

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**ABOUT SEVENTY-NINE PERCENT OF
OPIOID TREATMENT PROGRAM SERVICES
PROVIDED TO MEDICAID BENEFICIARIES
IN COLORADO DID NOT MEET FEDERAL
AND STATE REQUIREMENTS**

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Office of Inspector General

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Report in Brief

Date: September 2021

Report No. A-07-20-04118

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG 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 opioid use disorders. In 2019 alone, there were nearly 50,000 opioid-related overdose deaths in the United States. Opioid treatment programs (OTPs) provide medication coupled with counseling services (OTP services) for people diagnosed with an opioid use disorder. As part of OIG's oversight of the integrity and proper stewardship of Federal funds used to combat the opioid crisis, we audited OTP services in Colorado.

Our objective was to determine whether Colorado's oversight ensured that Medicaid OTP services in Colorado met Federal and State requirements.

How OIG Did This Audit

Our audit covered OTP services provided during the period October 1, 2016, through September 30, 2018, by OTP providers to Medicaid beneficiaries diagnosed with an opioid use disorder. During this period, 20 OTP providers submitted claims to Medicaid managed care organizations for almost 1.5 million OTP services totaling almost \$22.2 million provided to Medicaid beneficiaries. We selected and reviewed a random sample of 100 OTP services.

About Seventy-Nine Percent of Opioid Treatment Program Services Provided to Medicaid Beneficiaries in Colorado Did Not Meet Federal and State Requirements

What OIG Found

Colorado's oversight during the audit period did not ensure that OTP services provided to Medicaid beneficiaries met Federal and State requirements. Of the 100 OTP services we sampled, 21 complied with Federal and State requirements but 79 did not meet applicable Federal and State requirements. Colorado's oversight of the OTPs consisted primarily of biennial audits conducted by the State Opioid Treatment Authority (SOTA), which were not sufficient in scope and depth of coverage to ensure that OTPs maintained a recordkeeping system that was adequate to document and monitor patient care, or to ensure that OTP services met Federal and State requirements.

The biennial audits of each OTP were performed by a single person, covered approximately 10 percent of patient charts, and took between 1 and 2 days to perform. Given all of the tasks that these audits sought to conduct, we do not believe that reviewing 10 percent of patient charts over the course of 1 to 2 days was adequate for one person to be able to thoroughly review patient charts for deficiencies and to devote sufficient time to other tasks.

On the basis of our sample results, we estimated that over 1.1 million OTP services, or about 79 percent, did not meet Federal and State requirements during the audit period.

What OIG Recommends and Colorado Comments

We recommend that Colorado strengthen its biennial audits of OTPs to ensure that services provided are in accordance with Federal and State requirements, provide technical assistance to OTPs to ensure that the providers maintain adequate recordkeeping systems, and educate OTPs on the deficiencies we identified to increase their awareness of compliance issues regarding Federal and State requirements.

Colorado described corrective actions it had taken or planned to take to address our recommendations. Colorado said that it had hired a program coordinator to: support the SOTA in conducting the biennial audits; provide technical assistance to OTPs; and manage the Central Registry, a system used to ensure that individuals are not enrolled in more than one OTP. In addition, Colorado said that it was developing a new automated Central Registry system, and described several planned activities to educate OTPs and review the deficiencies we had identified.

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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 opioid use disorders. In 2019 alone, there were nearly 50,000 opioid-related 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 opioid use disorder. 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 Colorado.

OBJECTIVE

Our objective was to determine whether the Colorado Department of Health Care Policy and Financing’s (HCPF’s) and the Colorado Department of Human Services’ (DHS’s) oversight ensured that Medicaid OTP services in Colorado met 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.

States may contract with Managed Care Organizations (MCOs) to provide specific services to enrolled Medicaid beneficiaries, in return for a predetermined periodic payment, known as a capitation payment.

Opioid Treatment Programs

OTPs provide medication-assisted treatment (MAT) services for individuals diagnosed with an opioid use disorder. Medications used in MAT include methadone, buprenorphine products, and naltrexone (collectively referred to as “treatment drugs” for this report). 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 individuals receiving treatment.

Federal opioid treatment regulations at 42 CFR part 8 establish the procedures by which to determine whether a provider is qualified to dispense opioid drugs in the treatment of opioid

use disorders. The Code of Colorado Regulations (CCR) requires OTPs in the State to comply with the requirements of 42 CFR part 8 (2 CCR 502-1 § 21.320.41(A)). In addition, State regulations at 2 CCR 502-1 § 21.320 provide the requirements for Colorado’s opioid MAT program. Both sets of Federal and State regulations convey requirements for recordkeeping, central registry verification, take-home medications, accreditation certification and controlled substance use disorder licensing, toxicology screening, informed consent, medical orders, and diagnosis of opioid addiction.

Medicaid providers must comply with the MAT program requirements set forth at 2 CCR 502-1 § 21.320 (10 CCR 2505-10 § 8.746.6.G). State regulations also provide for the Medicaid Community Behavioral Services Program in Colorado and specify MAT as a required service of the program (10 CCR 2505-10 § 8.212.4).

Colorado’s Opioid Treatment Program

HCPF is the single Colorado State department responsible for administering the Medicaid program.¹ DHS, a co-equal department of the Colorado State government, administers and provides services related to substance abuse and substance use disorders including the prevention, education, and treatment of these conditions.² DHS maintains a Central Registry of individuals who are receiving treatment through an OTP. Within DHS, the Office of Behavioral Health (OBH) is responsible for the administration of substance use disorder treatment programs in Colorado.³ HCPF and DHS partner to administer OTP services to Medicaid beneficiaries in Colorado. For this report, we collectively referred to HCPF and DHS as “the State.”

The figure on the following page depicts the State’s responsibilities and lines of coordination for the administration of and payment for OTP services in Colorado.

Within DHS, the State Opioid Treatment Authority (SOTA) is responsible for licensing and regulatory issues involving OTP providers and is thus primarily responsible for State-level oversight of those providers. On an annual basis during our audit period, the SOTA conducted what its officials call “in-depth reviews” of OTP providers with particular attention to the providers’ licenses to maintain and administer controlled substances. In general, these in-depth reviews addressed diversion control protocols, security and safety of controlled substances, and complaints or grievances.

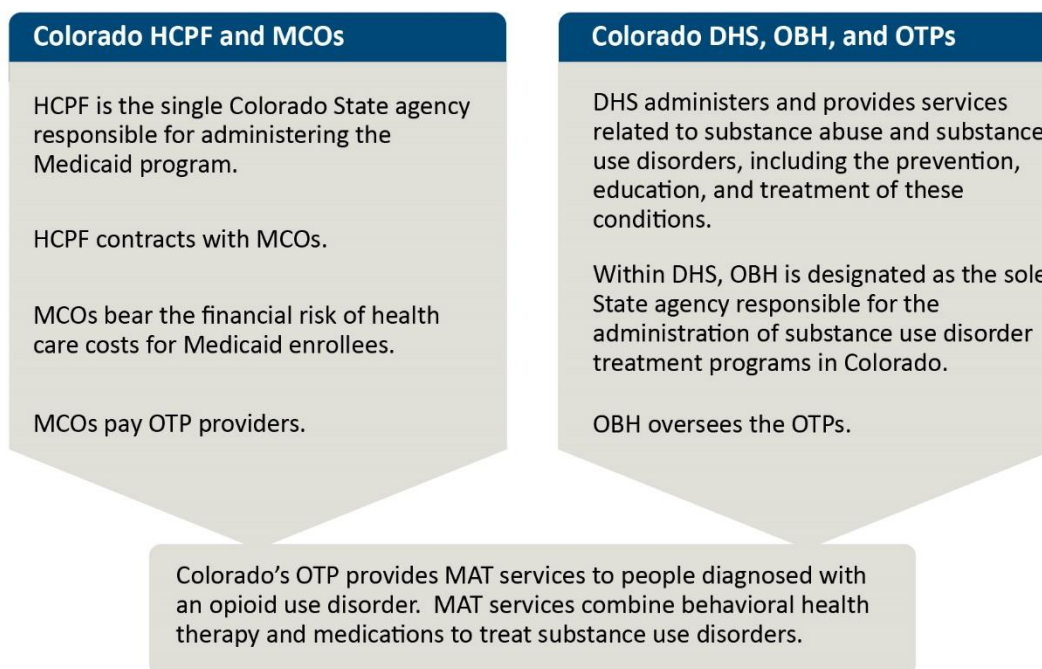
¹ Colorado Revised Statutes (CRS) § 25.5-4-104, *Program of medical assistance—single state agency*.

² CRS § 26-1-201(1), *Programs administered—services provided—department of human services*.

³ CRS § 27-80-102(2), *Duties of the office of behavioral health*.

During our audit period, the SOTA also conducted biennial audits of OTP providers to verify providers' compliance with the requirements of their substance use disorder licenses.⁴ During these audits, the SOTA reviewed patient charts for: general intake paperwork, such as the consent to treat a patient with a controlled substance; patient treatment plans and notes; staff- and patient-required signatures; patient discharge summaries; patient transitions from one phase of treatment to another; and levels of care. These audits covered approximately 10 percent of each OTP provider's patient charts and included certain other oversight activities, and took between 1 and 2 days to perform.

Figure: Colorado's Opioid Treatment Program: State Departments Responsible for Payments and Provider Oversight



Acronyms

HCPF: Department of Health Care Policy and Financing

MCO: Medicaid Managed Care Organization

OTP: Opioid Treatment Program

DHS: Department of Human Services

OBH: Office of Behavioral Health

MAT: Medication-Assisted Treatment

HOW WE CONDUCTED THIS AUDIT

Our audit covered OTP services provided during the period October 1, 2016, through September 30, 2018 (audit period), by OTP providers to Medicaid beneficiaries diagnosed with

⁴ Substance use disorder licenses are separate and distinct from the controlled substance use disorder licenses mentioned earlier. The latter involve the delivery of controlled substances for MAT services, and for the rest of this report will be referred to as "controlled substance licenses." DHS issues both types of licenses.

an opioid use disorder.⁵ During this period, 20 OTP providers submitted claims to MCOs for 1,472,721 OTP services totaling \$22,197,528 provided to Medicaid beneficiaries.⁶ We selected and reviewed a random sample of 100 OTP services to determine whether the State ensured that Medicaid OTP services 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, Appendix C contains our sample results and estimates, and Appendix D contains a list of related OIG reports.

FINDINGS

The State's oversight during the audit period did not ensure that OTP services provided to Medicaid beneficiaries met Federal and State requirements. Of the 100 OTP services we sampled, 21 complied with Federal and State requirements but 79 did not meet applicable Federal and State requirements. Table 1 breaks out the types of deficiencies we identified in the 79 sampled OTP services for which we found errors.

Table 1: Summary of Deficiencies in Sampled Services

Deficiency	Number of Sampled Services in Error ⁷
Services Not Supported	49
Central Registry Verification Not Adequately Documented	47
Treatment Plans Not Reviewed	13
Take-Home Medications Not Administered in Accordance With State Regulations	7
Accreditation Certifications and Controlled Substance Licenses Not Confirmed	5
Toxicology Screenings Not Documented	5
Informed Consent Forms Not Signed	3
Medical Orders Not Signed	2
Diagnosis of Opioid Addiction Not Documented	1

⁵ See our discussion earlier in "Opioid Treatment Programs" for a description of OTP services.

⁶ This amount represents reimbursement for the associated services from both Federal and State funding sources.

⁷ The total number of sampled services in error is more than 79 because 42 sampled services had more than 1 deficiency.

These deficiencies occurred because the State’s oversight of the OTPs consisted primarily of the biennial audits conducted by the SOTA, which were not sufficient in scope and depth of coverage to ensure that OTPs maintained a recordkeeping system that was adequate to document and monitor patient care, or to ensure that OTP services met Federal and State requirements. The SOTA’s other oversight activities—the in-depth reviews—focused on other aspects of OTP providers’ operations that did not have a direct bearing on preventing or minimizing the types of deficiencies we identified.

These deficiencies point to the risk that OTPs may be unable to accurately monitor patient care and may therefore not provide the most appropriate combination of services and treatment or the optimal dosages of treatment drugs. There may also be an increased risk of diversion of medications used in MAT from legitimate treatment use to illicit use.

On the basis of our sample results, we estimated that 1,163,450 OTP services provided during the audit period, or about 79 percent, did not meet Federal and State requirements.

THE STATE DID NOT ENSURE THAT OPIOID TREATMENT PROGRAM SERVICES MET FEDERAL AND STATE REQUIREMENTS

Services Not Supported

Providers must keep such records as are necessary fully to disclose the extent of the services provided to Medicaid beneficiaries (Social Security Act § 1902(a)(27)). Federal regulations state: “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)).

Federal regulations state that for purposes of recordkeeping and patient confidentiality, OTPs must establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system must comply with all Federal and State reporting requirements relevant to treatment drugs (42 CFR § 8.12(g)). Recordkeeping requirements include treatment plans (42 CFR § 8.12(f)(4)), medical orders (2 CCR 502-1 § 21.320.32(D)(5)), and informed consent (42 CFR § 8.12(e)(1); 2 CCR 502-1 §§ 21.320.31(A)(5)).

State regulations require medical evaluations to be done at admission prior to initial medication dosing and require OTPs to document, before an admitted patient has received his or her initial dose of treatment drugs, the medical evaluations that include evidence of current physiological dependence, a history of addiction, or both, as well as any exceptions to admission criteria (2 CCR 502-1 §§ 21.320.32(D)(1) and (2)).

Of the 100 sampled services we reviewed, OTPs lacked supporting documentation for 49 services.⁸ Specifically:

- OTPs were missing treatment plans that should have been developed at admission or for the sampled service date (33 services),
- OTPs were missing a medical order for the initial medication dosage at admission and for the sampled service date (13 services),
- OTPs were missing a signed informed consent verifying that the patient voluntarily agreed to treatment with a controlled substance (9 services),
- OTPs were missing all medical records to support the sampled services (5 services),
- OTPs were missing a medical evaluation and an initial assessment that should have been conducted before the initial dose (5 services), and
- OTPs were missing medical orders for dose increase (3 services).

In addition, for three sampled services, we could not determine whether the initial dose exceeded 30 milligrams, which is the initial dose limit set by Federal regulation.⁹ For one of these three sampled services, the OTP's records had no documentation of the patient's dependency on opioid drugs before admission.

Without adequate support for services, OTPs may be unable to accurately monitor patient care and may therefore not provide the most appropriate combination of services and treatment to the patients in their care.

Central Registry Verification Not Adequately Documented

Federal regulations specify that OTPs must include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled in any other OTP. A patient enrolled in an OTP cannot obtain treatment in any other OTP, except in exceptional circumstances (42 CFR § 8.12(g)(2)).

State regulations state that to prevent an individual from simultaneously enrolling in more than one treatment clinic, OTPs must initiate a clearance inquiry by submitting applicant information

⁸ The total number of sampled services in these bullets exceeds 49 because 22 sampled services contained more than 1 deficiency.

⁹ 42 CFR § 8.12(h)(3)(ii).

to DHS's Central Registry. Applicants are not to be admitted to treatment when DHS's Central Registry shows them as currently enrolled in another clinic (2 CCR 502-1 § 21.320.9(D)).

For 47 sampled services, the OTPs did not have adequate documentation that they had fully executed verification of the patients in question through DHS's Central Registry. Specifically, for 28 sampled services, OTPs did not have any documentation to support that they made a good faith effort to verify patients' enrollment in any other OTP. For the remaining 19 sampled services, the documentation provided did not show that the OTPs had submitted clearance inquiries to DHS's Central Registry to ensure that the patients were not already enrolled in another OTP. Specifically, OTPs showed us clearance forms for these 19 sampled services, but the forms did not reflect that the providers had obtained clearance from DHS's Central Registry. For example, the reporting form had data fields filled in for the patient's name, Social Security number, date of birth, admission date, and discharge date. However, the section to indicate that the patient had been cleared through DHS's Central Registry was blank.

Without adequate documentation of Central Registry verification—the purpose of which is to prevent patients from simultaneously enrolling in more than one OTP—there is an increased risk that patients might be able to obtain more than their appropriate amounts of treatment drugs for purposes of illicit use.

Treatment Plans Not Reviewed

Documentation requirements for OTPs involve both treatment plans and medical orders. Federal regulations require that each patient accepted for treatment at an OTP be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes: the patient's short-term goals and the tasks the patient must perform to complete those goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that the patient needs. The treatment plan must also identify the frequency with which these services are to be provided. The plan must periodically be reviewed and updated to reflect that patient's personal history; his or her current needs for medical, social, and psychological services; and his or her current needs for education, vocational rehabilitation, and employment services (42 CFR § 8.12(f)(4)).

State regulations require that all medical orders be properly signed or countersigned by the relevant medical director, including initial orders for approved controlled substances and other medications, subsequent dose increases or decreases, changes in take-home dose privileges, emergency situations, and other special circumstances (2 CCR 502-1 § 21.320.32(D)(5)).

For 13 sampled services at one OTP, one or both of the initial treatment plan for admission and the plan for the sampled service date were not signed. Absent any signatures, it is difficult to confirm that these plans were reviewed or that medication dosages had been approved. For

example, one treatment plan had data fields filled in to show the date that the plan was initiated, the dose at admission, and the review dates, but no signatures.

Without properly executed reviews and updates of treatment plans, OTPs may be unable to accurately monitor patient care and may therefore not provide the most appropriate combination of services and treatment to the patients in their care.

Take-Home Medications Not Administered in Accordance With State Regulations

To limit the potential for diversion of treatment drugs to the illicit market, Federal regulations restrict the dispensing of those medications to patients for unsupervised use (42 CFR § 8.12(i)). For example, determinations for self-administered doses must be made by the medical director and documented in the patient's medical record (42 CFR §§ 8.12(i)(2) and (3)).

State regulations permit 13 take-home doses per 2-week period under Phase 5 of MAT.¹⁰ A patient may qualify for Phase 5 when, in addition to other take-home requirements, the patient has completed 1 or more years in treatment, the patient's most recent six consecutive toxicology screens are negative, and the patient's transition to that phase has been approved by the State (2 CCR 502-1 § 21.320.81(A)(14)(e)).

For 7 of the 100 sampled services, there was no documentation supporting that the State approved the patients' advancement to Phase 5 of treatment. The State provides a form for phase advancement that includes data fields for entry of the authorized signatures from the counselor, clinic director, physician, and the State. However, for these sampled items, OTP providers could not show us this form or any other type of approval to support the patients' advancement to Phase 5.

Without adequate documentation to support State approval of take-home doses for qualifying patients, OTPs may incur an increased risk that treatment drugs may be diverted from legitimate treatment use to illicit use.

Accreditation Certifications and Controlled Substance Licenses Not Confirmed

OTPs must meet Federal opioid treatment standards and must be the subject of a current, valid accreditation by an accreditation body (42 CFR § 8.11(a)(2)).

State regulations specify that providers applying to be licensed as an opioid MAT program provider have a controlled substance license, Federal accreditation, and Drug Enforcement Administration registration (2 CCR 502-1 §§ 21.320.2(B) and 21.320.41(A)).

¹⁰ State regulations establish protocols for take-home dose privileges based on six phases. A patient may transition to a higher level of take-home privilege if he or she meets 14 specified requirements and has completed a designated length of time in each previous phase (2 CCR 502-1 § 21.320.81(A)).

For five sampled services, two OTPs did not provide support that they had a controlled substance license issued by DHS or that they were registered with the Drug Enforcement Administration to dispense or administer a controlled substance. In addition, for three of these five sampled services, the associated OTP did not have documentation that it was accredited by a federally approved accreditation body, such as the Commission on Accreditation of Rehabilitation Facilities, during our audit period. This OTP was able to show us its current accreditation.

Without confirmation of licensing or accreditation, OTPs may be unable or unqualified to provide the most appropriate combination of services and treatment to the patients in their care.

Toxicology Screenings Not Documented

Federal regulations state that OTPs must provide adequate testing or analysis for opioids and other illicit drugs, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice (42 CFR § 8.12(f)(6)).

State regulations direct that toxicology screens occur at a patient's admission and that the patient receive a minimum of one monthly random toxicology screen thereafter (2 CCR 502-1 §§ 21.320.7(D)(1-2)).

For five sampled services, OTPs did not document the initial toxicology screenings. The OTP for one of these sampled services also did not document the monthly random toxicology screenings while the patient was receiving OTP services.

Without documentation of all toxicology screens, OTPs may be unable to accurately monitor patient care and may not provide the most appropriate combination of services and treatment to the patients in their care.

Informed Consent Forms Not Signed

Federal regulations require that, before providing treatment, OTP physicians ensure that each patient voluntarily chooses maintenance treatment, that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent for treatment (42 CFR § 8.12(e)(1)).

State regulations state that all medical professionals will educate individuals regarding the risks and benefits of opioid MAT and will document that individuals are entering an OTP voluntarily (2 CCR 502-1 § 21.320.32(D)(4)). Full disclosure is to be made to individuals about opioids and their use in treatment, with written informed consents signed by the individuals for treatment drugs (2 CCR 502-1 §§ 21.320.31(A)(4-5)).

For three sampled services, the OTPs maintained the consent forms in the medical records, but the patients had not signed the forms to indicate that they voluntarily agreed to treatment with a controlled substance.

Without documentation of informed consent, OTPs incur increased risks that patients may be unaware of all of the risks and benefits of treatment and may not be able to recognize whether they are receiving the most appropriate combination of services and treatment.

Medical Orders Not Signed

State regulations require that all medical orders be properly signed or countersigned by the relevant medical director, including initial orders for approved controlled substances and other medications, subsequent dose increases or decreases, changes in take-home dose privileges, emergency situations, and other special circumstances (2 CCR 502-1 § 21.320.32(D)(5)).

For two sampled services, medical personnel did not sign the medical order for the initial dose of medication at admission.

Without signed medical orders, OTPs incur the risk that dosages of treatment drugs administered to patients at admission or thereafter may not have been appropriate because they were not approved by medical personnel.

Diagnosis of Opioid Addiction Not Documented

Federal regulations state that OTPs must maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined that the person is currently addicted to an opioid drug and that the person became addicted at least 1 year before admission for treatment (42 CFR § 8.12(e)(1)).

State regulations state that OTPs must document, before an admitted patient has received his or her initial dose of treatment drugs, the medical evaluations that include evidence of current physiological dependence, a history of addiction, or both, and must document any exceptions to admission criteria (2 CCR 502-1 § 21.320.32(D)(1)).

For one sampled service, the OTP did not have support in its records that the beneficiary who received the service had the required opioid addiction diagnosis.

Without documentation of a diagnosis of opioid addiction for each patient, OTPs may be unable to provide the most appropriate combination of services and treatment to the patients in their care.

THE STATE DID NOT CONDUCT SUFFICIENT OVERSIGHT

These deficiencies occurred because the State's oversight of the OTPs consisted primarily of the biennial audits conducted by the SOTA, which were not sufficient in scope and depth of coverage to ensure that OTPs maintained a recordkeeping system that was adequate to document and monitor patient care, or to ensure that OTP services met Federal and State requirements.

The biennial audits of each OTP were performed by a single person, covered approximately 10 percent of patient charts, and took between 1 and 2 days to perform. The SOTA reviewed patient charts for: general intake paperwork, such as the consent to treat a patient with a controlled substance; patient treatment plans and notes; staff- and patient-required signatures; patient discharge summaries; patient transitions from one phase of treatment to another; and levels of care. In addition, these biennial audits included certain other oversight activities, such as a review of policies and procedures, a review of personnel files, a physical walk-through of the provider's facility, and physical observation of the administration of treatment drugs.

Although the SOTA has been conducting oversight activities of OTPs, several considerations lead us to conclude that those oversight activities, as they were structured and resourced during the audit period, were not sufficient to ensure that OTPs complied with Federal and State requirements. Given all of the tasks that the biennial audits sought to conduct at each OTP provider, we do not believe that reviewing 10 percent of patient charts over the course of 1 to 2 days was adequate for one person to be able to thoroughly review patient charts for deficiencies and to devote sufficient time to the other tasks. In addition, the SOTA's other oversight activities—the in-depth reviews, which were performed by the same person—were more focused on other aspects of OTP providers' operations (diversion control protocols and security and safety of controlled substances) that, while important oversight activities, did not have a direct bearing on preventing or minimizing the types of deficiencies we identified.

These deficiencies point to the risk that OTPs may be unable to accurately monitor patient care and may therefore not provide the most appropriate combination of services and treatment or the optimal dosages of treatment drugs. There may also be an increased risk of diversion of medications used in MAT from legitimate treatment use to illicit use.

On the basis of our sample results, we estimated that 1,163,450 OTP services, or about 79 percent, did not meet Federal and State requirements during the audit period.

RECOMMENDATIONS

We recommend that the Colorado Department of Health Care Policy and Financing work with the Colorado Department of Human Services to:

- strengthen its biennial audits of OTPs to ensure that services provided are in accordance with Federal and State requirements,

- provide technical assistance to OTPs to ensure that the providers maintain adequate recordkeeping systems, and
- educate OTPs on the deficiencies we identified in this report to increase their awareness of compliance issues regarding Federal and State requirements.

STATE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

Although HCPF and DHS (i.e., the State) did not directly agree or disagree with our recommendations in their joint written comments on our draft report, the departments described corrective actions that they had taken or plan to take to address our recommendations. We believe these corrective actions are appropriate to address our recommendations.

For our first recommendation, the State said that HCPF will collaborate with DHS to amend the interagency agreement between the two departments and specify the roles and responsibilities related to annual and biennial audits of OTPs. The State added that OBH hired a program coordinator in July 2021 to support the SOTA's position in ensuring regulatory compliance with Federal and State requirements. The State said that the program coordinator will "support the OBH by strengthening the annual and biennial audits of OTPs and allow for a . . . more in-depth review of a larger sampling of patient charts and overall service delivery within the OTP."

For our second recommendation, the State said that the newly hired program coordinator will provide technical assistance and manage the Central Registry. The State added that OBH is in the process of developing a new Central Registry that will enable OTPs to automatically verify that their patients are not enrolled in any other OTP in Colorado and that will automatically document that OTPs submitted clearance inquiries to the Central Registry. According to the State, the new automated Central Registry system should be online by the first quarter of 2022.

For our third recommendation, the State described several planned activities to educate OTPS. Specifically, the State said that the SOTA and program coordinator will hold regular meetings with OTP directors and staff, as well as a special meeting to review deficiencies identified in our audit. The State added that the SOTA and program coordinator will request feedback on how the State can support OTPs in correcting deficiencies and maintaining compliance with Federal and State requirements. Furthermore, the State said that OBH will review any recommendations from OTPs and develop a work plan to implement solutions.

The State's comments appear in their entirety as Appendix E.

OTHER MATTERS

Federal and State requirements do not address how soon after medical orders are given, or treatment plans are developed, that those documents must be signed. We identified 25 instances in which the documents had not been signed on the dates that they were

created.¹¹ Of these, 14 medical orders had not been signed for a period that ranged from 10 to 1,161 days after the dates of the medical orders. In addition, 10 treatment plans within our audit period and 5 treatment plans outside our audit period had not been signed for a period that ranged from 30 to 755 days after the dates that those plans were developed. Also, we identified one initial treatment plan that was dated 1 month after the patient's admission. We believe that these delays in signatures and approvals could have put patients at risk because of the possibility that dosages of treatment drugs administered at admission or thereafter may not have been approved by medical personnel.

¹¹ The total number of sampled services delineated just below is more than 25 because 5 sampled services had more than 1 deficiency.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered OTP services provided during the period October 1, 2016, through September 30, 2018 (audit period), by OTPs to Medicaid beneficiaries diagnosed with an opioid use disorder. During this period, 20 OTPs submitted claims to MCOs for 1,472,721 OTP services totaling \$22,197,528 provided to Medicaid beneficiaries (footnote 5). We selected and reviewed a random sample of 100 OTP services to determine whether the State met Federal and State requirements.

During our audit, we did not assess the overall internal control structure of the State or selected providers. Rather, we limited our review to the State's internal controls that were significant to our audit objective. Specifically, we assessed the design, implementation, and operating effectiveness of the State's internal controls over the OTPs related to the control environment, control activities, information and communication, and monitoring.

Although our audit focused on services paid through the MCOs, we did not include in our audit a review of HCPF'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 OTP;
- held discussions with Federal and State officials to gain an understanding of the program;
- assessed the design, implementation, and operating effectiveness of internal controls applicable to our objective;
- assessed the reliability of data by analyzing for applicability, completeness, and accuracy;
- identified a sampling frame of services provided during the period October 1, 2016, through September 30, 2018, to Medicaid beneficiaries diagnosed with an opioid use disorder;

- selected a random sample of 100 services and reviewed each sample service according to criteria in the following areas:
 - inquiries to DHS's Central Registry,
 - admissions procedures,
 - diagnosis and treatment plans,
 - medication management procedures,
 - providers' operating certificates, accreditations, and controlled substance licenses,
 - toxicology screenings,
 - patients' informed consent,
 - initial assessments and medical evaluations,
 - readmissions procedures, if applicable, and
 - handling and storage of controlled substances;
- estimated the number and the percentage of services that did not meet Federal and State requirements; and
- discussed the results of our audit with State officials on May 17, 2021.

See Appendix B for our statistical sampling methodology and Appendix C for our sample results and estimates.

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 1,472,721 OTP services totaling \$22,197,528 provided to Medicaid beneficiaries from October 1, 2016, through September 30, 2018, and paid by MCOs to OTP providers.¹² The State extracted the OTP services from the MCOs' electronic files submitted monthly to the State.

SAMPLE UNIT

The sample unit was an OTP service.

SAMPLE DESIGN AND SAMPLE SIZE

We used a simple random sample of 100 services.

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 consecutively numbered the sample services in the frame from 1 to 1,472,721. After generating 100 random numbers, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG, Office of Audit Services, statistical software to estimate the number and the percentage of OTP services that did not meet Federal and State requirements using the point estimate. We also used the statistical software to calculate the lower and upper limits of the two-sided 90-percent confidence interval.

¹² See footnote 1.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Details and Results

Sampling Frame	Sample Size	Number of Errors
1,472,721	100	79

**Table 3: Estimated Number of Sampled Services in Error
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	1,163,450
Lower limit	1,048,383
Upper limit	1,258,813

**Table 4: Estimated Percentage of Sampled Services in Error
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	79.00 percent
Lower limit	71.19 percent
Upper limit	85.48 percent

APPENDIX D: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<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
<i>The Substance Abuse and Mental Health Services Administration Followed Grant Regulations and Program-Specific Requirements When Awarding State Targeted Response to the Opioid Crisis Grants</i>	<u>A-03-17-03302</u>	3/28/2019
<i>New York Did Not Provide Adequate Stewardship of Substance Abuse Prevention and Treatment Block Grant Funds</i>	<u>A-02-17-02009</u>	3/20/2019

APPENDIX E: STATE COMMENTS



COLORADO
Department of Health Care
Policy & Financing

1570 Grant Street
Denver, CO 80203

September 2, 2021

Patrick J. Cogley
Regional Inspector General for Audit Services
Office of Audit Services, Region VII
601 E. 12th Street, Room 0429
Kansas City, MO 64106

RE: Report Number A-07-20-04118

Dear Mr. Cogley,

Enclosed please find the Colorado Department of Health Care Policy and Financing's and the Colorado Department of Human Services, Office of Behavioral Health's responses to the draft report entitled *About Seventy-Nine Percent of Opioid Treatment Program Services Provided to Medicaid Beneficiaries in Colorado Did Not Meet Federal and State Requirements*.

Both Departments appreciate your work on identifying areas of improvement and have begun work on implementing your specific recommendations.

Sincerely,

/Christine Bickers/

Christine Bickers
External Audit Compliance Officer

Cc: Ms. Charlie Arnold
Acting Director
Audit & Review Branch
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services



We recommend that the Colorado Department of Health Care Policy and Financing work with the Colorado Department of Human Services to:

- **strengthen its biennial audits of OTPs to ensure that services provided are in accordance with Federal and State requirements**

The Colorado Department of Health Care Policy and Financing (Department) will collaborate with the Colorado Department of Human Services, Office of Behavioral Health (OBH) to amend the interagency agreement between the two entities to specific roles and responsibilities related to annual and biennial audits of Opioid Treatment Programs (OTPs).

The OBH recognizes the consistent growth of OTPs over the past few years, requiring more personnel to provide oversight of these programs. In response, the OBH hired a program coordinator in July 2021 to support the State Opioid Treatment Authority (SOTA) position in ensuring regulatory compliance with State and Federal laws. The program coordinator's responsibilities will include completing program audits with the SOTA, managing the Central Registry, and providing technical assistance to programs.

The additional staff member will support the OBH by strengthening the annual and biennial audits of OTPs and allow for a more robust review of patient charts. OBH staff will review more charts per site over a longer period of time to address the concerns outlined in the report. A more in-depth review of a larger sampling of patient charts and overall service delivery within the OTP will provide better adherence to State and Federal regulations.

- **provide technical assistance to OTPs to ensure that the providers maintain adequate recordkeeping systems, and**

OBH hired a program coordinator to support the SOTA role and one of their primary responsibilities will be to provide technical assistance and support a central registry. Thirty- five percent of violations occurred because OTPs did not adequately document that they had fully executed patient verifications in the central registry. OBH is in the process of developing a new central registry that will reduce many of the problems noted in the audit by:



1. Enabling OTPs to automatically verify that their patients are not enrolled in any other OTP in Colorado (28 violations); and,
2. Automatically documenting that OTPs submitted clearance inquiries to the central registry.

The new automated Central Registry system should be online in the first quarter of 2022.

- **educate OTPs on the deficiencies we identified in this report to increase their awareness of compliance issues regarding Federal and State requirements.**

The SOTA and program coordinator will hold regular meetings with OTP directors and staff. A special meeting with OTP directors and staff will focus on reviewing the deficiencies noted in this report and outline a revised audit process that will be more in-depth. The SOTA and program coordinator will also request feedback from OTP providers on how the State can support OTPs in correcting deficiencies and maintaining compliance with State and Federal regulations. OBH will review any recommendations from OTPs and develop a work plan to implement solutions.

