



340B Compliance Self-Assessment: Outpatient and Sub-WAC 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
1. Account Setup		
<ul style="list-style-type: none"> The terminal accumulator is set as non-GPO/WAC. The initial purchases were made via the WAC account. 	<input type="checkbox"/> <input type="checkbox"/>	
2. Charge Capture		
<ul style="list-style-type: none"> The patient had an encounter within the previous ____ months of medication dispense date at an eligible clinic registered on the HRSA 340B Database. Patient eligibility (determined by patient definition below) at time of dispensation matches the accumulation account. <ul style="list-style-type: none"> <input type="checkbox"/> 340B account if patient 340B eligible <input type="checkbox"/> Non-GPO/WAC account if patient 340B ineligible The information entered into the pharmacy system matches the data on the prescription hard copy. 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
3. Patient Definition		
<p>The patient meets the patient definition if accumulated in the 340B account.</p> <ul style="list-style-type: none"> The entity has a relationship with the patient and the entity maintains records of the patient's health care. The patient receives health care services from a health care professional: <ul style="list-style-type: none"> <input type="checkbox"/> Employed by the entity OR <input type="checkbox"/> Under contractual or other arrangements (e.g., referral for consultation) with the entity If health care provided under referral for consultation, HRSA-recommended documentation is accessible: <ul style="list-style-type: none"> <input type="checkbox"/> Request for referral <input type="checkbox"/> Summary of the referral visit The entity maintains responsibility for the patient's health care services. 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
4. Accumulation		
<ul style="list-style-type: none"> The 11-digit NDCs accumulated match the 11-digit NDCs dispensed. The correct quantity of medication was accumulated (e.g., were 60 tablets accumulated as 2 packages of 30 tablets?). Waste that is not associated with patient data was not accumulated in the GPO or 340B accounts. 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
5. Order Placement		
<ul style="list-style-type: none"> The order placement reduced the accumulators by the appropriate quantity. Accumulators were manually adjusted for manual orders. 	<input type="checkbox"/> <input type="checkbox"/>	
6. Order Reconciliation upon Receipt		
<ul style="list-style-type: none"> The quantities received were the same as the quantities ordered. If not, the accumulators were adjusted accordingly. The 11-digit NDCs received match the 11-digit NDCs ordered. 	<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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