The Menges Group

Strategic Health Policy & Care Coordination Consulting

Why New York Should Maintain its Medicaid Pharmacy Carve-In Approach

October 1, 2020

KEY FINDINGS

- **Fiscal Impact – Carve-Out Will Cost State Significantly:** The pharmacy carve-out will cost New York an estimated $154 million during the first year of implementation and $1.5 billion over five years.
- **Carve-In Savings Track-Record:** Savings from a carve-in approach are based in part on evidence from New York and other states showing the carve-in model has yielded savings of more than 20% relative to the carve-out model. The fee-for-service setting has had ample opportunity to yield savings – in New York and nationally – but has not done so.
- **Inaccurate DOH Fiscal Forecast:** The Department of Health's fiscal forecast for the carve-out does not address the key components that will lead to higher costs – including drug mix and premium tax impacts – and overestimates savings such as in administrative costs.
- **Undermining Consumer Care:** New York has been a leader in creating an integrated system of managed care coordination that emphasizes quality and robust care access for Medicaid consumers. A drug benefit carve-out will undermine integrated care coordination and adversely impact quality for consumers.

Prepared for:
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I. Executive Summary

Overview

In April 2020, Governor Cuomo signed the SFY2021 budget mandating that the Medicaid prescription drug benefit be "carved out" of the Medicaid managed care program and be administered in the fee-for-service (FFS) setting. The core objective of this policy change is to yield Medicaid savings.

Carving pharmacy benefits out of the Medicaid Managed Care Organizations' (MCO) plan benefit package will cost the state $154 million in the first year, based on a proven history of savings when the pharmacy benefit has been carved-in to the MCO benefit compared to carve-out models. These additional costs are projected to more than double in the subsequent year, with cumulative state costs across the first five years of the carve-out totaling $1.5 billion. Moreover, the savings analysis by the Department of Health (DOH) is in some parts flawed – for example, failing to account for a carve-in model's enhanced ability to lower the use of more expensive drugs. Further, the move to a pharmacy carve-out undermines the State's policy goals of improving quality through care integration, which will adversely impact consumer care. Numerous alternatives exist for State savings while maintaining a carve-in model including: ending prescriber prevails, increasing the use of the Drug Utilization Review Board (DURB) and allowing plans to use step-therapy.

The New York Health Plan Association and the Coalition of New York State Public Health Plans engaged The Menges Group to assess the financial and programmatic impacts of New York's proposed carve-out of the Medicaid pharmacy benefit.

Key Findings

The carve-out approach will result in increased Medicaid costs and diminished integration and care coordination.

1. **State Costs Will Increase $154 Million During Year 1 of a Medicaid Prescription Drug Benefit Carve-Out Implementation and $1.5 Billion Over Five Years**.

These estimates are derived through extensive data analyses of Medicaid pharmacy costs in the carve-in and carve-out settings. Our analyses are based on net costs per prescription, which take into account both the price (including initial ingredient and dispensing fee payments and all rebates) *and* drug mix for **all** Medicaid prescriptions in each state and each year:

- **New York Has Saved with a Carve-In Approach:** New York switched from a carve-out to a carve-in approach in 2011. Comparisons of New York's costs (relative to national Medicaid pharmacy costs) since implementing this policy change show that New York achieved a 21.4% savings on MCO-paid prescriptions compared to the rest of the nation during FFY 2019 by using a pharmacy carve-in model.

- **States that Switched to a Carve-In Approach Spend Less than States that Retained a Carve-Out Approach:** An 18.4% increase in net cost (post-rebate) per prescription occurred across states that retained their carve-out model between FFYs 2011 and 2019. In stark contrast, states that switched to a carve-in during this timeframe (one of which is New York) collectively experienced a 1.2% ***decrease*** in net cost per prescription.

- **Fee-For-Service States Paid More:** Data tabulations for all 16 FFS-dominant states – where 95% or more of Medicaid prescriptions have been paid in the FFS setting – shows performance on net costs per prescription were 15% below New York in FFY 2011 but ballooned to 16% above New York as of FFY 2019. The FFS carve-out model has had ample opportunity to yield Medicaid cost savings, but has failed to do so[1].

Each of the analyses above conclude that a carve-in is more cost-effective than a carve-out. Our overall fiscal impact estimate averages the results of these analyses and includes all offsetting savings from a carve-out model.

DOH has projected state savings of $125 million in the first year of the carve-out. We estimate that the overall New York State costs in the upcoming fiscal year will be $279 million higher than are currently forecasted – adding together the $125 million savings that will not happen and the $154 million additional cost that will occur if the carve-out is implemented. These adverse fiscal impacts are expected to become far larger in each subsequent year under the carve-out.

2. The Carve-Out Will Undermine Quality of Care for Medicaid Patients.

New York's MCOs have developed integrated staff, information systems, and care coordination processes that function optimally under a carve-in model which includes all Medicaid-covered services. Prescription drugs are a core benefit -- pulling prescription drugs out of this integrated structure will undermine care coordination and ultimately diminish care quality for Medicaid members, especially those with chronic illnesses.

Policy Recommendations

Reject the Costly Pharmacy Carve-Out that Will Undermine Quality and Find Savings within the Carve-In Model. Our analyses demonstrate switching to a carve-out approach will significantly increase Medicaid costs and undermine quality improvements achieved through the integrated care model that the State and its MCO partners have worked to develop. Instead, DOH should seek cost-saving alternatives within the carve-in model.

1. **Focus on Drug Mix, Not Just Price:** MCOs and their PBMs have successfully managed *both the mix and the price* of drugs. Recent Medicaid pharmacy benefit policy initiatives – such as New York's carve-out – focus on drug prices and do not adequately address the mix of drugs. The best remedy for a high-priced drug often involves not using it when clinically effective lower-cost alternatives are available. Negotiating a rebate discount can still result in

[1] These data were tabulated using CMS state drug utilization data files for FFY 2019. We identified 16 FFS-dominant states – where 95% or more of Medicaid prescriptions were paid in the FFS setting.

a higher net cost than the available alternatives and may not achieve net savings. MCOs have been more successful than FFS in this area, while also implementing strong processes to facilitate access and adherence to needed medication regimens. At best, the carve-out will result in better prices for brand drugs; however, evidence demonstrates that gains in this area are far outweighed by the forfeiture of optimally cost-effective drug mix management.

2. **Preserve Quality Integrated Care:** Over the past decade, New York has put tremendous effort into converting Medicaid to a highly coordinated system of care and coverage for low-income residents. Pharmacy is an integral component of member's overall health and care. Moving the pharmacy benefit outside of this coordinated system will undermine plans' ability to manage this critical aspect of members' healthcare and hinder their ability to access important data. This ultimately will lead to decreased quality outcomes for consumers.

3. **Accurately Estimate and Fully Share Fiscal Impact Estimates:** DOH's savings estimate does not clearly account for all costs, including ongoing administrative expenses and lost premium taxes. The continuation of existing administrative costs related to managing the Medicaid drug benefit in a switch to a carve-out appear to be missing in DOH's estimate. DOH estimates it will no longer need to pay for MCOs' collective annual pharmacy-related administrative costs of $285 million, and that the costs of replacing these functions in the carve-out setting will be just $43 million (meaning 85% of current administrative costs would be eliminated). DOH expects the MCOs to remain active partners in managing the pharmacy benefit, but appears not to account for the ongoing administrative expense this entails. Further, DOH appears not to have accounted for lost premium tax attributable to the carve-out. DOH should also provide a transparent detailed written document conveying all aspects of its fiscal impact calculations.

4. **Other Cost-Savings Opportunities *Within* the Carve-In Model Exist:** New York's health plans are aligned with DOH in seeking pharmacy savings and welcome the opportunity to work with DOH to determine the most appropriate steps to achieve savings within a carve-in model.

II. The Carve-Out Model Will Significantly Increase State Costs

We estimate that ***the cost of pharmacy carve-out to New York State will be $154 million during the first year of implementation, with these costs more than doubling in the ensuing year and accumulating to $1.5 billion over five years.*** Substantial additional costs will be borne by the federal government.

Derivation of Cost Impacts

A description of each step taken to produce these estimates is presented in the narrative below.

Step 1: Establish Baseline Costs

We used New York's FFY 2019 net costs for MCO-paid prescriptions of $2.7 billion as our baseline. This figure was derived through our tabulations using the State Drug Utilization Data files for pre-rebate costs, along with an average rebate of 51.7%.

Step 2: Trend Baseline Costs to Upcoming State Fiscal Years

To estimate upcoming pharmacy costs under the existing carve-in model, we derived an average annual increase of 5.24% in pharmacy expenditures across New York's Medicaid MCOs during the five-year timeframe FFY 2014 – FFY 2019. This trend factor captures changes in the volume of MCO-paid prescriptions (e.g., those driven by Medicaid enrollment increases) as well as changes in Medicaid costs per prescription. This annual cost trend was used throughout the cost estimation timeframe, with a 30-month trend used to estimate cost inflation between the mid-point of FFY 2019 and SFY 2021-22. Cost projections were produced for each of the five New York State fiscal years beginning with SFY 2021-22 and totaled across these five years.

Note that the FFY 2019 data do not capture the Medicaid enrollment increases that are occurring due to the COVID-19 pandemic, nor have we specifically estimated COVID-induced increases in enrollment from SFY 2021-22 forward.

Step 3: Estimate Percentage Impacts of Carve-In on Pharmacy Expenditures

We have quantified the cost differential between the carve-in and carve-out approaches in three ways,[2] taking advantage of the vast experience data available in both settings:

a. Progression of New York costs in comparison with the rest of the USA;

b. Progression of all 2011 carve-out states; and

c. Experience of 16 FFS states (where 95% or more of Medicaid prescriptions have been paid in the FFS setting).

[2] Additional analyses demonstrating the cost-effectiveness of the MCOs' efforts within various therapeutic classes and within high-cost curative Hepatitis C medications are presented in Appendix B.

Each approach considers all Medicaid prescriptions in each state, the MCOs' share of these prescriptions, initial ingredient costs, dispensing fees, statutory rebates, and supplemental rebates. All of our assessments involved hundreds of millions of annual prescriptions. Our analyses focused on statewide costs per Medicaid prescription for all Medicaid prescriptions to avoid any distortions that might be created by MCO enrollees having a different mix of health conditions than the Medicaid FFS enrollees in these same states.

a. Progression of New York Costs as Compared with the Rest of the Nation

Demonstrated Cost Savings. New York transitioned its pharmacy benefit from FFS to Managed Care beginning in SFY 2012. Because the vast majority of New York's Medicaid population had their benefits administered through MCOs at that time, this policy change resulted in 77% of Medicaid prescriptions being paid by MCOs during that same year (Exhibit 1). Under the carve-in, New York's net costs per Medicaid prescription decreased by 13.3% in 2012 versus 2011, compared to an increase of 1.6% in the rest of the US (excluding New York). In FFY 2013, net Medicaid costs per prescription continued to decrease by 13.6%, with 83% of statewide Medicaid prescriptions being administered through MCOs. We note that the 10.2% increase the State incurred in 2014 is likely a function of the introduction of the high-cost hepatitis C drugs, such as Sovaldi.

Significantly, during the first eight years of the pharmacy benefit carve-in to Managed Care (2012-19), net costs per prescription for all New York Medicaid prescriptions decreased by 8.9%. This decrease is even more significant considering the rest of the nation (excluding New York) experienced an overall increase of 8.9% in net costs per prescription during the same time period (Exhibit B-1 in Appendix B). New York's carve-in net decrease is likely even larger due to the fact that the decrease includes prescriptions still filled through FFS – in FFY 2019, 16.9% of New York's Medicaid prescriptions were paid FFS. When adjusting for the FFS performance, we estimate that New York achieved a 21.4% savings on MCO-paid prescriptions compared to the rest of the nation during FFY 2019.

Generic Dispensing Rate. Another important performance metric for pharmacy benefits management is generics as a percentage of all Medicaid prescriptions. New York's generic dispensing rate across all Medicaid prescriptions increased by 11.4 percentage points between the last year of the carve-out (2011) and the first year of the carve-in approach (2012). In comparison, the increase in generics as a share of all Medicaid prescriptions for the rest of the nation (excluding New York) was just 3.8 percentage points. By 2019, 88.8% of all New York Medicaid prescriptions filled were comprised of generic drugs (Exhibit 1).

Exhibit 1: New York's Medicaid Prescription Drug Costs, FFY 2010-2019[3]

	% of Prescriptions Paid for by MCOs	Net (Post-Rebate) Cost Per Prescription	Percent Change in Net Cost Per Prescription	Total Rebates Per Prescription	Generic Dispensing Rate
FFY2010	0.1%	$43.66	-	$42.28	61.9%
FFY2011	0.2%	$44.31	1.5%	$43.37	68.1%
FFY2012	77.0%	$38.43	-13.3%	$34.25	79.5%
FFY2013	82.8%	$33.19	-13.6%	$32.81	85.3%
FFY2014	84.6%	$36.59	10.2%	$37.22	86.7%
FFY2015	85.9%	$38.47	5.1%	$38.87	87.9%
FFY2016	86.3%	$39.96	3.9%	$41.18	88.2%
FFY2017	89.3%	$41.18	3.0%	$43.28	88.3%
FFY2018	86.6%	$41.01	-0.4%	$43.72	88.1%
FFY2019	83.1%	$40.37	-1.6%	$43.23	88.8%
Percent or Percentage Point Change, 2011-2019	82.9%	-8.9%	NA	-0.3%	20.7%

b. Progression of All 2011 Carve-Out States

Prior to 2011, 13 states with Medicaid managed care plans, including New York, used a pharmacy benefit carve-out approach. The carve-out approaches were driven by the fact that prior to passage of the Affordable Care Act (ACA), the large statutory rebates applied only to Medicaid prescriptions paid in the FFS setting.

Following passage of the ACA in 2011, ten states (Delaware, Illinois, Indiana, Iowa, Nebraska, New York, Ohio, Texas, Utah, and West Virginia) carved the Medicaid prescription drug benefit into their integrated, comprehensive benefit package. We compared the experiences of these states (with the exception of West Virginia, which returned to a carve-out model in 2017) to those of Missouri, Tennessee, and Wisconsin, who retained the pharmacy benefit in FFS (Exhibit 2), and found significant differences in both cost savings and proportion of generics prescribed. Our analysis showed that:

- The three states that retained the pharmacy benefit carved out of managed care between FFY 2011 and FFY 2019 saw an 18.4% increase in net cost (post-rebate) per prescription.
- In contrast, states that switched to a carve-in during this timeframe collectively experienced a 1.2% *decrease* in net cost per prescription when including New York, and an increase of 4.7% across the other eight states (excluding New York).

[3] Peach highlighting in FFY 2012 indicates the first full year of the prescription drug carve-in in New York.

- Similarly, states that kept the benefit carved out in saw a 7.9 percentage point increase in generics as a percentage of all prescriptions as compared to an increase of twice the size - 16.7 percentage points - for those that carved the benefit in.

This analysis included all Medicaid prescriptions in each state and year, and included all Medicaid rebates in these states between FFY 2011-2019 — including the formula-driven statutory rebates mandated by the ACA as well as the "supplemental" rebates that states, MCOs, and PBM companies have negotiated with brand drug manufacturers.

Exhibit 2. Prescription Drug Cost Progression from 2011-2019 Across States Using Carve-Out Approach During 2011

	Net Cost Per Prescription (Post-Rebate)			Generics as a Percentage of all Prescriptions			Rebates Per Prescription		
State Grouping	FFY 2011	FFY 2019	Percent Change	FFY 2011	FFY 2019	Percentage Point Change	FFY 2011	FFY 2019	Percent Change
States with a Prescription Drug Carve-Out Throughout FFY 2011-2019 (3 States)	$37.98	$44.97	**18.4%**	76.8%	84.7%	7.9%	$31.19	$59.09	89.5%
States with a Prescription Drug Carve-Out During 2011, Carve-In During 2019 (9 States including NY)	$39.31	$38.83	**-1.2%**	71.1%	87.8%	16.7%	$37.53	$47.93	27.7%
States with a Prescription Drug Carve-Out During 2011, Carve-In During 2019 (8 States excluding NY)	$36.26	$37.96	**4.7%**	73.0%	87.3%	14.3%	$33.97	$50.62	49.0%

c. Experience of FFS States (where 95% or more of Medicaid prescriptions have been paid in the FFS setting).

We also evaluated the experience of sixteen FFS states, where 95% or more of Medicaid prescriptions have been paid in the FFS setting (referred to as "FFS-dominant states") since FFY 2011. Thirteen of these sixteen states do not use the Medicaid MCO model extensively (if at all), and three states in this group use a pharmacy carve-out approach within their Medicaid MCO programs. This analysis shows that keeping the benefit in FFS has been less successful in decreasing net costs per prescription, as compared to the MCO carve-in approach in New York, and the nine states referenced earlier who adopted a carve-in model in 2011. For example, as of FFY 2019, the 16 FFS-dominant states' net costs per prescription ballooned to 16% above those of New York, despite being 15% below New York in FFY 2011 (Exhibit 3).

The generic usage data conveys a similar story: the generic dispensing rate across the 16 FFS-dominant states increased by 7.6 percentage points from FFY 2011 to FFY 2019—far below New York's 20.7 percent increase and the collective experience of the nine states that switched to a carve-in model (Exhibit 5).

Statistics comparing New York's cost per prescription and generic usage progressions with the remainder of the nation are summarized in Exhibit B-1 in Appendix B.

Exhibit 3. Performance of States Predominantly Paying for Medicaid Prescriptions in the Fee-For-Service Setting

	Net Cost Per Prescription			Generic Percentage of Prescriptions		
Jurisdiction	2011	2019	Percent Change	2011	2019	Percent Change
NY	$44.31	$40.37	-8.9%	68.1%	88.8%	20.7%
USA Overall	$37.03	$39.45	6.5%	75.3%	87.6%	12.3%
USA (excluding NY)	$36.13	$39.34	8.9%	76.2%	87.4%	11.3%
16 FFS-Dominant States	$37.62	$46.65	24.0%	75.3%	82.9%	7.6%
9 States Switching to Carve-In Approach Between 2011 and 2019	$39.31	$38.83	-1.2%	71.1%	87.8%	16.7%

These three (a-c) approaches all reached similar directional outcomes – with significant savings occurring in the carve-in setting relative to the carve-out setting. The percentage magnitude of the carve-in savings did differ with each approach taken. We therefore averaged the cost impact differential derived from each of the three approaches, as shown in Exhibit 4.

Exhibit 4. Cost Impacts of Different Comparisons of States' Carve-In and Carve-Out Experience

Net (Post-Rebate) Cost Per Prescription Progression Comparisons	Net Cost/Rx Difference (Carve-In Model's Savings)	MCO % of All Prescriptions	Adjusted % Difference -- Net Cost Advantage of Using Carve-In Approach
New York's Progression vs. Rest of USA	17.8%	83.1%	21.4%
Progression of All 2011 Carve-Out States	19.6%	88.5%	22.1%
16 FFS States vs. Carve-In States	24.5%	NA	24.5%
Average of Three Approaches			**22.7%**

Our aggregate finding is that the carve-in model results in pharmacy costs that are 22.7% below those in the carve-out setting. For the initial year of implementation, we estimate that the adverse impact will be only half as large (11.35%), due to an assumption that Medicaid MCO enrollees will be allowed to maintain continuity of existing drug therapies to soften the disruptions that this programmatic change will otherwise create. These assumptions result in a first-year increase in Medicaid payments to pharmacies of $349 million under the carve-out.

The full 22.7% differential is applied to the second through fifth years of the implementation of a New York carve-out.

As shown in Exhibit 5, we estimate that over five years, the carve-out would increase the Medicaid pharmacy payments in New York by $3.5 billion.

Exhibit 5. Pharmacy Expenditure Impacts of Carve-Out

Year	Net (Post-Rebate) Medicaid Costs Under Current Program Structure, MCO-Paid Prescriptions	Estimated Percentage Net Pharmacy Cost Increase of Carve-Out	Estimated Net Costs for Prescription Drugs Under Carve-Out Approach, MCO-Paid Prescriptions	Additional Medicaid Pharmacy Expenditures Due to Carve-Out
FFY2019 (baseline)	$2,707,636,523			
SFY 2021-2022	$3,076,247,760	11.3%	$3,425,232,013	$348,984,253
SFY 2022-2023	$3,237,380,073	22.7%	$3,971,907,820	$734,527,747
SFY 2023-2024	$3,406,952,416	22.7%	$4,179,954,357	$773,001,941
SFY 2024-2025	$3,585,406,873	22.7%	$4,398,898,268	$813,491,395
SFY 2025-2026	$3,773,208,685	22.7%	$4,629,310,351	$856,101,666
5-Year Total	**$17,079,195,807**	**20.6%**	**$20,605,302,808**	**$3,526,107,002**

Step 4: Estimate Carve-In Savings Due to Reduced Risk Margin Payments to MCOs

Medicaid MCOs are paid a risk margin via the capitation rate-setting process to provide a reasonable opportunity for the health plans to derive earnings from their considerable care coordination efforts and to provide a buffer against the financial risks they are responsible for. Under a pharmacy carve-out, it would no longer be necessary for DOH to pay Medicaid MCOs a risk margin on the pharmacy component of health care costs. We have estimated this risk margin payment to represent 1.0% of pre-rebate pharmacy expenditures, which is consistent with the percentage used by DOH in its recent capitation rate derivation calculations. Pre-rebate costs are used as the basis for this allocation because statutory rebates do not flow through the health plans' books. As a result, the pharmacy costs that must be included in the MCOs' capitation rate are roughly double the ultimate net (post-rebate) pharmacy costs that occur once manufacturers pay statutory rebates to government agencies. This component of our analysis estimates a cost of of approximately $70 million per year, as shown in greater detail in Appendix B (specifically Exhibit B-5). This savings component, however, does not come close to offsetting the increased pharmacy costs derived in the previous steps.

Step 5: Administrative Cost Impacts

We do not anticipate that administrative costs will change substantially under a carve-in model – no administrative cost increases nor decreases have been included in our modeling efforts. However, transitioning to a carved-out program may result in additional costs as the state scales-up its operations to handle the additional load of covering significantly more individuals.

Other than in specialized situations (e.g., the HIV SNP program where pharmacy represents more than 50% of the health plans' overall Medicaid revenue), no more than 5% of the Medicaid MCOs' existing administrative functions and corresponding costs should be eliminated under a pharmacy carve-out. The vast majority of the pharmacy-related administrative costs undertaken by MCOs will need to be replicated by the state in transition to the FFS, increasing DOH's administrative costs while the cost of administering other benefits remain with the MCOs. There may be additional administrative costs incurred by the state to ensure efficient data exchanged between the MCOs and the state including:

- Reporting and operations to enable coordination with medical benefits;
- Reporting and operations to ensure management/adherence of DOH quality measures; and
- System infrastructure to share and reconcile pharmacy data with the MCOs.

The administrative services that are most at risk of evaporating altogether are some of the plans' medication access and adherence programs that benefit patients, which will be more difficult and costly for the MCOs to operate in a carve-out setting. These access and adherence supports, many of which are catalogued in Appendix C, are services that New York policymakers should be highly interested in preserving and enhancing.

Given these factors, our fiscal impact estimates have not assumed that any administrative savings (nor increased costs) will occur under a switch to a carve-out approach.

Step 6: Estimating Premium Tax Impacts on State Funds

For-profit Medicaid MCOs pay a 2% premium tax to the State of New York, an amount that is built into their capitation payment rates. This tax mechanism is used to draw down additional federal funds, as described in greater detail in Section III. The carve-out lowers New York's annual capitation payments to the Medicaid MCOs, reducing the degree to which the premium tax yields increased Federal revenue. Exhibit 6 conveys the carve-out's adverse fiscal impact caused by a smaller premium tax. These estimates were derived through the following formula for each year:

- The net Medicaid pharmacy costs in the first column of Exhibit 5 were translated to initial pharmacy costs by dividing these figures by 0.483. We estimate that rebates represented 51.7% of New York's initial prescription drug costs during FFY2019.
- We multiplied the initial pharmacy costs by 1.04. This four percent figure assumes 2.5 percentage points for pharmacy-related administrative costs 1.0 percentage points for the risk margin paid to MCOs.
- We divided each year's figures from the above steps by two, in recognition that the premium tax applies only to for-profit health plans. We analyzed recent Medicaid MCO

enrollment in New York and found the membership to be very evenly divided among for-profit MCOs and not-for-profit MCOs.

- The resulting figure was multiplied by 2% to estimate the full premium tax amount that will disappear.
- The above figure was multiplied by 0.60 to represent the estimated Federal share of the premium tax for the pharmacy-related portion of the MCOs' capitation. These figures represent the adverse fiscal impact of the carve-out related to the MCO premium tax, and are shown in Exhibit 6 for each year. These adverse impacts are estimated to be $40 million in Year 1 and $220 million over five years of the carve-out's implementation.

Exhibit 6. Adverse Impact of MCO Premium Tax on State Funds

Year	Premium Tax Impact
FFY2019 (baseline)	
SFY 2021-2022	$39,559,947
SFY 2022-2023	$41,632,078
SFY 2023-2024	$43,812,745
SFY 2024-2025	$46,107,634
SFY 2025-2026	$48,522,729

Step 7: Estimate Overall Net Impacts of the Carve-Out Approach

Overall fiscal impacts if the carve-out were implemented are adverse and are shown in Exhibit 7. Under a carve-out, state fund Medicaid cost increases are estimated to total $154 million during Year 1 and $1.5 billion across the first five years of implementation. Overall Medicaid cost increases (Federal and state shares combined) are estimated to total $285 million during Year 1 and $3.2 billion across the first five years of implementation.

Exhibit 7. Carve-Out Impacts After Factoring in MCO Premium Tax Dynamics

Year	Total Medicaid Fiscal Impact (Added Cost of Carve-Out)	Premium Tax Impact	New York State Fund Fiscal Impact (Added Cost of Carve-Out)	Federal Fiscal Impact (Added Cost of Carve-Out)
FFY2019 (baseline)				
SFY 2021-2022	$285,280,634	$39,559,947	$153,672,201	$131,608,433
SFY 2022-2023	$667,487,364	$41,632,078	$308,627,023	$358,860,341
SFY 2023-2024	$702,450,017	$43,812,745	$324,792,752	$377,657,265
SFY 2024-2025	$739,243,996	$46,107,634	$341,805,233	$397,438,763
SFY 2025-2026	$777,965,226	$48,522,729	$359,708,820	$418,256,406
5-Year Total	**$3,172,427,238**	**$219,635,133**	**$1,488,606,029**	**$1,683,821,209**

Note that we have estimated a 60% Federal matching rate to allocate the state and Federal share of these additional Medicaid costs.

III. New York State's Pharmacy Carve-Out Savings Estimates are Flawed and Opaque

This section addresses the fiscal forecast information that has been made available to The Menges Group regarding the carve-out option. Importantly, the information we have received has been provided to us through notes taken by New York stakeholders who attended a DOH verbal summary of its forecast and its components. Minimal documentation of the assumptions has been made available for public review, and no detailed derivation of any kind has been made publicly available. The key components of the DOH fiscal forecast are shown in Exhibit 8.

Exhibit 8: DOH Fiscal Forecast Summary

Item #	Category	Description	Year 1 Total Medicaid Impact of Carve-Out in $ Millions (red figures represent added cost components; black figures represent savings components)
1	Claims Repricing	Assesses impact of MCO-paid mix and volume of drugs being paid according to NY Medicaid FFS reimbursement schedule	($39)
2	Administration	Estimates administrative payments to MCOs no longer needed and cost of providing administrative services in FFS setting	$242
3	Rebates	Additional rebates are estimated to occur under carve-out	$281
4	Other	Spread pricing, 340-B Program changes, MCO risk margin, provider prevails	($148)
Total Medicaid Impact			**$336**
State Fund Impact			**$125**

A. Components Excluded from DOH's Fiscal Forecast

Based on the limited projections made available for analysis, at least two critically important components were missing from the DOH forecast: (1) drug mix and (2) premium tax impacts.

1. Drug Mix. Across all the analyses we have conducted comparing the cost-effectiveness of a carve-in versus carve-out of prescription drugs, a consistent finding is that the front-end mix of drugs differs substantially between the two settings. The percentage of generics prescribed impacts overall costs – the higher the percentage, the more that can be saved. As was mentioned

earlier, under the carve-in, New York's generic percentage of all Medicaid prescriptions increased from 68.1% in 2011 to 88.8% in 2019 (Exhibit 1). These drug mix differences are central to explaining how New York's net (post-rebate) costs per Medicaid prescription ***decreased*** by 8.9% from 2011-2019 (Exhibit B-1 in Appendix B), whereas the three carve-out states' net cost per prescription ***increased*** by 18.4% (Exhibit 2).

2. Premium Tax. New York imposes a 2% premium tax on certain MCOs, as a mechanism to increase the Federal match rate. The model includes the following components (using a hypothetical starting point of $100 in capitation payments to a Medicaid MCO).

- DOH pays a for-profit Medicaid MCO an additional two percent to account for the MCOs' premium tax, or $102.00.
- The Federal government pays 60% of the Medicaid cost ($61.20), with New York State paying the remaining 40% ($40.80).
- The for-profit MCOs pay the two percent premium tax ($2.00) back to New York State, which New York State retains in its entirety.
- Through this mechanism, the affected MCOs ultimately retain the intended $100 payment, but instead of this amount being split $60.00 each Federal and $40.00 State, the Federal Government's net payment is $61.20 and New York State's net payment is $38.80.

New York would lose an estimated $40 million in 2021-2022 tax revenue from the pharmacy portion of the premiums if pharmacy is excluded from the plan benefit package, and the potential loss amounts to $220 million over five years (as shown previously in Exhibit 6). These impacts did not appear to be included in the fiscal forecast (although again, due to the lack of detail provided by DOH, this is not completely clear).

B. Assessment of Components Included in DOH Fiscal Forecast:

1. Repricing. Based on the limited information provided by the State, we have no basis to dispute DOH's repricing analysis. The repricing effort is a fairly straightforward calculation; using a vastly higher dispensing fee in conjunction with the Actual Acquisition Cost (AAC) payment schedule's relatively lower ingredient costs.[4]

[4] We note that no payer outside of those administering the fee-for-service Medicaid program has adopted the AAC approach New York uses for Medicaid FFS pharmacy claims. Given that all payers have an incentive to eliminate excess drug costs, it seems telling that the AAC payment methodology is in place only where it is required to be used.

However, we are concerned that DOH only appears to be conducting a re-pricing analysis in its effort to ascertain the carve-out model's impact on pre-rebate payments to pharmacies. As described above, the carve-in model's savings are significantly associated with drug mix differences. A repricing approach vastly undervalues the savings the carve-out model yields with regard to "front-end" pharmacy expenditures, if not paired with a drug mix impact assessment. Drug mix and drug prices need to be fully considered. Ample evidence of drug mix impacts is available and should be included in any sound fiscal forecast.

2. Administrative Costs. The DOH fiscal forecast has assumed that 85% of pharmacy-related administrative costs will be removed from the MCOs' capitation payments and that these will result in pure savings. The forecast only has 15% of existing pharmacy-related administrative costs reappearing under new, FFS management. As noted above, our analyses suggest that, other than in specialized situations (e.g., the HIV SNP program where pharmacy represents more than 50% of the health plans' overall Medicaid revenue), no more than 5% of the Medicaid MCOs' existing administrative functions and corresponding costs will be eliminated under a pharmacy carve-out and that MCOs will incur significant, additional administrative costs when replicating these functions in the transition to FFS. The MCO pharmacy-related administrative costs that do shift to the FFS setting will largely reoccur in that setting rather than disappear and become savings.

3. Rebates. Payers are often able to negotiate supplemental rebates on brand drugs above the large statutory rebates that these manufacturers must pay for Medicaid prescriptions under the provisions of the Affordable Care Act. However, the *additional* rebates occurring in the Medicaid FFS setting have not yielded cost-effective overall results. The states managing the front-end drug mix most effectively, rather than the states excelling at securing rebates, have consistently been the top-performers in Medicaid drug cost management.[5] In the aggregate, large rebates per prescription are inversely correlated with successful management of net Medicaid pharmacy costs. During FFY 2017 for example, the three states obtaining the largest rebates per Medicaid prescription – Connecticut, South Dakota, and Vermont – were the three states with the nation's highest net costs per Medicaid prescription in that year.

New York's ability to attain relatively favorable supplemental rebates is questionable since the state's large purchasing power is much smaller than that of most of nationwide PBMs who are currently negotiating rebates under contract with New York's Medicaid MCOs.

The rebate section of the DOH fiscal forecast, coupled with the absence of a drug mix component, creates further concern regarding an over-focus on each drug's price, while forfeiting the ability to optimally steer volume to lower cost drugs.

[5] Exhibit 6 of this report shows the ranking of each state on net cost per Medicaid prescription, generic percentage of all Medicaid prescriptions, and rebates per Medicaid prescription:
https://www.themengesgroup.com/upload_file/value_of_managed_care_for_medicaid_rx_.pdf
These rankings demonstrate the direct relationship that often exists between net costs per prescription and generic usage, and the inverse relationship that exists between net costs per prescription and rebates per prescription.

4. 340B Program Impacts. Our understanding is that DOH has modeled an opportunity to achieve Year 1 savings of approximately $166 million through making changes in how 340B Program outpatient drugs are procured. Based on the Federal match rate, we envision that roughly 40% of these savings, or $66 million would be the state fund impact. This is an area where DOH has recently provided relatively detailed data, via slides presented at the initial meeting of the 340B Advisory Group on August 5, 2020.

Unless FFS or the carve out has a mechanism to steer additional volume to 340B pharmacy providers, these savings will likely stem from reduced payments to 340B providers. The overall financial viability of 340B providers is typically fragile, and policymakers need to ensure that these points of access remain available. To that end, policy makers should avoid a savings approach that cuts safety net providers' revenues. Alternatively, some of the savings components, such as limiting the profit margin being attained by various contract pharmacies, can be secured under the carve-in model.

IV. The Carve-Out Will Undermine Quality of Care

This section of the report describes the anticipated programmatic impacts the carve-out model will have, beyond the adverse fiscal impacts shown in Section III, with additional detail included in the appendix. Through a survey of New York's Medicaid MCOs, we have conveyed several programmatic advantages and disadvantages of a carve-in versus carve-out approach below.

A. Benefits of the Carve-In Model for Members

Better Care Coordination for Medicaid Members

Integrated benefits allow MCOs to improve care coordination, deliver whole person care, and have timely visibility into member needs. MCOs' staff include pharmacists and other pharmacy-focused and care management personnel who facilitate access to medications and provide adherence and other forms of support to members. The in-house pharmacy team works closely and directly with the MCO's other care coordination personnel and within the same information technology platform. That level of integration has real implications on patient care; one health plan noted that their pharmacy department staff attends weekly behavioral health and medical rounds to provide information on treatment adherence that may explain emergency department utilization or inpatient admissions. This enables staff to quickly connect with at-risk members to prevent future hospital admissions. Carving the pharmacy benefit out of managed care will reduce integration across the care continuum, and will likely have significant, negative impacts on members with complex or chronic medical conditions.

Access to Real-Time Pharmacy Data

New York's MCOs provided extensive information regarding their efforts to integrate pharmacy data with other aspects of their coordinated care business operations in real-time and in accordance with their own data specification requirements. Several examples of how the MCOs currently use and integrate *their* pharmacy data are conveyed below. The carve-out model substantially weakens these aspects of the MCOs' care coordination efforts.

Several New York health plans operate Medicaid lines of business in other states where a carve-out model is used. In these states, the MCOs report that the pharmacy data they receive from the state (or the state's PBM contractor) is significantly delayed, often unreliable, and not easily integrated with plans' existing internal information system and staffing structures.

- **Impact on Member Care**. Real-time pharmacy data is critical in supporting members through transitions of care between various settings and ensuring members have access to the medication treatment needed, as well as reconciliation of treatments. Plans noted that transitions can frequently produce a gap in care that requires health plan intervention. For

example, when a member is discharged from an emergency room, it is critical for a health plan to coordinate on behalf of the member to resolve any pharmacy issues to prevent readmissions. Additionally, if a member is admitted to the hospital, the hospital may contact the health plan care coordination team to identify which medications the member was taking. Access to real-time data is particularly important for members with multiple co-morbidities and who are prescribed various medications. These data allow the health plan pharmacy to track polypharmacy, contraindications, prescription drug abuse, and adverse reactions for members, and intervene when needed. Some health plans also noted that they can immediately identify when a member is late in filling his or her ongoing medication treatment and can intervene proactively.

- **Impact on Quality**. Real-time pharmacy data that is integrated with the MCOs' overall data system is valuable in improving quality performance in various clinical and operational areas. Below are several ways in which a carve-out approach will reduce the current program oversight functions and their effectiveness.

  - The information obtained from medication reconciliation, pharmacy point of sale rejections, and medication adherence helps drive quality programs tied to oversight of clinical and behavioral health programs.
  - Components of quality programs allow health plans to audit coverage determinations across various member populations to ensure the decision is appropriate and individualized to the member. Override information, medication rejections, and inappropriate clinical decisions are used to identify individual-level concerns as well as broader population health issues.
  - Plans often conduct quality audits on adherence outreach. This allows the plan to connect with members and providers to work towards favorably impacting medication adherence and individualized care plans.
  - Health plans use pharmacy data for Quality Assurance Reporting Requirements and HEDIS measures such as Asthma Medication Ratio, Statin Therapy for Patients with Cardiovascular Disease, and Antidepressant Medication Management.

More detail regarding plans' use of real time data is included in the appendix, including several examples of how having the pharmacy benefit carved-in has optimized behavioral health and substance use disorder treatment adherence.

Medication Access and Adherence Support

Pharmacy data is critical for managing members' access to medications and adherence support, particularly for high-needs populations:

- For members with sickle cell disease, health plans use pharmacy data to identify which members may have missed a refill of their medication and follow-up with the provider as well as the member to identify any barriers.
- For high-risk pregnant members, health plans are able to structure their care management efforts around members' specific treatments such as diabetes and preeclampsia – information they learn from pharmacy records. If members are identified as being high risk through this data, the plan may reach out to the providers and members around treatment and education options.
- For HIV populations, health plans are regularly reviewing viral load information with the member's prescription to ensure medication adherence. Detailed information on the New York HIV SNP health plans' programs and anticipated impacts related to a pharmacy carve-out is presented in Section VII.
- Health plans regularly review claims data for medications with complex regimens that are associated with rare diseases to identify care management opportunities.
- Health plans use real-time pharmacy data to identify and arrange for durable medical equipment that may be needed for some specialized drugs.

Improved Value-Based Contracting with Providers

- New York Medicaid MCOs are increasingly engaging in value-based purchasing initiatives involving pharmacies and including pharmacy-related incentives in contracts with other network providers. These initiatives aim to better align MCOs, pharmacies, and other providers to achieve DOH's objectives regarding access, quality, and cost-effectiveness. Integrating pharmacy is critical to successful administration of these models and would be significantly impacted by a carve-out.

While the state is committed to integrated care, ***there is no realistic path to avoiding diminished programmatic performance under a carve-out model***. The MCOs have developed integrated staff, integrated information systems, and integrated care coordination processes that all function optimally under a carve-in model of all services – all with the purpose of providing the best care to Medicaid members. Pulling a benefit as central to health care and to care coordination as prescription drugs out of this integrated structure is an inherently problematic approach.

B. Considerations for Specialized Care: A Focus on the HIV Special Needs Plan Program

Since the implementation of the pharmacy benefit into managed care in 2012, the HIV SNPs have played an instrumental role in the broader state efforts toward "Ending the Epidemic"[6] and

[6] On June 29, 2014, Governor Andrew M. Cuomo detailed a three-point plan to move us closer to the end of the AIDS epidemic in New York State. https://www.health.ny.gov/diseases/aids/ending_the_epidemic/

have improved viral load suppression to 81% as of 2019. Under the carve-in setting the HIV Special Needs Plan Programs (HIV SNPs) have built exceptional in-house pharmacy teams and a comprehensive model of care coordination tailored to the unique needs of their enrollees. HIV SNP plans provide integral services to both their members and New York State through cost control, myriad clinical initiatives and tailored support for members, and fraud identification and prevention. The pharmacy carve-out would all but eliminate the role of these highly specialized plans, and have particularly adverse effects for HIV SNP members, the majority of whom are HIV positive.

1. Cost Control

In the face of rapidly rising drug prices, HIV SNPs leverage two primary strategies to curb drug costs:

a. A Transparent, Pass-Through Payment Model. With a transparent, pass-through financial model in place, plans do not profit off the spread-pricing practice, and PBMs are instead reimbursed more directly through fees. Detailed drug cost- and rebate-level reports are now being shared by the MCOs with DOH on a quarterly basis to ensure full transparency.

b. Maximize Rebate Potential Through Formulary Management. For HIV SNPs, the highest drug volume and costs come from HIV drugs and account for around 90% of overall drug use – rebates for which are already negotiated directly with manufacturers and collected by New York State (not the health plans). Clinically, the needs of a very complex HIV population with a high number of behavioral health/substance use and other comorbid conditions requires a very different type of formulary drug selection than is needed to optimally serve New York's overall Medicaid population.

2. Clinical Initiatives and Tailored Support

HIV SNP entities deliver fully integrated care coordination with exceptional attention to members' individual needs:

- **In-House Pharmacy Team with Tailored HIV Expertise and Experience.** Given the extreme importance of successful medication access and adherence for persons living with HIV, HIV SNPs have established integrated care pharmacy teams. These staff possess specialized knowledge of HIV treatment options and enrollee dynamics, and their careers are focused on working closely with enrollees, their MCO's care coordination staff, prescribers, and pharmacies to facilitate access and adherence to an optimal medication regimen.

  Clinical staff pharmacists are both physically and procedurally embedded within interdisciplinary care management teams. Throughout daily outreaches with members, care management staff and staff pharmacists "co-call" members to deliver education on the clinical and medication aspects of their treatment. This integrated approach and these joint conversations have led to positive outcomes such as resolving concerns related to

state complaints, providing education and information that has increased medication adherence, identifying and eliminating therapeutic duplications, and/or identifying potentially harmful and serious adverse effects. The quality and comprehensiveness of these interventions are heavily dependent on current access to historical and real-time claims data.

HIV SNP staff working on site with providers have repeatedly been told by these provider staff how much less the providers' administrative burdens have been under New York's pharmacy carve-in model.

- **Clinical Monitoring to Support Medication Adherence.** HIV SNPs' pharmacy departments actively monitor lab work for members living with HIV to ensure medication treatment adherence and to ensure their members are adequately protected from opportunistic infections. By ensuring labs for viral loads and CD4 counts are up to date, plans can assess if the appropriate therapy is being utilized and if members' treatments are optimized. Real-time access to optimal data and therapy is critical to achieving the goals of viral load suppression and reduced transmission.[7] The analysis for one HIV SNP that had implemented an intervention to avoid disruption of HCV therapy estimated an increased cost of $29 million was avoided through the health plan's intensive efforts to facilitate adherence to the full HCV medication treatment regimen.

- **Improving Access Barriers at Point-of-Sale.** An HIV SNP's pharmacy department reviews any medications rejected at the pharmacy on a daily basis, specifically for HIV, hepatitis C, antipsychotics, and gender-affirming medications. This allows the plan to proactively and quickly resolve any issues and prior authorizations to mitigate barriers to care related to medication access.

- **HIV Prevention for High-Risk HIV Negative Members.** The HIV SNPs also play a key role in preventing the spread of the virus. Each new infection has been projected to create increased lifetime treatment costs per individual of $400,000 - $500,000. An HIV SNP's pharmacy team counsels each HIV negative member who starts an HIV pre-exposure prophylaxis (PrEP) regimen, reviews the patient's pharmacy history to identify any drug interactions, and works with them to address any concerns about the treatment. The plan ensures that the patient has the appropriate tools to prevent HIV. In addition, HIV SNPs track whether refills are occurring and reach out if there are lags. Persistence in PrEP therapy is one of the key challenges to maximize this public health intervention.

[7] We note that while it is possible that DOH will provide the HIV SNPs (and other Medicaid MCOs) with "real time" pharmacy data under a carve-out model, this has yet to occur in the states that have carved out the pharmacy benefit. Obtaining pharmacy data in the state's format is also significantly different from an MCO working with its contracted PBM to provide data *on the MCO's terms* and in a manner that optimally supports that MCOs' care coordination activities.

In a carve-out scenario, the PBM would only approve the medication and not follow up to ensure initial usage and persistence in therapy.

The comprehensive nature of the various processes that an in-house pharmacy team employs to assist members with medication access and adherence are a result of the experience and expertise of the in-house pharmacy staff to use all the tools at their disposal to support members. Below, we share member-specific examples of the advantages of supporting HIV SNP members with an in-house team of staff pharmacists.

3. Fraud Identification and Prevention

Coverage determinations are scrutinized to ensure decisions are clinically appropriate, member-specific, and safe. Items identified during these audits include override errors, rejected medications, inappropriate clinical decisions, and missed information. The audits allow for continuous improvement to patient care by identifying individual issues and larger trends and implementing changes to promote the most clinically appropriate outcomes. The carve-in setting creates enhanced opportunities to identify and address fraudulent behaviors. The Fraud, Waste, and Abuse (FWA) programs developed by HIV SNPs work with the Office of the Medical Inspector General (OMIG) to curb FWA associated with HIV drugs in NYC. In a carve-out model, this audit process would be significantly limited by time and resources, opening the door for missed interventions that could have improved patient care.

One HIV SNP's program consists of a clinical team who develops analytical reports driven by live pharmacy claims data to conduct weekly reviews and outreach assessing each patient's problematic pharmacy claims patterns in conjunction with a retrospective review of antiretroviral treatment prescription data. This includes implementing a restricted member "lock-in" program and identification of overprescribing. Working closely together with OMIG, the HIV SNP has demonstrated as high as 97% intervention acceptance rates with provider and pharmacy networks to help the state combat inappropriate prescribing and medication dispensing in the community.

"Returning the management of the pharmacy benefit to FFS will devastate our comprehensive care model and threaten the very sustainability of the Plan. The pharmacy benefit accounts for 60% of our premium revenue. Consequent losses in administrative revenue would significantly alter, if not eliminate, our capacity to support critical components of the model including care coordination, value-based incentives including the LYL Undetectable viral load suppression programs and innovative interventions on social determinants of health.

The pharmacy counter has become the intersection where all of our care comes together. Most people living with HIV are require multiple medications to manage the multiple chronic conditions that accompany aging with HIV.

Divorcing management of the pharmacy benefit from other aspects of care management removes the very resources that have so dramatically transformed the others. It seems counter-intuitive to fragment the pharmacy benefit from the rest of the patient's care management, especially given the certain disruption and questionable savings that will result."

– HIV SNP Executive

VI. Conclusion

The analyses outlined in this report provide compelling evidence to encourage the state to reconsider their position on carve-out and reverse course. The state, plans and providers can find alternative savings within the carve-in model that protect Medicaid members, sustain the providers who care for them and continue to build on the state's successful model of integrated care for low-income New Yorkers.

After extensive and transparent data analysis included in this report, we conclude that the expected fiscal and programmatic impacts of a Medicaid pharmacy carve-out are all unfavorable and will result in increased Medicaid costs and weakened care coordination.

Contrary to the state's projected savings of $125 million in the first year of the carve-out, we estimate that it will cost the state $154 million during the first year. Taken together, we estimate that the overall New York State costs in the upcoming fiscal year will be $279 million higher than are currently forecasted – adding together the $125 million savings that will not happen and the $154 million additional cost that will occur if the carve-out is implemented.

The state's fiscal projections related to the pharmacy carve-out are flawed, as they appear to omit critical components related to changes in the mix of drugs, loss to the state of premium tax revenues and understatement of the administrative costs – to both plans and the state – of a carve-out model.

Equally critical, carving-out the pharmacy benefit will harm Medicaid enrollees, especially those with chronic illnesses who need medication management and care coordination to maintain and improve their health. Carve-out models cannot provide the same level of coordinated care. In addition, changes contemplated to 340B reimbursement could lead to the collapse of many safety-net providers who serve New York's most vulnerable Medicaid members.

APPENDIX A

Methodology and Data Sources

The Menges Group collected and analyzed an extensive array of quantitative and qualitative data in creating this report. Qualitatively, we collected information from more than a dozen New York Medicaid health plans, including three MCOs fully focused on serving HIV/AIDS populations. New York's MCOs provided information regarding their operations and interactions with members as they relate to the prescription drug benefit, and how they would change under a statewide carve-out and/or uniform preferred drug list (PDL). Plans also provided quantitative information related to the Medicaid pharmacy benefit, such as the cost and mix for certain medications, drug rebates received, and administrative costs associated with managing the drug benefit.

In addition to information received directly from health plans, we relied extensively on CMS State Drug Utilization Data. These files contain 100% of the Medicaid prescription drug utilization data reported directly from state Medicaid programs to CMS on a quarterly basis. Drug utilization is presented at the National Drug Code (NDC)-level and includes the volume of prescriptions and the Medicaid amount paid (before rebates) broken out by the Medicaid FFS and managed care settings. NDCs were classified as brand or generic using the National Average Drug Acquisition Cost (NADAC) weekly reference data from CMS. We conducted additional research on high-volume NDCs to classify them as brand or generic if they were not identified in the NADAC file. In instances of missing data or prescription drug volume or expenditures that are grossly unrealistic, we corrected the data. These adjustments were minimal, accounting for just 1.0% of prescription volume nationally over the past five years.

We relied on a separate file—the CMS Financial Management Reports (FMR)—to compile the amount of Medicaid drug rebates states receive in each federal fiscal year. The FMRs contain statutory rebates as well as supplemental rebates the states and MCOs/pharmaceutical benefits management (PBM) entities negotiate with manufacturers. The total rebates reported by states vary from year-to-year based on the timeliness and completeness of reporting. To account for these fluctuations, we distributed total rebates across years in each state (without changing the total) in a manner that better tied each year's rebates with each year's pre-rebate expenditures. The FFY2019 CMS FMRs were not yet available for this analysis. Average brand rebate percentages in each state from FFY2013-FFY2018 were applied to FFY2019 drug utilization data to estimate brand drug rebates. All generic drugs receive a 13% rebate and thus FFY2019 generic rebates were tabulated rather than estimated. While MCOs'/PBMs' supplemental rebates are not available or are underreported in the CMS FMR for most states (31 states in FFY2018), they are published for several states. The MCOs'/PBMs' average percentage of supplemental rebates in the states where this information was reported was used to estimate MCOs' supplemental rebates in the other states in which Medicaid MCOs operate.

Across these data sources, we are able to tabulate the following key performance statistics for any state (or any group of states) for any year:

- Initial (pre-rebate) cost per Medicaid prescription
- Rebates per Medicaid prescription (including statutory and supplemental rebates)
- Net (post-rebate) cost per Medicaid prescription
- Generics as percentage of all Medicaid prescriptions

APPENDIX B

Additional Analyses of States' Carve-Out Versus Carve-In Experience

Exhibit B-1. Net Cost Per Prescription and Generic Dispensing Trends from 2011-2019, New York and Nationwide

Jurisdiction	Net Cost Per Prescription		Percent Change	Generic Percentage of Prescriptions		Percent Change
	2011	2019		2011	2019	
NY	$44.31	$40.37	-8.9%	68.1%	88.8%	20.7%
USA Overall	$37.03	$39.45	6.5%	75.3%	87.6%	12.3%
USA (excluding NY)	$36.13	$39.34	8.9%	76.2%	87.4%	11.3%

Despite relying heavily on MCOs to pay for Medicaid prescriptions, New York still had nearly 17% - just below 13 million prescriptions - of its Medicaid prescriptions in fee-for-service (FFS) during FFY2019. New York's Medicaid FFS prescription volume is larger than the *total* Medicaid prescription volume of all but 19 states. While New York has a very different population (and clinical distribution of drugs) in the FFS setting than in the MCO setting, we deemed New York's FFS volume to be ample for purposes of comparing MCO-paid and FFS-paid costs per prescription within therapeutic classes. The 20 therapeutic classes with the largest Medicaid prescription volume during FFY2019 are shown in Exhibit 3 along with the average costs per prescription for New York's MCO-paid and FFS-paid medications within these classes.[8]

These comparisons demonstrate that vast differences in average costs per prescription often exist between the MCO and FFS settings, with these differentials almost always favoring the MCO setting as being far more cost effective. On average across these 20 therapeutic classes, the average cost per prescription in the FFS setting was 2.3 times above the MCOs' average cost. New York policymakers need to be extremely wary about transitioning responsibility for the MCO-paid prescriptions to the FFS setting given these performance dynamics.

[8] Note that we are not able to tabulate or accurately estimate net (post-rebate) costs per prescription at the therapeutic class level. The rebate information is available only at an aggregate level. The figures in Exhibit 3 are therefore produced on a pre-rebate basis.

Exhibit B-2. Comparison of New York's FFY2019 Cost Per Prescription in MCO and FFS Settings for 20 Top-Volume Therapeutic Drug Classes

	FFY2019 Medicaid Prescriptions		Average Cost Per Prescription During FFY2019 (Pre-Rebate)		
Detailed (Third Tier) Therapeutic Class	MCO	FFS	MCO	FFS	FFS Cost as % of MCO Cost
Nonsteroidal anti-inflammatory drugs	2,655,016	155,837	$5	$20	408%
Statins	2,430,318	279,622	$10	$13	133%
Antihistamines	1,900,438	581,108	$5	$11	251%
Platelet aggregation inhibitors	1,198,923	1,104,722	$9	$10	107%
Adrenergic bronchodilators	2,091,277	184,889	$46	$62	133%
Selective serotonin reuptake inhibitors	1,766,372	235,032	$6	$15	237%
Laxatives	898,607	988,745	$7	$11	160%
Proton pump inhibitors	1,625,924	111,314	$13	$76	601%
Calcium channel blocking agents	1,439,183	170,832	$5	$13	266%
Atypical antipsychotics	1,184,768	360,197	$193	$152	79%
Topical steroids	1,365,083	84,101	$24	$26	107%
Non-sulfonylureas	1,221,816	139,396	$9	$24	250%
Angiotensin Converting Enzyme Inhibitors	1,204,261	134,434	$4	$13	352%
Contraceptives	1,091,460	200,910	$45	$52	115%
Miscellaneous analgesics	812,530	418,558	$2	$10	551%
Inhaled corticosteroids	1,098,490	103,472	$87	$92	106%
Gamma-aminobutyric acid analogs	999,522	140,245	$58	$94	162%
Thyroid drugs	994,737	124,669	$11	$21	192%
Aminopenicillins	1,056,484	60,062	$5	$13	247%
Cardioselective beta blockers	933,911	143,931	$8	$14	164%

Management of High-Cost Drugs – Assessment of Curative Hepatitis C Medication Cost Progression in MCO and FFS Settings

One example of MCOs' ability to more quickly react to changes in the prescription drug market deals with emerging curative hepatitis C medications. In December 2013, Sovaldi was approved by the FDA as the first curative hepatitis C medication, followed by Harvoni in October 2014. These medications were quite expensive however, averaging around $23,000 and $27,000 per prescription, respectively. As less costly alternatives became available, New York's MCOs (and MCOs nationally) demonstrated their value by switching to less costly alternatives much more rapidly than was occurring in the Medicaid FFS setting.

Exhibit B-3 conveys how the Medicaid FFS and MCO settings used each medication as a share of their total hepatitis C usage for New York State and the entire nation. The MCO setting—both nationally and in New York—has been much faster to adopt lower-cost hepatitis C medications, such as Zepatier, Epclusa, Mavyret, and Velpatasvir / Sofosbuvir (generic Epclusa), as they became available.

Focusing on New York, Medicaid MCOs showed a more rapid uptake of lower-cost alternatives the year following their approval, compared to the FFS setting.

Exhibit B-3: Hepatitis C Medication Usage and Cost Per Prescription by Drug, New York and National, 2015-2019

Share of Medicaid Hepatitis C Volume: National MCO						
Drug	Average Cost Per Prescription, 2015-2019	CY2015	CY2016	CY2017	CY2018	CY2019
Sovaldi	$23,626	17%	13%	1%	0%	0%
Harvoni	$28,038	54%	43%	19%	6%	2%
Viekira Pak	$22,561	4%	5%	3%	1%	0%
Zepatier	$15,832	0%	9%	33%	3%	0%
Epclusa	$20,862	0%	7%	27%	11%	8%
Vosevi	$20,665	0%	0%	1%	3%	2%
Mavyret	$11,465	0%	0%	6%	73%	68%
Generic Velpatasvir & Sofosbuvir	$7,164	0%	0%	0%	0%	18%

Share of Medicaid Hepatitis C Volume: New York MCO						
Drug	Average Cost Per Prescription, 2015-2019	CY2015	CY2016	CY2017	CY2018	CY2019
Sovaldi	$24,118	18%	13%	1%	0%	0%
Harvoni	$29,000	60%	38%	12%	4%	1%
Viekira Pak	$21,540	3%	4%	0%	0%	0%
Zepatier	$17,507	0%	17%	45%	2%	0%
Epclusa	$23,113	0%	8%	26%	7%	2%
Vosevi	$18,170	0%	0%	1%	4%	4%
Mavyret	$9,100	0%	0%	10%	82%	59%
Generic Velpatasvir & Sofosbuvir	$7,743	0%	0%	0%	0%	34%

Share of Medicaid Hepatitis C Volume: National FFS						
Drug	Average Cost Per Prescription, 2015-2019	CY2015	CY2016	CY2017	CY2018	CY2019
Sovaldi	$22,073	17%	13%	1%	0%	0%
Harvoni	$26,390	47%	42%	39%	12%	6%
Viekira Pak	$25,496	8%	7%	4%	0%	0%
Zepatier	$14,429	0%	6%	14%	3%	2%
Epclusa	$21,276	0%	8%	26%	27%	34%
Vosevi	$21,382	0%	0%	1%	2%	2%
Mavyret	$11,631	0%	0%	6%	52%	48%
Generic Velpatasvir & Sofosbuvir	$6,562	0%	0%	0%	0%	5%

Share of Medicaid Hepatitis C Volume: New York FFS						
Drug	Average Cost Per Prescription, 2015-2019	CY2015	CY2016	CY2017	CY2018	CY2019
Sovaldi	$27,708	15%	13%	0%	0%	0%
Harvoni	$30,684	34%	43%	38%	5%	13%
Viekira Pak	$27,568	22%	15%	0%	0%	0%
Zepatier	$17,838	0%	6%	35%	3%	15%
Epclusa	$24,003	0%	1%	27%	30%	27%
Vosevi	$24,545	0%	0%	0%	2%	0%
Mavyret	$12,760	0%	0%	0%	59%	42%
Generic Velpatasvir & Sofosbuvir	$6,610	0%	0%	0%	0%	3%

This ability to more nimbly prioritize lower-cost medications resulted in lower costs in the Medicaid MCO setting.

Exhibit B-4 presents overall cost per prescription outcomes for the curative Hepatitis C drugs each year from 2015-2019, comparing the MCO and FFS settings. While both the FFS and MCO settings start out with relatively similar costs per Hepatitis C prescription in 2015 (in fact, New York's MCO costs per prescription were slightly above New York's Medicaid FFS setting average in 2015 when no competitive products were available), the New York MCOs' steerage of volume towards lower-cost drugs as they became available has led to large-scale savings in overall costs per prescription. During 2018 and 2019, the average cost per prescription for New York's MCOs was dozens of percentage points lower than the New York FFS average cost. New York's experience is similar to the national experience of Medicaid MCO and Medicaid FFS payments for these medications. New York's Medicaid MCO average cost per prescription was below the national MCO average during 2018 and 2019.

The New York Medicaid MCOs' collective management of drug mix in this category of medications has been highly cost-effective. *If New York's MCOs had paid for the curative Hepatitis C drugs in the same manner (price and mix) as occurred in the New York FFS setting, additional costs of $208 million would have occurred across the 2015-2019 timeframe.*

Exhibit B-4: Costs Per Prescription, Hepatitis C Medications, 2015-2019

	2015	2016	2017	2018	2019
New York's Medicaid Experience					
New York MCO	$22,867	$21,883	$19,659	$7,622	$11,897
New York FFS	$21,110	$24,148	$24,097	$17,534	$17,854
New York MCO as % of NY FFS	**108%**	**91%**	**82%**	**43%**	**67%**
Nationwide Medicaid Experience					
USA MCO	$20,803	$21,111	$17,900	$12,877	$12,215
USA FFS	$18,258	$19,358	$20,451	$16,015	$16,002
USA MCO as % of USA FFS	**114%**	**109%**	**88%**	**80%**	**76%**

Exhibit B-5. MCO Risk Margin Impacts of Carve-In

Year	Estimated Net Costs for Prescription Drugs Under Carve-Out Approach, MCO-Paid Prescriptions	Additional Medicaid Pharmacy Expenditures Due to Carve-Out	Offsetting Carve-Out Savings -- Removing MCO Risk Margin Allocation for Rx	Total Medicaid Fiscal Impact (Added Cost of Carve-Out)
FFY2019 (baseline)				
SFY 2021-2022	$3,425,232,013	$348,984,253	$63,703,619	$285,280,634
SFY 2022-2023	$3,971,907,820	$734,527,747	$67,040,383	$667,487,364
SFY 2023-2024	$4,179,954,357	$773,001,941	$70,551,924	$702,450,017
SFY 2024-2025	$4,398,898,268	$813,491,395	$74,247,398	$739,243,996
SFY 2025-2026	$4,629,310,351	$856,101,666	$78,136,440	$777,965,226
5-Year Total	**$20,605,302,808**	**$3,526,107,002**	**$353,679,764**	**$3,172,427,238**

APPENDIX C

COMPILATION OF EFFORTS NEW YORK MCOs ARE MAKING TO FACILITATE MEMBER ACCESS AND ADHERENCE TO MEDICATIONS

The following case examples have been provided by New York Medicaid health plans conveying instances in which plans had a meaningful impact on their members through full integration of the pharmacy benefit. The first section contains 22 specific accounts of the ways plans were able to improve members' access to medications.

The second section presents 22 specific instances in which plans helped members with their adherence to medications. The health plans did not view that similar services would occur under a pharmacy carve-out model in these instances – nor in many other case examples that were not included.

A. Helping Members Access Needed Medications – 22 Case Examples

1. Correcting Rejected Claims

During case management rounds, a health plan's pharmacist noted rejected claims for a member's antidiabetic medication. The reason for the rejection was due to the prescribed quantity exceeding the maximum recommended daily dose. The pharmacist reached out to the clinic, where the provider happened to be a first-year resident who mistakenly prescribed an incorrect dose. The prescription was adjusted to the appropriate dose and the plan's pharmacist was able to contact the member's pharmacy to process the claim and ensure the member had access to the proper dosage of the medication.

2. Monitoring Patient Prescriptions to Complete Treatment

A member of this plan had been taking medication to treat his Hepatitis C. Due to the high cost of Hepatitis C treatments, this plan has a team of in-house pharmacists that manages all Hepatitis C medications and track new products entering the market. This allows the plan to have a comprehensive offering of the most optimal and cost-effective therapies. After meeting with his physician, the member was prescribed a new medication with excellent cure rates for patients who complete the full course of treatment. In this member's case, one of the in-house pharmacists reviewed the member's prescribed treatment and identified that the physician had prescribed an eight-week course of therapy for the member, which is only half of the recommended 16-week treatment. The in-house pharmacist contacted the physician who then

adjusted the prescription. The member was then contacted to ensure he completed the full course of therapy. Without the access to real-time prescription data and the intense follow up from the in-house team, the member would not have completed the full course of treatment, and thus would have wasted tens of thousands of dollars on incomplete treatment that would not have successfully treated his Hepatitis C.

3. **Ensuring Continued Access to Medication Amid the COVID-19 Pandemic**

This plan has a member who is HIV+, has schizophrenia, and has a long history of emergency hospital admissions for mental and physical health issues. As a result of the COVID-19 pandemic, this member's regular physician's office closed, and she could no longer access the necessary monthly injections of an antipsychotic medication. This plan's social work and behavioral health care management teams immediately recognized that a missing injection could have disastrous health outcomes for the patient, so they worked to find a solution. The teams arranged for the patient to pick up the medication at her local pharmacy and for a provider who specializes in medical and psychiatric home care to administer the injections at the member's home. The plan's in-house pharmacists utilize the real-time pharmacy data to monitor when the prescription was filled and picked up by the member before sending the home care provider to administer the injection. Without the ability for plans to access real-time pharmacy data and the close integration of pharmacy and clinical teams, the plan would not be able to offer these services to its members.

4. **Medication Replacement to Maintain Access**

A member of this plan is homeless and has been diagnosed with HIV, generalized anxiety disorder, major depression, and substance use disorder. She has a long history of hospital admissions and numerous detoxes. Following her recent discharge from inpatient psychiatric treatment, she returned to the homeless shelter where she had been staying to find that all her medications had been stolen. When the plan's in-house team of pharmacists was completing their weekly multidisciplinary rounds with the Medical Director and the care management, social work, and behavioral health teams to review the status of individual members, this member's case was discussed and they identified better ways to support her. The in-house pharmacists contacted the pharmacy and the member's prescriber and arranged for all approvals necessary for the member's medications to be replaced. Within hours, the member had her medications and remained stable, likely averting another hospital admission.

5. Overriding a Prescription through Drug Utilization Review (DUR)

Upon receiving a request for a Hepatitis C medication, the pharmacist reviewed the member's genotype and previous treatments to see if it was an appropriate regimen for the member. The provider's requested therapy was not in line with the recommended regimen per the American Association for the Study of Liver Diseases (AASLD) guidelines for the management of Hepatitis C. The plan's pharmacist contacted the prescriber, explained what the correct treatment course should be, and had the regimen updated. DUR at point of sale helps prevent inappropriate utilization for members who are receiving specialty medications or with co-morbid conditions.

6. Outreach to Members with Specialty Needs Amid COVID-19

At the beginning of the COVID-19 pandemic, amidst the "New York Pause," a pharmacist at this plan created a list of all the Medisource patients with HIV or AIDS and personally reached out to each of these members to reassure them that their ability to access health and pharmaceutical care would not suffer due to the state-wide shut down. This pharmacist worked with the members to ensure they had access to pharmacies that were open and could fill or deliver 90-day supplies of their medications and to answer any questions about the status of the pandemic. If other obstacles to access their health or pharmaceutical care were identified, the pharmacist provided tips to overcome these barriers.

7. **Difficulty Accessing Medication for Newborn**

A newborn was discharged from the hospital with a prescription for Synagis to prevent respiratory distress syndrome. The newborn's parents were having difficulty obtaining the drug, so the NICU case manager intervened on behalf of the infant. The NICU case manager and health representatives called the pediatrician's office for several weeks in an attempt to obtain the medication but had no success. The NICU case manager utilized the health plan's pharmacy tool to paste hospital notes in order to get the prescription for Synagis approved due to a lack of response from the pediatrician. Without the use of real-time pharmacy data, the NICU case manager and health representatives would not have been able to override the system to ensure the baby had access to this necessary medication.

8. **Addressing Comorbidities Optimally**

A member has a high opioid dose to address her multiple chronic conditions including HIV, COPD, hypertension, and chronic pain. Despite this complexity, her health plan has worked with her to maintain a suppressed viral load. The pharmacy team reached out to the member's provider to try to modify her opioid dosage to prevent opioid reliance. While reviewing her pharmacy utilization and medical history, the plan's pharmacy team found that she had recently been admitted multiple times to the emergency room for COPD exacerbations. The pharmacy team determined that she had not refilled her COPD inhaler prescription. She did not realize that the prescription was missing because she uses two inhalers and was on multiple medications. They immediately advised the member to contact the doctor for a refill and to discuss the opioid prescriptions. The team reached out directly to the doctor, who felt that the member required the opioid dosage she was taking. The doctor not only agreed to add naloxone to prevent overdose in this member but prescribed the treatment to all of her other opioid patients as well.

9. **Difficulty Obtaining Medication from the Member's Regular Pharmacy**

A plan assisted a member in filling his oxycodone/acetaminophen prescription before a weekend when his regular pharmacy was having issues ordering it. The plan found another pharmacy that had the medication in stock and facilitated delivery.

10. **Navigating Prior Authorizations**

Case managers for plans utilize pharmacy data to identify drugs that are subject to prior authorization. With this information, case managers are able to assist members and providers with obtaining approval or navigating the denial process. These efforts facilitate and expedite members' access to their prescribed medications.

11. **Ensuring Access to a Prescription Despite Hospital Readmission**

A member was unable to obtain an antibiotic that was prescribed upon discharge from her hospital birth because she was later readmitted for treatment for a post-partum complication. The case manager intervened and advised the pharmacist that the provider needs to request a prior authorization due to a quantity limit. Without the ability to view real-time pharmacy claims for care gaps, the case manager would not have known that the member was unable to access the medication. The case manager's partnership with the pharmacist helped the member access her

prescribed antibiotic, likely preventing a second readmission.

12. **Overcoming Expired Prior Authorization**

A member had an existing prescription for Florastor 250mg capsules whose prior authorization expired. Even after the ordering physician provided a new prior authorization and prescription and the pharmacy authorization request was approved, the pharmacy still rejected the medication because they needed an "authorization reason." The member tried to address the issue for more than a week before contacting his case manager. When the case manager checked with the pharmacy, they found that the pharmacy was running this medication under a different National Drug Code (NDC) and amount. The case manager provided the pharmacy with the correct NDC and the correct amount to dispense according to updated guidelines. The pharmacy was then able to dispense after the corrections were made. This issue was resolved by the case manager and the member received his medication two days later.

13. Increasing Timely Access to Makena/17P

A plan received numerous reports of pharmacy issues due to Makena/17P prescriptions. Despite ongoing provider education efforts, pharmacies often struggle with ordering, procuring, stocking, and storing the injections. In addition, there is often a delay in obtaining accurate prior authorizations due to providers submitting inaccurate and/or incomplete prior authorization forms. The Medicaid average for timely access to this medication in New York state is 20%. Through the use of real-time pharmacy data and the ability to escalate urgent matters within the pharmacy team and medical directors, a plan was able to receive a 67% access to timely medication procurement for members. The plan would not be able to achieve the same results if the pharmacy benefit is carved out.

14. **Proper Dosage for Patients**

A plan utilized its drug utilization review (DUR) program to identify a pediatric patient living with HIV who was being under-dosed on an antiretroviral medication based on her age and weight. One of the plan's Clinical Pharmacists made several rounds of provider calls to discuss increasing the member's dose based on her weight and ensured the pharmacy was able to dispense the new prescription to the member.

15. **Obtaining Necessary Prior Authorizations**

A member was approved for a Prodigy talking glucometer but was unable to obtain the corresponding test strips because the prescriber had only submitted a prior authorization request for the glucometer and not the test strips. Upon outreach from the pharmacy, the plan worked internally with the prior authorization team to add the corresponding authorizations for the test strips, which was approved almost instantly. The plan's integrated ability to address these various dynamics resulted in the member easily getting her glucometer and test strips.

16. Ensuring Cost Sharing to Provide Continued Access

A plan's Care Management and Pharmacy Departments worked together in real time to resolve an issue where a member was unable to pick up insulin due to the pharmacy not adhering to

Medicaid law pertaining to cost share. After the member spoke with care management, the plan's pharmacy department was able to ensure the member received her insulin.

17. Combatting the Opioid Epidemic

A plan's pharmacy team employs a comprehensive strategy to combat the opioid epidemic by addressing and restricting overuse of opioid medications. This strategy includes providing comprehensive opioid counseling and medication review in close coordination with members and providers. To date, the program has reduced the total morphine equivalence for the plan's members on high-dose opioids by 37%.

18. Tailoring the Formulary to Meet Members' Needs

To maintain the best quality of care for patients living with HIV, at risk of contracting HIV, and patients who are of transgender experience, a plan integrates the pharmacy benefit into the model of care to meet the unique health care needs of these individuals. For example, the plan has elected to include Qvar (a corticosteroid inhaler indicated for maintenance therapy in patients with asthma) in its formulary in addition to other inhalers (e.g. Flovent) because Qvar does not have interactions with antiretrovirals.

19. Biosimilar Formulary Outreach

A plan has successfully launched biosimilar formulary changes using additional provider support to enhance existing written communications. This includes identifying members currently on reference medications, outreaching to their respective providers, and educating the providers on biosimilars. It also includes assisting providers in transitioning members to their respective biosimilar equivalents by proactively initiating phone-based prior authorization before the formulary changes go into effect. This initiative assists providers in planning with their members on the changes to ease the transition and supports providers through formulary exceptions if they feel that continued reference drug use is necessary.

20. Obtaining Easy to Use Alternatives

An Autistic teenager lives with his grandmother, who was recently diagnosed with diabetes. The teenager is responsible for helping his grandmother maintain her diabetes care, as his grandmother cannot read the numbers on the meter. When the teenager had difficulties using the meter and strips that were preferred, the plan's care management team worked with him and his grandmother to switch to an alternative meter and strips that are easier for him and his grandmother to use and understand.

21. Outreach to Prescriber to Obtain New Prescription

A member had several rejected claims for her prescription for Epclusa. She had a prior authorization approved for generic Epclusa but, per the specialty pharmacy, they could not fill the generic without a new prescription from the original prescriber, which they had not obtained. Her plan performed telephonic outreach to the prescriber's office and requested they send a new prescription to the pharmacy for a generic version of the medication.

22. Obtaining Prescriptions Despite COVID-19 Closures

A member of a plan's Restricted Recipient Program was having difficulty obtaining updated prescriptions because of the COVID-19 quarantine and closures. Because of this unprecedented situation, the member's prescriber was unable to write behavioral health and substance use disorder medication refill prescriptions. The plan's care management team worked internally with the pharmacy team and prescriber practice to find an alternative prescriber who would write the necessary prescriptions for this member.

B. Helping Members with Adherence to Prescribed Medication Regimens (23 Examples)

1. Encouraging Compliance with Course of Treatment

During a monthly Restricted Recipient Committee meeting it was noted that a member did not feel she was benefiting from her SSRI antidepressant and wanted to stop taking it. A health plan's pharmacist noted that the member had only picked up this medication one week prior. Following the meeting, the plan's pharmacist counseled the member on SSRIs and explained that they usually need to be taken for 2-4 weeks before the full benefit is felt. The member understood and continued with the treatment course.

2. Field Visits to Encourage Medication Adherence

In an effort to encourage adherence to medications, this plan has an internal team in place to perform outreach to members to ensure medication adherence. In addition to telephonic outreach, a representative from this team conducts field visits to meet members and assess what resources they need to stay on track with their medications. Members are referred to this outreach team based on their diagnosis with conditions that require prolonged or multiple medications (like Hepatitis C or HIV), or any member who may be having difficulty adhering to their antipsychotic medications. The team performs comprehensive medication reviews to help members improve their understanding of their medications and improve quality of care for members with diabetes or rare diseases like pulmonary arterial hypertension.

3. Intervening to Meet a Member's Needs Post-Discharge

This plan's care management team worked to engage a teen member and her guardian following her discharge from a behavioral health unit for an eating disorder. Through the use of both real-time and retrospective pharmacy claims, a care manager on the team identified a history of nonadherence with medications and that the teen's medications had not been filled for several months post-discharge. The care manager failed to make contact with the teen or her guardian, so he reached out to the outpatient psychiatrist the member had been seeing. The psychiatrist noted that the member had been decompensating psychiatrically and medically. Once this report was received, rapid crisis interventions were put into place to readmit the member to address her

severe weight loss. Without the plan's ability to access real-time pharmacy data, the care management team's outreach would have been delayed, which could have had detrimental impacts on her health.

4. Explaining Treatment Benefits for HIV/AIDS

One of this plan's members was having difficulty adhering to her antiretroviral medications due to her feelings of guilt, isolation, depression, and anxiety surrounding her diagnosis. She began skipping her medications due to her high levels of anxiety, which had been leading to anticipatory vomiting. She declined most interventions from case management or pharmacy and decided that the best way to cope was to avoid her appointments and often skip medications. Following continued attempts from this plan's care management team, she agreed to speak with the pharmacist about questions pertaining to her treatment plan. She worked with the pharmacist to create a new medication regimen based on past medications and patients with similar adverse event profiles. The pharmacist worked with her to overcome her nausea and vomiting, and she began to see the medication as a positive daily step toward overcoming her condition rather than as a punishment for it. Following her regular discussions with the pharmacist, the member has increased her self-advocacy and identity and has resumed taking her antiretrovirals regularly. In this member's circumstance, the frequent contact and psychosocial interaction has aided her in coming to terms with her diagnosis and adhering to medications that will help effectively manage it.

5. Weekly Review and Local Partnerships to Address Member Non-Adherence

Every week, MTM pharmacists at this plan monitor member adherence for both antidepressant and antipsychotic medications. Because of this, adherence concerns are captured in real time and any rejections due to DURs or prior authorizations are caught and managed quickly. The plan's ability to catch these concerns in real time allows for a rapid turnaround on rejections. An MTM pharmacist is able to Skype the pharmacist responsible for prior authorizations in order to expedite the approval process. The plan's MTM pharmacists are able to work with local behavioral health clinics and form trusting connections with nurses and counselors at these clinics. Without these connections to local clinics, members who rely on personal connections to maintain their medication adherence are likely to become liable to systemic issues that serve as barriers to adherence.

6. New Methods to Ensure Continued Adherence

During the UM process for an inpatient behavioral health admission, this plan discovered that one member had numerous recurring readmissions for the same diagnosis and symptoms over the past month. Throughout the course of each inpatient admission, the member improved enough to be discharged back to the community with psychopharmacologic medications. However, over the course of a week, his symptoms would rapidly resurface, leading to his

readmission. This plan's UM team reviewed his medication history through their internal processes and determined that he had been adherent with a long acting injectable (LAI) for a different health condition. The member was then offered a LAI antipsychotic as an alternative to his daily medication. He accepted and was able to remain stable upon return to the community.

7. **Switching Medications**

A member is a long-term survivor of HIV who is managing multiple health conditions and has a prior history of substance abuse. She had a heart attack last year and is diagnosed with high cholesterol, high blood pressure, and severe allergies. Using real-time pharmacy data, her health plan's pharmacy team regularly reaches out to help her manage the multiple daily medications she takes to manage her health and stay well. They reached out to the member and her provider to switch her HIV therapy to one with lesser side effects on her liver and kidney. Recently during the COVID-19 pandemic, the member reached out to the team for help accessing fresh food while following the "stay at home" order. The plan was able to connect her to Get Food NYC. Since becoming a member, she enrolled in the plan's workforce training program and is now a member of her plan's member advisory board. In response to the help she's received, this member said "My medicine is essential. If I wasn't positive, I might not have turned my life around. I might not have had regular checkups and found out I was on the verge of a stroke earlier this year because of terribly high blood pressure. Ironically, HIV has helped me take back my life in order to give to others."

8. **Referral to Treatment Adherence Specialists**

A member is living with HIV and was recently diagnosed with hepatitis C. This member's case was especially complex because she had a heart condition, a high HIV viral load, and a breast cancer diagnosis during her HCV treatment. To complicate matters further, the patient has a history of drifting into and out of care and often missed her appointments. Her plan's pharmacy team referred her to a treatment adherence specialist to ensure that the plan actively reaches out to the member and coordinates with providers. The first step in her treatment was to reduce her viral load, which was delayed due to her breast cancer diagnosis. Though difficult, the plan was able to help her achieve load suppression and recently confirmed that the member has been cured of her hepatitis C. The plan continues to follow up with this hard to reach member.

9. **Providing Resources for Illiterate Members**

A member of a plan is illiterate and was not able to navigate through his prescriptions. The plan's pharmacy team developed a medication list for him using pictures and other graphics to help him understand what each medication is used for, how much to take, and how to adhere to the prescribed regimen.

10. Identifying Members in MAT for Telephonic Outreach

A plan identified that 50% of individuals in New York who receive a prescription for Medication Assisted Therapy do not receive subsequent refills. Using the plan's Substance Abuse Gap in Fill Report, members were identified for telephonic outreach and their concerns regarding filling their prescriptions were addressed by the plan's pharmacy team.

11. Utilizing Real-Time Pharmacy Data to Ensure Adherence to Makena/17P

To address numerous issues in the procurement of Makena/17P medications, a health plan's pharmacy department generates biweekly reports from Makena/17P prior authorization requests for the case management team to identify members who are beginning to take the medication. Case managers monitor medication adherence via the pharmacy and medical claims database to identify when members receive their first prescription of Makena/17P and when it is administered by reviewing CPT codes for the administration and HHC claims. This medication has a short window for when it needs to be administered to ensure an optimal outcome, therefore it is critical to have real-time pharmacy information.

12. Collaboration Between Care Managers and Pharmacists for Daily Outreach Calls

Via integration teams and initiatives, a plan's Clinical Staff Pharmacists are both physically and procedurally imbedded within interdisciplinary Care Management teams. Throughout completed daily outreaches with members, Care Management staff utilize pharmacists for "co-calls" in order to articulate clinical information that the Care Management staff may not be best suited to complete. This has led to numerous beneficial and productive conversations with members that have helped in numerous ways. Some of these ways include lessening/resolving concerns related to state complaints, providing education/information that has increased medication adherence, identifying needed collaboration regarding potential therapeutic duplications, and/or identifying potentially harmful and serious adverse effects. Even though these types of interventions can still occur in a carve-out model, the quality of these interventions are heavily dependent on plans' current access to historical and real-time claims data.

13. Providing Clinical and Administrative Support for Members with Hepatitis C

A health plan contacts members across all lines of business who are approved for hepatitis C (HCV) medications to offer counseling and support to troubleshoot any barriers to care. In doing so, the HCV team routinely identifies and addresses both clinical issues (navigating through adverse effects, drug interactions, and stressing adherence) as well as administrative issues (such as ensuring medications are obtained by members if pharmacy or delivery issues are found). This leads to increased regimen completions and sustained viral responses. For example, one member of this plan believed that HCV treatment length was eight weeks. The plan's pharmacist contacted the member and explained that her individualized treatment plan is actually twelve weeks. The pharmacist was able to take the time to listen to the member on how direct-to-consumer advertisement caused the confusion, understand why she needed to complete an additional month's worth of medication, and have the member successfully finish their treatment.

14. Clinical Quality

Currently, members with certain chronic conditions such as COPD, asthma, diabetes, and hypercholesterolemia receive outbound calls from a plan's clinical outreach specialists. These calls are made to educate members on their medication regimens, the reasons why those medications are prescribed, how those medications work, and the importance of taking their medications exactly as prescribed. In addition to outbound telephone calls, this plan outreaches members on certain medications, such as antidepressants or beta blockers, via letter, SMS text, and email. If real-time pharmacy data are no longer consistently available to through a carve-out, these calls will not be effective nor likely possible, leaving the most at-risk members with chronic conditions further vulnerable.

15. Multidisciplinary Case Management

A plan was struggling to contact a young adult member with HIV who had not been taking his antiretroviral agents. Several outreach attempts from case managers had failed, but the plan's pharmacist successfully outreached in the form of motivational interviewing and several weekly conversations. During this time, rapport increased, and they spoke of various reasons for this patient's nonadherence, including debunking conspiracy theories, discussing the pros and cons of herbal medicine and other natural therapies, and concerns about his trust with the medical system. The member recently began taking antiretrovirals, and conversations continue about adverse event management, adherence tricks, continued trust with his healthcare team, and disclosure of his HIV status to family and friends. His HIV viral load is currently undetectable, and he is adherent to appointments and his medications.

16. Providing Early Refill in Emergency Circumstances

A pharmacist fielded a call from a member whose house burned down the previous night destroying her HCV treatment. The pharmacist worked with the pharmacy to allow for an early refill of her HCV medication to avoid any gap in treatment. The pharmacist also provided the member with information on obtaining a replacement supply from the manufacturer, thereby ensuring completion of her HCV regimen and providing savings of roughly $8,000 for a replacement supply.

17. Supporting ARV Therapy for Viral Load Suppression

A member in his upper 40s has multiple medical conditions, including HIV, hepatitis C, cardiovascular disease, hypertension, asthma, and chronic pain. To manage them all, he takes at least 15 medications. Last year, the member's physician was working with him to optimize his HIV antiretroviral medication. The physician changed his prescription to a different drug in January and then changed it again in July. In both instances the member's pharmacy dispensed both the old and new medications because he had refills remaining on the old prescription. One of his plan's in-house pharmacists identified the possible duplication of therapy during its regular weekly review of all antiretroviral pharmacy claims using real-time pharmacy data. The in-house pharmacist contacted the prescriber to confirm the therapy change, called the member to make sure he was taking the correct medication and alerted the pharmacy to stop refills on the old medications. The member is taking his HIV medication and has achieved viral load suppression.

This plan's approach as an HIV SNP is to remove barriers to achieving viral load suppression. In this member's case, that meant not requiring prior authorization for the new prescriptions and, instead, using its access to real-time pharmacy data and outreach to the prescriber, the member, and the pharmacy to validate the appropriate medication therapy. This plan believes this "no barriers" approach is instrumental in enabling 85% of its HIV-positive members to achieve viral load suppression—protecting their health, preventing them from spreading HIV, and helping with the Governor's mission to End the AIDS Epidemic in New York State.

18. Medication Reconciliations with Nurse Care Managers

Using pharmacy claims information from the member platform, nurse case managers are able to conduct medication reconciliation with patients. Through the reconciliation process the case managers can address adherence concerns, alert the patient's provider to potential issues, and escalate issues surrounding prior authorizations or co-pays to the appropriate pharmacy team.

19. Working with a Pharmacist to Provide Additional Case Management Support

A member suffers from debilitating depression. When he began taking antidepressants, he and a plan pharmacist spoke about the symptoms and prognosis of depression, realistic expectations for antidepressants, and side effect management. The member and pharmacist formed a bond through their discussions, and the member began to realize the benefits of having a continued support system through this pharmacist. Several months later, during the "New York Pause" as a result of COVID-19, the member lost his job and was living with his family to save money, despite ongoing disagreements.

His depression and anxiety steadily increased. He called the pharmacist back several months later and conversations picked up between the two. Currently, weekly scheduled conversations between the member and the pharmacist occur. These conversations involve positive coping mechanisms, natural management of depression, relationship building with his family, and follow up with his counselor and his patient advocate. At the same time, the pharmacist helped discuss advantages and disadvantages of increasing his prescription strength, streamlining prior authorizations to ensure adherence, and support/encouragement of positive weekly examples of his own self-advocacy.

20. Providing Support through a Pharmacy Management Program

A plan has developed an extensive pharmacy management program to achieve positive adherence results. Chronic diseases with complicated resistance patterns, such as HIV, also have complex drug regimens with many drug-drug interactions which require extensive support mechanisms in addition to the drug itself in order to assure safe use and beneficial outcomes. The program offers:

- An open line for providers to contact the plan's team directly for customized pharmacy benefit-related issues.

- Pharmacy PrEP program, which provides education to at-risk HIV-negative populations.
- Educational sessions for staff to improve understanding of HIV therapies and optimize care for members, encourage provider participation in the plan's pharmacy and therapeutics committee meetings to review emerging therapies, and many more resources to simplify, support, and encourage medication adherence.

21. Treatment Adherence Program (TAP)

Members of a plan are assigned to TAP to assist in medication adherence. The treatment adherence team works with the pharmacy team to track lab results and prescription fills as indicators of adherence. The team outreaches to identified members telephonically or in person. A personalized adherence program is created for each member. TAP also goes above and beyond medication assistance to provide escorts to appointments and reminder calls.

22. Counseling from MTM Pharmacists

A New York MCO was recently awarded a state grant to help "End the (HIV/AIDS) Epidemic" by offering an interdisciplinary approach to the management of members with HIV/AIDS as well as the community education about various HIV prevention mechanisms, particularly for our Medisource population. The Medication Therapy Management (MTM) pharmacist is tasked with adherence counseling for members with HIV/AIDS, which often relates not only to a member's antiretroviral drugs, but to medications used to treat or prevent various concomitant conditions as well.

These conversations often go beyond adherence tips and tricks, the management or alleviation of adverse events, and the management of drug-drug interactions. Using various psychosocial and behavioral health counseling techniques, the pharmacist can delve deeper into the reasons for a patient's nonadherence to medications, touching on topics such as stigma and distrust in the health care system, guilt over diagnosis, concerns about disclosure of serostatus, the use of complementary and alternative medical approaches to treatment, methods to help keep partners HIV-negative, spiritual concerns, or real time referrals to case management for legal, housing, transportation, behavioral health, or care coordination needs. The MTM Pharmacist also has a history of working with several prescribers in clinics known for excellence in HIV care, and this close working relationship allows a smooth flow of clinical information between providers.

The MTM pharmacist has been a vital aspect of the team that developed and conducts outreach to providers and members who have risk factors for HIV seroconversion. Outreach to patients will include a discussion of risk factors and various ways to prevent the transmission of blood borne infections, including HIV, such as the use of Pre-Exposure Prophylaxis, Treatment as Prevention, and routine testing. Further outreach will be directed at transgender females and the partners of people with HIV.

If the pharmacy benefit was carved out, this plan's process would become a challenge because they would not have consistent access to reports and real-time claims. The pharmacist dedicated to this project might not be supported in the carve out model and the broader care management team's ability to support members at the current level would be diminished.

23. Behavioral Health Prescription Drug Treatment and Adherence Support

Joe" has paranoid schizophrenia and was nonadherent to his provider appointments, medications, and case manager appointments. After running and reviewing a non-adherent antipsychotic treatment report, the health plan flagged Joe as needing support/intervention. The health plan staff reached out to his provider and community pharmacy to better understand the situation and obtain updated contact information. The case management team successfully reached out to him and relinked him to his care team.

The health plan continued to face challenges with the member's adherence given his mistrust of the medications and lack of understanding around the necessity of the treatment for his condition. Recognizing there is a social component of successful adherence, the health plan pharmacist reached out to the member's mother and discussed options for counseling and motivational interviewing (including the advantages and disadvantages of the medications) to encourage the member to adhere to treatment. Through continued involvement, pharmacist aids were able to ensure adherence by regular check ins, real time connections, and honest and trusting working relationships with family, pharmacy, case managers and counselors.

C. HIV Special Needs Plans – Examples of Efforts Made to Support Access and Adherence to Optimal Medication Regimens (2 Examples)

Below, we share two member-specific examples of the advantages of supporting Medicaid members with an MCO pharmacy carve-in model. These examples reflect support of HIV SNP members using an in-house team of staff pharmacists.

1. Facilitating Compliance For Member with Distorted Thoughts

Gloria" is HIV+, has schizophrenia, and a long history of emergency hospital admissions. She was receiving monthly injections of an antipsychotic at her physician's office. When the physician's office reduced services due to the pandemic, the plan's Social Work and Behavioral Health teams arranged for a provider who specializes in medical/psychiatric home care to do the injections at Gloria's home, with Gloria picking up the medication at her pharmacy. The second

month, Gloria told the provider she had not been able to pick up the medication as she had been thrown out of the pharmacy because of her behavior. Because people with Gloria's conditions sometimes experience thought distortions, the plan's in-house pharmacists checked the real-time pharmacy data and confirmed that the prescription had been filled and picked up. The plan's clinical team immediately arranged for the specialized provider to administer the medication.

2. Attaining Approval to Access a High-Cost Specialty Medication

"Michael" is an HIV positive male who was not responsive to conventional HIV therapy and had a history of substance use. He required a salvage regimen to stabilize his health. The regimen was in addition to his ARV therapy and cost in excess of $120,000. The plan's pharmacy team accessed his real-time utilization data and treatment history for a quick determination. The team worked directly with the provider to approve the medication and identify a specialty pharmacy for home delivery. They also arranged nursing visits to administer infusions required for the salvage therapy. The pharmacist assigned to the case conducted monthly utilization reviews to ensure proper use of the therapy. The plan's team also followed up with the doctor to ensure that monthly lab work was completed. ***For the first time in more than 10 years this member reached viral suppression***.