



# 340B Compliance Self-Assessment: Mixed-Use Areas Self-Auditing Tool for Hospitals Subject to the GPO Prohibition

**Purpose:** The purpose of this tool is to provide a checklist of review points that are necessary for the implementation of a compliant 340B pharmacy operation.

**Instructions:**

1. Perform at least quarterly.
2. Target at least 25 charges per quarter and review the data elements below for each charge.

Data Element	Check	Notes
<b>1. Account Setup</b>		
<ul style="list-style-type: none"> <li>The terminal accumulator is set as non-GPO/WAC.</li> <li>The initial purchases were made via the WAC account.</li> </ul>	<input type="checkbox"/>  <input type="checkbox"/>	
<b>2. Charge Capture</b>		
<ul style="list-style-type: none"> <li>The date of service matches the medication dispensing date (e.g., if accumulated to an inpatient, then the discharge date should occur after the dispense date).</li> <li>Patient status at time of dispense or administration (charge on dispense [COD] vs. charge on administration [COA]) matches the accumulation account (e.g., inpatient accumulated in GPO account, eligible outpatient accumulated in 340B account, and non-eligible outpatient accumulated in non-GPO/WAC account).</li> <li>The data sent to split-billing software is accurate.</li> </ul>	<input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	
<b>3. Accumulation</b>		
<ul style="list-style-type: none"> <li>The 11-digit NDCs accumulated match the 11-digit NDCs dispensed.</li> <li>The correct quantity of medication was accumulated (e.g., were 60 tablets accumulated as 2 packages of 30 tablets?).</li> <li>Waste that is not associated with patient data was not accumulated in the GPO or 340B accounts.</li> </ul>	<input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	
<b>4. Order Placement</b>		
<ul style="list-style-type: none"> <li>The order placement reduced the accumulators by the appropriate quantity.</li> <li>Accumulators were manually adjusted for manual orders.</li> </ul>	<input type="checkbox"/>  <input type="checkbox"/>	
<b>5. Order Reconciliation upon Receipt</b>		
<ul style="list-style-type: none"> <li>The quantities received were the same as the quantities ordered. If not, the accumulators were adjusted accordingly.</li> <li>The 11-digit NDCs received match the 11-digit NDCs ordered.</li> </ul>	<input type="checkbox"/>  <input type="checkbox"/>	

Verification performed by: \_\_\_\_\_ Date: \_\_\_\_\_

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 all stakeholders to include legal counsel as part of their program integrity efforts.

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