



COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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December 12, 2022

MEMORANDUM

TO: The Honorable Glenn Youngkin,
Governor, Commonwealth of Virginia

The Honorable Janet D. Howell
Chair, Senate Finance Committee

The Honorable Barry D. Knight
Chair, House Appropriations Committee

The Honorable Robert D. Orrock, Sr.
Chair, House Health, Welfare, and Institutions Committee

The Honorable L. Louise Lucas
Chair, Senate Education and Health Committee

FROM: Cheryl Roberts
Director, Virginia Department of Medical Assistance Services

SUBJECT: Over-The-Counter (OTC) Medications Direct Purchase Study

This report is submitted in compliance with the Virginia Acts of the Assembly, 2022 Special Session I – Chapter 12 (HB1046)., which states:

“§ 1. That the Department of Medical Assistance Services (the Department) shall study options for and develop a plan to implement a process by which recipients of medical assistance services shall receive payments, in the form of a voucher or electronic benefit transfer card, that may be used to purchase over-the-counter medications and medical supplies prescribed by an authorized prescriber directly in a retail setting. Such plan shall include identification of any statutory, regulatory, budgetary, or policy changes and any federal approvals necessary to implement such plan, as well as an estimate of the fiscal impact of implementation of the plan. Such plan shall also include provisions to prevent fraud and misuse of funds made available via vouchers or electronic benefit transfer card. The Department shall report its findings and plan to the Governor and the Chairmen of the House Committees on Appropriations and Health,

*Welfare and Institutions and the Senate Committees on Finance and Appropriations
and Education and Health by December 1, 2022.”*

Should you have any questions or need additional information, please feel free to contact me at (804) 664-2660.

CR/wf

Enclosure

Pc: The Honorable John Littel, Secretary of Health and Human Resources

Over-The-Counter (OTC) Medications Direct Purchase Study

A Report to the Virginia General Assembly

December 12, 2022

Report Mandate:

House Bill 1046 directed the Department of Medical Assistance Services (the Department) to “study options for and develop a plan to implement a process by which recipients of medical assistance services shall receive payments, in the form of a voucher or electronic benefit transfer card, that may be used to purchase over-the-counter medications and medical supplies prescribed by an authorized prescriber directly in a retail setting. Such plan shall include identification of any statutory, regulatory, budgetary, or policy changes and any federal approvals necessary to implement such plan, as well as an estimate of the fiscal impact of implementation of the plan. Such plan shall also include provisions to prevent fraud and misuse of funds made available via vouchers or electronic benefit transfer card. The Department shall report its findings and plan to the Governor and the Chairmen of the House Committees on Appropriations and Health, Welfare and Institutions and the Senate Committees on Finance and Appropriations and Education and Health by December 1, 2022.”

About DMAS and Medicaid

The mission of the Virginia Medicaid Agency is to improve the health and well-being of Virginians through access to high-quality health care coverage.

The Department of Medical Assistance Services (DMAS) administers Virginia’s Medicaid and CHIP programs for over 2 million Virginians. Members have access to primary and specialty health services, inpatient care, dental, behavioral health as well as addiction and recovery treatment services. In addition, Medicaid long-term services and supports enable thousands of Virginians to remain in their homes or to access residential and nursing home care.

Medicaid members historically have included children, pregnant women, parents and caretakers, older adults, and individuals with disabilities. In 2019, Virginia expanded the Medicaid eligibility rules to make health care coverage available to more than 600,000 newly eligible, low-income adults.

Medicaid and CHIP (known in Virginia as Family Access to Medical Insurance Security, or FAMIS) are jointly funded by Virginia and the federal government under Title XIX and Title XXI of the Social Security Act. Virginia generally receives a dollar-for-dollar federal spending match in the Medicaid program. Medicaid expansion qualifies the Commonwealth for a federal funding match of no less than 90% for newly eligible adults, generating cost savings that benefit the overall state budget.

Over-The-Counter (OTC) Medications Direct Purchase Study

Key Policy, Operational and Fiscal Considerations

Virginia Department of Medical Assistance
Services

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Section 1

Introduction

The Virginia Department of Medical Assistance Services (DMAS) engaged Mercer Government Human Services Consulting (Mercer), part of Mercer Health and Benefits LLC, to assist in assessing the feasibility of, and a proposed plan for, adopting an enrollee direct purchase program for over-the-counter (OTC) medications and medical supplies in response to HB 1046 – *Plan to Allow Direct Purchase of OTC Medications* [hereinafter *Plan*].

HB 1046 directs the Department of Medical Assistance Services (DMAS) to study options for and develop a plan to implement a process by which recipients of medical assistance services shall receive payments that may be used to purchase OTC medications and medical supplies prescribed by an authorized prescriber directly in a retail setting and to report its findings and plan to the Governor and the Chairmen of the House Committees on Appropriations and Health, Welfare and Institutions and the Senate Committees on Finance and Appropriations and Education and Health.¹

¹ [LIS > Bill Tracking > HB1046 > 2022 session \(virginia.gov\)](#)
Mercer

Section 2

Executive Summary

Approach

To assess the feasibility of implementing the specifications of HB 1046 – *Plan to Allow Direct Purchase of OTC Medications*, Mercer first evaluated state and federally funded pathways that DMAS can pursue to implement the Plan in their Medicaid population. Mercer then outlined key policy and operational considerations specific to Medicaid and provided a preliminary fiscal impact to implement the Plan.

Key Findings

Policy and Operational Review

Mercer identified two pathways that may allow for the direct purchase of OTC medications and medical supplies by Medicaid members. The first leverages State-only funds to pay for selected products and associated cost to administer the Plan. With this option, DMAS retains flexibility in how the Plan is operationalized, but results in the loss of federal financial participation (FFP) that is currently in place at a matching rate of 56.85%. The second option preserves the FFP but faces operational and regulatory barriers. The Centers for Medicare & Medicaid Services (CMS) will require a state plan amendment (SPA) to ensure that program integrity guardrails are in place to safeguard against fraud, waste and abuse (FWA) under the Plan. Of note, Mercer was unable to identify any similar existing Medicaid programs with CMS approval.

Fiscal Impact Review

Mercer projects that products purchased directly by members in a retail environment may cost ~45% more than Medicaid currently pays for the same products through reimbursement to pharmacy providers. Medicaid costs are consistently lower because they are able to incentivize utilization of the lowest priced option for products by setting a maximum allowable cost (MAC) for clinically identical generic products. The 'direct purchase' price on the shelf represents the price the market will bear and may vary depending on where the member is shopping, whereas the price Medicaid reimburses is set based on what is efficient and is consistent regardless of provider location. Mercer reviewed current Medicaid managed care organization (MCO) expenditures to generate a select list of commonly utilized and easily accessible OTC medications and medical supplies where cost differences between Medicaid paid and direct purchase could be evaluated for this study.

Conclusion

Mercer identified a substantial increase in the cost to provide OTC medications and medical supplies to the Medicaid population if purchased directly by members. Operational considerations include maintaining program integrity and administrative costs for maintenance and oversight of such an approach. Prior to implementation of the Plan, it is recommended that the anticipated benefits of the Plan are weighed against projected cost increases, resources required to maintain program integrity, potential member and/or provider disruption in current utilization and prescribing patterns, and the likelihood of CMS approval of a SPA to implement this change.

Section 3

Policy and Operational Considerations

Currently, Medicaid may reimburse providers for costs associated with supplying Medicaid members OTC medications and medical supplies when medically necessary. DMAS typically reimburses durable medical equipment (DME) providers for medical supplies and medical nutrition products and pharmacy providers for select OTC medications pursuant to a prescription. Medicaid MCOs may choose to cover medical supplies and medical nutrition products through pharmacy providers, as well.

Mercer reviewed potential policy requirements for the State to implement direct payments to Medicaid recipients for purchase of OTC medications and medical supplies. DMAS may choose to implement this option with State-only funding without federal restrictions or parameters. Alternatively, there may be federal authority pathways that preserve FFP for OTC medications currently covered under the State Medicaid program, but there may be significant barriers with implementation.

Federal Authorities

The Medicaid statute broadly states that reimbursement for covered services is restricted to the Medicaid recipient or the individual or institution providing those services. Federal regulations at 42 CFR 447.25 explicitly describe conditions for direct payments to certain beneficiaries for physician or dentist services² but do not address OTC drugs. Federal regulations describing payment for drugs at 42 CFR 447, Subpart I are silent on options for direct reimbursement to Medicaid recipients. There are other instances when “payment” is made directly to Medicaid recipients for covered services (e.g., gas cards in some non-emergency medical transportation programs) or a maximum budget is established for obtaining those covered services (e.g., self-directed care for home and community benefit services).

While there are no identifiable federal regulatory prohibitions on direct payments to Medicaid recipients for OTC medication purchases, negotiations with CMS may be especially complex because of the uniqueness of the Plan’s approach: Mercer was unable to identify any other state Medicaid program that has implemented this reimbursement structure for OTC medications or medical supplies. In particular, there would need to be significant negotiation and work with CMS on program integrity guardrails to safeguard against FWA.

The Plan would need to address the following considerations prior to obtaining CMS approval:

- A state Medicaid program does not have the flexibility to offer beneficiaries a prepaid card to purchase OTC medications or supplies and still receive FFP.
- OTC medication and supply purchases would need to comply with other Medicaid requirements, as well as State regulatory and legal requirements, as applicable.
- FFP is only available for OTC medications for which a prescription has been issued by a provider acting within their state scope of practice prescribing laws. While the State legislative proposal requires such a prescription, allowing member-direct purchases removes the pharmacist from the purchase process by allowing

² <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-447/subpart-A/section-447.25>
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transactions to occur within a retail pharmacy but outside of the pharmacy counter, making the prescription requirement difficult, if not impossible, to comply with. It would be nearly impossible to require a prescription and allow for direct purchase at retail locations other than pharmacies.

- Only OTC medications supplied by drug manufacturers that participate in the Medicaid Drug Rebate Program (MDRP) are covered by Medicaid.³ Under this program Medicaid is guaranteed the “best price” or lowest available price after rebates. Similar to FFP above, member-direct purchases would not meet program requirements without requiring a prescription for these products.
- The State also maintains an OTC formulary in fee-for-service (FFS) Medicaid, some of which require additional authorizations. MCOs also develop and maintain OTC formularies. These same restrictions would apply to the direct purchasing program, which may create administrative barriers with implementation (e.g., prohibitions on specific brands of medication eligible for purchase or prior authorizations for specific medications). It is reasonable to assume that these purchasing restrictions would also create confusion among beneficiaries on what types and brands of medications they could purchase with their prepaid card.⁴ In some cases, brand name products are preferred on these formularies because the net price after rebates is cheaper than the price of closest generic, especially in the case of medical supplies such as diabetes test strips. These rebates would likely not be available through a direct purchase program, as requirements such as prescriptions would be difficult to meet.

Implementation of the Plan: Advantages/Disadvantages

State-Only Funded Plan

- Advantages:
 - Flexibility in program design and implementation.
 - No Federal CMS approval required to pursue the Plan.
- Disadvantages:
 - Loss of FFP funding currently in place for eligible utilized products (currently matching rate 56.85%), combined with cost increases (projected ~45% increase) to pay for those products under direct purchase.

State and Federally Funded Plan

- Advantages:
 - Maintain FFP funding currently in place for utilized products.
- Disadvantages:
 - Potential for CMS to deny request due to operational and program integrity concerns.
 - OTC card vendors may be unable to provide this benefit customized in a manner applicable to Medicaid and required by CMS.

³ <https://www.dmas.virginia.gov/for-providers/pharmacy-and-drug-formularies/>

⁴ [medallion-40-contract-07262018.pdf \(virginia.gov\)](#)

Conclusion

In considering implementing an OTC medication direct reimbursement program, there are several considerations and CMS technical assistance would be required. Any eligible purchases made by Medicaid beneficiaries would need to comply with the restrictions described above. Member-direct purchase of OTC medications using a prepaid card would need to restrict the purchase of non-covered items (e.g., medications produced by manufacturers that do not participate in the federal Drug Rebate Program, medications that require additional authorizations, and medications not on the State's or MCO's formulary).

There are several program integrity considerations that would need to be resolved prior to requesting federal approval. Additional detail is also needed to be defined for the Plan, such as clarifying what constitutes a qualifying "medical supply" as this is not defined in the State legislative proposal. If the intent of the proposal is to save money while preserving Medicaid FFP for OTC medications and supplies, the operational considerations may be too costly or difficult to support to result in any meaningful savings.

Section 4

Fiscal Impact and Considerations

Virginia Medicaid currently reimburses providers for OTC medications and medical supplies provided to members, with reimbursement amounts for various products serving as a reference point by which to estimate the fiscal impact of a direct OTC purchase plan. Specifically, Mercer estimated the potential fiscal impact of repricing Virginia Medicaid's reimbursement for provider claims for the purchase of select OTC medications and medical supplies to prices currently available for direct purchase of the same product. Fiscal impact projections outlined consider only product costs. Additional administrative costs that could be necessary for DMAS to implement and oversee such a plan were not quantified or included. If the Plan is implemented, Mercer recommends further evaluation to quantify the full magnitude of fiscal impact to include, at a minimum, the cost of procuring a benefit card vendor to administer the change, DMAS resources assigned to vendor oversight and program integrity activities, and potential loss of rebate discounts and federal dollars that are currently in place for the selected products.

Approach

List Selection

Mercer identified a list of potential OTC medications and medical supplies for inclusion in a direct-purchase program using MCO claims encounter data from calendar year (CY) 2021. Products were selected to include those: readily available for purchase at retail locations, commonly utilized by the Medicaid population, and with lower utilization – but potentially higher attainable savings – through direct purchase. According to the encounter data, most utilization was housed within 11 drug or medical supply therapeutic categories. Expenditures within these 11 therapeutic categories (\$18 million) represented around 40% of total expenditures on OTC medications and medical supplies (\$43 million). The 34 individual products with the highest utilization within these 11 therapeutic categories were directly analyzed within the analysis. Expenditures on those 34 products represented around 65% of total expenditures within the 11 therapeutic classes or around one-quarter (26%) of total expenditures on OTC medications and medical supplies.

Price Comparison

Mercer selected several pharmacy retailers that would be accessible to Medicaid recipients and potentially offer the most competitive prices for the selected list of OTC medications and medical supplies. Each of the 34 products selected above was manually researched for available pricing across multiple retail locations to determine an average of currently available direct purchase prices for each product. These direct purchase price averages were reviewed to ensure that no high-price outliers were included in the analysis. Once the researched prices and averages were documented, Mercer grouped the 34 products into the 11 therapeutic categories to determine the weighted cost differential, by percentage difference, between Medicaid-paid and direct purchase costs by therapeutic category. Medicaid-paid amounts included only pharmacy claims, due to data limitations preventing accurate determination of a per unit paid amount for DME claims. Note that Medicaid-

reimbursed amounts include a dispensing fee in addition to the cost of the medication/medical supply, as this total amount that the MCOs pay for a drug. No dispensing fee is paid in a direct purchase environment.

Cost Estimates

In order to estimate the magnitude and direction of potential fiscal impact, the weighted price differential percent was applied to the entire spend within the relevant therapeutic category. For example, Mercer researched pricing for the top six products by spend and utilization within the category of Allergy (oral allergy tablets available OTC). Mercer created an average price variance between the Medicaid cost and the researched retail costs for those six products, and applied the percent difference to the remaining spend within the Allergy category.

Results

Scenario 1: Reprice Medicaid Paid Cost with Direct Purchase Cost

Table 1 below lists the therapeutic category, a representative example product, the total dollar amount that Medicaid managed care spent for these products in CY2021, the total estimated cost assuming direct purchase, the percent increase or decrease it would cost to acquire products in each therapeutic category when switching from Medicaid reimbursement to direct purchase prices, and the projected net fiscal impact to implement the Plan should the percent increase or decrease apply to all products within a given therapeutic class. According to the data, there were no instances of Medicaid reimbursement by therapeutic category (inclusive of added dispensing fees) being higher than direct purchase costs for the same product. As such, all figures in the projected fiscal impact columns are positive, and represent the potential fiscal impact to the Medicaid program if the selected products were purchased directly by Medicaid members.

Table 1: Summary of Fiscal Impact in Selected Therapeutic Categories

Therapeutic Category	Example Product	Medicaid Paid	Direct Purchase Cost	Direct Purchase Difference	Projected Fiscal Impact
Allergy	Cetirizine (generic Zyrtec)	\$2,455,000	\$5,700,000	132%	\$3,245,000
Diabetic Supplies (Test Strips)	OneTouch Test Strips	\$11,285,000	\$14,074,000	25%	\$2,789,000
Diabetic Supplies (Lancets)	OneTouch Lancets	\$553,000	\$1,066,000	93%	\$513,000
Blood Pressure Monitors*	Blood Pressure Monitor	\$20,000	\$21,000	5%	\$1,000
Eye Drops	Alaway Eye Drops	\$116,000	\$135,000	16%	\$19,000
Incontinence Supplies*	Depend Underwear	\$2,500	\$3,000	20%	\$500

Therapeutic Category	Example Product	Medicaid Paid	Direct Purchase Cost	Direct Purchase Difference	Projected Fiscal Impact
Infant Formulas*	Elecare Infant Formula	\$60,000	\$78,000	30%	\$18,000
Iron Replacement	Ferrous Sulfate Enteric Coated	\$366,000	\$578,000	58%	\$212,000
Laxatives	Miralax Powder	\$1,722,000	\$2,242,000	30%	\$520,000
Blood Thinners (Aspirin)	Aspirin Chewable	\$266,000	\$308,000	16%	\$42,000
Smoking Cessation	Nicotine Patch	\$1,510,000	\$2,326,000	54%	\$816,000
TOTAL within the 11 therapeutic classes analyzed		\$18,357,000	\$26,532,000	45%**	\$8,175,000
TOTAL across all OTC medications/medical supplies		\$42,991,000	\$44,906,000	45%**	\$19,145,000

* Analysis is limited to pharmacy claims only, therefore the magnitude of therapeutic product categories typically reimbursed through DME provider claims appear artificially low.

** Extrapolates from weighted average of direct purchase difference calculated from analysis of 34 products

Table 1 shows that, in aggregate, across all therapeutic categories researched, the retail cost to have members directly purchase select OTC medications and medical devices would be approximately 45% more expensive than it would be to cover the same products under the current Medicaid structure.

Conclusion

This report highlighted two pathways by which DMAS could implement a direct OTC medication and medical supplies purchase Plan – by using State-only funds and by using a combination of State and federal funds – as well as several considerations that would need to be considered to move forward. Focusing on the pathway that leverages Federal Financial Participation, Mercer identified a substantial increase in the cost to provide OTC medications and medical supplies to the Medicaid population if purchased directly by members. Additional challenges to implementing a direct OTC medication and medical supplies purchase Plan include: lack of any similar programs in place for Medicaid in other states, which could impact the likelihood of CMS approval for such a Plan; maintaining program integrity; removing the pharmacist from the purchase process which could make the Plan’s requirement for an OTC product prescription difficult, if not impossible, to comply with; and non-drug fiscal impact to the program including, but not limited to, vendor procurement and cost, additional administrative costs, rebate changes, impacts to managed care capitation rates, and provider or premium taxes. Should the Plan move forward, Mercer recommends that DMAS performs an extended review, prior to SPA submission to CMS, of these considerations.



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