

Chapter 6

Recertifying and Making Changes on OPAIS

Health centers' interaction with OPAIS does not end once all clinical and contract pharmacy sites are registered. Rather, it is imperative that health centers ensure their data in OPAIS is kept current at all times, as incorrect information can lead to audit findings, mandatory repayments to manufacturers, and even a loss of 340B eligibility.

The first section of this chapter discusses the need and processes for keeping OPAIS records up-to-date in real time. The second section discusses “recertification” — the requirement for health centers to review and certify to the accuracy of their OPAIS records each year.

A. Changing and Updating Information in OPAIS UPDATED

1. The importance of updating OPAIS in “real-time”

OPAIS should be updated *immediately* any time that there is a change in any of the information it contains. Updating OPAIS should not just be a once-a-year activity, done only during recertification.

As discussed in [Section 5.A](#), OPAIS is the official source of information related to an entity’s participation in the program. Therefore, it is very important that the information contained in OPAIS be current and correct. Incorrect or outdated information in OPAIS can disrupt a health center’s eligibility for 340B pricing — leading to adverse findings during an audit, and required repayments to manufacturers.

For detailed information on how to make changes to OPAIS, refer to:

<https://340bregistration.hrsa.gov/help/external/Resources/PDF%20User%20%20Guides/ExternalUserGuide.pdf>

2. Recent changes to process for updating OPAIS

With the launch of OPAIS in 2017, there were several changes to how “change requests” are handled. For example, some changes that formerly had to be done using a paper form can now be done on-line; also the Primary Contact (PC) can now initiate more change requests, although the Authorizing Official’s (AO) approval is still needed to formally submit the change.

3. More information on how to make changes in OPAIS

Change requests are discussed at length in the OPIAS Use Guide for AOs and PCs, available at <https://340bregistration.hrsa.gov/help/external/Resources/PDF%20User%20%20Guides/ExternalUserGuide.pdf>

4. Hearing from OPA about the status of a change request

Apexus addresses this issue in its FAQ #1564, last updated on April 15, 2015:

Q: When can I expect to hear from HRSA about the status of a change request?

A: HRSA makes every effort to process change requests as soon as possible. Changes take approximately 10 business days to appear in the 340B database, but the actual timeframe will depend on the volume of requests pending at HRSA. Also, the process may take longer if verification from a grant official, program officer or other external authority is required.

5. Special Note about Changes to Medicaid Billing Status

One type of change request merits special attention — changes to the Medicaid carve-in/carve-out status for any registered site. (See [Section 9.B](#) and [9.C](#) for further information.) Even after the A.O. has received an email indicating the request has been approved by OPA, **the change will not immediately be reflected in the Medicaid Exclusion File (MEF)**, as the MEF is not updated automatically, but only on a periodic basis. Therefore, health centers are advised check the MEF regularly and NOT operationalize the change until it is reflected in the MEF.

B. Annual Recertification UPDATED

To ensure accuracy, integrity and transparency, OPA requires every covered entity to “recertify” annually. The recertification process includes reviewing all the health center’s data in OPAIS, and then having the Authorizing Official attest that:

- all information in OPAIS is correct and up-to-date, and
- the health center will comply with all 340B requirements.

As discussed in [Section 5.D.4](#), it is important to thoroughly read the attestation statement and ensure that your FQHC will be able to comply with all the statements and that the Authorizing Official can certify to their truthfulness and accuracy.

Detailed information on how to recertify is available at:

<https://340bregistration.hrsa.gov/help/external/Resources/PDF%20User%20%20Guides/ExternalUserGuide.pdf>

1. What needs to be recertified?

All clinical sites and all contract pharmacy sites must be recertified. (These are the same sites that were initially registered.) See [Section 5.B.2](#) for a discussion of these sites. That includes checking all details, including but not limited to: addresses, ship-to information, bill-to information, Medicaid carve-in/out status, etc. FQHCs should review ALL the information for all their sites on OPAIS and compare this information against EHB, contract pharmacy data, wholesaler accounts, etc.

2. Why recertification is so important UPDATED

There are two reasons why recertification is a very important element of participating in 340B:

- The 340B statute requires covered entities to recertify, and OPA requires that this recertification occur on an annual basis. **Failure to complete the recertification within the specified timeframe will result in removal from the 340B Program for a minimum of 3 months.**

- The recertification process requires that the A.O. attest to health center's compliance with all aspects of the 340B program, and the A.O. will be held accountable for any non-compliance that may occur.

In addition, recertification can also serve as a triggering event for an annual review of the health center's entire 340B program, including policies, procedures, audit results, and reporting mechanisms.

3. When do health centers recertify? UPDATED

Each type of 340B provider (e.g., DSH hospital, FQHC, AIDS service provider) is designated a recertification period according to a schedule set by OPA. Each provider type does not always recertify at the same time each year. *From 2015 through 2018*, FQHCs have recertified in February – March, but there is no guarantee that this schedule will continue in future years.

4. How do FQHCs learn that when it's time to recertify? NEW

OPA will email this information to the Authorizing Official (AO) and Primary Contact (PC) who are listed on the health center's OPAIS record. (See [Section 5.A.4.](#)) This is one of several reasons why it is important to keep your AO and PC information up-to-date on OPAIS.

5. Where is information on how to recertify? NEW

Information for AOs and PCs on how to recertify is available at <https://340bregistration.hrsa.gov/help/external/Resources/PDF%20User%20%20Guides/ExternalUserGuide.pdf>

6. Updating OPAIS to match EHB

As stated in the following FAQ issued by Apexus, during the recertification process, FQHC site names and addresses are *supposed to be* automatically updated to match what is in EHB. However, some FQHCs have found that changes they have made in EHB were not automatically carried over to the OPA database during the next recertification cycle. Therefore, **FQHCs are well-advised to ensure that they proactively update OPAIS when the name and/or address of a clinical site changes.** See [Chapter Six](#) for information on how to update OPAIS.

Note that per the FAQ below, when the OPA database is automatically updated based on changes in EHB, the Authorizing Official will be able to review any changes before they are official.

FAQ ID: 1463

Last Modified: 08/14/2014

Q: How is the HRSA Electronic Handbook system used in the 340B recertification process?

A: Section 330 health center grantee and FQHC look-alike site names and addresses will be updated in the recertification process to match those on file in HRSA's Electronic Handbooks (EHB) system. Authorizing officials will be able to review any changes before they are effective; any major discrepancies should be brought to OPA's attention via e-mail to 340b.recertification@hrsa.gov (please include the affected grant number, 340B ID, and BPHC site ID). OPA encourages covered entities to proactively notify their manufacturer/wholesaler partners of any changes in participation and/or name/address that may result from recertification. Questions on recertification can be directed to ApexusAnswers at 1-888-340-2787 or by e-mail to ApexusAnswers@340bpvp.com.

During recertification, FQHCs should review ALL the information for their sites on OPAIS and compare this information against EHB, contract pharmacy info, wholesaler accounts, etc.

7. New sites cannot be registered during recertification

No new registrations may be submitted as part of the recertification process. This prohibition applies to both clinical sites and contract pharmacy sites.

C. For More Information

- OPA provides various resources and updates on its website. Refer to the July 2015 OPA Update – 340B Covered Entity Recertification, available at <http://www.hrsa.gov/opa/updates/2015/july.html>
- Apexus has a website dedicated to Database Technical Assistance, at <https://www.340bpvp.com/resource-center/faqs/database-technical-assistance>
- The Apexus FAQs at <https://www.340bpvp.com/faqs/>
- OPA has established an email address for recertification issues at 340b.recertification@hrsa.gov.