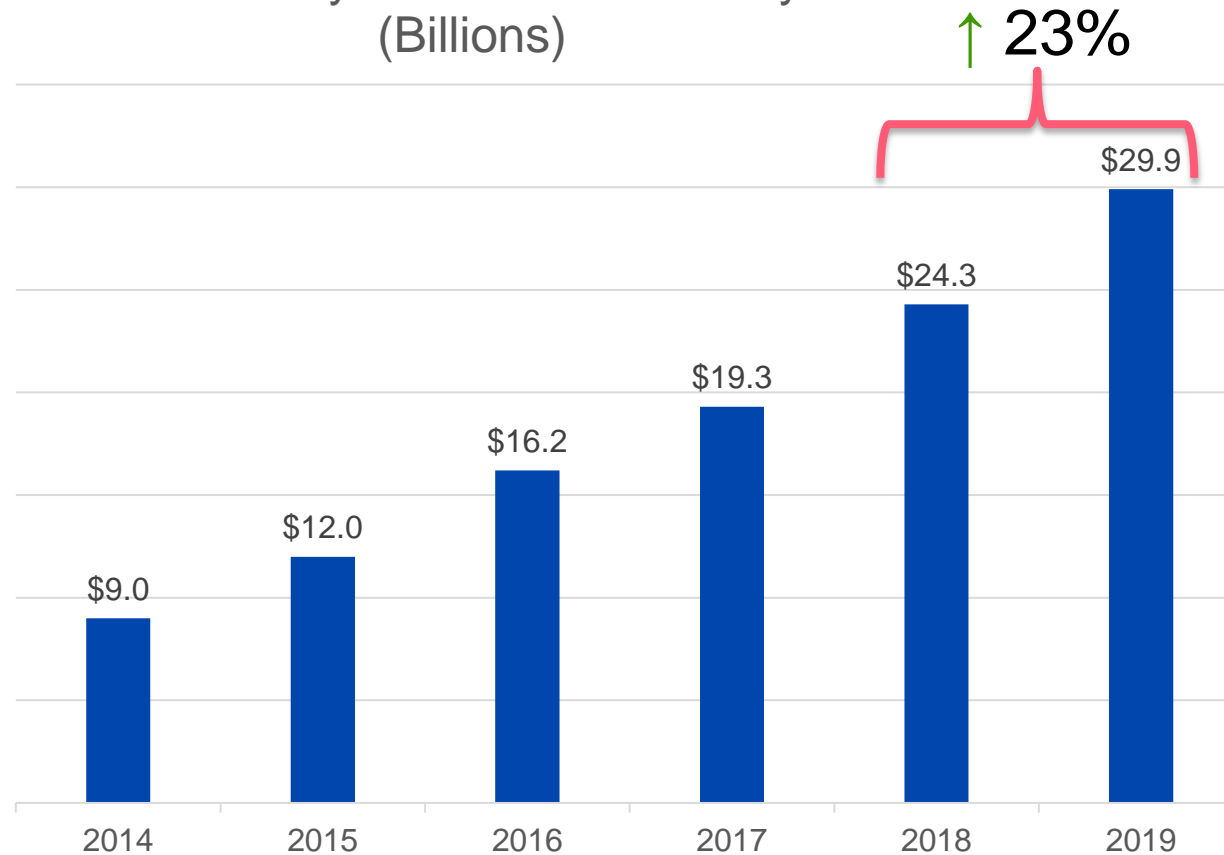


To Be or Not To Be: Benefits and Challenges of 340B

Dylan Kosaski, Pharm.D.
PGY-2 Health System Pharmacy Administration Resident
January 12, 2021

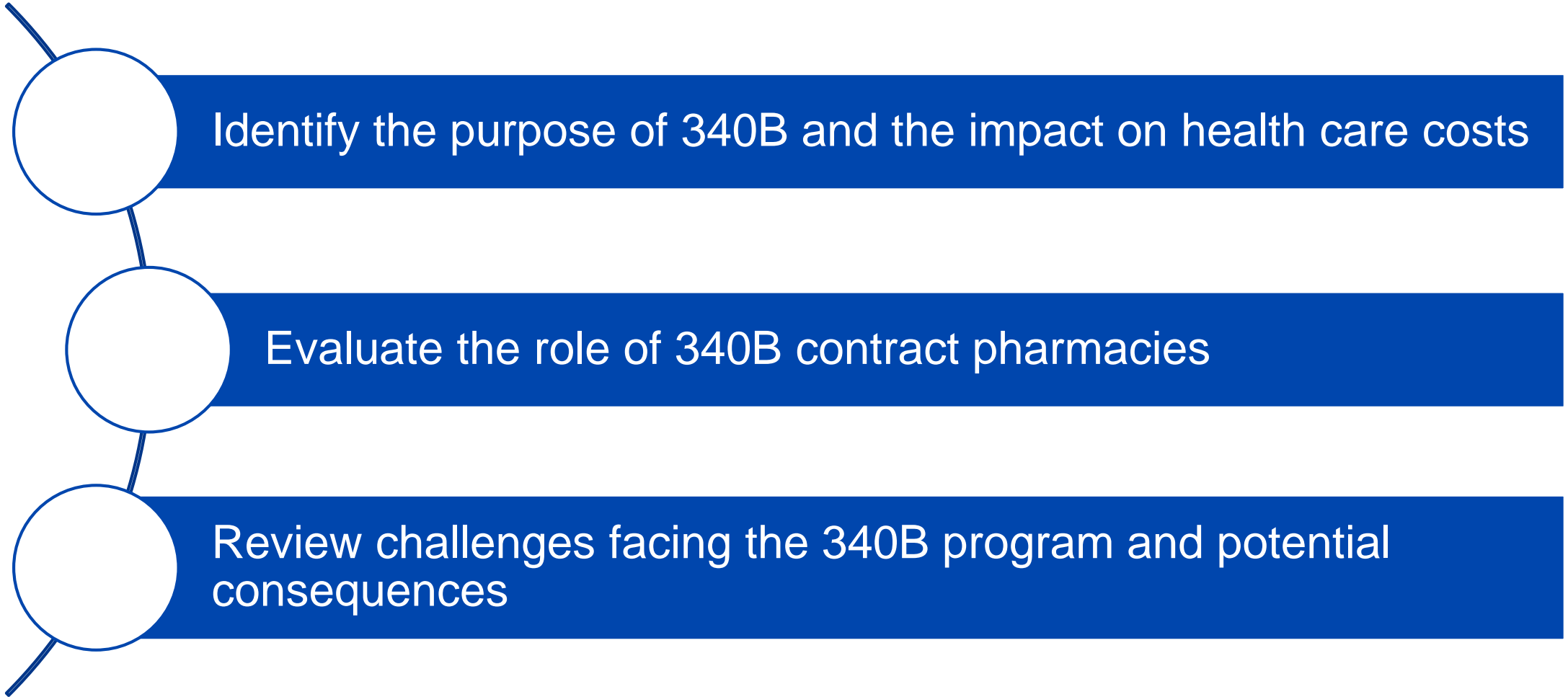
340B Purchases

Covered Entity 340B Purchases By Year
(Billions)



\$511 Billion in total U.S.
drug purchases in 2019

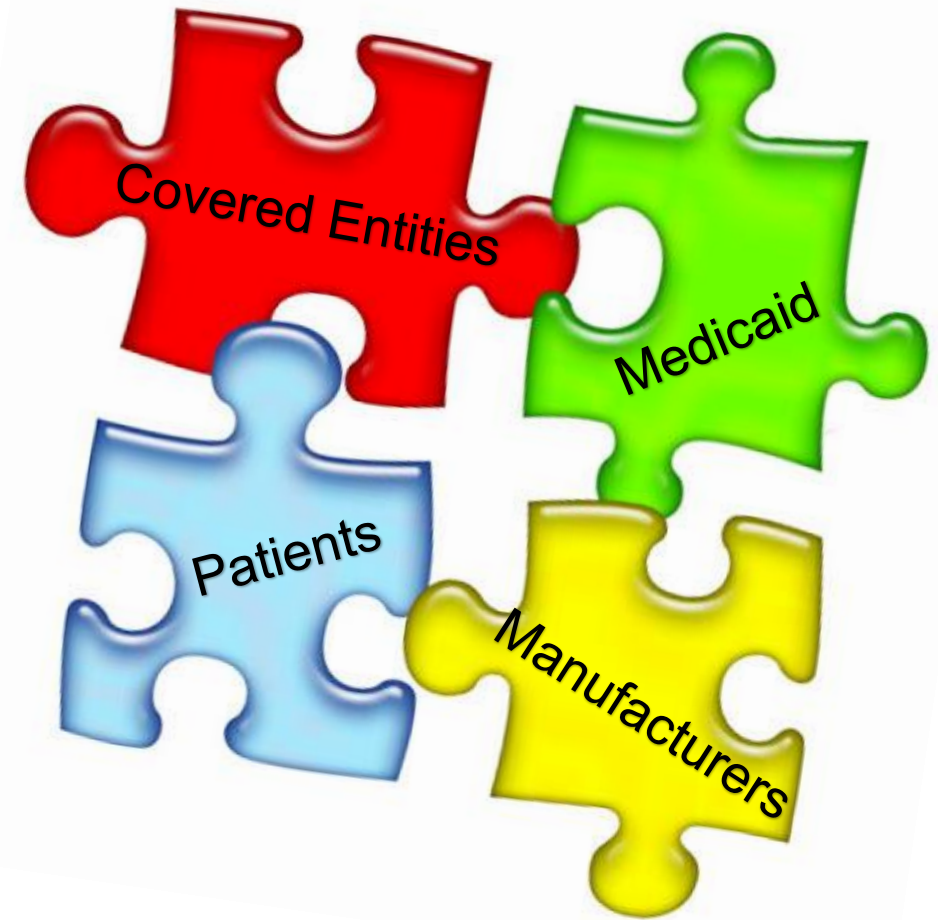
Learning Objectives



What is 340B?

- A national program designed to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”

-102nd Congress, 1992



Covered Entities

- Disproportionate share hospitals (DSH)
- Children's hospitals*
- Cancer hospitals*
- Sole community hospitals
- Rural referral centers
- Critical access hospitals
 - Eligibility is not a factor of their DSH adjustment factor

Eligibility is also subject to the hospital's DSH Adjustment Factor

$$\frac{\text{Medicaid, Non-Medicare Part A\&C days}}{\text{Total Patient Days}} \times \frac{\text{Medicare SSI Days}}{\text{Total Medicare Part A Days}} = \text{Medicare DSH Patient Percentage}$$

*Must be exempt from Medicare prospective payment system

Non-Hospital Covered Entities

- Federally qualified health centers (FQHCs)
- State-operated AIDS drug assistance programs
- Ryan White CARE Act clinics and programs
- Tuberculosis and black lung clinics
- Title X family planning clinics
- Sexually transmitted diseases clinics
- Hemophilia treatment centers
- Urban Indian and Native Hawaiian health centers

340B Pricing

- Covered entities get discounted rates on **outpatient** drugs
- Covered drugs are provided at the “best price” and often acquired through their usual wholesaler
- Manufacturers cannot charge above the 340B ceiling price
 - $AMP - URA = 340B \text{ ceiling price}$
- Hospitals can negotiate sub-ceiling prices

Patient Requirements

Patient – Entity Relationship	Provider – Entity Relationship	Federal Grantee
The entity must maintain records of the patient's care	Care provider must be: <ul style="list-style-type: none">- Employed by the covered entity OR <ul style="list-style-type: none">- Under contract or other arrangement with the covered entity such that responsibility of care remains with the covered entity	Patient must receive services consistent with the service for which grant funding was provided

 Patients are not eligible if the only health care service provided is dispensing

Billing Requirements

- Duplicate Discount – Covered entities must not provide 340B products for which Medicaid agencies are also billing manufacturers for Medicaid rebates
- Medicaid FFS and 340B programs
 - “Carve-in” – Include Medicaid patients in 340B
 - “Carve-out” – Exclude Medicaid patients from 340B

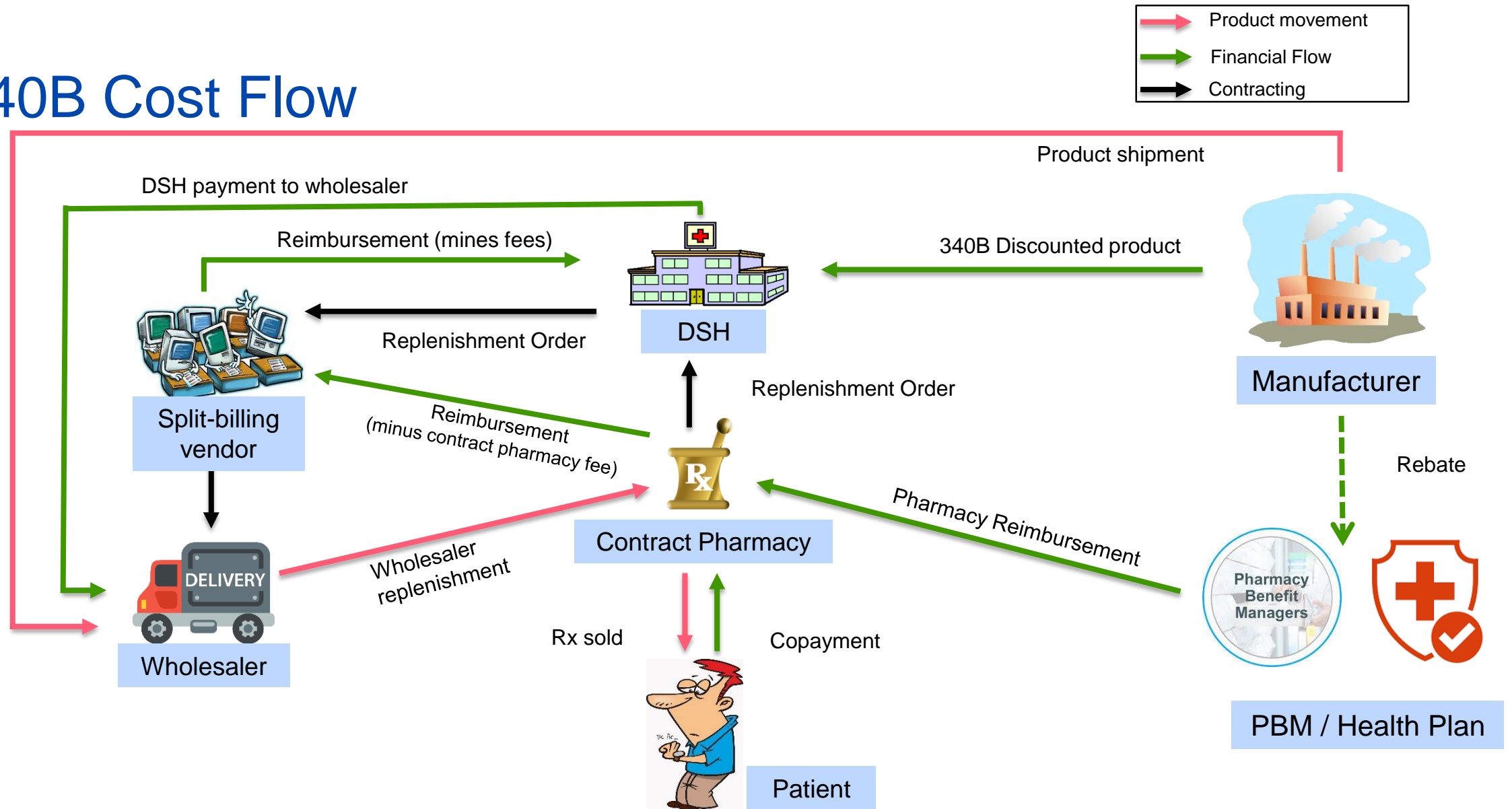
Brief History of 340B – Part 1

1990	1992	1994	1996
Congress created the Medicaid Drug Rebate Program	Section 340B of the Public Health Service Act creates the 340B Program	HRSA allows 340B hospitals to include off-campus outpatient sites (child sites)	HRSA allows covered entities to contract with one off-site pharmacy

340B and Contract Pharmacies

- Many patients had previously filled outpatient prescriptions at pharmacies not affiliated with the hospital, thus restricting the value of 340B pricing
- Contract pharmacies dispense drugs on the behalf of the covered entity and collect negotiated fees
- Extension of covered entities to expand access outside the traditional four walls of a hospital or clinic
- More than 80% of rural 340B hospitals use contract pharmacies

340B Cost Flow



Poll Question: True or False: Contract pharmacies must maintain a separate physical inventory for 340B products?

A. True

B. False

True for False: Contract pharmacies must maintain a separate physical inventory for 340B products?

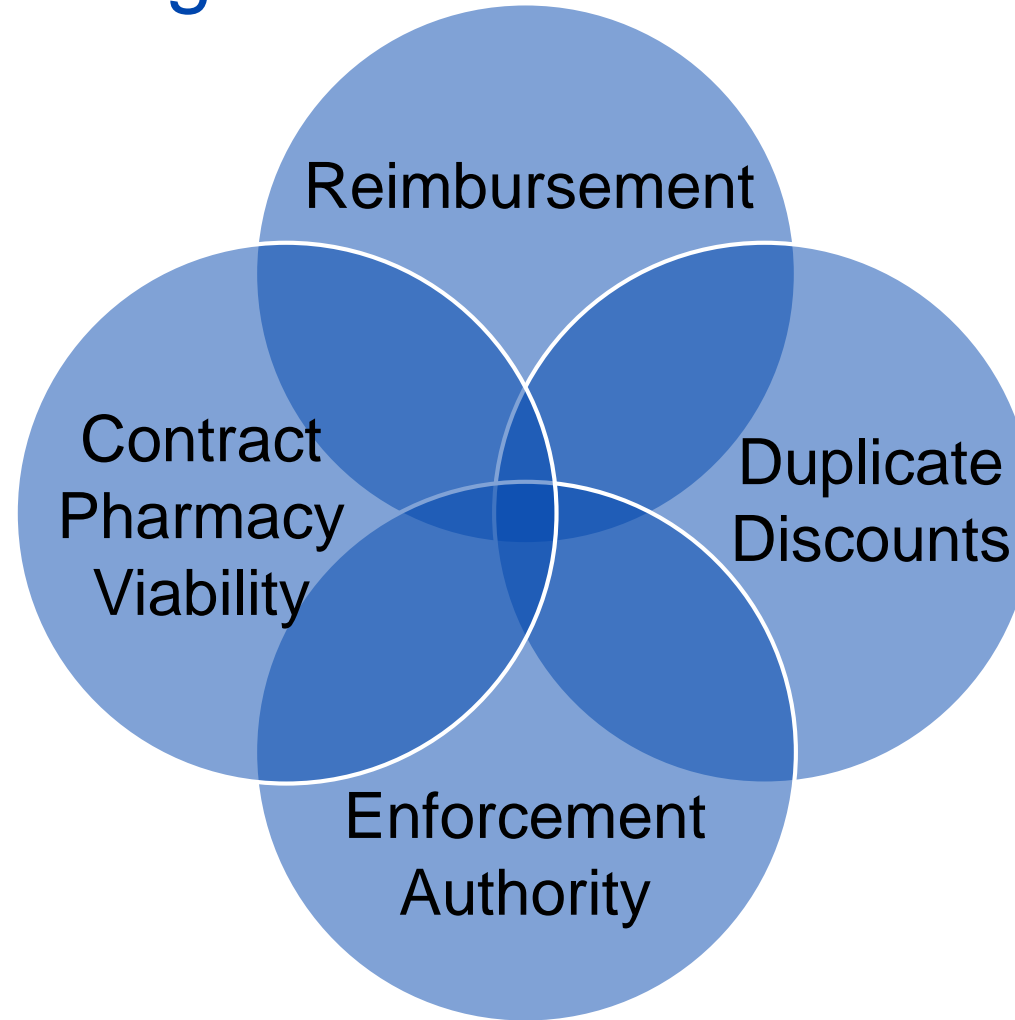
A. True

B. False

Brief History of 340B – Part 2

2010	2013	2018	2020
Expanded contract pharmacies	The Final Rule clarifies 340B orphan drug exclusion to only target rare disease indications	CMS reduces reimbursement for drugs acquired through 340B from ASP + 6% to ASP - 22.5%	HRSA claims no statutory authority to enforce 340B pricing offered by manufacturers to contract pharmacies
ACA extends 340B to CAH, SCH, RRC and cancer centers			
ACA introduces orphan drug exclusion for 340B			

Active 340B Challenges

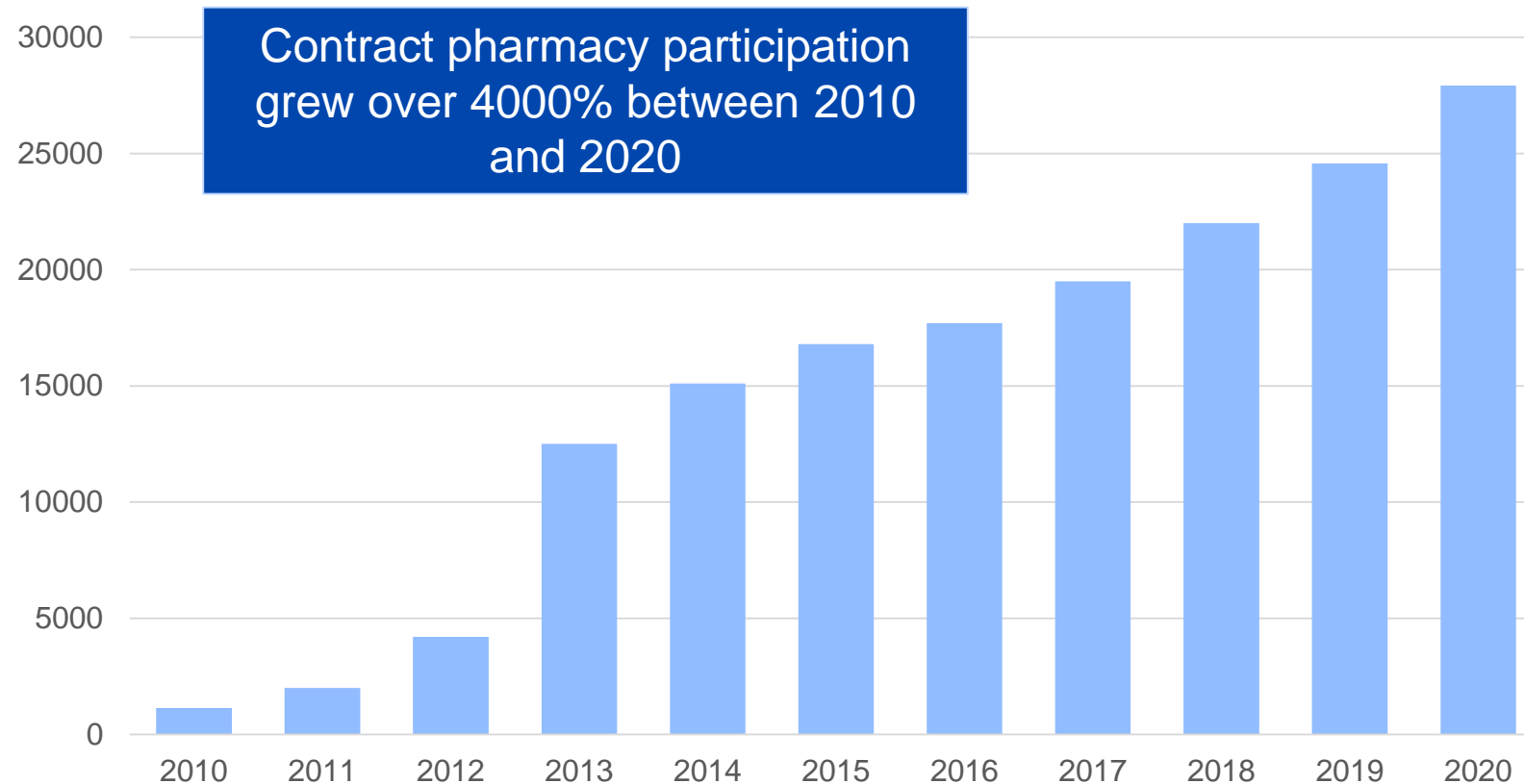


Contract Pharmacy Viability

- Critics cite concerns for the profitability for contract pharmacies at the expense of low-income patients
 - Hospitals contract on average with 22 distinct pharmacies
 - In 2020, the average distance between contract pharmacies and covered entities is 334 miles
- Chain pharmacies represent ~67% of contracted locations
- Contract structure and profit-sharing changes with the influence of large chains
- Vertical integration with PBMs, health plans, pharmacies and split-billing firms

Brand product	Estimated average profit margin
340B	72%
Non-340B	22%

Contract Pharmacies by Location



Company	2020 Contract pharmacies (%)
Walgreens	28
CVS	20
Walmart	10
Rite Aid	5
Kroger	4
Other	33

Manufacturers Response to Contract Pharmacies

1. Eli Lilly

1. July 2020 – limited Cialis distribution with new policy against contract pharmacies
2. September 2020 – expanded limited distribution policy

2. Merck, Sanofi and Novartis

- Demand excessive reporting of 340B claims. Non-compliance could result in:
 - “less collaborative and substantially more burdensome” action
 - Ineligibility to place replenishment orders for their products

3. AstraZeneca

- Honoring 340B only for covered entities’ outpatient pharmacies
- One contract pharmacy per covered entity

Continued Reimbursement Reductions

- CMS Social Security Act §1833
 - *“the amount of payment for a specified covered outpatient drug shall be equal to the average acquisition cost for the drug for that year”*
- CMS hospital acquisition cost surveys
 - Hospital drug acquisition data are unavailable (7% detailed responses)
 - Survey dates: April 23, 2020 – May 15, 2020
 - Acquisition cost data exceeding 340b ceiling prices



Duplicate Discounts

- Duplicate discount = Medicaid Rebate + 340B pricing
- Medicaid and CHIP Managed Care Final Rule 2016 (CMS-2390-F)
 - Covered entities do not have to submit claims data to manufacturers
 - States must have a mechanism to ensure compliance
 - Medicaid FFS: Medicaid Exclusion File (MEF)
 - Medicaid Managed Care Organizations
- 340B billing claims identifiers
- Contract pharmacy limitations
- Carve-in or Carve-out Medicaid patients from 340B programs

Carve-in vs. Carve-out?

- Consider how many Medicaid patients you serve
 - FFS vs. MCOs
- How does reimbursement compare between FFS and MCO?
- Compliance challenges with each model
- Costs associated with maintaining each model

340B Enforcement Authority

- 2014 – Federal court ruled HRSA’s regulatory authority is limited to
 1. Establishing and implementing an Administrative Dispute Resolution (ADR) process for resolving compliance with 340B disputes
 2. Providing for the imposition of civil monetary penalties against manufacturers that knowingly and intentionally overcharge a covered entity for a 340B drug
 3. Issuing precisely defined standards of methodology for calculation of 340B ceiling prices
- 2020 HHS guidance on the 340B program states
 - *The contents of this document do not have the force and effect of law and are not meant to bind the public in any way”*

340B Enforcement Authority

- HRSA continues to point out the value of contract pharmacies
 - Guidance is not legally enforceable
 - Dec. 30, 2020 HHS Advisory Opinion
- HRSA is unable to issue rules that clarify program requirements
- 340B growth has outpaced HRSA's oversight ability
- What does this mean for the future of manufacturer compliance?



Poll Question: Which of the following is not one of the challenges facing the current state of the 340B program?

- A. Limited drug supply
- B. Contract pharmacy exclusions
- C. Reduced reimbursement
- D. Operational challenges to limit duplicate discounts

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2020 Review – Dobson | DaVanzo

- Objective Metrics
 1. Medicaid/Medicare SSI patient load
 2. Medicaid revenue as a percent of operating revenue
 3. Hospital Operating margins
 4. Provision of highly specialized services, services targeting underserved populations, and promoting community health and access
- Analysis Timeframe: FY 2018

Methodology – Dobson | DaVanzo

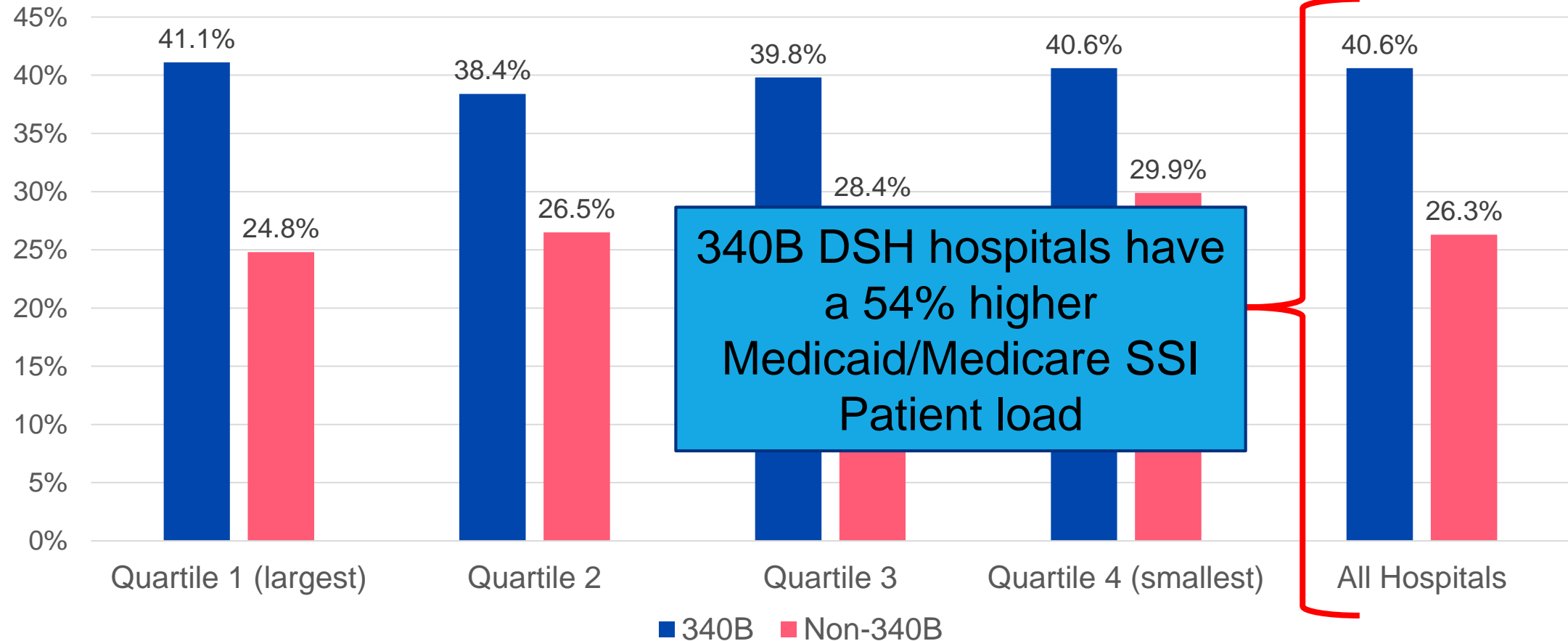
- FY 2020 Medicare IPPS final rule
- January 2020 HRSA OPAIS Covered Entity Daily Report



- Stratified by total patient care costs as a proxy for hospital size

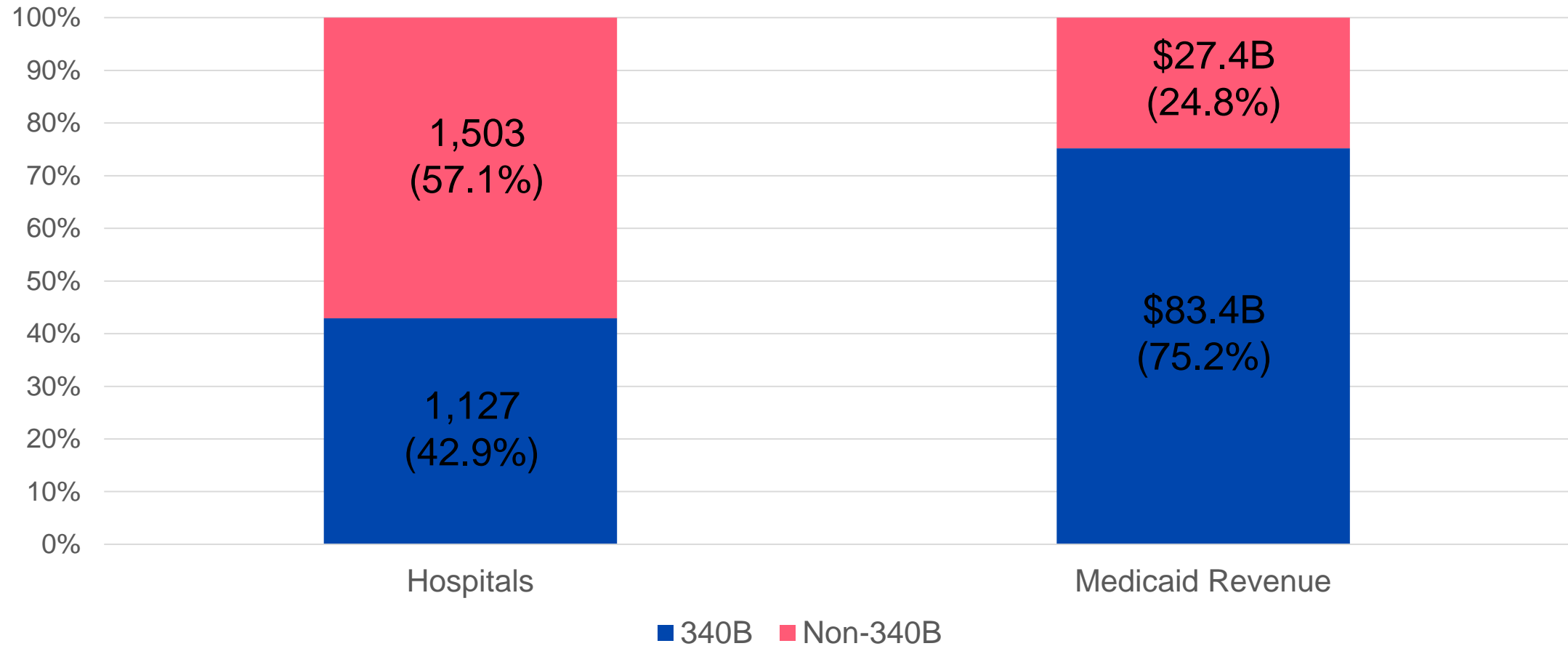
Patient Load – Dobson | DaVanzo

Average Medicaid/Medicare SSI Patient Load by Quartile of TPCC, FY 2018



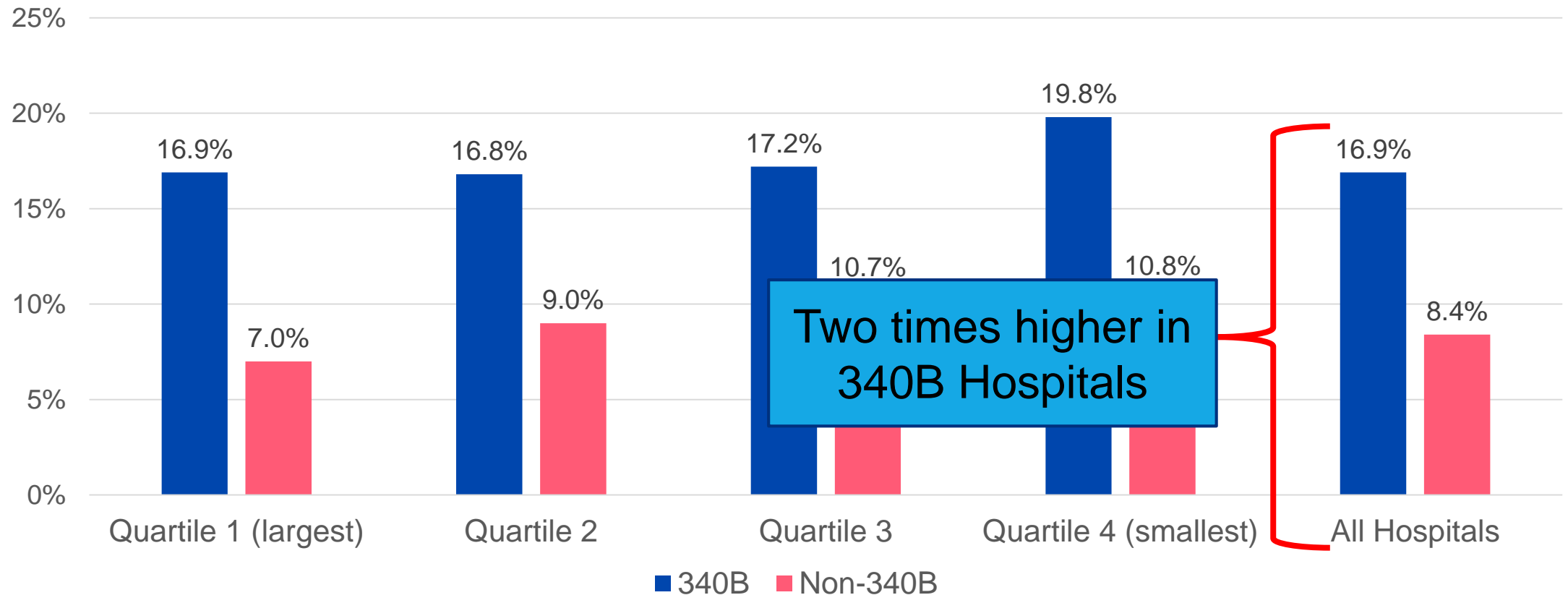
Medicaid Revenue – Dobson | DaVanzo

Distribution of 340B and Non-340B Hospitals and Medicaid Revenue, FY 2018



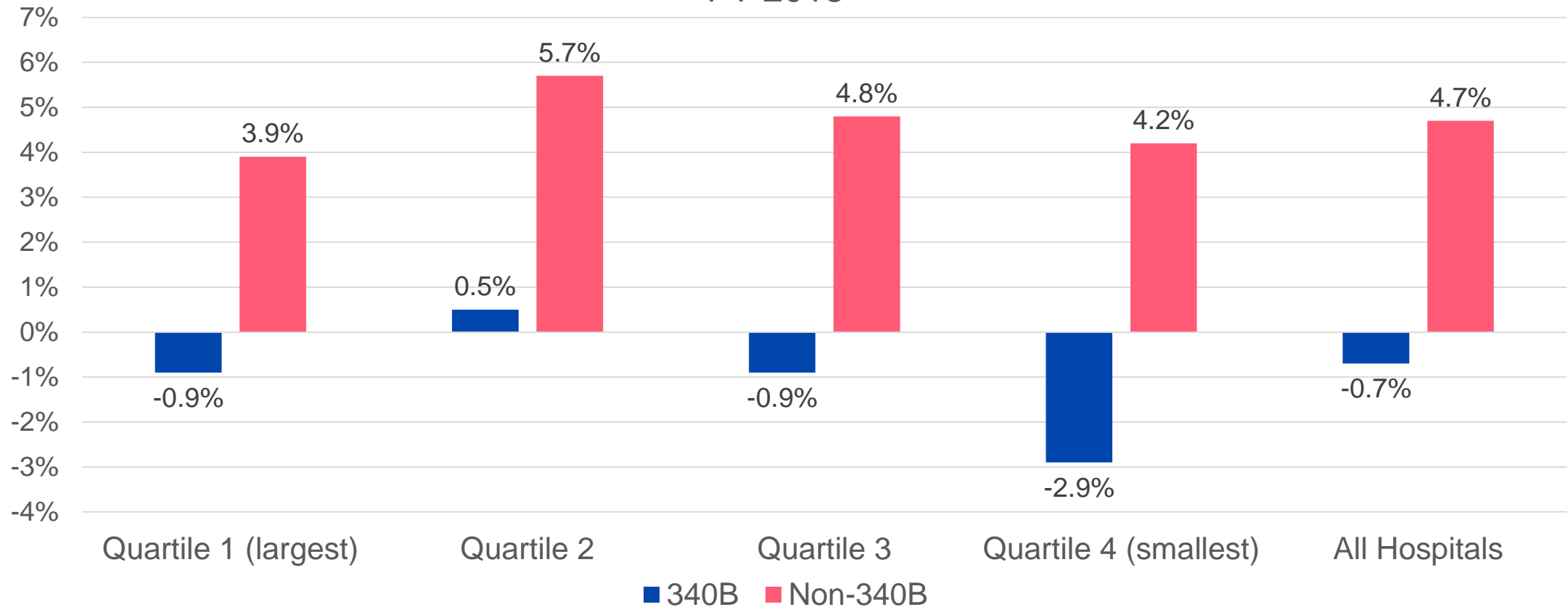
Medicaid Revenue – Dobson | DaVanzo

Medicaid Revenue as a Percent of Total Hospital Operating Revenue by
Quartile of TPCC, FY 2018



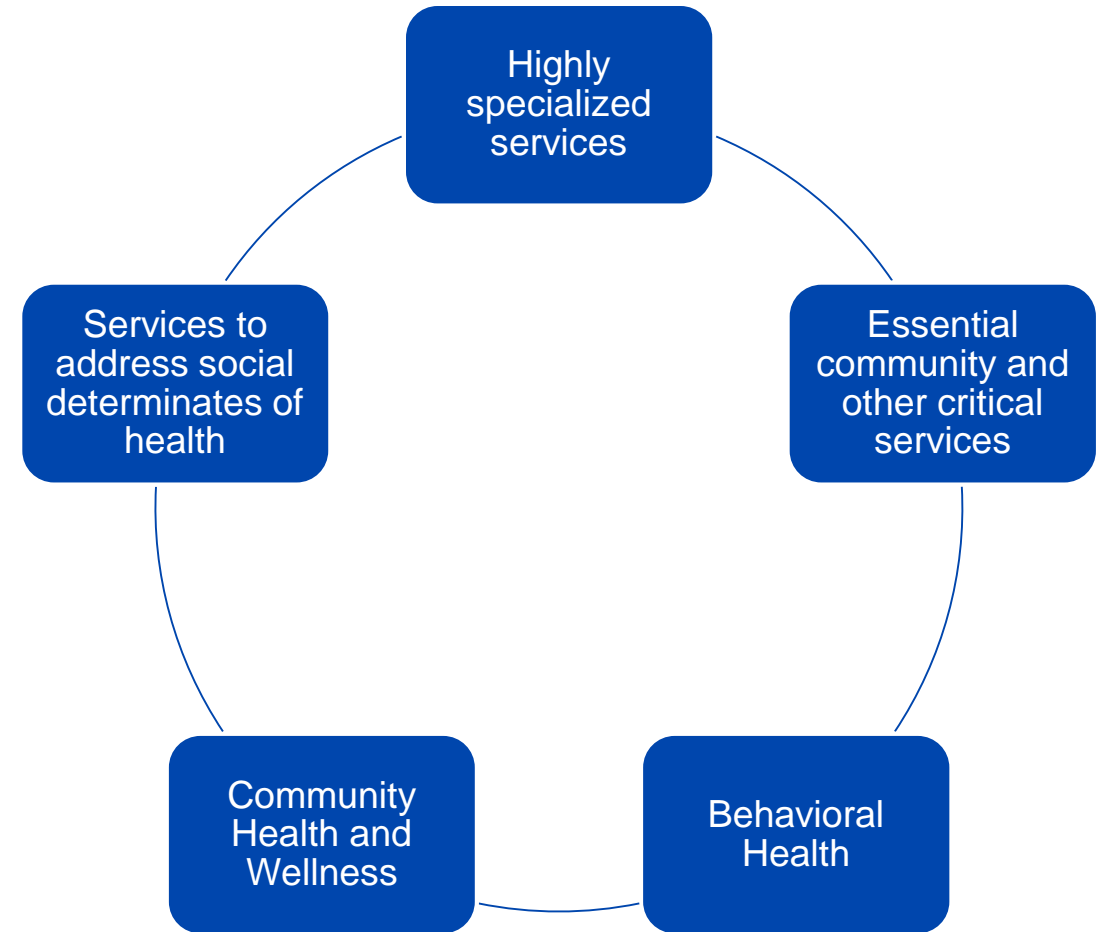
Operating Margins – Dobson | DaVanzo

Operating Margins for 340B and Non-340B Hospitals by Quartile of TPCC, FY 2018



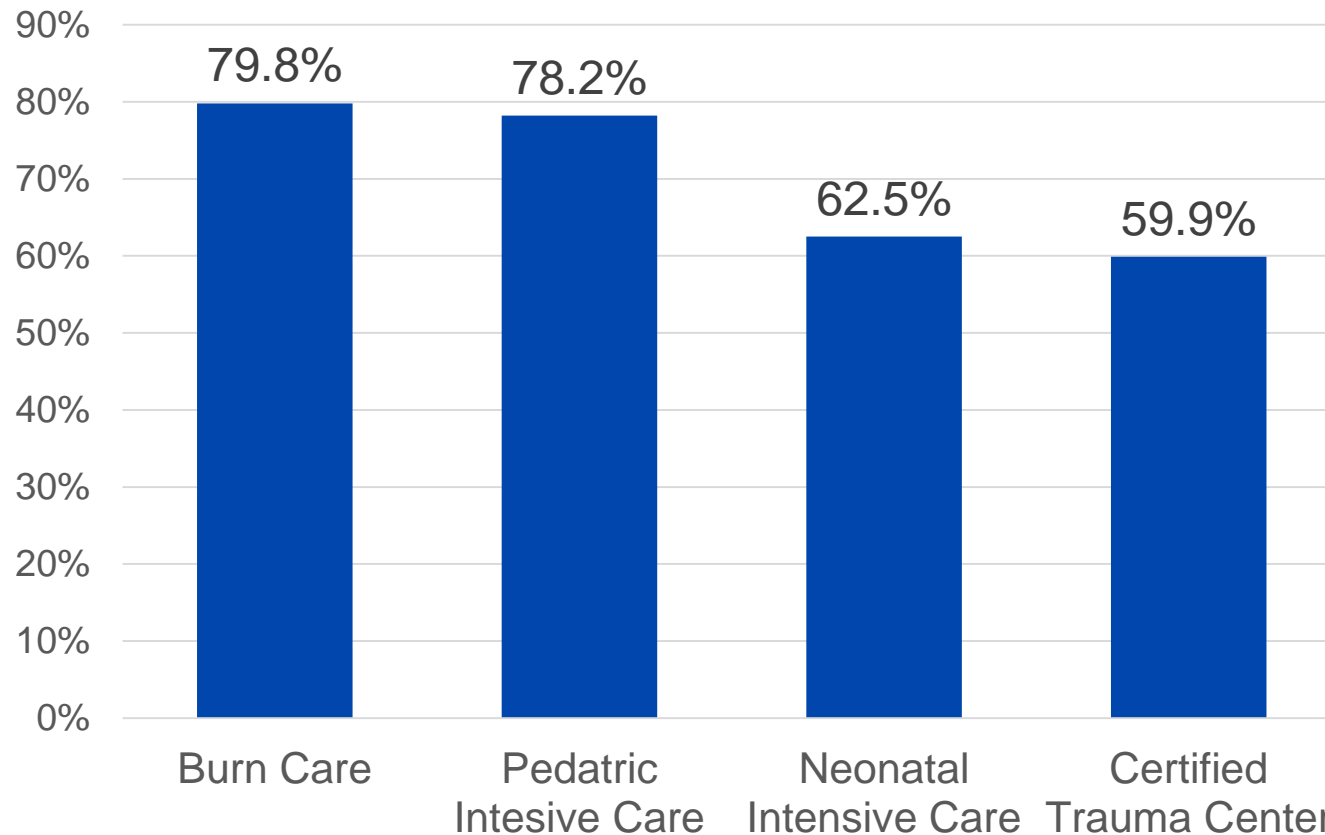
Provision of Services – Dobson | DaVanzo

- American Hospital Association survey data was used to determine services offered



Highly Specialized Services – Dobson | DaVanzo

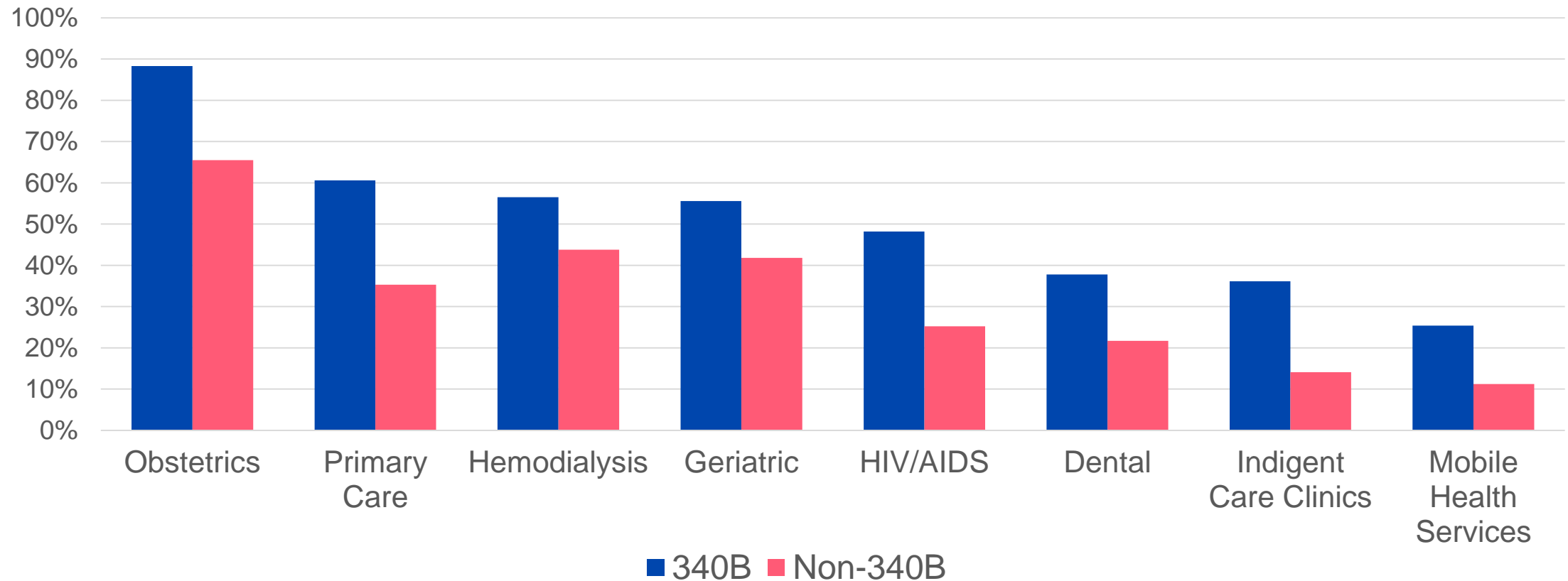
Percent of 340B Hospitals Offering Specialized Services



- “Essential community services” according to MACPAC
- Specialized services are highly concentrated in 340B hospitals

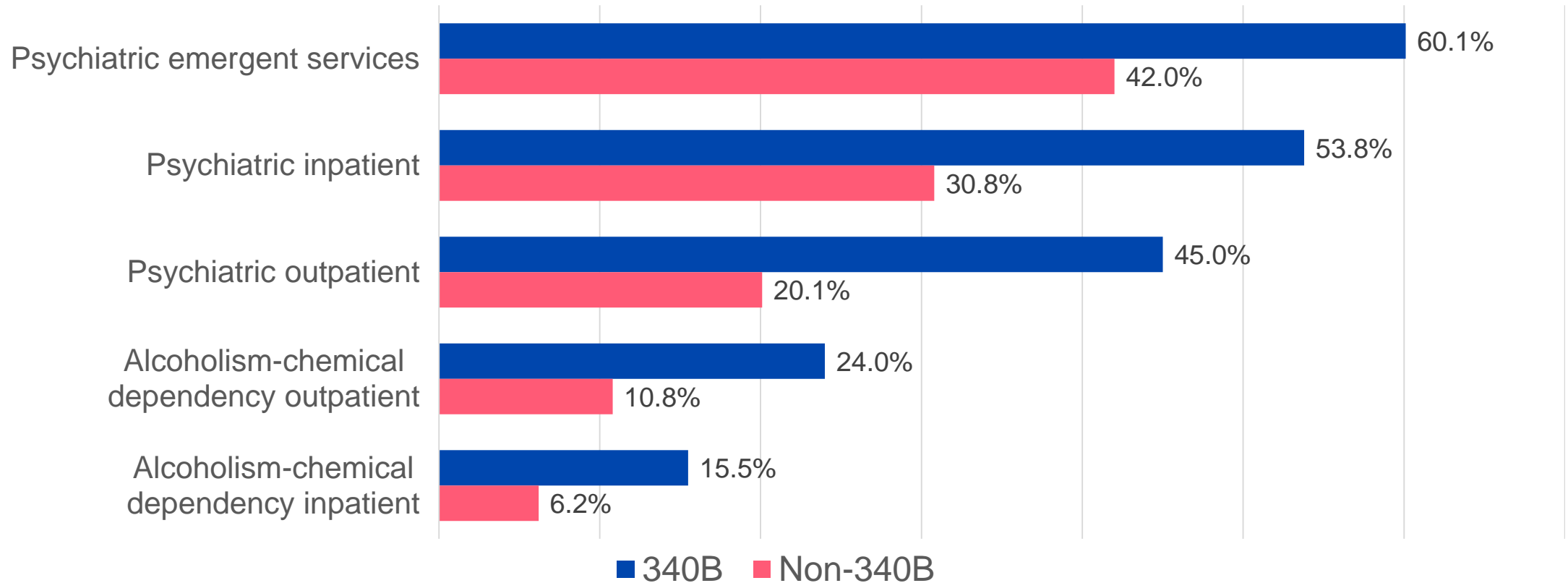
Essential Services – Dobson | DaVanzo

Percentage of 340B and Non-340B Hospitals Providing Essential Community Services



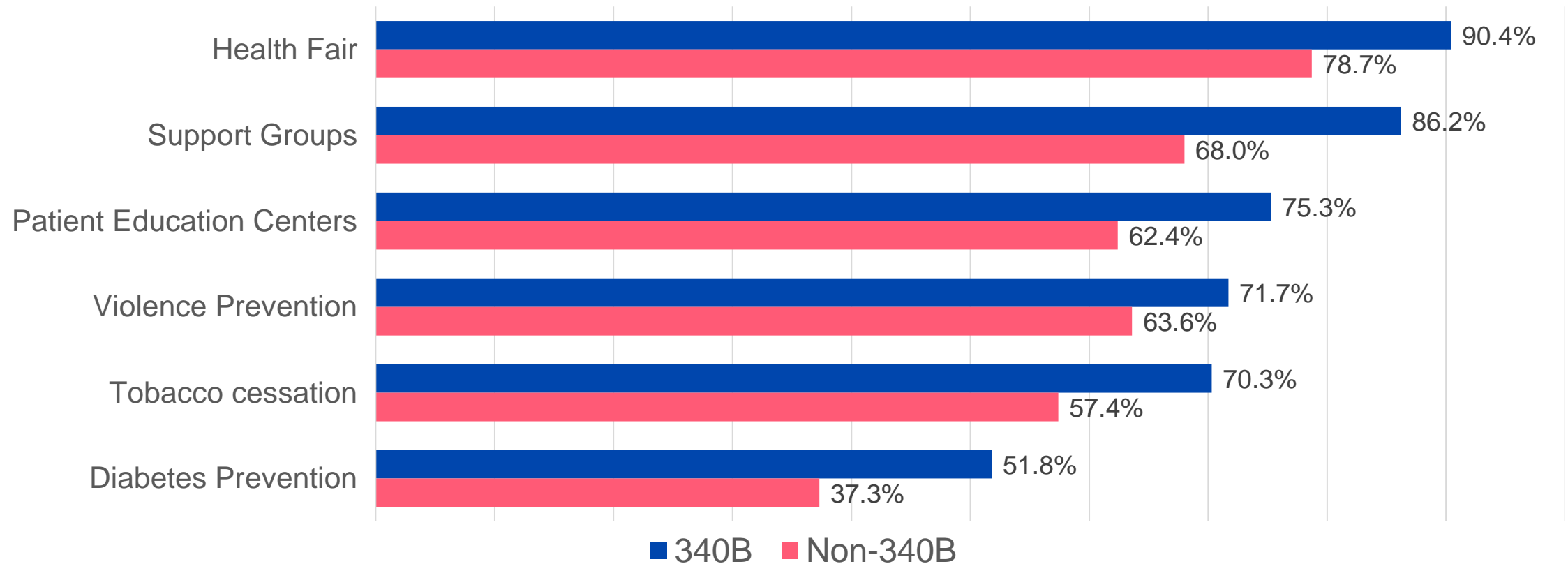
Behavioral Health – Dobson | DaVanzo

Percentage of 340B and Non-340B Hospitals Providing Behavioral Health Services



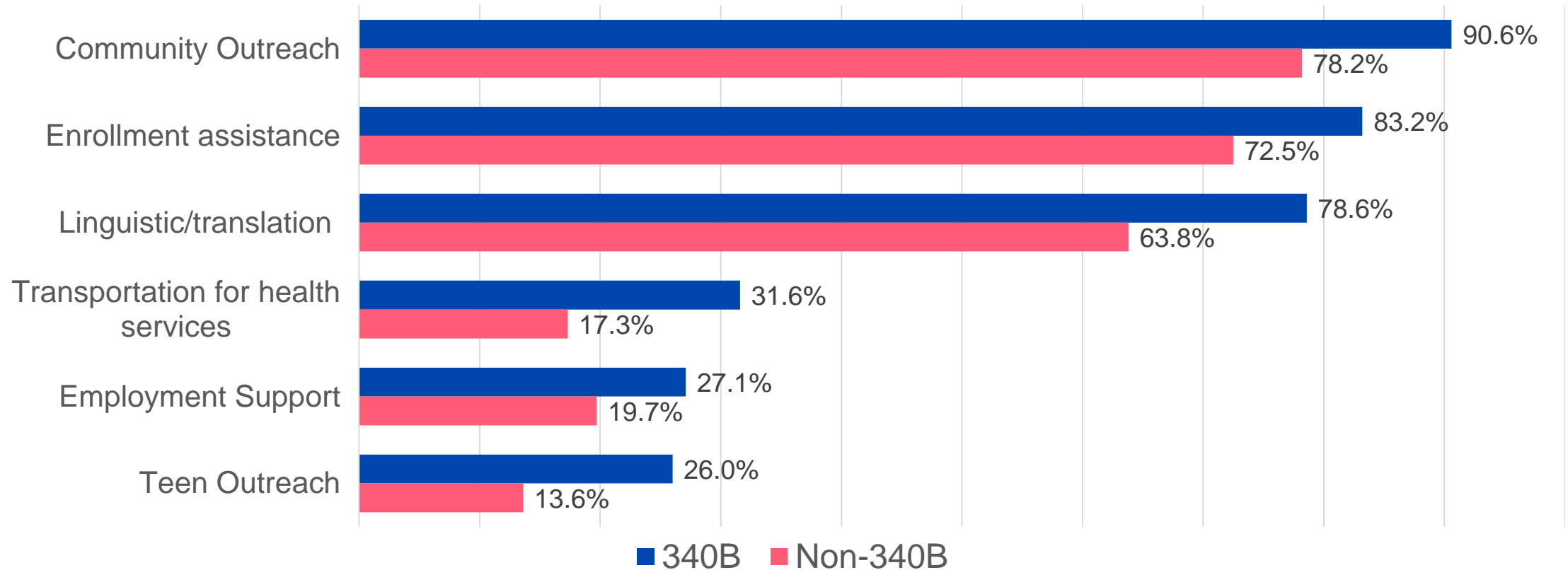
Community Health and Wellness – Dobson | DaVanzo

Percentage of 340B and Non-340B Hospitals Providing Community Health and Wellness Services



Social Determinates of Health – Dobson | DaVanzo

Percentage of 340B and Non-340B Hospitals Providing Services Targeting Social Determinates of Health



340B Report – 2020 Review Summary

340B Hospitals treat higher levels of Medicaid and Medicare SSI patients

340B Hospitals continue to offer specialized and essential services, despite unfavorable reimbursement

The 340B program recognizes inherent challenges and is critical to continued existence of many covered entities

Poll Question: According to the 2020 review, 340B hospitals are more likely to provide which services when compared to non-340B hospitals?

- A. Primary Care
- B. Behavioral Health
- C. Alcohol and chemical-dependency
- D. Obstetrics
- E. All of the above

Poll Question: According to the 2020 review, 340B hospitals are more likely to provide which services when compared to non-340B hospitals?

- A. Primary Care
- B. Behavioral Health
- C. Alcohol and chemical-dependency
- D. Obstetrics
- E. All of the above

Future Considerations and Opportunities

- Improve regulatory oversight and authority
 - Monitor and track use and associated benefits
- Program eligibility
 - Inpatient vs. outpatient metrics
- Improved transparency
 - Cost information sharing

Summary

340B serves a vital purpose in health care to meet the needs of uninsured and low-income patients

The program has expanded rapidly since the allowance of multiple contact pharmacies in 2010

Manufacturer non-compliance with the program poses significant risk

When compared to non-340B hospitals, 340b sites appear to meet the intent of the program

Considerable program review and clarification are needed to ensure compliance and sustainability

Questions?

Dylan Kosaski, Pharm.D.
PGY-2 HSPA Pharmacy Resident
E-mail: kosaski.dylan@mayo.edu