Audit Report

Maryland Department of Health
Pharmacy Services

August 2020

OFFICE OF LEGISLATIVE AUDITS
DEPARTMENT OF LEGISLATIVE SERVICES
MARYLAND GENERAL ASSEMBLY

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DEPARTMENT OF LEGISLATIVE SERVICES
OFFICE OF LEGISLATIVE AUDITS
MARYLAND GENERAL ASSEMBLY

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August 31, 2020

Senator Clarence K. Lam, M.D., Senate Chair, Joint Audit and Evaluation Committee
Delegate Carol L. Krimm, 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. To promote consistency in reporting of audit issues, we have modified our audit approach and consolidated our review of MDH pharmacy services provided under the Medical Care Programs Administration (MCPA) and the Prevention and Health Promotion Administration (PHPA) into one audit. This audit covers pharmaceutical benefits that MDH provides to eligible recipients through five separate programs for the following periods:

For the period beginning July 1, 2015 and ending June 30, 2019 (MCPA):

- Medicaid Managed Care Program
- Maryland Medicaid Pharmacy Program
- Kidney Disease Program

For the period beginning August 9, 2016 and ending June 30, 2019 (PHPA):

- Maryland AIDS Drug Assistance Program
- Breast and Cervical Cancer Diagnosis and Treatment Program

Under the Medicaid Managed Care Program, nine private Managed Care Organizations (MCOs) provide healthcare, including pharmacy services, to Medicaid recipients. Each MCO independently contracted with one of five Pharmacy Benefit Managers (PBMs) that were responsible for administering virtually all aspects of the MCO pharmacy activities. MDH makes a monthly capitation payment for each Medicaid recipient enrolled in the MCO. The portion

of capitation rates associated with pharmacy services for calendar year 2019 totaled approximately $729.0 million.

The remaining four programs are based on a fee-for-service model under which payments are made directly to pharmacies by MDH after claims have been adjudicated through a point-of-sale system operated by the pharmacy vendor. During fiscal year 2019, MDH paid pharmacies approximately $709.1 million.

Numerous concerns were raised by Maryland pharmacies about the MCOs operating under the Medicaid Managed Care Program primarily related to the payment of pharmacy claims. In this regard, the State passed House Bill 589 during the 2019 Session which required MDH to engage an independent firm to audit all of the MCOs PBMs. The primary purpose of the audit was to review contractual relationships between the MCOs, PBMs, and pharmacies, and analyze claims data to evaluate reimbursements to the pharmacies, and report the information gathered to MDH, with a final report to be submitted to the General Assembly.

The audit commenced in April 2019 and a final report was submitted to the General Assembly in January 2020. The independent audit disclosed that all nine MCOs used the spread-pricing payment method that accounted for approximately $72 million (or 10.4 percent) of the payments retained by the PBMs. Under spread-pricing, the difference between the amounts paid by the MCO to the PBM for a prescription and the amounts the PBM paid to the pharmacies, is retained by the PBM and referred to as "the spread". Furthermore, the audit noted that payments to pharmacies were also impacted by various fees and adjustments imposed by the PBMs that have the potential to increase the level of spread which were not taken into account during the audit. In addition, the independent audit noted that the average dispensing fee (the amount paid for filling the prescription) paid by the nine MCOs to the PBMs was $1 per claim, and paid by the PBMs to the pharmacies was $.50 per claim. In contrast, under each of the other four fee-for-service programs, MDH paid pharmacies a dispensing fee of $10.49 per claim.

Our audit disclosed that MDH did not establish financial and reporting requirements and did not monitor Medicaid Managed Care Program pharmacy services provided through MCOs. For example, the MCO agreements did not address the use of PBMs including the use of a pass-through or spread-pricing payment methodology, adjustments to paid claims, and dispensing fees. As a result, MDH had no knowledge of how the MCOs were operating in these areas. Consequently, we believe that the aforementioned legislatively-required independent audit provided valuable insight to MDH into the MCO and PBM operations.

In addition, our audit found that controls over processing pharmacy fee-for-service claims to mitigate key risks and verify the validity of claims were not always adequate. For example, MDH did not perform audits of three of the four fee-for-service model programs and did not use available data to identify improper claims. The purpose of these audits would be to perform manual verifications that are not possible through MDH's processing system, such as to ensure that a valid prescription was issued, was properly filled, or that the prescription was actually picked up. In addition, MDH did not have procedures to ensure that the pharmacy vendor obtained the required documentation and properly authorized high risk and high cost pharmacy claims for three of the four programs.

Furthermore, MDH's controls over certain drug rebates were not sufficient, resulting in significant rebates not being obtained or 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 its approved clients under each program that provides pharmacy services. Our audit disclosed that MDH did not submit certain required data to drug manufacturers when making requests for rebates, resulting in the untimely collection of approximately $20.6 million in rebates including $1.6 million that is no longer collectable based on the rebate agreements, and lost investment income totaling approximately $187,800. In addition, MDH did not ensure that drug manufacturers provided timely and proper drug rebate payments and as a result did not pursue collection of an additional estimated $7.3 million in outstanding rebates to which it was entitled.

Finally, our audit also disclosed that MDH did not obtain sufficient assurance that the pharmacy vendor operating the point-of-sale system for fee-for-service claims had sufficient security over its information system to protect sensitive data such as personally identifiable information and protected health information maintained by the vendor.

Our audit included a review to determine the status of the two findings pertaining to pharmacy services contained in our preceding MDH – Prevention and Health Promotion Administration, Office of Population Health Improvement, and Office of Preparedness and Response audit report. We determined that MDH satisfactorily addressed one of these findings. The remaining finding is 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 general agreement to our findings and related recommendations, and we will advise the Joint Audit

and Evaluation Committee of any outstanding issues that we cannot resolve with MDH.

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,

Gregory A. Hook, CPA
Legislative Auditor

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

Background Information

Agency Responsibilities

The Maryland Department of Health (MDH), through its Medical Care Programs Administration (MCPA) and Prevention and Health Promotion Administration (PHPA), operates the following 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 program provides pharmaceutical benefits to eligible recipients and is administered independently.

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. The two programs administered by MCPA with pharmacy services are:

- Maryland Medicaid Pharmacy Program (MMPP) - MMPP 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.

- 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.

MCPA also oversees MCOs under the Medicaid Managed Care Program which provide pharmacy services as further described below.

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. The two programs administered by PHPA with pharmacy services are:

- 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 to 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.

Pharmacy Vendor
On June 6, 2006, after a competitive procurement, MDH entered into a contract with a pharmacy vendor to develop, implement, and operate a point-of-sale electronic claims management system (pharmacy vendor system). Since then, there have been 15 contract modifications and 7 renewal options that ultimately extended the contracts terms so the entire contract period was from August 1, 2006 to August 31, 2020 for an amount not to exceed approximately $71.5 million.

Under the contract, the pharmacy vendor system fulfilled the responsibilities and daily operations for each program administered by MDH. Specifically, for MMPP, MADAP, BCCDTP, and KDP the pharmacy vendor system includes pharmacy claims processing, where claims submitted by pharmacies are adjudicated in real time. 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 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 did not provide claims processing services to the MCOs under the Medicaid Managed Care Program. Specifically, each MCO is responsible for maintaining its own system to process pharmacy claims. However, the pharmacy vendor system did perform rebate processing for MCO pharmacy claims.

In October 2019, MDH competitively awarded a contract to the same pharmacy vendor to provide a new pharmacy vendor system that would replace the system that has been in place since 2006. This contract includes a six-month implementation phase, followed by five years of operations, and two 2-year renewal options for the period between January 6, 2020 and July 5, 2029 for an amount not to exceed approximately $73.1 million.

Medicaid Managed Care Program - Pharmacy Services

Under the Medicaid Managed Care Program, known as HealthChoice, nine private MCOs provide healthcare, including pharmacy services, to Medicaid recipients. Each MCO independently contracted with one of five Pharmacy Benefit Managers (PBMs) that were responsible for administering virtually all aspects of the MCO pharmacy activities including pharmacy network management, claims processing, and payments to the pharmacies.

MDH makes a monthly capitation payment for each Medicaid recipient enrolled in the MCO. The capitation rates are calculated on a calendar year basis, using the MCOs' reported expenditures from three years prior, and vary by recipient depending on the assigned capitation rate category. Each recipient is placed in one of 62 capitation categories based on factors such as age, demographics, and historical medical services provided.

In the recent past, numerous concerns were raised by Maryland pharmacies about the MCOs primarily related to the payment of pharmacy claims by the PBMs, and the 2018 Joint Chairmen's Report (JCR) requested that MDH report on various aspects of MCO pharmacy reimbursement. PBMs make payments to the pharmacies for claims they approve, and are compensated through one of two payment methods (MDH did not mandate which methods were to be used by the MCOs):

- Pass-Through – The MCO pays the PBM for actual payments made by the PBM to pharmacies for dispensing drugs, plus a fixed administrative fee.

- Spread Pricing – The MCO pays a negotiated rate to the PBM, which often differs from the PBMs negotiated rates with pharmacies. The difference

between the amounts paid by the MCO to the PBM, and the PBM to the pharmacies is retained by the PBM and referred to as the spread.

According to industry literature, one method does not guarantee better pricing for the program than the other, the pass-through method provides for more transparency and visibility into the financial and operational practices and allows for better monitoring and accountability. Conversely, the spread-pricing method is generally ambiguous and lacks transparency into the amount of spread and actual payments being made between parties since much of the financial activity is deemed to be proprietary by the PBMs and is often not disclosed.

Following MDH's JCR report and in response to concerns raised by pharmacies, the General Assembly passed House Bill 589 during the 2019 Session which required MDH to engage an independent firm to audit all of the MCOs' PBMs. The primary purpose of the audit was to review contractual relationships between the MCOs, PBMs, and pharmacies, and analyze claims data to evaluate reimbursements to the pharmacies, and report the information gathered to MDH.

The independent auditor did not include findings or recommendations in its report, rather it reported the results of its analyses. The audit commenced in April 2019 and a final report was submitted to the General Assembly in January 2020. Copies of the independent audit, issued on January 3, 2020, are available at the Department of Legislative Services Library.[1] Observations disclosed by the independent audit included the following:

- Spread Pricing – All the MCOs used the spread-pricing payment method. During calendar year 2018, the MCOs paid PBMs $690 million, whereas the PBMs paid pharmacies $618 million. The difference of $72 million (or 10.4 percent) represented the spread retained by the PBMs. In addition, spread pricing for pharmacies not related to the PBMs was higher than those for pharmacies related to the PBMs through common ownership. Specifically, the average spread pricing for pharmacies not related to a PBM was 12.8 percent compared to 4.2 percent for related pharmacies. Furthermore, the audit noted that payments to pharmacies were also impacted by various fees and adjustments imposed by the PBMs that have the potential to increase the level of spread. However, the audit noted that it did not calculate the impact of the fees and adjustments due to the complexity of the calculations and the statutory deadline for submitting the report.

[1] At the time of our reporting, MDH's response, and the independent audit report were available at the following link: Report on Audit of Pharmacy Benefits Managers that Contract with Managed Care Organizations; Process for Appealing Decisions.

In response to the independent audit report, MDH modified its calendar year 2020 agreements with MCOs to require certain financial reporting, and requiring the MCOs to discontinue the use of spread pricing and move to the pass-through method by the end of the calendar year 2020. As noted above, the pass-through method provides for more transparency and visibility into the financial and operational practices and allows for better monitoring and accountability.

- Dispensing Fees – The audit noted that the average dispensing fee (the amount paid for filling the prescription) paid by the nine MCOs to the PBMs was $1 per claim, and paid by the PBMs to the pharmacies was $.50 per claim. In contrast, as approved by the federal Centers for Medicare and Medicaid Services (CMS), under MMPP, MDH paid pharmacies $10.49 per claim. The amount paid under MMPP was determined based on a study that determined the actual average cost of dispensing a drug.

  We were advised by MDH management that the lower dispensing fee was a reason MDH saved money for prescription drugs under the MCOs. However, the lower dispensing fees is also noted as a contributing cause of financial stress to the pharmacies,[2] primarily with small pharmacies (three or less pharmacies owned by the same person(s)) in hard to reach locations. In an effort to maintain network adequacy MDH acknowledges that it needs to ensure that small/rural pharmacies stay open. Therefore, MDH is planning to implement a grant program that would make available additional funds targeted at small pharmacies in rural areas of the State.

Pharmacy Payments

MMPP, MADAP, BCCDTP, and KDP 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 2019, MDH paid approximately 4.6 million pharmacy claims totaling approximately $709.1 million on behalf of 327,442 recipients (see Table 1 on the next page). 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 2019 totaled approximately $729.0 million.

[2] These comments are based on the Office of Legislative Audits' interviews with five pharmacies and the testimony provided to the House of Delegates' Health and Government Operations Committee on January 28, 2020.

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 $397.1 million for its fee-for-service pharmacy purchases during fiscal year 2019 and according to MDH records, it received $350.4 million in rebates for pharmacy purchases made by the MCOs during calendar year 2019. 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.

Table 1
Fiscal Year 2019 Fee-For-Service Claims and Rebates

Program	Recipients	Claims	Payments	Rebates
MMPP	320,648	4,521,830	$ 676,904,374	$ 345,082,126
MADAP	5,571	86,339	29,596,553	50,375,538
BCCDTP	389	3,179	1,971,465	1,108,179
KDP	834	11,252	650,871	549,869
Total	**327,442**	**4,622,600**	**$ 709,123,263**	**$ 397,115,712**

Source(s): State accounting records, Office of Legislative Audits analysis of MDH records

The scope of this pharmacy audit included the administration and monitoring of the four fee-for-service MDH programs including contract monitoring, claims adjudication and processing, security and controls, reimbursement rates, audits, and rebate management. Additionally, the scope included the rebate management and monitoring of the nine MCOs.

We conduct separate audits of MCPA and PHPA's primary functions (such as Medicaid recipient eligibility, long-term care, and hospital services), unrelated to pharmacy services.

Status of Findings From Preceding Audit Report

Our audit included a review to determine the status of two of the seven findings (related to programs that provide pharmacy services) contained in our preceding audit report on MDH – PHPA, Office of Population Health Improvement, and Office of Preparedness and Response, dated April 4, 2018. As disclosed in the following table, we determined that MDH satisfactorily addressed one of these two findings. The remaining finding is repeated in this report. Our audit did not include a review of the remaining five findings contained in our preceding PHPA audit report that related to non-pharmacy activities that will be included in our next audit of PHPA.

Our preceding audit report on MDH – MCPA dated August 18, 2017 did not contain any pharmacy services findings.

Table 2
Status of Preceding Findings

Preceding Finding	Finding Description	Implementation Status
Finding 1	PHPA did not ensure that all rebates from drug manufacturers were received and were accurate. Our tests disclosed one manufacturer did not pay rebates for six months, and rebates for 20 drugs were underpaid by as much as $2 million for one quarter in 2016.	**Repeated** (Current Finding 6)
Finding 4	PHPA did not recover pharmacy claim overpayments totaling $425,000 that were identified during pharmacy audits.	Not repeated

Findings and Recommendations

Medicaid Managed Care Program Pharmacy Services

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 (MCOs).

Analysis
MDH did not establish financial and reporting requirements and did not monitor pharmacy services provided through MCOs.

MDH Did Not Establish Financial and Reporting Requirements
Our review of MDH's agreements with the MCOs for calendar years 2019 and 2018 disclosed that they did not include any provisions pertaining to key financial requirements. For example, the agreements did not address the use of Pharmacy Benefit Managers (PBMs) including the use of a pass-through or spread-pricing payment methodology, adjustments to paid claims, and dispensing fees. In addition, the agreements did not include a requirement for the MCOs to submit their agreements with the PBMs to MDH for review and approval. As a result, MDH had no knowledge over how the MCOs were operating in these areas.

As noted in the background to this report, the recent audit of the MCOs and PBMs identified certain PBM practices, which had not been previously identified or addressed by MDH. In addition, certain pharmacies advised us that PBM financial arrangements and in particular the low dispensing fees and PBM payment adjustments, have created a financial hardship leading to reduced services. In this regard, we were advised by four pharmacists that due to the complexity and ambiguous nature of the payment adjustments, they could not determine if the adjustments were proper and could not determine what they actually received for each pharmacy claim.

In response to the independent audit report, MDH modified its calendar year 2020 agreements with MCOs to require certain financial reporting, and require the MCOs to discontinue the use of spread pricing and move to the pass-through method by the end of the calendar year 2020. However, the changes in calendar year 2020 agreements did not include a requirement for each MCO to submit its PBM agreement(s) to MDH for review and approval, and did not address adjustments to paid claims and dispensing fees.

MDH Did Not Monitor MCO Pharmacy Services

MDH did not have procedures to monitor MCOs to ensure that administration over pharmacy services and operational controls was adequate. For example, MDH did not have procedures to ensure that only appropriate claims were processed, sensitive information was properly safeguarded by the MCO and PBM, and programs were compliant with State regulations such as requirements regarding which drugs must be covered.

We were advised by MDH management that they did not provide oversight of the claims activity because the Medicaid Managed Care Program is based on capitation payments and not actual claim activity, and therefore, MDH has limited risk. For example, if the MCO improperly paid a claim twice, MDH does not actually pay that duplicate claim. Although this process does limit the risk of improper direct payments, there are other considerations with both financial-related and operational impacts. For example, MCO expenditures (such as claim payments) impact the calculation of future capitation payments, and poor MCO practices may result in a higher rate. In addition, MDH utilizes MCO claims data to recover rebates from drug manufacturers, therefore improper payments could also impact the accuracy of its rebates. MDH also needs to monitor the MCOs for non-financial issues such as ensuring sensitive patient data is protected and ensuring compliance with program requirements such as coverage for particular medications.

Notwithstanding the capitation payment issue, based on our research, we noted that other states' Medicaid programs have taken actions in recent years to provide better oversight of PBM administered pharmacy services. These actions include financial reporting requirements, mandating payment methodologies to be used, and conducting annual audits of PBM claims activity to ensure claims were proper and in compliance with program requirements. In addition, we noted the Office of Personnel Services and Benefits (OPSB) responsible for providing benefits to State employees, administered its PBM in a similar manner to that of other states' Medicaid programs. Specifically, since at least 2012, OPSB requires certain PBM financial reporting, mandated the use of the pass-through payment method, and performs independent annual audits of the PBMs activity.

Recommendation 1

We recommend that MDH

a. ensure that future agreements with MCOs include appropriate financial and reporting provisions that establish requirements over the payment methodology, allowable adjustments, and dispensing fees;

b. obtain and review financial reports and agreements between the MCOs and PBMs; and

c. implement comprehensive procedures, such as annual audits, to monitor pharmacy services provided through the MCOs to ensure that claims are proper and operational controls are appropriate.

Claims Processing

Finding 2
MDH did not perform audits of certain programs' pharmacy claims and did not use available data to identify improper claims.

Analysis
MDH did not perform audits of certain programs' pharmacy claims and did not use available data to identify improper claims. 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.

- MDH did not perform audits of the Maryland Medicaid Pharmacy Program (MMPP), Kidney Disease Program (KDP), and Breast and Cervical Cancer Diagnosis and Treatment Program (BCCDTP) pharmacy claims. By contrast, the Maryland AIDS Drug Assistance Program (MADAP) conducts at least 50 on-site pharmacy audits annually, including approximately 150 claims per audit (8 percent of total claims). MDH management advised that the MDH Office of Inspector General (OIG) audited certain MMPP claims when it conducted investigations of pharmacies. However, the OIG investigations focused on specific tips, referrals, and questionable activity and only reviewed a limited number of claims (less than one percent). In addition, as of January 2020 those investigations had not been performed since March 2019.

  We were advised that KDP and BCCDTP pharmacy claims were not audited because they were not significant compared to the medical claims in these programs. While there is a significant disparity in the amount of claims processed by these programs, and the relative insignificance compared to medical claims, MDH should have a formal policy for auditing these claims. Such a policy should include procedures to periodically audit the claims commensurate with the related risk or conduct a consolidated audit of claims from KDP and BCCDTP.

- MDH did not evaluate claims data for any of its four programs to identify pharmacies that may not be processing claim reversals when prescriptions are

not picked up by the recipient. Pharmacies submit claims for reimbursement when the prescriptions are filled, but before they are picked up. State regulations require pharmacies to reverse the charges when the prescriptions are not picked up within 14 days of the claim submission. Our analysis of claims data for all four MDH programs processed between January 1, 2019 and June 30, 2019 disclosed certain pharmacies that had reversal rates far below the program average.[3]

For example, our review of 1,264 pharmacies with 100 or more claims in MMPP totaling $337.6 million disclosed that 59 pharmacies with $16.7 million in paid claims had less than three percent of their claims reversed. This was far less than the program average of approximately 15 percent for the same six-month period. According to the United States Government Accountability Office, while there may be legitimate reasons for a pharmacy to have low percentages of claim reversals, such pharmacies may warrant a follow-up review.

- MDH did not utilize drug utilization claims data to identify fraud, waste, and abuse in the MMPP. Federal regulations require MDH to operate a Drug Utilization Review (DUR) to reduce clinical abuse and misuse of outpatient prescription drugs. As part of the DUR, MDH performs ongoing and periodic examination of claims data, which was primarily used to control recipient drug abuse and to educate recipients, providers, and pharmacies (such as by sending intervention letters). Our review disclosed that MDH did not utilize this data as part of an on-going monitoring process to identify patterns of improper activity for further investigation (such as questionable dispensing or prescribing practices).

Recommendation 2

We recommend that MDH, as applicable for each program,

a. establish procedures to periodically audit pharmacy claims on a test basis;

b. investigate the aforementioned pharmacies with below average reversals and take appropriate follow-up action; and

c. utilize all available data to help identify improper claims including fraud, waste, and abuse.

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[3] A July 2015 Government Accountability Office (GAO) 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.

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.

Analysis

MDH did not have procedures to ensure that its pharmacy vendor obtained the required documentation and properly authorized high risk and high cost pharmacy claims for the MMPP, KDP, and BCCDTP. MDH policy for the aforementioned three programs requires prior authorizations for certain high risk and high cost prescriptions, such as claims exceeding $2,500. In these cases, the prescribing provider generally completes a form documenting the medical rationale and need for the prescription which is submitted to MDH or the pharmacy vendor for review. In fiscal year 2019, the three aforementioned programs processed approximately 55,000 prior authorizations relating to approximately $26.2 million in paid claims. Of those prior authorizations, the pharmacy vendor processed approximately 45,000 relating to $16.7 million.

Our review disclosed that MDH did not review prior authorizations processed by the pharmacy vendor for MMPP, KDP, and BCCDTP to ensure they were adequately documented and the authorizations were proper. We were advised by MDH management that KDP and BCCDTP relied on the existing MMPP processes, however those "processes" were simply MMPP relying on quality assurance practices in place by the pharmacy vendor without periodically verifying the appropriateness of the practices or the propriety of the authorizations. Our testing of pharmacy claims processed for these units did not disclose any improper authorizations.

Although we verified that the pharmacy vendor had a documented quality assurance process that included supervisory reviews of the authorizations, MDH should have procedures to periodically verify that the vendor obtained the required documentation and properly authorized the transactions. For MADAP, we confirmed that procedures were in place to independently review prior authorizations on a test basis.

Recommendation 3

We recommend that MDH independently review prior authorizations, at least on a test basis, to ensure they are adequately documented and approved, and the related authorizations were proper.

Finding 4
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 to prescribe medications prior to approving pharmacy claims for payment. In fiscal year 2019, MDH paid 4.6 million claims, totaling $709.1 million, without first verifying the prescribing providers were properly licensed.

Most MDH recipients receive prescriptions from providers that enrolled in MDH programs at which time the provider license is validated during the provider enrollment process. However, pharmacy claims can be paid regardless of whether the prescribing provider was enrolled in the MDH program, and in such cases there would not be assurance that the providers' license was valid, as required by regulations. Consequently, all prescribing providers may not be properly licensed.

To quantify the effect of this condition, we analyzed the claims processed during fiscal year 2019 and identified 282,026 claims totaling approximately $42.1 million where the prescribing provider was not enrolled in a MDH program, and therefore was not subject to license validation (see Table 3). Furthermore, these claims were not flagged for a post-payment review. Our test of 20 providers associated to approximately $548,700 in paid claims, disclosed that, the prescribing provider was properly licensed, but had not been enrolled with MDH.

Table 3
Fiscal Year 2019 Pharmacy Claims and Non-Validated Prescribers

Program	Total Activity		Non-Validated Prescribers	
	Claims	Payments	Claims	Payments
MMPP	4,521,830	$ 676,904,374	277,777	$ 41,379,761
MADAP	86,339	29,596,553	3,537	662,780
KDP	11,252	650,871	602	22,908
BCCDTP	3,179	1,971,465	110	36,145
Totals	**4,622,600**	**$ 709,123,263**	**282,026**	**$ 42,101,594**

Source: State accounting records, Office of Legislative Audits analysis of MDH records

Each of the four programs included in Table 3 above established State regulations that require prescribing providers to be licensed in the State in which they practice. In addition, federal regulations established by the Affordable Care Act in 2011 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 finding was included in our MDH – Efforts to Identify and Analyze Improper Medicaid Payments Performance Audit dated June 23, 2020 which focused on providers in MMPP. In response to that report, MDH agreed to implement prescriber enrollment edits with the launch of its new pharmacy system which it anticipated would go live in winter 2021.

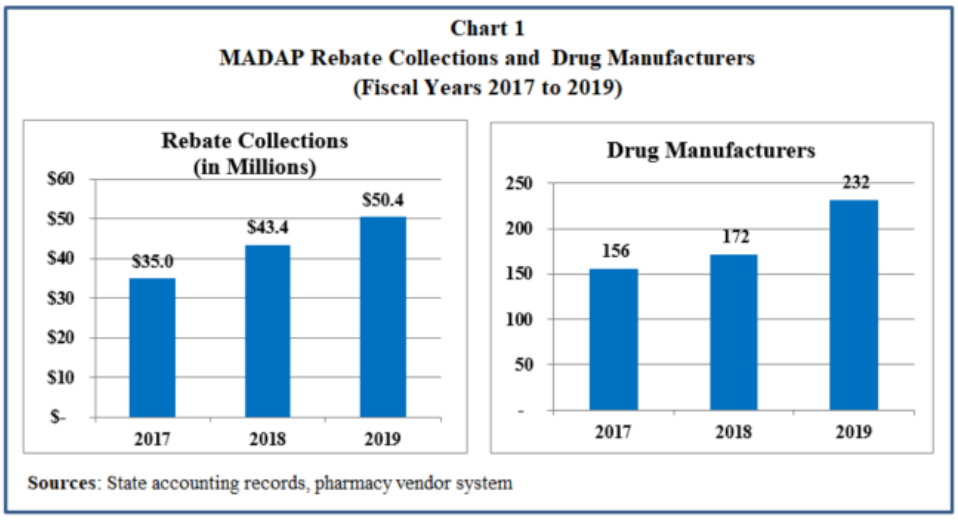
Recommendation 4
We recommend that MDH establish procedures to ensure that prescribing providers are licensed as required by program regulations prior to paying pharmacy claims.

Rebates

Background
MDH receives prescription drug rebates under two federal programs, the Medicaid Drug Rebate Program and Section 340B Drug Pricing Program which establishes which specific drugs are eligible for rebates, and the applicable rebate rates. Rebates are received from drug manufacturers for covered outpatient drugs dispensed to its approved clients under each program that provides pharmacy services. Drug manufacturers are responsible for paying a rebate on drugs for which a payment was made by MDH, regardless of whether MDH's payment was in full or partial as result of a third party payment (for example, insurance company).

The pharmacy vendor system tracks all drug purchases, referred to as drug utilization data, for each program by drug manufacturer. On a quarterly basis, MDH sends an invoice to each drug manufacturer for each program with 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, whereas the MADAP program is responsible for handling its own rebates.

We reviewed the procedures and performed testing on rebates for these programs, and noted several issues with rebates under the MADAP program. Chart 1 depicts rebate activity and the number of drug manufacturers for MADAP between fiscal years 2017 and 2019.



Finding 5
MDH did not submit certain 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.

Analysis
MDH did not submit certain 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 (these amounts are in addition to the rebates not collected that were disclosed in Finding 6).

- MDH did not submit required quarterly drug utilization data to one drug manufacturer resulting in no rebates being received for fiscal year 2019. At our request, MDH submitted the required data and, as of March 2020, collected approximately $19.5 million in rebates for fiscal year 2019 activity. Based on our calculations, the State lost investment income totaling approximately $174,600 due to the untimely collection of these funds.

  MDH management provided several explanations for not submitting the data, including the confidentiality of the information, technical difficulty generating the reports, and staffing availability. However, based on our review of the program guidance provided by the federal government and the rebate agreement with the drug manufacturer, we believe the data requested could have been timely provided. In this regard, prior to 2019, MDH had submitted

similar required information to this drug manufacturer and received the related rebates.

- MDH failed to submit certain detailed drug utilization data to another drug manufacturer on a timely basis resulting in the failure to recover $2.7 million in rebates including $1.6 million that is no longer collectable, and lost investment income totaling $13,200. In response to a prior audit report recommendation, in the summer of 2018, MDH performed a review of rebates and noted that this drug manufacturer did not remit certain rebates in calendar years 2015 through 2017. In September 2018, MDH submitted the data and received rebates totaling $1.1 million for calendar year 2017. However, the drug manufacturer denied the rebate requests for calendar years 2015 and 2016 because the data was not submitted within one year of the claim as required by the rebate agreement. Based on our estimates the denied rebates totaled approximately $1.6 million. In addition, the State lost investment income totaling $13,200 due to the untimely collection of the aforementioned $1.1 million. Our review of activity subsequent to the aforementioned period, disclosed that the drug utilization data was being submitted timely.

Recommendation 5
We recommend that MDH submit detailed drug utilization data in accordance with rebate agreements for each applicable drug manufacturer.

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.

Analysis
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 (this is in addition to the rebate amounts disclosed in Finding 5). On a quarterly basis, MDH reported MADAP drug utilization data to each drug manufacturer, and each manufacturer was to then calculate the rebate amount owed to MDH. However, MDH did not establish accounts receivable records to track outstanding MADAP rebates. In this regard, MDH could not readily determine the amount due and therefore, did not implement any collection efforts for outstanding rebates. MDH management advised that it did not establish accounts receivable records or pursue collections because of limited staffing resources.

Our review of quarterly reports of MADAP drug utilization during the period from July 2016 through June 2019 disclosed that MDH had drug utilization reported from 85 drug manufacturers in one or more quarters for which no rebates had been remitted from any manufacturer. Based on MDH records as of November 2019, we estimated that these 85 drug manufacturers owed MDH $7.3 million in rebates, including $1.5 million that was more than one year old. In addition, as of November 2019, the State lost its investment income of approximately $64,300 due to the untimely collection of these rebates.

Our review further disclosed that MDH did not adequately verify the propriety of the rebates that were remitted by the drug manufacturers. Specifically, MDH did not recalculate the amount due and instead relied on drug manufacturers to determine the amount of the rebate. Although prior to January 2019 MDH conducted certain procedures to verify that the amounts remitted were adequate, these procedures were not sufficiently comprehensive and had not been conducted for any collections after December 2018. For example, the reviews did not verify that certain rebates were calculated in accordance with the drug manufacturer's agreements. Our test of rebates and adjustments did not disclose any issues with manufacturer calculations reviewed.

Similar conditions regarding the lack of procedures to ensure that drug manufacturers submitted rebates accurately and timely were included in 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.

Recommendation 6
We recommend that MDH

a. establish procedures to ensure that all required drug manufacturers pay rebates accurately and timely (repeat); and
b. pursue collection of any outstanding rebates, including those noted above.

System Security

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 (PII) and protected health information (PHI) maintained by the vendor.

Analysis
MDH did not obtain adequate assurance for the period between July 1, 2015 and June 30, 2019 that the pharmacy vendor had sufficient security over its point-of-sale electronic claims management system (pharmacy vendor system), to protect sensitive data such as PII and PHI maintained by the vendor. According to agency records, during fiscal year 2019 the pharmacy vendor system contained information pertaining to at least 559,416 program enrollees with some type of claims activity including 327,442 for which a claim was paid.

The American Institute of Certified Public Accountants' guidance for service organizations (like the pharmacy vendor) includes an independent review of controls for which the resultant independent auditor's report is referred to as a System and Organization Controls (SOC) report. One type of report, referred to as a SOC 2 Type 2 report, includes the results of the auditor's review of controls placed in operation and tests of operating effectiveness for the period under review and could include an evaluation of system security, availability, processing integrity, confidentiality, and/or privacy.

Our review disclosed that MDH's contract with the pharmacy vendor required a SOC 1 Type 2 report instead of the aforementioned SOC 2 Type 2 report on a biennial basis. During the audit period, the vendor received two SOC 1 Type 2 reports that covered the period from July 1, 2015 to December 31, 2015, and July 1, 2017 to December 31, 2017. Although neither report disclosed any significant operational or security-related concerns, SOC 1 reports are generally intended to focus on service organization controls relevant to financial reporting for user entities and would not provide the degree of assurances necessary for confirming the security of sensitive enrollee information.

MDH management advised us that the requirements in the aforementioned contract were developed based on guidance received from the Department of Budget and Management. Subsequent to our review, MDH advised that it had entered into a new contract with the same pharmacy vendor effective January 2020 that requires a SOC 2 Type 2 audit be performed on an annual basis.

Recommendation 7

We recommend that MDH, consistent with its January 2020 contract, ensure that SOC 2 Type 2 reviews are performed, obtain and review the resultant reports required under the new contract, and ensure any recommendations for enhancing controls are implemented.

Audit Scope, Objectives, and Methodology

We have conducted a fiscal compliance audit of the Maryland Department of Health (MDH) pharmacy services. The audit focuses on pharmacy services provided by MDH through five separate programs of which three are in the Medical Care Programs Administration (MCPA) and two are in the Prevention and Health Promotion Administration (PHPA) for the following periods:

For the period beginning July 1, 2015 and ending June 30, 2019 (MCPA):

- Medicaid Managed Care Program
- Maryland Medicaid Pharmacy Program
- Kidney Disease Program

For the period beginning August 9, 2016 and ending June 30, 2019 (PHPA):

- Maryland AIDS Drug Assistance Program
- Breast and Cervical Cancer Diagnosis and Treatment 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 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 two of the seven findings contained in our preceding audit report on MDH – Prevention and Health Promotion Administration, Office of Population Health Improvement, and Office of Preparedness and Response.

Our audit did not include certain support services provided to each program providing pharmacy services 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 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.

This audit excluded a review of agreements between the Managed Care Organizations, Pharmacy Benefit Managers, and pharmacies, and analyses of claims data because these areas were included in an audit performed by the independent accounting firm as mandated by House Bill 589 of the 2019 Session. The final report was submitted to the General Assembly dated January 3, 2020.

To accomplish our audit objectives, our audit procedures included inquiries of appropriate personnel, inspections of documents and records, observations of MDH's operations, and tests of transactions. Generally, transactions were selected for testing based on auditor judgment, which primarily considers risk. Unless otherwise specifically indicated, neither statistical nor non-statistical audit sampling was used to select the transactions tested. Therefore, the results of the tests 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 and the pharmacy vendor system for the purpose of selecting test items and assessing user access. 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 each MDH program providing pharmacy services, 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 include findings regarding significant instances of noncompliance with applicable laws, rules, or regulations. Other less significant findings were communicated to MDH that did not warrant inclusion in this report.

The response from MDH, on behalf of MCPA and PHPA, to our findings and recommendations is included as an appendix to this report. For the ease of presentation in this report, we made our recommendations to MDH, but had previously shared administration-specific recommendations with all parties. As prescribed in the 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.

APPENDIX

Maryland
DEPARTMENT OF HEALTH

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

August 26, 2020

Mr. Gregory A. Hook, CPA
Legislative Auditor
Office of Legislative Audits
State Office Building, Room 1202
301 West Preston Street
Baltimore, MD 21201

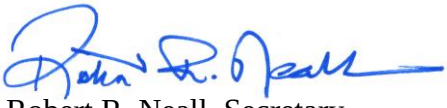
Dear Mr. Hook:

Enclosed, please find the responses to the draft audit report on the Maryland Department of Health – Pharmacy Services for the period beginning July 1, 2015 and ending June 30, 2019 for

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

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

Sincerely,



Robert R. Neall, Secretary
Maryland Department of Health

Enclosure

cc: Dennis R. Schrader, Deputy Secretary for Health Care Financing, MDH
Jinlene Chan, Acting Deputy Secretary for Public Health Services, MDH
Tricia Roddy, Acting Medicaid Director, MDH
Frederick D. Doggett, Inspector General, MDH
Dionne R. Washington, Chief of Staff, Health Care Financing, MDH
Erin Penniston, Chief of Staff, Public Health Services, MDH

Maryland Department of Health
Pharmacy Services

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Medicaid Managed Care Program Pharmacy Services

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 (MCOs).

We recommend that MDH

a. ensure that future agreements with MCOs include appropriate financial and reporting provisions that establish requirements over the payment methodology, allowable adjustments, and dispensing fees;

b. obtain and review financial reports and agreements between the MCOs and PBMs; and

c. implement comprehensive procedures, such as annual audits, to monitor pharmacy services provided through the MCOs to ensure that claims are proper and operational controls are appropriate.

Agency Response			
Analysis	**Factually Accurate**		
Please provide additional comments as deemed necessary.			
Recommendation 1a	**Agree**	**Estimated Completion Date:**	See note Below

Maryland Department of Health
Pharmacy Services

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Please provide details of corrective action or explain disagreement.	Ensure that future agreements with MCOs include appropriate financial and reporting provisions that establish requirements over the payment methodology: MDH agrees with this recommendation. The CY 2020 contract with MCOs does require that MCOs eliminate spread pricing effective CY2021. Ensure that future agreements with MCOs include appropriate financial and reporting provisions that establish requirements over allowable adjustments: MDH agrees with this recommendation. The CY 2021 MCO contract will include language as to which adjustments will be allowed and which ones will be prohibited that the MCOs will be required to incorporate in their PBM contracts by the end of the MCO contract term (12/31/2021). Ensure that future agreements with MCOs include appropriate financial and reporting provisions that establish requirements over dispensing fees**:** MDH agrees with this recommendation. Under the Managed Care model, the MCOs negotiate their own rates with their subcontractors, including the dispensing fees. Furthermore, since the MCOs are required to implement a pass-through/transparency model by 2021, they should be allowed to manage the pharmaceutical benefit package with their PBMs and their network pharmacy providers. The CY 2021 MCO contract will include language to require the MCOs to consider both ingredient costs and dispensing fees when determining their reimbursement to pharmacies. MDH should not be mandating specific dispensing fees.		
Recommendation 1b	**Agree**	**Estimated Completion Date:**	4th QTR CY 2021
Please provide details of corrective action or explain disagreement.	**Obtain and review agreements between MCOs and PBMs:** Under current regulations, MCOs are required to “report to the Department any material deviations from required procedures by its subcontractor which, in the MCO's judgment, can be expected to have a significant effect on quality of care, or on enrollees' ability to access care”. This includes deviations to their contracts with the PBMs. MDH will include in the CY2021 contracts a requirement for the MCOs to submit the agreements between the MCOs and their PBMs to MDH for review. MDH will only review these agreements to ensure that the MCOs restrict PBMs from engaging in spread pricing and that the PBMs are only allowed to		

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	perform adjustments as required by the contract between MDH and the MCOs. **Obtain and review financial reports between the MCOs and PBMs:** MDH currently reviews financial documents from the MCOs that shed light on the relationship between the MCOs and their PBMs. Per guidance from the Centers for Medicare and Medicaid Services (CMS) issued on May 15, 2019, MDH now specifically requires MCOs to report non-claims related expenses paid to a subcontractor as administrative expenses in the Medical Loss Ratio (MLR) calculation. Only the amount that the subcontractor actually pays the medical provider or supplier for providing Medicaid covered services to enrollees may be included in incurred claims. MDH implemented this requirement beginning with CY 2018 MLR reporting, submitted in the fall of 2019, and the submissions were audited by an independent accounting firm. Additionally, MCOs classify expenditures in the same manner for the HealthChoice Financial Monitoring Report (HFMR).		
Recommendation 1c	**Agree**	**Estimated Completion Date:**	4th QTR CY 2021
Please provide details of corrective action or explain disagreement.	MDH agrees with this recommendation. It will be the responsibility of the MCOs to implement procedures to monitor pharmacy services provided through their PBMs to ensure that claims are proper and operational controls are appropriate. However, MDH will require in the CY 2021 MCO contract that the MCO's PBM contract includes annual audit requirements. MDH will also require in the CY 2021 MCO contract that the MCOs submit summary reports of the audit findings upon request, including corrective actions that the MCOs will mandate of their PBMs, in the event issues have been identified by the audit. Furthermore, MDH will research as to how other states monitor their MCOs and their PBMs		

Claims Processing

Finding 2
MDH did not perform audits of certain programs' pharmacy claims and did not use available data to identify improper claims.

We recommend that MDH, as applicable for each program,
a. establish procedures to periodically audit pharmacy claims on a test basis;

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b. investigate the aforementioned pharmacies with below average reversals and take appropriate follow-up action; and
c. utilize all available data to help identify improper claims including fraud, waste, and abuse.

Agency Response			
Analysis	**Factually Accurate**		
Please provide additional comments as deemed necessary.			
Recommendation 2a	**Agree**	**Estimated Completion Date:**	4th QTR CY 2022
Please provide details of corrective action or explain disagreement.	**MMPP Response:** MDH agrees with the recommendation. MDH will conduct research to include current MADAP audit process in order to create appropriate audit protocol and work with OPASS to determine appropriate vehicle to procure this service. The estimated completion date will be in the 4th quarter of CY2022. **PHPA Response (BCCDTP and KDP):** MDH agrees with the recommendation. MDH will request from the pharmacy vendor to provide a cost proposal to periodically audit samples of pharmacy claims for BCCDTP and KDP. Upon approval from DBM of a budget initiative requesting funding for this service, MDH will need to modify the new contract with the vendor, in order to provide their audit services. Such modification must also be approved by the Board of Public Works. The estimated completion date will be the 4th quarter of CY2021.		
Recommendation 2b	**Agree**	**Estimated Completion Date:**	See dates below
Please provide details of corrective action or explain disagreement.	**MMPP Response:** MDH agrees with the recommendation. MDH will work with OPASS to determine appropriate vehicle to procure the following services: (a) investigate the aforementioned pharmacies with below average reversals and take appropriate follow-up action, and (b) periodically evaluate claims data to identify and investigate pharmacies that may not be processing claims reversals when prescriptions are not picked up by the		

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	recipient. The estimated completion date will be in the 4th quarter of CY2022. **PHPA Response (BCCDTP, KDP and MADAP)** MDH agrees with the recommendation. MDH will request from the pharmacy vendor to provide a cost proposal to (a) investigate the aforementioned pharmacies with below average reversals, and take appropriate follow-up action and (b) periodically evaluate claims data for BCCDTP, KDP and MADAP to identify and investigate pharmacies that may not be processing claim reversals when prescriptions are not picked up by the recipient. Upon approval from DBM of a budget initiative requesting funding for this service, MDH will need to modify the new contract with the vendor, in order to provide their audit services. Such modification must also be approved by the Board of Public Works. The estimated completion date will be in the 4th quarter of CY2021.

Recommendation 2c	**Agree**	**Estimated Completion Date:**	12/31/2020
Please provide details of corrective action or explain disagreement.	The OIG will work with the Pharmacy program to develop risk-based strategies using all available data, including drug utilization claims, to identify potential fraud, waste, and abuse. These strategies will be incorporated into the OIG's ongoing initiative to revise all of its Program Integrity policies and procedures.		

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.

We recommend that MDH independently review prior authorizations, at least on a test basis, to ensure they are adequately documented and approved, and the related authorizations were proper.

Agency Response	
Analysis	**Factually Accurate**
Please provide additional comments as deemed necessary.	

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Recommendation 3	**Agree**	**Estimated Completion Date:**	4th QTR CY 2020
Please provide details of corrective action or explain disagreement.	**MMPP Response:** MMPP will independently review prior authorizations approved by the pharmacy vendor on a test basis, to ensure that they are adequately documented and approved, and the related authorizations were proper. Frequency of reviews will be quarterly. **PHPA Response (BCCDTP and KDP):** BCCDTP and KDP will independently review prior authorizations for high cost pharmacy claims approved by the pharmacy vendor monthly on a test basis to ensure that the PAs were properly authorized and required documentation was obtained**.**		

Finding 4

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.

Agency Response			
Analysis	**Factually Accurate**		
Please provide additional comments as deemed necessary.			
Recommendation 4	**Agree**	**Estimated Completion Date:**	2nd QTR CY 2021
Please provide details of corrective action or explain disagreement.	**MMPP Response:** MMPP agrees to establish procedures to deny pharmacy claims at the point-of-sale if the prescriber NPI is not an actively enrolled Medicaid prescriber. As stated in Medicaid response to the recent Performance Audit, Finding #2, MMPP intends to implement the Prescriber		

	Enrollment edits for the FFS Program with the launch of the new Pharmacy POS system, which is expected to go-live Winter 2021. MMPP will start with a soft launch of the edits where the prescriptions do not deny at the point-of-sale for patient safety reasons, but MMPP and Medicaid Provider Services (MPS) are able to review compliance reports and work to get unenrolled prescribers enrolled. Hard edits/denials will begin two to four months after go-live. Medicaid enrollment does not directly equate to a real time license check. Additionally, not all lawful prescribers are fully licensed. To date, MDH's delay in implementing edits of FFS Pharmacy claims against a daily FFS Provider file of individual prescribers edits is due to concern for patient health and safety. Implementing these edits result in the denial of prescriptions at the point-of-sale. The additional time should mitigate impact to Medicaid participants. This aligns with MMPP's intent to include non-licensed medical students and interns with a valid student NPI in the valid FFS prescriber that will go to the POS vendor in 2021. **PHPA Response (KDP, BCCDTP, MADAP):** PHPA agrees to establish procedures that prescribing providers are licensed by having the pharmacy vendor utilize the Medicaid prescriber file when adjudicating pharmacy claims. Utilization of the Medicaid prescriber file is included in the business rules for processing pharmacy claims in the new POSECMS contract. KDP pharmacy providers are required to be enrolled in Medicaid; whereas, BCCDTP and MADAP do not have that requirement. BCCDTP, MADAP and KDP will apply the business rule to post the prescriber licensing edit and pay the claim. On a quarterly basis, assigned PHPA staff will review a report of the claims that post with the prescriber licensing edit and investigate to determine if the prescriber was licensed on the date of service. If the prescriber was not licensed, appropriate recoupment efforts will be initiated

Rebates

Finding 5 **MDH did not submit certain MADAP drug utilization data to two drug manufacturers resulting in the untimely collection of approximately $20.6 million in rebates including $1.6**

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million that is no longer collectable, and lost investment income totaling approximately $187,800.

We recommend that MDH submit detailed drug utilization data in accordance with rebate agreements for each applicable drug manufacturer.

Agency Response			
Analysis	**Factually Accurate**		
Please provide additional comments as deemed necessary.			
Recommendation 5	**Agree**	**Estimated Completion Date:**	July 1, 2020
Please provide details of corrective action or explain disagreement.	MADAP has taken action to bring all outstanding rebate accounts up-to-date including resolution of any reporting protocols with the cited drug manufacturers. Claim level detail has been submitted for the outstanding period of August 2019 through April 2020. Base and supplemental rebates have been invoiced and received for both manufacturers through fourth quarter 2019. Business rules definitions for the point of sales electronic claims management system (POSECMS) will include transition from data utilization report transmission to drug manufacturers to invoicing for MADAP base and supplemental rebates. MADAP policies and procedures have been updated to include drug manufacturer claim level data requirements, POSECMS invoicing, account receivable monitoring, and managerial oversight. Staff have been retrained and program management has developed monitoring tools to ensure fidelity to adopted policies and procedures.		

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.

We recommend that MDH

a. establish procedures to ensure that all required drug manufacturers pay rebates accurately and timely (repeat); and

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b. pursue collection of any outstanding rebates, including those noted above.

Agency Response			
Analysis	**Factually Accurate**		
Please provide additional comments as deemed necessary.			
Recommendation 6a	**Agree**	**Estimated Completion Date:**	April 2020
Please provide details of corrective action or explain disagreement.	MADAP has instituted quarterly review beginning April 2020 of all rebate transactions. Review includes receipt of all rebate accounts. This review has been retrospective to 2017 to verify receipt of all anticipated rebate both base and supplemental. Policies and procedures have been updated to include tracking instruments for accuracy and timeliness of all rebate payments. Staff have been retrained and program management has developed monitoring tools to ensure fidelity to adopted policies and procedures.		
Recommendation 6b	**Agree**	**Estimated Completion Date:**	April 2020
Please provide details of corrective action or explain disagreement.	MADAP has acted to vigorously pursue outstanding rebate accounts. Quarterly review of all rebate transactions and protocols for test base accuracy verification has been instituted on all MADAP base rebates. For MADAP supplemental rebates, all accounts receivable are reviewed for accuracy. Any discrepancy in expected verses received rebates generates collections action including written communication originating through the points of sales electronic claims management system. These claims are included in unit accounts receivable aging reports maintained by management and progressive payment action is included in revised policies and procedures. Business rules definitions for the point of sales electronic claims management system (POSECMS) will include automated invoice generation and collections written notification for MADAP base and supplemental rebates.		

System Security

Finding 7

Maryland Department of Health
Pharmacy Services

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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 (PII) and protected health information (PHI) maintained by the vendor.

We recommend that MDH, consistent with its January 2020 contract, ensure that SOC 2 Type 2 reviews are performed, obtain and review the resultant reports required under the new contract, and ensure any recommendations for enhancing controls are implemented.

Agency Response			
Analysis	**Factually Accurate**		
Please provide additional comments as deemed necessary.			
Recommendation 7	**Agree**	**Estimated Completion Date:**	4th QTR CY 2022
Please provide details of corrective action or explain disagreement.	MDH agrees with the recommendation. MDH had already implemented this requirement of SOC 2 Type 2 audit in the new point of sale request for proposals, which was published in 2017 and awarded in 2019. Also, MDH agrees to obtain and review the resultant reports required under the new contract and ensure any recommendations for enforcing controls are implemented.		

AUDIT TEAM

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