



**Purpose:** The purpose of this tool is to provide a sample internal 340B audit process to assist disproportionate share hospital (DSH) leaders subject to the GPO Prohibition in conducting a self-audit to promote 340B program integrity.

### Instructions:

1. Identify staff/other participants necessary for the self-audit and set a timeframe.
2. Gather the data listed in Table 1.
3. Select a sample using the criteria listed in Appendix 1.
4. Perform an assessment of the data by following the assessment criteria in Table 1.
5. Ask the 340B audit interview questions in Appendix 2 to entity staff participating in the self-audit.
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 program <a href="#">Policy and Procedure Manual</a> .
2. Data policies for any vendor software—e.g., wholesaler, split-billing	<input type="checkbox"/> Policies are identified, current, and signed.
3. Most recently filed Medicare cost report worksheets: <ul style="list-style-type: none"> <li>• A</li> <li>• C</li> <li>• E, Part A</li> <li>• S</li> <li>• S2</li> </ul>	<input type="checkbox"/> <u>Worksheet A</u> : All clinics participating in 340B are listed as reimbursable. <input type="checkbox"/> <u>Worksheet C</u> : All clinics participating in 340B have associated outpatient charges (column 7). <input type="checkbox"/> <u>Worksheet E, Part A</u> : Line 33 shows a number >11.75%. <input type="checkbox"/> <u>Worksheet S</u> : The signature block showing the official time/date of submission should be consistent with the addition or removal of any clinics from the HRSA 340B Database. <input type="checkbox"/> <u>Worksheet S2</u> : Line 21 should be consistent with the type of hospital control indicated at registration, Lines 3–19 will list sites that are on the cost report with a unique identifier (e.g., rural center/skilled nursing).
4. Copies of any contracts with state or local government to provide health care services to low-income individuals	<input type="checkbox"/> Contract is signed by an official authorized to bind the government. <input type="checkbox"/> The original date of the agreement predates the 340B registration date on the HRSA 340B Database (or is effective at date of registration). <input type="checkbox"/> The contract is for the care of indigent patients and is in force.
5. 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>
6. 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 is (1) accurate and complete, (2) based on current state policy requirements, and (3) reflects current actual practices by the entity.
<b>Drug Transactions</b>	
<b>Transaction Samples:</b> 7. Ensure that each 340B service area (main pharmacy, outpatient clinics, contract pharmacy, retail pharmacy, etc.) is included in the sample. 8. Identify a 6-month continuous time frame within the prior year. 9. Select two samples of approximately 25 transactions each <sup>1</sup> : <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"/> The entity maintains records of the patient’s health care. <input type="checkbox"/> The patient 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 (e.g., 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"/> The provider–entity relationship is substantiated by <a href="#">contract/employment/other records</a> per clinic site.</li> </ul>

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



Data	Assessment Criteria
	<ul style="list-style-type: none"> <li><input type="checkbox"/> The prescription was from a provider NPI matching 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 accessible and in operation.</li> <li><input type="checkbox"/> The patient had outpatient status at the time of the 340B drug administration/dispensing.</li> <li><input type="checkbox"/> The patient received health care services from the parent entity or at an outpatient clinic that is reimbursable on the hospital's most recently filed Medicare cost report and registered on the HRSA 340B Database.</li> <li><input type="checkbox"/> A group purchasing organization (GPO) was not used to purchase covered outpatient drugs in 340B registered areas per policy release criteria <a href="#">here</a>.</li> <li><input type="checkbox"/> If using 340B for Medicaid, the wholesaler invoice price for a specific NDC on a specific date matches the reported billing cost from dispensing/administration records for Medicaid.        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 the prior quarter's pricing due to delays in quarterly price fluctuations.</li> <li><input type="checkbox"/> Costs may not match if the DSH doesn't bill payer at cost; this should be explained.</li> </ul> </li> <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, or provider manual</li> <li><input type="checkbox"/> Documented discussion/engagement with Medicaid to ensure prevention of duplicate discounts</li> </ul> </li> <li><input type="checkbox"/> If state Medicaid does not have a 340B policy to exclude 340B claims from rebate requests, the entity does not use 340B for Medicaid prescriptions.</li> </ul>



## 340B Compliance Self-Assessment: Self-Audit Process A Quick Self-Assessment for DSH Leaders

Data	Assessment Criteria
10. Starting inventory balance at beginning of sample timeframe and end of sample timeframe, an accounting of all inventory (340B, GPO, non-GPO/WAC, etc.)	<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"/> The DSH has separate purchasing usage/records for 340B and GPO.</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. Admission and discharge date and time (source might be ADT system or other hospital data source)
3. Date of service (date entity's health care professional provided services to patient, resulting in the 340B Rx)
4. Service type—hospital 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)
5. Date and time the drug was dispensed/administered
6. Hospital identification number (often hospital billing number, used to look up insurer of record)
7. Item number (used in identifying actual drug)
8. NDC number
9. Item description (often from pharmacy system)
10. Prescriber name (prescribing health care professional)
11. 340B price paid
12. Drug charge (hospital's charge—full price, the amount billed to any insurer, including co-pays)
13. Dispensing fee (if any)
14. Amount paid by the payer
15. Payer (private third party, cash, Medicare, Medicaid, etc.)
16. Medicaid ID (transaction number and/or other identifying number)

#### 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. Hospital wholesaler account(s) list, description of accounts (340B, inpatient GPO, Non-GPO/WAC, etc.)
4. NCPDP number (if applicable, for retail pharmacies)
5. Description of hospital definitions used for outpatient and covered outpatient drugs
6. A list of hospital centers eligible for 340B
7. Current drug price list



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

#### Financial Management

1. On forms UB-04/837I and CMS-1500/837P, what is the price billed to Medicaid? (340B/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 and 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. How do you define "outpatient" at your institution for 340B purposes?
6. Explain how you handle referral prescriptions.
7. What are your major compliance concerns?
8. Describe the three most critical reports you review concerning 340B.
9. How do you know that your independent agreements on pharmaceuticals, IV solutions, and contrast media do not violate the GPO Prohibition?
10. Describe your split-billing software. Walk through what you do when there is a discrepancy in data.
11. What types of wholesaler accounts do you have for outpatient drug purchases?

#### 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 GPO 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?

#### Hospital 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?