



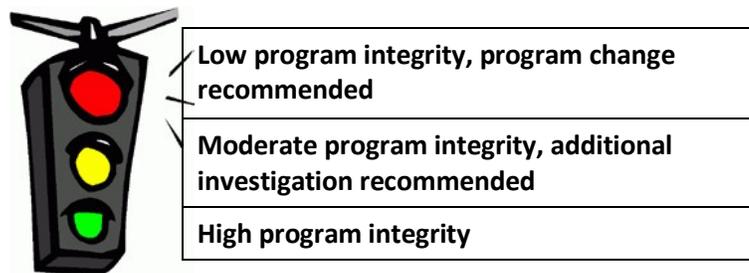
# 340B Compliance Self-Assessment: Policy

## 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 Your Entity...?”

1. Select the answer that best reflects the activities at your organization.
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:



*This tool, written to align with OPA policy, is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by the Office of Pharmacy Affairs 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 their program integrity efforts.*

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**Are you on the way to 340B  
program integrity?**

**This tool will help you find out!**





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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 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>● Some patients receiving 340B drugs do not meet part or all of the patient definition</li> <li>● Unsure; needs investigation</li> <li>● All patients receiving 340B drugs meet all requirements of the patient definition</li> </ul>	
<b>Medicaid/Duplicate Discounts</b>		
<ul style="list-style-type: none"> <li>• Maintain accurate information in the Medicaid Exclusion File?</li> <li>• Bill Medicaid appropriately?</li> <li>• Take action to ensure that no duplicate discounts are generated?</li> </ul>	<ul style="list-style-type: none"> <li>● The entity's Medicaid Exclusion File information is not accurate and/or Medicaid billing is not appropriate</li> <li>● The entity's Medicaid Exclusion File information is accurate, but the entity does not know if Medicaid requests duplicate discounts on entity's claims and/or does not know if it bills Medicaid appropriately</li> <li>● Entity is certain there are no duplicate discounts associated with entity's claims. The entity has:               <ul style="list-style-type: none"> <li>• Accurate Medicaid Exclusion File information</li> <li>• Verified it bills Medicaid appropriately</li> </ul>               An understanding of what triggers Medicaid to seek a rebate and verified a system is in place to ensure no duplicate discounts             </li> </ul>	



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Does the entity...	Answer, to estimate your level of 340B integrity	Notes
<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>	<ul style="list-style-type: none"> <li>Some or all of the following apply to the entity:               <ul style="list-style-type: none"> <li>Places 340B orders based upon recharacterization of claims in a manner that is not transparent to the manufacturer</li> <li>No way to separate 340B records from other inventory</li> <li>No regular evaluation of 340B utilization</li> <li>Regularly replenishes with generics or at the 9 digit NDC level</li> </ul> </li> <li>Unsure; needs investigation</li> <li>Entity has documented evidence to support both criteria for inventory management</li> </ul>	
<b>Registration</b>		
<ul style="list-style-type: none"> <li>Have all information completely and accurately reflected in the Office of Pharmacy Affairs (OPA) and PVP databases?</li> </ul>	<ul style="list-style-type: none"> <li>No</li> <li>Unsure; needs investigation</li> <li>Entity has documented evidence to support complete and accurate OPA and PVP database information, and a plan to regularly update the information with OPA when changes occur</li> </ul>	