OFFICE OF THE STATE AUDITOR

Official Audit Report – Issued March 20, 2025

State Office of Pharmacy Services For the period July 1, 2021 through June 30, 2023



OFFICE OF THE STATE AUDITOR

March 20, 2025

Donald Rogers, PharmD, BCPS Chief of Pharmacy State Office for Pharmacy Services 369 East Street Tewksbury, MA 01876

Dear Dr. Rogers:

I am pleased to provide to you the results of the enclosed performance audit of the State Office of Pharmacy Services. As is typically the case, this report details the audit objectives, scope, methodology, findings, and recommendations for the audit period, July 1, 2021 through June 30, 2023. As you know, my audit team discussed the contents of this report with agency managers. This report reflects those comments.

I appreciate you and all your efforts at the State Office of Pharmacy Services. The cooperation and assistance provided to my staff during the audit went a long way toward a smooth process. Thank you for encouraging and making available your team. I am available to discuss this audit if you or your team has any questions.

Best regards,

Iana Diloglio

Diana DiZoglio Auditor of the Commonwealth

TABLE OF CONTENTS

EXECUT	rive summary	1
OVERVI	IEW OF AUDITED ENTITY	2
AUDIT (OBJECTIVES, SCOPE, AND METHODOLOGY	6
DETAIL	ED AUDIT FINDINGS WITH AUDITEE'S RESPONSE	11
i	The State Office of Pharmacy Services did not establish or implement policies, procedures, or related internal controls to ensure that it submitted required reports to the House and Senate Committees on Ways and Means.	11

EXECUTIVE SUMMARY

In accordance with Section 12 of Chapter 11 of the Massachusetts General Laws, the Office of the State Auditor has conducted a performance audit of the State Office of Pharmacy Services (SOPS) during the period July 1, 2021 through June 30, 2023.

The purpose of our audit was to determine the following:

- whether SOPS had policies and procedures in place to standardize operations and monitor all prescription functions at facilities across the Commonwealth;
- whether SOPS complied with its internal Policy 2.08 Vendor Contract Overhead Fees;
- whether SOPS complied with General Chapter 797 from the United States Pharmacopeia safety standards and its own Policies 3.01 through 3.04; and
- whether SOPS established and implemented necessary policies, procedures, and related internal controls to ensure that SOPS appropriately sent required reports to the House and Senate Committees on Ways and Means and that the reports were signed by the executive director, as required in Chapter 24 of the Acts of 2021 and Chapter 126 of the Acts of 2022.

Below is a summary of our findings, the effects of those findings, and our recommendations, with links to each page listed.

Finding 1 Page <u>11</u>	SOPS did not establish or implement policies, procedures, or related internal controls to ensure that it submitted required reports to the House and Senate Committees on Ways and Means.
Effect	If SOPS does not submit these reports to the Legislature as required, then it is failing to comply with the law. Also, agencies in the Commonwealth that could be served by SOPS may not know that they have access to pharmaceutical cost savings through SOPS.
Recommendation Page <u>12</u>	SOPS should establish and implement the necessary policies, procedures, and related internal controls to ensure that it annually submits required reports to the House and Senate Committees on Ways and Means and that the reports contain all required information and are signed by the executive director.

OVERVIEW OF AUDITED ENTITY

The State Office of Pharmacy Services (SOPS) was established in 1992 through a study commissioned by the Department of Health, the Department of Developmental Services, and the Department of Public Health to address the concerns of rising costs in pharmacy services.

According to SOPS's 2023 Policies and Procedures, its mission is as follows:

[SOPS's mission] is to provide state of the art pharmaceutical care through clinically appropriate and operationally efficient drug therapy management in a safe and effective manner. Through this process optimal patient outcomes will be achieved. Our goal is to always be prepared and to service the needs of the Commonwealth.

According to SOPS, in fiscal years 2022 and 2023, SOPS spent \$38,404,485 and \$43,505,989 on medications, respectively. These purchases are made by SOPS's pharmacy vendor, Cardinal Health, and are purchased through the statewide pharmaceutical provider. If medications are unavailable through the state pharmaceutical provider, SOPS acquires the medications from an appropriate supplier. SOPS pharmaceutical purchases are made using net pricing that includes discounts and rebates for the medication. In addition to purchases through the state wholesaler and appropriate suppliers, SOPS also uses a group purchasing organization and Managed Health Care Associates to secure additional price reductions based on the group purchasing organization's leveraged contract prices. SOPS was able to receive \$26,698 in rebates for fiscal year 2022 and \$10,373 for fiscal year 2023 through purchases with the group purchasing organization. By using multiple sources to obtain pharmaceuticals, SOPS seeks the lowest price for the agencies it supports.

As of the end of the audit period, SOPS provided pharmaceutical services to the following facilities across the Commonwealth:

Massachusetts Department of Mental Health					
Worcester Recovery Center and Hospital	Solomon Carter Fuller Mental Health Center (Boston)				
Taunton State Hospital	Corrigan Mental Health Center (Fall River)				
Women's Recovery from Addiction Program (Taunton)	Cape Cod and the Islands Mental Health Center (Pocasset)				
Men's Recovery from Addiction Program (Taunton)					

Massach	husetts Departm	ent of Developmental	Services					
Hogan Regional Center (D	Danvers)	Wrentham Developmental Center						
Massachusetts Department of Public Health								
Lemuel Shattuck Hospital (Jama	aica Plain)	Te	wksbury Hospital					
Western Massachusetts Hospital	(Westfield)	Pappas Rehabilitation Health Center for Children (Canton						
Veterans Homes								
Veterans Home at Holy	yoke	Veterans Home at Chelsea						
Ν	/lassachusetts D	epartment of Correctio	n					
Bay State Correctional Center (Norfolk)	Substand	setts Alcohol and ce Abuse Center idgewater)	Bridgewater State Hospital					
Massachusetts Treatment Center (Bridgewater)	Institution (N	setts Correctional MCI) Cedar Junction Walpole)	MCI Concord					
MCI Framingham	M	CI Norfolk	MCI Plymouth					
MCI Shirley Medium/Minimum		l Correctional Center Gardner)	Northeastern Correctional Cente (Concord)					
Old Colony Correctional Center (Bridgewater)	Old Colony Mi	nimum (Bridgewater)	Pondville Correctional Center					
South Middlesex Correctional Center (Framingham)		nowski Correctional ter (Shirley)						
Sheriffs' Departments								
Barnstable House of Corr		-	se of Correction (three locations)					
Berkshire House of Corr		-	shire House of Correction					

	·
Bristol House of Correction (two locations)	Middlesex House of Correction
Dukes County Sheriff's Department	Norfolk House of Correction
Essex House of Correction (three locations)	Plymouth House of Correction
Franklin House of Correction	Suffolk House of Correction (two locations)

Standardization and Monitoring of Prescription Functions

SOPS fulfills its responsibilities to the agencies to which it provides pharmaceutical services through a contract with Cardinal Health for pharmacy management and staffing services. SOPS oversees the process to ensure that medication orders are prepared with a high rate of accuracy. An order that is filled incorrectly and identified before or after it is delivered to the patient is considered a medication error. SOPS and Cardinal Health identify and track these errors to determine the cause of the error and whether any harm came to the patient.

SOPS requires its vendor to have a prescription medication error rate below 0.25% for each fiscal year. Prescription medication errors are documented in a Medication Event Report, which provides the total number of medication errors and calculates the error rate for the month. If a month's medication error rate is greater than 0.15%, a corrective action plan is implemented and documented in Cardinal Health's Medication Event Report.

According to SOPS, Cardinal Health can earn monetary bonuses from SOPS by achieving a medication error rate of less than 0.20%, which provides an additional incentive for medication orders to be filled with a high rate of accuracy.

Vendor Contract Overhead Fees

Cardinal Health can make purchases of up to \$250,000 per fiscal year for products or services in order to achieve its objective of providing pharmacy management services for SOPS using funding designated in its contract. These are known as overhead fees. Items purchased may include medication carts, office supplies, office equipment, and database services.

For Cardinal Health to make an overhead fee purchase, it must submit a proposal for approval to SOPS's chief of pharmacy. SOPS's chief of pharmacy, along with SOPS's fiscal director, ensures that all contract fees are used within the scope of their proposed use.

General Chapter 797 from the United States Pharmacopeia Safety Standards

Within the Pharmacy Distribution Center, SOPS has a compounding room where pharmacy technicians prepare compounded pharmaceuticals under clean and sterile conditions for the patients it serves across the Commonwealth.

To ensure the sterility and integrity of compounded sterile preparations, SOPS has policies and procedures in place that comply with General Chapter 797 from the United States Pharmacopeia safety standards. SOPS's internal policies and procedures require that an accredited environmental company complete an external review of surface and air testing in its compounding room to ensure that SOPS adheres to General Chapter 797 from the United States Pharmacopeia safety standards.

To maintain competency with compounding procedures, employees who use the compounding room to prepare compounded pharmaceuticals are required to complete at least five hours of training in the area of sterile compounding and pass competency evaluations for media fill and cleaning procedures. They also must display competency in garbing and gloving procedures in order to prepare compounded pharmaceuticals.

Reports to the Legislature

Under Chapter 24 of the Acts of 2021 and Chapter 126 of the Acts of 2022, SOPS was responsible for sending reports to the House and Senate Committees on Ways and Means by April 15, 2022 and April 14, 2023, respectively. These reports were to detail SOPS's recommendations for other entities that may benefit from the cost savings SOPS provides.

AUDIT OBJECTIVES, SCOPE, AND METHODOLOGY

In accordance with Section 12 of Chapter 11 of the Massachusetts General Laws, the Office of the State Auditor has conducted a performance audit of certain activities of the State Office of Pharmacy Services (SOPS) for the period July 1, 2021 through June 30, 2023.

We conducted this performance audit 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.

Below is a list of our audit objectives, indicating each question we intended our audit to answer; the conclusion we reached regarding each objective; and, if applicable, where each objective is discussed in the audit findings.

Ob	Conclusion	
1.	Did SOPS have policies and procedures in place to standardize operations and monitor all prescription functions at facilities across the Commonwealth?	Yes
2.	Did SOPS comply with its internal Policy 2.08 Vendor Contract Overhead Fees?	Yes
3.	Did SOPS comply with General Chapter 797 from the United States Pharmacopeia safety standards and its own Policies 3.01 through 3.04?	Yes
4.	In response to our previous recommendation (from Audit No. 2012-0293-3S) did SOPS establish and implement necessary policies, procedures, and related internal controls to ensure that SOPS appropriately sent required reports to the House and Senate Committees on Ways and Means and that the reports were signed by the executive director, as required in Chapter 24 of the Acts of 2021 and Chapter 126 of the Acts of 2022?	No; see Finding <u>1</u>

To accomplish our audit objectives, we gained an understanding of the aspects of SOPS's internal control environment relevant to our objectives by reviewing applicable agency policies and procedures and by interviewing SOPS management. We evaluated the design and implementation and tested the operating effectiveness of internal controls related to the annual review of compounding safety standard policies and the monthly reconciliation of vendor overhead fees. In addition, to obtain sufficient, appropriate evidence to address our audit objectives, we performed the procedures described below.

Standardization and Monitoring of Prescription Functions

To determine whether SOPS has standardized operations for all prescription functions, we performed an audit review of the processing, filling, and delivery of prescriptions by verifying that the practices used by Cardinal Health employees were in compliance with the Pharmacy Distribution Center policies approved by SOPS.

To determine whether SOPS ensured that Cardinal Health met its medication error rate goal, outlined in its vendor contract, at facilities across the Commonwealth, we obtained all Medication Event Reports from Cardinal Health from the audit period and completed the following actions.

- We recalculated the medication error rate by dividing the medical events by the total number of orders processed each month.
- We calculated the average medication error rate for each fiscal year.
- For Medication Event Reports with a monthly percentage greater than 0.15%, we verified that assessment and action plans were documented on the Medication Event Reports.

To determine whether SOPS's policies over the monitoring of all prescription functions were operating effectively, we reviewed email documentation and annual reports to determine whether SOPS held both annual meetings with its vendor, Cardinal Health, during the audit period regarding the plans for the clinical pharmacy program. Additionally, we selected a random, nonstatistical sample¹ of 35 out of 104 weekly scorecard reports and reviewed the correspondence between SOPS and Cardinal Health to ensure that SOPS provided the oversight needed to ensure effective operations.

Based on the results of our testing, we determined that, during the audit period, SOPS had policies and procedures in place to standardize operations and monitor all prescription functions at facilities across the Commonwealth.

Vendor Contract Overhead Fees

To determine whether SOPS complied with its internal Policy 2.08 Vendor Contract Overhead Fees, we obtained a list of all 371 overhead fee transactions from the audit period, totaling \$442,236 (\$210,648 in

^{1.} Auditors use nonstatistical sampling to select items for audit testing when a population is very small, the population items are not similar enough, or there are specific items in the population that the auditors want to review.

fiscal year 2022 and \$231,588 in fiscal year 2023), and selected a random, nonstatistical sample of 40

transactions, totaling \$45,484, and completed the following actions for each sampled transaction.

- We examined supporting documentation (including emails, invoices, and contracts) to determine whether a proposal for each overhead fee was made.
- We reviewed the contract overhead fee proposals to determine whether each selected fee was used within the scope of its proposed use.
- We reviewed each contract overhead fee for approval by SOPS's chief of pharmacy before its purchase.

Based on the results of our testing, we determined that, during the audit period, SOPS complied with its internal Policy 2.08 Vendor Contract Overhead Fees.

Compounding Safety Standard

To determine whether SOPS complied with its internal Policies 3.01 through 3.04 and General Chapter 797 from the United States Pharmacopeia safety standards, we completed the following actions.

- We requested and reviewed all 10 surface tests conducted during the audit period to determine whether SOPS passed each review and whether SOPS conducted surface testing reviews quarterly from July 2021 through December 2021 and biannually from January 2022 to June 2023.
- We requested and reviewed all seven air tests conducted during the audit period to determine whether SOPS passed each review and whether SOPS conducted biannual air testing reviews.
- We compared SOPS's internal policies to General Chapter 797 from the United States Pharmacopeia safety standards to determine whether SOPS met the United States Pharmacopeia's safety standards.

Additionally, from the list of 41 compounding employees who prepared compounded pharmaceuticals during the audit period, we selected a random, nonstatistical sample of 10 employees and reviewed continuing professional education completion data and both initial and annual evaluations to determine whether each employee completed the following:

- five compounded pharmaceutical continuing professional education hours annually;
- initial and annual garbing and gloving evaluations;
- initial and annual cleaning and disinfecting evaluations; and
- initial and annual media fill evaluations.

Based on the results of our testing, we determined that, during the audit period, SOPS complied with General Chapter 797 from the United States Pharmacopeia safety standards and its own Policies 3.01 through 3.04.

Chapter 24 of the Acts of 2021 Reporting

To determine whether, in response to our previous recommendation (from Audit No. 2012-0293-3S), SOPS established and implemented necessary policies, procedures, and related internal controls to ensure that SOPS appropriately sent required reports to the House and Senate Committees on Ways and Means by April 15, 2022 and April 14, 2023, respectively, and that the reports were signed by the executive director, as required in Chapter 24 of the Acts of 2021 and Chapter 126 of the Acts of 2022, we interviewed SOPS's chief of pharmacy and reviewed SOPS's policies and procedures that were in effect during the audit period.

See Finding <u>1</u> for more information regarding the results of our testing related to SOPS's updating its policies, procedures, and related internal controls in response to our previous recommendation.

We used nonstatistical sampling methods for testing and therefore did not project the results of our testing to the population.

Data Reliability Assessment

Weekly Scorecard Reports

To determine the reliability of the weekly scorecard reports that Cardinal Health submitted to SOPS during the audit period, we obtained all 104 reports from SOPS and reviewed them to ensure that there were no missing reports.

Vendor Contract Overhead Fees

To determine the reliability of the list of 371 overhead fees paid during the audit period, provided by SOPS, we interviewed SOPS officials who were knowledgeable about the data. We reviewed the data to ensure that there were no blank fields or duplicates and that all of the data was from within the audit period. Further, we selected a random sample of 20 overhead fee transactions from the dataset and matched the amounts, invoice numbers, and dates to the original invoices.

Compounding Safety Standard

To determine the reliability of the list of 41 employees with access to the compounding room provided by Cardinal Health, we interviewed SOPS officials who were knowledgeable about the list. We reviewed the employee list to ensure that there were no duplicate employees. Further, we reconciled the vendor's employee list to an independent list provided by SOPS of employees who were granted badge access by SOPS to the compounding room to ensure that all employees who were granted badge access were on the vendor list.

Based on the results of the data reliability assessment procedures described above, we determined that the information we obtained was sufficiently reliable for the purposes of our audit.

DETAILED AUDIT FINDINGS WITH AUDITEE'S RESPONSE

1. The State Office of Pharmacy Services did not establish or implement policies, procedures, or related internal controls to ensure that it submitted required reports to the House and Senate Committees on Ways and Means.

Despite the recommendation in a previous audit by the Office of the State Auditor, issued in 2014, SOPS did not establish or implement policies, procedures, or related internal controls to ensure that it submitted required reports to the House and Senate Committees on Ways and Means and that those reports were signed by the executive director. Furthermore, we determined that SOPS did not submit both required reports during the audit period.

If SOPS does not submit these reports to the Legislature as required, then it is failing to comply with the law. Also, agencies in the Commonwealth that could be served by SOPS may not know that they have access to pharmaceutical cost savings through SOPS.

Authoritative Guidance

Chapter 24 of the Acts of 2021 states, "Not later than April 15, 2022 [SOPS] shall report to the house and senate committees on ways and means detailing recommendations for the inclusion of other entities that may realize cost savings by joining SOPS."

Chapter 126 of the Acts of 2022 states, "Not later than April 14, 2023 [SOPS] shall report to the house and senate committees on ways and means detailing recommendations for the inclusion of other entities that may realize cost savings by joining SOPS."

Reasons for Issue

During an interview with the chief of pharmacy, they stated that reports were not sent to the Legislature because almost every agency that could benefit from SOPS's service is currently receiving services from SOPS. SOPS was under the impression that the recommendation from the previous report was for the Department of Public Health to update its policies and not SOPS because the Department of Public Health accepted responsibility for not filing the required reports.

Recommendation

SOPS should establish and implement the necessary policies, procedures, and related internal controls to ensure that it annually submits required reports to the House and Senate Committees on Ways and Means and that the reports contain all required information and are signed by the executive director.

Auditee's Response

[The Department of Public Health (DPH)] and SOPS recognize and agree with this finding and the Auditor's recommendation. SOPS will develop an internal policy for such legislative reporting requirements. The Commissioner's Office within DPH monitors and tracks legislative reporting requirements and deadlines internal to the Department. In addition, DPH is working to remove from future appropriations acts the language that requires the reporting of other entities that could benefit from the SOPS program as SOPS feels that all appropriate Commonwealth entities that could benefit from the SOPS program have already been converted.

Auditor's Reply

Based on its response, SOPS is taking measures to address our concerns regarding this matter. As part of our post-audit review process, we will follow up on this matter in approximately six months.