

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MASSACHUSETTS OPIOID
TREATMENT PROGRAM SERVICES MET
MANY OF THE FEDERAL AND
STATE REQUIREMENTS**

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Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.



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Massachusetts Opioid Treatment Program Services Met Many of the Federal and State Requirements

Why OIG Did This Audit

- The United States currently faces a nationwide public health emergency because of the opioid crisis that has led to alarming trends across the country, including record numbers of people developing opioid use disorders (OUDs).
- Opioid treatment programs (OTPs) provide medication and counseling services for people diagnosed with an OUD. OTPs are integral to combating opioid-related diagnoses and deaths.
- This audit examined whether Massachusetts ensured that OTPs provided services in accordance with certain Federal and State requirements.

What OIG Found

Massachusetts could improve its oversight to OTPs to ensure that they complied with certain Federal and State requirements.

- Of the 100 OTP sampled services, only 74 complied with Federal and State requirements.
- Of the remaining 26 OTP sampled services, 23 OTP services did not meet the treatment plan review requirements and 3 were not supported by the medical records.

Massachusetts had procedures in place to oversee the OTPs, but these procedures were not always strong enough to prevent the errors identified in this report.

What OIG Recommends

We recommend that Massachusetts follow up with OTP providers about the three services that were not supported by the medical records and continue its procedures to prevent OTP noncompliance with Federal and State requirements.

Massachusetts concurred with our recommendations and described the actions that it has taken or plans to take in response to our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

The United States currently faces a nationwide public health emergency due to the opioid crisis. The high potential for misuse of opioids has led to alarming trends across the country, including record numbers of people developing an opioid use disorder (OUD). In 2021 alone, there were nearly 81,000 overdose deaths in the United States. Opioid treatment programs (OTPs) provide medication coupled with counseling services (referred to in this report as “OTP services”) for people diagnosed with an OUD. As part of the Office of Inspector General’s (OIG’s) oversight of the integrity and proper stewardship of Federal funds used to combat the opioid crisis, we audited OTP services provided in Massachusetts.

OBJECTIVE

Our objective was to determine whether the Massachusetts Executive Office of Health and Human Services (State agency) provided oversight to OTPs so that they complied with certain Federal and State requirements.

BACKGROUND

Medicaid Program

The Medicaid program provides medical assistance to low-income individuals and individuals with disabilities. The Federal and State governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services administers the program. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

Opioid Treatment Programs

OTPs provide medication for addiction treatment for individuals diagnosed with an OUD. Medications used include methadone, buprenorphine products, and naltrexone. OTPs also provide a range of services to reduce, eliminate, or prevent the use of illicit drugs, potential criminal activity, and the spread of infectious disease. OTPs focus on improving the quality of life of those people receiving treatment.

Federal and State regulations convey requirements including recordkeeping, diagnosis of opioid addiction, medical orders, counseling services, and toxicology screenings.

Massachusetts’ Opioid Treatment Program

In Massachusetts, the State agency administers the Medicaid program (MassHealth) and

provides reimbursement to OTP providers. MassHealth provides health benefits and assistance with payments for qualifying individuals. Within the State agency, the Massachusetts Department of Public Health (DPH), the Bureau of Substance Addiction Services (BSAS) is the State department responsible for overseeing the statewide system of prevention, intervention, treatment, and recovery support services for individuals affected by substance addiction. BSAS is primarily responsible for the State-level oversight of the OTP providers in collaboration with MassHealth.

Bureau of Substance Addiction Services Oversight

BSAS and DPH ensure OTP compliance through required annual reports, in depth investigation of operations, onsite visits, and license inspections. They review data and medical records, perform desk audits, ad hoc reporting, receive notifications of potential investigations, and track personnel changes at the OTP executive level.

BSAS conducts multiple site visits in a variety of functions to assess potential noncompliance and licensing adherence. For example, there are inspections every other year to assess contract compliance with State service agreements. There are onsite visits every 2 years for the inspection of personnel records and provision of services.

HOW WE CONDUCTED THIS AUDIT

Our audit covered OTP services provided during the period July 1, 2021, through June 30, 2022 (audit period), for individuals enrolled in Medicaid and diagnosed with an OUD. During this period, three OTPs submitted claims for 2,187,024 OTP services totaling \$33,693,213. We selected and reviewed a stratified random sample of 100 OTP services to determine whether the OTPs met Federal and State requirements.

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.

Appendix A contains the details of our audit scope and methodology, Appendix B contains our statistical sampling methodology, and Appendix C contains a list of related OIG reports.

FINDINGS

The State agency could improve its oversight to OTPs to ensure that they complied with certain Federal and State requirements. Specifically, we found that only 74 of the 100 sampled OTP services complied with certain Federal and State requirements.

Of the remaining 26 OTP sampled services, 23 OTP services did not meet the treatment plan review requirements and 3 were not supported by the medical records. Adherence to treatment plan review requirements is not a condition of payment and is presented here for information purposes only.

The State agency had procedures in place to oversee the OTPs, but these procedures were not always strong enough to prevent the errors identified in this report.

OF THE 100 OTP SAMPLED SERVICES, 26 DID NOT COMPLY WITH REQUIREMENTS

Treatment Plan Review Requirements Were Not Met

Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment (42 CFR § 8.12(f)(4)).¹

Massachusetts State regulations require OTPs to ensure individual treatment plans are reviewed with each client at least once every 3 months when the treatment continues for 3 months or more. The client and staff reviewing the plan will sign it, and it will be incorporated into the client's record (105 CMR 164.073(B)). Further, each client record shall contain the original service plan and service plan reviews (105 CMR 164.083(B)(7)). Massachusetts Medicaid regulations require providers to meet the recordkeeping requirements as set forth in 105 CMR 164.000 (130 CMR 418.409).

For 23 OTP services, the treatment plan was not reviewed at least once every 3 months as required. For example, one OTP service did not have a treatment plan review for more than 6 months.

Although these errors did not cause an overpayment, they potentially increased the risk of individuals not receiving the most appropriate treatment. Specifically, without properly executed reviews and updates of treatment plans, OTPs may be unable to accurately monitor individual needs and, therefore, provide the most optimal care to achieve the desired goals for the individual.

Services Were Not Documented

Every person or institution providing services under a State plan must agree to keep such records as are necessary to fully disclose the extent of the services provided to individuals receiving assistance under the State plan. In addition, the aforesaid group will also furnish the

¹ Following our audit period, a final Federal rule modified certain provisions of 42 CFR § 8.12 (89 Fed. Reg. 7528 (Feb. 2, 2024)) and the State's requirements were also modified (Mass. Register #1482, Nov. 11, 2022, and Mass. Register #1485, Dec. 23, 2022). Any references to Federal and State requirements reflect requirements that were in effect during our audit period.

State agency or the Secretary with such information regarding any payments claimed by such person or institution for providing services under the State plan, as the State agency or the Secretary may from time to time request (Social Security Act § 1902(a)(27)).

OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care (42 CFR § 8.12(g)). Additionally, Massachusetts Medicaid regulations require substance use disorder providers to maintain a complete record of all treatments, including counseling (130 CMR 418.409).

For three OTP services, there was no documentation supporting that the counseling services were provided.

The State agency had procedures in place to oversee the OTPs, but these procedures did not prevent the errors identified in this report.

Based on our sample results, we identified three OTP services that may have been overpaid.

RECOMMENDATIONS

We recommend the Massachusetts Executive Office of Health & Human Services:

- follow up with the OTP providers to correct the three services that were not supported by the medical records, and
- review its procedures designed to prevent OTP noncompliance with Federal and State requirements and make changes to improve documentation of counseling and more timely review of OTP treatment plans.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with our recommendations and described the actions it has taken and plans to take to address them. Specifically, the State agency indicated it will continue its efforts to ensure OTP compliance with Federal and State regulations. The State agency agreed that treatment plan review is important and noted that the regulations governing treatment plan review have changed since the end of our audit period. Lastly, the State agency agreed that billed services must be supported by appropriate documentation and that it will review the three services identified in the report and recover overpayments as deemed appropriate.

The State agency's comments are included in their entirety as Appendix D.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered Medicaid claims for OUD treatment services provided individuals enrolled in the Medicaid program during the period July 1, 2021, through June 30, 2022. During this period, three OTPs submitted fee-for-service claims and claims paid through MCOs for 2,187,024 OTP services totaling \$33,693,213 provided for individuals enrolled in the Medicaid program. We selected and reviewed a stratified random sample of 100 OTP services totaling \$3,263.

During our audit, we did not assess the overall internal control structure of the State agency or selected providers.

Although our audit focused on services paid through the MCOs, we did not include in our audit a review of the State agency's oversight of the MCOs or its payment methodology, and we did not audit the MCOs' capitation payments.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed applicable State laws, policies, and procedures related to the OTPs;
- held discussions with State officials to gain an understanding of the program;
- identified a sampling frame of services provided during our audit period for individuals enrolled in the Medicaid program and diagnosed with an OUD;
- selected a stratified random sample of 100 OTP services (Appendix B) and reviewed each OTP service according to criteria in the following areas:
 - initial medical examination did not meet requirements,
 - initial methadone dose exceeded allowable amount,
 - required counseling services were not provided,
 - documentation related to the delivery of services was insufficient,
 - drug screenings did not meet requirements, and

- discharge summaries were missing or incomplete.
- determine the number of OTP services in the sample that did not meet Federal and State requirements; and
- discussed the results of our audit with State officials.

See Appendix B for our statistical sampling methodology.

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 objective.

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

The sampling frame consisted of 2,187,024 reimbursable units of service (OTP services) totaling \$33,693,213 provided for individuals enrolled in the Medicaid program from July 1, 2021, through June 30, 2022, and paid by the State agency and through MCOs to providers.

SAMPLE UNIT

The sample unit was an OTP service.

SAMPLE DESIGN AND SAMPLE SIZE

Our sample design was a stratified random sample containing 4 strata as follows:

Stratum	Opioid Treatment Program*	Number of Frame Units	Frame Dollar Value	Sample Size
1	Program A	471,872	\$7,020,573	30
2	Program B	985,882	\$14,258,139	30
3	Program C – Group 1	683,242	\$8,803,803	20
4	Program C – Group 2	46,028	\$3,610,697	20
	Total	2,187,024	\$33,693,213	100

* Program C was divided into two groups (strata) based on dollar amount paid for the OTP service. Group 1 consists of OTP services with paid amounts of \$11.26 to \$28.68. Group 2 consists of OTP services with paid amounts of \$30.54 to \$492.93.

SOURCE OF RANDOM NUMBERS

The source of the random numbers for selecting sample services was the OIG, Office of Audit Services, statistical software.

METHOD OF SELECTING SAMPLE ITEMS

We sorted the sample items by claim control number, from date, and procedure code, and then consecutively number the items in each stratum in the sampling frame. We generated the random numbers for our sample according to the sample design, and we then selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We have chosen not to report any estimates due to the low error rate found in the sample results.

APPENDIX C: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>About Seventy-Nine Percent of Opioid Treatment Program Services Provided to Medicaid Beneficiaries in Colorado Did Not Meet Federal and State Requirements</i>	<u>A-07-20-04118</u>	09/21/2021
<i>California Claimed at Least \$2 Million in Unallowable Medicaid Reimbursement for a Selected Provider's Opioid Treatment Program Services</i>	<u>A-09-20-02001</u>	1/25/2021
<i>Ohio Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program</i>	<u>A-05-18-00004</u>	12/29/2020
<i>Opioid Treatment Programs Reported Challenges Encountered During the COVID-19 Pandemic and Actions Taken To Address Them</i>	<u>A-09-20-01001</u>	11/18/2020
<i>Update on Oversight of Opioid Prescribing and Monitoring of Opioid Use: States Have Taken Action To Address the Opioid Epidemic</i>	<u>A-09-20-01000</u>	10/7/2020
<i>SAMHSA's Oversight of Accreditation Bodies for Opioid Treatment Programs Did Not Comply With Some Federal Requirements</i>	<u>A-09-18-01007</u>	3/6/2020
<i>New York Claimed Tens of Millions of Dollars for Opioid Treatment Program Services That Did Not Comply With Medicaid Requirements Intended To Ensure the Quality of Care Provided to Beneficiaries</i>	<u>A-02-17-01021</u>	2/4/2020
<i>California Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program</i>	<u>A-09-18-01006</u>	12/10/2019
<i>New York Achieved Program Goals for Enhancing Its Prescription Drug Monitoring Program</i>	<u>A-02-18-02001</u>	8/8/2019
<i>Oversight of Opioid Prescribing and Monitoring of Opioid Use: States Have Taken Action To Address the Opioid Epidemic</i>	<u>A-09-18-01005</u>	7/24/2019
<i>The University of Kentucky Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program</i>	<u>A-04-18-02012</u>	5/30/2019
<i>Washington State Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program</i>	<u>A-09-18-01001</u>	4/15/2019

APPENDIX D: STATE AGENCY COMMENTS



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Re: Department of Health and Human Services, Office of Inspector General (OIG) draft report
Massachusetts Opioid Treatment Program Met Many of the Federal and State Requirements, Report
Number A-01-23-00002

Dear Mr. Roy:

The Massachusetts Executive Office of Health and Human Services (EOHHS) is writing to respond to the Department of Health and Human Services, Office of Inspector General (OIG) draft report titled Massachusetts Opioid Treatment Program Met Many of the Federal and State Requirements.

Research indicates that for many individuals, treatment at an Opioid Treatment Program (OTP) can reduce the use of illicit opioids, retain people in the recovery continuum of care, improve general health and functioning, and reduce the risk of opioid overdose death. Medication for Opioid Use Disorder (MOUD) is integral to recovery for many people with Opioid Use Disorder (OUD). Additionally, treatment with medication results in better outcomes than outpatient treatment without medication (SAMHSA TIP 63).

The Massachusetts Bureau of Substance Addiction Services (BSAS) and MassHealth are dedicated to cross agency collaboration to support the OTP system in providing quality treatment through consistent regulatory oversight, and through the provision of technical support and funding opportunities to expand OTPs and access to life saving methadone treatment. EOHHS is proud that the OIG's findings demonstrate the success of our robust oversight of the delivery of services through OTPs. We intend to continue these efforts to prevent OTP noncompliance with Federal and State requirements. EOHHS will also be following up with the OTP providers regarding the three claims that were identified by the OIG as being unsupported by the medical records.

In addition, EOHHS has the following overall responses to the report:

Treatment Plan Review Requirements

For 23 OTP services, the OIG found that the treatment plan was not reviewed at least once every 3 months as required by the regulations in effect at the time of the audit.

EOHHS agrees that review and updating of a treatment plan is an important part of good clinical practice. During the audit period, which overlapped with the COVID-19 pandemic, OTPs were required to comply with infection control measures implemented by the state while simultaneously preserving the health and safety of members and staff and ensuring consistent access to compliant services for the approximately 20,000 unduplicated MassHealth members in OTPs. Although EOHHS does not know the specific circumstance of the 23 records identified by the OIG, the challenges faced by patients and providers during the pandemic may have been a factor in some cases.

Additionally, following the audit period, federal and state regulations were updated to remove specific requirements regarding the timing for the review of treatment plans. Today, OTPs are required to review and update treatment plans as clinically indicated for the member. *See* 105 CMR 164.073(B). The standard of updating treatment plans as clinically indicated supports properly executed and updated reviews based on individual need.

EOHHS engages in robust oversight and administration of OTP services, which includes annual chart review, issuing guidance, offering training opportunities, involving stakeholders during regulatory promulgation processes, and issuing sub-regulatory guidance to clarify and support provision of services in accordance with regulations, best practices and clinician quality standards. Where deficiencies are identified, EOHHS engages in corrective actions, as appropriate. EOHHS believes that these processes, along with the recent updates to treatment plan review requirements will continue to prevent OTP noncompliance with Federal and State requirements.

Services Were Not Documented

For three OTP services, the OIG found that there was no documentation supporting that the counseling services were provided.

EOHHS agrees that services billed must be supported by appropriate documentation. EOHHS will review the three OTP services identified by the OIG as lacking documentation and will recover overpayments as appropriate.

Thank you for your consideration of EOHHS' response.

Sincerely,



Kathleen Walsh

cc: Mike Levine, Assistant Secretary for MassHealth and Medicaid Director