

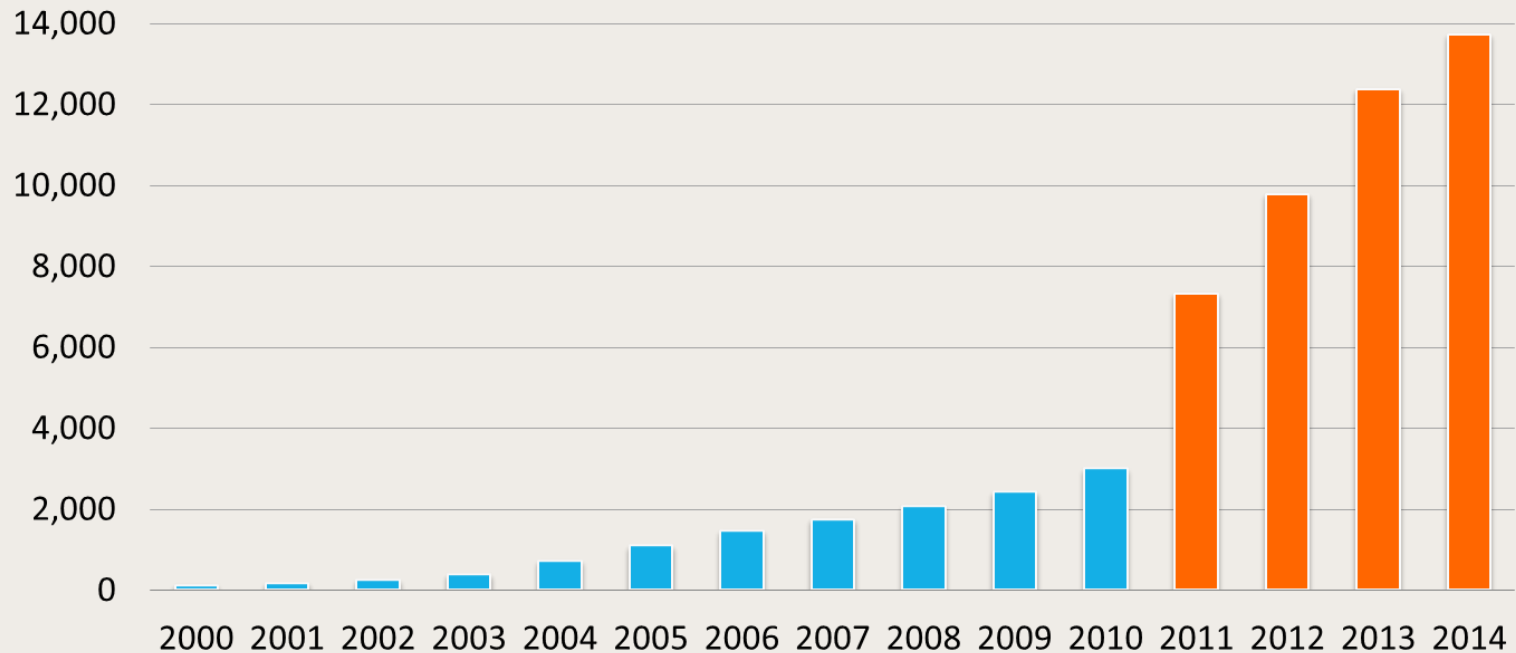
# **340B**

# **Drug Pricing Program**

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# 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/](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.”

# HISTORY

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 that 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

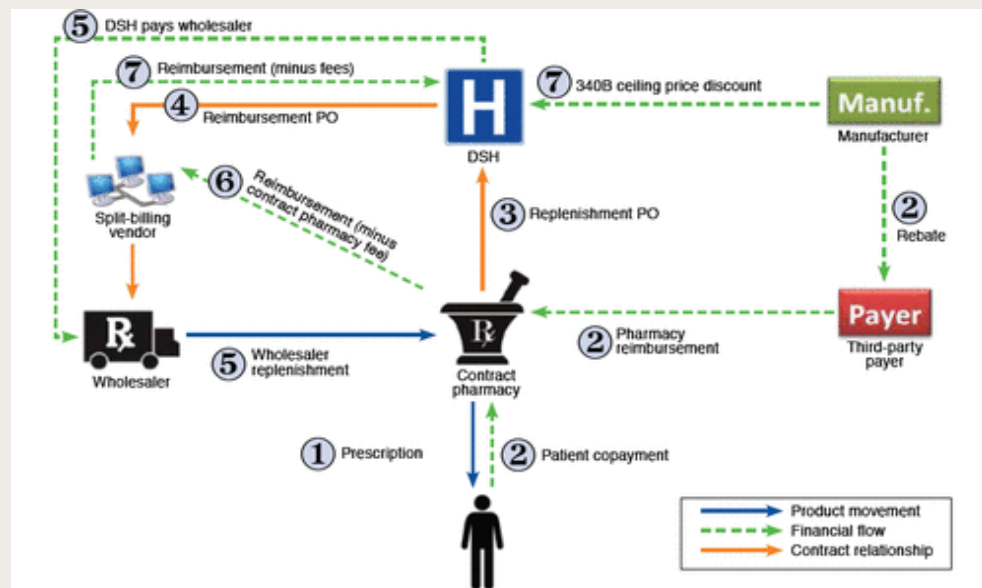
- ❖ Facilities can apply by completing the online registration process during the first two weeks of any calendar quarter.
- ❖ Once approved by the Office of Pharmacy Affairs (OPA), entities are eligible to receive discounts through wholesaler or other channels approved by the manufacturer.
- ❖ Covered 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

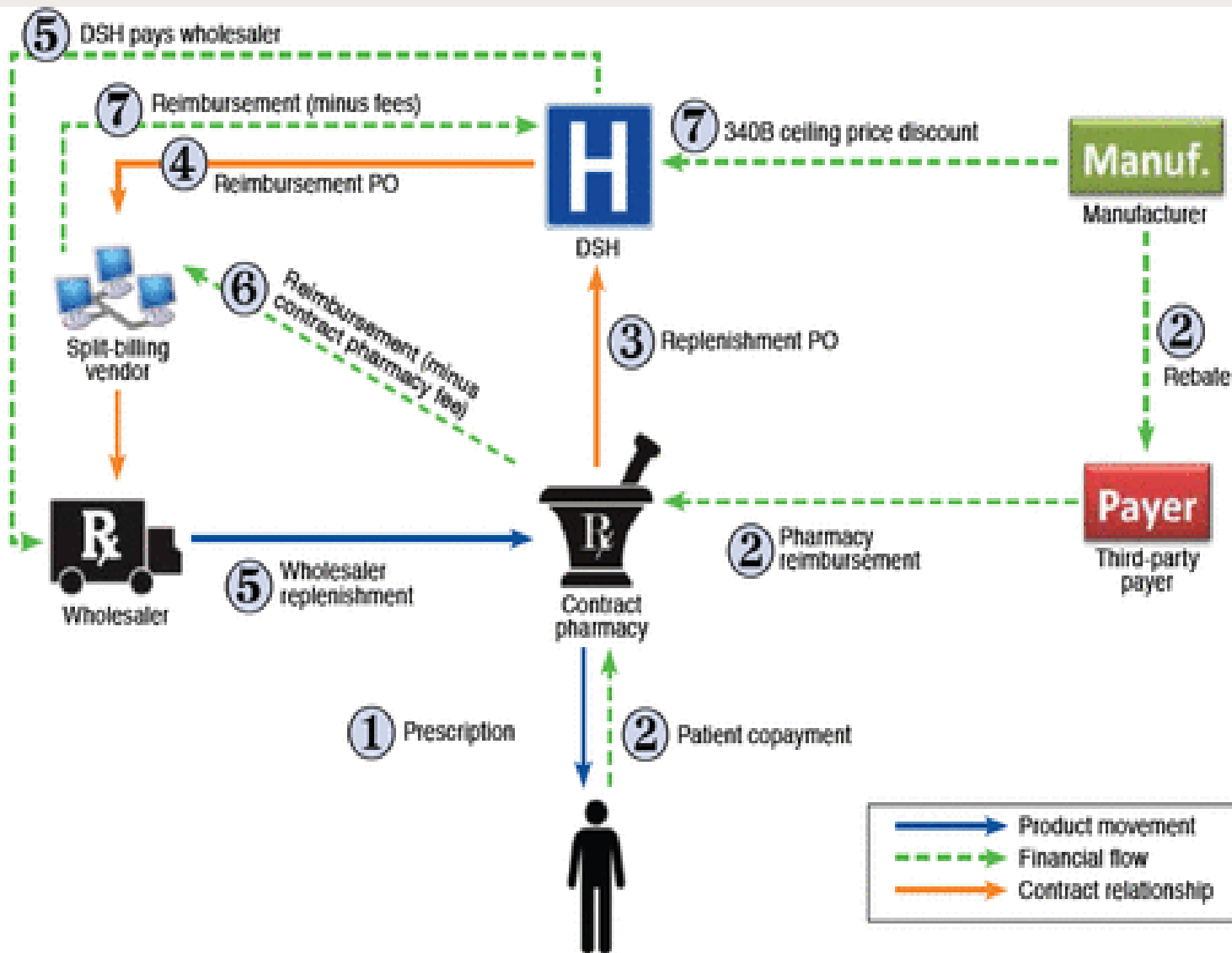
- ❖ Covered entity can purchase and dispense 340B drugs through internal or external (contract) pharmacies
  - ❖ “ship to-bill to” procedure
- ❖ Most 340B contract pharmacies are retail pharmacies, with Walgreens being the biggest participant



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.



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.

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# 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](http://www.340bhealth.org)
- ❖ Contact Vice President, Legal and Policy Counsel Greg Doggett  
❖ [greg.doggett@340bhealth.org](mailto:greg.doggett@340bhealth.org) or 202-552-5859
- ❖ Vice President, Legislative & Policy Counsel Jeff Davis  
❖ [jeff.davis@340bhealth.org](mailto:jeff.davis@340bhealth.org) or 202-552-5867.

# QUESTIONS



# REFERENCES

- ❖ Fein, A. J. (2016). Challenges for Managed Care from 340B Contract Pharmacies. *Journal of managed care & specialty pharmacy*, 22(3), 197-203.
- ❖ Overview of the 340B Drug Pricing Program.  
<https://www.340bhealth.org/340b-resources/340b-program/overview/>
- ❖ <https://www.hrsa.gov/opa>