Report Required by HB 382, Chapter 217 of the 2023 Acts of Maryland

Maryland Department of Health and Prescription Drug Affordability Board - Managed Care Organizations and Prescription Drug Claims - Study

MSAR # 14994

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I. Introduction

Pursuant to the requirements of House Bill 382, the Maryland Department of Health (MDH) respectfully submits this report, which addresses:

1. A review of the current National Average Drug Acquisition Cost (NADAC) Fee-For-Service (FFS) reimbursement methodologies and related Federal requirements;
2. A review of the total amount that Maryland Medicaid HealthChoice managed care organizations (MCOs) paid pharmacies for prescription drug claims in calendar years (CY) 2021 and 2022 versus what the total amount paid to pharmacies would have been if prescription drug claims had been reimbursed at Maryland Medicaid FFS rates; and
3. A review of pharmacy business openings and closures for CY 2021 and CY 2022.

The Maryland Medicaid Program serves more than 1.7 million low-income Marylanders. More than 86 percent of Maryland Medicaid participants receive their care through HealthChoice, Maryland's statewide mandatory managed care program implemented in 1997 under the authority of Section 1115 of the Social Security Act. The HealthChoice program seeks to improve access and quality of care to Medicaid participants by providing comprehensive, patient-focused, coordinated care through Managed Care Organizations (MCOs). Eligible Medicaid participants enroll in the MCO of their choice and select a primary care provider (PCP) to oversee their medical care. MCOs receive a capitation payment in exchange for providing care to their Medicaid participants. Certain drugs are carved out of the MCO benefit package and provided on a Fee-For-Service (FFS) basis, including drugs used to treat specialty behavioral health conditions and HIV/AIDS. Based on preliminary estimates, MDH anticipates that pharmacy costs attributable to the HealthChoice program exceeded $1.110 billion for CY 2021 and $1.234 billion in CY 2022, while FFS costs were approximately $574.1 million and $615.5 million, respectively, in each of the aforementioned calendar years.

Maryland, like other states, elected to cover pharmacy services as part of its Medicaid benefit package, although it is not required to by the federal Centers for Medicare and Medicaid Services (CMS). Under the authority of Section 1927 of the Social Security Act, Medicaid programs have the option to cover outpatient drugs. Pharmacy reimbursement methodologies vary by state, subject to certain federal requirements. Pharmaceutical drug manufacturers must participate in the federal rebate program for a drug/product to qualify for Medicaid federal matching funds. Once a pharmaceutical drug manufacturer agrees to participate in the federal rebate program, state Medicaid programs are required to cover almost all Food and Drug Administration (FDA) approved drugs those manufacturers produce.

Maryland FFS reimburses pharmacies based on a two-part formula consisting of the ingredient cost of the drug/product and the Professional Dispensing Fee. Following regulatory changes in 2016 required under the Affordable Care Act (ACA), effective April 2017, Maryland FFS began reimbursing for drugs using NADAC as a proxy for Average Acquisition Cost (AAC). Prior to 2017, Maryland FFS reimbursed pharmacies on an Estimated Acquisition Cost (EAC) basis.

II. Reimbursement Methodologies

A. Overview of Current Federal Requirements

In early 2016, CMS released the final rule for the Covered Outpatient Drug Rule.[1] Included in the rule was a requirement for states' FFS programs to change their outpatient drug reimbursement to an AAC system. Prior to this regulation change, the state basis for pharmaceutical reimbursement was the EAC. AAC is determined by the pharmacy providers' actual price paid to acquire drugs marketed or sold by specific manufacturers.[2] The shift from EAC to AAC was considered necessary by CMS as it represents a more accurate reference price to be used by states to reimburse providers for drugs.[3]

CMS further changed the term "dispensing fees" to "Professional Dispensing Fees" to reflect the pharmacist's professional services and costs to dispense a drug to a Medicaid participant.[4] CMS requires Professional Dispensing Fees to be consistent with efficiency, economy, and quality of care while assuring sufficient participant access.[5] The Professional Dispensing Fees and ingredient cost reimbursement must be considered to ensure that total reimbursement to the pharmacy provider is calculated in accordance with requirements in the ACA.[6]

B. Maryland's Reimbursement System

Maryland FFS reimburses pharmacies based on a two-part formula consisting of the ingredient cost of the drug and the Professional Dispensing Fee. When federal regulatory changes became effective in April 2017, Maryland FFS began reimbursing drugs using NADAC as a proxy for AAC. NADAC is derived by surveying randomly selected, retail community pharmacies nationwide on a monthly basis to establish the national average invoice price for drugs.[7] The NADAC files are published on a monthly basis and updated weekly.[8]

Under Maryland's approach, the Medicaid reimbursement rate is the NADAC rate or the provider's Usual and Customary charges, whichever is lower. If a NADAC rate does not exist for a drug, reimbursement is tied to whichever is lowest between the Wholesale Acquisition Cost

[1] https://www.govinfo.gov/app/details/FR-2016-02-01/2016-01274
[2] Id.
[3] Id.
[4] CMS-2345-FC.
[5] Id.
[6] Id.
[7] Department of Health and Human Services, Centers for Medicare and Medicaid Services, Implementation of the Covered Outpatient Drug Final Regulation Provisions Regarding Reimbursement for Covered Outpatient Drugs in the Medicaid Program, Feb. 11, 2016.
[8] https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html

(WAC)[9], the federal upper limit (FUL)[10], and the State Actual Acquisition Cost (SAAC)[11] or the provider's Usual and Customary charges[12]. As of February 1st, 2021, the Professional Dispensing Fee for both brand-name and generic drugs dispensed to FFS participants is $10.67. The Professional Dispensing Fee for brand-name and generic drugs dispensed to FFS participants residing in nursing home facilities is $11.67. (The FFS professional dispensing fee for claims of drugs purchased through the 340B drug purchase program is $12.12.)

Table 1: Maryland Medicaid FFS Pharmacy Reimbursement Methodologies, Current

	Current NADAC-based FFS Pharmacy Reimbursement Methodology*
Brand-name Drugs	*Lower of:* ● NADAC ● Usual and Customary charges *If no NADAC exists, then the lower of:* ● WAC+0% ● SAAC ● Usual and Customary charges
Generic Drugs	*Lower of:* ● NADAC ● Usual and Customary charges *If no NADAC exists, then the lower of:* ● WAC+0% ● FUL ● SAAC
Professional Dispensing Fee	● $10.67 for brand-name and generic drugs ● $11.67 for brand-name and generic drugs dispensed to FFS participants residing in nursing home facilities

* This table outlines MDH's primary reimbursement methodologies. However, for a small subset of claims (e.g., 340B drugs) the methodology is slightly different (see COMAR 10.09.03.07).

III. Maryland Reimbursement Rate Comparison: MCO and FFS Data

All nine MCOs utilize pharmacy benefits managers (PBMs) in their respective programs. PBMs provide many services for the MCOs, including pharmacy provider network management, maintaining an in-network pharmacy directory, participant eligibility management, creating

[9] The WAC is the published amount for a drug by the manufacturer for sale via a wholesaler.

[10] The FUL is a drug pricing benchmark based on a formula derived from no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly Average Manufacturer Prices (AMP) for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis

[11] SAAC is a Maryland Medicaid specific survey capturing the ingredient cost of any drug based upon a survey of providers' actual prices paid to acquire a drug marketed or sold to specific manufacturers.

[12] Usual and Customary charges are the "cash" price that individuals without drug coverage would pay a retail pharmacy.

identification cards and welcome communications to new participants, claims processing, drug utilization review, call center helpdesks, formulary/therapeutic management programs, financial services (including pharmacy reimbursement), drug rebate management, and prior authorization management. The use of PBMs may result in cost savings and added efficiencies. Contrary to the MCOs, MDH does not use a PBM for its FFS program and instead utilizes a Point-of-Sale (POS) electronic claims processing system through a vendor, Conduent State Healthcare, LLC. MDH's POS vendor does not negotiate rebates and costs, nor do they perform financial services. The vendor processes claims, provides a call center help desk, makes prior authorization determinations, provides clinical services, and monitors drug utilization based on MDH's rules and regulations. Moreover, MDH utilizes Provider Synergies, LLC, an affiliate of Magellan Medicaid Administration, to negotiate additional supplemental rebates and assist in creating the Preferred Drug List. MDH utilizes a third vendor, Keystone Peer Review Organization, Inc., to oversee all aspects of retrospective drug utilization review that are not conducted by MDH's POS vendor. Furthermore, MDH manages its own pharmacy provider network.

The tables in Appendix A provide an overview of all pharmacy claims paid by MCOs in CY 2021 and CY 2022. The tables summarize the ingredient costs, dispensing fees, and total reimbursement associated with these claims. Additionally, each table summarizes the amounts MCOs would have paid for each of the above cost categories if the current FFS reimbursement methodologies were used to calculate the different reimbursement rates.

A. Ingredient Cost

In general, the total amount paid in ingredient costs was higher than what it would have been if the MCO pharmacy claims were paid using the current FFS reimbursement methodology. In both CY 2021 and CY 2022, this observation was true for eight out of the nine MCOs as well as for all nine MCOs combined. Only one MCO paid less in ingredient costs than it would have using the FFS methodology. Additional observations include the following:

- The total amount paid in ingredient costs for all of the MCO pharmacy claims was approximately $1.103 billion in CY 2021 and approximately $1.228 billion in CY 2022. If these claims had been paid using the FFS methodology, the total amount paid in ingredient costs for all of the MCO pharmacy claims would have been approximately $1.076 billion in CY 2021 and approximately $1.195 billion in CY 2022.
- The average ingredient cost per claim across all of the MCO pharmacy claims was $104.50 for CY 2021 and $109.78 for CY 2022. If these claims had been paid using the FFS methodology, the average ingredient cost per claim would have been $101.92 in CY 2021 and $106.84 in CY 2022.
- The MCOs paid an average of $2.58 or 2.5% more in ingredient costs per pharmacy claim in CY 2021 and $2.94 or 2.8% more per pharmacy claim in CY 2022 compared to the FFS methodology.

B. Professional Dispensing Fee

In both CY 2021 and CY 2022, all nine of the MCOs paid less in Professional Dispensing Fees than they would have using the current FFS reimbursement methodology. Additional observations include the following:

- The total amount paid in Professional Dispensing Fees for all of the MCO pharmacy claims was approximately $7.0 million in CY 2021 and approximately $6.6 million in CY 2022. If these claims had been paid using the FFS methodology, the total amount paid for all MCO pharmacy claims would have been approximately $111.0 million in CY 2021 and approximately $117.7 million in CY 2022.
- The average Professional Dispensing Fee paid per claim across all of the MCO pharmacy claims was $0.67 for CY 2021 and $0.59 for CY 2022. If these claims had been paid using the FFS methodology, the average Professional Dispensing Fee paid per claim would have been $10.52 in both CY 2021 and CY 2022.
- The MCOs paid an average of $9.85 or 93.6% less per pharmacy claim in CY 2021 and $9.93 or 94.4% less per pharmacy claim in CY 2022 in Professional Dispensing Fees compared to the FFS methodology.

C. Total Reimbursement

Total reimbursement is calculated by adding the ingredient cost with the Professional Dispensing Fee for each claim. In CY 2021, seven out of nine of the MCOs paid less in total reimbursement for all MCO pharmacy claims than they would have if they had used the current FFS reimbursement methodology. In CY 2022, eight of the nine MCOs paid less in total reimbursement. While two MCOs in CY 2021 and one MCO in CY 2022 paid more in total reimbursement than they would have using the FFS methodology, the total amount paid in total reimbursement across all MCO pharmacy claims was less than it would have been using the FFS methodology for both CY 2021 and CY 2022. Additional observations include the following:

- The total amount paid in total reimbursement costs for all of the MCO pharmacy claims was approximately $1.110 billion in CY 2021 and approximately $1.234 billion in CY 2022. If these claims had been paid using the FFS methodology, the total amount paid in ingredient costs for all of the MCO pharmacy claims would have been approximately $1.187 billion in CY 2021 and approximately $1.313 billion in CY 2022.
- The average total reimbursement per claim across all of the MCO pharmacy claims was $105.17 for CY 2021 and $110.37 for CY 2022. If these claims had been paid using the FFS methodology, the total reimbursement per claim would have been $112.44 in CY 2021 and $117.37 in CY 2022.
- Based on the difference between the average total reimbursement per MCO pharmacy claim and the average total reimbursement per claim if the FFS methodology were used, the MCOs would have paid an average of $7.27 more in total reimbursement per pharmacy claim in CY 2021 and $7.00 more per claim in CY 2022.

IV. Commercial Dispensing Fees

In August 2021, the average commercial market dispensing fee was less than $2.00 per pharmacy claim.[13] Commercial dispensing fees have historically been less than $1.00 per pharmacy claim;[14] This does not cover the true cost of dispensing a prescription in a community pharmacy. As a result of nominal dispensing fees, profitable pharmacies have depended on an ingredient cost margin obtained through buying a drug at a lower cost than the amount reimbursed by the PBM through the pharmacy network contract.[15]

V. Pharmacy Business Openings and Closures

The Maryland Board of Pharmacy provided MDH with a report summarizing the total number of pharmacies that opened and closed for business in the State of Maryland in CY 2021 and CY 2022. MDH compared this report with Maryland Medicaid pharmacy enrollment records to identify any pharmacies that were enrolled in Maryland Medicaid during this time period. Based on this comparison, in CY 2021 there were 20 pharmacies that opened and were enrolled in Maryland Medicaid; in contrast, there were nine pharmacies that were enrolled in Maryland Medicaid which closed during this time period. In CY 2022, there were 20 pharmacies that opened and were enrolled in Maryland Medicaid; in contrast, there were six pharmacies that were enrolled in Maryland Medicaid which closed during this time period. These figures exclude pharmacies that were pre-existing and "opened" or "closed" during either of these calendar years on the basis of new ownership or the issuance of a new Maryland Board of Pharmacy license.

VI. Conclusions

While the majority of the MCOs paid slightly more in ingredient costs for their pharmacy claims in both CY 2021 and CY 2022, all of the MCOs paid significantly less in Professional Dispensing Fees for the same years as compared to the current FFS reimbursement methodology. Appendix B shows the projected fiscal impact on the MCOs if the Dispensing Fees were to increase by various dollar increments, including the current FFS Professional Dispensing Fee rate of $10.67 per claim, based on the CY 2022 MCO pharmacy claims data outlined in Appendix A.

If the methodology that the MCOs use to pay pharmacy claims were to change to that of the FFS model for both the ingredient cost and the dispensing fee, the fiscal impact to Maryland's Medicaid program would have been approximately $78.3 million in total funds in calendar year 2022.

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[13] https://www.pcmanet.org/mandating-pharmacy-reimbursement-increase-spending/#:~:text=The%20average%20dispensing%20fee%20in,the%20state's%20Medicaid%20FFS%20rate.

[14] http://www.insidepatientcare.com/issues/2016/march-2016-vol-4-no-3/404-cms-introduces-professional-dispensing-fees-for-pharmacies

[15] Id.

Appendix A: Summary of Fiscal Impact Utilizing Fee-for-Service (FFS) Methodology, All Pharmacies
Based on Maryland HealthChoice MCO pharmacy claims with dates of service between 1/1/2021 and 12/31/2022

CY 2021

		Ingredient Amount		Dispensing Fee		Total Reimbursement		Impact
	Total Number of Claims	Actual Paid per Claims Data	Repriced with FFS Methodology	Actual Paid per Claims Data	Repriced with FFS Methodology	Total - Actual Paid per Claims Data	Total - Repriced FFS Methodology	Total Impact
Total	10,557,136	$1,103,230,027	$1,076,011,257	$7,055,208	$111,037,028	$1,110,285,235	$1,187,048,285	$76,763,050
Average Per Claim		$104.50	$101.92	$0.67	$10.52	$105.17	$112.44	$7.27

CY 2022

		Ingredient Amount		Dispensing Fee		Total Reimbursement		Impact
	Total Number of Claims	Actual Paid per Claims Data	Repriced with FFS Methodology	Actual Paid per Claims Data	Repriced with FFS Methodology	Total - Actual Paid per Claims Data	Total - Repriced FFS Methodology	Total Impact
Total	11,185,503	$1,227,895,133	$1,195,102,928	$6,626,309	$117,724,738	$1,234,521,442	$1,312,827,666	$78,306,224
Average Per Claim		$109.78	$106.84	$0.59	$10.52	$110.37	$117.37	$7.00

The following assumptions were used within the fiscal impact methodology:

- The model relies on paid pharmacy claims from the nine HealthChoice plans with dates of service between January 1, 2021, and December 31, 2022.
- Claims for compounded medications were not included in this analysis.
- Claims that had been reimbursed through the HealthChoice program based on a pharmacy's submitted usual and customary charge (UCC) were included in the analysis; however, the claims reprice was modeled to not yield any difference in net payment amount since this would be a function of comparing the provider's UCC as compared to the FFS reimbursement methodology.
- Claims which reported a third-party liability (TPL) amount were included in the analysis; however, the fiscal impact for these claims was calculated as zero since claims with TPL should primarily be reimbursed by Medicaid based on the residual amount after the third-party pays (e.g., patient responsibility amounts associated with co-payment or co-insurance).

Appendix A: Summary of Fiscal Impact Utilizing Fee-for-Service (FFS) Methodology, All Pharmacies *(cont.)*

- Claims for clotting factor products were not included in the analysis since insufficient data was available to reproduce the FFS payment methodology.

- Claims for COVID-19 vaccinations were not included in this analysis since claims payments represent administration fees only since the cost of the vaccine was subsidized by the federal government during this time period.

- Claims which were indicated to have been dispensed with drugs purchased through the 340B Drug Pricing Program did not have ingredient costs repriced based on the FFS methodology. However, the FFS professional dispensing fee of $12.12 was applied to claims submitted by 340B covered entities and Federally Qualified Health Centers (FQHCs).

- HealthChoice claims for over-the-counter (OTC) products were repriced utilizing an average of state AAC rates obtained from other states (unless any of the preceding conditions relating to UCC, TPL, etc. were met).

Appendix B: Summary of Projected Fiscal Impact on MCOs Based on Incremental Adjustments to the Professional Dispensing Fee per Pharmacy Claim

Based on the total number of Maryland HealthChoice pharmacy claims in CY 2022 as outlined in Appendix A

Modeled Increase in Average Dispensing Fee Paid by MCOs	Estimated Fiscal Impact on Total Dispensing Fees Paid
$1.00	$11.19 million
$2.00	$22.37 million
$3.00	$33.56 million
$4.00	$44.74 million
$5.00	$55.93 million
$6.00	$67.11 million
$7.00	$78.30 million
$8.00	$89.48 million
$9.00	$100.67 million
$10.00	$111.85 million
$10.08*	$112.74 million
$11.00	$123.04 million

*An increase of $10.08 from the CY 2022 average dispensing fee of $0.59 would be the equivalent to $10.67, the current FFS professional dispensing fee.