WHAT IS 340B?

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DISCLOSURE

• No conflicts of interest to disclose
OBJECTIVES

• At the end of this presentation we should be able to:
  • Describe the origin of the 340b drug pricing program
  • Explain government divisions that oversee the 340b program
  • Define “carve-in” and “carve-out”
  • Explain what it takes to have an eligible patient

340B ORIGINS

• Medicaid Drug Rebate Program in 1990
• Required manufacturers to provide rebates for medication purchases
• Hospital prices increased in excess of normal rates
• Public Law 102-585, section 340b of the Public Health Service Act under the Veterans Health Care Act in 1992
340B ORIGINS\textsuperscript{1,4}

- “U.S. federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations”
- “...requires drug manufacturers to provide outpatient drugs to eligible organizations/covered entities at significantly reduced prices”
- “…enables covered entities to stretch scarce federal resources as far as possible, reaching more patients and providing more comprehensive services”
  -HRSA/OPA Website\textsuperscript{4}

340B ORIGINS\textsuperscript{1}

- Created in 1992
- Drug manufacturers provide front-end discounts to covered entities
- The program promotes
  - Access to affordable medications
  - Efficient business practices
  - Outcomes-driven pharmacy services
  - Quality assurance
340B PROGRAM INTENT AND PURPOSE

- The intent of the program is to permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” (HRSA)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

- The Government’s principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.
HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)\textsuperscript{4}

- An agency of the HHS and is the primary Federal agency for improving access to health care... to people who are geographically isolated, economically or medically vulnerable.

OFFICE OF PHARMACY AFFAIRS (OPA)\textsuperscript{5}

- The OPA is responsible for administering the 340B program.
- They have three primary functions:
  - 1) administer the 340B program
  - 2) develop innovative pharmacy delivery models and provide technical assistance
  - 3) act as a federal resource for pharmacy issues
OFFICE OF PHARMACY AFFAIRS (OPA)\(^5\)

- They provide:
  - General information about the program
  - Database of covered entities
  - Charts and reports relating to program participation
  - Legal resources
  - Registration forms for health centers with contract pharmacies
  - Information on contract pharmacy services
  - Information on patient safety and clinical pharmacy services
  - Glossary of pharmacy terms

OFFICE OF THE INSPECTOR GENERAL (OIG)\(^6\)

- An independent and objective oversight unit of the HHS to carry out the mission of promoting economy, efficiency and effectiveness through the elimination of waste, abuse and fraud.
OFFICE OF THE INSPECTOR GENERAL (OIG)  

- Conduct/supervise audits, inspections, investigations,
- Identify weaknesses
- Detects wrongdoers and abusers of HHS programs
- Keeps the Secretary and the Congress informed about problems and deficiencies in the administration of HHS programs

GOVERNMENT ACCOUNTABILITY OFFICE (GAO)

- An independent, nonpartisan agency that works for Congress. GAO investigates how the federal government spends taxpayer dollars.
SAFETY NET HOSPITALS FOR PHARMACEUTICAL ACCESS (SNHPA)

- Nonprofit organization of nonprofit hospitals and health systems in the U.S. that participate in the 340B program. Work to maintain the affordability and accessibility of pharmaceutical care for the nation’s poor and underserved populations.
- Advocate and resource for those providers who serve their communities through participation in the program.

SAFETY NET HOSPITALS FOR PHARMACEUTICAL ACCESS (SNHPA)
The government was required to establish a Prime Vendor Program (PVP) to provide additional discounts (sub-ceiling) on outpatient drugs and other pharmacy related items as well as other value-added services for participating 340B entities.

- Apexus
  - Negotiates sub-ceiling 340B pricing on branded and generic pharmaceuticals
  - Establishes distribution solutions and networks that improve access to affordable medications
  - Provides other value-added pharmacy related products and services to its participants
PRIME VENDOR PROGRAM (PVP)

• Apexus bids to be the PVP
• Surveys sent to CE to ensure satisfaction

POP QUIZ

• Of all the mentioned government entities mentioned, which department provides the greatest insight to operating a 340b program?
  • HHS
  • HRSA/OPA
  • OIG
  • GAO
PATIENT DEFINITION

An individual is a “patient” of a covered entity only if:

- Established relationship
- Seen by employed or contracted health care professional
- Services provided are consistent with the services of the provider

Discounted drugs may be administered only to patients of a covered entity.

According to HRSA, an individual is not considered a patient if the only service provided to the individual is the dispensing of drugs.

Qualify

- Patient sees employed provider in the hospital clinic, prescription for infusions to be given in IV Therapy

Not-Qualify

- Patient fills prescription from a provider in a neighboring town in your contract pharmacy
ELIGIBLE COVERED ENTITIES

Hospitals
- Children’s Hospitals
- Critical Access Hospitals
- Disproportionate Share Hospitals
- Free Standing Cancer Hospitals
- Rural Referral Centers
- Sole Community Hospitals

Children’s Hospital (PEDS): Non-profit serves patients under 19 with a DSH Adjustment Percentage > 11.75%

Critical Access Hospital (CAH): Maintain no more than 25 inpatient beds, located in a rural area or be treated as rural with 24-hr emergency care services. (10 mile requirement)
ELIGIBLE COVERED ENTITIES

• Disproportionate Share Hospital (DSH): Serve a significantly disproportionate number of low-income patients. DSH Adjustment Percentage > 11.75%

• Free-Standing Cancer Hospital (CAN): Non-profit entities that are financially and administratively independent. DSH Adjustment Percentage > 11.75%

ELIGIBLE COVERED ENTITIES

• Rural Referral Centers (RRC): Medicare participating acute care hospital located in a rural area, 275+ beds, at least 50% of Medicare patients are referred, etc.

• Sole Community Hospitals (SCH): Provide short-term, acute care, are not CAH, at least 35 miles from other like hospitals
OTHER ELIGIBLE COVERED ENTITIES

Health Centers
- Federally Qualified Health Centers
- Federally Qualified Health Center Look-Alikes
- Native Hawaiian Health Centers
- Tribal / Urban Indian Health Centers

Specialized Clinics
- Black Lung Clinics
- Comprehensive Hemophilia Diagnostic Treatment Centers
- Title X Family Planning Clinics
- Sexually Transmitted Disease Clinics
- Tuberculosis Clinics

HIV/AIDS Program Grantees

Ryan White HIV/AIDS Program Grantees

CHILD SITES 2,5

- Eligible Clinics, Surgery Centers and Other Outpatient Facilities
  - To be eligible a hospital outpatient unit must be listed on a reimbursable line of the Medicare cost report
  - Offsite units must be registered under the covered entity
  - Units are considered off site if they have a separate address.
  - On site units (within the four walls) don’t have to be registered, but can be
  - If a unit is moving off site or has the potential to move, it should be registered before it moves and a change form used when it moves
  - Use 340B drugs for patients that meet the Patient Definition
**OPA DATABASE**

[Image of the OPA Database page]

- **GPO Prohibition**
  - Disproportionate Share Hospitals
  - Children’s Hospitals
  - Free-Standing Cancer Hospitals

- **Orphan Drug Exclusion**
  - Critical Access Hospitals
  - Free-Standing Cancer Hospitals
  - Sole Community Hospitals
  - Rural Referral Centers

[Link to OPA Database: http://opanet.hrsa.gov/340B/Views/CoveredEntity/CESearch]
GPO PROHIBITION

- Prohibits DSH, PED, and CAN hospitals from obtaining covered outpatient drugs through group purchasing organizations.

The GPO prohibition applies to all disproportionate share hospitals, children’s hospitals, and freestanding cancer hospitals enrolled in the 340B Program. The GPO Policy Release does not apply to entities registered as any other type of covered entity.

SPLITTERS/ACCOUNTS

- **WAC**
  - Wholesale Acquisition Cost

- **GPO**
  - Group Purchasing Organization (Regular)

- **340b**
  - 340b
ORPHAN DRUG EXCLUSION

- Entities subject to the Orphan Drug Exclusion may not use 340B purchased drugs for patients with the orphan indication.

ORPHAN DRUG EXAMPLE

- Order for patient to receive 600 mg RITXimab
  - For Hodgkins lymphoma
  - Patient has private insurance
  - Contracted MD
  - IV Therapy in hospital
GPO Prohibition

- Disproportionate Share Hospitals
- Children’s Hospitals
- Free-Standing Cancer Hospitals

Orphan Drug Exclusion

- Critical Access Hospitals
- Free-Standing Cancer Hospitals
- Sole Community Hospitals
- Rural Referral Centers

COVERED OUTPATIENT DRUGS

Covered
- FDA-approved prescription drugs
- OTC drugs WITH a prescription
- Biological Products
- FDA-approved Insulin

Not Covered
- Vaccines
- Inpatient Drugs
- Drug not directly reimbursed
- Product where FDA doesn’t require NDC
MEDICAID BEST PRICE ¹²

- The lowest manufacturer price paid for a drug by any purchaser (some exceptions).
- A drug’s reported best price is required to reflect all discounts, rebates, and other pricing adjustments.

340B PRICING ⁹,¹⁰,¹²

- HRSA Estimates 20% to 50% Savings on Covered Drugs
- Maximum price calculated using the Medicaid rebate formula
- Discount of 23.1% off average manufacturer’s price (AMP) for most brand name drugs
- Discount of 17.1% for brand name drugs exclusively approved for pediatric use
- 13% discount for generic drugs and OTCs
- Additional discount on brand name drugs if the manufacturer’s best price is lower
- Penny Pricing
- Prime Vendor Pricing
PENNY PRICE

• The price that results when the calculation for a 340B price yields zero.

340B Ceiling Price = [(AMP) - (URA)] * Drug Package Size

AMP = Average Manufacturer Price
URA = Unit Rebate Amount


PENNY PRICE

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Healthcare Systems Bureau
Office of Pharmacy Affairs

Date: November 21, 2011

4/3/2015
The government was required to establish a prime vendor program (PVP) to provide additional discounts (sub-ceiling) on outpatient drugs and other pharmacy related items as well as other value-added services for participating 340B entities.

Apexus
- Negotiates sub-ceiling 340B pricing on branded and generic pharmaceuticals
- Establishes distribution solutions and networks that improve access to affordable medications
- Provides other value-added pharmacy related products and services to its participants
DRUG PRICING

**SUB-WAC**
- Order covered outpatient drugs in situations that would require the entity to purchase at WAC pricing.
- Negotiated without regard to 340B pricing
- Use of Sub-WAC is GPO Prohibition compliant

**SUB-340b**
- Pricing that is negotiated with branded and/or generic manufacturers offering pricing less than the 340B price.
- Negotiated by Apexus

RESPONSIBILITY

- The covered entity has total responsibility for compliance. Main tenants of compliance include:
  1. Diversion
  2. Duplicate Discount
  3. GPO Exclusion (where applicable)
  4. Orphan Drug Exclusion (where applicable)
DIVERSION

• The use of 340b purchased drug for ineligible patients

DUPLICATE DISCOUNT

• Idaho could obtain Medicaid rebates for a drug that a covered entity bought through the 340B program.
  • Carve In: include Medicaid patients
  • Carve Out: do not include Medicaid patients
EXAMPLES OF DUPLICATE DISCOUNTS

- Patient receives 340B medication (prescription from outpatient procedure)
- Medication is billed through the pharmacy’s billing system
- National Drug Code (NDC) level data are transmitted to state Medicaid agency
- Medicaid agency submits NDC claim information to manufacturer for rebate

Example 1: Take-home prescription

- Patient is administered medication (by outpatient procedure provider)
- Medication is billed through hospital or clinic billing system
- NDC level data are transmitted to state Medicaid agency through billing system
- Medicaid submits NDC level claim for manufacturer rebate

Example 2: Provider-administered

CARVE IN VS CARVE OUT

- Carve In: Purchase drugs for Medicaid patients at the 340B price
- Carve Out: Do not purchase drugs for Medicaid patients at the 340B price

**The state of Utah carves IN, Idaho however is currently carve OUT.**
WHY CARVE-OUT OR CARVE-IN?

- Reasons to Carve-In
  - Large patient population
  - Opportunity to receive significant discounts on pricing for large patient volumes
  - Significant revenue realization to the entity
  - Medications are not individually paid by Medicaid
  - Medicaid is not trying to get rebates
  - Required by Medicaid (some states)
  - Prevent buying Medicaid drugs on WAC
  - Want to lose money?

- Reasons to Carve-Out
  - Required by Medicaid
  - Evidence of duplicate discount
  - Contract Pharmacy

TWO WAYS TO REALIZE 340B SAVINGS

1. Services to Outpatients
   a) Physician/Clinic Administered Drugs
   b) Mixed Use areas (OR/ER)
   c) Infusion Centers

2. Discharge Services (340B drugs can be used for discharge prescriptions to the extent that the drugs are for outpatient use.)
   a) Contract Pharmacy
   b) Entity Owned Pharmacy
CONTRACT PHARMACY

• A covered entity contracts with a pharmacy to distribute the covered entity’s drugs on the covered entity’s behalf.
  • Reduced readmissions
  • Continuity of care
  • Offset losses
  • Patient satisfaction

CONTRACT PHARMACY

• Written Contract
  • CE must register as a contract pharmacy entity with OPA
  • CE must buy, maintain title, and assume pricing responsibility
  • CE is responsible for ensuring compliance with 340B requirements
TO PARTICIPATE, A CE MUST…¹²

- Ensure capability to maintain compliance with program requirements
- Register as a Covered Entity
- Recertify with HRSA annually

REGISTRATION¹¹/¹²

- OPA updates the database for NEW entities four times/year and requires a minimum of one month to process the application.
- Must be government owned
- Non-profit with government contract
REGISTRATION PERIODS

- July 1-15 for October 1 start
- October 1-15 for January 1 start
- January 1-15 for April 1 start
- April 1-15 for July 1 start

ANNUAL RECERTIFICATION

- Website information must be kept current
- Must be completed by AO (Authorizing Official)
  (CEO, CFO, ETC.)
- Must designate a primary contact (DOP)
- Includes attestation of compliance, eligibility etc.
AUTHORIZING OFFICIAL (AO)\textsuperscript{12}

- Authorizing Official: Ultimately responsible for ensuring the entity’s compliance with 340B program requirements. Any changes to an entity’s 340B database record require AO approval.

THREATS TO THE 340B PROGRAM…

- AIR340B (Alliance for Integrity and Reform of 340B)
- Big pharmaceutical companies
- Concern that health systems are making discounted medicines available at regular prices to patients with health insurance and then pocketing the difference…
MANUFACTURERS AND 340B

- Manufacturers must participate in the 340B program or their drugs cannot be covered by Medicaid.
- Prices to covered entities for outpatient drugs are to be capped at a deeply-discounted ceiling price:
  - Manufacturer must agree to charge a price that will not exceed the amount determined under statute (ceiling price) when selling covered outpatient drugs to 340B covered entities.
  - Ceiling price is calculated by subtracting the Unit Rebate Amount (URA) from the Average Manufacturer Price (AMP). The formal calculation is: [340B Ceiling Price = Quarterly AMP – URA].

AUDIT TIME MIXED USE

- Determine patients that received 340B medications (i.e. use software, or manual processes).
- Make sure you eliminate 340B drug to patients:
  - Being treated for orphan drug indication
  - Medicaid (if carve-out)

* Ideal to show what drug went to each patient
** Need to make sure you work with your distributor to have a separate PHS account for 340B pricing and processing.
AUDIT TIME-CONTRACT PHARMACY

- Obtain list of all claims processed
- Confirm claim relates to hospital care
- Ensure Provider eligibility
- If unable to reverse claims, disclose and correct**

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AUDIT TIME-CONTRACT PHARMACY

- Disclosure to the OPA

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CDE Krista Pedley, Director
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Re: Participation in the 340B Contract Pharmacy Program

Dear Commander Krista Pedley:

[Redacted]

is part of [Redacted], a not-for-profit healthcare organization operating multiple hospitals across [Redacted] has been enrolled as a 340B covered entity in the 340B Drug Purchasing Program ("340B Program") since April 1, 2013.
AUDIT TIME-CONTRACT PHARMACY

- Disclosure to drug manufacturers
- Determined to send out letters, wait for response
- Second send out demonstrates “due-diligence”

AUDIT TIME-CONTRACT PHARMACY

- Determine weaknesses (software/no-software, vendor, provider list, dates of eligibility etc…)
- Address prior to turning back on and notify OPA
CONTRACT PHARMACY (CP) FINANCIAL BENEFIT

CP processes claim

CE pays for medication to be shipped to CP

Claim determined eligible, purchase by CE

CE accumulates inventory of medication

CE pays CP

MIXED USE FINANCIAL BENEFIT

• Drug vertigotron (Typsy) administered in IV Therapy
  • WAC cost $1100
  • GPO Price $975
  • 340b cost $575
  • Patient billed cost + markup/handling fee of GPO price
  • Determined after patient was eligible for 340b price

**Savings to department
  Employee cost (initial)
  Charity Prescriptions (more ideal)
HOW CAN THIS HELP?

• Cost to provide service (employee's)
  • Diabetes clinic
  • Anticoagulation Service (inpatient/outpatient)
  • Discharge prescription (bedside delivery)
• Charity Care
  • Prescription Vouchers**
  • Use to offset care written off

**Not just for the financial benefit

HOW CAN I LEARN MORE?

• 340b University (free registration)
• 340b Winter Coalition Conference
HOW CAN I LEARN MORE?  

- Enable all pharmacy members to understand 340b benefits and implications
- Be able to prove benefit to administration, and HRSA in the future

QUESTION 1

1. The 340b program name comes from
   A: Number of covered entities allowed to participate
   B: Patent number of a prescription claim process
   C: Section of law from 1992
QUESTION 2

To Carve In patients for eligible 340b purchases, you would:
A: Include patients being treated for orphan drug indications
B: Include patients with private insurance
C: Make sure OPA registration would indicate that you will include Medicaid patients for eligible 340b drug purchases

QUESTION 3

Which of the following medications would qualify for 340b purchases (eligible patient):
A: Medications administered while inpatient
B: Medications administered under orphan drug indication
C: Non-Medicaid patient being treated with a medication being used for an indication not on the orphan drug indication list, in an outpatient area
D: Vaccines for outpatient use
QUESTION 4

• True / False
To start a 340b program you should trust software vendors to audit data feeds and trust they will support you if there are any diversion/duplicate discounts.

REFERENCES

5. “340b Drug Pricing Program” HRSA Website. 10 Jan. 2015
REFERENCES CONT…

12. “HRSA FAQs” HRSA Website. 10 Jan. 2015
13. “Orphan Drugs Exclusion” HRSA Website. 10 Jan. 2015
15. Sample Hospital Audit Findings 2/2014