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"You are never wrong, if you do the right thing."



**GCA340B Monthly Educational
Webinar Series:
OPAIS Recertification for Non-Hospitals**

2/25/2026

Non-Hospital 340B Recertification Windows



- Current Recertification Window:
 - February 2 – March 2, 2026
- Covered Entity Types:
 - Federally Qualified Health Centers (CH / CHC)
 - Federally Qualified Health Center Lookalikes (FQHCLA)
 - Black Lung Clinics (BL)
 - Hemophilia Treatment Centers (HM)
 - Native Hawaiian Health Care Centers (NH)
 - Ryan White Grantees – Part C (HV)
 - Ryan White Grantees – Parts A, B, D, F (RW)
 - State Operated AIDS Drug Purchasing Assistance Programs (ADAP)
 - Tribal and Urban Indian Organizations (FQHC638 / UI)
- Estimated Recertification Window:
 - Beginning of May – Beginning of June
- Covered Entity Types:
 - Title X Funded Family Planning Projects (FP)
 - Sexually Transmitted Disease Clinics (STD)
 - Tuberculosis Clinics (TB)

OPAIS Recertification Steps

All Covered Entities currently listed in 340B OPAIS are required to recertify annually (*except those with a pending termination date*).

PC and/or AO will review OPAIS listing information for completeness and accuracy.

HRSA/OPA will review submitted information and accept or reject all proposed changes to CE listing.

AO and PC will receive email notification of HRSA/OPAs recertification decision.

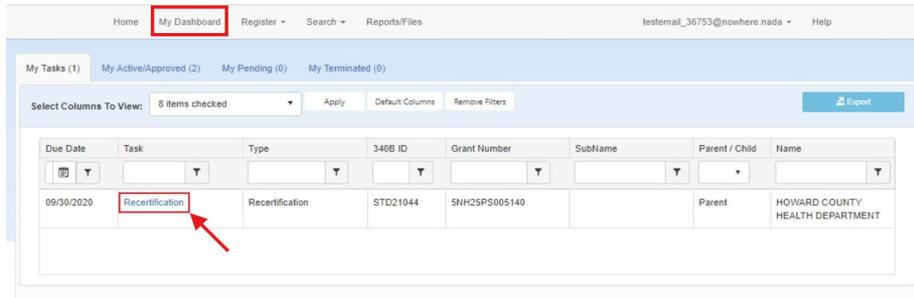
Primary Contact (PC) and/or Authorizing Official (AO) will recertify using 340B OPAIS login credentials.

AO will “attest” to the recertification submission and submit to OPA.

Remember: HRSA/OPA can recertify or decertify the CE.

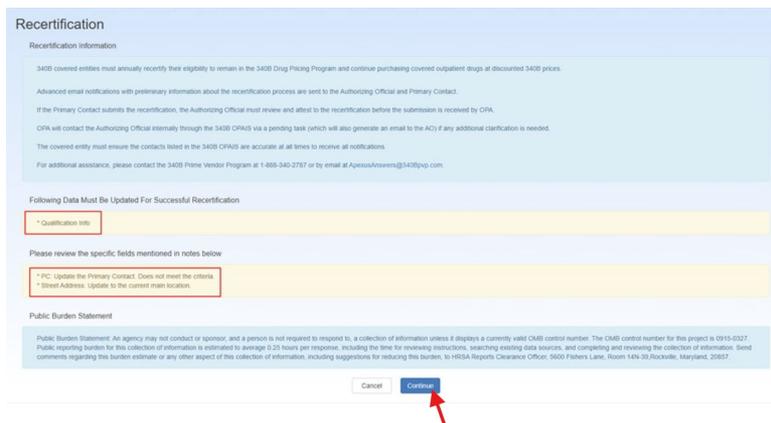
Starting a CE Recertification

- Advanced email notifications with preliminary information about the recertification process are sent by OPA to the AO and PC.
 - Once the recertification window officially opens, *and until the recertification process has been completed*, daily email notifications will be sent to the AO and PC reminding them of the open “Recertification” task in their OPAIS “My Dashboard.”
- PC or AO will start the recertification process by logging into OPAIS; entities requiring certification will appear as “Recertification” tasks in “My Dashboard.”



The screenshot shows the OPAIS 'My Dashboard' interface. At the top, there are navigation links: Home, My Dashboard (highlighted with a red box), Register, Search, Reports/Files, and a user profile for 'testemail_36753@nowhere.nada'. Below the navigation, there are tabs for 'My Tasks (1)', 'My Active/Approved (2)', 'My Pending (0)', and 'My Terminated (0)'. A 'Select Columns To View' dropdown shows '8 items checked'. Below this is a table with columns: Due Date, Task, Type, 340B ID, Grant Number, SubName, Parent / Child, and Name. The table contains one row with the following data: Due Date: 09/30/2020, Task: Recertification (highlighted with a red box and an arrow), Type: Recertification, 340B ID: STD21044, Grant Number: SNH2SPS005140, SubName: (empty), Parent / Child: Parent, Name: HOWARD COUNTY HEALTH DEPARTMENT.

- Clicking on “Recertification” link will display the “Recertification Information” page which shows the updates needed for specific sections to obtain a successful recertification.



The screenshot shows the 'Recertification Information' page. It contains the following sections:

- Recertification Information**
 - 340B covered entities must annually recertify their eligibility to remain in the 340B Drug Pricing Program and continue purchasing covered outpatient drugs at discounted 340B prices.
 - Advanced email notifications with preliminary information about the recertification process are sent to the Authorizing Official and Primary Contact.
 - If the Primary Contact submits the recertification, the Authorizing Official must review and attest to the recertification before the submission is received by OPA.
 - OPA will contact the Authorizing Official internally through the 340B OPAIS via a pending task (which will also generate an email to the AO) if any additional clarification is needed.
 - The covered entity must ensure the contacts listed in the 340B OPAIS are accurate at all times to receive all notifications.
 - For additional assistance, please contact the 340B Prime Vendor Program at 1-888-340-2787 or by email at ApexusAnswers@340b.gov.
- Following Data Must Be Updated For Successful Recertification**
 - * Qualification Info
- Please review the specific fields mentioned in notes below**
 - * PC: Update the Primary Contact. Does not meet the criteria.
 - * Street Address: Update to the current main location.
- Public Burden Statement**
 - Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327.
 - Public reporting burden for this collection of information is estimated to average 0.25 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and reviewing the collection of information, sending comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HHS/A Reports Clearance Officer, 5600 Fishers Lane, Room 14N-39, Rockville, Maryland, 20857.

At the bottom of the page, there are 'Cancel' and 'Continue' buttons. The 'Continue' button is highlighted with a red box and an arrow.

Review CE Listing Details

- Clicking on “Continue” button will display the “Recertification Covered Entity Details” page.
 - This page will display:
 - “**Please Update**” messages to indicate where required information **must be** updated (Click on the “Edit” link on the right side of the page to access the details where updates are required);

Qualification Info Attachments Info **Medicaid Billing** Parent/Child Comments History

Medicaid Billing Information (Please update Medicaid Billing information) Edit MedicaidBilling

- “**Please Review**” messages to indicate fields that are **recommended** for updates.

Covered Entity Details (Please provide value(s) for all required field(s)) Edit Main Details

Please review the specific fields mentioned in notes below

* PC: Update the Primary Contact. Does not meet the criteria.
 * Street Address: Update to the current main location

- For CH/CHC and FQHCLA entities, the information in OPAIS must be consistent with the grantee’s information on Form 5B in HRSA’s grant system, the Electronic Handbook (EHB). Any changes requested during 340B Program recertification will only be accepted if they are reflected and match what is listed in HRSA’s EHB. The following EHB information is displayed on the 340B Program recertification page:

EHB Field Name	Description
EHB Organization Name	This field is used to validate the Entity Name in OPAIS
EHB Site Name	This field is used to validate the Entity Sub-Division Name in OPAIS
EHB  Grant Number	This field is used to validate the Grant Number field in OPAIS (which contains the FQHCLA Designation Number for FQHCLAs)
EHB Address Information (Physical Street Address, City, Zipcode and Zip4Code)	This field is used to validate the Street Address in OPAIS
EHB Site Status	This field corresponds to the EHB Site Status. The EHB Site Status It is either Pending Verification, Active, or Terminated.
EHB Last Uploaded On	This field displays the most recent date when EHB data was uploaded into OPAIS

Key Details to Review

Main Details



Name, CE Type, Site ID, 340B ID,
Grant Number conferring 340B
eligibility

Contacts



Authorizing Official and Primary
Contact Information accuracy

Medicaid Billing



“At this site, will the covered entity
bill Medicaid fee-for-service for drugs
purchased at 340B prices?”

Clinic Sites and Contract
Pharmacies



All locations listed? All addresses,
ship-to information, bill-to
information accurate?

Recertification Submittal: by PC

- If you are the PC, when all updates are complete, review the information displayed on the “Covered Entity Details” page and select the action you wish to perform: Cancel, Submit, or Terminate.

Covered Entity Details Print Edit Main Details

340B ID: DSH120002A

Entity Name: MAUI HEALTH SYSTEM, A KAISER FOUNDATION HOSPITALS, LLC, dba Maui Memorial Medical Center
Entity Sub-Division Name: MAUI MEMORIAL MEDICAL CENTER OUTPATIENT CLINIC - MAUI MEMORIAL MEDICAL CENTER OUTPATIENT CLINIC
Employer Identification Number (EIN): 81-1059376
Outpatient EIN:

Entity Type: Disproportionate Share Hospital

Medicare Provider Number: 120602
Outpatient Facility Provider Number:

Participant Approval Date: 4/22/2019
Last Recertification Date: 9/13/2019

Addresses Edit Addresses

Type	Name	Address Line 1	Address Line 2	Suite	City	State	Zip
Street Address		85 MAUI LANI PARKWAY			WAILUKU	HI	96793
Billing Address	MAUI MEMORIAL MEDICAL CENTER	221 MAHALANI STREET			WAILUKU	HI	96793
Shipping Address		85 MAUI LANI PARKWAY			WAILUKU	HI	96793

Contacts Edit Contacts

Authorizing Official: Joyce Tamori, Chief Financial Officer, Phone: 808.243.2094, Email: TextEmail_24756@nothere.nada

Primary Contacts: Daniel Neves, Director of Pharmacy, Phone: 808.242.1120, Email: TextEmail_10625@nothere.nada

Attachments Info: Medicaid Billing, Parent/Child, Comments, History

Upload Attachments | Select from Existing Attachments

ID	FileName	Document Name	Attachment Type	Uploaded On	Uploaded By	Comment	Modify Attachments
No attachments to display.							

Submission Comment
Please provide any additional information that may be helpful in reviewing this recertification for 340B eligibility:

Cancel Submit Terminate

- Upon clicking the “Submit” button, the confirmation page is displayed, and the submission is forwarded to the CE’s AO for review and attestation before submission to OPA.

Recertification Submittal: by AO

- If you are the AO, when all updates are complete, and after reviewing the information displayed on the “Covered Entity Details” page, you must “attest” to the recertification submission.

Print

Covered Entity Details [Edit Main Details](#)

340B ID: DSH12002A
Entity Name: MAUI HEALTH SYSTEM A KAISER FOUNDATION HOSPITALS, LLC, dba Maui Memorial Medical Center
Entity Type: Disproportionate Share Hospital
Entity Sub-Division Name: MAUI MEMORIAL MEDICAL CENTER OUTPATIENT CLINIC - MAUI MEMORIAL MEDICAL CENTER OUTPATIENT CLINIC
Employer Identification Number (EIN): 81-1559375
Outpatient EIN:
Participant Approval Date: 4/22/2019
Last Recertification Date: 9/13/2019
[Edit Main Details](#)

Addresses [Edit Addresses](#)

Type	Name	Address Line 1	Address Line 2	Suite	City	State	Zip
Street Address		85 MAUI LANI PARKWAY			WAILUKU	HI	96793
Billing Address	MAUI MEMORIAL MEDICAL CENTER	221 MAHALANI STREET			WAILUKU	HI	96793
Shipping Address		85 MAUI LANI PARKWAY			WAILUKU	HI	96793

Contacts [Edit Contacts](#)

Authorizing Official: Joyce Tamoori, Chief Financial Officer, Phone: 8082433995, Email: TestEmail_24755@nowhere.nada

Primary Contacts: Daniel Navas, Director of Pharmacy, Phone: 8082422120, Email: TestEmail_10625@nowhere.nada

Attachments Info: [Medicaid Billing](#) [Parents/Child](#) [Comments](#) [History](#)

[Upload Attachments](#) [Select from Existing Attachments](#)

ID	FileName	Document Name	Attachment Type	Uploaded On	Uploaded By	Comment	Modify Attachments
No attachments to display.							

Submission Comment

Please provide any additional information that may be helpful in reviewing this recertification for 340B eligibility:

Authorizing Official 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. 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:

- All information listed on the 340B OPAIS for the covered entity is complete, accurate, and correct.
- The covered entity meets 340B Program eligibility requirements.
- The covered entity will comply with all requirements of Section 340B of the Public Health Service Act and any accompanying regulations including, but not limited to, the prohibition against duplicate discounts and diversion (section 340B(a)(5)(A) and (B) of the Public Health Service Act.
- The covered entity maintains auditable records pertaining to compliance with the requirements described in paragraph (3) above, pursuant to section 340B(a)(5)(C) of the Public Health Service Act.
- If the covered entity uses contract pharmacy services, that the contract pharmacy arrangement will be performed in accordance with OPA requirements and guidelines.
- The covered entity acknowledges its responsibility to contact OPA as soon as possible if there is any change in 340B eligibility and/or breach by the covered entity of any of the foregoing; and
- The covered entity acknowledges that if there is a breach of the requirements described in paragraph (3) that the covered entity may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and, depending upon the circumstances, may be subject to removal from the list of eligible 340B entities.

Failure to upload required documentation will delay approval of your recertification and result in termination if not provided by the recertification deadline.

Please provide any additional information that may be helpful in reviewing this registration for 340B eligibility:

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

[Cancel](#) [Submit](#) [Terminate](#)

- Upon clicking the “Submit” button, the confirmation page is displayed, and your recertification request has been submitted to OPA.

What Does the AO Attest To?

The CEs recertification submission is not complete until the Authorizing Official Attests that all information for the CEs OPAIS listing is truthful and accurate.

- All information listed on OPAIS is complete, accurate, and correct.
- The CE meets all applicable 340B Program eligibility requirements.
- The CE will comply with all requirements under Section 340B of the Public Health Services Act, including the prohibition against duplicate discounts and diversion.
- The CE maintains auditable records pertaining to 340B Program compliance.
- Contract retail pharmacy arrangements are performed in accordance with OPAIS requirements.
- The CE acknowledges its responsibility to notify OPAIS of any change in their 340B Program eligibility or material breach by CE.
- The CE acknowledges that if there is a breach in the requirements pertaining to duplicate discounts or diversion, they might be liable to the manufacturer of the outpatient drug, and they may be subject to removal from the 340B Program.

Once AO Attestation is complete () , AO must click on “Submit” button for recertification submission to be marked as completed.



Helpful Hints

- 340B Registration and 340B Recertification are two separate processes.
 - If your Registration “effective date” falls within the same calendar year as your entity type’s Recertification window, you will still need to complete the Recertification process.
 - Ex: FQHCLA with OPAIS effective date of 1/1/26 must still complete Recertification during the 2/2/26-3/2/26 window.
- 340B Recertification and OPAIS Change Requests are two separate processes.
 - On the Recertification window start date, all OPAIS Change Requests (excluding AO or PC Change Requests) and Termination Requests that are waiting for OPA review or for AO attestation will be removed.
 - Requests waiting for OPA review will be rejected by the system.
 - Requests waiting for AO Attestation will be canceled by the system.
 - The AO and PC of the impacted CE will receive an email notification advising of the cancelation/rejection.
 - The changes on those requests can be submitted during the Recertification process.
- If your Grant Award / Information changes, an assessment needs to be made on whether or not it affects the CEs OPAIS listing.
 - For Example: if a Grant Award allows for a new CE site, that site may need to be added to the CEs OPAIS listing.
 - GCA340B clients: make sure to reach out to your account manager when any Grant Award / Information changes so we can ensure this assessment is made!
- CHC/ FQHC/FQHCLA's are given an *extended registration window* each quarter up to 6 weeks. From the close of the two-week standard registration period through the end of the 6-week extended quarterly registration period, once a site is “active” in the CEs EHB, the health center can request OPA to open their account to allow them to submit a registration. Health centers will be asked to provide the following information to the 340B call center staff when requesting the link:
 - Health center name
 - Site/clinic name
 - Site IDs for all sites
 - HRSA/BPHC grant number
 - Primary Contact name and email address
 - Authorizing official name and email address

We're Here to Help!

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