ANNUAL SEMINAR

340B Overview: Learning the Basics

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Objectives

• Review the 340B Drug Pricing Program and the intent of the Program

• Explain how the 340B Program is utilized and monitored

• Determine if a prescription is 340B eligible
What is the 340B Drug Pricing Program?

- Certain manufacturers are required to provide medications at a significant discount

- Eligible safety-net health care providers
  - Serve indigent and vulnerable patient populations
  - Must register with HRSA to participate
What drugs are part of the 340B Program?

- Outpatient drugs
  - Discharge prescriptions
  - Prescriptions
- Over-the-counter drugs (with a prescription)
- Clinic administered drugs
- Biologics (exception: vaccines)
- Insulin

Types of Drug pricing

Adapted from: 340B University. Apexus 2017.
What is the intent of the 340B Program?

“To permit covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

## What Sites are eligible to participate in the 340B Program?

<table>
<thead>
<tr>
<th>Hospitals</th>
<th>HRSA Federal Grantees</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Disproportionate Share Hospitals (DSH)</td>
<td>- Federally Qualified Health Centers/Look-Alike</td>
</tr>
<tr>
<td>- Children’s Hospitals (PED)</td>
<td>- Tribal/Urnal Indian Health Centers</td>
</tr>
<tr>
<td>- Critical Access Hospitals (CAH)</td>
<td>- Tuberculosis Clinic</td>
</tr>
<tr>
<td>- Sole Community Hospitals (SCH)</td>
<td>- Native Hawaiian Health Program</td>
</tr>
<tr>
<td>- Rural Referral Centers (RRC)</td>
<td></td>
</tr>
<tr>
<td>- Freestanding Cancer Hospitals (CAN)</td>
<td></td>
</tr>
</tbody>
</table>
How are savings generated through the 340B Program?

- Buy medications at a discounted price
  - Difference between original and discounted price
- Reimbursed the same amount
  - Additional margin based on discounted drug price
Savings Example

BreatheBetter Inhaler
- Non-340B Price: $83
- 340B Price: $51
- Reimbursement: $106

Non-340B Purchase
Reimbursement: $106
- Non-340B Price: $83
Margin: $23

340B Purchase
Reimbursement: $106
- 340B Price: $51
Margin: $55

Difference: $32
How is the 340B Program monitored?

- HRSA: Office of Pharmacy Affairs (OPA)
  - Responsible for oversight of the 340B Program
  - Performs audits to ensure compliance with the 340B Program

Image: https://340bopais.hrsa.gov/
What are the Main Responsibilities of 340B institutions?

1. Prevent Duplicate Discounts
2. Prevent Diversion
Rule 1: Prevent Duplicate Discounts

340B price

Medicaid rebate
Carve In vs. Carve Out

Carve-In

Carve-Out


Rule 2: Prevent Diversion

The resale or transfer of 340B medications to anyone other than an eligible patient of the institution.
Which patients are 340B eligible?

- Outpatient or Discharge Prescription
- Receive care from a provider employed by the institution
- Location of service must be eligible
- Documentation in the health record
- Medicaid is not the insurance if the institution carves-out
Texas Hospital
HRSA Registration: DSH123456

<table>
<thead>
<tr>
<th>Clinic Name</th>
<th>On the Medicare Cost Report?</th>
<th>On the HRSA Database?</th>
<th>340B Eligible Location?</th>
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<tr>
<td>Dermatology</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Medical Oncology</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Asthma and Allergy</td>
<td>Yes</td>
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- **Credentialed Providers**
  - Austin Star
  - Antonio Alamo
  - Stan Houston

- Texas Hospital **carves out** Medicaid at all pharmacy locations.
Eligibility Example

- GA was admitted to Texas Hospital.
- At discharge, GA received a prescription from Dr. Stan Houston for HeartFix 25mg.
- Dr. Houston noted the prescription in the health record.
- GA has private insurance (non-Medicaid).
- Is this prescription 340B eligible?
  - Yes
  - No

Want to learn more?

- **Resources:**
  - **Apexus: 340B On Demand**
  - **Apexus: 340B University Live**
  - **Apexus: Advanced 340B Operations Certificate Program**
    - [https://www.apexus.com/340b-certificate-program](https://www.apexus.com/340b-certificate-program)
  - **Apexus: Compliance Tools**
  - **HRSA Website**
    - [https://www.hrsa.gov/opa/index.html](https://www.hrsa.gov/opa/index.html)
  - **340B Health**
    - [https://www.340bhealth.org/](https://www.340bhealth.org/)
Conclusion: It’s complicated!

Image: https://www.aier.org/article/life-complicated-and-good
Assessment 1

Which of the following is an example that upholds the intent of the 340B Program?

A. Using Program savings to open a primary care clinic for indigent patients
B. Using Program savings to provide free medications to patients
C. Using Program savings to hire a clinical pharmacist
D. All of the above
Assessment 2

- LG had an outpatient visit at the Asthma and Allergy clinic.

- Dr. Dallas Love wrote LG a prescription for BreatheBetter inhaler.

- Dr. Love noted the prescription in the health record.

- LG has Medicaid.

- Is this prescription 340B eligible?
  - Yes
  - No
Thank You

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- Antonio Alamo
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Texas Hospital carves out Medicaid at all pharmacy locations.

Eligibility Example:
- GA was admitted to Texas Hospital.
- At discharge, GA received a prescription from Dr. Stan Houston for HeartFix 25mg.
- Dr. Houston noted the prescription in the health record.
- GA has a private insurance plan (non-Medicaid).
- Is this prescription 340B eligible?
  a. Yes
  b. No

Assessment Questions:
1. Which of the following is an example that upholds the intent of the 340B Program?
   a. Using Program savings to open a primary care clinic for indigent patients
   b. Using Program savings to provide free medications to patients
   c. Using Program savings to hire a clinical pharmacist
   d. All of the above

2. Is this prescription 340B eligible? (Use the 340B Eligibility Determination on the next page and the 340B institution information for Texas Hospital.)
   - LG had an outpatient visit at the Asthma and Allergy clinic.
   - Dr. Dallas Love wrote LG a prescription for BreatheBetter inhaler.
   - Dr. Love noted the prescription in the health record.
   - LG has Medicaid.
     a. Yes
     b. No

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340B Eligibility Determination

- Is the medication a covered outpatient drug?
  - Yes – Eligible
    - Discharge/outpatient prescriptions
    - Prescription for over-the-counter medication
    - Biologics (exception: vaccines)
    - Insulin
  - No – Not Eligible
    - Vaccine
    - Inpatient medications

- Is the patient an outpatient at the time of service?
  - Yes – Eligible
    - Prescription
  - No – Not Eligible
    - If no, is this a discharge prescription?
      - Yes – Eligible
      - No – Not Eligible

- Did the patient receive care from a professional employed by the 340B institution?
  - Yes – Eligible
  - No – Not Eligible

- Did the patient receive the prescription from an eligible location?
  - Yes – Eligible
    - Dermatology
    - Virginia Hospital admission
  - No – Not Eligible
    - Asthma and Allergy
    - Medical Oncology

- Is there documentation in the health record?
  - Yes – Eligible
  - No – Not Eligible

- Is this a Medicaid patient?
  - If CE Carves-In
    - Yes – Eligible
    - No – Eligible
  - If CE Carves-Out
    - Yes – Not Eligible
    - No – Eligible