



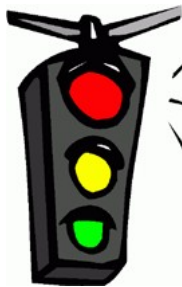
340B Compliance Self-Assessment: Policy

A Quick Self-Assessment for DSH Leaders

Purpose: The purpose of this quick assessment tool is to enable participating disproportionate share hospital (DSH) leaders to determine a basic level of compliance for their 340B pharmacy operations.

Instructions: Read the question under the column “Does the Entity...”

1. Select the answer that best reflects the activities at your hospital.
2. Make notes for further investigation or program changes.
3. Use this general key to help understand the estimated level of program integrity for the answer you selected.



Low program integrity; program change recommended

Moderate program integrity; additional investigation and possible program change recommended












High program integrity

Does the Entity...	Answer, to Estimate Your Level of 340B Integrity		Notes
Patient Definition			
<ul style="list-style-type: none"> • Have a relationship with the individual and maintain records of the individual's health care? • Provide health care services from a health care professional: <ul style="list-style-type: none"> ▪ Employed by the entity? ▪ Under contractual or other arrangements (e.g. referral for consultation) with the entity? • Maintain responsibility for the patient's health care services? 	●	Some patients receiving 340B drugs do not meet part or all of the patient definition.	
	●	Uncertain; needs investigation.	
	●	All patients receiving 340B drugs clearly meet all requirements of the patient definition.	
Registration			
<ul style="list-style-type: none"> • Have all information completely and accurately reflected in the HRSA 340B and PVP databases? 	●	No.	
	●	Uncertain; needs investigation.	
	●	The entity has documented evidence to support complete and accurate HRSA and PVP database information, and a policy to regularly update the information with HRSA when changes occur.	



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Does the Entity...	Answer, to estimate your level of 340B Integrity	Notes
Medicaid/Duplicate Discounts		
<ul style="list-style-type: none"> Take action to ensure that no duplicate discounts are generated? Bill Medicaid appropriately? 	<ul style="list-style-type: none">  The entity's Medicaid Exclusion File information is not accurate and/or Medicaid billing does not match Exclusion File or state policy requirements.  The entity's Medicaid Exclusion File information is accurate, but the entity does not know if Medicaid requests duplicate discounts on the entity's claims and/or does not know if it bills Medicaid according to state policy requirements.  The entity is certain there are no duplicate discounts associated with entity's claim. The entity has: <ul style="list-style-type: none"> Accurate Medicaid Exclusion File information. Verified it bills Medicaid according to state requirements. Understands when Medicaid seeks rebates and has a verified system to ensure no duplicate discounts. 	
Outpatient Clinics		
<p>Use 340B only in clinics that:</p> <ul style="list-style-type: none"> Appear as reimbursable on the most recently filed Medicare cost report? Are registered and listed on the HRSA 340 Database? Are integral parts of the hospital? Use 340B for patients who meet the 340B patient definition? 	<ul style="list-style-type: none">  There is 340B use in clinics not on the cost report, not registered in the HRSA database, and/or in clinics that are not an integral part of the hospital.  Uncertain; needs investigation.  The entity has documented evidence to support all criteria for 340B use in outpatient clinics. 	
Group Purchasing Organization (GPO), "Quick"		
<ul style="list-style-type: none"> Have appropriate accounts set up in its system including a non-340B / non-GPO account for ineligible outpatients Use only non-GPO accounts to purchase drugs for outpatients? 	<ul style="list-style-type: none">  Entity does not have/use an outpatient GPO account, unless the four criteria listed in GPO, Part II (below) are met.  	
Group Purchasing Organization (GPO) Exclusion, Part I		
<p>Use a GPO for covered outpatient drugs in any of the following circumstances:</p> <ul style="list-style-type: none"> In a HRSA-registered (or within entity's four walls) participating clinic for 340B ineligible patients or when 340B is not available? Via a contract pharmacy? 	<ul style="list-style-type: none">  Yes; a GPO is used sometimes (e.g., for 340B-ineligible outpatients).  Uncertain; needs investigation.  No GPO is used in any of these situations. 	



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Group Purchasing Organization (GPO), Exclusion, Part II		
<p>Use a GPO for covered outpatient drugs only in certain off-site outpatient hospital facilities that meet all the following criteria:</p> <ol style="list-style-type: none"> 1. Are located at a different physical address than the parent; 2. Are not registered on the HRSA 340B Database as participating in the 340B program; 3. Purchase drugs through a separate pharmacy wholesaler account than the 340B participating parent; and 4. The hospital maintains records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not used or otherwise transferred to the parent hospital or any outpatient facilities registered on the HRSA 340B Database? 	<p> No, the entity uses a GPO for covered outpatient drugs in facilities that do not meet all four criteria.</p> <p> Uncertain; needs investigation.</p> <p> Yes, the entity uses a GPO for covered outpatient drugs only in facilities that meet all four criteria listed.</p>	
Inventory Management/Record Keeping		
<ul style="list-style-type: none"> • Maintain separate, auditable records for all 340B purchasing and dispensing? • Regularly evaluate 340B utilization reports to catch and correct problems? 	<p> Some or all of the following apply to the entity:</p> <ul style="list-style-type: none"> ▪ No way to separate 340B records from other inventory. ▪ No regular evaluation of 340B utilization. ▪ Does not regularly at the 11-digit NDC level. ▪ Undertakes re-characterization of claims in a manner that is not transparent to the manufacturer. <p> Uncertain; needs investigation.</p> <p> The entity has documented evidence to support both criteria for inventory management.</p>	

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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