340B
Drug Pricing Program

Mary Stepanyan, PharmD Candidate 2018
University of Southern California, School of Pharmacy
Pro Pharma Pharmaceutical Consultants
Under the preceptorship of Dr. Craig Stern
WHY IS 340B IMPORTANT?

Total Number of 340B Contract Pharmacies, 2000-2014

Data show contract pharmacies as of July of each year. For 2014, data show contract pharmacies as of January. Source: Avalere Health (2000-2012); Pembroke Consulting (2013-2014)
Note: This chart appears as Exhibit 95 in the 2013-14 Economic Report on Retail, Mail and Specialty Pharmacies, Drug Channels Institute, January 2014. (http://drugchannelsinstitute.com/products/industry_report/pharmacy/)
OUTLINE

• BACKGROUND

• REQUIREMENTS FOR PARTICIPATION

• PROCESS

• MANAGED CARE PHARMACY

• OUTLOOK
OVERVIEW

❖ Passed by Congress in November 1992 and signed into law as part of the Veterans Health Care Act by George H. W. Bush.

❖ Administered by the Office of Pharmacy Affairs (OPA) which is located within the Health Resources and Services Administration (HRSA)

❖ Manufacturers enter a pharmaceutical pricing agreement (PPA), where they agree to provide discounts on outpatient drugs to certain safety net health providers.

❖ Purpose: “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”
Drug manufacturers would donate prescription drugs to health facilities with low-income patients.

In 1990 Congress created the Medicaid rebate program to lower the cost of pharmaceuticals reimbursed by Medicaid agencies.

This mandate constricted charitable giving.

Hospitals with high volumes of low-income patients had to absorb the added cost of providing drugs.
COVERED ENTITIES

❖ SIX CATEGORIES OF HOSPITALS:
- Disproportionate share hospitals (DSH)
- Children’s hospitals and cancer hospitals exempt from the Medicare prospective payment system
- Sole community hospitals
- Rural referral centers
- Critical access hospitals (CAHs)

REQUIREMENTS:
- Owned or operated by state or local government
- Granted as a public or private non-profit corporation
- Private non-profit organization
COVERED ENTITIES

❖ HEALTH CENTERS:
  ❖ Federally Qualified Health Centers (FQHC)
  ❖ FQHC “look-alikes”
  ❖ Urban Indian clinics
  ❖ Native Hawaiian health centers

❖ The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act clinic and programs

❖ SPECIALIZED CLINICS:
  ❖ Tuberculosis, black lung, family planning, and STD clinics
  ❖ Hemophilia treatment centers
  ❖ Title X public housing primary care clinics
  ❖ Homeless clinics
  ❖ State-operated AIDS drug assistance programs
REQUIREMENTS TO PARTICIPATE

COVERED ENTITIES MUST:
❖ Keep 340B Office of Pharmacy Affairs Information System accurate and up to date

❖ Recertify eligibility every year

❖ Prevent diversion to ineligible patients

❖ Prohibit discount duplication or rebates

❖ Maintain program audits
DUPLICATE DISCOUNT PROHIBITION

- Drugs dispensed or administered to Medicaid recipients on a FFS are prohibited from 340B if they are subject to rebates.

- Contract pharmacy: covered entity may not use 340B unless the entity, Medicaid, and contract pharmacy have an agreement.

- Outpatient Location/Entity-owned pharmacy: entity must inform OPA of its decision to use 340B and ensure the numbers used to bill are in the OPA’s Medicaid exclusion file database.
COVERED DRUGS

❖ Generally, the program includes:
   ❖ FDA-approved prescription drugs
   ❖ OTC drugs written on a prescription
   ❖ Biological products than can be dispensed only by a prescription
   ❖ FDA-approved insulin

❖ Does NOT include:
   ❖ Inpatient drugs
   ❖ Vaccines
   ❖ Drugs that are bundled with other services (such as physician and hospital outpatient services) for payment purposes.
COVERED PATIENTS

❖ The 1996 Federal Register guidelines define a covered patient as one who:
  ❖ Has an established relationship with the covered entity
  ❖ Receives care from a professional employed by the covered entity or under contract
  ❖ Receive health services that are consistent with grants funding the entities

❖ The individual is NOT a patient of the covered entity if they are receiving only one drug that is for self-administration or administration in the home setting.
HOW THE PROGRAM WORKS

❖ Facilities can apply by completing the online registration process during the first two weeks of any calendar quarter.

❖ Once approved by the Office of Pharmacy Affairs (OPA), entities are eligible to receive discounts through wholesaler or other channels approved by the manufacturer.

❖ Covered entity should contact its wholesaler to set up its 340B account.
   ❖ Entity may request a price list for 340B drugs from its wholesaler
HOW THE PROGRAM WORKS

❖ HRSA calculates ceiling price for each covered outpatient drug:
  ❖ Ceiling price =
    ❖ (AMP-URA) x package size x case package size
  ❖ Manufacturers submit the AMP and URA to CMS for quarterly Medicaid Drug Rebate Program reporting

❖ If a covered entity suspects it is not receiving the 340B price, it should contact the wholesaler and/or manufacturer
CONTRACT PHARMACIES

❖ Covered entity can purchase and dispense 340B drugs through internal or external (contract) pharmacies
❖ “ship to-bill to” procedure
❖ Most 340B contract pharmacies are retail pharmacies, with Walgreens being the biggest participant
Source: Author's research.

This exhibit illustrates the most common arrangements between a 340B hospital and its contract pharmacy. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.

DSH = disproportionate share hospital; PO = purchase order.
CHALLENGES FOR MANAGED CARE PHARMACY

❖ FORMULARY REBATES
  ❖ Managed care organizations may receive lower formulary rebates from manufacturers and incur higher net pharmacy benefit reimbursement expenses.

❖ PROFITS FROM MANAGED CARE PAID PRESCRIPTIONS
  ❖ 340B entity profits from prescriptions that are paid at non-discounted rates by commercial payers and Medicare
CHALLENGES FOR MANAGED CARE PHARMACY

❖ DISRUPTION OF MANAGED CARE PHARMACY NETWORKS
  ❖ Some 340B entities have large pharmacy networks
  ❖ 340B entities can afford fees that often exceed a pharmacy’s typical profits from dispensing a third-party-paid prescription.

❖ REDUCED GENERIC DISPENSING RATES
  ❖ Hospitals receive the most 340B purchase discounts from brand-name drugs which can encourage more brand-name prescriptions
  ❖ Raise costs for third-party payers.
OUTLOOK

❖ 340B Drug Pricing Program allows many health care providers to obtain discount prices to reach more patients

❖ The growth of this program has affected managed care pharmacy through formulary rebates, profits from managed care paid prescriptions, disruption of networks, and a decrease in generic dispensing rates

❖ Solutions needed for:
  ❖ Disclosure of financial arrangements with contract pharmacies
  ❖ Requirements to identify 340B prescriptions
  ❖ Size of contract pharmacy networks
ADDITIONAL RESOURCES

❖ Visit www.340bhealth.org

❖ Contact Vice President, Legal and Policy Counsel Greg Doggett
  ❖ greg.doggett@340bhealth.org or 202-552-5859

❖ Vice President, Legislative & Policy Counsel Jeff Davis
  ❖ jeff.davis@340bhealth.org or 202-552-5867.
REFERENCES


❖ [https://www.hrsa.gov/opa](https://www.hrsa.gov/opa)