



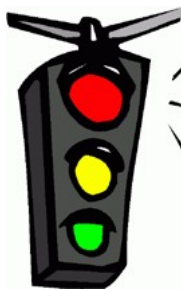
# 340B Compliance Self-Assessment: Policy

## A Quick Self-Assessment for Family Planning Program Leaders

**Purpose:** The purpose of this quick assessment tool is to enable participating family planning (Title X grantee) 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
<b>Patient Definition</b>			
<ul style="list-style-type: none"> <li>• Have a relationship with the individual and maintain records of the individual’s health care?</li> <li>• Provide health care services from a health care professional:               <ul style="list-style-type: none"> <li>▪ Employed by entity?</li> <li>▪ Under contractual or other arrangements (e.g., referral for consultation) with the entity?</li> </ul> </li> <li>• Maintain responsibility for the patient’s health care services?</li> <li>• Deliver health care services consistent with the entity’s range of services for which grant funding or status has been provided?</li> </ul>	<ul style="list-style-type: none"> <li>● Red</li> <li>● Yellow</li> <li>● Green</li> </ul>	<ul style="list-style-type: none"> <li>Some patients receiving 340B drugs do not meet part or all of the patient definition.</li> <li>Uncertain; needs investigation.</li> <li>All patients receiving 340B drugs meet all requirements of the patient definition.</li> </ul>	
<b>Registration</b>			
Have all information completely and accurately reflected in the HRSA 340B and PVP databases?	<ul style="list-style-type: none"> <li>● Red</li> <li>● Yellow</li> <li>● Green</li> </ul>	<ul style="list-style-type: none"> <li>No.</li> <li>Uncertain; needs investigation.</li> <li>The entity has documented evidence to support complete and accurate HRSA and PVP database information, and a plan to regularly update the information with HRSA when changes occur.</li> </ul>	



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Does the Entity...	Answer, to estimate your level of 340B Integrity	Notes
<b>Medicaid/Duplicate Discounts</b>		
<ul style="list-style-type: none"> <li>Take action to ensure that no duplicate discounts are generated?</li> <li>Bill Medicaid appropriately?</li> </ul>	<p> The entity's Medicaid Exclusion File information is not accurate and/or Medicaid billing does not match Exclusion File or state policy requirements.</p> <p> The entity's Medicaid Exclusion File information is accurate, but the entity does not know whether Medicaid requests duplicate discounts on the entity's claims and/or does not know whether it bills Medicaid according to state policy requirements.</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"> <li>Accurate Medicaid Exclusion File information.</li> <li>Verified that it bills Medicaid according to state requirements.</li> </ul> <p>The entity understands when Medicaid seeks rebates and has a verified system to ensure that there are no duplicate discounts.</p>	
<b>Inventory Management/Record Keeping</b>		
<ul style="list-style-type: none"> <li>Maintain separate, auditable records for all 340B purchasing and dispensing?</li> <li>Regularly evaluate 340B utilization reports to catch and correct problems?</li> </ul>	<p> Some, or all, of the following apply to the entity:</p> <ul style="list-style-type: none"> <li>There is no way to separate 340B records from other inventory.</li> <li>There is no regular evaluation of 340B utilization.</li> <li>It regularly replenishes with generics or at the 9-digit NDC level.</li> <li>It places 340B orders based on recharacterization of claims in a manner that is not transparent to the manufacturer.</li> </ul> <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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