



# 340B Compliance Self-Assessment: Self-Audit Process

## A Sample Self-Audit Process for Community Health Centers

**Purpose:** The purpose of this tool is to provide a sample internal audit process to assist participating community health center (CHC) leaders in conducting a self-audit to promote program integrity.

### Instructions:

1. Identify staff/other participants necessary for the self-audit and set a timeframe.
2. Gather data listed in Table 1.
3. Select a sample using the criteria listed in Appendix 1.
4. Perform an assessment of data by following the assessment criteria in Table 1.
5. Ask entity staff participating in the self-audit the 340B audit interview questions in Appendix 2.
6. Review self-audit results and correct any area not meeting the assessment criteria. If you need help, contact Apexus Answers ([ApexusAnswers@340bpvp.com](mailto:ApexusAnswers@340bpvp.com)), who will provide assistance or connect you with a resource that can provide help.
7. Incorporate this practice into organizational/departmental policies and procedures.
8. Repeat at regular intervals and maintain records of all self-assessment activity.



**Are you on the way to  
340B program integrity?**

**This tool will help you find out!**

*This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B program compliance and compliance with all other applicable laws and regulations. Apexus encourages each stakeholder to include legal counsel as part of its program integrity efforts.*

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Table 1. Audit Procedures – Data Assessment

Data	Assessment Criteria
<b>Policies, Entity Eligibility, HRSA 340B Database</b>	
1. All policies and procedures related to 340B	<input type="checkbox"/> Policies include relevant criteria from entity’s 340B pharmacy <a href="#">Policy and Procedure Manual</a> :
2. Data policies for any vendor software—e.g., wholesaler, contract pharmacy	<input type="checkbox"/> Policies are identified, current, and signed.
3. Scope of services for which CHC or FQHC Look-alike (FQHC-LA) status was awarded to the clinic (usually available from the grants officer)	<input type="checkbox"/> Only patients receiving health care services within the scope of services for which CHC funding or FQHC-LA status was awarded to the clinic receive 340B drugs
4. Copy of 340B contract(s) with pharmacies and/or other 340B service provider(s)	<input type="checkbox"/> Contract(s) align with all criteria in the Final Notice Regarding 340B Drug Pricing Program: <a href="#">Contract Pharmacy Services</a>
5. Medicaid ID Number, Provider Number, or NPI for all entity sites billing Medicaid for 340B drugs, and point of contact with state Medicaid agency	<input type="checkbox"/> <a href="#">Medicaid billing</a> information in the HRSA 340B Database for all entity sites (1) is accurate and complete, (2) is based on current state policy requirements, and (3) reflects current actual practices by the entity.
<b>Drug Transactions</b>	
<p>Transaction Samples:</p> <p>6. Ensure that each 340B service area (in-house pharmacy, clinics, contract pharmacy, retail pharmacy, etc.) is included in the sample</p> <p>7. Identify a 6-month continuous time frame within the prior year</p> <p>8. Select two samples of approximately 25 transactions each<sup>1</sup>:</p> <ul style="list-style-type: none"> <li>a. Sample #1: 3–5 high-cost drugs</li> <li>b. Sample #2: Medicaid transactions</li> </ul>	<input type="checkbox"/> Entity maintains records of the individual's health care. <input type="checkbox"/> Individual received health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (referral for consultation) such that responsibility for the care provided remains with the covered entity. <ul style="list-style-type: none"> <li><input type="checkbox"/> Provider–entity relationship is substantiated by contract/employment/other records per clinic site.</li> <li><input type="checkbox"/> Prescription was from a provider NPI matching one on the eligible provider list at the time of prescribing.</li> <li><input type="checkbox"/> If 340B drugs are used for referral prescriptions, a policy is documented and consistently applied.</li> </ul> <input type="checkbox"/> Patient received health care services from the entity that are within the scope of the grant, and at a site that is registered on the HRSA 340B Database. <input type="checkbox"/> If using 340B for Medicaid, wholesaler invoice price for a specific NDC on a specific date matches reported billing cost records for Medicaid (if using 340B for Medicaid). <input type="checkbox"/> Note: <ul style="list-style-type: none"> <li><input type="checkbox"/> May need to convert from units to quantity dispensed.</li> <li><input type="checkbox"/> May need to look at prior quarter's pricing due to delays in quarterly price fluctuations.</li> <li><input type="checkbox"/> Costs may not match if clinic doesn't bill payer at cost; this should be explained.</li> </ul>

<sup>1</sup> See Appendix 1 for suggested data elements.



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Data	Assessment Criteria
	<ul style="list-style-type: none"> <li><input type="checkbox"/> The entity pays for, owns, and receives reimbursement for 340B drugs (especially in a contract pharmacy situation).</li> <li><input type="checkbox"/> If using 340B to bill for Medicaid patients, the entity has information and documentation to support the policy that Medicaid does not seek a rebate on any 340B drug (e.g., Fee-for Service (FFS) or Managed Care (MCO), and physician-administered drugs), including:               <ul style="list-style-type: none"> <li><input type="checkbox"/> Citations from state regulations, policy, provider manual.</li> <li><input type="checkbox"/> Documented discussion/engagement with Medicaid to ensure prevention of duplicate discounts.</li> <li><input type="checkbox"/> If state Medicaid does not have a 340B policy to exclude 340B claims from rebate requests, entity does not use 340B for Medicaid prescriptions.</li> </ul> </li> </ul>
<p>9. Starting inventory balance at beginning of sample timeframe and end of sample timeframe, an accounting of all inventory (340B, GPO, etc.)</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> 340B drugs are not resold or transferred to a non-patient.</li> <li><input type="checkbox"/> The entity is able to provide an accounting for disposition of all inventory in the selected sample.</li> <li><input type="checkbox"/> Expired or unused 340B drugs are returned to the wholesaler or destroyed (not donated/diverted).</li> </ul>



### Appendix 1: Suggested Data Elements for Audit Sample

#### Specific Data Elements for Transactional Sample

1. An identifying number (prescription number or any other prescription tracking number)
2. Date of service (date entity's health care professional provided services to patient, resulting in the 340B Rx)
3. Service type—clinic location associated with health care service (clinic code or other identifying element); this may be two separate data elements (clinical service received location and prescription dispensing location)
4. Date and time the drug was dispensed/administered
5. Clinic identification number (often billing number, used to look up insurer of record)
6. Item number (used in identifying actual drug)
7. NDC number
8. Item description (often from pharmacy system)
9. Prescriber name (prescribing health care professional)
10. 340B price paid
11. Drug charge (entity's charge—full price, the amount billed to any insurer, including co-pays)
12. Dispensing fee (if any)
13. Amount paid by the payer
14. Payer (private third party, cash, Medicare, Medicaid, etc.)
15. Medicaid ID (transaction number and/or other identifying number) Identify staff/other participants necessary for the self-audit and set a timeframe.

#### General Data Elements

1. Proof of provider–entity relationship (contract/employment records, referral documentation, other)
2. Eligible provider list for entity (including credentialed and per diem: name, NPI, date of eligibility/termination, assigned clinics and contracts/employment/referral/other documents)
3. Clinic wholesaler account(s) list, description of accounts (340B, etc.)
4. NCPDP number (if applicable, for retail pharmacies)
5. A list of clinics eligible for 340B
6. Current drug price list



### Appendix 2: Sample 340B Staff Interview Questions

#### Financial Management

1. What is the price billed to Medicaid for 340B drugs? (340B/Acquisition (AAC)/other)
2. How did you identify areas eligible for 340B?
3. What level of confidence do you have in your entity's compliance with the 340B program?
4. What questions do you have about the 340B program?
5. Describe reports you use to ensure that your entity complies with preventing duplicate discounts.
6. Describe 340B internal audits performed

#### Pharmacy Director

1. How often are your 340B policies/procedures updated?
2. What level of confidence do you have in your entity's compliance with the 340B program?
3. Describe 340B internal audits performed.
4. Who has access to update the entity's current health care professional list (for 340B)?
5. Explain how you handle referral prescriptions.
6. What are your major compliance concerns?
7. Describe the three most critical reports you review concerning 340B.
8. Describe any contract pharmacy tracking software. Walk through what you do when there is a discrepancy in data.

#### Purchasing Coordinator

1. How many wholesaler accounts do you purchase from?
2. What is your role in maintaining 340B compliance?
3. Describe the process for transferring items between 340B and non-340B (if applicable) on an emergency basis.
4. For a multi-dose item, how is the product accumulation accounted for, regarding replenishment of a full package size?
5. Expired medications:
  - a. What is the process for their disposition?
  - b. What records do you provide to the return company to ensure that the 340B price is credited?

#### Administration

1. What level of confidence do you have in your entity's compliance with the 340B program?
2. What is the intent of the 340B program, and how does your entity use 340B program savings?