The Menges Group

Strategic Health Policy & Care Coordination Consulting

Assessment of the Pharmacy Carve-In Model for Virginia's Medicaid Program

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I. Introduction and Executive Summary: Key Findings and Recommendations

A. Introduction

Virginia's Medicaid Managed Care Organizations (MCOs) coordinate and pay for the pharmacy benefit for the vast majority of the Commonwealth's Medicaid enrollees. Five MCOs – Aetna Better Health, Anthem HealthKeepers Plus, Molina Healthcare of Virginia, Sentara Health, and UnitedHealthcare Community Plan of Virginia – collectively paid for 99.2% of Virginia's Medicaid prescriptions during CY2023, well above the national percentage of 59.8%. This approach is commonly known as a "pharmacy carve-in."

Over the last few years, some Virginia stakeholders have indicated an interest in moving to a pharmacy "carve-out," whereby the Commonwealth would instead manage the pharmacy benefit for MCO enrollees, including directly paying for drugs made available to Medicaid members. According to proposed Senate Bill 875[1] and House Bill 2610[2], a full carve-out model would create a single government-payer system for retail pharmacies. This system would be administered by the Commonwealth using a fee-for-service (FFS) payment methodology.

The Menges Group has been engaged by Virginia's Association of Health Plans to assess the fiscal impacts of Virginia switching to a carve-out model, as well as the programmatic advantages and disadvantages of this potential change.

Our report conveys an array of quantitative and qualitative analyses:

1. Emerging trends in Medicaid prescription drug rebates, particularly regarding the degree to which brand name drugs have become "better than free" to the Medicaid program.
2. Estimated cost impacts of a switch to a carve-out approach.
3. Capitation rate-setting dynamics related to the drug benefit.
4. Transition/implementation risks of moving to a new program design, focusing on other states' early-year experience with their pharmacy carve-out programs.
5. Quality comparisons between the pharmacy carve-in and carve-out settings.
6. Data integration advantages of the carve-in model, primarily drawing upon insights and input from Virginia's Medicaid MCOs.
7. Virginia MCO efforts to facilitate and track medication access and adherence.

[1] SB875
[2] HB2610

8. Case examples of Virginia MCOs "going the extra mile" to meet their enrollees' medication needs in the current carve-in environment.

9. Recommended policy actions based on the above information.

B. Key Findings

- Virginia's Department of Medical Assistance Services (DMAS) and the Commonwealth's Medicaid MCOs are already conducting the cost-containing activities that may seem attractive about a pharmacy carve-out. Since 2018, DMAS and the MCOs have effectively worked in partnership to follow the Common Core Formulary.

- This is a win-win situation. DMAS leverages its unique ability to steer drug volume to the lowest (to DMAS) net cost drugs while limiting its financial risk through the carve-in model, navigating the unusual Medicaid drug rebate dynamics that currently exist. Also, under this approach the health plans are optimally integrating real-time drug data with their medical management activities and tracking members' access to prescriptions.

- Our financial impact analyses indicate that the Commonwealth would incur greater costs if it adopts a carve-out. **If a carve-out were implemented, Virginia's annual state fund cost is estimated to increase by $44 million.**

- Additionally, the carve-out model raises significant concerns due to its adverse programmatic impacts, as detailed in Sections V – VIII. Examples include:

    - The carve-in model improves quality. A detailed, multi-year set of national and regional comparisons resoundingly shows that the carve-in approach delivers superior scores on pharmacy-related HEDIS quality measures. The Virginia MCOs' collective scores on these quality measures have been favorable, well above the average scores across MCOs in Virginia's neighboring states.

    - Virginia's Medicaid MCOs collectively operate in several states that use the pharmacy carve-out model, along with dozens of states that use the carve-in approach. The carve-in models have been shown to enhance care coordination practices for individual members.

    - Virginia's Medicaid MCOs have implemented a compelling array of efforts to facilitate medication access and adherence. These include systematic and program-wide activities – as well as innovative and compassionate efforts to address individual enrollee needs and situations.

- More than a dozen additional case examples have been shared further demonstrating the health plans' acumen and willingness to support their enrollees, including prompt problem-solving with prescribers, pharmacies, caregivers, and other stakeholders.

- Several states that have recently transitioned to a carve-out model have encountered numerous implementation issues. We conducted a detailed assessment of California's transition, which involved enormous medication access barriers and cost increases.

C. Recommendations

Based on the analyses detailed in this report, we offer the following recommendations:

1) Preserve the current carve-in pharmacy model for the Medicaid program.

Financially, we estimate that a switch to a carve-out approach would have an adverse annual state fund impact of roughly $44 million. A carve-in model also keeps the considerable financial risks associated with Medicaid pharmacy costs with the MCOs, giving the Commonwealth valuable budget predictability relative to the carve-out model.

Programmatically, a pharmacy carve-out diminishes the Medicaid program's ability to deliver whole-person integrated care. It disrupts MCO care coordination systems and is associated with lower quality scores and reduced medication access and adherence compared to the carve-in model. A carve-out model also introduces implementation transition risks, creating upheaval in a mature, successfully operating program.

2) Preserve the Common Core Formulary

A key factor driving the previous recommendation is that DMAS has an established mechanism – the Common Core Formulary – to identify which drugs yield the lowest net cost to the overall Medicaid program (and thus to Virginia taxpayers) and require MCO steerage to those drugs. DMAS is currently in a win-win scenario, as they can steer drug volume to the lowest (to DMAS) net cost drugs while limiting financial risk related to high-cost drugs. This mechanism, typically referred to as a "uniform preferred drug list" is critically important under current rebate dynamics where many brand drugs have become "better than free" to Medicaid.

We also recommend transparency from DMAS around the disclosure of which therapeutic classes do not contain a "better than free" drug to the Commonwealth. Thus, in these identified classes, MCOs could be given greater latitude to discern and utilize the lowest net-cost drug.

3) Enhance Reimbursements to Critical Access Pharmacies

There are many situations – particularly in Virginia's more rural areas – where a specific pharmacy creates far superior geographic access to Medicaid enrollees than would be available if

that pharmacy were to cease operations. To support these pharmacies' existence, we suggest that the Virginia MCOs be required by DMAS to pay critical access pharmacies at relatively robust payment rates. DMAS would identify which pharmacies should be designated as critical access stores (looking objectively at geographic access dynamics but not at subjective factors such as ownership) and would establish the amounts MCOs would pay these pharmacies for Medicaid enrollees.

4) Increase MCO Policymaking Representation

Currently, the Virginia MCOs have one representative on the Drug Utilization Review Board Committee and one representative on the Pharmacy and Therapeutics Committee. Because the MCOs account for 99% of the total Medicaid spend, we recommend additional MCO representation on both committees. This will ensure policymaking decisions have the benefit of considerable input from the organizations that play such a central role in the daily management of Virginia's pharmacy benefit and often bring extensive national experience.

5) Consider Capitation Rate-Setting Revisions for the Pharmacy Component

Virginia's MCOs have experienced a balanced, fair ongoing partnership with DMAS and with its actuarial contractor (Mercer), which has been a critical component of the coordinated care program's stability and success. Despite this, MCOs have considered the pharmacy component of the capitation rate to be underfunded for several years. MCOs are concerned that the cost dynamics of this benefit may require methodological revisions to prevent ongoing issues, as the prices of newly introduced drugs continue to rise. One option would be to commit to revisiting rates at mid-year and to consider retroactive rate adjustments when there are new drugs or gene therapies that enter the market, or new indications for drugs.

II. Current Rebate Dynamics

A. Summary of Ramifications for Virginia

DMAS implemented a Common Core Formulary in 2018, allowing Virginia's Medicaid program to optimize the usage of drugs with the lowest net (post-rebate) cost. Their managed care contracts hold MCOs responsible for timely and complete encounter submissions, which further guarantee that rebates are not being forfeited. Below, we describe recent nationwide changes in market rebates that seem likely to require DMAS and the MCOs to manage the drug mix strategy together – with DMAS identifying which drug(s) yield the lowest net cost in a given drug class, and the MCOs leveraging their ability to nimbly steer volume to the drugs (and implement clinically appropriate exceptions).

Given the current rebate dynamics, DMAS is well prepared to steer prescription volume to their lowest-cost drugs, whereas other states without a state-driven MCO formulary or preferred drug list (PDL) in place may have to first make this policy change to reap the benefits. Shifting the pharmacy benefit to a carve-out model would not create savings on the rebate front, as the Commonwealth is already conveying to the MCOs exactly what drugs to purchase. DMAS is currently in a win-win scenario, as they can steer MCO drug volume to the lowest (to DMAS) net cost drugs while limiting financial risk related to high-cost drugs.

B. In-Depth Description of the Challenges and Opportunities

We have analyzed the cost-effectiveness performance of carve-in and carve-out policy options in numerous states and on a national level. Links to several of these assessments are provided in the footnote below.[3] These analyses have tabulated comparative data on all Medicaid prescriptions in each setting and included all initial ingredient costs, dispensing fees, and rebates. We have conducted "pre versus post" comparisons when a state switches (in either direction) between a carve-in and carve-out approach. We have also compared cost levels between groups of states using the carve-in approach relative to the group of carve-out states.

All these analyses indicate that the carve-in approach (including the pharmacy benefit in MCOs' capitation payments) has consistently delivered lower net prescription drug costs than by relying on the FFS setting through the carve-out approach. A driver in the carve-in model's overall cost-effectiveness has been the MCOs' drug mix management, steering volume to generics and to lower-cost brands at the "front-end." This approach has proven more effective than focusing more on "back-end" rebate maximization as occurs under FFS.

[3] Links to several analyses assessing the carve-in and carve-out models are provided below:
1) Medicaid Prescription Drug Benefit Management: Performance Comparison Across Different State Policy Approaches
2) Assessment of New Jersey's Medicaid Prescription Drug Management Performance and Policy Options
3) Assessment of Virginia Medicaid Pharmacy Benefits Carve-Out Impacts
4) Assessment of Medi-Cal Pharmacy Benefits Policy Options

These analyses have also demonstrated that MCO latitude over drug mix has outperformed implementing a uniform PDL across all Medicaid MCOs.

This section of our report demonstrates why the previous assessments and findings may not serve as a good predictor of the effectiveness of adopting any certain approach from 2024 forward. Brand drug prices and brand rebates are evolving in a manner that appears likely to disrupt the cost-effectiveness of the "traditional" MCO strength in managing pharmacy costs – steering prescription volume towards the drugs that yield their own lowest net cost.

It has become increasingly common for the lowest-cost drug from an MCO's vantage point to be different than the drug that yields the lowest net cost to the Medicaid program (and taxpayers). This section describes the dynamics creating "perverse incentives" under the carve-in arrangement.

Due to the statutory rebate formula, many brand drugs have literally been "free" to Medicaid for the past few years, as illustrated in Exhibit 1 for a hypothetical brand drug.

Exhibit 1. Sample Brand Drug Rebate Dynamics

Row	Description	Amount	Derivation
1	Price of drug in CY2010 when introduced	$200	Hypothetical example
2	Current price in CY2024	$1,000	Hypothetical example
3	CY2024 price if increases matched Consumer Price Index (since CY2010)	$400	Hypothetical example
4	Rebate owed by manufacturer due to price increases	$600	Row 2 – Row 3
5	Best price currently offered	$400	Hypothetical example
6	Rebate owed by manufacturer due to best price	$600	Row 2 – Row 5
7	Total rebate owed by manufacturer	$1,200	Row 4 + Row 6

In the Exhibit 1 situation, the rebate owed of $1,200 would actually exceed the drug's current price of $1,000. Until January 2024, the Medicaid rebate for this drug was capped at 100% of the drug's initial price, meaning this drug was essentially "free" to the Medicaid program when used.

Through the American Rescue Plan Act (ARPA) of 2021, from January 2024 forward, the 100% rebate cap is no longer in effect. In the above example, this drug would create a net revenue of $200 per prescription for the Medicaid program. This will increase further whenever the manufacturer increases the price beyond the Consumer Price Index (CPI) inflation factor.

The Exhibit 1 scenario is not an anomaly. According to work produced by Christopher Park and his colleagues at the Medicaid and CHIP Payment and Access Commission (MACPAC), 18.2% of Medicaid pre-rebate drug spending during FFY2020 was on brand drugs that had already reached a "free to Medicaid" situation. The full document provides an excellent explanation of

Medicaid drug pricing and rebate regulatory parameters.[4] If the cap had been lifted on these drugs, the average additional "better than free" rebate owed on these drugs would have been 30.7%. Therefore, these drugs were typically *much* better than free as of 2020, with four additional years of price increases potentially driving this percentage upward.

Since 2020, the ongoing pricing behavior of brand manufacturers has led to a growing number of brand drugs entering the "beyond free zone," with the drugs' rebates exceeding their initial costs.

A key programmatic and policymaking challenge is that the statutory (federally mandated) rebates are paid to the government and do not in any way flow to or through MCOs. As a result, MCOs typically drive volume toward drugs that minimize their own net cost.

This issue is illustrated in Exhibit 2, continuing the example of the hypothetical drug depicted in Exhibit 1. In this example, the Medicaid rebate formula takes the brand drug 20% "beyond free" for the State, with the Medicaid program realizing a $200 surplus every time a prescription for this drug is filled. This surplus grows to $226 relative to prescribing the generic alternative drug shown.

Note that for drugmakers whose products are primarily used by the Medicare and commercial populations, where large profit margins often occur, "taking a loss" in Medicaid at this level is acceptable, and further price increases often continue to net out in the manufacturer's favor.[5]

Exhibit 2. Hypothetical Example of Current Unaligned Financial Incentives

Drug	Pre-Rebate Cost per Prescription	Statutory Rebate %	Net Cost to MCO	Net Cost to Medicaid Program
Brand Drug	$1,000	120%	$1,000	-$200
Generic Alternative	$30	13%	$30	$26
Impact of Using Brand Drug Instead of Generic			MCO experiences an **increased cost of $970**	Medicaid Program realizes a **net savings of $226**

From an MCO's current perspective, the financial incentives of this drug mix choice are completely opposite those facing the State. The MCO faces a cost of $1,000 for the brand drug

[4] Trends in Medicaid Drug Spending and Rebates

[5] While an ongoing incentive to increase prices appears to persist, the magnitude of the additional rebates some manufacturers will owe Medicaid in 2024 (when the rebate cap of 100% is lifted) does appear to be motivating some manufacturers to reduce prices on drugs that have otherwise become "better than free" to Medicaid. This Reuters article describes recent manufacturer price increases and decreases.

and just $30 for the generic alternative – and thus has a strong incentive to utilize the generic (saving $970 each time it does so).[6]

The proliferation of "better than free" brand drugs for Medicaid upends the value of the MCOs' traditional drug mix management efforts in an ever-increasing number of therapeutic drug classes. These dynamics also eliminate the opportunity and value of negotiating supplemental rebates on brand drugs in a considerable and growing number of drug classes.

For example, brand drug manufacturers whose cost to produce a pill is $1.00 have some incentive to offer enhanced rebates all the way to the point where their net revenue will be above $1.00 per pill – if these rebates are perceived to be needed to get their product used in Medicaid in lieu of alternative drugs. However, manufacturers have no reason to agree to any supplemental rebate amount once the statutory rebates have put them in the position of literally paying Medicaid each time their drug is used. Manufacturers in this situation will have an incentive to minimize the degree to which their product is used by Medicaid patients.

A large set of brand drugs are now in this "better than free" situation, and many additional drugs are trending in the same situation. While each drug's pricing dynamics will be its own "sample of one," we expect that price increases that are greater than the CPI will continue to commonly occur. Being in a loss position with Medicaid will not likely prevent manufacturers from continuing to aggressively raise drug prices. The marginal (price increase-related) revenue they receive from Medicaid will be "rebated" back, but the marginal revenue they receive from other payers will be retained. These rebate dynamics represent the current realities of Medicaid prescription drug finances and can profoundly affect which Medicaid drug policies make sense for states to implement.

[6] This example does not take into account any supplemental rebates that manufacturers are negotiating with the State and/or with MCOs, in addition to the statutory rebates. These supplemental rebates often represent several percentage points of additional rebates, but will not likely significantly "change the story" being depicted. Manufacturers will not offer supplemental Medicaid rebates for drugs where the statutory rebates already put them in a loss position.

III. Cost Impact Modeling

Our cost impact modeling of the carve-out assessed the following components:

- Drug mix
- Drug rebates
- Initial (pre-rebate) payments to pharmacies
- Risk margin payments
- Administrative cost impacts
- 340B program impacts

Each of these components is addressed below.

A. Drug Mix

On a national scale, numerous studies have demonstrated that effective management of drug mix has been a key driver in the carve-in model's traditional cost-effectiveness. However, as shown in Section II, the brand rebate dynamics have evolved such that DMAS is best-positioned to drive volume to the *Medicaid program's* lowest-net cost drugs in many therapeutic classes. Virginia's Common Core Formulary, implemented by DMAS in 2018, ensures that the MCOs steer volume to the drugs that are most cost-effective to Virginia's taxpayers.

Because of the mature existence of the Common Core Formulary, we expect that the drug mix would not be meaningfully different under a carve-in or carve-out model going forward.

B. Drug Rebates

Until recently, the MCOs' acumen to steer volume to generics was more cost-effective than the Medicaid FFS setting's focus on optimizing rebates on brand drugs. However, the evolution of brand rebates has "changed the game" in terms of which approach is likely to be most cost-effective. Through the Common Core Formulary, DMAS is positioned to require the Virginia MCOs to steer volume to Medicaid's lowest net cost drug. Therefore, for reasons similar to the above paragraph, we do not envision a cost impact (in either direction) if a carve-out model were implemented.

C. Initial (Pre-Rebate) Payments to Pharmacies

Each MCO pays pharmacies based on negotiated contracts as occurs throughout all aspects of the health care system other than Medicaid FFS payments. In the Medicaid FFS setting, which would apply under a carve-out model, the Actual Acquisition Cost (AAC) payment model is required. The AAC model creates favorable pricing on ingredient costs but involves a far higher dispensing fee (more than $10 versus MCO payments which are typically below $2).

One of Virginia's MCOs – in partnership with its pharmacy benefit manager (PBM) – conducted a pricing comparison on its Medicaid pharmacy claims. Across a twelve-month timeframe (September 2023 through August 2024) the PBM compared this MCO's brand and

generic costs (Ingredient Cost + Dispensing Fee) to costs using the DMAS fee-for-service pricing. This proposed pricing was based on Virginia administrative code (12VAC30-80-40) and included the lowest price between NADAC or Wholesale Acquisition Cost plus a $10.65 Dispensing Fee. Note that mail order, compound, and COVID-19 vaccine/treatment-related claims were excluded from this analysis.

These analyses indicated that annual pharmacy payments for the health plan's Virginia Medicaid enrollees would be $10.6 million higher under DMAS pricing. Working from the DMAS website, we identified that as of December 15, 2024, the health plan's Medallion 4 enrollment, 101,592, was 6.97% of statewide enrollment (1,456,777).[7] Using these figures, the additional health plan costs extrapolate to an annual statewide cost increase of $152.0 million. This overall Medicaid cost increase would be expected to be distributed 75% to the federal government ($114 million) and 25% ($38 million) to Virginia state funds.

Beyond the adverse impacts the health plan's side-by-side pricing comparison yielded, we also caution against relying on payments that are derived in the political setting rather than the business setting, which is what would occur under a pharmacy benefit carve-out. No private insurer voluntarily uses the AAC methodology, which suggests it is not a cost-effective alternative to the private sector contracts that are in place throughout Virginia and the nation. The politically derived payments run the risk of either paying the pharmacies above typical market rates (based on stakeholder lobbying effectiveness) or paying pharmacies inadequately (based on state budget circumstances). The MCO payments to pharmacies are closely in line with the pharmacy payment methodologies used in the commercial insurance and Medicare Part D arenas – and these widely used payment approaches are fundamentally acceptable to and viable for the pharmacies.

D. Risk Margin Payments

MCOs must be compensated for bearing the full risk of health care costs. A pharmacy carve-out would reduce the financial risk that health plans face, thereby reducing the amount of risk margin compensation that would need to be included in the MCO capitation rates. Exhibit 3 presents our estimate of the "savings" DMAS would realize under a carve-out by virtue of these reduced risk margin payments.

Exhibit 3. Risk Margin Impacts of a Pharmacy Carve-Out

Line Item	Total	Federal Share	State Share
Medicaid MCO (capitation payments), FFY2023	$13,947,249,357	$9,673,898,062	$4,273,351,295
Estimated Risk Margin (2%)	$278,944,987	$193,477,961	$85,467,026
Estimated Pharmacy % Share of Risk Margin	16.4%	17.8%	13.3%
Estimated Pharmacy Share of Risk Margin ($$)	$45,857,202	$34,511,660	$11,345,542

[7] Virginia Medicaid Enrollment

DMAS paid nearly $14 billion to the Medicaid MCOs during Federal Fiscal Year 2023, of which 4.3 billion involved state funds. A 2% risk margin across these state funds represents an overall capitation allocation of roughly $85 million. We estimate that 13.3% of the state's share of capitation payments are pharmacy-related. These figures yield an estimated annual impact from the carve-out of $11.3 million.

Note that these risk margin payments have significant value to DMAS in creating budget security. This is particularly the case with regard to the pharmacy component, where the introduction of high-cost drugs, the tendency of manufacturers to increase prices aggressively for existing products, and other factors create particularly high expenditure risks.

E. Administrative Cost Impacts

Under a carve-out, many administrative functions will transition to the FFS setting – to DMAS and/or to one or more contractors used by DMAS. However, the administrative functions that currently occur will not diminish, and there is no reason to expect administrative savings to occur.

Extensive pharmacy-related work would continue to be performed by the MCOs to deliver their whole-person care coordination model. While these efforts would be complicated and likely inhibited by a carve-out model (e.g., losing access to pharmacy data in real-time and in the well-established formats/structures that each MCO has in place), the costs of these efforts would not decrease.

The administrative work that transitions from the MCOs to DMAS should not occur at a meaningfully different cost. The MCOs are at full risk for their administrative costs and have no incentive to "overpay" for these activities. Examples of these functions include:

- *Pharmacy claims processing:* The volume of Medicaid prescriptions – and the corresponding claims processing costs – are not expected to materially change under the carve-out model (although this administrative work would shift from the MCOs to the state).

- *Prior authorizations:* The volume of prior authorization requests – and the corresponding costs of handling these requests – are not expected to materially change under the carve-out model. Generally, this is because MCOs staff their pharmacy call centers by either delegating to a PBM or using a model that leverages resources across several plans. Additionally, some plans may use pharmacists to assess clinical appropriateness or necessity for medications under the medical benefit, thereby still needing full-time employees under a pharmacy carve-out.

- *Member and provider calls regarding the prescription drug benefit:* The volume of pharmacy-related issues that members will experience is not expected to change significantly under the carve-out model. However, many of these calls will continue to be directed to the MCOs as beneficiaries will often not know whom to contact. Members

may also experience frustration in no longer having a "one-stop shop" for questions related to their Medicaid benefits.

What would change administratively under the carve-out is the federal match rate for the new administrative duties that DMAS takes on. While the federal share of Virginia's capitated services (including the pharmacy component and all MCO administrative activities) averaged 75.3% in FFY2023, the federal match rate for administration is 50%. Exhibit 4 estimates the loss in federal matching funds that would occur under the carve-out – and the corresponding increased state funding needed to conduct the same work – to be $17.4 million annually.

Exhibit 4. Federal Match Impacts of a Pharmacy Carve-Out -- Administration

Line Item	Total	Federal Share	State Share	State %
Estimated Pharmacy Admin that would Transition to FFS Setting Under Carve-Out (3% of pre-rebate spend)	$68,785,804	$51,767,490	$17,018,314	24.7%
Estimated Pharmacy Admin under Carve-Out	$68,785,804	$34,392,902	$34,392,902	50.0%
Loss of Federal Matching Funds			$17,374,588	

F. 340B Program Impacts

A pharmacy carve-out could have a significant adverse fiscal and programmatic impact on Virginia's Federally Qualified Health Centers (FQHCs) due to the 340B Drug Pricing Program's rules and requirements.

FQHCs are non-profit entities chartered by the federal government to provide primary medical, dental, and behavioral health services to Medically Underserved Areas or Medically Underserved Populations. FQHCs provide services regardless of a patient's ability to pay and, therefore, attract and serve a disproportionately large share of uninsured and underinsured subgroups – along with those covered by Medicaid.

The federal 340B program, created in 1992, requires drug companies that participate in the Medicaid program to provide substantially discounted drugs to certain healthcare entities (such as FQHCs) that serve vulnerable populations. These discounts are often dozens of percentage points below standard prices paid in the pharmacy setting. Safety-net providers delivering pharmacy services can generate savings through reimbursement from Medicaid managed care programs, which are reinvested into health and wraparound social services to better fulfill their broader mission.

A recent report focused on a potential pharmacy carve-out in Washington State demonstrated the central importance of 340B to their FQHCs' ability to support their communities.[8] This report consolidated 22 FQHCs' collective financial outcomes from January through September 2023.

[8] Assessment of Washington State's Medicaid Prescription Drug Management Performance and Policy Options

While the FQHCs' pharmacy line of business represented "only" 21% of overall revenue, it accounted for more than these organizations' entire collective operating margins. Washington State's FQHCs collectively lost money on all their non-340B operations, which represented 90% of their expenditures. These services include primary medical care, dental care, and behavioral health care, along with care coordination and an array of services that address adverse social drivers of health.

Under a carve-out, DMAS could potentially "take for itself" the savings that Virginia's FQHCs currently derive through their participation in the 340B program. These savings would, however, directly come at the cost of impairing the ability of the FQHCs to fulfill their mission. A carve-out could cause substantial cuts to FQHC's pharmacy programs, staffing, clinical programs, and capital facilities projects.[9]

For these reasons, we do not encourage 340B program savings to be pursued under a carve-out and have not estimated any 340B-related fiscal savings.

G. Summary

Exhibit 5 summarizes the above components of our cost impact analysis. **The net cost impact of a pharmacy carve-out is an annual state fund cost increase of $44 million**.

Exhibit 5. Overall Annual Impacts of a Pharmacy Carve-Out – State Funds

Cost Impact Area	Net Cost of Carve-Out (negative figure denotes state fund savings)	Comments
Drug Mix	$0	With the Common Core Formulary in place for several years, drug mix is currently controlled by DMAS as would be the case under a carve-out. No change in drug mix is anticipated.
Drug Rebates	$0	For same reason as above (no drug mix change), no change in rebates is anticipated to occur under a carve-out.
Pre-Rebate Payment to Pharmacies	$38,000,000	Dispensing fees would be much higher and brand drug ingredient costs lower under the Actual Acquisition Cost (AAC) that would be used under a carve-out. Molina and CVS/Caremark modeled the cost impacts of a switch to Virginia's AAC payments. The results identified the carve-out would increase annual pharmacy payments by $10.6 million for Molina's enrollees. This figure extrapolates to a $152.0 million additional annual cost across all MCO Medallion 4 enrollees. The state share is anticipated to be 25% of the overall Medicaid cost increase.
Reduced Risk Margin in MCO Capitation Payments (removing Rx component)	-$11,345,542	This impact is derived in Exhibit 3.
Administrative Cost Impact	$17,374,588	This impact is derived in Exhibit 4.
340B Impact	$0	While 340B savings could occur under a carve-out, such savings would predominantly come at the expense of safety net providers, compromising their ability to fulfill their mission. Pursuing savings in this area is therefore not recommended and not modeled.
Net Annual Impact	$44,029,046	Sum of above figures

[9] In light of these concerns, even states that have moved to a carve-out model have sought to avoid impairing their safety net providers. New York, for example, has entered into a State Plan Amendment with CMS to return to each FQHC any lost revenues that might otherwise occur related to 340B program changes related to their carve-out.

We are aware of previous cost impact reports on carve-outs in other states, such as Kentucky[10] and West Virginia[11], that contradict our estimated cost impacts. Based on a review of these reports and our own cost modeling, we do not find the cost savings in these states – even if accurately calculated – to be applicable to Virginia's circumstances.

- **Kentucky:** Senate Bill 50[12], which created Kentucky's Medicaid pharmacy carve-out, also created a preferred drug list for the program. Because of the rebate dynamics discussed earlier in this section, we believe that much of the savings cited after the passage of this legislation can be attributed to the use of the preferred drug list steering the drug mix and maximizing the State's rebates. Because Virginia MCOs already follow a state-determined preferred drug list, the savings reported in Kentucky would not occur in Virginia.

- **West Virginia:** The Pharmacy Savings Report on West Virginia's Medicaid carve-out for prescription drugs was flawed in several ways, leading to inaccurate cost savings estimates. It overestimated savings by using incorrect re-pricing methods and failed to account for actual changes in Medicaid pharmacy costs, which increased by $18 million annually, rather than saving $15 million as the report suggested. Additionally, it overestimated administrative cost savings by miscalculating MCO expenses and incorrectly allocating a disproportionate share of their administrative costs to the pharmacy benefit.[13] Also, West Virginia's move to a carve-out switched drug mix management to the state-administered PDL, a change that has already occurred in Virginia through the Common Core Formulary.

[10] Kentucky Single PBM Report, 2023
[11] West Virginia Pharmacy Savings Report, Navigant 2019
[12] Kentucky Senate Bill 50, 2020
[13] Assessment of Report of Impacts of West Virginia Medicaid Prescription Drug Carve-Out, 2019

IV. Capitation Rate-Setting Issues

Virginia's MCOs have – over the course of many years – experienced a balanced and fair partnership with DMAS and with its actuarial contractor (Mercer). The program's strong rate-setting quality has been a critical component of the coordinated care program's stability and success.

Notwithstanding the favorable overall history, the MCOs have viewed the pharmacy component of the capitation rate to be under-funded for multiple years. They are concerned that the cost dynamics of this benefits component may warrant some methodological revisions to prevent a reoccurring miscalculation that becomes unsustainable.

Several of these issues are described below.

- The recent "unwinding" of Medicaid eligibility has disproportionately terminated Medicaid coverage for persons who were non-users (or relatively low users) of the prescription drug benefit. The pharmacy component of the capitation rate (along with all other components) needs to accurately factor in the degree to which the persons retaining coverage collectively have considerably higher per capita pharmacy costs than those who have recently lost Medicaid coverage.

- The prices of newly introduced drugs are becoming increasingly high and aggressive, and many drugs are in the "pipeline" for new market entry. For example, as shown in Exhibit 6, at the beginning of 2014, spending on drugs over $1,000 per prescription made up almost 32% of total Medicaid pharmacy spending. This rose to 48% at the beginning of 2019, and almost 63% at the beginning of 2024. From 2014 to 2024, there was a nearly 400%, or five-fold, increase in pre-rebate spend on drugs priced over $1,000 per prescription. Additionally, the average cost per prescription for drugs over $1,000 (i.e., primarily drugs still on a patent) increased from $2,455 in 2014 to $3,403 in 2024. Meanwhile, the cost per prescription for drugs under $1,000 (likely experiencing more market competition) in 2014 was $61, compared to $53 in 2024.

Exhibit 6. Increase in Total Medicaid Spend Over Time on Expensive Drugs

Nationwide Medicaid Pharmacy Data	Pre-Rebate Spend by Price Category			Percent of Total Spend by Price Category		
	Q1 2014	Q1 2019	Q1 2024	Q1 2014	Q1 2019	Q1 2024
Total spent on drugs >=$1,000 per script	$ 3,191,300,913	$ 8,186,214,667	$ 15,828,679,553	31.6%	48.2%	62.9%
Total spent on drugs <$1,000 per script	$ 6,892,972,077	$ 8,793,022,057	$ 9,340,788,333	68.4%	51.8%	37.1%
Grand Total Spent	$ 10,084,272,990	$ 16,979,236,724	$ 25,169,467,886	100.0%	100.0%	100.0%

- Brand manufacturers' reactions to some of their drugs now being in the "better than free" category when used in Medicaid are, for the most part, yet to play out. This situation

became possible only recently (in January of 2024), and the dynamics associated with this are very difficult to predict.

- One drug class, GLP-1 agonists (sometimes referred to as "weight loss drugs"), alone creates tremendous financial uncertainty at the present time. The high costs of these medications, coupled with the prevalence of obesity (and overweight persons), create the potential for enormous new costs to emerge.

- The drug benefit has a relatively large stream of changes occurring, which creates particular financial uncertainties. These changes include the movement of brand drugs off-patent, the introduction of new drugs, and price changes for existing drugs.

While the pharmacy arena poses particular capitation rate-setting challenges, carving in the drug benefit is valuable to DMAS (and to the Commonwealth of Virginia more broadly) in creating budget predictability. The partnership between DMAS, Mercer, and the MCOs creates the best opportunity to identify and manage these risks and costs. Conversely, a pharmacy carve-out shifts the risks for all the above dynamics upon DMAS. In so doing, the Commonwealth would lose the ability to accurately predict its own Medicaid pharmacy costs.

V. Implementation Risks of Moving to a New Model

Virginia's integrated carve-in program, featuring a Common Core Formulary overseen by DMAS, is a mature, well-established approach. Policymakers considering a switch to a carve-out need to assess not just the financial and programmatic pros and cons of each model (as this report is doing) but also the implementation risks of significantly altering a long-operating model of care coordination. The remainder of this section describes various implementation challenges that have arisen in several states that have recently carved out the pharmacy benefit.

California

California's recent experience with a Medi-Cal (Medicaid) pharmacy carve-out illustrates these implementation risks, as significant access challenges and cost increases occurred. California's Medicaid (Medi-Cal) program switched from a carve-in model to a carve-out approach effective in January of 2022.

Access: The combination of the claims volume that transitioned to the FFS setting, and the algorithms used by Magellan Health, the pharmacy benefit manager (PBM) entity enlisted by the Medicaid agency, had the effect of preventing medication access on a highly concerning scale. California's carve-out implementation issues included long call center wait times, delayed prior authorizations, confusion with physician-administered drugs, compounding pharmacies no longer providing services, and multiple member medication access issues. Across the first two calendar quarters of 2022, the Medi-Cal population had accessed ***8.3 million fewer prescriptions*** than would have occurred if the Q4 2021 volume had been maintained throughout the first half of 2022.

Costs: In response to the clinical endangerment and large-scale frustration that was occurring at the outset of the carve-out, California's Medicaid agency removed all barriers to prescription access. A moratorium was placed on deploying prior authorizations, requirements were lifted related to PDL compliance, and the practice of initially denying "too soon" refills was curtailed.

These actions were successful in restoring – by the third calendar quarter – Medi-Cal's prescription volume to the levels occurring under the carve-in model. However, these actions also temporarily stripped Medi-Cal of the levers needed to deliver cost-effective pharmacy benefits management. Taking all Medi-Cal drug rebates into account (as reported in the Financial Management Reports published by CMS), net costs per prescription were $47.25 in FFY2021 and jumped to $73.73 in FFY2022 – **a 56% increase. Medi-Cal's net pharmacy costs during FFY2022 were $2.07 billion above the prior year**.

The significant clinical, fiscal, and administrative challenges that California experienced at the outset of the carve-out implementation are perhaps important for Virginia policymakers to consider. Beyond the inherent programmatic disadvantages of the carve-out approach described in later sections of this report, moving the drug benefit to the FFS setting introduces significant transition risks.

California's experience also illustrates the importance of maintaining the cost containment rigor that the Virginia MCOs deploy. California's experience under their carve-out, when the cost containment tools were temporarily relaxed, strongly refutes that the drug benefit can "safely" be managed with less administrative effort and rigor.

Kentucky

Kentucky's Medicaid program switched from a carve-in model to a carve-out approach effective in January of 2022. While the operational challenges with Kentucky's transition were nowhere near the scale of what occurred in California, the following are examples of disruptions that were repeatedly experienced:

- Dual eligible members had to pay copays/coinsurances on Medicare Part B covered products (e.g., diabetic supplies).
- Coordination of Benefits (COB) rejections occurred at such a high rate that the State's PBM needed to turn off all the COB-related point of service rejections.

Mississippi

Mississippi's Medicaid program switched to a carve-out approach, effective July 1, 2024, with Gainwell serving as the single PBM for Medicaid pharmacy claims administration. Transition-related issues arose during the first few months of the carve-out, as described below.

- Gainwell turned off prescriber edits, due to the credentialing deadline occurring the same day as the carve-out transition and place of service
- Uncertainties have arisen regarding whether certain office-administered drug claims should be processed under the medical or pharmacy benefit.

New York

New York transitioned from a Medicaid carve-in model to a carve-out approach, effective in April of 2023. Examples of challenges MCOs have encountered with the new approach include:

- The State did not provide a clear delineation of what drugs would not be covered under the pharmacy benefit (and would therefore be covered under medical benefit), so there was fragmentation in care coordination
- The State's lack of responsiveness led to shortages of necessary medications which had harmful effects on some enrollees (e.g., one enrollee was unable to get her insulin for over one month and her glucose increased to unhealthy levels)
- The State had limited hours of operation compared to the MCOs, making it so that the NY MCOs could not assist members with changes needed after hours due to fragmentation in the lock-in process. Some members were unable to fill their prescriptions, leaving them without needed medications for their substance use disorder and other chronic medical conditions.

VI. Quality Comparison of Carve-In and Carve-Out Approaches

A. National Analyses

An important consideration in evaluating carve-in and carve-out policy options is access to care. A 2023 Elevance Public Policy Institute report, "Medicaid Prescription Drug Management: Quality Scores Compared Across Different Approaches," looked in detail at medication access in each setting. This analysis demonstrated that quality scores across pharmacy-related HEDIS measures have been superior in the carve-in setting.

Twenty-nine HEDIS measures were assessed, with the vast majority of these measures involving access to appropriate medication therapy. Examples of the 29 measures included in the study are shown below:

- Pharmacotherapy Management of COPD Exacerbation (PCE)
- Controlling High Blood Pressure (CBP)
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
- Statin Therapy for Patients with Cardiovascular Disease and Diabetes (SPC, SPD)
- Antidepressant Medication Management (AMM)
- Adherence to Antipsychotic Medications for Individuals with Schizophrenia (SAA).

Large-scale comparisons of HEDIS quality scores were made between the MCO (carve-in) and FFS (carve-out) settings. The study created 34 group comparisons between the two settings. In 33 (97%) of these instances, the fully MCO-managed model outperformed the FFS model.[14]

This pattern occurred across several years, across a wide set of behavioral health and physical health HEDIS measures, and in different regions of the country.

Exhibit 7 summarizes one of the analyses that compared enrollment-weighted average quality scores in a carve-out state with its neighboring carve-in states, with the carve-in MCOs' score being higher in 67.9% of the 533 group-to-group comparisons tabulated.

[14] Medicaid Prescription Drug Management: Quality Scores Compared Across Different Approaches

Exhibit 7: Regional Cluster Comparisons of Average Scores Across 29 Pharmacy-Related HEDIS Measures and Across the 2014-2022 Timeframe

Carve Out State	Comparisons Where Carve-In MCOs' Weighted Average Score was Better than Carve-Out MCOs' Score	Comparisons Where Carve-Out MCOs' Weighted Average Score was Better than Carve-In MCOs' Score	% Of Comparisons Where Carve-In MCOs' Score was More Favorable
Missouri	139	29	82.7%
Tennessee	120	67	64.2%
Wisconsin	103	75	57.9%
Total	**362**	**171**	**67.9%**

B. Regional Analyses

For this engagement, we compared the Virginia MCOs' scores on the pharmacy-related measures for performance years 2022 and 2023 with those of each of its neighboring states.

We created a weighted average score for each state, based on each Medicaid MCO's quality score on the measure and each Medicaid MCO's overall Medicaid enrollment level. These calculations were made for 28 pharmacy-related HEDIS measures.

Once each state's weighted average was derived for each of the 28 measures, we ranked the six jurisdictions (Virginia, the District of Columbia, Kentucky, Maryland, Tennessee, and West Virginia) based on whose scores were most favorable for each measure. We then averaged the state rankings, with Virginia having the third most favorable HEDIS scores among these six states. Virginia's average rank was 2.9, well below (better than) the other five states' average rank of 3.5. Thus, Virginia much more often ranked closer to 1st than to 6th.

This assessment indicates that Virginia's MCOs are performing well on the pharmacy-related HEDIS measures, as compared to the collective results across its neighboring states. The national analyses described above indicate that under a transition to a pharmacy carve-out model, the quality performance in Virginia can be expected to decline.

C. Input from Virginia's Medicaid MCOs

The remainder of this section presents content from Virginia's Medicaid MCOs regarding ways in which high-quality care (and high-quality care coordination) occurs in the existing carve-in model, which would be compromised if DMAS switched to a carve-out approach. Collectively, Virginia's Medicaid MCOs have vast experience operating in both carve-in and carve-out models and are well-positioned to describe the differences they have directly observed.

Multiple and Sometimes Contradictory Information Sources

"When prescription benefits are carved-out, there can be incongruent therapeutic pathways supported between the health plan and PBM. The member can easily be provided with conflicting information from the PBM versus a case manager at the health plan. This confusion can result in an adverse event such as a drug-drug interaction (DDI), duplicative therapy, or gaps in therapy which can lead to increased ER utilizations and hospitalization."

Prompt, Proactive Use of Technology

"Care Management is a critical aspect of the MCO's ability to provide appropriate services to members in need. These teams rely on live pharmacy claims data for their high-quality services. In carved-out states, data provided back to MCOs is lagging and is often incomplete in truly assisting the member. This results in having to contact the FFS agency for support, which increases the time needed to resolve the issue for the member."

"Integration of pharmacy data enables MCOs to be proactive rather than reactive. They can use technology to identify high-risk members and engage them in quality programs before major problems occur."

"If a member calls the MCO, the lack of immediate access to comprehensive care management information (including pharmacy data) hampers the MCO's ability to effectively assist the member."

Following Treatment Guidelines

"By monitoring real-time data, MCOs ensure providers and members are following optimal treatment guidelines."

"Case Managers and other clinicians at the plan will find it more difficult to effectively address issues related to whether medications are appropriate in the context of a disease or condition (i.e. drug-to-disease interactions, suboptimal pharmacologic therapy) which can lead to disease instability and an increased need for consuming medical services."

Fostering Innovation

"Disconnected Medicaid programs result in care silos and limit the Medicaid MCO's ability to develop innovative programs that improve the quality and coordination of care for vulnerable populations."

Chemotherapy Integration

"Chemotherapy medications are often dispensed together to ensure the safety and clinical appropriateness of the regimens, which is critical for these narrow therapeutic index drugs. With a carve-out, some parts of the chemotherapy regimen would be part of the pharmacy benefit covered by FFS, and others would be covered by the MCO under the medical benefit. This requires providers to complete additional authorizations to an additional agency and removes the clinical efficacy of the pharmacist reviewer, who can only assess part of the regimen being dispensed, resulting in the member getting a part of their regimen approved but not the other, as well as receiving the medications at different times. The fragmentation of these regimens is not cost-effective, as separate agencies need to review the regimen but only dispense, approve, and/or ship a portion of it."

VII. Integration of Data in Carve-In and Carve-Out Settings

An important consideration with regard to a carve-out option is the degree to which the MCOs' data-driven care coordination capabilities will be compromised relative to the current carve-in model. The data-related advantages of the carve-in model are explored throughout this section.

A. Real-Time Data Access

Within the carve-in, prescription drug data are available on the MCO's own terms, integrated with their staff and information systems in the manner they find to be most effective. Additionally, the prescription drug claims information is available to the MCO immediately.

Unlike other health services, prescription drugs have no claims submission/payment lag time. These transactions are visible immediately and, using proprietary disease management programs and data-mining algorithms can flag issues that trigger prompt and valuable care coordination actions, such as the creation of Interdisciplinary Care Teams (ICTs).

A comprehensive benefit carve-out negates efforts to fully integrate care for members and diminishes MCOs' capacity to fully manage and optimize care delivery. Pharmacy data is nearly real-time when carved in, and even the best carve-out data-sharing approaches fall well short of full utility. Even a daily claims feed requires thorough system integration and quality control, which significantly inhibits MCOs' ability to incorporate the data into care management platforms, risk stratification models and other core functions. This creates disruption and avoidable delay when pharmacy-related issues occur.

The carve-out model isolates pharmacy data from medical data, leading to fragmented care and disjointed treatment plans. This separation creates silos within the healthcare system, making it difficult for care teams to access comprehensive patient information in real time, which is crucial for effective care coordination.

B. Ease of Member and Provider Communications

The carve-out approach risks reducing the efficiency of member and provider interactions, as MCOs will no longer handle many pharmacy-related inquiries directly. This shift may lead to a fragmented experience for members and providers, affecting care coordination and satisfaction. An issue that arose in California (which still persists) is confusion around who is responsible for dual-eligible enrollees' medications, particularly regarding certain physician-administered drugs delivered outside of the pharmacy setting. Throughout the tenure of California's carve-out model, enrollees, prescribers, and MCOs have been repeatedly navigating situations where Medicaid, Medicare Part B, and Medicare Part D are not approving payment for a covered drug. Without real-time data, health plans cannot quickly identify when members fail to fill a prescription.

Under a carve-out model, the need to coordinate with external entities for pharmacy data introduces significant challenges, including communication breakdowns between healthcare providers and pharmacists, leading to delays in care planning and treatment.

Pharmacy data helps locate members and update contact information, allowing timely completion of contractually required outreaches and providing necessary support to transient members.

Under a carve-out, members do not understand the separation of pharmacy services from medical and behavioral health services. Members often reach out with urgent pharmacy issues and experience delays in resolution due to the complicated coordination that a carve-out requires. This impacts transition of care, emergency supplies, and prior authorization approvals. Full integration allows MCOs to manage members and solve pharmacy related issues without delay and with complete up to date information. Integrated MCOs can also leverage innovative technologies such as automated prior authorization, diagnosis-drug matching, real-time care manager flags, dynamic lock-in, etc.

Rapid, accurate responses to medication needs enhance member satisfaction and trust in healthcare providers.

C. Value of Real Time Pharmacy Data for Case Managers

Virginia MCOs provided the following quotes regarding the ways in which real-time pharmacy data are needed to support optimal case management efforts.

> *"Real-time data allows care teams to promptly address issues related to prescription fills, such as non-adherence, potential drug interactions, or inappropriate medications, facilitating swift intervention."*

> *"Even in cases where data exchanges with the state occur, it still does not offer the same experience from a case manager or member services standpoint. The data exchanges are simply not the same as actually looking at claims in our PBM system."*

> *"Care management is often forced to rely on data with excessive lag time such as during medication reconciliation after facility discharge or when assessing adherence, creating undue challenge in medication optimization."*

> *"Contact information gathered by pharmacies – the MCO's PBM provides [our MCO] with a regular extract of additional member contact information (e.g., phone numbers). This information is loaded into different systems (e.g., Care Management) which supplement the phone number obtained during enrollment and minimize the number of members [our MCO] is unable to reach. These extracts would not be available in carve-out model leading to members being unreachable."*

> *"When members need authorization for services or medications, having one entity managing all the benefits has efficiency in member service and resolving any barriers to care."*

"Case management and member services staff would find it far more difficult to service the member when real-time claim access is taken away."

"Access to real-time pharmacy data ensures seamless integration into broader treatment plans, aligning all aspects of care for collaborative management."

"Up-to-date information allows for personalized care strategies, improving health outcomes by tailoring treatments to current data."

"[Care Management] teams rely on live pharmacy claims data for their high-quality services. In carved-out states, data provided back to MCOs is lagging and is often incomplete in truly assisting the member. This results in having to contact the FFS agency for support, which increases the time needed to resolve the issue for the member."

"Delays can result in a worsening of chronic conditions, preventable hospitalizations, and higher PMPM. Missed medication issues can result in increased use of ED and inpatient, and preventable adverse events, such as heart attacks, strokes, or uncontrolled diabetes, can become more common."

D. Real-Time Pharmacy Data and Specialized Enrollee Needs

Enrollees with complex conditions and other specialized medication needs can be more optimally supported through the real-time data available under Virginia's carve-in setting. Examples of input in this area from Virginia's MCOs' are presented below.

"Another state carved out Hepatitis C medications and care and launched an initiative to substantially decrease Hepatitis C in its communities. The state wants our help to treat as many members as possible, but we don't know which members have already received treatment and who has not because we do not receive adequate data in a carve-out scenario."

"With regard to opiate abuse, it is imperative to have access to real-time pharmacy history (i.e., paid, rejected, reversed) to minimize opiate abuse when a patient may be doctor/pharmacy shopping. The Virginia Prescription Monitoring Program may be used to supplement information but is also not real-time."

"Real-time monitoring and management of medication regimens for chronic conditions [currently occurs], enabling timely adjustments to treatments."

"Immediate identification of patterns such as frequent medication changes or failed adherence allows proactive addressing of potential health concerns before they escalate."

"A carve-out can hinder MCOs' ability to timely detect and manage drug non-adherence, drug abuse, or any other prescription drug patterns that indicate an underlying medical condition, affecting the most complex and high-cost patients who need coordinated care."

VIII. Access and Adherence Advantages of Carve-In Model

Virginia's Medicaid MCOs deliver a compelling level and mix of support to their members regarding accessing needed medications and adhering to prescribed regimens. A pharmacy carve-out model compromises the MCOs' technical ability to deliver these supports and the financial viability of doing so.

This section conveys additional information obtained from Virginia's MCOs specific to their efforts to facilitate and monitor their enrollees' medication access and their adherence to their medication regimens.

Adherence calls: One health plan's technicians drive adherence by calling each patient approximately a week before the patient would run out of the current stock of medication (based on day's supply) to set up the next medication refill. In addition, the technicians ask a set of questions to assess patient adherence as well. For example, the technician asks the patient how many doses the patient has remaining and evaluates if this number makes sense with what the patient should have remaining. If the technician determines an issue may exist, they will "warm transfer" the call to a pharmacist who works with the patient to determine a reason for the apparent non-adherence and provides tips to overcome these barriers.

Ensuring continued adherence to prescribed therapies: One plan uses an adherence program that identifies members that may not be following a prescriber's medication instructions. There are several information technology (IT) driven components to this program:

- The IT system identifies members beginning therapy with a long-term medication, such as a blood pressure-lowering medication. Pharmacists counsel the member regarding the importance of adherence with their medication.

- The IT system targets members who are 14 or more days late on filling their medication. The plan identifies adherence barriers that may be contributing to non-adherence. The plan focuses on educating members about the benefits of taking their medication as prescribed and supporting members to improve adherence.

- The IT system targets members who are late on refills; members are contacted by interactive voice response (IVR) and can opt to immediately call the pharmacy for a refill. Refill rates for members reached by IVR are approximately 1.5 times higher than for other members.

Medication assisted treatment (MAT) education: This plan's pharmacy team supplies reports that are used for various care management activities and adherence programs. One example includes a first fill/drop-off report that informs the care manager when a member begins or stops MAT. The care manager can engage the member to discuss whether MAT is still needed or educate the member on the importance of continuing the medication for those on therapy.

Assessing needs post-discharge: This plan's pharmacy team assists its care management team with post-discharge transitions. A clinical pharmacist reviews the discharge summary to ensure medications are being filled. A full medical review is carried out to determine baseline adherence to existing medications, drug-to-drug interactions, polypharmacy, and potential gaps in care. In one case, the pharmacist and care management collaborated on reaching out to a member where current demographic information was not accurate. After contacting the prescriber and pharmacy, a more current phone number was obtained. It was learned the member had moved and was having trouble getting their medication. The clinical pharmacist and the care manager determined what pharmacy would be nearest the member and assisted the member with transferring the needed medications to a pharmacy closer to where they were living. Additional education was carried out around the importance of taking the prescribed medications to avoid hospitalizations in the future.

Explaining complex treatments for asthma: One of this plan's pharmacists outreached to a member and her caretaker as part of the asthma adherence programs. The pharmacist spoke with the member's mother, who was very concerned about her daughter's medication and wondered if something might be wrong. The pharmacist informed her that the call was to provide tips and helpful information so that she can get the most benefit out of her daughter's medication. The member's mother was confused about the inhalers the doctor had provided for her daughter to use. She had never heard of asthma before. The member seemed overwhelmed with all the medication the doctor had provided her. The pharmacist carefully reviewed her long-acting inhaler, described its use, priming the inhaler, side effects as well as what she could expect from the use of the medication. The pharmacist also eased her fears by stating that the medication can be used for long term care of her daughter's lungs. She was very grateful for the information stating that she now understood the difference between rescue and long-acting prevention inhalers and thanked the pharmacist for discussing other medications as well.

Nebulizer access and readmission prevention: Upon receiving a call from a member care specialist about a recent emergency department visit, a member's caregiver brought up concerns regarding their medication. Through the discussion, it was discovered the member had been to the hospital due to issues breathing from chronic bronchitis. The member had been prescribed Albuterol Nebulizing Solution and Nebulizer, but was having trouble getting their Nebulizer due to an issue with the way the prescription was written. The member's caregiver was concerned because they had been using more of his emergency Albuterol Inhaler to supplement until the physician corrected the prescription. They were concerned about running out of their medication and being without it for the entire weekend.. While the care coordinator assisted the member in getting the corrected prescription, the health plan, with assistance from a pharmacist, decided it was in the best interest of the member to give them an override for the Albuterol Inhaler.

Providing override support to access Suboxone: A relatively new member was unable to get her Suboxone filled. She had been using an out of network provider for the past 90 days under the continuity of care process. In this specific area, there was geographical scarcity of ARTS/SUD providers. A Care Coordinator and the member were able to work towards an in-network appointment, but it was after the 90-day continuity of care period. The Care Coordinator reached out to a pharmacist to support an override to maintain member's adherence and followed

up to ensure the member's appointment and transfer of care was completed. The pharmacy staff provided an approval so the member could obtain her Suboxone.

Ensuring continued access to medications during emergencies and disasters: This plan and its PBM collaborate during emergencies and disasters to ensure that their members have ready and continued access to their medications. In August 2018, officials feared that a dam in Lynchburg, Virginia was going to overflow. The plan alerted its PBM that many of its members were being evacuated to higher ground and would need access to their medications. Per the shared protocol, the PBM relieved the requirements for authorizations and reporting; members obtained their medications seamlessly for the period of their evacuation. Afterward, the plan received an accurate and complete follow-up report from the PBM to ensure that the business plan was on track with monitoring medication utilization. After a disaster is over, the PBM provides the plan with a follow-up report so the plan can monitor the medications that were dispensed during the period of disruption.

Finding vitamins for members with dietary restrictions: The plan had a member who would only take vegan vitamins, so a staff member worked with Virginia Commonwealth University students to find vitamins in a vegan form and provided the member with this information so she could order them. The member mailed her invoice to the plan. The plan added the vitamins to their system and the member was able to receive reimbursement.

Troubleshooting a drug utilization review (DUR) issue: A member and her therapist reported a denial issue with filling the member's Zyprexa 20mg through her pharmacy. A Care Coordinator spoke to the pharmacy, determined the pharmacy needed additional support from the plan, then reached out to a plan pharmacist for support and guidance. This medication was denied due to having already filled Zyprexa 15 mg and Latuda. In this case they had duplicate therapy with another antipsychotic medication and a high dose due to a dose change but the previous dose was filled recently. The health plan pharmacy tech was able to verify with the prescriber's office that the member was stopping the 15 mg and only taking the 20 mg. The Pharmacy Director allowed the pharmacy tech to enter an override for this medication on a one-time basis and the pharmacy was confirmed to have a paid claim.

Increased day supply: An MCO allows up to a 90 day supply and has found this to be valuable to adherence as well as cost-effective.

"Under a carve-out, the ability to directly influence medication adherence is reduced, which may lead to higher healthcare costs due to non-adherence and potentially increased risk levels."

– Virginia MCO Pharmacy Executive

IX. Case Examples of Virginia MCOs' Management of the Drug Benefit

Virginia's MCOs provided several case examples illustrating the way in which they "go the extra mile" for an enrollee in the challenging situations that can often arise across the large population being served. The support rendered in these examples would not likely occur (or occur as expeditiously) in a pharmacy carve-out setting.

Case Example 1: Supporting An Enrollee Through an Out-Of-State Emergency

In early 2024, a Virginia member was flown to the Cleveland Clinic for a cardiac procedure and was scheduled to fly back late on Friday. Unfortunately, inclement weather canceled the flight, so this patient was suddenly and unexpectedly stranded in Cleveland until another flight could be scheduled. As a result, the care management team was pulled in to find a hotel for at least one night as well as transportation.

Early on Saturday, the pharmacy team received a call from care coordinators indicating that the member was high acuity and out of multiple medications. The pharmacy director immediately contacted the PBM to (1) locate pharmacies near the hotel, (2) engage with pharmacies about the targeted medications to ensure they had adequate supplies, and (3) grant early-refill overrides for these medications. The care management team then supplied transportation to get the patient to the pharmacy as well as meal coordination and arranged an alternate flight back to Virginia.

This level of care coordination, and the speed at which services were available to the member would be compromised in a carve-out scenario.

Case Example 2: Addressing Member Needs When Drug is Discontinued

Earlier this year, Relyvrio, a medication used to treat amyotrophic lateral sclerosis (ALS), was discontinued following reports from Amylyx that the drug failed to provide clinical benefits. For members who were currently on Relyvrio, ensuring continuity of care was crucial due to the debilitating nature of ALS.

Our MCO took a proactive approach by reviewing the utilization of Relyvrio among our members. We reached out to the prescribing physicians to assess their plans for transitioning to alternative treatments based on this new information. Our pharmacy team worked closely with both the prescribing physicians and pharmacies to expedite the authorization process for new medications. This ensured that there were no delays in getting the necessary approvals and that members received their new treatments promptly.

By proactively coordinating care and expediting necessary approvals, we ensured continuity of treatment and minimized disruptions. Such comprehensive support and coordination may be challenging to achieve in a carve-out setting, where fragmented care management can hinder timely and effective responses to significant changes in medication availability.

Case Example 3: Comprehensive Care for a Diabetic Member

A diabetic member required comprehensive disease management. Our clinical pharmacy team conducted a thorough medication review and identified several care gaps, including missing annual screenings and guideline-recommended therapies (e.g., statin and ACE/ARBs).

The team facilitated the member's completion of required screenings and the prescription of necessary medications, including a GLP-1 for additional glucose lowering. This holistic approach, supported by real-time data, enabled our team to address multiple care gaps, significantly enhancing the member's health management. This integrated support is less achievable in a carve-out model due to the fragmented nature of care coordination.

Our MCOs clinical pharmacy program showcases how our comprehensive support system significantly benefits enrollees, advantages that would likely not be possible in a carve-out setting. Here are three notable case examples that illustrate our commitment to going the extra mile for our members:

Case Example 4: Timely Pharmacological Intervention for COPD Exacerbation

A member was discharged from the ER after a COPD exacerbation and was prescribed an antibiotic and cough syrup. Our team noticed the absence of a crucial medication, a bronchodilator, likely required for the member's condition. They promptly reached out to the member's primary care provider (PCP) to address this care gap.

Within a short timeframe, the PCP prescribed the bronchodilator, and it was promptly filled by the pharmacy. This prompt action improved patient outcomes by ensuring that all necessary medications were prescribed and available. The intervention highlights the advantage of having access to real-time pharmacy data, which facilitated swift identification and resolution of care gaps.

Case Example 5: Addressing Medication Adherence in an Asthmatic Member

An asthmatic member was not adherent to their prescribed medications (fluticasone, montelukast, and albuterol) and was overusing a rescue inhaler. Through pharmacy claims, we identified the non-adherence issue and provided education to the member about their health condition and the importance of regular medication use. Additionally, we coordinated with the pharmacy to ensure all medications were refilled and ready for pickup.

The member quickly received the necessary refills, significantly improving medication adherence and management of their condition. Regular monitoring and real-time data access allowed our team to intervene effectively before the situation worsened, something less feasible in a carve-out model lacking such integration.

Case Example 6: Community Pharmacy Total Care (CPTC) Program

This comprehensive partnership between our MCO and Virginia community-based pharmacies requires real-time pharmacy data to coordinate pharmacy care. This pharmacy value-based concierge program provides personalized care, education and adherence support contributing to improved health outcomes and well-being of members.

The CPTC program showcases a successful model of personalized pharmacy care with substantive improvements in health outcomes and robust data coordination, driving better HEDIS scores and overall cost savings. This innovative program would be less successful in a carve-out model due to the fragmented care coordination and implementation delays caused due to data access issues.

Case Example 7: Clinically Warranted Brand Over-Ride of Generic Drug

Recently, a member under 2 years of age needed sildenafil suspension. The provider had submitted a Prior Authorization request and the medication (generic) was approved. The parents contacted the plan indicating that they needed the brand version of the medication. Given the provider had not submitted a brand medically necessary request, our case manager and pharmacy team opted to place an override to ensure the member could get their much-needed medication.

The pharmacy was called, and a paid claim occurred. Unfortunately, this situation occurred again the subsequent month. To ensure the member would not go without their medication a second authorization was placed, the pharmacy called, and our case manager engaged the provider to ensure a Prior Authorization request with clinical supporting information was shared.

Moments later the pharmacy notified the plan that the branded medication was no longer being manufactured. The pharmacist from the pharmacy notified the member and provider. Our case manager also engaged with the parents. Our case manager and pharmacy team ensured there was an authorization on file for the generic from a previous submission and the pharmacy worked with the plan and member to get the medication to the member.

Having access to the claims data and carrying out the prior authorizations provides immeasurable information that allows a multidisciplinary approach to help ensure our members navigate the health care they need. We are able to address issues and create solutions to avoid delays in care.

Case Example 8: Age Restriction Over-Ride to Prevent a Likely Readmission

A 17-year-old female with a history of paranoid schizophrenia and major depressive disorder was discharged from an inpatient psychiatric facility on a Friday afternoon. She went to the pharmacy to get her Latuda filled but it was rejected based on DMAS criteria requiring a prior authorization for antipsychotics in members < 18 years of age.

The member reached out to her case manager who in turn contacted our Virginia pharmacy department at 3PM. The member did not receive her Latuda on her discharge date and was at high risk for readmission if she did not get it filled. Our pharmacy technician immediately outreached the pharmacy and guided them on how to submit a 72-hour emergency fill. The pharmacy dispensed the medication late Friday afternoon to allow enough time for the Prior Authorization to be submitted which was approved, potentially avoiding a readmission.

Case Example 9: Overcoming a Medication Access Barrier

Our member is a 47-year-old male living with bipolar disorder, major depressive disorder, and Huntington's disease. The member is homeless and currently living in a shed. His assigned case manager met with the member to complete the health risk assessment (HRA) during which the member reported his main concern was a neck injury he sustained because of an altercation. He is being followed by

Neurology due to nerve damage reports stating that he will likely need surgery but will need to go through physical therapy first.

The member reports his pain is 10/10 and that it has caused him to lose the desire to live some days. After the HRA was completed, the member was to go and pick up his pain medication from his pharmacy utilizing public transportation. Our case manager later received a call from the member who was upset and noted that after arriving at the pharmacy, the pharmacy informed him that they would not be able to fill the medication due to the medication requiring prior authorization.

The case manager spent time on the phone empathizing with the member's situation and reassuring him that she would reach out to pharmacy team immediately to try to assist. Our case manager contacted our pharmacy team, describing the member's situation and requesting assistance. The case manager was informed by the pharmacy team that the prior authorization had been received, however it was still being processed. Our pharmacy team contacted the retail pharmacy filling the prescription and put in for a 3-day emergency fill to provide therapy while the prior authorization was being approved.

Our case manager then called the member to let him know he will be getting a 3-day supply of his medication, until the prior authorization is approved. The member was very appreciative and thankful for our assistance so that he could fill his prescription and have relief from his neck pain without having to wait. Our case manager will continue to work with the member to address his other SDOH and health care concerns.

Case Example 10: Same Day Replacement Medications Due to House Fire

A 24-year-old member with a history of major depressive disorder, anxiety, and obstructive sleep apnea receives case management and medication management services at Mount Rogers Community Services Board. Her family experienced a house fire early one morning and most of the inside of the house was lost including the member's medications. Her medications included two antipsychotics, antidepressant, oral contraceptive, and vitamin D.

The member contacted her Care Manager on the day of the fire at 3:00PM for assistance. Since she recently had them filled, the member's pharmacy told her the replacement medications would not be covered. Our Care Manager immediately accessed the member's pharmacy history in the MCO's PBM's portal and identified the specific medications processed by the pharmacy on the same day that rejected for early refill. Our Care Manager then reached out to our pharmacy team for assistance and early refill overrides were entered into the pharmacy claims system. The Pharmacy team contacted the pharmacy to reprocess the claims and the member ultimately received her medications ***on the same day*** *avoiding any medication discontinuation issues.*

Case Example 11: Accessing an Alternative Drug Upon a Medication Denial

A member received a denial letter for a new pain medication, oxycodone, due to it being non-preferred on the PDL. Confused by the letter, the member contacted a care manager, who clarified the issue with the pharmacy and guided the member on the next steps. The care manager coordinated with the member's physician to obtain an alternative prescription.

The issue was resolved timely, and the member expressed gratitude for the assistance and reported feeling better with the new medication regimen. The successful resolution was due to effective

interdepartmental collaboration as well as the ability to have real time pharmacy data and a fully integrated care model.

Case Example 13: Leveraging Real-Time Data to Address Medicaid Duplication

The health plan's integrated specialty pharmacy noticed therapeutic duplication of Rybelsus and Mounjaro for one of our members through real time pharmacy data in Sentara's care management platform, JIVA. The nurse care manager reached out to the member's provider and confirmed member should only be utilizing Mounjaro. The member was contacted and the duplicative drug, Rybelsus, was discontinued. This integrated approach would not have occurred without real time pharmacy data and an integrated care management team.

X. Recommendations

Based on the analyses detailed in this report, we offer the following recommendations:

Preserve the current carve-in pharmacy model for the Medicaid program.

Financially, we estimate that a switch to a carve-out approach would have an adverse annual state fund impact of roughly $44 million. A carve-in model also keeps the considerable financial risks associated with Medicaid pharmacy costs with the MCOs, giving the Commonwealth valuable budget predictability relative to the carve-out model.

Programmatically, a pharmacy carve-out diminishes the Medicaid program's ability to deliver whole-person integrated care. The MCOs' staff teams, data structures, and care coordination processes are all designed to deliver optimal care coordination – and carving out something as central as prescription drugs "unwinds" many important aspects of the systems of care they have put in place and worked with DMAS to strengthen. MCO quality scores on pharmacy-related measures are superior in the carve-in setting. Access and adherence to needed medications are best supported under the carve-in model, taking advantage of the MCOs' comprehensive set of programs in these areas.

A carve-out model also introduces implementation and transition risks, creating upheaval in a mature, successfully operating program. California's recent transition to a carve-out model illustrated the degree to which medication access and state cost problems can occur.

"The carve-in model is financially advantageous to the Commonwealth in that it preserves and encourages the "whole person care" model for managed Medicaid that is gaining traction throughout the US. This model allows for the coordinated treatment of the individual, evaluated through coordinated real time data and a care team to reconcile and manage all aspects of the member's care. This model enhances the "right care, in the right place, at the right time" model that has been most effective in controlling both quality and cost."

– Virginia MCO Pharmacy Executive

Preserve the Common Core Formulary

A key factor driving the previous recommendation is that DMAS has an established mechanism – the Common Core Formulary – to identify which drugs are yielding the lowest net cost to the overall Medicaid program (and thus to Virginia taxpayers) and require MCO steerage to those drugs. This mechanism, typically referred to in other Medicaid programs as a "uniform preferred drug list" (or uniform PDL) is critically important in the current era where many brand drugs have become "better than free" to Medicaid.

We also recommend that MCOs be given latitude to discern and utilize the lowest-cost drug in therapeutic classes where there is not a "better than free" brand drug available. For this to occur, DMAS would need to disclose to the MCOs (without conveying any specific drug's rebate level) which therapeutic classes are applicable to this approach.

"The Commonwealth's uniform PDL provides consistency among prescribers, pharmacies, and MCOs to favor drugs that are clinically effective and cost efficient."
– Virginia MCO Pharmacy Executive

Enhance Reimbursements to Critical Access Pharmacies

There are many situations — particularly in Virginia's more rural areas — where a certain pharmacy creates far superior geographic access to Medicaid enrollees than would be available if that pharmacy were to cease operations. We recognize the importance of identifying and supporting critical access pharmacies.

We suggest that DMAS require the Virginia MCOs to pay critical access pharmacies at relatively robust payment rates. DMAS would identify which pharmacies should be designated as critical access stores (looking objectively at geographic access dynamics but not at subjective factors such as ownership) and establish the amounts MCOs would pay these pharmacies for Medicaid enrollees. These enhanced payments would also be explicitly taken into account in the capitation rate-setting process.

We caution, however, that it is also important to avoid propping up reimbursement to all pharmacies — or to any group of non-critical access pharmacies — in order to achieve the focused objective of strengthening the viability of critical access pharmacies.

Increase MCO Policymaking Representation

Currently, the Virginia MCOs have one representative on the Drug Utilization Review Board Committee and one representative on the Pharmacy and Therapeutics Committee. Because the MCOs account for 99% of the total Medicaid spend, we recommend additional MCO representation on both committees. This will ensure the policymaking decisions have the benefit of considerable input from the organizations that are playing such a central role in the daily management of Virginia's pharmacy benefit. The MCOs often can also bring extensive national experiences and perspectives to the deliberations related to Common Core Formulary modifications and other policy issues and options.

Consider Capitation Rate-Setting Revisions for the Pharmacy Component

Virginia's MCOs have through the years experienced a balanced, fair partnership with DMAS and with its actuarial contractor (Mercer) which has been a critical component of the coordinated care program's stability and success. Notwithstanding that, the MCOs have viewed the pharmacy component of the capitation rate to be underfunded for multiple years, and are concerned that the cost dynamics of this benefits component may warrant some methodological revisions to prevent this from continually re-occurring.

Examples of some of the issues currently in play include:

- The prices of newly introduced drugs are becoming increasingly high and aggressive, and many drugs are in the "pipeline" for new market entry.

- Brand manufacturers' reactions to some of their drugs now being in the "better than free" category when used in Medicaid are yet to play out. This situation became possible only recently (in January of 2024), and the dynamics associated with this are very difficult to predict.

- One drug class, GLP-1 agonists (sometimes referred to as "weight loss drugs"), alone creates tremendous financial uncertainty at the present time. The high costs of these medications, coupled with the prevalence of obesity (and overweight persons), creates the potential for enormous new costs to emerge.

We are not offering a specific recommendation, other than encouraging DMAS, Mercer, and the MCOs to collaboratively consider how to best address the rate-setting challenges these dynamics create. One option would be to commit to revisiting rates at mid-year and to consider retroactive rate adjustments when there are new drugs or gene therapies that enter the market, or new indications for drugs.