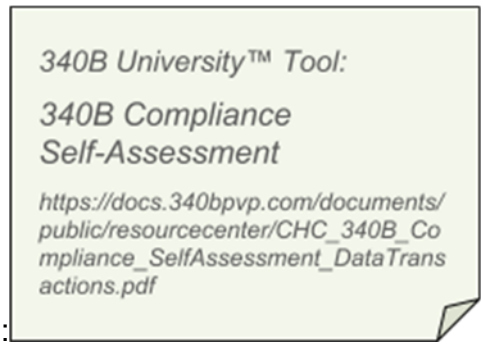
B. Self-Audits:

1. How can FQHCs self-audit?

A FQHC can use a variety of methods to self-audit its 340B Program. These include both:



- independent audits conducted by outside organizations (see Section 13.B.3) and
- internal audits conducted by FQHC staff (see Section 13.B.4)

Apexus 340B University™ website contains a compliance self-assessment tool for community health centers. Refer to Appendix EightAppendix Six for more information about audit procedures and tools that health centers may use.

2. How often should FQHCs self-audit?

FQHCs are well advised to perform some type of self-assessment each month, and more often if possible. Refer to Appendix EightAppendix Six for more information about audit procedures and tools that health centers may use. Also see Section 13.B.4 for information a brief discussion of internal audits.

3. What types of organizations may do our independent audits?

OPA has not established requirements around what types of external organizations may audit either in-house or contract pharmacies. (For example, there is no requirement that the auditor be a CPA.) However, FQHCs are well-advised to:

- Ensure that the entity which conducts the audits is completely independent from the program – aka, has no "skin in the game." (For example, it is not advisable to have the PBM, VIM, or contract pharmacy audit a program in which they are participating.)

- Carefully examine all audit proposals, including the fees being proposed, before selecting an auditor.

To address both of these concerns, some health centers use a "peer audit" process, in which two health centers audit each other's 340B program.

Peer Perspective

"Our health center conducts routine daily audits as part of its quality management program. Pharmacy staff pull a sample of scripts filled each day to check for patient eligibility and other compliance re-quirements. Errors can be corrected through virtual inventory management and the Director of Pharmacy reports the error rate on the department's monthly performance dashboard."

4. Should FQHCs have on-going internal audit procedures?

Absolutely. In addition to establishing a mechanism for regular, periodic independent audits, health centers are well-advised to have standard operating procedures that include on-going "audits" to identify and correct incidents of diversion or duplicate discount when they occur. Most health conduct this type of routine self-audit on at least a weekly or monthly basis. Some audit daily and require the employee who erred to make the correction. This serves as not only a compliance mechanism, but also a teaching tool. See Appendix EightAppendix Six for self-audit tools, including a tool for "testing" the compliance of individual prescriptions.

5. What if we find a problem during a self-audit?

It is the FQHC's responsibility to alert HRSA OPA to a "material" violation or breach. (See Section 13.B.6Section 12.B.6 for a discussion of how to define a "material" breach.) During the annual recertification process, the

FQHC's Authorizing Official attests to the fact that:

FQHCs must self-disclose all material violations to HRSA OPA as soon as reasonably possible.

> "the covered entity acknowledges its responsibility to contact HRSA as soon as reasonably possible if there is any material breach by the covered entity of any of the foregoing (points of 340B compliance).

According to HRSA, a covered entity should self-disclose as soon as reasonably possible after a material violation. Currently there is no standard self-disclosure process.

In situations where there is a material breach (as yet undefined by HRSA – see Section 13.B.6), HRSA has recommended the following steps:

1. FQHC Reports Issue to HRSA – *including the following information*:
   - 340B ID;
   - the violation that occurred;
   - scope of the problem;
   - a corrective action plan (CAP) to fix the problem moving forward;
   - a strategy to inform affected manufactures (if applicable); and
   - a plan for financial remedy if repayment is owed.

   (See Section 13.B.7Section 12.B.7 for information about a tool to assist with self-disclosure.)

2. FQHC Works with Manufacturer
   - The FQHC and the manufacturer work out any necessary financial remedy in good faith. (See Section 13.A.7Section 12.A.7 for a discussion of repayments.)

3. HRSA Reviews Self-Disclosure, *including*:
   - violation information;
   - CAP, ensuring that it fully addresses issues causing the violation;
   - repayment plan and/or completion of plan; and
   - completion of contact to all affected manufacturers.
   - NOTE: HRSA staff will follow-up with the FQHC Authorizing Official if any of the requested information is missing from the self-disclosure.

4. HRSA Closes Self-Disclosure
    - When all criteria under Step #3 are met, the FQHC receives written communication from HRSA that the matter is closed.

6. What constitutes a "material" breach?

As previously discussed, HRSA/OPA requires FQHCs (and other covered entities) to report "material" breaches (aka violations) to HRSA OPA when identified during a self-audit. However, HRSA /OPA has no official definition of a "material" breach. Therefore, FQHCs are well-advised to:

- Develop a definition of what constitutes a "material" breach,
- Develop a process to determine when a breach qualifies as "material" under the FQHC's documented definition, and
- Document this definition and process in their policies and procedures

Apexus has developed a one-page tool to help covered entities to formulate internal policies defining a material breach, and the action to take when a material breach is identified. This "Defining Material Breach Documentation Tool" is available at https://docs.340bpvp.com/documents/public/resourcecenter/Establishing_Material_Breach_Threshold.pdf

7. Is there a tool for self-disclosure?

The 340B Prime Vendor Program, managed by Apexus, has worked with HRSA, covered entities, and manufacturers to develop a suggested tool for the self-disclosure process. The self-disclosure tool includes a sample letter to HRSA, a tool for assessing materiality of a violation, a sample letter to manufacturers, a format for summarizing non-compliance, and a template for a corrective action plan.

340B University™ Tool:

340B Self-Disclosure to HRSA

https://www.apexus.com/solutions/education/340b-tools