340B Program Overview
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Pharmacist Learning Objectives

1.) Introduce the importance of 340B drug pricing
2.) Discern which entities are eligible and what drug can be purchased under the program
3.) Establish the pharmacist’s role in maintaining 340B inventory
4.) Establish how pharmacists play a role in maintaining compliance
Technician Learning Objectives

1.) Introduce the importance of 340B drug pricing
2.) Discern which entities are eligible and what drug can be purchased under the program
3.) Establish the technician’s role in maintaining 340B inventory
4.) Establish how technicians play a role in maintaining compliance
Description of 340B

• The program allows certain hospitals and other covered entities to purchase medications at manufacturer discounted prices for drugs for outpatient use.

• The intent of the program is to allow those covered entities to stretch scarce federal funds to provide care to more patients.

• Manufacturers must offer 340B pricing to covered entities in order to have their drugs covered under government reimbursement (Medicaid/Medicare).
  – Furthermore, manufacturers cannot distribute drugs in a way that discriminates against covered entities.
  – For example, they cannot put a requirement on drug sales or mandate minimum purchase amounts.
Economic Impact

• The Health Resources and Services Administration (HRSA) estimates that covered entities saved an estimated $3.8 billion on outpatient drugs in the fiscal year of 2013.

• This program has grown substantially during the past decade: covered entities and affiliated sites spent over $7 billion on 340B drugs in 2013 (three times the amount in 2005).

• The number of hospital organizations covered in the program increased from 583 in 2005 to 1,365 in 2010 and 2,140 in 2014.

• About 45 percent of all Medicare acute care hospitals participated in 340B.
Economic Impact

- From 2004 to 2013, Medicare spending in nominal dollars for Part B drugs at hospitals that participate in 340B grew from $0.5 billion to $3.5 billion (543 percent).

- Hospitals in 340B accounted for 22 percent of Medicare spending for Part B drugs at all Medicare acute care hospitals in 2004, which grew to 48 percent in 2013.
340B DRUG PRICING PROGRAM

Small Program, Big Benefits

2%
Portion of the United States’ $374 billion in annual drug purchases made through the 340B program

$3.8 BILLION
Total annual savings for 340B eligible providers

340B creates valuable savings on outpatient drug expenditures to reinvest in patient care and health activities to benefit the communities they serve. It also saves money for state and federal governments.

62%
Percentage of all uncompensated care provided by 340B hospitals

340B increases access to care for our most vulnerable populations - participating hospitals provided $28.6 billion in uncompensated care in 2013.

PROTECTING THE SAFETY NET
For more than 20 years, Congress has provided relief from high prescription drug costs through the 340B Drug Pricing Program. The program requires participating pharmaceutical companies to sell covered outpatient drugs at a discount to eligible health care organizations. To be eligible, hospitals must serve a disproportionate share of uninsured and low-income patients. This program gives patients better access to drugs they need and helps hospitals enhance care capabilities by stretching scarce federal resources.

Who Are 340B Hospitals?

About half are urban; half are rural.

929 (43.4%) are critical access hospitals (CAHs).

Located in 1,529 or 47% of all US counties.

340B Hospitals Meet Rigorous Requirements

340B ELIGIBILITY
Hospitals must:
- Be designated as a not-for-profit hospital.
- Be classified as a Children’s Hospital, Cancer Hospital, Sole Community Hospital, Rural Referral Center, Critical Access Hospital or a Medicare Disproportionate Share Hospital.
- Serve a large proportion of uninsured and low-income patients.
- Undergo random audits by the federal government and pharmaceutical manufacturers.
- Recertify annually as an eligible 340B provider.

Preserve the 340B Program; Protect the Safety Net
Sources: Health Resources and Services Administration; IMS Health; 2013 American Hospital Association Annual Survey Data; APhA

Health
Questions

The classification of drugs purchased under the 340B drug pricing program is:

A. Inpatient dispensing use only
B. Outpatient dispensing use only
C. Both inpatient and outpatient use
B: 340B Drug pricing applies to medications for outpatient use.

According to HRSA: The program applies to “covered outpatient drugs” which are defined as prescription drugs and biologics other than vaccines.
Who is Eligible?

- In 2014, there were 14,061 hospitals and affiliated sites in the 340B program.

- New hospitals must be owned by a state or local government, be a public organization or private nonprofit hospital that is under contract with state or local governments to provide service to low-income patients.

- There are 6 types of hospitals that are eligible for the program.
  - Critical access hospital (CAH), disproportionate share hospital (DSH), children’s hospitals, cancer hospital, sole community hospital or rural referral center
Who is Eligible?

- The two primary types of sites eligible to participate are critical access hospitals and disproportionate share hospitals
  - 11.75% of disproportionate share hospitals’ patient demographic must be low-income with poor access to healthcare resources.
  - Covered entities may provide drugs through an in-house pharmacy and one or more community pharmacies (contract pharmacies)
    - The community pharmacies contracted with the hospitals do not affect the DSH percentage because it is based on the inpatient demographic.
UC Health
University of Cincinnati Medical Center (UCMC)
What Patients are Eligible?

- Covered entities may provide 340B drugs only to those who are “patients” of the covered entity.

  - HRSA has established general criteria to be a covered patient. Omnibus guidance released 8/27/15 and is closed for comment as of 10/27/15.
    - Must have a relationship with the patient (defined as maintaining the patient’s health records).
    - The individual receives healthcare services from a healthcare professional who is employed by the entity.
    - The provided service is within the scope of allowable services.
What Patients are Eligible?

• 340B status does not restrict how the savings resulting from the program are used so long as it is used to expand the number of patients served or increase the scope of services offered to low-income individuals.

• At UCMC, this revenue has been used to:
  – Expand clinic access to patients (i.e. podiatry clinic, dental clinic)
  – Increase access to medications through outpatient Rx Medication Assistance Programs, Financial Counselors, and drug company programs
  – Support transitions in care through discharge medication concierge program.
Who is Responsible?

- Health Resources and Services Administration (HRSA)
  - Establishes the guidelines for covered entities to participate in the 340B program

- Office of Pharmacy Affairs (OPA)
  - Audit covered entities for compliance with these established guidelines

- Covered entities must ensure integrity of purchases through distribution of program medications to qualified patients.
Questions

Ceiling Price is:

A. The lowest price allowed to be charged by manufacturers.
B. The level of savings.
C. The highest price a manufacturer can charge
C: The highest price a manufacturer can charge.

The 340B ceiling price is statutorily defined as the Average Manufacturer Price (AMP) reduced by the rebate percentage, which is commonly referred to as the Unit Rebate Amount (URA).

– This is established by HRSA
Requirements to Register

• Eligible entities must register on the HRSA 340B database.
  – Annually, these entities must recertify that the information on the database is accurate.

• Covered entities must also enroll with the Office of Pharmacy Affairs (OPA) and yearly recertification is done through OPA.

• Two required steps to enrolling in the 340B program for eligible entities:
  – Register with HRSA
  – Register with OPA (annual recertification)
  – +/- Registration with the prime vendor program (PVP) for additional benefits
Opposition

- In recent years, there has been a debate between 340B hospitals and drug manufacturers about the scope of the program.

- Manufacturers question whether all of the hospitals in the program need the discount on drugs and look to limit the DSH criteria.

- 340B hospitals want to maintain the current status of unrestricted use of savings for expansion of services for those patients.
Alliance for Integrity and Reform AIR340B.
Types of Drugs Covered

- The program applies to “covered outpatient drugs” which are defined as prescription drugs and biologics other than vaccines.
  - This term excludes inpatient drugs and drugs that are bundled with other services (such as physician and hospital outpatient services).
  - CAHs are prohibited from purchasing orphan drugs and if purchased must verify that they were used for non-orphan indications.
    - Orphan drugs are those developed specifically to treat a rare medical condition (less than 200,000 diagnoses per year).
- The discount to the covered entity is the AWP reduced by a minimum rebate percentage of:
  - 23.1% for most brand-name drugs
  - 17.1% for pediatric drugs and clotting factor
  - 13% for generic and over-the-counter drugs
Prime Vendor Program

• The Prime Vendor Program (PVP) was established to provide a consolidated contracting and distribution process for covered entities.

• The PVP serves three primary roles:
  – Negotiating sub-340B pricing
  – Establishing national distribution solutions and networks that improve access to medications.
  – Providing value-added products and services including education and compliance assistance.
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Prime Vendor Program

• Enrolling enables covered entities to obtain prices lower than the 340B statutory prices and access cost-saving contracts for items such as diabetic supplies, vaccines, diagnostic kits, software, etc.

• Enrollment is voluntary to participate in the Prime Vendor Program.
  – Apexus is the current PVP contract
Questions

The primary intent of the Prime Vendor Program is to:

A. Control Cost of Healthcare
B. Provide Savings on the cost of medications
C. Provide low cost loans
B: Provide savings on the cost of medications.

- This is accomplished through three mechanisms:
  - Negotiating sub-340B pricing
  - Establishing national distribution solutions and networks that improve access to medications
  - Providing value-added products and services including education and compliance assistance
Maintaining Compliance

• The 340B statute authorizes the Health Resources and Services Administration (HRSA) to audit covered entities to make sure they are compliant with the program.

• Manufacturers are also authorized to audit covered entities, but this must be done under HRSA guidelines.
  – This requires reasonable cause and prior approval of an audit work plan.

• Compliance is also enforced through an annual recertification process conducted by OPA.

• Manufacturers are also subject to auditing by HRSA to ensure compliance with the 340B program.
Inventory Control

• Because 340B pricing is for medications used in the outpatient setting only, covered entities must have inventory control to ensure 340B drugs are not administered to inpatients.

• There are two common ways to ensure this:
  – Maintain a separate 340B inventory
  – Use a replenishment system (split-billing software)
Inventory Control

- In a replenishment system, a separate physical inventory is not maintained, but instead medications purchased under the 340B program are replaced as they are administered to an eligible patient (tracked via scan on administration).
  - This system requires software to maintain accurate records of how much of the 340B inventory has been dispensed to eligible patients: UCMC uses Macrohelix

- OPA requires there be an exact match between the drug used and the replenished drug using 11-digit NDC
Inventory Control: Diversion

- Diversion: The anti-diversion requirements of the 340B program prohibit the resale of or transfer of 340B outpatient drugs to individuals who are not considered patients.

- There are three categories of prohibited diversion:
  - Non-patients of the covered entity
  - Ineligible facilities
  - Excluded services of the covered entity

- Split-billing software allows for inventory to be separated and managed virtually
Summary: Impact to you

- 340B is a program that enables covered entities to purchase outpatient medications at a considerable discount.

- This in turn allows the hospital to expand the clinical services, access to medications and assistance programs available to patients.

- It is important to ensure compliance with the program (340B-purchased drugs can only be administered to 340B-eligible patients) in order to maintain eligibility as a covered entity and hence maintain the same level of cost-savings.
References

• 340B Drug Pricing Program Overview. Health Resources and Services Administration (HRSA)