GCA

340B

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

GCA340B Education Series: OPAIS Recertification for Hospitals

08/26/2026

Overview of Today's Discussion

- ✓ What is Recertification?
- ✓ Key Areas for Recertification
- ✓ OPAIS Recertification Steps
- ✓ Hospital Recertification Specifics
- ✓ 340B OPAIS: Helpful Hints
- ✓ Authorizing Official: Who Should it Be / What do they Attest To?
- ✓ Key Takeaways
- ✓ Questions

What is 340B Program Recertification?

“Recertification” refers to the annual recertification process in the 340B Office of Pharmacy Affairs Information System (340B OPAIS).

Purpose: Recertification ensures program integrity, compliance, transparency, and accountability of the hospital.

- Required by Statue.
- All fields can be edited during recertification for accuracy and compliance.
- Confirms accuracy of Covered Entity (CE) information in the 340B OPAIS database.
- Confirms accuracy of Contract Pharmacies (CP) in OPAIS.
- Confirms CE complies with 340B program rules, including preventing drug diversion and duplicate discounts.

When: August 10th – September 9th, 2026 (Close of Business)

If a CE does not complete recertification within the recertification window,* ***they may be terminated from the 340B Program*.*

Key Areas for Recertification

- ✓ Verify and Update Necessary Contact Information (AO/PC) for *all* Associated Hospital and Child Sites in OPAIS
- ✓ Monitor 340B Program Webpage and emails *prior to* Recertification
  - *Only the AO and PC Receive Communication from HRSA*
- ✓ Understand the Difference Between a 340B OPAIS Online Registration or Change Request During Recertification
  - Recertification is ONLY to Recertify and **NOT** to Register a Hospital, New Child Site, or Contract Pharmacy
  - 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 → the changes on these requests can be submitted during the Recertification process.
- ✓ All Covered Entities Currently Listed in 340B OPAIS will be Required to Recertify Annually (*Except those Sites with a Pending Termination Date*)

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OPAIS Recertification Steps

Notification: HRSA sends recertification notices to Authorizing Official (AO) and Primary Contact (PC)

Log-In to OPAIS: PC and/or AO will recertify using 340B OPAIS login credentials

Review Information: PC and/or AO will review OPAIS listing for completeness and accuracy.

Complete Recertification "Task": Recertification task will appear in AO and PC "My Tasks" list.

AO Attestation: AO will "attest" to the recertification submission.

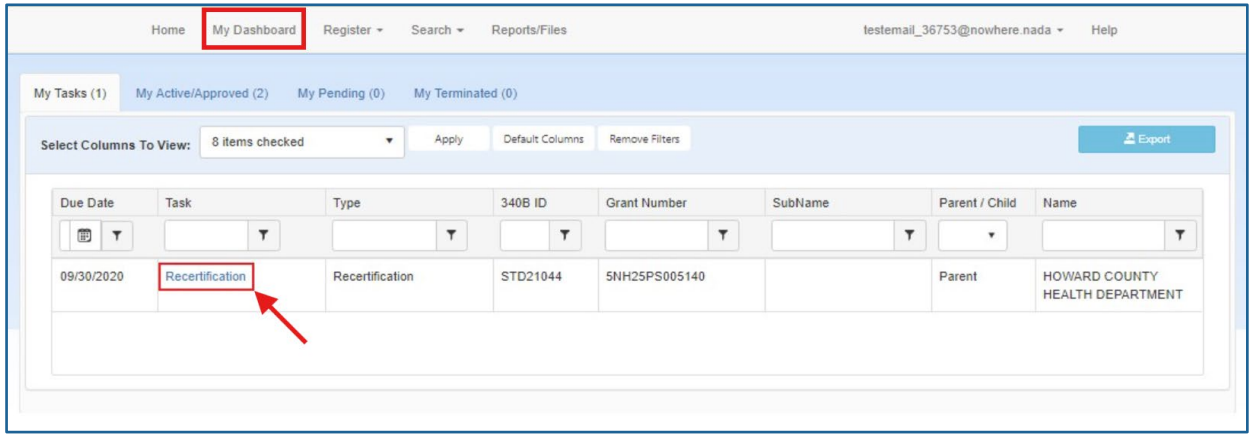
HRSA Review: HRSA/OPA will review submitted information and accept or reject all proposed changes to CE listing.

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

OPAIS Recertification Steps (continued)

Advance Notification: 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."



AO Attestation: Only the AO can formally attest that the information is correct and submit the recertification to HRSA. OPA will only receive recertification requests that have been attested to by the AO.

OPAIS Recertification Steps (continued)

HRSA Review: Once AO submits CE recertification, HRSA/OPA will review all submitted information and determine to accept all or reject all proposed CE changes to OPAIS database.

- ✓ HRSA/OPA can recertify or decertify the CE.
- ✓ The AO and PC (unless changed during this process) will receive a completion email notification and have the ability to review the CE record.

Hospital Recertification Specifics

- ✓ Hospitals registered in the 340B Drug Pricing Program (340B Program) as a Private non-profit hospital with a contract with a unit of State or Local government *must* have a contract in place to participate in the 340B Program.
- ✓ Hospitals with expired contracts or contracts that are due to expire during the recertification period *must* provide an updated contract during recertification.
  - Hospital's 340B OPAIS record *must* be updated during recertification to reflect the new contract start and expiration dates.
- ✓ When updating/recertifying qualifying data such as the DSH%, cost reporting period, and file date, the most recently filed Medicare Cost Report (MCR) should be used.
- ✓ Once qualifying data is updated/certified for the parent, all child sites will be updated but still require individual certification. The parent record should be certified first, followed by all child sites.
- ✓ If the data entered does not match what CMS has on file, the covered entity will be required to submit the most recently filed MCR and signed/dated Worksheet S with digital encryption via document upload in the parent record.
- ✓ It is **highly recommended** that CEs have their MCR available during the recertification to ensure accuracy of qualifying data.

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340B OPAIS: Helpful Hints

- ✓ CEs are not eligible for the 340B Program unless listed in the 340B OPAIS.
- ✓ The 340B OPAIS is the primary data source for the Office of Pharmacy Affairs, CEs, manufacturers and wholesalers.
- ✓ Each parent/child site must have a specific 340B ID.
- ✓ Wholesalers will not ship discounted drugs unless the address is an exact match to 340B OPAIS.
- ✓ PCs can complete recertifications, but they are sent to the AO for attestation and submission.
- ✓ AOs and PCs have the ability to upload .pdf and .xls information to meet recertification requirements.
  - No encrypted or password protected files are accepted.
  - Documents uploaded are NOT viewable to the public.
  - CEs will have the ability to add/remove attachments prior to submission to OPA or if OPA returns the request.
  - Once OPA approves the record, CEs will **not** be able to remove the documents.
- ✓ Certifications are not complete until the AO attest and submits to OPA.

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340B OPAIS: Helpful Hints (continued)

- ✓ AOs and PCs can use 340B OPAIS review box to ask questions or send comments and/or messages during recertification.
  - Pay attention to 340B OPAIS review box for communications or document requests when tasks are returned by OPA.
- ✓ Recertifications can be sent back to the AO and PC for clarification or correction.
  - Comments from OPA will be displayed in top left of “My Tasks” screen.
- ✓ The PC may complete any corrections, but the AO must still attest and submit to OPA.
- ✓ AO/PC will receive one email per day containing a chart that summarizes the status of their recertification activities.
- ✓ AO/PC will no longer receive emails once all recert tasks are completed.

Authorizing Official

Who Can or Should be Listed as the CE Authorizing Official?

- ✓ The AO is someone who is authorized to legally bind the CE into a relationship with the Federal Government and has knowledge of the practices and eligible programs at the CEs sites.
- ✓ The AO would be the person responsible for and whom the Federal Government would contact with requests about compliance and HRSA audits.
- ✓ It is **recommended** that someone at the CEO/CFO/President/Vice-President level perform this role.

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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.

Key Takeaways

- ✓ *Entities **should not** wait until the last day to recertify!*
- ✓ Once the CE completes the recertification, the entity **does not** have the ability to adjust the record unless OPA returns the record for correction.
- ✓ If the PC performs a recertification task, the AO **must** attest before it is submitted to HRSA/OPA.
- ✓ HRSA/OPA will only approve the recertification after the AO attests and submits.
- ✓ If a parent/child site is to be set for termination, AO/PC will be required to answer the following questions:
  - Date the site became ineligible
  - Description of reason for termination
  - Last day 340B drugs were or will be purchased under the 340B ID.

We’re Here to Help!

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