Department of Health

340B Advisory Group

Meeting # 1

August 5, 2020

Agenda

- Introduction and Overview of Advisory Group
- Intersection of 340B and the Medicaid Program
- Historical and Current 340B Data in Medicaid Managed Care
- Discussion
- Next Steps

Introduction and Overview of Advisory Group

340B Advisory Group Members

The 340B Advisory Group is charged with providing non-binding recommendations by 10/1/20 on available methods of achieving savings for 340B drugs in the SFY beginning on April 1, 2021.

Members

340B Providers and Covered Entities (DSH Hospitals/FQHCs)

- **Wendy Stark** – Executive Director of Callen-Lorde
- **Tucker Slingerland** – CEO of Hudson Headwaters Health Network
- **James Sinkoff** – CFO of Hudson River Health Care
- **Angela Langdon** – COO at Universal Primary Care
- **Michael Lee** – Vice President and COO at Evergreen Health Services (EHS)
- **Michele Steiner, PharmD** – Chief Pharmacy Officer at Neighborhood Health Center
- **Christian Oleck** – Vice President and CFO of Planned Parenthood of Central & Western NY, North Country and Upper Hudson
- **Curtis Haas, PharmD., FCCP** – Chief Pharmacy Officer at the University of Rochester Medicaid Center (URMC)
- **Larry McReynolds** – Clinical Associate Professor, Department of Population Health at NYU Langone
- **Danielle DiBari** – Senior Vice President of Business Operations and Chief Pharmacy Officer at NYC Health + Hospitals

Pharmacies

- **Debra Barber, RPh** – Vice President of Managed Care Contracting and Payor Relations at Kinney Drugs
- **Steve Moore, PharmD** – Owner of Condo Pharmacy
- **Falguni Shah, RPh., MBA** – Medicaid Segment Director at Walgreens

Medicaid Managed Care Plans

- **Doug Wirth** – President and CEO of Amida Care HIV Special Needs Plan
- **James Hopsicker RPh., MBA** – Vice President of Pharmacy at MVP Health Plan
- **Wahyan Connie Yuen** – Pharmacy Account Director at Empire BlueCross Blue Shield HealthPlus
- **Bhavesh Modi** – Vice President of Pharmacy at Healthfirst
- **Aron Weisskopf MPH, CPhT** – Pharmacy Director, C&S Medical Economics at United Healthcare

Purpose and Focus of 340B Advisory Group

- The 340B Advisory Group was enacted as part of the legislation to transition the pharmacy benefit from Managed Care to Fee-for-Service (FFS), effective April 1, 2021.
- The State and the legislature recognize that the 340B program is important to many safety net providers throughout the State. As such, the FY21 budget savings assume the transition of 340B reimbursement from the current reimbursement in Managed Care to the FFS reimbursement rate.
- In helping accomplish this goal, the 340B Advisory Group is charged with making recommendations to achieve savings on 340B eligible drugs in the FFS program
- This advisory group is a non-public policy group that is not subject to the Open Meetings Act.

§ 1-a. The commissioner of health shall convene an advisory group composed of stakeholder representatives determined in the commissioner's sole discretion, for purposes of providing non-binding recommendations to the department by October 1, 2020 on available methods of achieving savings in the state fiscal years beginning on and after April 1, 2021, with respect to reimbursement for drugs eligible for pricing those under section 340B of the public health service act, and for which the department has existing authority to take such action.

Goals & Expectations

Recommendations that Advance Must:

- Achieve savings associated with 340B eligible claims starting in State Fiscal Year 2021-22 (April 1, 2021 – March 30, 2022)
- Comply with federal requirements for pharmacy reimbursement of 340B eligible claims, per the Center for Medicare and Medicaid Services (CMS) Covered Outpatient Drug rule
- Can be operationalized in a way that is practical for providers and is systemically supported
- Consider the viability of the most vulnerable safety net providers
- Ensure that consumers have continued access to medications

Advisory Group Timeline

Today

July 13th

- Announce 340B Advisory Group Membership

August 5th - Meeting 1

- Overview of Advisory Group timeline, process and charge
- Background on the 340B program and Federal/State requirements regarding FFS reimbursement of 340B claims
- Presentation of relevant 340B data in Medicaid
- Brainstorming/discussion of ideas

August 26th - Meeting 2

- Review group feedback and options for policy proposals
- Discuss potential recommendations that align with Advisory Group goals and objectives

September 16th - Meeting 3

- Review any recommendations
- Discuss modifications and identify recommendations that align with Advisory Group goals
- Open discussion and next steps on implementation of pharmacy carve out

Intersection of 340B and Medicaid Drug Rebate Program

340B Background & Intersection with the Medicaid Drug Rebate Program

- The stated purpose of the 340B program is to help covered entities stretch scarce federal resources as far as possible.[1] This is achieved when the margin from drugs purchased at significantly reduced prices (comparable to the Medicaid price net of rebates) is used to provide more comprehensive services.
- Authorized by Section 1927 of the Social Security Act, the Medicaid Drug Rebate Program (MDRP), helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients.
- The MDRP enables a drug manufacturer to enter into an agreement with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of its drugs and it also requires the manufacturer to offer 340B pricing to covered entities
- While Medicaid Fee for Service (FFS) pays 340B claims at the actual acquisition cost plus a dispensing fee, MCOs pay using their usual reimbursement formula, which results in a significantly higher cost to Medicaid.
- Importantly, Medicaid program is prohibited from accessing rebates (of any kind) on 340B submitted claims – meaning the Medicaid program is not only reimbursing at a higher cost for 340B drugs in Managed Care but also is losing significant federal and supplemental rebates, which increases budgetary pressures under the Medicaid Global Cap.

[1] *Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106 Stat. 4943, 4967-4971 (1992)*

Federal Requirements for Reimbursement of 340B Claims in FFS

- Per the Covered Outpatient Drug (COD) Rule, there are two cost components that can be used to reimburse pharmacies for 340B eligible claims in the Medicaid FFS program: .
  - Actual Acquisition Cost (AAC), which is the pharmacy's cost to purchase the drug; and;
  - A Professional Dispensing Fee (PDF), which reimburses for the cost associated with dispensing the drug.

- States may develop a separate reimbursement methodology for drugs dispensed through 340B covered entities (aka 340B drugs), subject to federal approval;

340B and Transition of the Pharmacy Benefit to FFS

- The transition of the pharmacy benefit to FFS will impact reimbursement for only the 340B claims that are billed through retail pharmacies (i.e., NCPDP claim format) – these claims account for roughly 60% of Medicaid spending on 340B
- 340B drugs billed through institutional/medical claims (40% of Medicaid spending on 340B) will remain under the managed care benefit (i.e., status quo)

- Typically billed as a pharmacy claim (point of sale) using the NCPDP claim format and appropriate 340B claim indicators.
- 340B NCPDP (Outpatient/Retail) Drug Claims ***will be*** subject to the Pharmacy Carve out to FFS.

Outpatient/Retail

- Typically billed using a medical or institutional claim format (via UD Modifier)
- 340B Medical (Physician Administered) Drug Claims ***will NOT be*** subject to the Pharmacy Carve out to FFS and will remain in Managed Care.

Physician Administered Drugs (PAD)

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340B In Medicaid Managed Care

Current Landscape: 340B in Managed Care

Growth

- The exponential growth of contract pharmacies in the 340B program reduced transparency in the program.
- The number of 340B sites and relationships between contract pharmacies and covered entities has grown dramatically over the last three years.

Spending

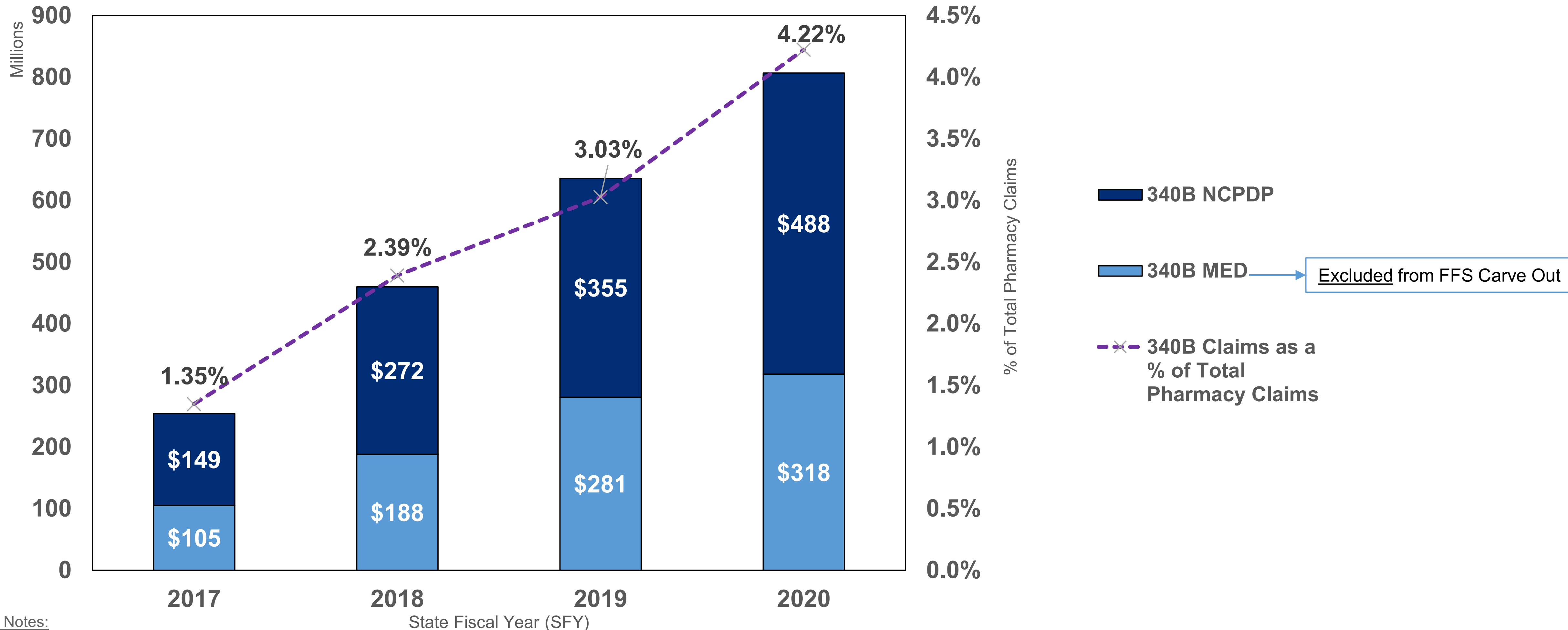
- Both 340B spending and claims, respectively, have grown by over 200% since SFY 2017.
- The 340B margin available under Managed Care is costing the Medicaid program over $200 million (gross) each year – not accounting for lost rebates.

Rebates

- Medicaid is precluded from claiming manufacturer rebates on *340B drugs* under federal rules, because the manufacturer has already extended 340B pricing to the 340B Entity.
- This loss of rebates has totaled over $800 million (gross) over the past four years and continues to increase year over year.

The term 'gross' refers to the total cost/(savings) prior to the federal and state split of total costs which is determined by the federal matching assistance percentage (FMAP) also referred to as the Federal Share.

Total 340B Spending in Managed Care



Data Notes:
Dates of Service April 2016 - March 31st, 2020
Claims represent claims where the dollar amount was $0
Pharmacy 340B defined as rx_ovrd_cd = 20 or rx_ovrd_cd_ 2 = 20 or rx_ovrd_cd_3 = 20
Physician Administered Claims defined as modifier (in any location) of UD, JG or TB

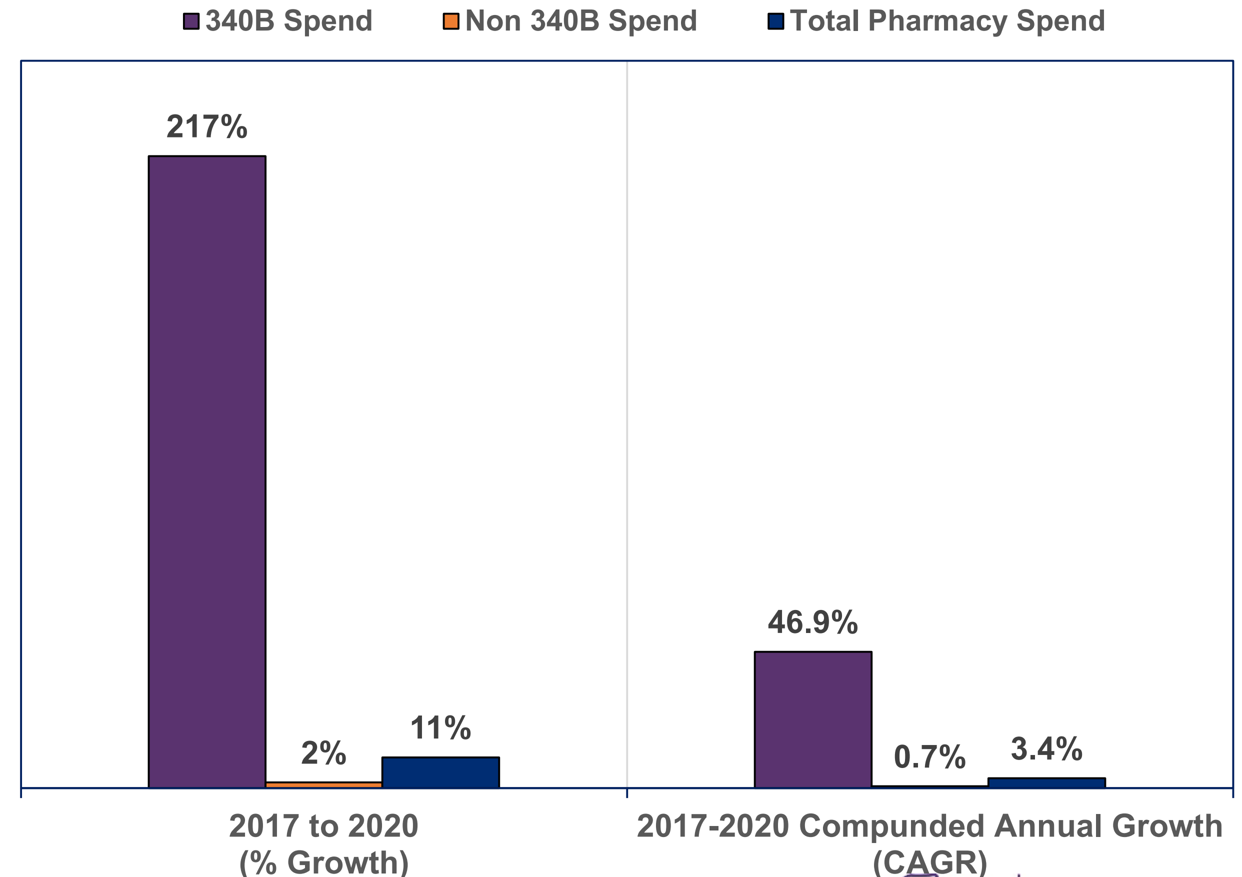
340B Spending Growth in Managed Care is Reducing Medicaid Rebate Revenue

Historical and Actual 340B Spending in Managed Care

SFY	Total Paid Amount (Gross)	Total Claims	Rebates Lost (Gross)
2017	**$254,253,829**	**1,018,287**	**$107,545,812**
Retail	$148,809,682	778,115	$79,794,353
PAD	$105,444,147	240,172	$27,751,459
2018	**$459,814,752**	**1,810,365**	**$179,954,331**
Retail	$271,670,926	1,498,205	$143,262,966
PAD	$188,143,826	312,160	$36,691,364
2019	**$635,669,921**	**2,273,096**	**$240,888,682**
Retail	$355,048,832	1,840,842	$183,352,432
PAD	$280,621,089	432,254	$57,536,249
2020	**$805,984,475**	**3,030,658**	**$272,694,050**
Retail	$488,392,254	2,429,626	$207,482,469
PAD	$317,592,221	601,032	$65,211,581
Total (2017-2020)	**$2,155,722,977**	**8,132,406**	**$801,082,875**
CAGR (2017-2020)	***47%***	***44%***	***36%***

SFY = State Fiscal Year; PAD = Physician Administered Drug Claims; CAGR = Compounded Annual Growth Rate

Rate of Pharmacy Spending Growth in Managed Care



Data Notes:
- Total Amount Paid: Incudes both retail and physician administered 340B spending in Managed Care for service dates between April 2016 - March 31st, 2020.
- Rebates Lost: calculates the actual rebates that would have been invoiced if these claims were not 340B-billed by assuming the NDC specific unit rebate amount for the last quarter of each calendar year (respectively) to calculate the estimated rebate loss.

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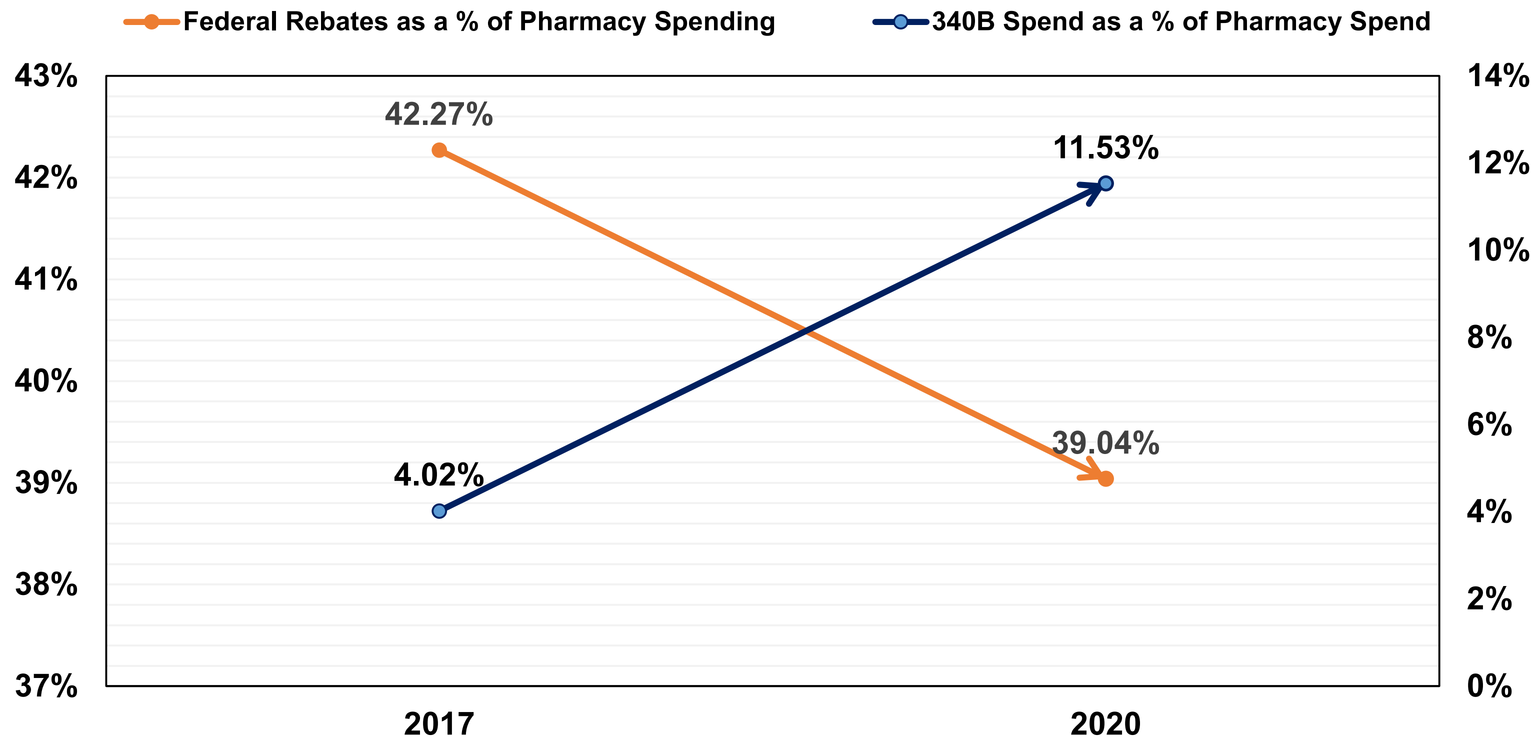
340B Growth in Managed Care is Marginalizing the States Ability to Leverage Rebates



- In Managed Care, there is an inverse relationship between 340B spending and rebates.
- Because 340B spending has grown as an overall percentage of total pharmacy spending, the state is experiencing lower federal rebate collections (due to the duplicate discount prohibition).
- This growth of spending coupled with the loss of federal rebates is putting significant pressure on the Medicaid Global Cap.

Data Notes:
- Rebates: Invoice Totals By Processing Year Quarter summarized from Rebate DataMart
- Spend: Dates of Service April 2016 - March 31st, 2020. Includes both retail and physician administered 340B spending in Managed Care

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340B Margin = Medicaid Rebate

- Unlike commercial payers, Medicaid is generally protected against large price increases for drugs. This is primarily attributable to the **inflationary component of federal rebates** – whereby if a drug's price increases faster than inflation, the manufacturer must rebate the difference to Medicaid.
- The total inflation-based rebate amount currently is capped at 100% of the Average Manufacturer Price (AMP), but these rebates still account for a significant share of overall Medicaid rebates.

- 340B Claims in Managed Care are the <u>only</u> instance where the Medicaid program is paying list price for drugs. Due to the federal prohibition of double discounts, the Medicaid program is forgoing its largest portion of rebate revenue (inflationary component) for 340B claims in managed care while paying full price for very expensive drugs.

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Top 20 340B <u>Retail</u> Drugs in Managed Care

State Fiscal Year 2020 – Top 20 NCPDP 340B Drugs			
Therapeutic Class	**Drug Name**	**Paid Amount**	**Rebates Lost**
Antiretrovirals (ARVs)	GENVOYA TRIUMEQ BIKTARVY DESCOVY TRUVADA ODEFSEY TIVICAY PREZCOBIX ATRIPLA	**$198,082,033**	**$102,716,696**
Hepatitis C	MAVYRET VOSEVI SOFOSBUVIR-VELPATASVIR	**$34,289,098**	**$18,758,001**
Cystic Fibrosis	SYMTUZA TRIKAFTA	**$16,214,938**	**$4,631,470**
Insulins, Inhibitors (TNF and DPP-4) and Other Agents (Immunological and Antineoplastic)	HUMIRA PEN HUMIRA (CF) PEN JANUVIA BASAGLAR KWIKPEN STELARA TAGRISSO	**$29,042,009**	**$15,670,266**
Total (Top 20) NCPDP 340B Drugs		**$277,610,081**	**$141,776,732**

- Efforts by the State to reduce drug costs through the elimination of PBM spread pricing and enhanced rebate authorities (i.e. the Drug Cap and volume-based rebates for the Ending AIDS initiative) are being undermined by 340B spending, which is growing at a compound annual growth of 47%

- It is important to note that the transition to FFS will have **zero** impact on Medicaid members accessing these medications nor will it prevent 340B covered entities from purchasing these medications at the 340B ceiling price

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340B Eligible Providers [Covered Entities (CE)] in New York State

New York State	# of 340B CEs	# of 340B Sites [3]
340B Covered Entities (CEs) [1]	**209**	**2,191**
Federal Grantees	113	797
Consolidated Health Center Program [2]	*61*	*553*
Ryan White & Hemophilia Treatment Centers	*17*	*189*
Family Planning, STD and Tuberculosis Clinics	*35*	*116*
Eligible Hospitals	96	1,333
Critical Access Hospitals (CAH)	*14*	*40*
Disproportionate Share Hospitals (DSH)	*71*	*1,054*
Rural Referral Center (RRC)	4	*127*
Sole Community Hospital (SCH)	*7*	*112*

1) Not unique. Some covered entities are classified under multiple categories
2) Includes FQHCs, FQHC look-alikes, Community Health Centers and School based health centers
3) The number of 340B sites includes both parent and child sites. A parent site is the main facility of a hospital. In contrast, outpatient clinics/departments/services that have a different street address than the hospital's main facility must be separately registered as "child sites" with Office of Pharmacy Affairs (OPA). FQHCs and FQHC look-alikes are also required to list on the OPA website all offsite locations where 340B drugs are purchased or provided. For non-FQHC grantees and sub-grantees, offsite locations are considered separate covered entities.

Source: DOH Analysis of the Office of Pharmacy Affairs (OPA) Covered Entity Database

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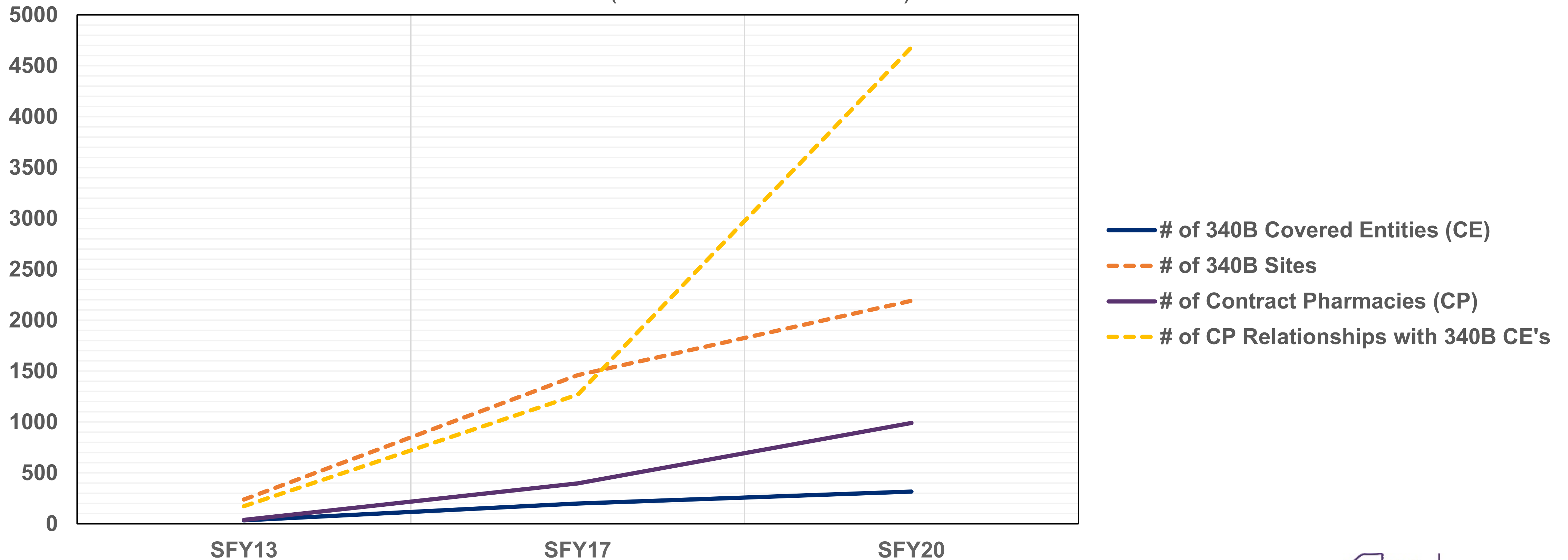
Growth of Contract Pharmacies Has Reduced Transparency in the 340B Program



Source: DOH Analysis of the Office of Pharmacy Affairs (OPA) Covered Entity Database and Contract Pharmacy Database

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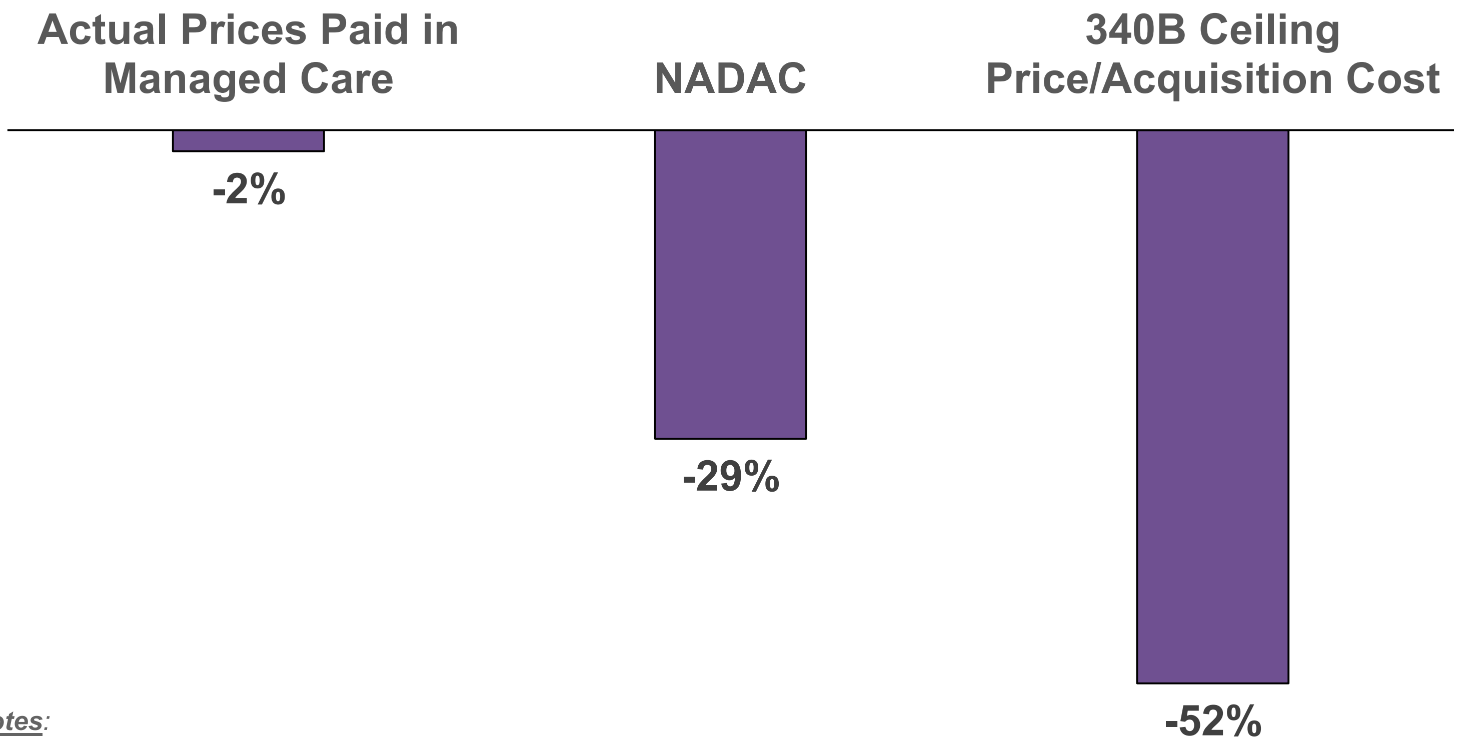
Comparison of Paid 340B Claims in Managed Care Versus Other Industry Benchmarks



- Managed Care reimbursement for 340B claims is 50% higher than it would be if FFS reimbursed that same claim – this means that for every $1 the state spends on a 340B drug in FFS the state spends $2 for the same exact drug in Managed Care

- Subject to CMS approval, DOH is willing to explore ways to phase down reimbursement from the current prices paid in Managed Care to Actual Acquisition Cost over a multi-year process.

__Notes__:
- *NADAC = National Average Drug Acquisition Cost; WAC = Wholesale Acquisition Cost*
- *WAC price is based on date of service. Spending data includes NCPDP claims for only brand name drugs reported by Medicaid Managed Care plans.*

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Discussion

Informational Questions

1. How have Covered Entities used the revenue generated under the 340B program since SFY 2012 (when the benefit was carved into Managed Care)?

2. What are the compensation arrangements between covered entities, contract pharmacies and others?

3. How do 340B claims paid by other payers (e.g., commercial/Medicare) compare to those under Medicaid Managed Care?

4. What other benefits accompany pharmacy spend in Managed Care that could be replicated during the transition to Fee for Service (FFS)?

Discussion Questions

1. Given our goals and expectation, what is your current thinking regarding possible solutions over a multi-year process?

2. Is there any other information you would need that can assist with informing your recommendations?

3. Is there pertinent data/information you would like to share with DOH that would inform possible solutions?

Next Steps

Next Steps

- The 2nd Advisory Group meeting is scheduled for August 26
- We expect that Advisory Group members will use the time in between meetings to explore and develop policy recommendations for discussion at the 2nd meeting
- DOH staff are willing to provide any data that would inform policy recommendations as well as feedback on preliminary ideas as it relates to federal and state requirements

Questions?

Appendix Slides

Illustration of 340B Interaction with Medicaid Rebates

Key	Illustrative Example of Medicaid Rebate Calculation(s)	Brand Drug A	
		Non-340B	340B
	Current Period Prices		
(a)	Current WAC Per Unit	$120	$120
(b)	Current AMP per unit	$100	$100
(c)	Best price per unit	$80	$80
	Medicaid Rebates		
(d)	Statutory Minimum Medicaid Rebate *- for brand drugs = (b) x 23.1%; for generic drugs = (b) x 13%*	$23	$0
(e) = (b)-(c)	340B Ceiling Price (AMP—best price)	$20	$20
(f)	**Statutory Minimum Medicaid Rebate** *[Greater of (d) and (e)]*	**$23**	**$0**
	Inflationary Rebate		
(g)	Baseline AMP per unit	$70	$70
(h)	CPI-U trend factor from baseline to current period	1.10	1.10
(i) = (g) x (h)	Baseline AMP trended to current period	$77	$77
(j)	**Statutory Mandated Inflationary rebate** *[= (b)–(i) if i < b]*	**$23**	**$0**
(k)	**State Negotiate Supplemental Rebate** *[3% of WAC]*	**$4**	**$0**
(l)=(f)+(j)+(k)	**Total Medicaid Rebate**	**$50**	**$0**

- **Using the same drug, below is an illustrative example of the reimbursement when the claim is submitted to FFS vs. a Managed Care Plan as a "340B claim"**

Illustrative Example of Medicaid Reimbursement of a "340B claim"	340B Brand Drug A	
	FFS	MCO
Reimbursement to the Pharmacy	**$20**	**$120**
Medicaid Rebate	**N/A**	**$0**
Total Paid	**$20**	**$120**

- **The Medicaid program pays six times more for the same 340B drug in Managed Care than it would in FFS.**

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340B claims billed through Contract Pharmacies

- In SFY 2020, Contract pharmacies represented 51% of 340B spending and 74% of 340B claims submitted via NCPDP (retail).

340B Billing Entity (NCPDP)	SFY 2017		SFY 2020	
	Spending	Claims	Spending	Claims
Contract Pharmacy	**$73,208,249**	**519,882**	**$249,759,048**	**1,808,133**
Covered Entity	**$75,601,433**	**258,233**	**$238,633,206**	**621,493**
Hospital	*$41,699,759*	*137,503*	*$149,935,440*	*317,196*
Non-Hospital	*$33,901,674*	*120,730*	*$88,697,866*	*304,297*
Total	**$148,809,682**	**778,115**	**$488,392,254**	**2,429,626**

Summary of Fees Paid by 340B Covered Entities to Contract Pharmacies

Type of Fee(s) Paid By 340B Covered Entities to Contract Pharmacies	# of Agreements	Avg Flat Fee for Brand Drug	% Fee (Range)
Flat Fee Per Rx	15	$23	0%
Flat Fee Per Rx + % of Reimbursement (Between the Pharmacy and the Payer)	9	$19	16% (12%-20%)
Flat Fee Per Rx + % of 340B Spread	4	$8	20%

Source: GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480 (2018).