A Sample Self- Audit Process for DSHs

Purpose: The purpose of this tool is to provide a sample internal audit process to assist participating DSH leaders in conducting a self-audit in order to promote program integrity.

Instructions:

1. Identify staff/other participants necessary for the self-audit and set time frame.
2. Gather data listed in Table 1.
3. Select sample using criteria listed in Appendix 1.
4. Perform assessment of data by following the assessment criteria in Table 1.
5. Ask entity staff participants in the self-audit the 340B audit interview questions in Appendix 2.
6. Correct any area not meeting the assessment criteria. If you need help, contact Apexus Answers (ApexusAnswers@340bpvp.com) and they will provide assistance or connect you with a resource that can provide help.
7. Incorporate this practice into organizational/departmental policy 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!

Table 1. Audit Procedures – Data Assessment	
Data	**Assessment Criteria**
Policies, Entity Eligibility, OPA Database	
1. All policies and procedures related to 340B	☐ Policies include relevant criteria from DSH 340B Comprehensive Policy and Procedure Manual: https://www.340bpvp.com/resource-center/other-resources/standard-operating-procedures/
2. Data policies for any vendor software, i.e., Wholesaler, split-billing, etc.	☐ Policies are identified, current, and signed.
3. Most recently filed Medicare Cost Report Worksheets: • A • C • E, Part A • S • S2	☐ Worksheet A: all clinics participating in 340B are listed as reimbursable (typically lines 50-118). ☐ Worksheet C: all clinics participating in 340B have associated outpatient costs. ☐ Worksheet E-Part A: line 33 shows a number >11.75%. ☐ Worksheet S: the signature block showing the official time/date of submission should be consistent with the addition or removal of any clinics from the OPA database. ☐ Worksheet S2: 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 (i.e., rural center/skilled nursing).
4. Copies of any contracts with state or local government to provide health care services to low income individuals	☐ Contract is signed by an official authorized to bind the government. ☐ The original date of the agreement pre-dates (or effective at date of registration) the 340B registration date on the OPA database. ☐ 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)	☐ Contract(s) align with all criteria in the Final Notice Regarding 340B Drug Pricing Program: Contract Pharmacy Services http://www.hrsa.gov/opa/programrequirements/federalregisternotices/contractpharmacyservices030510.pdf.
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	☐ Medicaid billing information in the OPA database for all entity sites is accurate and complete, based upon state policy, and reflects current practices by the entity.

Drug Transactions	

7. Transaction Samples:
8. Ensure that each 340B service area is included in the sample (main pharmacy, outpatient clinics, contract pharmacy, retail pharmacy, etc.)
9. Identify a 6 month continuous time frame within the prior year
10. Select two samples, of approximately 25 transactions each[1]:
   a. SAMPLE #1: 3-5 high cost drugs
   b. SAMPLE #2: Medicaid transactions
	☐ Entity maintains records of the individual's health care.
	☐ 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 (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity.
	   ☐ Provider-entity relationship is substantiated by contract/employment/other records per clinic site.
	   ☐ Prescription was from Provider NPI matching the eligible provider list at the time of prescribing.
	   ☐ If 340B drugs are used for referral prescriptions, a policy is accessible and in operation.
	☐ Individual had outpatient status at 340B administration/dispensing.
	☐ Patient received health care services from clinics reimbursable on the hospital's most recently filed Medicare cost report (and registered on the OPA database, for sites outside the four-walls of the hospital).
	☐ A GPO was not used to purchase covered outpatient drugs in 340B registered areas per Policy Release criteria here.
	☐ Wholesaler invoice price for a specific NDC on a specific date matches reported billing cost from dispensing/administration records for Medicaid (if using 340B for Medicaid).
	Note:
	   ☐ May need to convert from units to quantity dispensed;
	   ☐ May need to look at prior quarter's pricing due to delays in quarterly price fluctuations; and/or
	   ☐ Costs may not match if DSH doesn't bill payer at cost, and this should be explained.
	☐ The entity pays for, owns and receives reimbursement for 340B drugs (esp. in a contract pharmacy situation).
	☐ Medicaid did not seek a rebate on a 340B drug.
	☐ State Medicaid Pharmacy Director(s) verify (in writing/via email, entity maintains record of contact with Medicaid):
	
	   ☐ Claims from sample were billed per Medicaid's requirements and in a consistent manner with the entity's listing in the Medicaid Exclusion File, unless special arrangement has been made with OPA-entity-Medicaid.
	   ☐ State Medicaid's method of determination for whether or not to collect rebates on entity's claims (including

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[1] See Appendix 1 for suggested data elements

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	managed care, physician administered drugs, dual eligible patients, or in any other circumstances).
	☐ Entity has had satisfactory discussion/engagement with Medicaid to ensure prevention of duplicate discounts.
	☐ If State Medicaid does not have a 340B policy to exclude 340B claims from rebate requests, entity does not use 340B for Medicaid prescriptions.
11. Starting inventory balance at beginning of sample timeframe and end of sample timeframe, an accounting of all inventory (340B, GPO, non-GPO/WAC, etc.)	☐ 340B drugs are not resold or transferred to a non-patient ☐ Entity is able to provide an accounting for disposition of all inventory in the selected sample. ☐ DSH has separate purchasing usage/records for 340B and GPO. ☐ Expired or unused 340B drugs are returned to the wholesaler or destroyed (not donated/diverted).

Appendix 1: Suggested Data Elements for Audit Sample

<u>Specific Data Elements for Transactional Sample</u>

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 2 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 # (used in identifying actual drug)
8. NDC #
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 3rd party, cash, Medicare, Medicaid, etc.)
16. Medicaid ID (transaction number and/or other identifying number)

<u>General Data Elements</u>

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 (if applicable, for retail pharmacies)
5. Description of hospital definitions used for outpatient and covered outpatient drug
6. A list of hospital centers eligible for 340B
7. Current drug price list

Appendix 2. Sample 340B Staff Interview Questions

<u>Financial Management</u>

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 your entity complies with preventing duplicate discounts.
6. Describe 340B internal audits performed.

<u>Pharmacy Director</u>

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. 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 3 most critical reports you review concerning 340B.
9. How do you know your independent agreements on pharmaceuticals, IV solutions, and Contrast media do not violate the GPO Prohibition?
10. Describe your split-billing software. Walk me through what you do when there is a discrepancy in data.
11. What types of wholesaler accounts do you have for outpatient drug purchases?

<u>Purchasing Coordinator</u>

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 340B price is credited?

<u>Hospital Administration</u>

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 you entity use 340B Program savings?