

# Background and Opportunities for the Future

## MISSOURI & 340B



# 340B EVOLUTION



1990 - Medicaid Drug Rebate program

1992 -Veterans Health Care Act establishes 340B Drug Pricing Program

2010 Patient Protection and Affordable Care Act (ACA) 340B Expansion

# 1990 MEDICAID DRUG REBATE PROGRAM

Requires rebates based on the drug manufacturers' "best price"

However:

- ✘ *Manufacturers have little incentive to reduce their prices in non-Medicaid markets because doing so could lead to larger rebates in the Medicaid market*
- ✘ *Non-Medicaid patients may have been charged higher rates.*

For more info . . .

<https://www.cms.gov/medicaidrugrebateprogram/>

# ● 1992 – VETERANS HEALTH CARE ACT

The 340B program was developed in response to unintended consequences stemming from the 1990 Medicaid Drug Rebate program.

- 340B empowers select Safety Net Providers by providing discounts on outpatient prescription drugs
- Goals - reach more eligible patients and provide more comprehensive services.

For more info . . .

<http://www.hrsa.gov/opa/pl102585.htm>

# COVERED ENTITIES

## Nationwide, covered entities include:

- Federally qualified health center lookalike programs
- Certain disproportionate share hospitals owned by, or under contract with, State or local governments
- Several categories of facilities or programs funded by Federal grant dollars, including federally qualified health centers, AIDS drug assistance programs, hemophilia treatment centers, STD and TB grant recipients
- Family planning clinics.





# 2010 PATIENT PROTECTION AND AFFORDABLE CARE ACT

## 340B EXPANSION

The Affordable Care Act added new hospital types to the definition of covered entities:

- certain qualifying children hospitals
- free standing cancer centers
- critical access hospitals
- rural referral centers
- sole community hospitals

Managed by



For more info . . . <http://www.hrsa.gov/opa/>

# COVERED ENTITIES

In Missouri these most commonly include *some but not all*:

- Federally-qualified health centers
- Family planning projects
- Facilities treating tuberculosis
- Critical Access Hospitals
- Comprehensive hemophilia diagnostic treatment centers
- Disproportionate Share Hospitals
- Critical Access Hospitals
- Sole Community Hospitals
- Rural Referral Centers

# COVERED INDIVIDUALS

As long as they are patients of the covered entity, non-Medicaid patients may receive discounted drugs from a participating provider under Section 340B.



# COVERED INDIVIDUALS

With a few exceptions, an individual is a 'patient' of a covered entity if:

- (1) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care: and
- (2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains for the covered entity; and
- (3) the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. *Disproportionate share hospitals are exempt from this requirement.*

# “NON-COVERED” INDIVIDUALS

An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

# DUPLICATE DISCOUNTS PROHIBITED

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The legislation that created the 340B program also protects manufacturers from paying a “duplicate discount” on a drug claim.

A “duplicate discount” would occur if the **340B discount** and a **Medicaid rebate** were provided on the same drug.

# COST AFTER REBATE

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In 2010, 340B prices were on average 51 percent lower than average wholesale prices and 23 percent below the Medicaid net price (what states pay for drugs minus manufacturer rebates received).

*More recent studies indicate that 340B discounts are **even deeper** as a result of health reform.*

# 340B Price Comparisons (2005)



Source: Data derived from [Prices for Brand-Name Drugs Under Selected Federal Programs](#), Congressional Budget Office (June 2005); [Pharmaceutical Discounts under Federal Law: State Program Opportunities](#), William H. von Oehsen (May 2001).



# 340B OPPORTUNITIES FOR STATES

- State Partnerships with covered entities provide 340B pharmaceuticals to Medicaid, mental health, and nursing home populations.
- Potential for these partnerships to generate substantial savings

# 340B OPPORTUNITIES FOR STATES

- Drugs are about 35 percent more costly when purchased through PBMs instead of 340B program
- Shifting drug purchases from PBMs to 340B providers can lower costs for the plan and be passed on to the state
- For MO HealthNet, this further supports the Managed Care carve-out for pharmacy
  - 340B claims still eligible for Pharmacy Provider Tax

# 340B OPPORTUNITIES FOR STATES:

## ENCOURAGING 340B PARTICIPATION

- 340B program can reduce Medicaid reimbursement for outpatient drugs
- MHD looking at developing policy to encourage 340B providers to bill Medicaid
- Many hospitals, community health centers, and other eligible facilities are not participating in 340B (or carving out Medicaid patients)

# 340B OPPORTUNITIES FOR MISSOURI

- ✘ Short-term – Partnering with Hemophilia Treatment Centers to provide factor and wrap around patient-care services
- ✘ Mid-Range – Partnering with Health Home Provider covered entities (FQHCs) that contract with pharmacies
- ✘ Long-term – Partnering with Hospital Providers (MHA) for Outpatient Drug Services

# MHD HEMOPHILIA SPEND

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- CY 2012
- Hemophilia Factor Claims
  - 1514 Claims
- Hemophilia Factor Paid Amount
  - \$38,262,729



**At least 250 Missouri organizations are currently registered as 340B.**

*Cumulatively over time there have been over 390*

Missouri has approximately 10 of 20 possible organization types participating.



# NATIONWIDE 340B INTEREST

25 States have  
Pharmacy Rules  
and/or Policies  
addressing 340B



At least 18 States already  
have legislation or  
administrative codes  
regarding 340B

Reinventing the wheel can be a rough ride!



# DISCUSSION

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- Questions??

