Department of Health

340B Advisory Group

Meeting # 2

August 26, 2020

Agenda

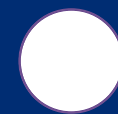
- Advisory Group Timeline
- Recap of Meeting #1
- Follow Up Questions from Members
- Advisory Group Feedback and Ideas for Policy Proposals
- Open Forum
- Next Steps

Advisory Group Timeline

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



Today

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

Meeting #1 Recap

What We Shared

- The number of 340B sites and relationships between contract pharmacies and covered entities has grown dramatically over the last three years, which has reduced transparency in the program
- The growth of 340B in Managed Care has resulted in a significant reduction in rebate collections because federal rules prohibit Medicaid from claiming manufacturer rebates on 340B drugs
- 340B spending, which is the largest component of pharmacy spending growth in Managed Care, is growing at an annual rate of 47%
- 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 the growth in 340B claims

What We Heard
(Use of 340B Revenue)

- **How have Covered Entities used the revenue generated under the 340B program since SFY 2012 (when the benefit was carved into Managed Care)?**
  - *Several Covered Entities noted that 340B revenue is used to expand care for the underserved or uninsured who are not eligible for public health insurance programs (e.g., undocumented) and for care management or other ancillary services for high need, complex patients that may not reimbursed by payors (e.g., transportation, nutrition, housing, etc.)*
  - *Some Covered Entities use 340B revenue for general operations, pharmacy staff, and program staff that implement medication adherence programs for vulnerable populations*

Note: This slide reflects comments made by individual workgroup members during meetings. It may not reflect all uses or benefits of 340B revenue, and comments do not represent the position of all working group members or DOH.

What We Heard
(Compensation Arrangements)

- **What are the compensation arrangements between covered entities, contract pharmacies and others in the supply chain?**
  - *Many noted that compensation arrangements have changed over time – previously contract pharmacies were only compensated based on a flat dispensing fee – and that Third Party Administrators (TPAs) can also receive significant fees as part of 340B Covered Entity operations*
  - *Some shared that large pharmacy chains have leveraged their relationships to introduce alternative models, often without negotiation.*
  - *One covered entity stated that 340B related operations cost is somewhere between $8 - $12 per prescription.*

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What We Heard
(Medicaid Share of Total 340B Revenue)

- **How do 340B claims paid by other payers (e.g., commercial/Medicare) compare to those under Medicaid Managed Care?**
  - *Some Covered Entities mentioned that approximately 50-60% of their total 340B revenue through Medicaid Managed Care*
  - *One member shared an observation that New York as an outlier in that respect that a larger portion of Medicaid volume in New York is 340B than seen in most other states*

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Advisory Group Follow Up Questions and Data Requests

1) Please share the total Medicaid pharmacy spend since State Fiscal Year 2017, including a breakdown for total spend and scripts amongst the Top 20 classes of drugs

Medicaid Pharmacy Spending and Claims in Managed Care – *Including the Top 20 Classes (SFY 2017-2020)*

Managed Care – Retail Pharmacy Spending and Claims *$ in Gross (federal and non-federal)*	**State Fiscal Year**							
	2016-17		**2017-18**		**2018-19**		**2019-20**	
Therapeutic Class	**Claims**	**Total Paid Amount**	**Claims**	**Total Paid Amount**	**Claims**	**Total Paid Amount**	**Claims**	**Total Paid Amount**
ANTIRETROVIRALS (ARVS)	1,131,063	$1,170,163,529	1,155,572	$1,226,934,546	1,107,679	$1,256,131,339	1,147,135	$1,311,976,466
DIABETES	6,512,878	$683,105,088	6,603,828	$735,319,263	6,630,261	$782,417,348	6,081,953	$744,213,996
RHEUMATOID ARTHRITIS	123,723	$312,010,555	134,430	$406,654,222	144,434	$502,258,589	152,380	$593,471,100
RESPIRATORY	2,913,844	$277,219,769	3,008,020	$301,919,959	3,049,491	$316,786,730	3,110,077	$305,853,980
HEPATITIS C	22,898	$484,667,278	16,814	$309,117,493	12,317	$176,342,882	11,989	$130,442,241
ONCOLOGY	183,685	$202,374,494	188,469	$240,682,266	192,463	$281,125,072	193,986	$329,954,603
ANTIPSYCHOTIC	1,465,406	$226,121,232	1,500,590	$220,177,806	1,538,106	$244,175,687	1,559,232	$261,377,296
TOPICAL	3,407,779	$197,671,398	3,376,364	$171,723,328	3,447,942	$159,226,670	3,280,934	$125,509,163
ANTICONVULSANTS	2,479,774	$143,600,189	2,582,727	$160,985,462	2,637,725	$164,322,681	2,609,587	$133,137,742
OPIOID DEPENDENCE	321,899	$96,602,534	396,051	$124,666,306	471,009	$145,882,335	529,969	$123,078,331
GLUCOCORTICOIDS	1,245,274	$120,895,106	1,246,818	$121,355,029	1,239,452	$120,925,700	1,205,526	$112,539,969
MULTIPLE SCLEROSIS (MS)	20,219	$110,911,850	19,592	$116,290,509	18,328	$115,456,329	16,735	$108,384,159
HEMOPHILIA/BLOOD FACTOR	102,932	$39,018,343	136,574	$91,439,103	170,888	$115,612,526	190,358	$137,380,835
ANTIBIOTICS	3,964,493	$95,743,148	3,893,259	$92,387,353	3,809,324	$85,313,772	3,691,365	$80,127,595
OPHTHALMIC AGENTS	1,898,798	$65,278,416	1,987,465	$72,103,243	1,926,741	$77,335,044	1,780,017	$72,356,646
ANTICHOLINERGICS	255,655	$52,860,376	261,935	$58,824,260	268,866	$63,814,194	262,581	$64,887,564
GASTROINTESTINAL MEDICATIONS	226,185	$46,572,835	238,986	$58,046,587	241,216	$63,104,704	230,362	$65,935,950
GROWTH HORMONES	13,201	$49,435,108	14,717	$57,886,736	14,394	$59,516,180	14,508	$61,854,604
ADRENERGIC AGENTS	490,886	$56,962,724	518,871	$57,874,641	548,243	$54,719,934	573,893	$50,077,944
ATTENTION DISORDER	419,290	$66,880,371	424,425	$57,000,388	434,515	$47,253,399	455,926	$43,136,619
Total for the *Top 20* Classes	**27,199,882**	**4,498,094,340**	**27,705,507**	**4,681,388,499**	**27,903,394**	**4,831,721,113**	**27,098,513**	**4,855,696,804**
Total for all Retail Pharmacy in Managed Care	**74,353,607**	**5,768,015,011**	**74,614,878**	**5,940,953,581**	**74,135,673**	**6,069,186,170**	**69,998,233**	**6,071,939,187**

Data Notes: Total Amount Paid incudes only retail pharmacy claims in Managed Care for service dates between April 2016 - March 31st, 2020.

2) Please outline how the budget savings or cost increases are achieved

The analysis to transition the pharmacy benefit from Managed Care to FFS involves several components, each of which, factor into the overall fiscal impact of the proposal. These factors and the respective impacts (in gross dollars) are described below:

	Summary FFS Pharmacy Carve Out Budget Savings	SFY 2021-22	
		Gross Cost/(Savings)	State Share Cost/(Savings)
A	**Repricing Managed Care Claims** *(as if they were paid under FFS)*	**$97M**	**$36M**
	Ingredient Cost [1]	*($508M)*	*($188M)*
	Dispensing Fee	*$605M*	*$224M*
B	**The Cost of Administrating the Benefit** [2]	**($242M)**	**($90M)**
C	**Impact of Federal and Supplemental Rebates**	**($281M)**	**($104M)**
D	**Risk Margin** *(to account for transfer of risk from MMC to FFS)*	**$89M**	**$33M**
E	**Reinvestment of 340B Savings** [3]	**$101M**	**$37M**
	Total SFY 2021-22 Cost/(Savings)	**($234M)**	**($87M)**

1. The repricing of Managed Care claims using the FFS reimbursement logic includes $166 million in savings (gross) associated with 340B reimbursement. In addition, the repricing assumes increased FFS utilization of non-preferred drugs due to the impact of prescriber prevails; and applies the savings from the SFY 2019-20 budget action to eliminate spread pricing in Managed Care as a cost to FFS (given that these savings were achieved prior to 4/1/21 carve out).

2. FY 21 includes (new) state expenses that are necessary to support current Managed Care volumes in the FFS system, such as upfront investments for staff and systems enhancements, which are a state cost ($11M) in FY 2020-21 and embedded into the FY 2021-22 savings figure.

3. The value of the 340B reinvestment reflects only the 1st year of a three-year reinvestment. The value of the reinvestment is intended to decrease in each of the subsequent two years (ending in SFY 2023-24).

Note: Figures are Rounded

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3) What are the factors that affect rebate differentials by drug and drug class?

Several factors drive rebate differentials between drugs and drug classes, including but not limited to:

- Drug specific supplemental rebate agreements between the State and a drug manufacturer;
- Federal rebates, and specifically the inflation based component of rebates (which can fluctuate each quarter depending on price changes in the commercial market);
- Whether the drug is a single source brand name drug without competition as compared to a multi-source brand name drug in a competitive class
- Preferred versus non-preferred status on the formulary

4) Why can't Supplemental Rebates be sought on 340B claims?

- Supplemental rebates are in addition to federal rebates and they are embedded in the 340B price, which has already been extended to the 340B entity. Therefore, New York State Medicaid is precluded from claiming these rebates.

Advisory Group Feedback and Ideas for Policy proposals

Recap of Advisory Group Charge

- The State and the legislature recognize that the 340B program is important to many safety net providers throughout the State. As such, the State Fiscal Year 2021-22 (April 1, 2021 – March 30, 2022) 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

Recommendations that Advance Must:

- Achieve savings associated with 340B eligible claims starting in State Fiscal Year 2021-22
- Comply with federal requirements for pharmacy reimbursement of 340B eligible claims, per the Center for Medicare and Medicaid Services (CMS) Covered Outpatient Drug rule
- 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

Open Forum

Please share any preliminary ideas and explain how they align with the goals and expectations of the Advisory Group

Next Steps

Next Steps

- The 3nd Advisory Group meeting is scheduled for September 16
- We ask that Advisory Group members use the time in between meetings to further develop and refine preliminary policy recommendations for discussion at the 3rd meeting
- DOH staff continue to available to assist with the development and feedback on recommendations

Questions?