



Purpose: The purpose of this tool is to enable entity leaders to quickly assess the basic level of 340B program integrity resources provided by contract pharmacy vendors to help the entity achieve 340B compliance.

Instructions: Read the question under the column “Does the Entity...?”

1. Review the information in the chart. Consider including green light criteria as part of a vendor request for proposal (RFP).
2. After receiving vendor proposals, read the question under the column “Does the vendor offer...”
3. Select the answer that best reflects the vendor’s services.
4. Make notes for further question, investigation, or program changes.
5. Use the general key below to help understand each vendor’s estimated level of program compliance support for the answer selected.



Low program integrity, program change recommended

Moderate program integrity, additional investigation recommended

High program integrity

Notes: Criteria for assessing vendors is categorized into two groups for purposes of this tool:

Law/Policy: These descriptions are guided by HRSA 340B published statute and regulation guidelines. Local, state, and other federal laws/regulations were not incorporated into this brief assessment.

Financial/Contractual: These factors are guided by the entity’s corporate structure, practices, or state laws. In developing this tool, generally accepted business practices were used, as it would be impossible to include the universe of all possible state and organizational legal considerations.

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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Does the Vendor offer...	Answer, to estimate your level of 340B Integrity	Notes
Law/Policy		
<p>A system that supports identification of eligible patients and adherence to the 340B patient definition?</p> <ul style="list-style-type: none"> The entity has a relationship with the individual and maintains records of the individual's health care. The individual receives health care services from a health care professional: <ul style="list-style-type: none"> Employed by the entity or Under contractual or other arrangements (e.g., referral for consultation) with entity. The individual received a health care service (or range of services) from the entity that is consistent with the grant scope of services (or federal designation/status; this does not apply to hospitals). The entity maintains responsibility for the individual's health care services. If using a contract pharmacy that dispenses inventory of another 340B entity's products (unique 340B ID), a system is in place to prevent misallocated transactions between entities. 		Criteria are not met.
		Uncertain; needs investigation.
		Criteria are met.
<p>A system that supports the entity's aim for no duplicate discounts?</p> <ul style="list-style-type: none"> The vendor has a process such as excluding Medicaid managed care claims from 340B replenishment if Medicaid rebates will be collected, and/or Medicaid fee-for-service prescriptions are not included in the 340B program unless a special arrangement has been made among the entity, HRSA, and the state Medicaid program to prevent duplicate discounts. 		Criteria are not met.
		Uncertain; needs investigation.
		Criteria are met.
<p>Adequate inventory management and records/reporting?</p> <ul style="list-style-type: none"> The drug ordering process is transparent to the entity and the entity is ultimately in control of the process (which parties may order and by what mechanisms). The vendor does not recommend or engage in re-characterization of claims or banked replenishment without full disclosure to all parties (entity, manufacturer, wholesaler, etc.). Inventory tracking is perpetual and the entity has access to inventory reports at any time or as requested. If the entity is subject to the GPO Prohibition (DSH, PED, CAN), its inventory system does not allow the entity to obtain covered outpatient drugs from a GPO. The entity establishes/controls reorder trigger points. 		Criteria are not met.
		Uncertain; needs investigation.
		Criteria are met.



Does the Vendor offer...	Answer, to estimate your level of 340B Integrity	Notes
Law/Policy (continued)		
<ul style="list-style-type: none"> The vendor's reporting capabilities include patient name, patient DOB, provider NPI, drug name, 11-digit NDC, quantity, date, third party/cash revenue, dispensing fees paid to pharmacy, and fee paid to vendor. All pharmacy- and patient-related data and records remain the sole property of the entity; if the entity allows use of the data by the vendor, the vendor must agree that all data will be de-identified, reported in the aggregate only, and comply with HIPAA requirements. Data privacy is addressed to the entity's satisfaction. A process is in place to reimburse the pharmacy for drugs that cannot be replenished at an 11-digit NDC match, at reasonable rates and reasonable intervals. A process is in place to reconcile inventory following the termination of the contract pharmacy or vendor contract. A process is in place to regularly reconcile purchasing, distribution, dispensing, and billing records (time interval clearly stated). Records are maintained for at least three years, or longer if required by state/federal law, including after the termination of the contract. Contract pharmacy provides data to the entity regarding how many prescriptions for entity patients are presented to the pharmacy, and how many are filled for the 340B program. 		
Financial/Contractual		
<p>An entity fee/term structure for vendor services that aligns with 340B program intent?</p> <ul style="list-style-type: none"> The vendor fully discloses all fees, including any fees for low usage velocity or formulary removal. \$4 generic programs are exempt from fees to the entity or adjudication cost to the pharmacy. The vendor has logic that compares these prices (340B, the pharmacy's usual and customary, and a maximum allowable cost [MAC] + dispensing fee); the entity should pay the lowest of the three. The vendor allows for a non-penalty early cancellation during the first term (i.e., 90-day, no-cause termination). Entity permitted to select wholesaler The vendor's fees (including fees negotiated for contract pharmacy) are in line with prevailing market rates. The vendor discloses the standards by which it evaluates contract pharmacies prior to inclusion into a network (e.g., the pharmacy is required to respond to patient complaints/recurring problems with dispensing). Entity patient recruitment to a vendor-owned or affiliated mail-order pharmacy is fully disclosed (information is obtained on these relationships as part of the proposal process). The contract defines net paid claim; the entity does not pay an adjudication fee on claim reversals. 	<div style="display: flex; flex-direction: column; gap: 10px;"> <div style="display: flex; align-items: center;"> <div style="width: 15px; height: 15px; background-color: red; border-radius: 50%; margin-right: 5px;"></div> <p>Criteria are not met.</p> </div> <div style="display: flex; align-items: center;"> <div style="width: 15px; height: 15px; background-color: yellow; border-radius: 50%; margin-right: 5px;"></div> <p>Uncertain; needs investigation.</p> </div> <div style="display: flex; align-items: center;"> <div style="width: 15px; height: 15px; background-color: green; border-radius: 50%; margin-right: 5px;"></div> <p>Criteria are met.</p> </div> </div>	



Does the Vendor offer...	Answer, to estimate your level of 340B Integrity		Notes
Financial/Contractual (continued)			
<p>Ultimate control to the entity over third party and cash revenue issues?</p> <ul style="list-style-type: none"> • The entity can create pre-edits to maximize 340B use (brand DAW indicator as less expensive than generic). • The vendor has a “stop-loss” functionality, which prevents third party adjudication if the claim will result in a net loss to the entity. • The entity can choose not to utilize 340B (without fee penalty) as needed. • The vendor supports a sliding fee scale approved or designed by the entity. • The vendor fully discloses and/or shares all rebate collections involved through participation with any business (PBM, etc.). 	  	<p>Criteria are not met.</p> <hr/> <p>Uncertain; needs investigation.</p> <hr/> <p>Criteria are met.</p>	



340B Compliance Self-Assessment: Vendors

A Tool to Help 340B Entity Leaders Assess Contract Pharmacy Vendors

	Vendor #1	Vendor #2	Vendor #3	Vendor #4
Services Offered				
Fees paid by entity to vendor				
All fees paid by entity to contract pharmacy				
Entity annual net revenue (estimate)				
Integrity concerns (red and yellow lights from chart above)				
Notes				