

Apexus Advanced 340B Operations Certificate Program | Curriculum

This assessment-based certificate program offers specialized and thorough training on the implementation considerations within the 340B Drug Pricing Program. The curriculum provides an in-depth review of policy around 340B requirements and guidance on how to apply that policy in support of 340B operational integrity. The education series evaluates decision points, potential compliance challenges, and audit areas of focus for each topic.

Module Title	Description
Levels of 340B Policy	Describes the mechanisms HRSA uses to issue policy and the associated enforceability. The module also provides references to policy resources, where to locate them, and how to apply them to operational situations.
Use of 340B Savings	Highlights best practices in calculating and documenting the use of 340B savings at an entity and how it aligns with the organization's mission and program intent.
Eligibility for Hospitals	Discusses compliance requirements around eligibility for hospitals, registration of sites for participation in the program, and a review of certain documents and records that facilitate the eligibility verification process.
Eligibility for Grantees and Designees	Discusses compliance requirements around eligibility for non-hospitals (grantees and designees), registration of sites for participation in the program, and a review of certain records that facilitate the eligibility verification process.
Diversion	Outlines program requirements regarding the prevention of 340B drug diversion, including guidance surrounding the operational challenges of this compliance cornerstone.
Covered Outpatient Drugs	Discusses the definition of a covered outpatient drug and how to write and apply policies and procedures to support an interpretation of the definition of a covered outpatient drug.
340B Pricing	Discusses the establishment of the 340B ceiling price by the manufacturer, sub-ceiling 340B pricing and sub-WAC pricing available through Apexus, pricing available from the Apexus Generics Portfolio through wholesale drug distributors, and the frequency and timing of pricing changes.
Verifying the 340B Price	Describes the processes that a covered entity may use to verify 340B pricing, including comparison of prices among different 340B accounts, comparing with WAC and GPO pricing, comparison among wholesalers via the Apexus secure website, contacting Apexus Answers for assistance, verifying the 340B ceiling price directly with the manufacturer, and contacting HRSA, if necessary.

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Module Title	Description
340B and Distributor Accounts	Outlines the process by which a covered entity accesses distributor accounts offered to participants in the Prime Vendor Program and the implications to be considered when returning products and processing expired medications.
Chargeback Disputes	Describes the chargeback process whereby wholesalers purchase medications from manufacturers, sell to covered entities at the 340B price, and charge back to the manufacturer the difference between purchase and selling price, enabling the covered entity to determine reasons for chargeback rejections and enabling more efficient dispute resolution.
Medicaid Perspectives and 340B	Outlines the intersection of the Medicaid Drug Rebate Program with the 340B Program and how the perspectives of Medicaid and CMS play a role in 340B policy and implementation.
Duplicate Discount Prevention	Describes the various mechanisms that support prevention of duplicate discounts, including accurate maintenance of the Medicaid Exclusion File. The module also discusses considerations in determining which circumstances support an entity using 340B for Medicaid patients.
Medicaid Reimbursement and 340B	Highlights federal and state policy regarding Medicaid reimbursement and discusses various 340B-Medicaid reimbursement models that exist in the marketplace. The module also outlines how covered entities and Medicaid agencies/managed care organizations can engage in discussions regarding reimbursement options.
Replenishment and Separate Physical Inventory Models	Discusses key considerations in identifying the optimized inventory model (separate physical inventory model, replenishment inventory model, hybrid model) for various settings of 340B implementations and how to manage those inventory models to support compliant operations.
GPO Prohibition	Outlines the GPO Prohibition as it applies to purchasing of medications for hospital mixed-use settings, including the use of WAC, GPO, and 340B accounts using a replenishment model to ensure that no purchases of outpatient covered drugs are made through a GPO account.
Split-Billing Software Vendor Selection and Setup Considerations	Discusses the functionality and features important in selecting split-billing software, including full compliance with the GPO Prohibition, NDC loading and matching, ease of auditability, interoperability with wholesaler system and controlled substance order system (CSOS), reporting and dashboard capability, and user support.
Split-Billing Software Maintenance and Compliance	Details maintenance functions that must be performed to ensure split-billing system compliance, including medication load options by 11-digit NDC, unit building assignments to ensure accurate accumulation, monitoring for compliance assurance, documentation of manual adjustments, and reporting and audit processes.

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Module Title	Description
Minimizing Unnecessary WAC Expenditure	Describes purchasing processes that may be employed to minimize unnecessary WAC expenditures, focusing on mixed-use inventory settings and optimal medication data collection to build accumulation for purchases through appropriate accounts.
Entity-Owned Pharmacy Considerations	Discusses the requirements and ongoing compliance oversight required for entities operating in-house pharmacies that dispense 340B medications.
Contract Pharmacy and Vendor Selection Standards	Describes the decision points for the covered entity to determine whether establishing a contract pharmacy network is supportive of its mission, selecting retail pharmacy partners, registering contract pharmacy locations, and compliance and auditing requirements.
Contract Pharmacy Inventory Management and Compliance	Discusses the options for the covered entity's partner contract pharmacies for dispensing and replenishing inventory for the entity's 340B-eligible patients.
Orphan Drug Exclusion	Outlines the HRSA Orphan Drug Policy and the various stakeholder roles with implementation of the exclusion. The module also discusses the factors to consider when a covered entity evaluates its participation in the 340B Program as a rural hospital subject to the exclusion, as well as the operational challenges and solutions in operationalizing the exclusion in a compliant manner.
HRSA and Self-Audit Preparedness	Discusses audit preparedness initiatives, including the formulation of the data request, the conduction of transaction tracers, and review of policies and procedures for HRSA and self-audits.
Resolving 340B Noncompliance	Outlines compliant remedy options for instances of noncompliance to various extents, including the process around self-disclosures.

The Advanced 340B Operations Certificate Program is a separate Apexus offering that is not a part of the 340B Prime Vendor Program or otherwise associated with the Prime Vendor Agreement between HRSA and Apexus.

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