

Audit Report

Maryland Department of Health Pharmacy Services

August 2024

Public Notice

In compliance with the requirements of the State Government Article Section 2-1224(i), of the Annotated Code of Maryland, the Office of Legislative Audits has redacted cybersecurity findings and related auditee responses from this public report.



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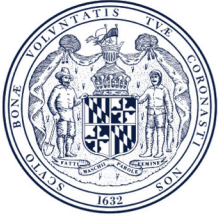
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DEPARTMENT OF LEGISLATIVE SERVICES
OFFICE OF LEGISLATIVE AUDITS
MARYLAND GENERAL ASSEMBLY

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August 9, 2024

Brian S. Tanen, CPA, CFE
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Senator Clarence K. Lam, M.D., Senate Chair, Joint Audit and Evaluation Committee
Delegate Jared Solomon, House Chair, Joint Audit and Evaluation Committee
Members of Joint Audit and Evaluation Committee
Annapolis, Maryland

Ladies and Gentlemen:

We have conducted a fiscal compliance audit of the Maryland Department of Health (MDH) pharmacy services for the period beginning July 1, 2019 to December 31, 2022. MDH provides pharmacy services under the Medical Care Programs Administration (MCPA) and the Prevention and Health Promotion Administration (PHPA) as indicated through the following five programs:

- Maryland Medicaid Pharmacy Program (MCPA)
- Medicaid Managed Care Program (MCPA)
- Kidney Disease Program (PHPA)
- Maryland AIDS Drug Assistance Program (PHPA)
- Breast and Cervical Cancer Diagnosis and Treatment Program (PHPA)

Our audit found that MCPA did not ensure that manually processed pharmacy claims for the Maryland Medicaid Pharmacy Program were proper. While the majority of pharmacy claims are paid at established rates, certain prescription drugs require an MCPA employee to determine the allowable drug cost based on criteria provided in State regulations, and to manually record the price into MDH's point-of-sale system to process the claim. Our test of 15 manual claims processed between June 2020 and November 2022 disclosed that 11 claims were overpaid by approximately \$397,000 because the employee who processed the claim entered an amount that exceeded the allowable drug cost.

Our audit also found that MDH had not established procedures to ensure that prescribing providers were licensed prior to approving pharmacy claims for payment. In addition, our audit disclosed that MCPA did not perform audits of three of the four fee-for-service programs and did not use available data to identify improper claims. The audits would perform manual verifications that are

not possible through MDH's automated pharmacy claims processing system, such as to ensure that a valid prescription was issued, properly filled, and actually picked up by a recipient.

Furthermore, MDH's controls over Maryland AIDS Drug Assistance Program drug rebates were not sufficient, resulting in significant rebates not being obtained timely. MDH receives prescription drug rebates under two federal programs which are paid by drug manufacturers for covered outpatient drugs dispensed to approved clients under each MDH program that provides pharmacy services. Our audit disclosed that MDH did not ensure that drug manufacturers provided timely and proper drug rebate payments and as a result did not pursue collection of certain outstanding rebates, including \$1.5 million in rebates outstanding for at least one year.

Our audit also disclosed a cybersecurity-related finding. However, in accordance with the State Government Article, Section 2-1224(i) of the Annotated Code of Maryland, we have redacted the finding from this audit report. Specifically, State law requires the Office of Legislative Audits to redact cybersecurity findings in a manner consistent with auditing best practices before the report is made available to the public. The term "cybersecurity" is defined in the State Finance and Procurement Article, Section 3.5-301(b), and using our professional judgment we have determined that the redacted finding falls under the referenced definition. The specifics of the cybersecurity finding were previously communicated to those parties responsible for acting on our recommendations.

Finally, our audit included a review to determine the status of the seven findings contained in our preceding audit report. For the non-cybersecurity-related findings we determined that MDH satisfactorily addressed three of those six findings. The remaining three findings are repeated in this report.

MDH's response to this audit, on behalf of MCPA and PHPA, is included as an appendix to this report. We reviewed the response and noted agreement to our findings and related recommendations, and while there are other aspects of MDH's response which will require further clarification, we do not anticipate that these will require the Joint Audit and Evaluation Committee's attention to resolve. Consistent with State law, we have redacted the elements of MDH's response related to the cybersecurity audit finding.

We wish to acknowledge the cooperation extended to us during the audit by MCPA and PHPA. We also wish to acknowledge MDH's, MCPA's, and PHPA's willingness to address the audit issues and implement appropriate corrective actions.

Respectfully submitted,

Brian S. Tanen

Brian S. Tanen, CPA, CFE
Legislative Auditor

Table of Contents

| | |
|--|----|
| Background Information | 7 |
| Agency Responsibilities and Audit Scope | 7 |
| Ransomware Security Incident | 10 |
| Status of Findings From Preceding Audit Report | 10 |
| Findings and Recommendations | 12 |
| Claims Processing | |
| Finding 1 – The Medical Care Programs Administration did not ensure manually processed pharmacy claims were proper, resulting in overpayments of approximately \$397,000 related to 11 of the 15 claims we tested. | 12 |
| * Finding 2 – The Maryland Department of Health (MDH) did not have procedures to ensure that prescribing providers were licensed prior to approving pharmacy claims for payment. | 13 |
| * Finding 3 – MDH did not audit three of the four fee-for-service programs’ pharmacy claims, did not analyze claim reversals, and did not use available drug utilization claims data to identify improper claims. | 15 |
| Rebates | |
| * Finding 4 – MDH did not ensure that drug manufacturers provided timely and proper drug rebate payments for the Maryland AIDS Drug Assistance Program. | 18 |
| System Security | |
| Finding 5 – Redacted cybersecurity-related finding | 20 |
| Audit Scope, Objectives, and Methodology | 21 |

* Denotes item repeated in full or part from preceding audit report

Exhibit 1 – Listing of Most Recent Office of Legislative Audits Fiscal Compliance Audits of Maryland Department of Health Units as of June 2024 25

Agency Response Appendix

Background Information

Agency Responsibilities and Audit Scope

The Maryland Department of Health (MDH), through its Medical Care Programs Administration (MCPA) and Prevention and Health Promotion Administration (PHPA), operates four significant fee-for-service programs under which they pay for prescription drugs:

- Maryland Medicaid Pharmacy Program
- Kidney Disease Program
- Maryland AIDS Drug Assistance Program
- Breast and Cervical Cancer Diagnosis and Treatment Program

In addition, pharmacy claims are paid by the nine Managed Care Organizations (MCOs) under contract with the State under the Medicaid Managed Care Program. Each of the five programs provide pharmaceutical benefits to eligible recipients and is administered independently.

The scope of this pharmacy audit included the administration and monitoring of claims adjudication and processing, security and controls, reimbursement rates, audits, and rebate management under the aforementioned four fee-for-service programs. According to MDH records, fiscal year 2022 claim payments for these four programs totaled \$631 million (see Figure 1 on page 8). Additionally, the scope included the rebate management and monitoring of the nine MCOs.

Medical Care Programs Administration (MCPA)

MCPA operates under both Title XIX of the federal Social Security Act (Medicaid) and State law. Medicaid is a joint federal and State entitlement program for low-income individuals. The program is administered by the states, which are required to provide healthcare coverage, including optional pharmacy services, to all applicants who meet the program's eligibility criteria.

MCPA administers the Maryland Medicaid Pharmacy Program (MMPP) which provides pharmacy services to Medicaid recipients through a fee-for-service business model. MMPP has oversight of all policies and operations related to pharmacy services such as claims processing, preferred drug listing, and reimbursement methodology. MMPP covers all point-of-sale pharmacy services for fee-for-service recipients carved out of the MCO benefits.

MCPA also oversees the Medicaid Managed Care Program which provides pharmacy services to Medicaid recipients who are enrolled in the Managed Care

Program. MCPA contracts with MCOs to provide healthcare, including pharmacy services, to enrolled Medicaid recipients in exchange for specified capitation payments.¹ Each MCO independently contracted with one of six Pharmacy Benefit Managers that were responsible for administering virtually all aspects of the MCO pharmacy activities including pharmacy network management, claims processing, and payments to the pharmacies.

Prevention and Health Promotion Administration (PHPA)

PHPA protects, promotes, and improves the health and well-being of Marylanders and their families through the provision of public health leadership and community-based public health efforts. PHPA administers three programs with pharmacy services:

- Maryland AIDS Drug Assistance Program (MADAP) – MADAP is a state and territory-administered program authorized under Part B of the Ryan White HIV/AIDS Program, a federal program codified under Title XXVI of the Public Health Services Act. MADAP helps low to moderate-income Maryland residents with HIV disease who have limited or no coverage from private insurance or Medicare pay for HIV/AIDS related drugs. Individuals cannot be enrolled in both Medicaid and MADAP.
- Breast and Cervical Cancer Diagnosis and Treatment Program (BCCDTP) – BCCDTP is a State-run program that provides breast cancer and cervical cancer diagnostic and treatment services to eligible low-income Maryland residents, including medical and pharmacy services.
- Kidney Disease Program (KDP) – KDP is a State-run program designed to help low to moderate-income Maryland residents pay for the treatment costs associated with end stage renal disease. KDP provides medical and pharmacy services to eligible individuals and is a payer of last resort after all other options, such as private insurance, Medicare, and Medicaid have been exhausted. Starting in October 2019, the administration of KDP was transferred from MCPA to PHPA.

Pharmacy Vendor

Since August 2006, MDH has contracted with a pharmacy vendor to provide a point-of-sale electronic claims management system (pharmacy vendor system). The original contract was modified and extended multiple times and ultimately ended May 31, 2021. In October 2019, MDH competitively awarded a contract

¹ Capitation payments are included within the scope of our audit of MCPA's Managed Care Program.

valued at approximately \$73.1 million (including renewal options) to the incumbent pharmacy vendor to develop, implement, and operate a new pharmacy vendor system. MDH continued to use its legacy system until the new pharmacy vendor system was implemented in October 2022.

The new pharmacy vendor system includes pharmacy claims processing, where claims submitted by pharmacies are adjudicated in real time for MMPP, MADAP, BCCDTP, and KDP. Claims processing includes functionality such as verifications of recipient eligibility, reviewing requests for prior authorizations, and identifying other parties, such as private insurers, that may be responsible for payment. Furthermore, the new pharmacy vendor system performs drug utilization reviews and supports drug manufacturer rebate programs, such as by capturing and reporting MDH's detailed utilization activity to drug manufacturers so that MDH can obtain rebates.

The pharmacy vendor system does not provide claims processing services to the MCOs under the Medicaid Managed Care Program. Rather, each MCO is responsible for maintaining its own system to process pharmacy claims. However, the pharmacy vendor system is used to perform rebate processing for MCO pharmacy claims.

Pharmacy Payments

MMPP, MADAP, BCCDTP, and KDP payments are based on a fee-for-service model under which payments are made directly to pharmacies by MDH after claims have been adjudicated through the pharmacy vendor system. During fiscal year 2022, MDH paid approximately 5.2 million pharmacy claims totaling approximately \$631 million on behalf of 361,000 recipients. In addition, MDH makes monthly capitation payments for each Medicaid recipient enrolled in the MCO. According to agency records, the portion of capitation rates associated with pharmacy services for calendar year 2022 totaled approximately \$711.5 million.

Pharmacy Rebates

Certain drugs purchased under these programs and by MCOs were eligible for drug manufacturer rebates. According to State accounting records, MDH received rebates totaling approximately \$402.2 million for its fee-for-service pharmacy purchases during fiscal year 2022 (see Figure 1 on the following page) and according to MDH records, it received \$508 million in rebates for pharmacy purchases made by MCOs during calendar year 2022. The rebate amount is based on the total cost of the drug regardless of the portion paid by MDH, which resulted in MADAP receiving rebates in excess of the amounts paid.

Figure 1
Fiscal Year 2022 Fee-For-Service Claims and Rebates by Program

| Program | Number of Recipients | Number of Claims | Claim Payments | Rebates Received | Net Payments |
|----------------|-----------------------------|-------------------------|-----------------------|-------------------------|----------------------|
| MMPP | 355,083 | 5,073,694 | \$597,193,372 | \$355,569,550 | \$241,623,822 |
| MADAP | 5,049 | 100,002 | 31,461,854 | 45,249,199 | (13,787,345) |
| BCCDTP | 314 | 2,270 | 1,763,151 | 783,900 | 979,251 |
| KDP | 759 | 14,553 | 626,493 | 583,298 | 43,195 |
| Total | 361,205 | 5,190,519 | \$631,044,870 | \$402,185,947 | \$228,858,923 |

Source: MDH records

Ransomware Security Incident

In December 2021, MDH experienced a broad security incident resulting from a ransomware attack.² This incident affected the entire MDH computer network and disrupted information technology (IT) operations for all MDH servers and end user computers, resulting in substantial impact on all MDH business operations, including MCPA and PHPA. MDH notified the Department of Information Technology’s (DoIT) Office of Security Management, which initiated incident response measures. Various other parties were informed of this incident or engaged for recovery efforts. DoIT concluded that no evidence existed indicating that sensitive or regulated information had been improperly acquired.

The incident, response measures, and related controls were subject to review as part of our recent audit of the MDH Office of the Secretary and Other Units (report dated October 19, 2023). This incident did not significantly impact our audit, and we were able to obtain information needed to satisfy our audit objectives and related conclusions.

Status of Findings from Preceding Audit Report

Our audit included a review to determine the status of the seven findings contained in our preceding audit report dated August 31, 2020. As disclosed in Figure 2 (on the following page), for the non-cybersecurity-related findings, we determined that MDH satisfactorily addressed three of those six findings. The remaining three findings are repeated in this report.

² As defined by the Federal Department of Homeland Security Cybersecurity and Infrastructure Security Agency, ransomware is an ever-evolving form of malware designed to encrypt files on a device, rendering any files and the systems that rely on them unusable. Malicious actors then demand ransom in exchange for decryption.

Figure 2
Status of Preceding Findings

| Preceding Finding | Finding Description | Implementation Status |
|--------------------------|--|--|
| Finding 1 | The Maryland Department of Health (MDH) did not establish financial and reporting requirements and did not monitor pharmacy services provided through Managed Care Organizations. | Not Repeated |
| Finding 2 | MDH did not perform audits of certain programs' pharmacy claims and did not use available data to identify improper claims. | Repeated (Current Finding 3) |
| Finding 3 | MDH did not have procedures to ensure the pharmacy vendor obtained the required documentation and properly authorized high risk and high cost pharmacy claims for three of the four programs. | Not Repeated |
| Finding 4 | MDH did not have procedures to ensure that prescribing providers were licensed prior to approving pharmacy claims for payment. | Repeated (Current Finding 2) |
| Finding 5 | MDH did not submit certain Maryland AIDS Drug Assistance Program (MADAP) drug utilization data to two drug manufacturers resulting in the untimely collection of approximately \$20.6 million in rebates including \$1.6 million that is no longer collectable, and lost investment income totaling approximately \$187,800. | Not Repeated |
| Finding 6 | MDH did not ensure that drug manufacturers provided timely and proper MADAP drug rebate payments and as a result did not pursue collection of \$7.3 million in outstanding rebates. | Repeated (Current Finding 4) |
| Finding 7 | MDH did not obtain adequate assurance that the pharmacy vendor had sufficient security over its information system to protect sensitive data such as personally identifiable information and protected health information maintained by the vendor. | Status Redacted ³ |

³ Specific information on the current status of this cybersecurity-related finding has been redacted from the publicly available report in accordance with State Government Article, Section 2-1244(i) of the Annotated Code of Maryland.

Findings and Recommendations

Claims Processing

Finding 1

The Medical Care Programs Administration (MCPA) did not ensure manually processed Maryland Medicaid Pharmacy Program (MMPP) claims were proper, resulting in overpayments of approximately \$397,000 related to 11 of the 15 claims we tested.

Analysis

MCPA did not ensure manually processed MMPP claims were proper, resulting in overpayments of approximately \$397,000. Pharmacy claims are generally paid based on rates (known as the allowable drug cost) programmed in the pharmacy vendor system. However, the allowable costs for certain drugs⁴ are calculated and processed manually by an MMPP employee using criteria provided in State regulations to process the claim. According to MCPA records, during fiscal year 2022 there were approximately 1,400 manual claims totaling \$46.8 million processed in the pharmacy vendor system.

MCPA management advised that it performed a monthly review of manually processed claims, but could only document that this review was performed for one month (December 2022) during our audit period. According to MCPA management, the employee responsible for performing this review left State employment and it could not locate evidence of reviews performed prior to December 2022.

Our test of 15 manual claims judgmentally selected based on materiality (that is, price per pill) totaling \$9.6 million and processed between June 2020 and November 2022 disclosed that 11 claims were overpaid by approximately \$397,000 because the employee who processed the claim entered an amount that exceeded the allowable drug cost by \$1,959 to \$170,000. MCPA was not aware of these overpayments until we brought them to its attention in May 2023. As of May 2023, MCPA had recovered \$289,000 of the overpayments and advised that it would pursue recovery of the remaining \$108,000.

⁴ According to State regulations, the amount MMPP pays is the lower of the wholesale acquisition cost or the actual acquisition cost plus eight percent for certain high-cost drugs.

Recommendation 1

We recommend that the Maryland Department of Health (MDH)

- a. perform independent documented reviews of manually processed claims including those processed during the audit period; and**
- b. recover any overpayments identified, including those noted above.**

Finding 2

MDH did not have procedures to ensure that prescribing providers were licensed prior to approving pharmacy claims for payment.

Analysis

MDH did not have procedures to ensure that prescribing providers were licensed prior to approving pharmacy claims for payment. MDH validated that providers were licensed by the appropriate Health Professional Board during the provider enrollment process for each of the four programs.⁵ However, pharmacy claims can be paid regardless of whether the prescribing provider was enrolled in the program (and therefore subject to prior licensure verification), and in such cases, MDH lacked assurance that the provider was properly licensed, as required by regulations.

We analyzed pharmacy claims activity during fiscal year 2022 and identified claims totaling approximately \$17.6 million paid to 9,318 prescribing providers who were not enrolled in the MDH programs, and therefore were not subject to license validation (see Figure 3 on the following page). Our test of 60 providers with significant paid claims for the respective programs during fiscal year 2022 (totaling approximately \$7 million), disclosed that, although the prescribing provider was not enrolled in the respective program at the time of the claim, they were properly licensed.

⁵ For the MCO pharmacy-related costs, since MDH does not directly administer the program, it is the responsibility of each MCO to ensure that participating prescribing providers were licensed.

Figure 3
Fiscal Year 2022 Pharmacy Claims and Non-Validated Prescribers

| Program | Total Activity | | Non-Validated Prescribers | |
|---------------|------------------|----------------------|---------------------------|---------------------|
| | Claims | Payments | Claims | Payments |
| MMPP | 5,073,694 | \$597,193,372 | 280,881 | \$16,947,913 |
| MADAP | 100,002 | 31,461,854 | 3,469 | 640,080 |
| KDP | 14,553 | 626,493 | 513 | 31,226 |
| BCCDTP | 2,270 | 1,763,151 | 35 | 7,095 |
| Totals | 5,190,519 | \$631,044,870 | 284,898 | \$17,626,314 |

Source: MDH records

State regulations for each of the four programs included in Figure 3 require prescribing providers to be licensed in the State in which they practice. In addition, federal regulations require that for MMPP, prescribing providers be enrolled in the Medicaid program. According to federal guidance, ensuring that prescribing and referring physicians are prescreened and enrolled in Medicaid helps to reduce fraud and lowers risk to consumers.

A similar condition was commented upon in our preceding audit report. In its response to that report, MDH, on behalf of MCPA and PHPA, indicated that edits in the new pharmacy vendor system would deny claims from providers who had not enrolled in the respective MDH program. Although the new pharmacy vendor system went live in October 2022, as of July 2023, these edits had not been implemented, and as noted above, MDH had not implemented alternative procedures to ensure prescribing providers are properly licensed prior to paying claims.

Recommendation 2

We recommend that MDH establish procedures to ensure that prescribing providers are licensed as required by program regulations prior to paying pharmacy claims (repeat).

Finding 3

MDH did not audit three of the four fee-for-service programs' pharmacy claims, did not analyze claim reversals, and did not use available drug utilization data to identify improper claims.

Analysis

MDH did not audit three of the four fee-for-service programs' pharmacy claims, did not analyze claim reversals, and did not use available drug utilization claims data to identify improper claims.

MDH Did Not Audit Most of the Participating Pharmacies' Claims

MDH did not have procedures to audit the majority of its pharmacy activity to identify policy and billing violations as well as any potential fraud, waste, or abuse. While 52 pharmacies under MADAP were audited, no audits of MMPP, BCCDTP, and KDP pharmacies were conducted; which means that only 2 percent of the 2,585 pharmacies with activity during fiscal year 2022 were audited. We noted that the MADAP audits, which were conducted by MDH's pharmacy vendor and related to calendar year 2020 activity, identified claims totaling approximately \$425,000 that needed to be recovered.

MDH should develop criteria to ensure appropriate audit coverage for these programs. According to industry best practices, pharmacy claims should be audited on a routine basis. The primary purpose of these audits is to perform manual verifications that are not possible through the pharmacy vendor system, such as to ensure that a valid prescription was issued, was properly filled, or that the prescription was actually picked up by the recipient.

A similar condition was commented upon in our preceding audit report. MDH's response to that report, on behalf of MCPA and PHPA, indicated that MDH planned to procure a vendor to perform these audits by the end of calendar year 2022. MDH had not procured these services for MMPP, BCCDTP, or KDP and advised us that it no longer plans to procure the audit services and had not developed a formal plan to audit the claims.

MDH Did Not Evaluate Pharmacy Claim Reversals

MDH did not evaluate claims data to identify pharmacies that may not be processing claim reversals when prescriptions are not picked up by the recipient. Pharmacies are paid by the State based on claims submitted when the prescriptions are filled, rather than when the prescriptions are picked up. State regulations require pharmacies to reverse the charges (and reimburse the State) when the prescriptions are not picked up within 14 days of the claim submission.

Our analysis of fiscal year 2022 claims data for the four fee-for-service programs disclosed that 710 of the 2,585 participating pharmacies had reversal rates under 10 percent, which was in some cases significantly below the respective program averages (see Figure 4). For example, our review of the 1,413 pharmacies in MMPP with paid claims totaling \$597.2 million disclosed an average reversal rate of 19 percent. We noted 364 pharmacies had a reversal rate under 10 percent including 201 pharmacies with \$90.3 million in paid claims that had less than 5 percent of their claims reversed. According to the United States Government Accountability Office, there may be legitimate reasons for a pharmacy to have a low percentage of claim reversals, however such pharmacies may warrant a follow-up review.⁶

Figure 4
OLA Analysis of Pharmacy Reversal Rates
During Fiscal Year 2022

| Program | Total Count of Pharmacies | Average Reversal Rate | Pharmacies with Reversal Rates Under 10 Percent | |
|--------------|---------------------------|-----------------------|---|----------------------|
| | | | Count | Claims Paid |
| MMPP | 1,413 | 19% | 364 | \$221,843,456 |
| MADAP | 752 | 22% | 182 | 9,410,226 |
| BCCDTP | 221 | 21% | 90 | 51,318 |
| KDP | 199 | 23% | 74 | 101,809 |
| Total | 2,585 | - | 710 | \$231,406,809 |

Source: OLA analysis of MDH records

A similar condition was commented upon in our preceding audit report. In response to that report, MDH, on behalf of MCPA and PHPA, indicated that it planned to procure a vendor to identify and investigate pharmacies with low reversal rates by the end of calendar year 2022. During our current audit, MDH management advised us that it no longer plans to procure a vendor for these services and had not developed a formal plan to identify and investigate low reversal rates.

⁶ A July 2015 Government Accountability Office report on Medicaid titled ‘*Additional Reporting May Help CMS Oversee Prescription-Drug Fraud Controls*’ noted that pharmacies with too few adjustments may be a red flag for concern.

MDH Did Not Analyze MMPP Claims Data to Identify Fraud, Waste, and Abuse

MDH did not have a comprehensive process to utilize MMPP drug utilization claims data to identify fraud, waste, and abuse.⁷ In accordance with federal law, MDH operates a Drug Utilization Review to reduce clinical abuse and misuse of outpatient prescription drugs. Although MDH advised that it also utilized drug utilization claims data to identify patterns of improper activity for further investigations (such as questionable dispensing or prescribing practices), MDH's written procedures at the time of our review did not specify how this data was to be used and MDH could not document that it analyzed the data for this purpose. Furthermore, we noted that MDH only conducted two investigations during our audit period that were initiated based on concerns identified using drug utilization claims data.

A similar condition was commented upon in our preceding audit report. In response to that report, MDH indicated that it would incorporate the use of drug utilization claims data to identify potential fraud, waste, and abuse by December 31, 2020. However, as noted above, MDH could not document how this data was used.

Recommendation 3

We recommend that MDH,

- a. establish procedures to periodically audit each program's pharmacy claims on a test basis (repeat);**
- b. investigate the aforementioned pharmacies with below average reversals and take appropriate follow-up action (repeat); and**
- c. utilize all available data to help identify improper MMPP pharmacy claims including fraud, waste, and abuse (repeat).**

Rebates

Background

MDH receives prescription drug rebates under two federal programs, the Medicaid Drug Rebate program and Section 340B Drug Pricing Program which establish the specific drugs that are eligible for rebates and the applicable rebate rates. Rebates are received from drug manufacturers for covered outpatient drugs dispensed to approved clients under each MDH pharmacy program.

The pharmacy vendor system tracks all drug purchases, referred to as drug utilization data, for each program by drug manufacturer. On a quarterly basis,

⁷ We did not review the other three programs for this control given the lesser claims activity (see Figure 3 on page 12).

MDH sends an invoice for rebates to each drug manufacturer for each of the four fee-for-service programs and the MCO program based on drug utilization activity for the period. MDH's fiscal services handles the invoicing, accounts receivables, and collections processes for MCO, MMPP, KDP, and BCCDTP rebates, and the MADAP program is responsible for handling its own rebates. We reviewed the procedures and performed testing on rebates for these five programs, and noted the following issues with rebates under the MADAP program.

Finding 4

MDH did not ensure that drug manufacturers provided timely and proper MADAP drug rebate payments.

Analysis

MDH did not ensure that drug manufacturers provided timely and proper MADAP drug rebate payments. Specifically, MDH's accounts receivable records were not sufficient to enable MDH to determine the total amount owed by each manufacturer and the age of the related receivable balances and could not document its collection efforts for the outstanding rebates. In addition, MDH did not have a documented process to verify the propriety of rebates remitted by one drug manufacturer that accounted for \$22.1 million (49 percent) of the \$45.2 million in MADAP rebates received during fiscal year 2022.

MDH Had Inaccurate Accounting Records and Could Not Document Collection Efforts

MDH did not maintain accurate accounts receivable records for use in monitoring MADAP rebates owed by drug manufacturers. Although MDH established a separate receivable for each amount it invoiced to the drug manufacturers, it did not always apply payments to the correct receivable. Consequently, MDH could not readily determine the total amount owed by each drug manufacturer and the age of the receivables.

MDH also could not document that it pursued collection of outstanding amounts or referred delinquent accounts to the State's Central Collections Unit (CCU). Our analysis of MDH accounts receivable records for calendar years 2021 and 2022 disclosed that as of March 22, 2023, outstanding MADAP rebates totaled \$12.4 million, including at least \$1.5 million in rebates that were outstanding for more than a year. MDH could not provide documentation of its efforts to collect these outstanding rebates or referral to the CCU of any amounts that remained delinquent.

An accurate report to age delinquent accounts is required by the Comptroller of Maryland's *Accounting Procedures Manual*. In addition, State regulations provide that outstanding accounts which remain uncollected for 90 days be transferred to CCU for additional collection activity.

MDH Could Not Document That Rebates From One Drug Manufacturer Were Verified

MDH could not document that it verified the propriety of rebate payments from one drug manufacturer. According to agency records, MDH invoiced the manufacturer for rebates totaling \$75 million between July 2019 and March 2022. Our review disclosed that the rebates remitted by this manufacturer during this period totaled only \$61.4 million. Although MDH advised that the manufacturer reduced the amount paid because certain drug costs were not eligible for rebate, MDH could not document that it had verified that the reduced payments were properly calculated in accordance with the drug manufacturer's agreement. Our review of all rebates for the first quarter of calendar year 2022 for this drug manufacturer did not disclose any issues with the manufacturer's calculation. We noted that MDH had a process in place to verify the propriety of rebates remitted by the other participating drug manufacturers.

Similar conditions regarding the lack of procedures to ensure that drug manufacturers submitted drug rebates timely and accurately were commented upon in our preceding audit report and our April 2018 audit report of the Maryland Department of Health – Prevention and Health Promotion Administration, Office of Population Health Improvement, Office of Preparedness and Response. MDH's response to our prior reports indicated that it would establish procedures to ensure drug manufacturer rebates were paid accurately and timely, and pursue collection of outstanding amounts by April 2020. However, as noted above, these procedures were not in place at the time of our review.

Recommendation 4

We recommend that MDH

- a. establish procedures to ensure that all required drug manufacturers pay rebates accurately and timely (repeat), including the development of accounts receivable records that provide sufficient information to monitor outstanding rebates and pursue collection activities; and**
- b. pursue collections of any outstanding rebates, including those noted above (repeat).**

System Security

We determined that Finding 5 related to “cybersecurity,” as defined by the State Finance and Procurement Article, Section 3.5-301(b) of the Annotated Code of Maryland, and therefore is subject to redaction from the publicly available audit report in accordance with the State Government Article 2-1224(i). Consequently, the specifics of the following finding, including the analysis, related recommendation(s), along with MDH’s responses, have been redacted from this report copy.

Finding 5
Redacted cybersecurity-related finding.

Audit Scope, Objectives, and Methodology

We have conducted a fiscal compliance audit of the Maryland Department of Health (MDH) pharmacy services for the period beginning July 1, 2019 and ending December 31, 2022. The audit focuses on pharmacy services provided by MDH through five separate programs of which two are in the Medical Care Programs Administration (MCPA) and three are in the Prevention and Health Promotion Administration (PHPA):

MCPA

- Medicaid Managed Care Program
- Maryland Medicaid Pharmacy Program

PHPA

- Maryland AIDS Drug Assistant Program
- Breast and Cervical Cancer Diagnosis and Treatment Program
- Kidney Disease Program

The audit was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

As prescribed by the State Government Article, Section 2-1221 of the Annotated Code of Maryland, the objectives of this audit were to examine MDH's financial transactions, records, and internal control, and to evaluate its compliance with applicable State laws, rules, and regulations.

In planning and conducting our audit, we focused on the major financial-related areas of operations based on assessments of significance and risk. The areas addressed by the audit included MDH's pharmacy point-of-sale electronic claims management system (pharmacy vendor system) security and controls, claims adjudication and processing, manual overrides, rate setting, program monitoring and audits, and rebate processing. We also determined the status of the findings contained in our preceding audit report.

Our audit did not include certain support services provided to MCPA by MDH. These support services (such as payroll, purchasing, maintenance of accounting records, and related fiscal functions) are included within the scope of our audit of the MDH – Office of the Secretary and Other Units. In addition, our audit did not

include an evaluation of internal controls over compliance with federal laws and regulations for federal financial assistance and programs and an assessment of MDH's compliance with those laws and regulations because the State of Maryland engages an independent accounting firm to annually audit such programs administered by State agencies, including MDH.

Our assessment of internal controls was based on agency procedures and controls in place at the time of our fieldwork. Our tests of transactions and other auditing procedures were generally focused on the transactions occurring during our audit period of July 1, 2019 to December 31, 2022, but may include transactions before or after this period as we considered necessary to achieve our audit objectives.

To accomplish our audit objectives, our audit procedures included inquiries of appropriate personnel, inspection of documents and records, tests of transactions, and to the extent practicable, observations of MDH's operations. Generally, transactions were selected for testing based on auditor judgment, which primarily considers risk, the timing or dollar amount of the transaction, or the significance of the transaction to the area of operation reviewed. As a matter of course, we do not normally use sampling in our tests, so unless otherwise specifically indicated, neither statistical nor non-statistical audit sampling was used to select the transactions tested. Therefore, unless sampling is specifically indicated in a finding, the results from any tests conducted or disclosed by us cannot be used to project those results to the entire population from which the test items were selected.

We also performed various data extracts of pertinent information from the State's Financial Management Information System (such as revenue and expenditure data). The extracts are performed as part of ongoing internal processes established by the Office of Legislative Audits and were subject to various tests to determine data reliability. We determined that the data extracted from this source were sufficiently reliable for the purposes the data were used during the audit.

We also extracted data from the Medicaid Management Information System (such as claim payments) for the purpose of selecting test items and performing data analytics. We performed various tests of the relevant data and determined that the data were sufficiently reliable for the purposes the data were used during the audit. Finally, we performed other auditing procedures that we considered necessary to achieve our audit objectives. The reliability of data used in this report for background or informational purposes was not assessed.

MDH's management is responsible for establishing and maintaining effective internal control. Internal control is a process designed to provide reasonable

assurance that objectives pertaining to the reliability of financial records; effectiveness and efficiency of operations, including safeguarding of assets; and compliance with applicable laws, rules, and regulations are achieved. As provided in *Government Auditing Standards*, there are five components of internal control: control environment, risk assessment, control activities, information and communication, and monitoring. Each of the five components, when significant to the audit objectives, and as applicable to MDH, were considered by us during the course of this audit.

Because of inherent limitations in internal control, errors or fraud may nevertheless occur and not be detected. Also, projections of any evaluation of internal control to future periods are subject to the risk that conditions may change or compliance with policies and procedures may deteriorate.

Our reports are designed to assist the Maryland General Assembly in exercising its legislative oversight function and to provide constructive recommendations for improving State operations. As a result, our reports generally do not address activities we reviewed that are functioning properly.

This report includes findings relating to conditions that we consider to be significant deficiencies in the design or operation of internal control that could adversely affect MDH's ability to maintain reliable financial records, operate effectively and efficiently, and/or comply with applicable laws, rules, and regulations. Our report also includes a finding regarding a significant instance of noncompliance with applicable laws, rules, or regulations. Other less significant findings were communicated to MDH that did not warrant inclusion in this report.

State Government Article Section 2-1224(i) requires that we redact in a manner consistent with auditing best practices any cybersecurity findings before a report is made available to the public. This results in the issuance of two different versions of an audit report that contains cybersecurity findings – a redacted version for the public and an unredacted version for government officials responsible for acting on our audit recommendations.

The State Finance and Procurement Article, Section 3.5-301(b), states that cybersecurity is defined as “processes or capabilities wherein systems, communications, and information are protected and defended against damage, unauthorized use or modification, and exploitation.” Based on that definition, and in our professional judgment, we concluded that certain findings in this report fall under that definition. Consequently, for the publicly available audit report all specifics as to the nature of cybersecurity findings and required corrective actions have been redacted. We have determined that such aforementioned practices, and

government auditing standards, support the redaction of this information from the public audit report. The specifics of these cybersecurity findings have been communicated to MDH and those parties responsible for acting on our recommendations in an unredacted audit report.

The response from MDH, on behalf of MCPA and PHPA, to our findings and recommendations, is included as an appendix to this report. Depending on the version of the audit report, responses to any cybersecurity findings may be redacted in accordance with State law. As prescribed in State Government Article, Section 2-1224 of the Annotated Code of Maryland, we will advise MDH regarding the results of our review of its response.

Exhibit 1
Listing of Most Recent Office of Legislative Audits
Fiscal Compliance Audits of Maryland Department of Health Units
As of June 2024 (Page 1 of 2)

| | Name of Audit | Areas Covered | Most Recent Report Date |
|----|--|--|-------------------------|
| 1 | Laboratories Administration | Laboratories Administration | 06/05/24 |
| 2 | State Psychiatric Hospital Centers | <ul style="list-style-type: none"> • Clifton T. Perkins Hospital Center • Eastern Shore Hospital Center • Spring Grove Hospital Center • Springfield Hospital Center • Thomas B. Finan Hospital Center | 05/29/24 |
| 3 | Health Regulatory Commission | <ul style="list-style-type: none"> • Maryland Health Care Commission • Health Services Cost Review Commission • Maryland Community Health Resources Commission | 01/25/24 |
| 4 | Medical Care Programs Administration – Managed Care Program | Managed Care Program, known as HealthChoice including oversight of the nine private Managed Care Organizations | 12/14/23 |
| 5 | Medical Care Programs Administration | Medical Care Programs Administration | 11/02/23 |
| 6 | Office of the Secretary and Other Units | <ul style="list-style-type: none"> • Office of the Secretary • Deputy Secretary and Executive Director for Behavioral Health • Deputy Secretary for Developmental Disabilities • Deputy Secretary for Public Health • Deputy Secretary for Health Care Financing and Chief Operating Officer • Deputy Secretary for Operations | 10/19/23 |
| 7 | Chronic Care Hospital Centers | <ul style="list-style-type: none"> • Deer’s Head Center • Western Maryland Hospital Center | 05/10/23 |
| 8 | Developmental Disabilities Administration | Developmental Disabilities Administration | 10/26/22 |
| 9 | Behavioral Health Administration and Medical Care Programs Administration - Administrative Service Organization for Behavioral Health Services | <ul style="list-style-type: none"> • Behavioral Health Administration • Medical Care Programs Administration Administrative Service Organization for Behavioral Health Services | 10/25/22 |
| 10 | Intellectual Disabilities Residential Centers | <ul style="list-style-type: none"> • Holly Center • Potomac Center • Secure Evaluation and Therapeutic Treatment | 10/24/22 |

Exhibit 1
Listing of Most Recent Office of Legislative Audits
Fiscal Compliance Audits of Maryland Department of Health Units
As of June 2024 (Page 2 of 2)

| Name of Audit | | Areas Covered | Most Recent Report Date |
|---------------|--|--|-------------------------|
| 11 | Regional Institute for Children and Adolescents | <ul style="list-style-type: none"> • John L. Gildner Regional Institute for Children and Adolescents • Regional Institute for Children and Adolescents – Baltimore | 07/13/22 |
| 12 | Office of the Chief Medical Examiner | Office of the Chief Medical Examiner | 05/12/22 |
| 13 | Prevention and Health Promotion Administration, Office of Population Health Improvement, Office of Preparedness and Response, and Office of Provider Engagement and Regulation | <ul style="list-style-type: none"> • Prevention and Health Promotion Administration • Office of Population Health Improvement • Office of Preparedness and Response • Office of Provider Engagement and Regulation – Office of Controlled Substances Administration • Office of Provider Engagement and Regulation – Prescription Drug Monitoring Program | 02/23/21 |
| 14 | Regulatory Services | <ul style="list-style-type: none"> • 22 Health Professional Boards and Commissions • The Office of Health Care Quality | 01/19/21 |
| 15 | Vital Statistics Administration | Vital Statistics Administration | 11/10/20 |



DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

August 8, 2024

Mr. Brian S. Tanen, CPA, CFE
Legislative Auditor
Office of Legislative Audits
The Warehouse at Camden Yards
351 West Camden Street, Suite 400
Baltimore, MD 21201

Dear Mr. Tanen:

Enclosed, please find the responses to the draft audit report on the Maryland Department of Health – Pharmacy Services for the period beginning July 1, 2019 to December 31, 2022.

If you have any questions, please contact Frederick D. Doggett at 410-767-0885 or email at frederick.doggett@maryland.gov.

Sincerely,

Laura Herrera Scott, M.D., M.P.H.
Secretary

Enclosures

cc: Erin K. McMullen, R.N., Chief of Staff, MDH
Marie Grant, Assistant Secretary for Health Policy, MDH
Nilesh Kalyanaraman, M.D., Deputy Secretary, Public Health Services, MDH
Erin S. Penniston, Chief of Staff, Public Health Services, MDH
Ryan B. Moran, Dr. P.H., Deputy Secretary, Health Care Financing & Medicaid Director, MDH
Frederick D. Doggett, Director, Internal Controls, Audit Compliance & Information Security, MDH
Tricia C. Roddy, Deputy Medicaid Director, MDH
Warren Waters, Jr., Chief of Staff, Health Care Financing, MDH
Deneen Toney, Deputy Director, Audit & Compliance, Internal Controls, Audit Compliance & Information Security, MDH
Carlean Rhames-Jowers, Chief Auditor, Internal Controls, Audit Compliance & Information Security, MDH

Maryland Department of Health Pharmacy Services

Agency Response Form

Claims Processing

Finding 1

The Medical Care Programs Administration (MCPA) did not ensure manually processed Maryland Medicaid Pharmacy Program (MMPP) claims were proper, resulting in overpayments of approximately \$397,000 related to 11 of the 15 claims we tested.

We recommend that the Maryland Department of Health (MDH)

- a. perform independent documented reviews of manually processed claims including those processed during the audit period; and
- b. recover any overpayments identified, including those noted above.

| Agency Response | | | |
|--|---|-----------------------------------|-----------|
| Analysis | Factually Accurate | | |
| Please provide additional comments as deemed necessary. | | | |
| Recommendation 1a | Agree | Estimated Completion Date: | Complete |
| Please provide details of corrective action or explain disagreement. | MDH has implemented policies and procedures to ensure future manually processed pharmacy claims undergo independent documented review to ensure propriety. For the past claims, MMPP has performed a review of all manually processed claims for each of the 4 fiscal years and has performed recovery of identified overpayments. | | |
| Recommendation 1b | Agree | Estimated Completion Date: | 8/31/2024 |
| Please provide details of corrective action or explain disagreement. | MMPP has recovered the vast majority of the overpayments identified by its review. The review identified overpayments totaling \$451,864. MDH successfully recovered \$360,326. The remaining overpayments of \$91,538 were to a pharmacy which is no longer in business. The amount will be referred to the Central Collections Unit to finalize recovery. | | |

Maryland Department of Health Pharmacy Services

Agency Response Form

Finding 2

MDH did not have procedures to ensure that prescribing providers were licensed prior to approving pharmacy claims for payment.

We recommend that MDH establish procedures to ensure that prescribing providers are licensed as required by program regulations prior to paying pharmacy claims (repeat).

| Agency Response | | | |
|--|---|-----------------------------------|-----------------|
| Analysis | Factually Accurate | | |
| Please provide additional comments as deemed necessary. | | | |
| Recommendation 2 | Agree | Estimated Completion Date: | Complete |
| Please provide details of corrective action or explain disagreement. | <p>MMPP Response: Maryland Medicaid went live with full implementation of the mechanism for POS denial of claims submitted with prescribers that have not registered with Maryland Medicaid as of July 1, 2024. Now for all FFS Medicaid pharmacy claims, prescribers must be enrolled with Maryland Medicaid.</p> <p>PHPA Response: MDH has established procedures to determine if prescribing providers are licensed by having the pharmacy point of sale (POS) vendor utilize the Maryland Medicaid prescriber file when adjudicating pharmacy claims.</p> <p>MDH rolled out a mechanism for POS denial for claims submitted with prescribers that have not registered with Maryland Medicaid which will also capture those not licensed so that claims can be denied at POS. This new system automated MADAP’s review of these claims and essentially decreased the amount of invalid prescriber claims from being paid at POS. MADAP is currently working with the PBM to implement a mechanism to deny pharmacy claims submitted with unlicensed prescriber credentials after September 1, 2024. Until such time, MADAP will maintain a weekly review of the invalid prescriber report.</p> | | |

Maryland Department of Health Pharmacy Services

Agency Response Form

Finding 3

MDH did not audit three of the four fee-for-service programs' pharmacy claims, did not analyze claim reversals, and did not use available drug utilization data to identify improper claims.

We recommend that MDH,

- a. establish procedures to periodically audit each program's pharmacy claims on a test basis (repeat);**
- b. investigate the aforementioned pharmacies with below average reversals and take appropriate follow-up action (repeat); and**
- c. utilize all available data to help identify improper MMPP pharmacy claims including fraud, waste, and abuse (repeat).**

| Agency Response | | | |
|--|--|-----------------------------------|-----------------|
| Analysis | Factually Accurate | | |
| Please provide additional comments as deemed necessary. | | | |
| Recommendation 3a | Agree | Estimated Completion Date: | Complete |
| Please provide details of corrective action or explain disagreement. | The OIGH continually reviews pharmacy claims to detect instances of fraud, waste, and abuse within the Medicaid program utilizing all available data. OIGH is recruiting for additional resources to conduct these reviews. OIGH has developed policies and procedures to audit each program's pharmacy claims and will work to have members of its existing staff conduct these audits while recruitment continues. | | |
| Recommendation 3b | Agree | Estimated Completion Date: | 1/1/2025 |
| Please provide details of corrective action or explain disagreement. | OIGH has begun data mining pharmacies that have below average reversal rates. The OIGH will conduct on-site reviews of those pharmacies. | | |
| Recommendation 3c | Agree | Estimated Completion Date: | Complete |
| Please provide details of corrective action or explain disagreement. | The OIGH continually reviews pharmacy claims to detect instances of fraud, waste, and abuse within the Medicaid program utilizing all available data. The OIGH continues to run regular data mining surveillance runs on MMPP data. OIGH also conducts on-site | | |

Maryland Department of Health Pharmacy Services

Agency Response Form

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|--|--|
| | investigations of pharmacies that present as outliers in these surveillance runs or in response to a referral. |
|--|--|

Rebates

Finding 4
MDH did not ensure that drug manufacturers provided timely and proper MADAP drug rebate payments.

We recommend that MDH

- a. establish procedures to ensure that all required drug manufacturers pay rebates accurately and timely (repeat), including the development of accounts receivable records that provide sufficient information to monitor outstanding rebates and pursue collection activities; and**
- b. pursue collections of any outstanding rebates, including those noted above (repeat).**

| Agency Response | | | |
|--|---|-----------------------------------|-----------------|
| Analysis | Factually Accurate | | |
| Please provide additional comments as deemed necessary. | | | |
| Recommendation 4a | Agree | Estimated Completion Date: | Complete |
| Please provide details of corrective action or explain disagreement. | MDH/MADAP has revised rebate documentation procedures for invoice accuracy, payment accuracy including verification of disputed claims resulting in reduced payments, monitoring of outstanding rebates, and collection activities. | | |
| Recommendation 4b | Agree | Estimated Completion Date: | Complete |
| Please provide details of corrective action or explain disagreement. | As of June 2023, MADAP established an account with the Maryland Central Collection Union (CCU) to send delinquent labeler accounts to CCU for collection. Also in June 2023, MADAP received the first list of manufacturers from the PBM which represented 3Q2022 outstanding balances. MADAP has revised the procedures for pursuing collections of any outstanding rebates. | | |

Maryland Department of Health
Pharmacy Services
Agency Response Form

System Security

The Office of Legislative Audits (OLA) has determined that Finding 5 related to “cybersecurity,” as defined by the State Finance and Procurement Article, Section 3.5-301(b) of the Annotated Code of Maryland, and therefore is subject to redaction from the publicly available audit report in accordance with the State Government Article 2-1224(i). Although the specifics of the finding, including the analysis, related recommendation(s), along with MDH’s responses, have been redacted from this report copy, MDH’s responses indicated agreement with the finding and related recommendations.

Finding 5
Redacted cybersecurity-related finding.

Agency Response has been redacted by OLA.

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