Getting Started with 340B Compliance

An Information Guide for Eligible Entities

Purpose: The purpose of this tool is to serve as a high-level summary of major points of compliance addressed in the 340B statute and guidance, and encountered in common business practices. Entity leadership may use it to provide an overview of requirements of the 340B program. This tool is not all-inclusive, but intended as a summary only. For more detailed information, visit 340BU Tools and Resources**.**

Issue	Summary
Source: 340B Statute **(Major points only; please review entire 340B Statute)**	
340B Eligibility	Entities must meet the specific requirements listed in the 340B statute.
340B Eligibility State/local government requirements: hospitals only	Certain hospitals must provide certification of specific eligibility requirements before registration. For a hospital to be eligible, a unit of state/local government must (1) own/operate the hospital, (2) formally grant governmental powers to the hospital, or (3) contract with the hospital to provide services to low-income patients (non-Medicaid/Medicare).
Audits	HRSA and 340B drug manufacturers (submitting audit plans to OPA) may audit the entity.
Disproportionate Share Adjustment Percentage (all hospitals but CAH)	Certain hospitals must meet disproportionate share adjustment percentages for the most recent cost reporting period before the calendar quarter involved: disproportionate share, children's, free-standing cancer, >11.75%; sole community, rural referral center, ≥8%.
Duplicate Discount Prohibition	A 340B price may not be provided for a drug that is also subject to a Medicaid rebate. For each unique Medicaid Provider Number/NPI, entities can either (1) use 340B drugs for Medicaid patients (and list the Medicaid Provider Number/NPI on the OPA website) or (2) use a non-340B contract to purchase drugs for Medicaid patients. Note that GPO use is not permitted by DSH/PEDs/CAN. States have different requirements for billing/identifying 340B drugs for Medicaid patients. Some states may REQUIRE eligible entities to use 340B; others may require entities to use certain methods to identify claims as 340B (e.g., NCPDP or UB-04 form); and others may not allow use of 340B at all when billing Medicaid.
Entity Sanctions for Noncompliance	Entities that cannot document compliance with 340B requirements may (1) be removed from the 340B program and/or (2) be liable to the manufacturer in an amount equal to the reduction in the price of the drug; violations could be considered as one of several federal reporting requirement with referral to appropriate authorities/associated sanctions.
Group Purchasing Organization (GPO) Prohibition (some hospitals)	Certain hospitals *only* (disproportionate share, children's, and free-standing cancer centers) may NOT use a GPO or other group purchasing arrangement to purchase covered outpatient drugs, as of the date of 340B registration. Hospitals with large non-340B outpatient populations may see significant financial impact.
HRSA 340B Database/ Recertification	Entities must keep their information on the HRSA 340B database up to date. Entities are required to recertify this information annually, as requested by HRSA.
No Diversion	340B drugs may not be resold or transferred to a person who is not a patient of the entity.
Prime Vendor Program	HRSA is required to establish a program to facilitate contracting/distribution for entities. The HRSA Prime Vendor Program, managed by Apexus, is free for entities to join. It negotiates sub-ceiling discounts on drugs and value-added products/services.

Issue	Summary
Source: 340B Guidance/Policy Release **(partial list only; please review all guidance documents)**	
Changes to 340B HRSA Database	Entities must complete a change form to update existing entity information.
Contract Pharmacy	Entities may contract with pharmacy(ies) to provide 340B drugs per guidelines.
Deadlines for Registration	**Register:** / **Start Date:** January 1–15 / April 1 April 1–15 / July 1 July 1–15 / October 1 October 1–15 / January 1 of the following year
Hospital Outpatient Clinics	Must be fully integrated into the hospital, appear as reimbursable on the hospital's most recently filed Medicare cost report, and have associated outpatient charges.
Patient Definition	An individual is considered a patient of the entity only if the entity: 1. Has a relationship with the individual and maintain records of his or her health care 2. Provides health care services from a health care professional a. Employed by the entity b. Under contractual/other arrangements (e.g., consultation referral) with the entity 3. Maintains responsibility for the patient's health care services 4. Delivers health care services consistent with the entity's range of services for which grant funding or status has been provided (hospitals exempt)
Select 340B Business Considerations with Compliance Implications	
"Banking" 340B Eligibility	Occurs when an entity was initially registered in the HRSA 340B database as participating, but for a period of time did not place 340B purchases. At some point later in time, the entity places 340B replenishment orders based on 340B-eligible transactions that theoretically could have been placed, but were not. Manufacturers may not permit banking, as it may cause noncompliance with their pricing calculations.
Recharacterization of Claims	Occurs when a credit–rebill process is used to reclassify information about a transaction after it initially occurred. Examples of information reclassified might include the purchasing contract used or the time of dispensing. Recharacterization of transactions may not be transparent to manufacturers and may cause noncompliance with pricing calculations. OPA has not specifically authorized recharacterization.
Replenishment	Occurs when a neutral inventory drug is initially dispensed to a patient, and an entity later replaces the neutral inventory drug by purchasing on the contract associated with the eligibility status of the patient—for example, 340B, GPO, or WAC. This is often encountered in mixed-use hospital areas, contract pharmacies, and entity-owned "open" pharmacies (that serve both 340B and non-340B). HRSA has not authorized a specific replenishment model, and has commented on using GPOs in replenishment here.
Startup/Maintenance Cost Considerations	Varies with entity complexity and existing resources—for example, consultants for initial financial analysis, split-billing software/crosswalk build, GPO Prohibition compliance, writing policies and procedures, staff to maintain program compliance, or contract pharmacy/vendor fees.

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.