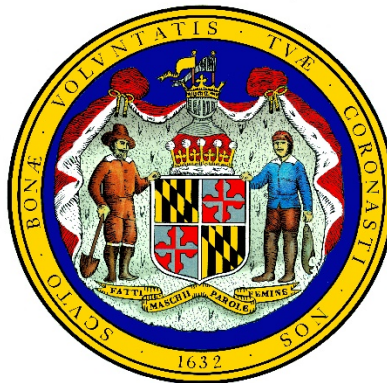


Audit Report

Maryland Department of Health

**Prevention and Health Promotion Administration
Office of Population Health Improvement
Office of Preparedness and Response
Office of Provider Engagement and Regulation**

August 2024



**OFFICE OF LEGISLATIVE AUDITS
DEPARTMENT OF LEGISLATIVE SERVICES
MARYLAND GENERAL ASSEMBLY**

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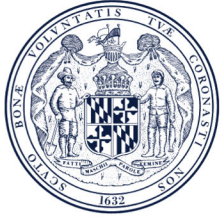
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Victoria L. Gruber
Executive Director

DEPARTMENT OF LEGISLATIVE SERVICES
OFFICE OF LEGISLATIVE AUDITS
MARYLAND GENERAL ASSEMBLY

Brian S. Tanen, CPA, CFE
Legislative Auditor

August 9, 2024

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) –Prevention and Health Promotion Administration (PHPA), Office of Population Health Improvement (OPHI), Office of Preparedness and Response (OPR), and Office of Provider Engagement and Regulation (OPER) for the period beginning October 21, 2019, and ending June 30, 2023.

Our audit disclosed that certain inspections were not conducted in a timely manner. Specifically, PHPA did not conduct timely inspections of food-processing facilities to ensure they were complying with applicable food safety regulations and OPER did not conduct timely inspections of assisted living facilities licensed to dispense controlled dangerous substances (CDS).

Our audit also disclosed that OPR did not establish adequate controls over its inventory of equipment and supplies stored for use during public health emergencies. In March 2020, OPR began storing equipment and supplies and distributing these items to Local Health Departments and other entities (such as hospitals). According to a count conducted in July 2023, the estimated value of its inventory totaled approximately \$193.2 million.

Finally, our audit included a review to determine the status of the three findings contained in our preceding audit report. We determined that two of these three findings were satisfactorily addressed. The remaining finding is repeated in this report.

MDH's response to this audit, on behalf of PHPA, OPHI, OPR and OPER, is included as an appendix to this report. We reviewed the response to our findings and related recommendations. Subsequent to the response receipt, but prior to the

issuance of the final report, we contacted MDH and obtained verbal clarification that satisfactorily resolved all outstanding questions and issues. Consequently, we have concluded that the written responses and verbal clarification together indicate that the corrective actions identified are sufficient to address all audit issues. In accordance with our policy, we have edited the response to remove vendor names or products.

We wish to acknowledge the cooperation extended to us during the course of this audit by MDH and the applicable administration and offices, and their collective willingness to address the current audit issues and implement appropriate corrective actions.

Respectfully submitted,

Brian S. Tanen

Brian S. Tanen, CPA, CFE
Legislative Auditor

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

Background Information

Agency Responsibilities

The Prevention and Health Promotion Administration (PHPA), the Office of Population Health Improvement (OPHI), the Office of Preparedness and Response (OPR), and the Office of Provider Engagement and Regulation (OPER) are units within the Maryland Department of Health (MDH).

- **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, including partnerships with local health departments, with special attention to at-risk and vulnerable populations. PHPA provides State grant funding to the local health departments for various public health initiatives related to maternal and child health, cancer and chronic disease, and environmental health and infectious disease. PHPA administers several programs including the Maryland AIDS Drug Assistance Program, Food Protection Program, and the Breast and Cervical Cancer Diagnosis and Treatment Program.
- **OPHI** maintains and improves the health of Marylanders by assuring access to and quality of primary care services and school health programs, and by supporting local health systems.
- **OPR** organizes and prepares for public health and medical emergencies through statewide partnerships with public, private, and government agencies to coordinate an effective emergency response for the health and safety of all Maryland residents. OPR is responsible for the receipt, storage, and distribution of critical equipment and supplies during times of emergency through the federal Strategic National Stockpile Program. As noted in Finding 1, OPR's operations related to this Program significantly expanded in March 2020 because of the COVID-19 public health emergency.
- **OPER** provides support for prescribers and dispensers to promote professional education and best practices so that Maryland patients experience optimal access, efficacy, and safety in connection with controlled substances. OPER is responsible for issuing Controlled Dangerous Substances (CDS) permits to practitioners, researchers, and establishments that administer, prescribe, dispense, distribute, manufacture, and conduct research of CDS. OPER is also responsible for the Prescription Drug Monitoring Program which collects and stores information on CDS dispensed to patients in Maryland.

According to State records, during fiscal year 2023, expenditures for PHPA, OPHI, OPR, and OPER totaled approximately \$524.9 million, \$137.0 million, \$460.2 million, and \$3.1 million, respectively (see Figure 1).

Figure 1
PHPA, OPHI, OPR, and OPER
Positions, Expenditures, and Funding Sources

Full Time Equivalent Positions as of June 30, 2023					
	PHPA	OPHI	OPR	OPER	Percent
Filled	406	12	25	18	89.0%
Vacant	48	2	2	5	11.0%
Total	454	14	27	23	
Fiscal Year 2023 Expenditures					
Salaries, Wages and Fringe Benefits	\$ 50,713,954	\$ 1,649,302	\$101,114,355 ¹	\$2,287,751	13.9%
Technical and Special Fees	9,985,678	226,387	2,376,115	103,716	1.1%
Operating Expenses	464,204,297	135,082,002	356,708,437	670,109	85.0%
Total	\$524,903,929	\$136,957,691	\$460,198,907	\$3,061,576	
Fiscal Year 2023 Funding Sources					
General Fund	\$ 76,287,977	\$111,164,733	\$ 3,566,720	\$2,655,352	17.2%
Special Fund	149,111,153	3,972,514	259,826,378	58,957	36.7%
Federal Fund	240,740,254	11,075,339	15,367,304	198,474	23.8%
Reimbursable Fund	3,189,455	0	0	148,793	0.3%
COVID Related Funding	55,575,090	10,745,105	181,438,505	0	22.0%
Total	\$524,903,929	\$136,957,691	\$460,198,907	\$3,061,576	

Source: State financial and personnel records

¹ The majority of the Special and COVID Related Funding under OPR's expenditures was for activity administered by MDH Office of the Secretary and other State agencies. Similarly, OPR's total Salaries, Wages, and Fringe Benefits reflected in Figure 1 is comprised of \$2.4 million for OPR's 25 positions and \$98.7 million related to staff working at other State agencies.

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 operations for all MDH servers and end user computers, resulting in substantial impact on all MDH business operations including PHPA, OPHI, OPR and OPER. 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. The 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 three findings contained in our preceding audit report on PHPA, OPHI, OPR, and OPER dated February 23, 2021. As disclosed in Figure 2 (on the following page), we determined that two of these findings were satisfactorily addressed. The remaining finding is repeated in this report.

² As defined by the federal Department of Homeland Security's 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	PHPA did not monitor a State grant to the University of Maryland Medical System related to the former Prince George's Hospital Center with funding totaling \$55 million for fiscal years 2018 and 2019.	Not Repeated
Finding 2	OPER had not established adequate controls over controlled dangerous substance permits and related collections.	Not Repeated
Finding 3	PHPA did not conduct timely inspections to ensure food-processing facilities were operating in accordance with State regulations.	Repeated (Current Finding 1)

Findings and Recommendations

Food Protection Program

Finding 1

The Prevention and Health Promotion Administration (PHPA) did not conduct timely inspections to ensure food-processing facilities were operating in accordance with State regulations.

Analysis

PHPA did not conduct timely inspections of food-processing facilities to ensure the facilities were complying with applicable State food safety regulations. PHPA licenses and inspects food-processing facilities (such as food manufacturing plants, warehouses, shellfish plants, and food transportation vehicles) to promote the safety of food processed in Maryland. State regulations generally require inspections to be performed quarterly, semi-annually, annually, or biennially, based upon the risk associated with the type of food-processing facility. According to agency records, there were 1,003 active food-processing facilities requiring an inspection as of June 30, 2023.

Our test of 30 arbitrarily selected food manufacturing facilities disclosed that inspections were not always conducted timely in accordance with State regulations. Specifically, 3 facilities that required semi-annual inspections were between 1 to 8 months overdue for an inspection as of June 30, 2023. In addition, although 27 of the 30 facilities tested had completed current inspections, 11 of the inspections were performed at least one month late, including 8 that were conducted between 6 months to 1 year after the inspection was due.

This condition may have been caused, in part, because PHPA did not maintain a complete and accurate scheduling sheet to monitor the timeliness of these inspections. Specifically, our review disclosed that certain information (such as the inspection date and license type) was not always accurately recorded on the scheduling sheet. For example, the aforementioned test of 30 inspections disclosed that the dates recorded on the scheduling sheet for 13 inspections did not accurately reflect the date the actual inspection occurred. Without an accurate scheduling sheet, PHPA did not have an effective mechanism to ensure that food-processing facilities were inspected in a timely manner.

PHPA's failure to conduct the required inspections was commented upon in our two preceding audit reports of PHPA dating back to April 4, 2018. MDH's response to our preceding audit report, on behalf of PHPA, indicated that PHPA planned to implement an information management system by December 31, 2022

to help monitor and ensure inspections are being performed timely. However, as of August 2023, this system had not been implemented and PHPA was relying on the aforementioned scheduling sheet to monitor inspections.

Recommendation 1

We recommend that PHPA

- a. take the necessary actions to ensure that food-processing facility inspections are conducted timely, in accordance with State regulations (repeat); and**
- b. maintain complete and accurate scheduling information to monitor the timeliness of these inspections.**

Controlled Dangerous Substance Inspections

Finding 2

The Office of Provider Engagement and Regulation (OPER) did not conduct required biennial inspections of assisted living facilities licensed to dispense controlled dangerous substances (CDS).

Analysis

OPER did not conduct biennial inspections of all assisted living facilities licensed to dispense CDS³ as required by its policy. OPER conducts inspections to ensure that licensed establishments complied with regulatory requirements for the physical security and accountability of CDS. For example, licensed establishments are required to have effective controls and procedures to guard against theft and unlawful diversion of controlled dangerous substances. According to OPER records, as of June 30, 2023, there were 2,702 establishments subject to inspection, including 1,233 pharmacies and 782 assisted living facilities.

³ Controlled dangerous substances are drugs or substances listed in Federal Drug Schedule I through Schedule V (for example, fentanyl and oxycodone).

Our analysis of OPER pharmacy and assisted living facility inspection records as of June 30, 2023, disclosed that although pharmacies were generally inspected as required, 455 of the 782 assisted living facilities (or 58 percent) were at least one year overdue for inspection (see Figure 3). OPER primarily attributed this backlog to the COVID-19 public health emergency and the aforementioned ransomware security incident. OPER advised that it plans to hire additional inspectors to resolve the backlog.

Figure 3
Overdue Inspections
as of June 30, 2023

Range of Overdue Inspections	Number of Assisted Living Facilities
1 to 3 years	284
3 to 6 years	89
> 6 years	82
Total	455

Source: OPER Records

Recommendation 2

We recommend that OPER take the necessary actions to ensure that inspections of assisted living facilities are conducted timely.

Office of Preparedness and Response (OPR) Equipment and Supplies

Background

During the audit period, OPR's operations significantly expanded because of the COVID-19 public health emergency. Specifically, in March 2020, OPR began storing equipment and supplies and distributing these items to local health departments and other entities (such as hospitals). Prior to COVID-19, OPR was only responsible for coordinating distributions of these items from the federal government without taking physical possession of the equipment and supplies. Based on a complete count performed in July 2023, OPR's inventory had an estimated value of approximately \$193.2 million (see Figure 4 on the following page).

Figure 4
OPR Inventory as of July 2023

Type	Count of Items	Estimated Value of Items (in millions)	Examples of Items
Equipment	458,770	\$ 57.8	Beds, medical monitors, ventilators, heaters, radios
Supplies	153,020,624	135.4	Rapid COVID tests, masks, gowns, syringes
Total	153,479,394	\$193.2	

Source: OPR's physical inventory and State records

Finding 3

OPR did not establish adequate controls over its inventory of equipment and supplies stored for use during public health emergencies.

Analysis

OPR did not establish adequate controls over its inventory of equipment and supplies stored for use during public health emergencies. Our review as of October 2023 disclosed the following conditions:

- OPR's equipment and supplies inventory records were not accurate and reliable. Specifically, the detail inventory records did not accurately reflect the number of items on hand, their location, and other required information such as the identification number and acquisition cost. OPR advised that the inventory records were generally not updated due to the volume of equipment and supplies received and distributed during the COVID-19 public health emergency.
- Prior to July 2023, OPR had not conducted any of the required physical inventories of equipment and supplies. In July 2023, OPR conducted a complete count of the equipment and supplies on hand, which identified approximately 153 million supply items and 459,000 equipment items (see Figure 4 above). However, OPR did not reconcile the results with the detail records or investigate differences between the inventory and the detail records. OPR advised that due to the unreliable and incomplete inventory records, it intended to adjust the inventory records to reflect the results of the count but had not made the adjustment as of October 2023.

- OPR did not maintain an equipment control account to ensure that the detail records accurately reflected the equipment balances.

The Department of General Services' (DGS) *Inventory Control Manual* requires agencies to maintain detail inventory records that accurately reflect the equipment and supplies on hand. The *Manual* also requires that physical inventories of both equipment and supplies be conducted periodically. It further requires that an independent equipment control account be maintained on a current basis and be periodically reconciled with the detail records.

Similar concerns were noted in our December 2021 *Review of Certain Emergency Procurements Related to the State of Maryland's COVID-19 Response* and in the federal Single Audit for fiscal year ending June 30, 2022.⁴ Our December 2021 review did not include recommendations, and as such, OPR was not required to provide a written response to the finding. However, OPR's response to the Single Audit indicated that it was procuring a new inventory system and developing formal procedures to comply with the DGS *Inventory Control Manual*. As of October 2023, OPR had not procured a new inventory system, and had not developed formal procedures and processes related to inventory accountability and recordkeeping.

Recommendation 3

We recommend that OPR comply with the requirements of the DGS *Inventory Control Manual*. Specifically, OPR should

- ensure the detail records of equipment and supplies accurately reflect the items on hand and include all required information,**
- conduct periodic physical inventories of equipment and supplies and reconcile the results to the detail records, and**
- maintain an independent equipment control account.**

⁴ The Single Audit is performed by independent auditors under contract with the State of Maryland and is intended to provide assurance to the federal government that adequate internal controls are in place, and the entity is generally in compliance with program requirements.

Audit Scope, Objectives, and Methodology

We have conducted a fiscal compliance audit of the following units of the Maryland Department of Health (MDH) for the period beginning October 21, 2019 and ending June 30, 2023.

Prevention and Health Promotion Administration (PHPA)
Office of Population Health Improvement (OPHI)
Office of Preparedness and Response (OPR)
Office of Provider Engagement and Regulation (OPER)

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 the respective MDH units' 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 certain grants and contracts (except as described below), warehouse operations, food protection, controlled dangerous substances, system security, and certain HIV operations. We also determined the status of the three findings included in our preceding audit report.

Our audit did not include certain support services provided by MDH's Office of the Secretary. 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. Furthermore, responsibilities related to grants awarded to local health departments are divided between the MDH – Office of the Secretary and the various administrations. Our audit included a review of the calculations of amounts awarded which is the responsibility of the administrations, but did not include other responsibilities related to these grant awards such as ensuring the grant funds are expended in accordance with the related agreements which is within the scope of our audit of MDH – Office of the Secretary. In addition, our audit did not include a review of

prescription rebates because they were included within the scope of our audit of MDH – Pharmacy Services.

Our audit also did not include an evaluation of internal controls over compliance with federal laws and regulations for federal financial assistance programs and an assessment of compliance with those laws and regulations by MDH and its units 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 October 21, 2019 to June 30, 2023, 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 operations at the respective MDH units. 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. 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 at the respective units 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 the respective MDH units, 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 the respective MDH unit's ability to maintain reliable financial records, operate effectively and efficiently, and/or comply with applicable laws, rules, and regulations. Our report also includes findings regarding significant instances of noncompliance with applicable laws, rules, or regulations. Other less significant findings were communicated to the respective MDH units that did not warrant inclusion in this report.

The response from MDH, on behalf of PHPA, OPHI, OPR and OPER, to our findings and recommendations is included as an appendix to this report. 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 Commissions	<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 Institutes 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	Regulatory Services	<ul style="list-style-type: none"> 22 Health Professional Boards and Commissions Office of Health Care Quality 	01/19/21
14	Vital Statistics Administration	Vital Statistics Administration	11/10/20
15	Pharmacy Services	Pharmacy Services for <ul style="list-style-type: none"> Medicaid Managed Care Program Maryland Medicaid Pharmacy Program Kidney Disease Program Maryland AIDS Drug Assistance Program Breast and Cervical Cancer Diagnosis and Treatment Program 	08/31/20



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

August 6, 2024

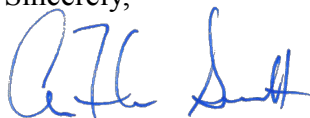
Mr. Brian S. Tanen, CPA, CFE
Legislative Auditor
Office of Legislative Audits
The Warehouse at Camden Yards
351 West Camden Street, Suite 400
Baltimore, MD 21201

Dear Mr. Tanen:

Enclosed, please find the responses to the draft audit report on the Maryland Department of Health – Prevention and Health Promotion Administration - Office of Population Health Improvement - Office of Preparedness and Response - Office of Provider Engagement and Regulation for the period beginning October 21, 2019 and ending June 30, 2023.

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
Elizabeth Edsall Kromm, Ph.D., Director, PHPA
Courtney McFadden, Deputy Director, PHPA
Kimberly A. Hiner, Director, OPHI
Sara Barra, Director, OPR
Ana C. Lazarides, Acting Director, OPER
Sandra A. Yankosky, Acting Deputy Director, OPER
Frederick D. Doggett, Director, Internal Controls, Audit Compliance & Information Security, MDH

Deneen Toney, Deputy Director, Audit & Compliance, MDH
Carlean Rhames-Jowers, Chief Auditor, Internal Controls, Audit Compliance &
Information Security, MDH

Maryland Department of Health

Prevention and Health Promotion Administration Office of Population Health Improvement Office of Preparedness and Response Office of Provider Engagement and Regulation

Agency Response Form

Food Protection Program

Finding 1

The Prevention and Health Promotion Administration (PHPA) did not conduct timely inspections to ensure food-processing facilities were operating in accordance with State regulations.

We recommend that PHPA

- a. take the necessary actions to ensure that food-processing facility inspections are conducted timely, in accordance with State regulations (repeat); and**
- b. maintain complete and accurate scheduling information to monitor the timeliness of these inspections.**

Agency Response			
Analysis	Factually Accurate		
Please provide additional comments as deemed necessary.			
Recommendation 1a	Agree	Estimated Completion Date:	10/1/24
Please provide details of corrective action or explain disagreement.	<p>The Department agrees. Please note that the response to prior findings in this area included development of a new information management system and improved staffing. The Department has succeeded in improving staffing levels, but to date has not been able to replace the information system. The Department continues to work to identify a technology solution.</p> <p>To ensure timely inspections of firms, the Office Chief will conduct bi-weekly reviews of the inspection spreadsheet with the Section Heads and will redirect prioritization to High Risk firms followed by Moderate and Low Risk. The review will allow the Office Chief and Section Heads to assess inspection needs and ensure firms are inspected in a timely fashion before they are overdue. The Program is also working to update COMAR 10.15.04 to better reflect national inspection frequencies.</p>		

Maryland Department of Health

Prevention and Health Promotion Administration Office of Population Health Improvement Office of Preparedness and Response Office of Provider Engagement and Regulation

Agency Response Form

	<p>Current inspection frequencies are:</p> <ul style="list-style-type: none">• High Risk 1 x 6 months• Moderate Risk 1 x 12 months• Low Risk 1 x 24 months <p>New inspection frequencies will be:</p> <ul style="list-style-type: none">• High Risk 1 x 12 months• Moderate Risk 1 x 24 months• Low Risk 1 x 36 months <p>Current FDA/national inspection frequencies are:</p> <ul style="list-style-type: none">• High Risk 1 x every 3 years• Non-High Risk 1 x every 5 years		
Recommendation 1b	Agree	Estimated Completion Date:	Complete
Please provide details of corrective action or explain disagreement.	<p>PHPA will ensure that the information recorded on the scheduling sheet used to monitor inspections is accurate.</p> <p>Section Heads are required to review inspection reports and the spreadsheet on a weekly basis at a minimum. Their position descriptions will be updated to include properly reviewing and documenting inspection spreadsheet reports as an essential function and will be reviewed as part of their PEPs. The Program Chief has conducted a quarterly internal audit by initially selecting a random sample of 10% of each section head's reviews (a total of 10% of all inspections) completed throughout the previous quarter to review for accurate dates and details. This review will be documented in the inspection spreadsheet. After two quarters the percentage of inspections reviewed may be increased or decreased by 5 percent, depending on the rate of errors identified in the inspections.</p>		

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Controlled Dangerous Substance Inspections

Finding 2

The Office of Provider Engagement and Regulation (OPER) did not conduct required biennial inspections of assisted living facilities licensed to dispense controlled dangerous substances (CDS).

We recommend that OPER take the necessary actions to ensure that inspections of assisted living facilities are conducted timely.

Agency Response			
Analysis	Factually Accurate		
Please provide additional comments as deemed necessary.			
Recommendation 2	Agree	Estimated Completion Date:	12/31/24
Please provide details of corrective action or explain disagreement.	<p>OPER agrees with the finding and will take necessary actions to ensure that inspections of assisted living facilities are conducted timely.</p> <p>As the IT network incident has been resolved, the ALs have resumed in-person visits from inspectors enabling inspections to be conducted timely. OCSA has returned to normal operations. To meet the inspection demands, OCSA has hired two new Clinical Pharmacist inspectors and is in the process of recruiting one more inspector. A full staff of inspectors will allow OCSA to increase the number of timely inspections at ALs. OCSA anticipates having the remaining inspections completed by December 31, 2024.</p>		

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Office of Preparedness and Response (OPR) Equipment and Supplies

Finding 3

OPR did not establish adequate controls over its inventory of equipment and supplies stored for use during public health emergencies.

We recommend that OPR comply with the requirements of the DGS *Inventory Control Manual*. Specifically, OPR should

- ensure the detail records of equipment and supplies accurately reflect the items on hand and include all required information,
- conduct periodic physical inventories of equipment and supplies and reconcile the results to the detail records, and
- maintain an independent equipment control account.

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.	OP&R agrees to ensure the detailed inventory records accurately reflect the items on hand and include all required information. A 100% physical inventory has been completed and data entry into the inventory system is completed as of June 20, 2024. The team has implemented a quality assurance process to review and refine the inventory details and make updates as needed to ensure all items are accurately reflected in the inventory system.		
Recommendation 3b	Agree	Estimated Completion Date:	Complete

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Please provide details of corrective action or explain disagreement.	OP&R agrees and has complied with DGS ICM guidance in support of periodic physical inventories, accounting for 10% monthly or at least 25% quarterly. OP&R will maintain a quarterly schedule that will serve as a contingency inspection schedule in recognition of real-life mission events that may preclude monthly accountability activity.		
Recommendation 3c	Agree	Estimated Completion Date:	Complete
Please provide details of corrective action or explain disagreement.	OP&R has maintained an equipment control account, as applicable, within its inventory management system and also an independent equipment control account per DGS ICM guidance.		

AUDIT TEAM

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