



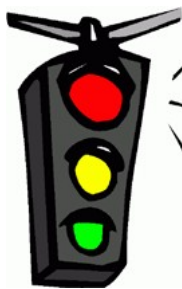
340B Compliance Self-Assessment: Policy

A Quick Self-Assessment for Community Health Center Leaders

Purpose: The purpose of this quick assessment tool is to enable participating community health center (CHC) leaders to determine a basic level of compliance for selected areas of 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 health center.
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 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? • Deliver health care services consistent with the entity’s range of services for which grant funding or status has been provided? 	●	Some patients receiving 340B drugs do not meet part or all of the patient definition.	
	●	Uncertain; needs investigation.	
	●	All patients receiving 340B drugs meet all requirements of the patient definition.	
Registration			
<ul style="list-style-type: none"> • Have all information completely and accurately reflected in the HRSA 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"> Maintain accurate information in the Medicaid Exclusion File? Bill Medicaid appropriately? Take action to ensure that no duplicate discounts are generated? 	<p> The entity's Medicaid Exclusion File information is not accurate and/or Medicaid billing is not appropriate.</p> <p> 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.[DC1]</p> <p> The entity is certain that there are no duplicate discounts associated with the entity's claim. The entity has:</p> <ul style="list-style-type: none"> Accurate Medicaid Exclusion File information. Verified it bills Medicaid according to state requirements. <p>Understands when Medicaid seeks rebates and has a verified system to ensure no duplicate discounts.</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> 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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