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The 340B Program: Benefits and Limitations

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The 340B Program: Benefits and Limitations

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Collaborative Study

- School of Pharmacy and Lewis College of Business, Marshall University, Marshall Health, Valley Health Systems, Thomas Memorial Health System
- The purpose of ongoing research is to analyze and quantify the financial impact and humanistic and challenges concerning the 340B program in the tri-state [KY, OH, and WV] and quantify how program is meeting its intent in this area.
- In-progress analysis: financial impacts for institutions
- Analysis of the impact to patients via sliding scale pricing

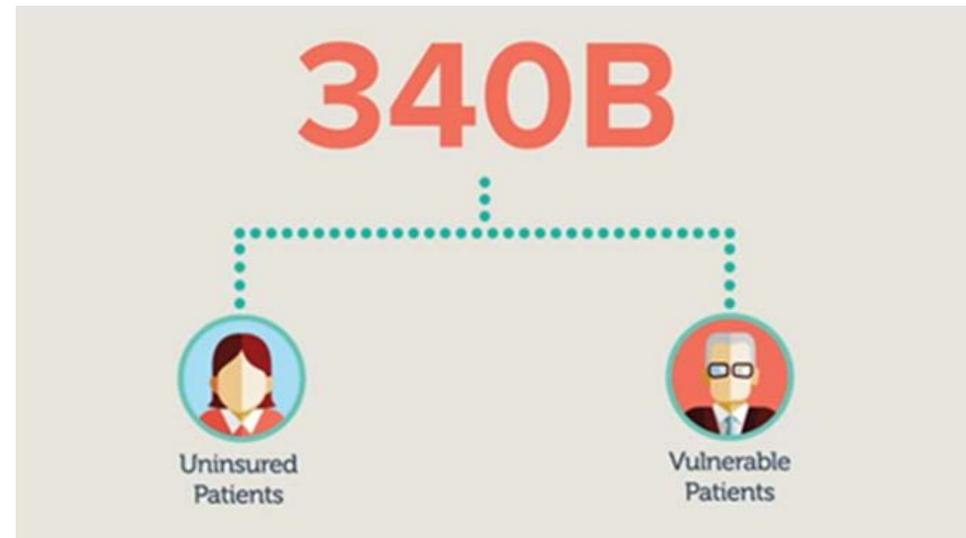
Introduction

- One third of Americans are living at or below 200% of the FPL and struggle to afford prescriptions
- Many Americans fall in the gap between Medicaid and fully insured = “the working poor” or “vulnerable populations”
- This program targets assistance for this population and allows qualifying facilities to fund care and expand services for patients that are unable to pay.



Introduction: Timeline of the 340B Program

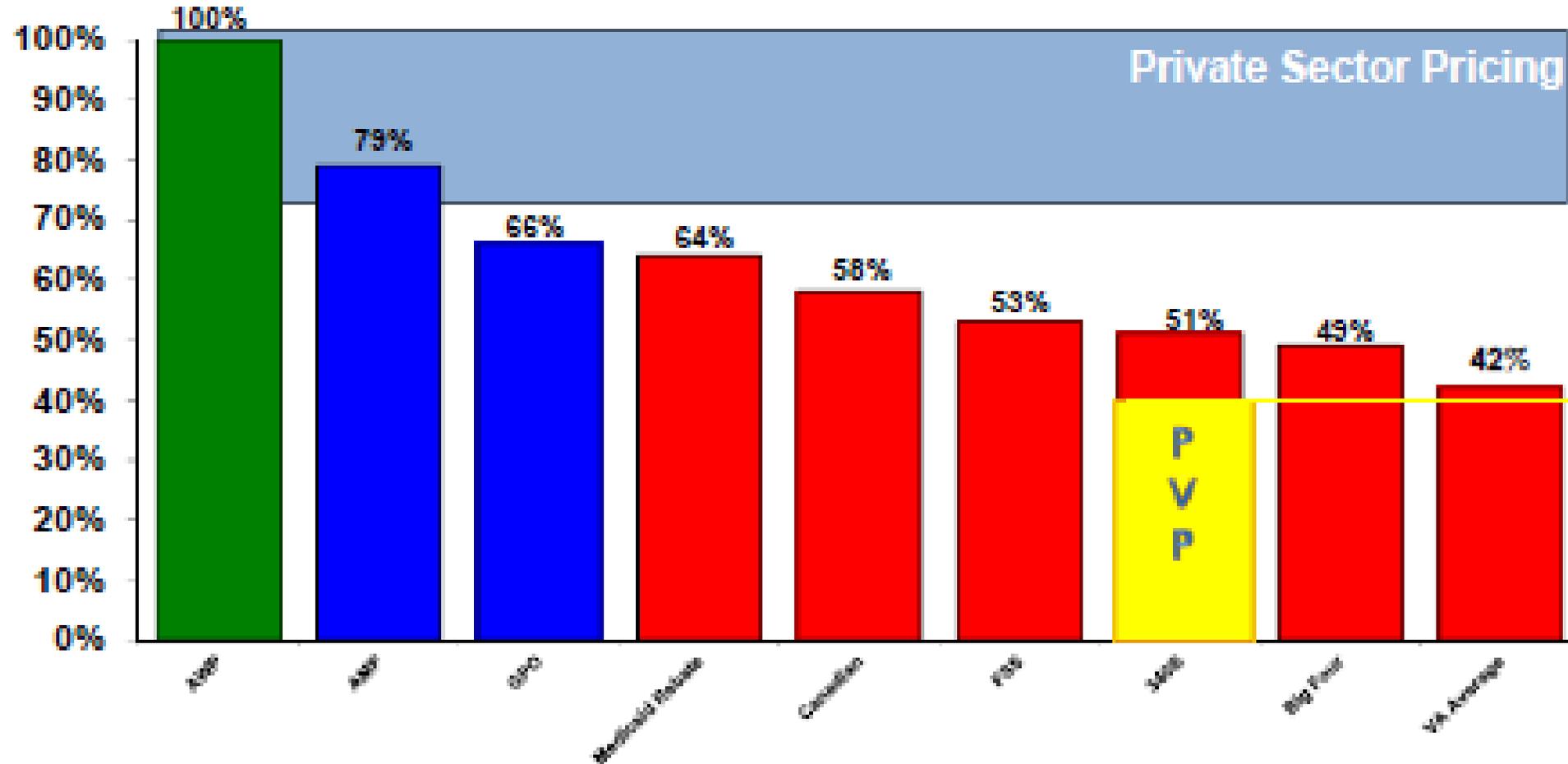
- 1990 - US created Medicaid Rebate Program
- **1992 - Veterans Health Care Act of 1992 established the 340B Drug Pricing Program in section 340B of the Public Health Service Act (PHSA)**
- 1996 - 340B expanded by HRSA to allow a single “contract pharmacy”
- 2010 - 340B revised as part of the ACA to allow multiple contract pharmacies
- 2018 – CMS proposed significant cuts to the program



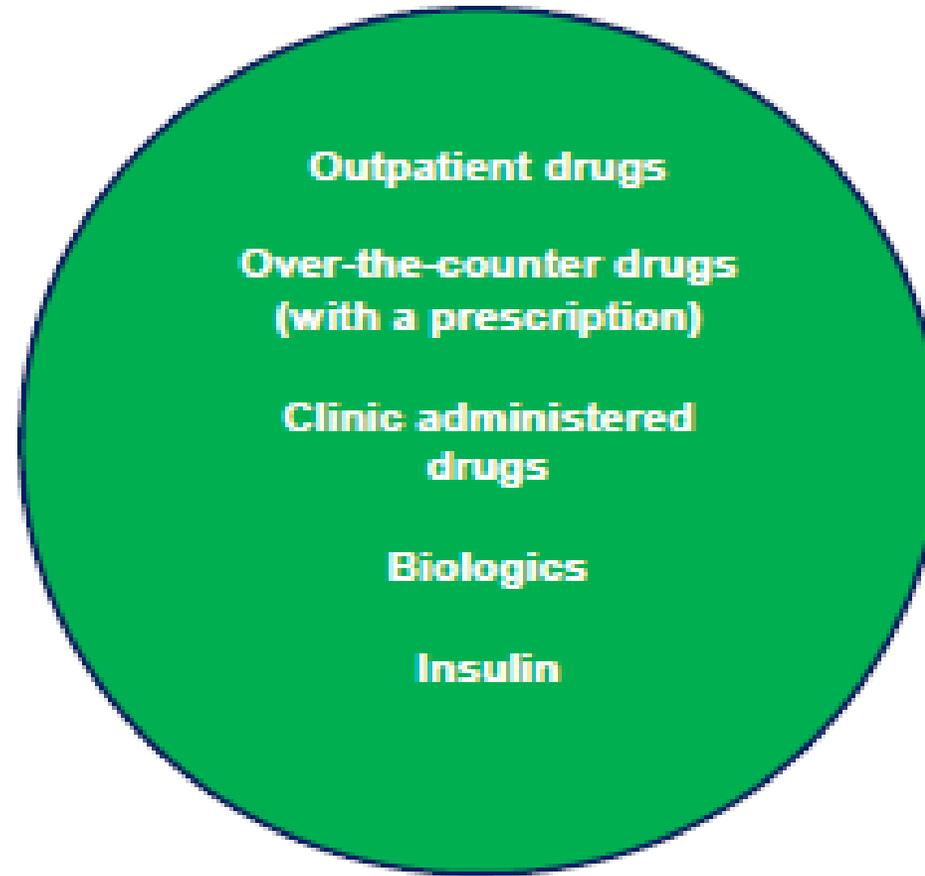
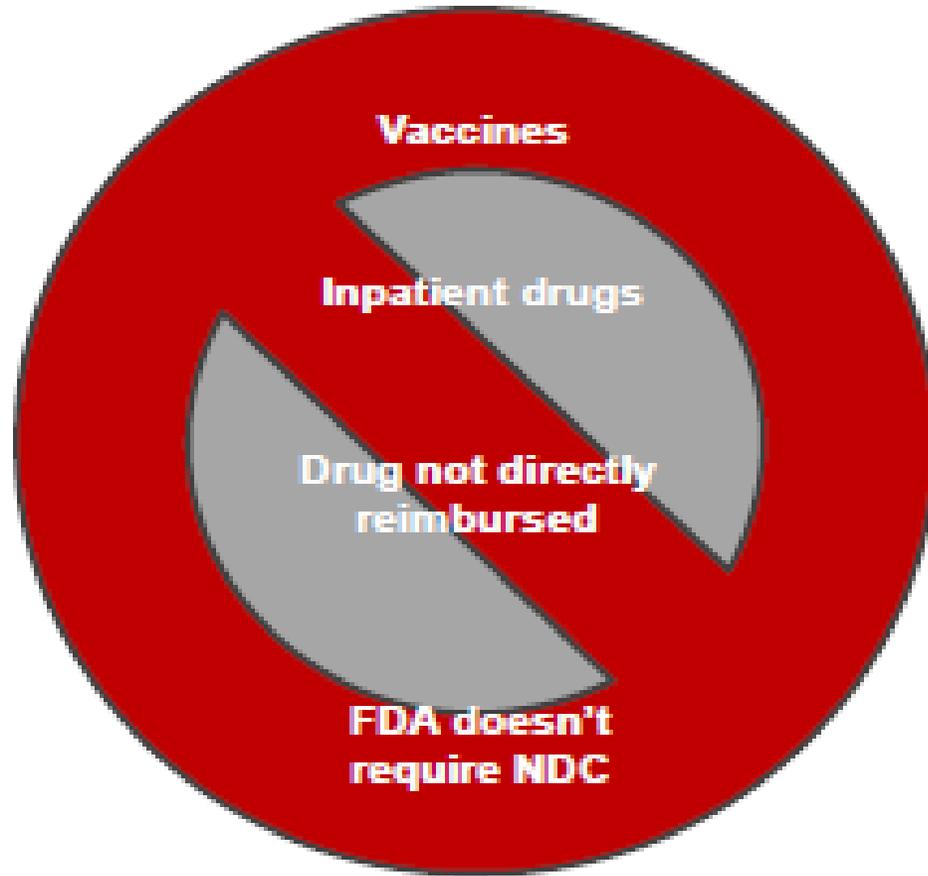
Introduction

- The Intent of program 340 is to allow covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.
- Program helps to reduce outpatient drug costs for safety net providers, including Title X agencies and their patients by statutorily mandating deep discounts from drug manufacturers as a condition of Medicaid reimbursement.
- Providers typically save 20-50% on outpatient drug costs (known as a ceiling price) through participation in the program. These savings can be used to reduce the price of pharmaceuticals for patients, expand services offered to patients, or provide services to more patients.

Why Participate? → Pricing = Lowest in Market



Introduction: 340B Covered Outpatient Drugs: What is Included and What is Not Included?



Introduction: Eligibility for the Program

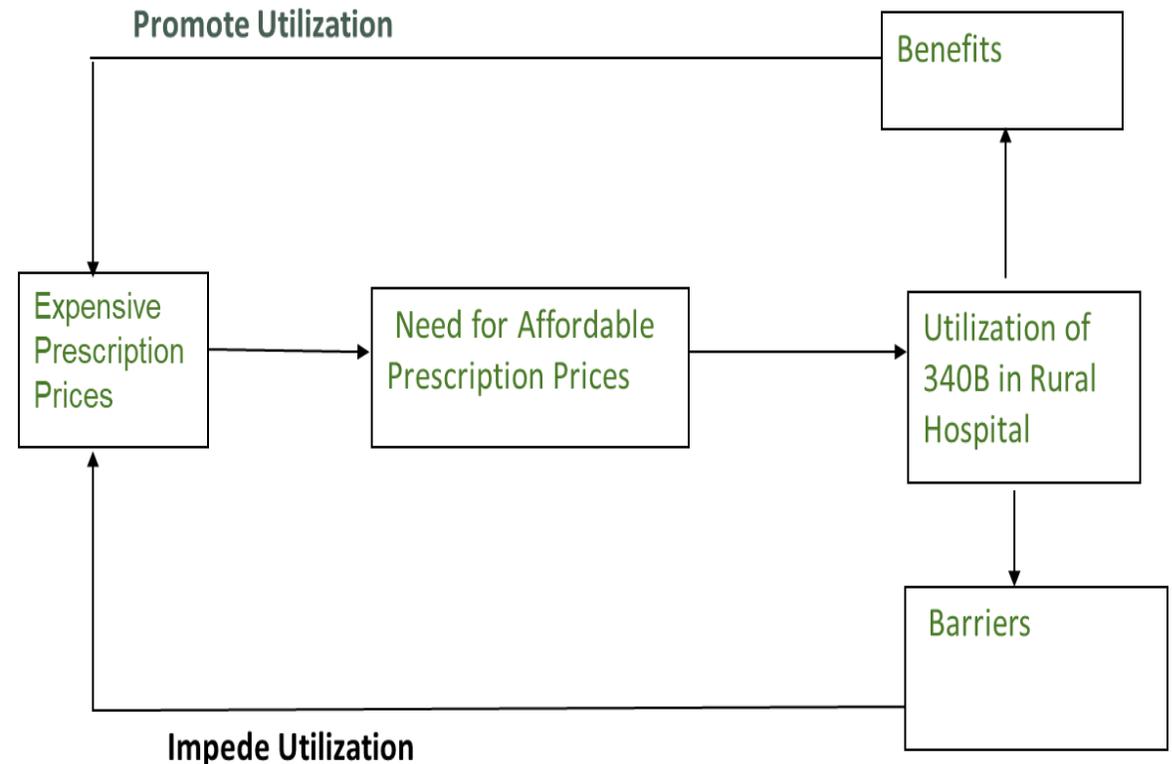
Federal Grantees / Designees	Certain Hospitals
Federally qualified health center	Disproportionate share hospitals
Federally qualified health center lookalikes	Children's hospitals
Title X family planning grantees	Critical access hospitals
State aids drugs assistance programs	Free standing cancer hospitals
Ryan white care act grantees (A,B,C,D,F)	Rural referral centers
Black lung clinics	Sole community hospitals
Hemophilia treatment centers	
Native Hawaiian health centers	
Urban Indian organizations	
Sexually transmitted disease grantees	
Tuberculosis grantees	

<https://www.hrsa.gov/opa/eligibility-and-registration/index.html>

Methodology

- Primary Hypothesis: Participation in the 340B program benefits both patients and health systems and has aided in expansion of access to medications and expanded health care services, and improved financial viability to health systems.
- The methodology for this qualitative study was a literature review complemented with semi structured interviews and analysis of the impact of the program with Marshall University affiliates,
- Databases searched: PubMed, EbscoHost, ProQuest, CINHALL, Alt-Health Watch, LexisNexis Academic, and Google Scholar.
- Key Terms: 340B, 340B Drug Pricing Program, 340B Program, issues, intent, benefits, financial impact, FQHC, contract pharmacies, or discount outpatient drugs.

- Conceptual Framework- Source: Yao, Chu, & Li, 2010

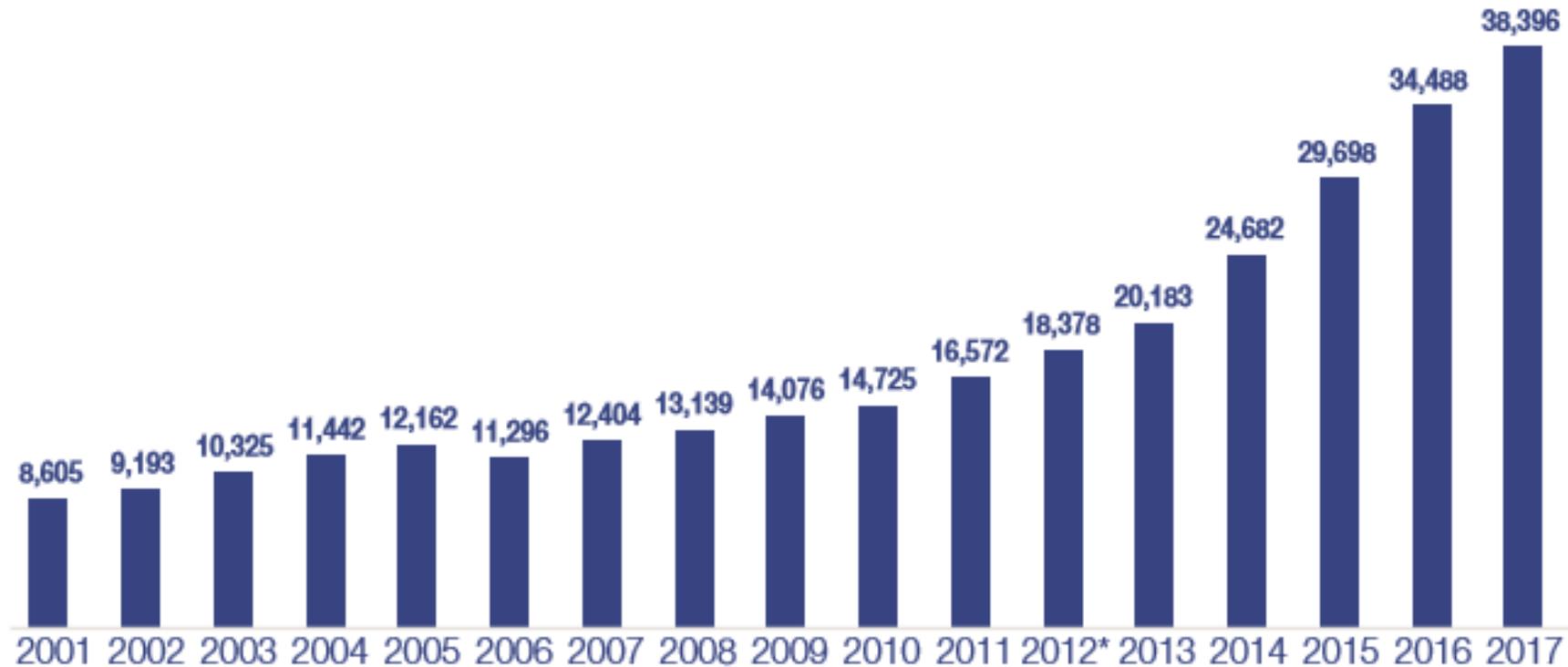


Results

- In 2016, hospitals provided nearly \$38.3 billion in uncompensated care
- 45% of all Medicare acute care hospitals participate in the 340B program
- 2014–2016, the volume of purchases made through 340B more than doubled, expanding 125%.
- 340B Discount Purchases = \$16.2 billion in 2016 — (\$12 billion in 2015)
- 340B program grew at a compound annual growth rate of 31% (2013 to 2016).
- Average savings of 25% –50% through negotiated ceiling / sub-ceiling price

Growth of the 340B Program

FIGURE 1: Number of 340B Covered Entity Sites
2001 - 2017



Source: Government Accountability Office

*The 2012 data point is extrapolated from the trend.

Benefits Realized with 340B Program:

- Better access to medications to the un/underinsured population - sliding scale fee.
- Increases revenue for affiliated provider = **reduced acquisition costs** for meds
- Hospital overall profitability enhanced due to patient compliance and reduced hospitalizations within 30 days of discharge.
- There is an impact – noted in 340B Health Fiscal Year 2015 Study:
 - 340B Disproportionate Share Hospitals (DSH) - responsible for 60% of all uncompensated and unreimbursed care while they make up only 38% of acute care hospitals studied
 - 340B DSH hospitals treated significantly more low-income patients than non-340B hospitals. Low-income patients made up 42% of 340B hospitals' patient load compared with 27% for non-340B hospitals
 - 340B hospitals provided 52.9% more uncompensated and unreimbursed care than non 340B hospitals
 - 340B DSH hospitals are more likely to offer services that are critical to low-income patients but are often underpaid, including outpatient alcohol and drug abuse services, trauma care, and care for patients with HIV/AIDS.

Limitations of the program 340B

- 340B savings are not required to be passed on to patients directly.
- More guidance is needed to clarify what is “eligible patient” / intent
- Most savings realized in the program are related to branded prescription drugs.
- Limited to outpatient services.
- Complex program to participate in (especially in mixed use areas)
- Concern it drifted from its initial mission, and that hospitals are not always using the money to serve disadvantaged patients.
- Hospitals should be required to document how they are using dollars saved to meet the intent of the program

Limitations: Debate of Scope of 340B Program

Covered Entities

- 1992 – 50 hospitals participating in 340B
- About 1/3 of all acute care hospitals in US participated in 340B in 2018.
- Est. drug sales to 340B-CE's increased 125% from 2015-2017.
- 340B hospitals seek to preserve the current criteria for program eligibility and their ability to use revenue generated through the program without restrictions.
- Argument is that the program is essential for maintaining the full range of services they provide to low-income and other patients in their communities.
- Argue drug makers want to limit participation to save themselves money.

Manufacturer's

- Concern expansion of the program will result in manufacturers increasing prices for other purchasers (Conti and Bach 2013, Government Accountability Office 2011, Hirsch et al. 2014).
- Manufacturers question whether all of the entities in the program need discounted drugs and whether the criteria for hospitals to participate in the program—such as the DSH adjustment percentage—should be changed (Government Accountability Office 2011).
- Manufacturers seek to narrow the program's focus to helping patients who are poor and uninsured gain access to outpatient drugs.

Marshall University Affiliate Results (Ongoing Research)

- Cabell Huntington Hospital and Marshall Health
 - Cabell Huntington Hospital is a 340B entity under nonprofit, disproportionate share rural hospital
 - Marshall Health became provider based clinics of CHH
 - Under 340B program, Marshall Pharmacy provides outpatient prescriptions
 - Expansion of clinical services, implementation of “Meds-to-beds” program, implementation of sliding scale program to benefit community, development of residency program
 - Financial impact analysis pending
 - Expansion of number of pharmacies participating in the program
 - Humanistic impact
- Valley Health System
 - FQHC participant in 340B program
 - In house pharmacies (now expanded to 3 total) with contract pharmacies
 - Expansion of services, sliding scale program, development of residency program
 - Financial impact analysis pending
- Thomas Health Systems
 - Nonprofit, disproportionate share hospital
 - Established Thomas Family Pharmacy
 - Grew internal coverage for employee prescriptions
 - Expanded services for all patients, implemented sliding scale program, established jointly funded clinical program
 - Financial analysis impact pending

Discussion

- Because savings are not required to be passed on directly to patients, some patients who need assistance do not directly receive it
 - Patients have to ask for sliding scale pricing
 - Not automatic due to lack of regulatory guidance
- CE do not have to share how they use the \$ and patients with commercial insurance and some private pay do not benefit safety net and often see increased copays / rates.
- Have seen growth of the plan in areas with more affluent populations with higher paying insurance plans (may not be target populations)
- Possible increased costs to overall system
- Created large industry for program that should be simple

CONCLUSION

1. 340B does provide benefits to Vulnerable & Underserved patient by:
 - Expanded services
 - Increased access to healthcare.
 - Increased access to prescription drugs
2. This type of benefit, while indirect, has fulfilled the intent of the 340B program at its inception.

Questions?

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To Participate:

Qualified Provider/Qualified Pharmacy/ Qualified Patient

- Records of individual's care reside with the covered entity
- Health care services, health care professional
 - Employed by, under contractual or other arrangements (referral)
 - "Qualified provider"
- Entity has responsibility for care
- Service received is consistent with funding or designation status (hospitals exempt)
- Services must be more than dispensing
- Pharmacy is "in house" or contract pharmacy
- AIDS Drug Assistance Program (ADAP) exception