password" feature as we require frequent password changes.

Certifying and Revalidating Information

Receive Activation Email



Step 1. Receive Account Activation E-mail

- Open E-mail
- Click on Link to the login screen or copy and paste the address into your internet browser

Login to Recertification Tool



Step 2. Password Verification screen leads to the Login Page

- Click the Login Page button
- Enter your Username in the User Name box
- Enter the new password you created into the Password box
- Click the Login button to view records awaiting recertification

View Records to be Recertified

Welcome to OPA - Public Record Recertification

[Sign Out]

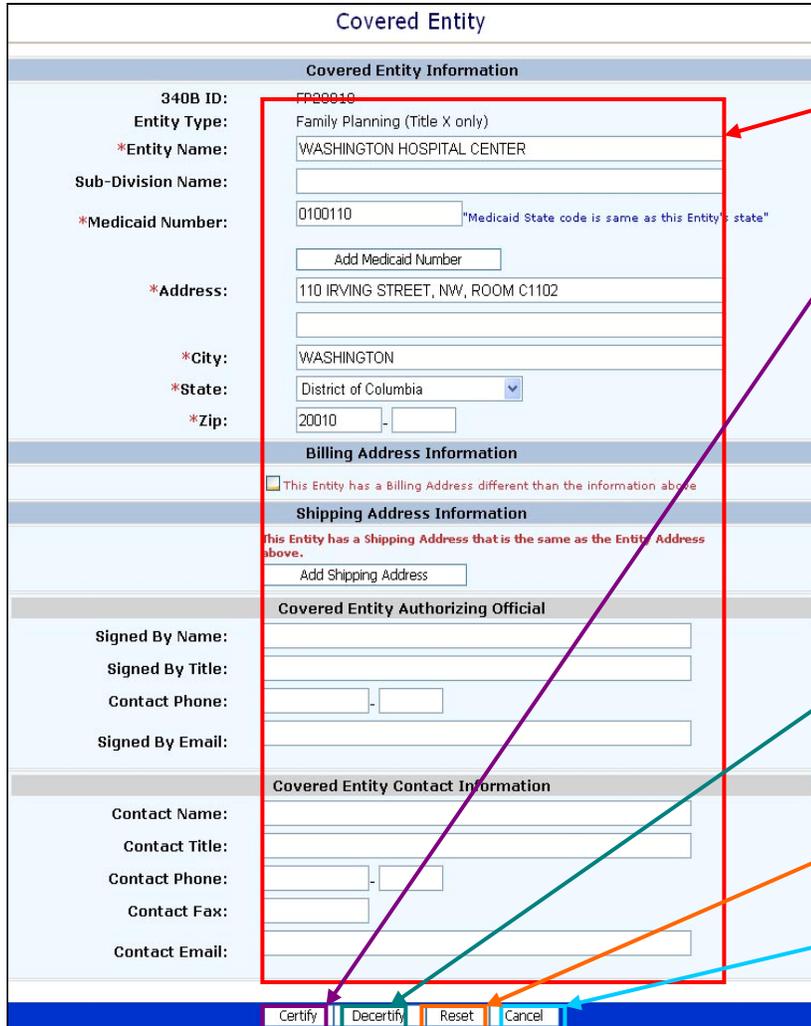
340B ID	Entity Name	Status
FP003160	CENTRAL MICHIGAN DIST HEALTH DEPT	Incomplete
FP003182	DISTRICT HEALTH DEPT NO 10	Incomplete
FP003183	LMAS DIST HEALTH DEPT	Incomplete
FP480018	ST CLAIR COUNTY HEALTH DEPT	Incomplete
FP480143	ST CLAIR COUNTY HEALTH DEPT	Incomplete
FP480354	PLANNED PARENTHOOD SOUTHEAST MICHIGAN	Incomplete
FP480431	MACOMB COUNTY HEALTH DEPT	Incomplete
FP480605	ST CLAIR COUNTY HEALTH DEPT	Incomplete
FP480673	OAKLAND CO HEALTH DEPT	Incomplete
FP480751	OAKLAND CO HEALTH DEPT	Incomplete
FP480915	PLANNED PARENTHOOD OF SOUTHEAST MICHIGAN	Incomplete
FP480935	MACOMB COUNTY HEALTH DEPT	Incomplete
FP480978	ST CLAIR COUNTY HEALTH DEPT	Incomplete
FP481043	PLANNED PARENTHOOD MID-MICHIGAN ALLIANCE	Incomplete
FP481463	WAYNE CO HEALTH DEPT	Incomplete
FP481509	PLANNED PARENTHOOD SOUTHEAST MICHIGAN	Incomplete

Step 3. View Records to be Recertified

- To sort columns, click on the column title (to sort the information by that column in ascending order)
- Click on a 340B ID number to open the Entity record and view the detailed information to be updated and recertified (see next page)

View Details, Update, Recertify or Decertify Records

Detailed record information reflects contents of the 340B OPA database at the time the recertification batch was created.



Step 4. Review and update Entity information

- Review all editable fields
- Make updates as needed
- If an Entity is still receiving funding and is continuing to participate, click the Certify (Revalidate) button when you are finished
- Confirm or cancel your selection when the message below appears



- If an Entity is no longer funded or chooses not to participate, click the Decertify (Terminate) button and fill in a reason for termination*.
- Reset will return the original page data
- Cancel will return you to the list without making changes to a record (this is good for viewing or printing)
- Confirm or cancel your selection when the message below appears



- When selection is confirmed, the changes are saved and the list of records shows ONLY remaining the records to be completed
- When all records have been updated, a notification message will indicate that the recertification process is complete.

Update all information that has changed for the entity.

Please verify that all fields marked with a red asterisk contain information; they are required fields.

To enter multiple Medicaid Provider numbers, click the “Add Medicaid Number” button and complete the fields that appear.

* Among the list of valid termination reasons are:

- Defunded or decertified
- Site closed
- Terminated at request of the Entity
- Duplicate record
- Failed validation

View Completion Message

Welcome to OPA - Public Record Recertification

[Sign Out]

Thank you. You have completed all certifications.

- When selection is confirmed, the changes are saved and shows ONLY the remaining records to be completed.
- When all records have been updated, a notification message appears indicating that the recertification process is complete.

Completing the Certification Documents

Receive Certification Document Email

Once the batch of Entities has been electronically completed, HRSA will send an email containing Certification Documents and a batch summary.

Upon receipt of the Certification Documents:

STD, TB, RW I and RW II Entities

1. Complete the estimated dollar amount expended for covered outpatient drugs for the preceding year
2. Sign and date the document
3. Fax completed document to 202-449-9473 or mail the signed original to:
Office of Pharmacy Affairs
HRSA 340B Recertification
5600 Fishers Lane, Room 10C-03
Rockville, MD 20857

FP Entities

1. Sign and date the document
2. Fax completed document to 202-449-9473 or mail the signed original to:
Office of Pharmacy Affairs
HRSA 340B Recertification
5600 Fishers Lane, Room 10C-03
Rockville, MD 20857

When this signed document is received by HRSA, the annual recertification process is complete. The updated Entities will be reflected in the database on the first day of the next calendar quarter.

Frequently Asked Questions

How do I use the 340B Recertification application?

Please use **Internet Explorer** as your internet browser. The application use is explained in this Recertification/Revalidation Manual.

How do I log in?

This Recertification/Revalidation Manual will take you through the log in process step by step. It's available online at <http://opanet.hrsa.gov/opa/Login/MainMenu.aspx>. Click on the Need Help (?) icon and download the manual there.

I clicked the link in the activation email but nothing happens?

You may have received the email in plain text instead of HTML. Copy the address from the email and paste it into your internet browser address field, or type in the address: <https://opanet.hrsa.gov/opa/Certification/Login.aspx>

I entered the wrong password several times and it says I am locked out, contact the Administrator. What should I do?

Please notify us at 340B.recertification@hrsa.gov or by calling 202-429-4110. We can “unlock” the account so you can log in.

I can't log in. What should I do?

Accessing the internet through other applications (Lotus Notes) can cause problems with log in. Also, your individual computer or network settings may interfere with log in.

If you cannot log in, please call 202-429-4110 or email 340B.recertification@hrsa.gov for assistance.

I want to delegate this project to someone on my staff. Will they be able to log in?

Yes, please email the person's name, email address, 340B ID and your organization name to us at 340B.recertification@hrsa.gov and we will resend a link to them.

Don't simply forward the email to your designee. If you do, when they log in, the automatic activation email will still be sent back to your email address. We need to update the 340B Database with your designee's information so they receive the activation email, which is essential to complete the log-in process.

How do I look at a record without making changes?

Log in to the recertification/revalidation batch and Click on the 340B ID number. Click Cancel to exit the record without making changes.

When I look at an entity record, why are most of the fields completed?

The entity record shows the existing information in the 340B Database when we sent out the recertification batch.

I need a worksheet of each record. How can I print them?

- Click on the 340B ID number
- Select File at the top menu, Select Page Setup, Select Landscape Orientation and OK
- Click on File again, Select Print, and OK
- To exit the detail record click Cancel

How do I get out of the record if I'm not ready to Certify or Decertify?

Click Cancel at the bottom of the page. This returns you to the main list and keeps the record in your list to be completed.

How do I make changes to the information?

Tab or click on the field you want to change, then type in changes. You must then click Certify at the bottom of the page to save changes. There is no need to make changes to records you will be decertifying.

Can I make changes and not Certify?

No, the only way to save changes is to click Certify.

When I click Certify or Decertify, why is the record removed from my main list?

When you click Certify or Decertify, you have completed the record so it is removed visually from your list. The only records on your main list are the ones you need to complete. When you decertify a record, be sure to enter the reason for termination in the pop up window that appears.

How do I get back into the application after I log off?

Add this link to your Favorites in your Internet Browser: <https://opanel.hrsa.gov/OPA/Certification/Login.aspx>
To log in the next time, click this favorite and log in with the user name and password you created.

I have two records for the same program. How can I correct this?

Decide which one you want to keep, make updates, and click Certify. On the duplicate you do not want to keep, click Decertify and enter "Duplicate record" along with the 340B ID of the active record, in the pop up window that appears.

I have a record that shows a shipping address. Do I need to click Add Shipping Address button?

No, if a shipping address shows, it is already in the record. You may modify shipping address if you need to by clicking in the fields and updating the information there. Click Certify to save the updates, when you are finished.

Where do I send my completed Certification Documents?

Completed Certification Documents can be:

Faxed to: 202-449-9473 or

Mailed to: Office of Pharmacy Affairs, HRSA 340B Recertification, 5600 Fishers Lane, Room 10C-03, Rockville, MD 20857

When do I add a Medicaid Provider Number?

If your entity is billing a states' Medicaid program directly (by NDC) for drugs purchased at 340B prices, the Office of Pharmacy Affairs is responsible for posting an entity's Medicaid Provider Number in the 340B Covered Entity Database, so you should include it.

State Medicaid Programs use the 340B Medicaid Provider Numbers to create an exclusion file. The exclusion file is used to exclude Medicaid payment data for 340B priced drugs from states' Medicaid Rebate Claims to drug manufacturers. Legally, the manufacturers do not have to pay a Medicaid Rebate on drugs that were purchased at 340B discount. The state Medicaid programs only have to reimburse 340B drugs at acquisition cost plus dispensing.

If you do not directly bill states' Medicaid programs for 340B drugs or if you purchase drugs from non-340B sources for your Medicaid patients, then there is no possibility for a double discount and rebate and those rules do not apply. A non-340B drug may be billed at your standard Medicaid rate. In this situation you would enter "N/A" in the 340B Covered Entity database in the Medicaid Provider Number field because you do not bill Medicaid for 340B drugs. If you include your Medicaid Provider Number for drugs not billed to Medicaid, you will cause your state to erroneously exclude legitimate claims from their unit rebates.

When do the changes actually appear in the 340B Database?

Once approval is received from the Approving Manager, updated records will be activated in the 340B Database. All approved updates will appear at the beginning of the next calendar quarter.

If I have additional questions, who do I contact?

Recertification Process Questions:

HRSA 340B Recertification Help Line

Phone: 202-449-9473

Email: 340B.recertification@hrsa.gov

General 340B Questions:

HRSA Pharmacy Services Support Center

Phone: 202-429-4110 (local)

Email: pssc@aphanet.org