

340B Program

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THE ESSENTIALS OF COMPLIANCE

340B Drug Discount Program

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- The 340B Drug Discount Program is a federal government program that requires drug manufacturers to provide outpatient drugs to eligible covered entities at significantly reduced pricing.
- The intent is to allow covered entities to stretch scarce federal resources.
- The savings are used to provide healthcare services to more patients and/or provide more comprehensive services.

Covered Entities

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Safety net providers including, but not limited to, non-hospitals, such as county health departments, are eligible to participate in the 340B Program.

Entities are considered eligible on the basis of their federal designations or receipt of funding from specific federal sources and are statutorily described as “covered entities”.

HRSA Office of Pharmacy Affairs (OPA) 340B Database

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- The Office of Pharmacy Affairs (OPA) is the division within the Health Services Resources and Administration (HRSA) that manages the 340B Program.
- As a condition of participation in the 340B Program, covered entities must register with OPA and are required to recertify annually.
- OPA requires that covered entities list every covered entity site, or location, on the OPA online database.
- OPA has taken the position that failure to register or list a site on the agency's website disqualifies the site.

HRSA Office of Pharmacy Affairs (OPA) 340B Database

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- HRSA Office of Pharmacy Affairs 340B database can be found at <https://opanet.hrsa.gov/340B/>.
 - It is the official listing of 340B eligible entities.
 - The covered entity must maintain information in the database to ensure that it is accurate, up-to-date, and reflects what the organization is doing in practice.
 - It is used by wholesalers and pharmaceutical manufacturers to ensure entity is 340B certified while buying medications with 340B pricing.
 - It does not require a log in.

HRSA Office of Pharmacy Affairs (OPA) 340B Database

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- These actions can be performed on the HRSA OPA 340B Database site:
 - Register an entity.
 - Complete a change request for a covered entity.
 - Search for a covered entity.
 - Find detailed information about a covered entity.
 - Obtain reports regarding covered entities.

Compliance with the 340 B Program

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- Each covered entity must maintain auditable records showing that:
 - The patient is eligible (defined on slide 13).
 - Medicaid does not reimburse for a medication that qualifies for a rebate. (See duplicate discount on slide 15).
 - All criteria for eligibility are met.
- Covered entities may be audited by HRSA and pharmaceutical manufacturers to assure compliance of its 340B operations.
- Entities must self-disclose programmatic violations.

Recertification

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- The covered entity must apply for recertification once a year.
- The covered entity must verify that
 - The information in the OPA 340B Database is accurate and up-to-date.
 - It is still eligible.
- Recertification does not occur the same time each year so the Authorizing Official (AO) must watch for communication from HRSA.
- The Family Planning, STD and TB program managers serve as AOs.

Recertification

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- HRSA will send an email to the AO and the alternate announcing the recertification period.
- Only the AO can complete the recertification process.
- The day recertification begins, HSRA will send the AO an email with specific instructions including the link and log in information.
- The AO must log in via the link and change the temporary password provided in the email.
- The AO edits or confirms the information and submits it for recertification.
- HSRA accepts or denies recertification.

Change of Scope

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Any change affecting a 340B covered entity must be reported immediately to the program manager(s) located in the central office. A change includes, but is not limited to, an addition or deletion of services, change in location or address, and an opening or closing of a location.

None of these changes can be implemented until approved by HRSA and updated in the 340B Database.

Change of Scope

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- Registration and any change in scope of services is conducted online during the first 15 days of the quarter and is effective on the first day of the next quarter.
 - ❖ Example: A county health department opens a satellite facility to provide family planning services. The registration of this location can occur only during the first 15 days of the quarter (such as April 1-15) and will become effective July 1.
- A change in scope can be an addition or deletion of services.
- No 340B medications can be dispensed from a location until it is certified.

Registration and Change in Scope of Services Deadlines

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Registration Period	January 1- January 15	April 1- April 15	July 1- July 15	October 1- October 15
Start Date	April 1	July 1	October 1	January 1

340B Program Definition of a Patient

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- Covered entity must have an established relationship with the patient and maintain a record of the patient's health care.
- Patient must receive health care services from a health care professional employed by the covered entity or one who has a contractual relationship with the covered entity.
- The covered entity is responsible for health care of patient, including when the patient is referred for services outside the covered entity.
- The patient receives services or a range of services consistent with services for which grant funding has been provided to the entity.
- The covered entity must provide the patient health care services in addition to medications.

Diversion and Duplicate Discount

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Diversion occurs when

- 340B purchased medication is dispensed to a patient who is not eligible,
- the entity dispensing 340B medications is not certified by HRSA, or

Duplicate discount occurs when Medicaid receives a rebate from the drug manufacturer for 340B purchased medications.

Diversion and Duplicate Discount

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- To avoid diversion, it is crucial to understand how “patient” is defined in the 340B Program.
- Family Health Services at ADPH has established a billing procedure with Medicaid that ensures duplicate billing will not occur.
- At this time, TB and STD do not bill Medicaid for medications dispensed in the county health departments.

Inventory

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- 340B purchased medications must be stored separately from medications purchased from other funding sources and dispensed only to 340B eligible patients.
- Each program (Family Planning, TB, and STD) must keep separate physical inventories.

Audit Process

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- OPA requires that covered entities have written policies and procedures.
- Four types of audits:
 - HRSA
 - Pharmaceutical Manufacturers
 - State Board of Examiners
 - Self
- In Self Audits, the covered entity:
 - Monitors compliance
 - Establishes integrity of program
 - Prepares for other audits

Audit Process

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- HRSA audits can be random or targeted and looks for:
 - Eligibility
 - Diversion
 - Duplicate discounts
- The HRSA auditor will review:
 - Policies and Procedures
 - Patient health records
 - Other auditable records
 - ✦ Procurement
 - ✦ Inventory
 - ✦ Drug distribution

Self Audit

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- Ensures procuring, maintaining, and dispensing medications accurately reflects the entity's Policies and Procedures.
- Review of patient records and inventory transfer documentation to identify any diversion or duplicate discounting.
- Must be consistent, thorough and scheduled regularly.

Apexus

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- Apexus is the 340B Prime Vendor and contracts with wholesalers for distribution, negotiates with manufacturers for sub-340B pricing, and is a resource for covered entities with questions regarding the 340B rules.
- <https://www.Apexus.com>
- Offers online 340B education, 340B University OnDemand.

340B University OnDemand

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- Modules that are 10-30 minutes in length.
- Go to www.apexus.com/solutions/education.
- Click on 340B Education Portal.
- Click on Covered-Entities.
- Sign up as a new user.

Post Test Instructions

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Return to the 340B Training page and click on the link for the post test. A passing grade of 70% is required.