



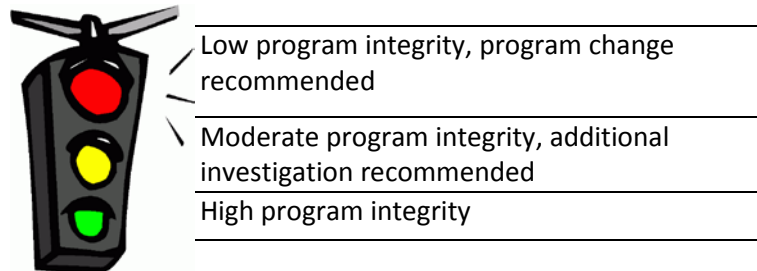
340B Compliance Self-Assessment: Policy

A Quick Self-Assessment for DSH Leaders

Purpose: The purpose of this quick assessment tool is to enable participating DSH leaders to determine a basic level of compliance for selected areas of their 340B pharmacy operations.

Instructions:

1. Read the question under the column "Does Your Entity...?"
2. Select the answer that best reflects the activities at your hospital.
3. Make notes for further investigation or program changes.
4. 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
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 entity – under contractual or other arrangements (e.g. referral for consultation) with entity? • Maintain responsibility for the patient's health care services? 	<ul style="list-style-type: none"> ● Some patients receiving 340B drugs do not meet part or all of the patient definition. ● Unsure; needs investigation. ● All patients receiving 340B drugs meet all requirements of the patient definition. 	
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 is not appropriate. ● 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. ● Entity is certain there are no duplicate discounts associated with entity's claims. The entity has: <ul style="list-style-type: none"> • Accurate Medicaid Exclusion File information; • Verified it bills Medicaid appropriately; and • An understanding of what triggers Medicaid to seek a rebate and verified a system is in place to ensure no duplicate discounts. 	



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Does the entity...	Answer, to estimate your level of 340B integrity	Notes
Group Purchasing Organization, "Quick"		
<ul style="list-style-type: none"> What outpatient accounts do you have? How do you purchase drugs for ineligible outpatients? 	<ul style="list-style-type: none"> Entity does not have an outpatient GPO account, unless 4 criteria listed in GPO, Part II below, are met. Entity does not use a GPO for ineligible outpatients, unless 4 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 OPA-registered (or within entity's 4 walls) participating clinics 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 (i.e. for 340B ineligible outpatients). Unsure; needs investigation. No GPO is used in any of these situations. 	
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 of the following criteria?</p> <ol style="list-style-type: none"> Are located at a different physical address than the parent; Are not registered on the OPA 340B database as participating in the 340B Program; Purchase drugs through a separate pharmacy wholesaler account than the 340B participating parent; and The hospital maintains records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not utilized or otherwise transferred to the parent hospital or any outpatient facilities registered on the OPA 340B database. 	<ul style="list-style-type: none"> No, we use a GPO for covered outpatient drugs in facilities that do not meet all criteria. We are unsure; needs investigation. Yes, we use a GPO for covered outpatient drugs only in facilities that meet all criteria listed. 	



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Does the entity...	Answer, to estimate your level of 340B integrity	Notes
Outpatient Clinics		
Use 340B only in clinics that: <ul style="list-style-type: none"> • Appear as reimbursable on the most recently filed Medicare Cost Report? • Are integral parts of the hospital? • Use 340B for patients that meet the 340B patient definition? 	<ul style="list-style-type: none"> ● There is 340B use in clinics not on the cost report and/or in clinics that are not an integral part of the hospital. ● We are unsure; needs investigation. ● Entity has documented evidence to support all criteria for 340B use in outpatient clinics. 	
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? 	<ul style="list-style-type: none"> ● Some or all of the following apply to the entity: <ul style="list-style-type: none"> • Places 340B orders based upon recharacterization of claims in a manner that is not transparent to the manufacturer; • No way to separate 340B records from other inventory; • No regular evaluation of 340B utilization; and/or • Regularly replenishes with generics or at the 9 digit NDC level. ● Unsure; needs investigation ● Entity has documented evidence to support both criteria for inventory management 	
Registration		
<ul style="list-style-type: none"> • Have all information completely and accurately reflected in the HRSA 340B and PVP databases? 	<ul style="list-style-type: none"> ● No. ● Unsure; needs investigation. ● 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. 	