Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

OPIOID TREATMENT PROGRAMS IN WASHINGTON STATE DID NOT FULLY COMPLY WITH FEDERAL AND STATE REQUIREMENTS, WHICH MAY HAVE PUT MEDICAID ENROLLEES AT RISK FOR POOR TREATMENT OUTCOMES

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

Opioid Treatment Programs in Washington State Did Not Fully Comply With Federal and State Requirements, Which May Have Put Medicaid Enrollees at Risk for Poor Treatment Outcomes

Why OIG Did This Audit

The United States currently faces a nationwide public health emergency due to the opioid crisis. In 2021 alone, there were more than 80,000 opioid-related overdose deaths in the United States. Opioid treatment programs (OTPs) provide medication coupled with counseling services for people diagnosed with an opioid use disorder. OTPs' failure to comply with Federal and State requirements for providing and documenting opioid treatment services may lead to poor treatment outcomes for individuals, including relapses, overdoses, or deaths. As part of OIG's oversight of States' efforts to combat the opioid crisis, we audited OTP services provided to Medicaid enrollees in Washington State.

Our objective was to determine whether Washington ensured that OTPs complied with Federal and State requirements.

How OIG Did This Audit

Our audit covered the Medicaid OTP services that 22 OTPs in Washington provided from January 1, 2019, through July 31, 2020. We excluded from our audit OTP services provided by tribally owned and operated OTPs.

We selected a random sample of 100 enrollee-months. An enrollee-month (which we refer to as a "sample item") included all OTP services that an OTP provided to an enrollee in a calendar month. We reviewed supporting documentation for each sample item to determine compliance with Federal and State requirements.

What OIG Found

Washington did not ensure that OTPs fully complied with Federal and State requirements for OTP services they provided. Of the 100 sample items, 4 met the requirements, but 96 sample items did not meet the requirements. Among other findings, we found that OTPs did not adequately document enrollee admissions, treatment plans, opioid treatment services, the results of drug screens, checks of Washington's prescription drug monitoring program (PDMP) prescription data, and enrollee assessments. We also found that OTPs did not provide take-home medications in accordance with Federal and State requirements. These deficiencies occurred, in part, because Washington's oversight was not effective in ensuring that OTPs complied with Federal and State requirements for providing and documenting OTP services.

On the basis of our sample results, we estimated that OTPs did not comply with Federal and State requirements for 132,002 enrollee-months, or 96 percent of the enrollee-months in our audit period. OTPs' lack of compliance with Federal and State requirements may have put enrollees at risk for poor treatment outcomes, including relapses, overdoses, or deaths.

What OIG Recommends and Washington Comments

We recommend that the Washington State Health Care Authority work with its contracted managed care organizations and the Department of Health to ensure that OTPs comply with Federal and State requirements for providing and documenting OTP services, including ensuring that OTPs: (1) adequately document enrollee admissions, treatment plans, opioid treatment services, the results of drug screens, checks of Washington PDMP prescription data, and enrollee assessments; and (2) provide take-home medications in accordance with Federal and State requirements. The report contains additional procedural recommendations.

The Health Care Authority concurred with all of our recommendations and described actions that it planned to take to address them. These planned actions include partnering with the Department of Health to update the Washington Administrative Code (WAC) to reflect alignment with new Federal regulations for OTPs that were enacted on April 2, 2024, and developing procedures to review compliance with those regulations and the WAC.

The full report can be found on the OIG website.

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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 2021 alone, there were more than 80,000 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. OTPs' failure to comply with Federal and State requirements for providing and documenting opioid treatment services may lead to poor treatment outcomes for individuals, including relapses, overdoses, or deaths. As part of the Office of Inspector General's (OIG's) oversight of States' efforts to combat the opioid crisis, we audited OTP services provided to people enrolled in Medicaid (enrollees) in Washington State from January 1, 2019, through July 31, 2020. (See Appendix B for related OIG reports on OTPs.)

OBJECTIVE

Our objective was to determine whether Washington State's Health Care Authority (State agency) ensured that OTPs complied with 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 (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements. In Washington State, the State agency administers or supervises the administration of the Medicaid program, including OTP services.

Opioid Treatment Program Services

Each State's Medicaid program may cover substance use disorder (SUD) treatment services, including opioid maintenance treatment services provided by OTPs.[1] During maintenance treatment, an enrollee receives narcotic replacement medication, such as methadone and

[1] Opioid use disorder is a type of SUD.

buprenorphine, in stable and medically determined doses.[2] (We refer to the administration of these medications as "dosing services.") OTPs must also provide counseling services to each enrollee as clinically necessary. The purpose of comprehensive maintenance treatment is to reduce or eliminate chronic opioid addiction while an enrollee is provided a comprehensive range of additional treatment services.[3]

The Substance Abuse and Mental Health Services Administration (SAMHSA), an agency within the Department of Health and Human Services, has issued Federal regulations (42 CFR § 8.12) that establish treatment standards with which OTPs must comply.[4] These Federal regulations establish requirements for accrediting OTPs, recordkeeping, conducting dual enrollment checks, dispensing take-home medications, performing laboratory testing (e.g., drug screening), obtaining informed consent, providing medical orders, and diagnosing opioid addiction.[5]

Washington State's Opioid Treatment Program Services

The State agency provides funding for SUD treatment services for enrollees in Washington State. Under the Washington State Medicaid program, OTP services are provided to enrollees under either a fee-for-service or managed care model. (Most OTP services in Washington State are provided by managed care organizations (MCOs) under contract with the State agency.) The services may include psychosocial assessments, treatment planning, physician and nursing services related to substance abuse, individual or group counseling, and laboratory tests.[6] Under the fee-for-service model, OTPs submit service-line data to the State agency, and under the managed care model, OTPs submit service-line data to either a behavioral health

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[2] Methadone and buprenorphine are medications that reduce opioid cravings and withdrawal and can blunt the effects of other opioids.

[3] Chronic opioid addiction is a long-lasting disease that can cause major health, social, and economic problems. Opioid addiction is characterized by a powerful, compulsive urge to use opioid drugs, even when they are no longer required medically.

[4] SAMHSA published a final rule, effective Apr. 2, 2024 (after our audit period), that modified certain provisions of 42 CFR § 8.12 (89 Fed. Reg. 7528 (Feb. 2, 2024)). Any references to 42 CFR § 8.12 in this report reflect Federal requirements that were in effect during our audit period.

[5] Dual enrollment is when an individual is enrolled in more than one OTP at the same time, which is permitted only in exceptional circumstances (42 CFR § 8.12(g)(2)). A take-home medication is a medication dispensed to a patient for unsupervised use.

[6] Psychosocial assessments include assessing an enrollee's current needs and relevant history (e.g., the enrollee's documented substance misuse history, history of trauma, family history of SUDs, ethnic and cultural background, housing, education, and job histories). Treatment planning is the preparation of a treatment plan that includes an enrollee's short-term goals, tasks that the enrollee must perform to complete those goals, and services that the enrollee needs. The treatment plan must identify the frequency at which these services are to be provided.

organization (BHO) or a contracted MCO.[7, 8] BHOs and MCOs in turn submit these service lines to the State agency. Service-line data for both fee-for-service and managed care are captured in the State agency's Medicaid management information system (MMIS).[9]

The State agency also performs oversight of OTP services. According to State agency officials, oversight activities include audits of MCOs and reviews of medical charts. In addition, the contracts between the State agency and the MCOs include oversight and quality provisions that the MCOs must ensure their providers meet while providing those services. BHOs also perform oversight of OTPs, including reviewing claims and authorization requests.

Beginning July 1, 2018, the Washington State Department of Health (DOH) became responsible for licensing and certifying OTPs, issuing regulations relating to OTP services, and monitoring OTPs' compliance with the regulations.[10, 11] As part of the licensing process, DOH inspects each OTP for compliance with Federal and State requirements and issues a report to the OTP indicating the standards that were met and the deficiencies that were identified.[12] Additionally, other entities, including behavioral health administrative service organizations (BH-ASOs), county behavioral health departments, and accrediting bodies have conducted inspections of OTPs and issued similar reports.[13]

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[7] A service line represents one or more OTP services included on a claim that an OTP submits to the State agency, a BHO, or a contracted MCO to be reimbursed for those services.

[8] Under managed care, the State agency pays MCOs a per-member, per-month capitation payment to coordinate and provide services to Medicaid enrollees. BHOs were regionally grouped, quasi-governmental entities responsible for the behavioral health needs of the people of that region. The responsibility for managing behavioral health services was later transitioned to managed care plans. As of Jan. 1, 2020, the State agency no longer uses BHOs.2024

[9] The State agency used the MMIS, a computerized payment and information reporting system, to process payments and maintain enrollee eligibility and enrollment information.

[10] On Apr. 1, 2018, the regulations at Washington Administrative Code (WAC) chapters 388-877 and 388-877B were combined into chapter 388-877. On July 1, 2018, WAC chapter 388-877 was renumbered to WAC chapter 246-341. With these changes, some requirements were added, removed, or modified. Where changes occurred in the regulations that had an impact on our findings, we noted the changes.

[11] Before July 1, 2018, the Washington State Department of Social and Health Services, Division of Behavioral Health and Recovery, was responsible for licensing and certifying OTPs, issuing regulations related to OTP services, and monitoring OTPs' compliance with the regulations.

[12] Before July 1, 2018, the Division of Behavioral Health and Recovery performed State-run inspections of OTPs.

[13] BH-ASOs may also provide certain SUD services to people who are not enrolled in or eligible for the State agency's Medicaid program. Accrediting bodies evaluate OTPs and perform accreditation surveys to ensure that SAMHSA's opioid-use-disorder treatment standards are met.

The Washington Administrative Code (WAC) requires OTPs to provide treatment in compliance with 42 CFR part 8.[14] In addition, WAC chapter 246-341 provides the State requirements for OTPs. The State's Medicaid regulations require OTPs to provide all services according to Federal and State laws and rules, which include WAC chapter 246-341.[15] Additionally, State Medicaid regulations indicate that behavioral health services are subject to the exclusions, restrictions, limitations, and eligibility requirements contained in WAC chapter 246-341.[16]

When a Medicaid enrollee seeks treatment at an OTP, the OTP performs the admission process (e.g., performing a physical evaluation and laboratory tests and conducting a dual enrollment check). Once an enrollee is admitted to the program, a program physician or other qualified provider writes an order for a narcotic replacement medication, and the enrollee begins to receive dosing services.[17] Throughout treatment, dosing is evaluated and changed as medically necessary. Upon admission, the OTP also conducts a psychosocial assessment and prepares an initial treatment plan, which is reviewed and updated periodically. The enrollee then starts to receive counseling as clinically necessary and may become eligible to receive take-home medication.

COVID-19 Pandemic's Impact on Opioid Treatment Program Requirements

In March 2020, in response to the COVID-19 pandemic, SAMHSA granted OTPs and States flexibilities to ensure the delivery of OTP services and to protect enrollees and staff from COVID-19. One example of a flexibility was the flexibility to provide enrollees with more take-home doses than Federal regulations allow: "stable" enrollees may receive 28 days of take-home doses, and "less stable" enrollees may receive 14 days of take-home doses as long as the OTP determines that an enrollee can safely handle that amount.

HOW WE CONDUCTED THIS AUDIT

Our audit covered Medicaid service lines for OTP services that 22 non-Tribal OTPs in Washington State provided from January 1, 2019, through July 31, 2020 (audit period).[18] The OTP services consisted of individual and group counseling services, medication for opioid use disorder, case management, and physician consultation. We grouped the service lines into

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[14] WAC § 246-341-1000(8)(b), effective July 1, 2018, through June 30, 2021; WAC § 246-341-1000(7)(b), effective beginning July 1, 2021.

[15] WAC § 182-502-0016(1)(b).

[16] WAC § 182-501-0065(2)(c).

[17] Other qualified providers consist of advanced registered nurse practitioners or certified physician's assistants when under the supervision of a program physician (WAC § 246-341-0200; WAC § 246-341-1025(4)(b), effective July 1, 2018, through June 30, 2021; and WAC § 246-341-1025(3)(c), effective beginning July 1, 2021).

[18] We excluded from our audit all services provided by the four tribally owned and operated OTPs in Washington State.

137,502 enrollee-months. Each enrollee-month included all OTP services that were: (1) provided to an enrollee in a month in which the enrollee received at least one dose of a treatment medication (referred to as a "dosing service") and (2) submitted to the State agency, a BHO, or an MCO under one national provider identifier (NPI) number.[19]

We selected a random sample of 100 enrollee-months, consisting of service lines that 17 of 22 non-Tribal OTPs submitted. (We refer to each sampled enrollee-month as a "sample item.") We reviewed supporting documentation (e.g., admission records, treatment plans, counseling notes, and dosing records) for each sample item to determine whether the OTP complied with Federal and State requirements for the OTP services it provided.

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 describes our audit scope and methodology, Appendix C describes our statistical sampling methodology, and Appendix D contains our sample results and estimates.

FINDINGS

The State agency did not ensure that OTPs fully complied with Federal and State requirements for OTP services they provided to Medicaid enrollees. Of the 100 sample items, 4 met the requirements, but 96 sample items did not meet the requirements. Table 1 on the following page summarizes the deficiencies we identified, the number of sample items that contained each type of deficiency, and the number of OTPs that had at least one sample item with the deficiency.

[19] An NPI is a unique identification number for a health care provider. When submitting OTP service-line data to the State agency, some OTPs used more than one NPI for the same location, and some OTPs used one NPI for multiple locations.

Table 1: Summary of Deficiencies in Sample Items*

Deficiency Type	Number of Sample Items That Did Not Comply With Requirements
Enrollee admissions were not adequately documented	78
Treatment plans were not adequately documented	62
Take-home medications were not provided in accordance with Federal and State requirements	40
Opioid treatment services were not adequately documented	34
Drug screen results were not adequately documented	29
Checks of Washington State prescription drug monitoring program prescription data were not adequately documented	24
Enrollee assessments were not adequately documented	18
Opioid treatment service documentation did not demonstrate that services were provided under appropriate supervision	9
Annual medical examinations were not completed or adequately documented	6
Opioid treatment service documentation did not identify staff members who provided SUD assessment services	3
An enrollee's discharge was not adequately documented	1

* The total number of sample items that did not comply with requirements is more than 96 because 89 sample items had more than 1 deficiency.

At the OTP level, these deficiencies occurred because OTPs made human errors and were not aware of or misinterpreted Federal and State requirements. OTPs were also unable to provide us with documentation to support some of the services they provided. At the State level, the State agency's oversight was not effective in ensuring that OTPs complied with Federal and State requirements for providing and documenting OTP services for Medicaid enrollees. Specifically, the State agency relied on DOH, BHOs, and MCOs to oversee OTPs. Although DOH has issued regulations related to providing and documenting OTP services, and various entities (including DOH) have identified that OTPs are not complying with applicable requirements, the State agency did not track or follow up on any findings involving Medicaid enrollees identified by those entities or take any additional steps to ensure that OTPs complied with the requirements for OTP services provided to Medicaid enrollees.

On the basis of our sample results, we estimated that OTPs did not comply with Federal and State requirements for 132,002 enrollee-months, or 96 percent of the enrollee-months in our audit period. OTPs' lack of compliance with Federal and State requirements may have put enrollees at risk for poor treatment outcomes, including relapses, overdoses, or deaths.

OPIOID TREATMENT PROGRAMS DID NOT COMPLY WITH FEDERAL AND STATE REQUIREMENTS

Enrollee Admissions Were Not Adequately Documented

An OTP is required to include documentation in each enrollee's record that the OTP made a good-faith effort to review whether the enrollee was enrolled in any other OTP.[20, 21] The OTP is also required to document that a physical evaluation of the enrollee was completed before admission to the OTP.[22] Additionally, within 14 days of admission, a medical examination of the enrollee must have been completed that included documentation of the results of serology tests.[23] (A serology test examines blood serum to identify signs of the immune system's response to pathogens, such as those that cause syphilis.)

At the OTP, the program physician or a medical practitioner under supervision of the program physician: (1) is responsible for verifying that the enrollee is currently addicted to an opioid drug and that the enrollee became addicted at least 12 months before admission to treatment; or (2) may waive the 12-month requirement upon receiving documentation that the enrollee was released from a penal institution within the previous 6 months, is pregnant, or was treated within the previous 24 months.[24] Before the enrollee receives maintenance treatment, the enrollee should sign an informed written consent to participate in opioid treatment.[25]

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[20] 42 CFR § 8.12(g)(2); WAC § 388-877B-0420(1)(b), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-1015(1), effective April 1 through June 30, 2018; and WAC § 246-341-1015(1), effective beginning July 1, 2018.

[21] An enrollee is permitted only in exceptional circumstances to be enrolled in more than one OTP at a time (42 CFR § 8.12(g)(2)).

[22] 42 CFR § 8.12(f)(2); WAC § 388-877B-0440(2), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-1020(2), effective April 1 through June 30, 2018; and WAC § 246-341-1020(2), effective beginning July 1, 2018.

[23] 42 CFR § 8.12(f)(2); WAC § 388-877B-0440(7), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-1020(7), effective April 1 through June 30, 2018; and WAC § 246-341-1020(7), effective beginning July 1, 2018.

[24] 42 CFR §§ 8.12(e)(1) and (3); WAC § 388-877B-0440(1), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-1020(1), effective April 1 through June 30, 2018; and WAC § 246-341-1020(1), effective beginning July 1, 2018.

[25] 42 CFR § 8.12(e)(1); WAC § 388-877B-0440(6), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-1020(6), effective April 1 through June 30, 2018; WAC § 246-341-1020(6), effective beginning July 1, 2018; WAC § 388-877-0640(9), effective April 1 through June 30, 2018; WAC § 246-341-0640(9), effective July 1, 2018, through June 30, 2021; and WAC § 246-341-0640(1)(e), effective beginning July 1, 2021.

For 78 sample items, OTPs did not document enrollees' admissions in accordance with Federal and State requirements:[26]

- For 70 sample items, OTPs did not document that they made a good-faith effort to review whether the enrollee was enrolled in any other OTP.[27] Generally, the OTPs had enrollees sign a document authorizing the OTP to contact other OTPs to check for dual enrollment; however, for these sample items, the OTPs did not document that they attempted to contact any other OTPs.

- For 44 sample items, OTPs did not complete the serology tests or document the results of the tests within 14 days of admission.

- For 24 sample items, OTPs did not document that the program physician, or a medical practitioner under the supervision of the program physician, determined that the enrollee had been addicted to an opioid drug for at least 1 year, was released from a penal institution within the previous 6 months, was pregnant, or was treated for an opioid use disorder in the previous 24 months.

- For 12 sample items, OTPs did not have documentation that the enrollee provided informed written consent before receiving maintenance treatment. For eight of these sample items, the OTPs did not provide documentation of signed consent from enrollees. For the remaining four sample items, the consent was signed after maintenance treatment had started.

- For three sample items, OTPs did not document that they performed a physical evaluation of the enrollee before admission.

Treatment Plans Were Not Adequately Documented

An OTP is required to document that the treatment plan was mutually agreed upon (i.e., by the enrollee and the OTP) and that a copy of the treatment plan was made available to the enrollee.[28] The treatment plan must address issues identified by the enrollee or, if applicable,

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[26] The total number of sample items that did not comply with Federal and State requirements is more than 78 because 49 sample items had more than 1 deficiency.

[27] During our audit period, an OTP generally faxed other OTPs nearby to check for dual enrollment. As of Aug. 1, 2021, the State agency had contracted with a third party to provide a dual-enrollment verification system that an OTP could use to determine whether an enrollee was also enrolled in another OTP.

[28] WAC § 388-877-0620(1)(d), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-0620(1)(d), effective April 1 through June 30, 2018; WAC § 246-341-0620(1)(d), effective July 1, 2018, through June 30, 2021. Following our audit period, under WAC § 246-341-0640(1)(d)(iv), effective beginning July 1, 2021, and WAC § 246-341-0600(2)(h), effective beginning July 1, 2021, OTPs were no longer required to document that a treatment plan was made available to an enrollee, and an enrollee only had to receive a copy of the plan if desired.

the enrollee's parent (or parents) or legal representative.[29] The treatment plan should include the enrollee's: (1) short-term goals and the tasks that the enrollee must perform to complete the short-term goals and (2) requirements for education, vocational rehabilitation, employment, medical, psychosocial, economic, legal, or other supportive services that the enrollee needs. The treatment plan also must identify the frequency at which these services are to be provided.[30] The treatment plan must contain measurable goals or objectives, or both, and interventions.[31]

Each enrollee accepted for treatment at an OTP must be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The treatment plan must be reviewed and updated to reflect the enrollee's personal history and the enrollee's current needs for supportive services.[32] The enrollee's record must contain documentation that the treatment plan was reviewed quarterly in the first 2 years of continuous treatment and semiannually after 2 years of continuous treatment.[33]

For 62 sample items, OTPs did not document treatment plans in accordance with Federal and State requirements:[34]

- For 45 sample items, OTPs did not document that a copy of the treatment plan was made available to the enrollee.
- For 23 sample items, OTPs did not document in the treatment plan the frequency at which services were to be provided.
- For 19 sample items, OTPs did not document that the enrollee agreed with the treatment plan.

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[29] WAC § 388-877-0620(1)(b), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-0620(1)(b), effective April 1 through June 30, 2018; WAC § 246-341-0620(1)(b), effective July 1, 2018, through June 30, 2021; and WAC § 246-341-0640(1)(d)(ii), effective beginning July 1, 2021.

[30] 42 CFR § 8.12(f)(4).

[31] WAC § 388-877-0620(1)(h), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-0620(1)(e), effective April 1 through June 30, 2018; WAC § 246-341-0620(1)(e), effective July 1, 2018, through June 30, 2021; and WAC § 246-341-0640(1)(d)(iii), effective beginning July 1, 2021.

[32] 42 CFR § 8.12(f)(4).

[33] WAC § 388-877B-0420(1)(f), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-1015(3), effective April 1 through June 30, 2018; and WAC § 246-341-1015(3), effective beginning July 1, 2018. Before Apr. 1, 2018, treatment plans were also required to be reviewed monthly for the first 90 days of treatment.

[34] The total number of sample items that did not comply with Federal and State requirements is more than 62 because 38 sample items had more than 1 deficiency.

- For nine sample items, OTPs did not document in the treatment plan the need for certain counseling services that were provided to the enrollee.

- For nine sample items, OTPs did not document that they periodically reviewed the treatment plan quarterly or semiannually as applicable.

- For five sample items, OTPs did not document that the treatment plan addressed issues identified by the enrollee or included supportive services based on the enrollee's needs. For example, for one sample item, the assessment stated that the enrollee wanted to find a job and an apartment so that the enrollee could stop living out of his car. However, the treatment plan did not include services related to obtaining employment or housing.

- For two sample items, OTPs did not document measurable goals or objectives, or both, and interventions in the treatment plan.

- For one sample item, the OTP did not provide a treatment plan.

Take-Home Medications Were Not Provided in Accordance With Federal and State Requirements

The decision to dispense opioid treatment medications to an enrollee for unsupervised use beyond a single take-home dose for a day that the facility is closed, including Sundays and holidays, shall be determined by an OTP's medical director. In determining which enrollees may be permitted unsupervised use, the medical director shall consider the eight take-home criteria, which we refer to as the "8-point criteria," and document in the enrollee's record the determination and the basis for that determination consistent with the 8-point criteria.[35] Before admission, the program physician, or a medical practitioner under the supervision of the program physician, must complete a physical evaluation of the enrollee, including an assessment of the appropriateness of Sunday and holiday take-home medication.[36]

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[35] 42 CFR §§ 8.12(i)(1)–(3). The 8-point criteria consist of the following: (1) absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol; (2) regularity of clinic attendance; (3) absence of serious behavioral problems at the clinic; (4) absence of known recent criminal activity, e.g., drug dealing; (5) stability of the enrollee's home environment and social relationships; (6) length of time in comprehensive maintenance treatment; (7) assurance that take-home medication can be safely stored within the enrollee's home; and (8) whether the rehabilitative benefit the enrollee derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

[36] WAC § 388-877B-0440(2), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-1020(2), effective April 1 through June 30, 2018; WAC § 246-341-1020(2), effective July 1, 2018, through June 30, 2021; and WAC § 246-341-1020(2), effective beginning July 1, 2021. Beginning July 1, 2021 (after our audit period), OTPs were no longer required to complete an assessment of the appropriateness of Sunday and holiday take-home medication before admission (Washington State Register (WSR) 21-12-042).

Beginning in March 2020, because of the COVID-19 public health emergency, SAMHSA granted OTPs the flexibility to provide up to 28 days of take-home medication to a stable enrollee and up to 14 days of take-home medication for an enrollee who was "less stable" but who the OTP believed could safely handle this level of take-home medication. The enrollee's clinical stability and ability to safely manage the take-home medication must be documented in the enrollee's record.[37]

For 40 sample items, OTPs did not provide take-home medications in accordance with Federal and State requirements:[38]

- For 21 sample items, OTPs did not document that a program physician, or a medical practitioner under the supervision of a program physician, completed an assessment of the appropriateness of Sunday and holiday take-home medication before the admission of the enrollee.

- For 14 sample items, OTPs did not document that the medical director considered the 8-point criteria when determining whether the enrollee qualified for take-home medication beyond the single dose for days that the facility was closed.

- For 11 sample items, OTPs did not document the enrollee's clinical stability and ability to manage the additional take-home medication that was provided beginning in March 2020.

Opioid Treatment Services Were Not Adequately Documented

An OTP must maintain documentation in an enrollee's record to verify the level, type, and extent of services provided, including a detailed description of treatment provided.[39] An OTP documents this information in progress notes, which must include the date, time, and duration

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[37] SAMHSA's *Opioid Treatment Program (OTP) Guidance,* Mar. 16, 2020. Available at https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf. Accessed on Jan. 25, 2021. SAMHSA's *FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency,* Mar. 19, 2020. Available at https://www.nabh.org/wp-content/uploads/2020/03/faqs-for-oud-prescribing-and-dispensing.pdf. Accessed on July 6, 2020. SAMHSA's *FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency,* updated Apr. 21, 2020. Available at https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf. Accessed on May 28, 2020. Washington State Health Care Authority's *COVID-19 and opioid treatment programs – Frequently asked questions,* Mar. 4, 2020. Available at https://www.hca.wa.gov/assets/program/opioid-treatment-program-faq.pdf. Accessed on Feb. 9, 2021.

[38] The total number of sample items that did not comply with Federal and State requirements is more than 40 because 6 sample items had more than 1 deficiency.

[39] WAC § 182-502-0020(1)(k).

of the session; the enrollee's name and response to interventions; a brief summary of the session; and the name and credential of the staff member who provided the session.[40]

An OTP must also maintain documentation of the medications prescribed (e.g., through a dosing order) in the enrollee's records to verify the level, type, and extent of services provided to the enrollee to fully justify the services.[41] An OTP must ensure that all dosing and administrative decisions are made by a program physician or by a medical practitioner under the supervision of a program physician.[42]

For 34 sample items, OTPs did not document opioid treatment services in accordance with State requirements. Of the 34 sample items, 31 had deficiencies related to progress notes, and the remaining 3 had deficiencies related to dosing orders.

For the 31 sample items that had deficiencies related to progress notes, we found the following:[43]

- For 19 sample items, the progress notes did not contain the names and credentials of the staff members who provided the session.

- For 11 sample items, the progress notes did not include the enrollees' responses to the interventions provided.

- For seven sample items, the progress notes did not contain a response to interventions or a brief summary of the session. For example, for one sample item, the progress notes for a counseling session contained statements that the enrollee made but did not indicate which interventions, if any, the OTP provided.

In addition, for the three sample items that had deficiencies related to dosing orders, OTPs did not have dosing orders that adequately supported the dosing levels that the enrollees received during the sampled month:

- For one sample item, the OTP did not provide a dosing order.

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[40] WAC § 246-341-0640(17), effective July 1, 2018, through June 30, 2021; WAC § 246-341-0640(1)(f), effective beginning July 1, 2021. Beginning July 1, 2021 (after our audit period), progress and group notes must include either a response to interventions or clinically significant behaviors during a group session.

[41] WAC § 182-502-0020(1)(g).

[42] WAC § 246-341-1025(4)(b), effective July 1, 2018, through June 30, 2021; WAC § 246-341-1025(3)(c), effective beginning July 1, 2021.

[43] The total number of sample items that did not comply with State requirements is more than 31 because 6 sample items had more than 1 deficiency.

- For one sample item, the OTP provided a dosing order but there was no evidence of who wrote the order.

- For one sample item, the OTP did not provide dosing orders for all days that the enrollee received a dose, or the dosing amount that the enrollee received exceeded the amount prescribed in the dosing order.

Drug Screen Results Were Not Adequately Documented

An enrollee's record must contain documentation of drug screen results (e.g., the substance or substances that the enrollee tested positive for) and the discussion held with the enrollee about any positive drug-screen result in the counseling session immediately following the notification of the positive result.[44] When an enrollee refuses to provide a sample for a drug screen, the enrollee's record must contain documentation of the refusal, and the refusal is considered a positive drug-screen result.[45]

For 29 sample items, OTPs did not complete or follow up on the results of enrollees' drug screens in accordance with State requirements:[46]

- For 28 sample items, OTPs did not document that a positive drug-screen result was discussed with the enrollee in the counseling session immediately following the notification of a positive result.

- For two sample items, the OTP did not identify that it considered the enrollee's refusal to provide a urine sample for a drug screen as a positive drug-screen result.

- For one sample item, the OTP did not identify which substance or substances the enrollee had tested positive for in the initial drug screen.

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[44] WAC § 388-877B-0420(1)(j), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-1015(5), effective April 1 through June 30, 2018; and WAC § 246-341-1015(5), effective beginning July 1, 2018. After our audit period, beginning July 1, 2021, OTPs are no longer required to document that discussions were held in the first counseling session after a positive drug-screen result. Instead, OTPs are required to document in progress notes the timely interventions used to therapeutically address a positive result.

[45] WAC § 388-877B-0420(1)(i), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-1015(4), effective April 1 through June 30, 2018; and WAC § 246-341-1015(4), effective beginning July 1, 2018.

[46] The total number of sample items that did not comply with State requirements is more than 29 because 2 sample items had more than 1 deficiency.

Checks of Washington State Prescription Drug Monitoring Program Prescription Data Were Not Adequately Documented

An OTP must review prescription drug monitoring program (PDMP) data for an enrollee to identify an enrollee's prescriptions at admission, annually after the date of admission, and after any incidents of concern.[47]

For 24 sample items, OTPs did not provide evidence that they checked Washington State PDMP prescription data on enrollees at admission or annually.

Enrollee Assessments Were Not Adequately Documented

Each enrollee accepted for treatment at an OTP must be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment.[48] The OTP must maintain documentation of the clinical assessment in the enrollee's record to verify the level, type, and extent of services provided to the enrollee to fully justify the services.[49] In addition, an OTP must document that it conducted an age-appropriate, strengths-based psychosocial assessment that considered an enrollee's current needs and relevant history.[50] Such information may include, if applicable, such things as a history of problem gambling and pathological gambling and a diagnostic assessment statement, including sufficient information to determine a diagnosis supported by the current and applicable *Diagnostic and Statistical Manual of Mental Disorders.*[51, 52] Finally, an OTP must ensure that the assessment includes a placement decision, using American Society of Addiction Medicine

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[47] WAC § 388-877B-0440(3), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-1020(3), effective April 1 through June 30, 2018; and WAC § 246-341-1020(3), effective beginning July 1, 2018.

[48] 42 CFR § 8.12(f)(4).

[49] WAC § 182-502-0020(1)(m).

[50] WAC § 388-877-0610(2), effective April 1 through June 30, 2018; WAC § 246-341-0610(2), effective July 1, 2018, through June 30, 2021; and WAC § 246-341-0640(1)(c), effective beginning July 1, 2021.

[51] WAC § 388-877-0610(2), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877B-0430(2), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-0610(2), effective April 1 through June 30, 2018; WAC § 246-341-0610(2), effective July 1, 2018, through June 30, 2021; and WAC § 246-341-0640(1)(c), effective beginning July 1, 2021. Although OTPs are no longer required to document in the assessment the enrollee's problem gambling history, before Apr. 1, 2018, WAC section 388-877-0610(2) stated that the initial assessment must include and document the enrollee's problem gambling and pathological gambling history. After our audit period, beginning July 1, 2021 WAC section 246-341-0610 was repealed (WSR 21-12-042).

[52] *The Diagnostic and Statistical Manual of Mental Disorders* (DSM), published by the American Psychiatric Association, is the authoritative guide that health care professionals use to diagnose mental disorders. The *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5), was published in 2013 and was applicable during our audit period. The current edition, *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision* (DSM-5-TR), was published in March 2022. Available at https://www.psychiatry.org/psychiatrists/practice/dsm/about-dsm/history-of-the-dsm#section_0. Accessed on Nov. 14, 2023.

(ASAM) criteria dimensions, when the assessment indicates that the enrollee needs SUD services.[53, 54]

For 18 sample items, OTPs did not document assessments in accordance with Federal and State requirements:[55]

- For seven sample items, OTPs did not document that they considered all of the required information in the assessments. Specifically, the assessments for six sample items did not address the enrollees' gambling history, and one sample item was almost entirely blank.
- For seven sample items, OTPs provided an initial assessment that did not include a placement decision using ASAM criteria dimensions.
- For three sample items, OTPs did not provide documentation of an initial assessment.
- For three sample items, OTPs did not document in their initial assessments of the enrollees the services and treatments that the enrollees needed.

Opioid Treatment Service Documentation Did Not Demonstrate That Services Were Provided Under Appropriate Supervision

An enrollee's treatment plan must be completed or approved by a professional who is appropriately credentialed or qualified to provide one or more of the following services: mental health, SUD, or problem and pathological gambling services.[56] An OTP is also required to ensure that all SUD assessment and counseling services are provided by a substance use

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[53] WAC §§ 388-877B-0430(3) and 388-877-0200, effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-0610(3)(b), effective April 1 through June 30, 2018; WAC § 246-341-0610(3)(b), effective July 1, 2018, through June 30, 2021; and WAC § 246-341-0640(1)(c), effective beginning July 1, 2021.

[54] ASAM's criteria include the following six dimensions in an assessment: (1) acute intoxication and/or withdrawal potential; (2) biomedical conditions and complications; (3) emotional, behavioral, or cognitive conditions and complications; (4) readiness to change; (5) relapse, continued use, or continued problem potential; and (6) recovering/living environment (David Mee-Lee, *The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions,* 3rd ed., 2013, American Society of Addiction Medicine).

[55] The total number of sample items that did not comply with Federal and State requirements is more than 18 because 1 sample item had more than 1 deficiency.

[56] WAC § 388-877-0620(1)(a), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-0620(1)(a), effective April 1 through June 30, 2018; WAC § 246-341-0620(1)(a), effective July 1, 2018, through June 30, 2021; and WAC § 246-341-0640(1)(d)(i), effective beginning July 1, 2021.

disorder professional (SUDP) or by a SUDP trainee (SUDP-T) under the supervision of an approved supervisor.[57]

For nine sample items, although OTPs provided treatment plans or counseling services that were completed by SUDP-Ts, the documentation did not demonstrate that the services were provided under appropriate supervision. For example, documentation for a treatment plan and a counseling service did not include the name or signature of a supervisor when a signature line was on the forms. In addition, the enrollee's case file did not include any evidence that services were provided under appropriate supervision. Without the name or signature of a supervisor or other documentation, the OTP did not demonstrate that the SUDP-T's work was appropriately supervised.

Annual Medical Examinations Were Not Completed or Adequately Documented

An OTP must conduct an annual medical examination of each enrollee that includes an assessment of the enrollee's overall physical condition and response to medication.[58]

For six sample items, OTPs did not complete or adequately document the enrollee's annual medical exam:

- For five sample items, OTPs did not complete an annual medical examination.

- For one sample item, the OTP did not document in the annual medical examination the enrollee's overall physical condition and response to medication.

Opioid Treatment Service Documentation Did Not Identify Staff Members Who Provided Substance-Use-Disorder Assessment Services

An OTP is required to ensure that each mental health service is provided by qualified staff members who meet professional standards, clinical supervision requirements, and licensure and credentialing requirements for their scope of practice and services provided.[59] An OTP is also required to ensure that all SUD assessment and counseling services are provided by an SUDP or by an SUDP-T under the supervision of an approved supervisor.[60]

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[57] WAC § 388-877B-0410(4), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-0515(2)(a), effective April 1 through June 30, 2018; and WAC § 246-341-0515(2)(a), effective July 1, 2018, through June 30, 2021.

[58] WAC § 388-877B-0440(12), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-1020(12), effective April 1 through June 30, 2018; and WAC § 246-341-1020(12), effective beginning July 1, 2018.

[59] WAC § 388-877-0515(1)(a), effective April 1 through June 30, 2018; and WAC § 246-341-0515(1)(a), effective July 1, 2018, through June 30, 2021.

[60] WAC § 388-877B-0410(4), effective July 1, 2013, through Mar. 31, 2018; WAC § 388-877-0515(2)(a), effective April 1 through June 30, 2018; and WAC § 246-341-0515(2)(a), effective July 1, 2018, through June 30, 2021.

For three sample items, two OTPs did not identify in SUD assessments the staff members who completed the assessments; therefore, the staff members' credentials could not be verified.

An Enrollee's Discharge Was Not Adequately Documented

An OTP is required to complete for an enrollee who leaves treatment and provides the OTP notice of their leaving a discharge summary within 7 working days of the enrollee's discharge. The summary must include, among other things, a continuing-care plan.[61]

For one sample item, the OTP did not complete the discharge summary until 33 days after the enrollee's discharge and did not include in the summary a continuing-care plan.[62]

STATE AGENCY'S OVERSIGHT WAS NOT EFFECTIVE IN ENSURING THAT OPIOID TREATMENT PROGRAMS COMPLIED WITH FEDERAL AND STATE REQUIREMENTS

The State agency's oversight was not effective in ensuring that OTPs complied with Federal and State requirements for providing and documenting OTP services. Specifically, the State agency relied primarily on DOH, BHOs, and MCOs to oversee OTPs and the services they provided. DOH was responsible for determining whether OTPs complied with Federal and State requirements as part of the OTP licensing and accreditation process, and BHOs and MCOs were responsible for overseeing the delivery and the quality of the services they provided to enrollees. In addition, the State agency's actions were limited to meeting with OTPs at least monthly to provide training and technical assistance and reviewing OTP policies and enrollee records on a case-by-case basis when the State agency was made aware of a concern about an enrollee's care. Although DOH has issued regulations related to providing and documenting OTP services, and various entities (including DOH) have identified that OTPs are not complying with applicable requirements, the State agency did not track or follow up on any findings identified by those entities or take any additional steps to ensure that OTPs complied with the requirements.

OPIOID TREATMENT PROGRAMS' LACK OF COMPLIANCE WITH FEDERAL AND STATE REQUIREMENTS MAY HAVE PUT ENROLLEES AT RISK FOR POOR TREATMENT OUTCOMES

On the basis of our sample results, we estimated that OTPs did not comply with Federal and State requirements for 132,002 enrollee-months, or 96 percent of the enrollee-months in our audit period.

OTPs' failure to fully comply with Federal and State requirements for providing and documenting opioid treatment services may have put enrollees at risk for poor treatment

[61] WAC § 246-341-0640(15), effective July 1, 2018, through June 30, 2021; and WAC § 246-341-0640(1)(h), effective beginning July 1, 2021.

[62] We did not consider this a systemic issue; therefore, we did not include a recommendation for this finding.

outcomes, including relapses, overdoses, or deaths. For example, an OTP's potential failure to check whether an enrollee was enrolled in another OTP may have increased the risk of the enrollee being prescribed more doses of a treatment medication than necessary or possible negative effects on the community if medication was obtained for the purpose of being diverted to another individual.

RECOMMENDATIONS

We recommend that the Washington State Health Care Authority work with its contracted MCOs and the Department of Health to ensure that OTPs comply with Federal and State requirements for providing and documenting OTP services, including ensuring that OTPs:

- complete required tests for enrollee admissions and adequately document enrollee admissions,
- adequately document treatment plans,
- provide take-home medications in accordance with Federal and State requirements,
- adequately document opioid treatment services,
- adequately document the results of drug screens,
- adequately document checks of Washington State PDMP prescription data to identify enrollees' prescriptions,
- adequately document enrollee assessments,
- demonstrate through documentation that treatment plans and progress notes are reviewed by qualified staff,
- complete and adequately document annual medical examinations, and
- identify in the enrollee records the staff members who provided SUD assessments.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with all of our recommendations and described actions that it planned to take to address them. The State agency acknowledged that changes to Federal regulations for OTPs were enacted on April 2, 2024. It stated that its planned actions include: (1) partnering with DOH to update the WAC, and new rules to be published by DOH for OTPs, to reflect alignment with the new

Federal regulations; and (2) developing procedures to review compliance with those regulations and the WAC. The State agency's comments are included in their entirety as Appendix E.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered Medicaid service lines for OTP services that 22 non-Tribal OTPs in Washington State provided from January 1, 2019, through July 31, 2020.[63] The OTP services consisted of individual and group counseling services, medication for opioid use disorder, case management, and physician consultation. We grouped the service lines into 137,502 enrollee-months. Each enrollee-month included all OTP services that were: (1) provided to an enrollee in a month in which the enrollee received at least one dosing service and (2) submitted to the State agency, a BHO, or an MCO under one NPI.[64]

We selected a random sample of 100 enrollee-months, consisting of service lines that 17 of 22 non-Tribal OTPs submitted, to determine compliance with Federal and State requirements.

Our audit allowed us to establish reasonable assurance of the authenticity and accuracy of the data provided by the State agency for our audit period.[65] We also established reasonable assurance of the completeness of the data by: (1) interviewing State agency officials to obtain an understanding of the data and controls in place to verify the data, (2) identifying dosing services in the data and confirming that SAMHSA had certified the OTPs that billed those services, (3) reviewing the query that the State agency used to retrieve the data, (4) verifying that all of the relevant fields were populated with the correct data types, (5) checking for missing values in certain fields and checking that no service dates were outside of our audit period, and (6) comparing record counts in the data with record counts from the Transformed Medicaid Statistical Information System (T-MSIS).[66]

During our audit, we did not assess the overall internal control structure of the State agency or the OTPs. Rather, we limited our review of internal controls to the State agency's policies and procedures for monitoring OTPs' compliance with Federal and State requirements.

We conducted our audit from March 2021 to May 2024.

[63] We excluded from our audit all services provided by the four tribally owned and operated OTPs in Washington State.

[64] When submitting OTP service-line data to the State agency, some OTPs used more than one NPI for the same location, and some OTPs used one NPI for multiple locations.

[65] The State agency extracted the data from its MMIS.

[66] The T-MSIS collects Medicaid data from States, Territories, and the District of Columbia.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal and State requirements;
- held discussions with State agency, DOH, and OTP officials;
- reviewed contracts between the State agency and MCOs to identify requirements for MCOs to review OTPs;
- obtained State agency data that contained records of Medicaid OTP services provided in Washington State;
- created a sampling frame of 137,502 enrollee-months for OTP services provided by 22 non-Tribal OTPs (Appendix C);
- selected a random sample of 100 enrollee-months and, for each sample item, reviewed enrollee records (e.g., admission records, treatment plans, counseling notes, and dosing records), which included admission documentation if the enrollee had been admitted to the OTP on or after January 1, 2014, to determine compliance with Federal and State requirements;[67]
- verified provider qualifications using the DOH Provider Credential Search website;[68]
- obtained from DOH and OTPs reports of reviews by the Division of Behavioral Health and Recovery, DOH, a BH-ASO, BHOs, county behavioral health departments, and accrediting bodies;
- estimated the total number and the percentage of enrollee-months that did not comply with Federal and State requirements (Appendix D); and
- discussed the results of our audit with State agency and OTP officials.

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.

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[67] We did not determine the medical necessity of services that were provided.

[68] Available at https://fortress.wa.gov/doh/providercredentialsearch/. Accessed on June 16, 2022.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
West Virginia Lacked Effective Oversight of Its Opioid Response Grants	A-06-22-01005	4/22/2024
New Jersey Complied With Federal Regulations When Implementing Programs Under SAMHSA's Opioid Response Grants, But Did Not Meet Its Program Services Goals	A-09-22-02002	3/27/2024
Medicare Made $17.8 Million in Potentially Improper Payments for Opioid-Use-Disorder Treatment Services Furnished by Opioid Treatment Programs	A-09-22-03005	8/17/2023
Vermont Complied With Regulations When Implementing Programs Under SAMHSA's Opioid Response Grants, but Claimed Unallowable Expenditures	A-01-20-01501	5/24/2023
More Than 90 Percent of the New Hampshire Managed Care Organization and Fee-for-Service Claims for Opioid Treatment Program Services Did Not Comply With Medicaid Requirements	A-01-20-00006	6/23/2022
California Improperly Claimed at Least $23 Million of $260 Million in Total Medicaid Reimbursement for Opioid Treatment Program Services	A-09-20-02009	4/20/2022
Louisiana Faced Compliance and Contracting Challenges in Implementing Opioid Response Grant Programs	A-06-20-07003	4/8/2022
SAMHSA's Oversight Generally Ensured That the Commission on Accreditation of Rehabilitation Facilities Verified That Opioid Treatment Programs Met Federal Opioid Treatment Standards	A-09-20-01002	10/1/2021
About Seventy-Nine Percent of Opioid Treatment Program Services Provided to Medicaid Beneficiaries in Colorado Did Not Meet Federal and State Requirements	A-07-20-04118	9/21/2021
Oklahoma's Oversight of Medicaid Outpatient Services for Opioid Use Disorder Was Generally Effective	A-06-20-08000	8/12/2021
California Claimed at Least $2 Million in Unallowable Medicaid Reimbursement for a Selected Provider's Opioid Treatment Program Services	A-09-20-02001	1/25/2021
Choctaw Nation of Oklahoma Made Progress Toward Meeting Program Goals During the First Year of Its Tribal Opioid Response Grant	A-07-20-04121	1/20/2021
Ohio Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program	A-05-18-00004	12/29/2020

Report Title	Report Number	Date Issued
Opioid Treatment Programs Reported Challenges Encountered During the COVID-19 Pandemic and Actions Taken To Address Them	A-09-20-01001	11/18/2020
Update on Oversight of Opioid Prescribing and Monitoring of Opioid Use: States Have Taken Action To Address the Opioid Epidemic	A-09-20-01000	10/7/2020
SAMHSA's Oversight of Accreditation Bodies for Opioid Treatment Programs Did Not Comply With Some Federal Requirements	A-09-18-01007	3/6/2020
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	A-02-17-01021	2/4/2020
California Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program	A-09-18-01006	12/10/2019
New York Achieved Program Goals for Enhancing Its Prescription Drug Monitoring Program	A-02-18-02001	8/8/2019
Oversight of Opioid Prescribing and Monitoring of Opioid Use: States Have Taken Action To Address the Opioid Epidemic	A-09-18-01005	7/24/2019
The University of Kentucky Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program	A-04-18-02012	5/30/2019
Washington State Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program	A-09-18-01001	4/15/2019
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	A-03-17-03302	3/28/2019
New York Did Not Provide Adequate Stewardship of Substance Abuse Prevention and Treatment Block Grant Funds	A-02-17-02009	3/20/2019

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

The sampling frame consisted of 137,502 enrollee-months for OTP services provided by 22 non-Tribal OTPs from January 1, 2019, through July 31, 2020.[69]

SAMPLE UNIT

The sample unit was an enrollee-month.

SAMPLE DESIGN AND SAMPLE SIZE

We selected a simple random sample of 100 enrollee-months.

SOURCE OF RANDOM NUMBERS

The source of the random numbers was the OIG, Office of Audit Services (OAS), statistical software.

METHOD OF SELECTING SAMPLE ITEMS

We sorted the enrollee-months by billing NPI, enrollee ID, and service month, and then consecutively numbered the items in the sampling frame. After generating the random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OIG-OAS statistical software to estimate the total number and the percentage of enrollee-months that did not comply with Federal and State requirements (Appendix D). We calculated a point estimate and a two-sided 90-percent confidence interval.

[69] Each enrollee-month included all OTP services that an OTP: (1) provided to an enrollee in a month in which the enrollee received at least one dosing service and (2) submitted service lines under one NPI. When submitting OTP service lines, some OTPs used more than one NPI for the same location, and some OTPs used one NPI for multiple locations.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Details and Results

No. of Enrollee-Months in Sampling Frame	Sample Size	No. of Sampled Enrollee-Months With at Least One Deficiency
137,502	100	96

Table 3: Estimated Number of Enrollee-Months in the Sampling Frame With at Least One Deficiency (Limits Calculated at the 90-Percent Confidence Level)

Point estimate	132,002
Lower limit	125,240
Upper limit	135,606

Table 4: Estimated Percentage of Enrollee-Months in the Sampling Frame With at Least One Deficiency (Limits Calculated at the 90-Percent Confidence Level)

Point estimate	96.00
Lower limit	91.08
Upper limit	98.62

APPENDIX E: STATE AGENCY COMMENTS

STATE OF WASHINGTON
HEALTH CARE AUTHORITY
626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

July 1, 2024

Jessica Yun Kim
Regional Inspector General for Audit Services
90 – 7th Street, Suite 3-650
San Francisco, California 94103

Dear Ms. Yun Kim:

Thank you for the opportunity to respond to the Department of Health and Human Services, Office of Inspector General (OIG), draft report *Opioid Treatment Programs (OTP) in Washington State Did Not Fully Comply With Federal and State Requirements, Which May Have Put Medicaid Enrollees at Risk for Poor Treatment Outcomes*. We appreciate the OIG's recommendations regarding the areas of concern identified during the audit.

The Washington State Health Care Authority (HCA) will begin reviewing OTP providers based on the recently updated federal and state rules. Changes to the code of federal regulations (CFR) were enacted on April 2, 2024, with significant updates to criteria for OTPs. The federal government has given OTP providers nationwide until October 2, 2024, to enact policies, procedures, and practices in alignment with the CFR changes. This compliance date will also allow states to review their respective regulations that impact how the new CFR rules will be implemented. Washington State rules (WAC) will be updated, and new rules published by the Washington State Department of Health (DOH), in consultation with HCA, for OTP providers by the end of 2024, to reflect alignment with the new CFR.

By January 1, 2025, HCA will convene at least one meeting with all OTP provider stakeholders to ensure they are informed of both the new federal CFR, and state WAC changes, and to inform the OTP providers of the importance and expectation of compliance with rules for Medicaid program integrity. External partners at DOH and managed care organizations (MCOs) will be invited as well, with the following intended outcomes:

- All OTP provider stakeholders will be informed of the findings of the OIG survey and the OIG recommendations for HCA.
- HCA will identify OTP providers who may self-report not meeting standards and allow OTP providers a chance to implement self-directed corrective actions based on OIG report findings.
- HCA will assess barriers identified by the OTP providers that prevent them from complying with state and federal rules identified in the OIG report.

By January 1, 2025, HCA will develop monitoring procedures to review compliance with new CFR and WAC.

- HCA will partner with DOH and MCOs to request copies of all OTP provider regulatory/quality assurance audits and corrective action plans completed by DOH/MCOs moving forward, and review for OTP provider compliance with the new CFR and WAC.
- HCA will request this documentation be sent from DOH and MCOs to the State Opioid Treatment Authority (SOTA) office at HCA.
- HCA will also request all OTP providers in the state to provide the SOTA office with a copy of all federal accreditation body surveys completed by the OTP's respective accreditation bodies. These surveys check for CFR compliance, as required by federal law. HCA will ask that this documentation be sent to the HCA SOTA office.
- The SOTA team will compare the documentation noted above with the OIG report findings.
- If ongoing and overlapping concerns regarding OTP providers continue in relation to recommendations per the OIG findings, the HCA SOTA staff will inform HCA Medicaid Program Integrity staff.
- At that point, HCA Medicaid Program Integrity staff could move to audit individual OTP programs directly and consider progressive negative actions and/or corrective actions, including referral to the Medicaid Fraud Control Division.

Please find our responses to the recommendations summarized in the following table:

Recommendation	Concurrence/non concurrence	Corrective action taken or planned
We recommend that the HCA work with its contracted MCOs and the Department of Health to ensure that OTPs comply with Federal and State requirements for providing and documenting OTP services, including ensuring that OTPs: complete required tests for enrollee admissions and adequately document enrollee admissions	HCA concurs with this recommendation.	Federal CFR rule changes effective April 2, 2024, update criteria for patient admissions to OTPs and could impact corresponding documentation of patient admissions to OTPs. HCA will partner with DOH to update WAC, and new rules published by DOH for OTP providers by the end of 2024, to reflect alignment with new CFR. By January 1, 2025, HCA will develop procedures to review compliance with new OTP CFR and WAC.
We recommend that the HCA work with its contracted MCOs and the Department of Health to ensure that OTPs comply with Federal and State requirements for providing and documenting OTP services, including ensuring that OTPs: adequately document treatment plans	HCA concurs with this recommendation.	Federal CFR rule changes effective April 2, 2024, update criteria for patient care within OTPs with potential to impact patient treatment planning. HCA will partner with DOH to update WAC, and new rules published by DOH for OTP providers by the end of 2024, to reflect alignment with new CFR.

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		By January 1, 2025, HCA will develop procedures to review compliance with new OTP CFR and WAC.
We recommend that the HCA work with its contracted MCOs and the Department of Health to ensure that OTPs comply with Federal and State requirements for providing and documenting OTP services, including ensuring that OTPs: provide take-home medications in accordance with Federal and State requirements	HCA concurs with this recommendation.	Federal CFR rule changes effective April 2, 2024, update criteria for consideration of take-home doses of methadone. HCA will partner with DOH to update WAC, and new rules published by DOH for OTP providers by the end of 2024, to reflect alignment with new CFR. By January 1, 2025, HCA will develop procedures to review compliance with new OTP CFR and WAC.
We recommend that the HCA work with its contracted MCOs and the Department of Health to ensure that OTPs comply with Federal and State requirements for providing and documenting OTP services, including ensuring that OTPs: adequately document opioid treatment services	HCA concurs with this recommendation.	This is a recommendation based on WAC. WAC will be updated, and new rules published by DOH for OTP providers by the end of 2024, to reflect alignment with new CFR. These rules will impact how documentation occurs for opioid treatment services. By January 1, 2025, HCA will develop procedures to review compliance with new OTP CFR and WAC.
We recommend that the HCA work with its contracted MCOs and the Department of Health to ensure that OTPs comply with Federal and State requirements for providing and documenting OTP services, including ensuring that OTPs: adequately document the results of drug screens	HCA concurs with this recommendation.	This is a recommendation based on WAC. WAC will be updated, and new rules published by DOH for OTP providers by the end of 2024, to reflect alignment with new CFR. By January 1, 2025, HCA will develop procedures to review compliance with new OTP CFR and WAC.
We recommend that the HCA work with its contracted MCOs and the Department of Health to ensure that OTPs comply with Federal and State requirements for providing and documenting OTP services, including ensuring that OTPs: adequately document checks of Washington State PDMP prescription data to identify enrollees' assessments	HCA concurs with this recommendation.	This is a recommendation based on WAC. WAC will be updated, and new rules published by DOH for OTP providers by the end of 2024, to reflect alignment with new CFR. By January 1, 2025, HCA will develop procedures to review compliance with new OTP CFR and WAC.

We recommend that the HCA work with its contracted MCOs and the Department of Health to ensure that OTPs comply with Federal and State requirements for providing and documenting OTP services, including ensuring that OTPs: adequately document enrollee assessments	HCA concurs with this recommendation.	Federal CFR rule changes effective April 2, 2024, update criteria for patient care within OTPs and will impact enrollee assessment documentation. HCA will partner with DOH to update WAC, and new rules published by DOH for OTP providers by the end of 2024, to reflect alignment with new CFR. By January 1, 2025, HCA will develop procedures to review compliance with new OTP CFR and WAC.
We recommend that the HCA work with its contracted MCOs and the Department of Health to ensure that OTPs comply with Federal and State requirements for providing and documenting OTP services, including ensuring that OTPs: demonstrate through documentation that treatment plans and progress notes are reviewed by qualified staff	HCA concurs with this recommendation.	This is a recommendation based on WAC. WAC for OTP providers will be updated by the end of 2024. New rules will be published by DOH sometime in late Fall 2024, to reflect alignment with new CFR.
We recommend that the HCA work with its contracted MCOs and the Department of Health to ensure that OTPs comply with Federal and State requirements for providing and documenting OTP services, including ensuring that OTPs: complete and adequately document annual medical examinations	HCA concurs with this recommendation.	This is a recommendation based on WAC. WAC will be updated, and new rules published by DOH for OTP providers by the end of 2024, to reflect alignment with new CFR. By January 1, 2025, HCA will develop procedures to review compliance with new OTP CFR and WAC.
We recommend that the HCA work with its contracted MCOs and the Department of Health to ensure that OTPs comply with Federal and State requirements for providing and documenting OTP services, including ensuring that OTPs: identify in the enrollee records the staff members who provided SUD assessments	HCA concurs with this recommendation.	This is a recommendation based on WAC. WAC will be updated, and new rules published by DOH for OTP providers by the end of 2024, to reflect alignment with new CFR. By January 1, 2025, HCA will develop procedures to review compliance with new OTP CFR and WAC.

We would like to thank the audit staff for their efforts and diligence in reviewing this complex area. Please do not hesitate to contact Medicaid Director Charissa Fotinos at charissa.fotinos@hca.wa.gov with any questions.

Sincerely,

Lou Mc Dermott
Deputy Director

cc: Sara Multanen-Karr, Manager of Behavioral Health Clinical SU, Clinical Quality and Care Transformation, (CQCT) HCA
Jessica Blose, Manager of Behavioral Health Clinical SU, CQCT, HCA
Kari Summerour, External Audit and Compliance Manager, HCA