Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

SAMHSA'S OVERSIGHT GENERALLY ENSURED THAT THE COMMISSION ON ACCREDITATION OF REHABILITATION FACILITIES VERIFIED THAT OPIOID TREATMENT PROGRAMS MET FEDERAL OPIOID TREATMENT STANDARDS

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Office of Inspector General

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Report in Brief
Date: October 2021
Report No. A-09-20-01002

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

SAMHSA's Oversight Generally Ensured That the Commission on Accreditation of Rehabilitation Facilities Verified That Opioid Treatment Programs Met Federal Opioid Treatment Standards

Why OIG Did This Audit

The Substance Abuse and Mental Health Services Administration (SAMHSA) estimated that, in 2019, 1.6 million people in the United States suffered from opioid use disorders. Opioid treatment programs (OTPs) provide medication-assisted treatment (MAT), which combines the use of medications with other therapies to treat opioid use disorders. Federal regulations established an oversight system for the treatment of substance use disorders with MAT. Because the Commission on Accreditation of Rehabilitation Facilities (CARF), a SAMHSA-approved accreditation body, accredited approximately 60 percent of OTPs in the United States, we conducted this audit of SAMHSA's oversight of CARF.

Our objective was to determine whether SAMHSA's oversight ensured that: (1) CARF verified that OTPs met Federal opioid treatment standards and (2) CARF's survey teams met Federal requirements.

How OIG Did This Audit

To determine whether SAMHSA's oversight ensured that CARF verified OTPs' compliance with Federal opioid treatment standards, we reviewed: (1) CARF's latest renewal application submitted to SAMHSA, which included CARF's policies and procedures and accreditation elements, and (2) a judgmental sample of 30 accreditations for OTPs that CARF surveyed from September 2019 through February 2020. We also reviewed CARF's processes for hiring surveyors and selecting them to conduct surveys.

What OIG Found

SAMHSA's oversight generally ensured that CARF verified that OTPs met Federal opioid treatment standards. As part of its oversight activities, SAMHSA: (1) reviewed CARF's renewal application, which included CARF's policies and procedures and accreditation elements; (2) inspected a selected sample of OTPs that CARF accredited and surveyed; and (3) reviewed accreditation reports submitted by CARF. In addition, SAMHSA's oversight ensured that CARF's survey teams met Federal requirements. Specifically, SAMHSA's review of CARF's renewal application included a review of CARF's policies and procedures for: (1) hiring surveyors with required education and experience, (2) training provided to surveyors, (3) selecting surveyors for each survey, and (4) avoiding conflicts of interest.

SAMHSA could improve its oversight to ensure that CARF's records contain sufficient detail to support each accreditation decision made by CARF. SAMHSA's policies and procedures did not require verification that accreditation bodies' (including CARF's) records contained sufficient detail supporting each accreditation decision. Not reviewing an accreditation body's records to determine whether they contain sufficient detail could make it difficult for SAMHSA to determine whether accreditation decisions are supported and to effectively evaluate the accreditation body's performance.

What OIG Recommends and SAMHSA Comments

We recommend that SAMHSA update its policies and procedures to require verification that accreditation bodies maintain records that contain sufficient detail to support each accreditation decision.

SAMHSA concurred with our recommendation and stated that it will update its current policies and procedures to ensure that records include sufficient detail to support accreditation bodies' decisions. SAMHSA stated that it anticipates the updated policies and procedures will be in place by January 2022.

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INTRODUCTION

WHY WE DID THIS AUDIT

According to the Centers for Disease Control and Prevention, opioids were involved in nearly 50,000 deaths in 2019, which was more than 6 times the number of opioid-involved overdose deaths in 1999.[1] The Substance Abuse and Mental Health Services Administration (SAMHSA) estimated that, in 2019, 1.6 million people in the United States suffered from opioid use disorders.[2]

Opioid treatment programs (OTPs) provide medication-assisted treatment (MAT), which combines the use of medications with counseling and behavioral therapies to treat opioid use disorders. OTPs must be accredited by a SAMHSA-approved accreditation body.[3] Federal regulations (42 CFR part 8) established an oversight system for the treatment of substance use disorders with MAT. These regulations (42 CFR § 8.12) contain the Federal opioid treatment standards, which are the minimum acceptable standards for the operation of OTPs and are intended to ensure, to the greatest extent possible, the safety of both patients and the public. Appendix B contains areas covered by the Federal opioid treatment standards.

A prior audit of SAMHSA's oversight of accreditation bodies that accredited OTPs found that SAMHSA's oversight did not comply with some Federal requirements.[4] Because the Commission on Accreditation of Rehabilitation Facilities (CARF), an accreditation body, accredited approximately 60 percent of OTPs in the United States, we conducted this audit of SAMHSA's oversight of CARF.

OBJECTIVE

Our objective was to determine whether SAMHSA's oversight ensured that: (1) CARF verified that OTPs met Federal opioid treatment standards and (2) CARF's survey teams met Federal requirements.

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[1] Available at Opioid Data Analysis and Resources | Drug Overdose | CDC Injury Center. Accessed on May 27, 2021.

[2] Available at Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (samhsa.gov). Accessed on Feb. 18, 2021.

[3] An accreditation body evaluates an OTP using the Federal opioid treatment standards and the accreditation elements or standards developed by SAMHSA-approved accreditation bodies.

[4] *SAMHSA's Oversight of Accreditation Bodies for Opioid Treatment Programs Did Not Comply With Some Federal Requirements* (A-09-18-01007), issued Mar. 6, 2020.

BACKGROUND

Medication-Assisted Treatment

MAT is the use of medications, with counseling and behavioral therapies, to treat substance use disorders and prevent opioid overdoses. MAT is primarily used to treat addiction to opioids, such as heroin and prescription pain relievers that contain opiates.

Three Food and Drug Administration-approved medications (methadone, buprenorphine, and naltrexone) are used to treat opioid dependence and addiction to opioids. Methadone used in MAT can be dispensed through only a SAMHSA-certified OTP.

Opioid Treatment Programs

OTPs provide MAT to individuals diagnosed with an opioid use disorder and also provide a range of services to reduce, eliminate, or prevent the use of illicit drugs. As of December 2020, approximately 1,800 OTPs operated in the United States.[5] These OTPs were located in every State except Wyoming.[6] OTPs must be licensed by a State agency, registered with the Drug Enforcement Administration, certified by SAMHSA, and accredited by a SAMHSA-approved accreditation body.

Accreditation of Opioid Treatment Programs by Accreditation Bodies

SAMHSA-approved accreditation bodies must be nonprofit accreditation organizations or State governmental entities (42 CFR § 8.3(a)). As of December 2020, there were six SAMHSA-approved accreditation bodies, including CARF.[7] OTPs may choose one of the six accreditation bodies for accreditation. (One of those accreditation bodies accredited only OTPs located at correctional facilities.)

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[5] Treatment for drug abuse and addiction is delivered in different settings—including inpatient, outpatient, and residential settings—using a variety of behavioral and pharmacological approaches. In the United States, more than 14,500 specialized drug treatment facilities provide counseling, behavioral therapy, medication, case management, and other types of services to people with substance use disorders. OTPs offer medication-assisted outpatient treatment for people who are dependent specifically on opioids.

[6] The District of Columbia and the territories of Puerto Rico and the Virgin Islands also had active OTPs. SAMHSA's website at OTP Directory (samhsa.gov) lists active OTPs in States and territories. Accessed on July 19, 2021.

[7] The six SAMHSA-approved accreditation bodies were: (1) CARF, (2) Council on Accreditation, (3) The Joint Commission, (4) Missouri Department of Mental Health, (5) National Commission on Correctional Health Care, and (6) Washington State Department of Health. SAMHSA's website at Approved Accreditation Bodies | SAMHSA lists the current accreditation bodies.

SAMHSA-approved accreditation bodies evaluate OTPs' compliance with Federal opioid treatment standards (found at 42 CFR § 8.12) and conformance with the accreditation elements or standards (accreditation elements) developed by the accreditation bodies (42 CFR § 8.2).[8] The accreditation process includes onsite surveys of OTPs by specialists from the accreditation body.[9]

SAMHSA's Oversight of Accreditation Bodies

In 2001, SAMHSA began overseeing MAT for substance use disorder under the Federal regulations codified at 42 CFR part 8. These regulations contain requirements for SAMHSA's oversight of accreditation bodies and procedures for an entity to become an approved accrediting body. SAMHSA oversees an accreditation body by evaluating the accreditation body's application and granting initial approval or renewal of approval if it determines that the accreditation body substantially meets applicable requirements (42 CFR § 8.3(d)(1)). The application should include a set of the accreditation elements and a detailed explanation showing how the proposed elements will ensure that each OTP surveyed by the applicant is qualified to meet or is meeting each of the Federal opioid treatment standards (42 CFR § 8.3(b)(3)).

In addition, SAMHSA evaluates periodically the performance of each accreditation body primarily by inspecting selected OTPs accredited by the accreditation body and by evaluating the accreditation body's reports summarizing the results of conducted surveys. (CARF calls these accreditation reports.) This evaluation determines whether surveyed and accredited OTPs complied with Federal opioid treatment standards (42 CFR § 8.5).

An accreditation body should make a summary of the results of each accreditation survey available to SAMHSA upon request, and the summary should contain sufficient detail to justify the accreditation action taken (42 CFR § 8.4(d)(2)).

Appendix C contains the details of SAMHSA's oversight activities.

Commission on Accreditation of Rehabilitation Facilities and Its Accreditation Process

CARF is a nonprofit organization that accredits OTPs. It is one of the six accreditation bodies and accredits approximately 60 percent of OTPs. CARF's *Opioid Treatment Program Standards Manual*, updated and published annually, contains CARF's accreditation elements and its accreditation policies and procedures. As part of its review of CARF's application for renewal as

[8] Federal regulations (42 CFR § 8.2) define accreditation elements as "the elements or standards that are developed and adopted by an accreditation body and approved by SAMHSA." An example of an accreditation element would be accredited OTPs' commitment to continually improving their organizations and service delivery to the people served. CARF incorporated the Federal opioid treatment standards into its accreditation elements.

[9] In response to the COVID-19 pandemic, CARF suspended accreditation surveys in early March 2020 and resumed them using virtual surveys (to replace onsite visits) in June 2020.

an accreditation body, SAMHSA reviews CARF's accreditation elements, which are intended to ensure that each OTP surveyed by CARF is qualified to meet or is meeting each of the Federal opioid treatment standards in 42 CFR § 8.12.

Commission on Accreditation of Rehabilitation Facilities' Survey Teams

CARF's survey teams conduct accreditation surveys of OTPs to determine their compliance with Federal opioid treatment standards. These teams consist of two or more surveyors with clinical and administrative expertise. CARF employs part-time, intermittent professionals as surveyors, with primary employment at CARF-accredited organizations and at least 5 years of relevant experience at the time of application. Surveyors receive training on CARF's standards and accreditation survey process as part of the onboarding process for new employees and are required to obtain ongoing training while employed by CARF. CARF lists the names of survey team members on its accreditation reports.

Commission on Accreditation of Rehabilitation Facilities' Accreditation Process

An organization applying to become an accredited OTP begins its process for accreditation by submitting a request for survey to CARF. Before the survey, surveyors review background information about the organization by reviewing its prior accreditation report (if the organization was previously accredited) and any comments received from interested parties (e.g., the State authority).

Surveys usually take 2 days and assess an organization's conformance with over 1,000 CARF accreditation elements, approximately 180 of which relate to the Federal opioid treatment standards in 42 CFR § 8.12. To record the organization's level of conformance with each accreditation element, surveyors use a proprietary electronic checklist. For each accreditation element on the checklist, including those associated with Federal opioid treatment standards, the surveyors assign a rating to indicate the level of conformance. The surveyors interview staff, patients, and their families; observe organizational practices; review documentation; and suggest ways to improve the organization's operations and service delivery.

After the survey is completed, CARF makes an accreditation decision (see the box to the right) and issues an accreditation report that identifies the organization's strengths and

CARF Accreditation Decisions

3-Year Accreditation: The organization demonstrates substantial conformance with the accreditation elements.

1-Year Accreditation: The organization demonstrates conformance with many accreditation elements, with significant need for improvement in some areas. After the 1-year accreditation, if the organization still demonstrates conformance with many accreditation elements, with significant need for improvement in some areas, the organization receives provisional accreditation.

Nonaccreditation: The organization has a major need for improvement related to accreditation elements.

areas for improvement and its level of demonstrated conformance with the accreditation elements, including recommendations for elements with which the organization is noncompliant or partially compliant. CARF requires the organization to submit a Quality Improvement Plan (QIP) indicating the actions that it will take to address recommendations in the accreditation report and a timeline for completion of those actions. CARF generally does not verify completion until the organization's next survey, when the survey team scrutinizes the implementation of changes made in response to the QIP from the previous survey.[10]

SAMHSA's Evaluation of the Commission on Accreditation of Rehabilitation Facilities' Accreditation Reports

SAMHSA officials said that they review the accreditation report that CARF submits after each survey of an OTP. To help facilitate its oversight, SAMHSA provided a template (the "AB [Accreditation Body] Report Template") for accreditation bodies to incorporate in their accreditation reports.[11] This template included, for each Federal opioid treatment standard, places for recording of surveyors' observations, findings, and recommendations.

SAMHSA, however, did not require accreditation bodies to use the "AB Report Template"; CARF used a crosswalk instead of the template. Since November 2020, CARF has submitted, along with the accreditation report, a supplemental report that contains a crosswalk between its accreditation elements and the Federal opioid treatment standards and that indicates which Federal standards are cited in the accreditation report. However, CARF's supplemental report does not include the surveyors' observations and findings. When SAMHSA is notified of CARF's nonaccreditation decisions, SAMHSA reviews deficiencies resulting in nonaccreditation and issues a warning letter to the OTP covering those areas with deficiencies involving Federal regulations.

HOW WE CONDUCTED THIS AUDIT

We reviewed SAMHSA's activities in overseeing CARF, including reviewing SAMHSA's policies and procedures. To determine whether SAMHSA's oversight ensured that CARF verified OTPs' compliance with Federal opioid treatment standards, we reviewed: (1) CARF's latest renewal application submitted to SAMHSA, which included CARF's policies and procedures and accreditation elements, and (2) a judgmental sample of 30 accreditations for OTPs that CARF surveyed from September 1, 2019, through February 29, 2020 (audit period).[12] To determine

[10] CARF officials stated that CARF follows up more rapidly to verify completion if any issues warrant immediate attention (e.g., those related to health and safety).

[11] SAMHSA officials said that the "AB Report Template" was provided to accreditation bodies in February 2019 in response to our prior audit, *SAMHSA's Oversight of Accreditation Bodies for Opioid Treatment Programs Did Not Comply With Some Federal Requirements* (A-09-18-01007), issued Mar. 6, 2020.

[12] To select accreditations for review, we considered whether a complaint had been filed against the OTP, whether it was a new accreditation or a renewal, the type of accreditation decision, and where the OTP was located.

whether SAMHSA's oversight ensured that CARF's survey teams met Federal requirements, we reviewed CARF's processes for hiring surveyors and selecting them to conduct surveys. For our sample of OTP accreditations, we also reviewed information for surveyors who conducted the surveys, such as the surveyor's role (program or administrative), OTP experience, and credentials.

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.

FINDINGS

SAMHSA's oversight generally ensured that CARF verified that OTPs met Federal opioid treatment standards. As part of its oversight activities, SAMHSA: (1) reviewed CARF's renewal application, which included CARF's policies and procedures and accreditation elements; (2) inspected a selected sample of OTPs that CARF accredited and surveyed; and (3) reviewed accreditation reports submitted by CARF. In addition, SAMHSA's oversight ensured that CARF's survey teams met Federal requirements.[13] Specifically, SAMHSA's review of CARF's renewal application included a review of CARF's policies and procedures for: (1) hiring surveyors with required education and experience, (2) training provided to surveyors, (3) selecting surveyors for each survey, and (4) avoiding conflicts of interest. CARF listed the names of survey team members in its accreditation reports. During SAMHSA's inspections of OTPs accredited by CARF, the compliance officer asked about the OTPs' experience with CARF's surveys, including the number of survey team members.

SAMHSA could improve its oversight to ensure that CARF's records contain sufficient detail to support each accreditation decision made by CARF. SAMHSA's policies and procedures did not require verification that accreditation bodies' (including CARF's) records contained sufficient detail supporting each accreditation decision. Not reviewing an accreditation body's records to determine whether they contain sufficient detail could make it difficult for SAMHSA to determine whether accreditation decisions are supported and to effectively evaluate the accreditation body's performance.

[13] Federal regulations require that, at a minimum, an accreditation body's survey team consist of at least two health care professionals with expertise in drug abuse treatment and, in particular, opioid treatment (42 CFR § 8.4(h)(1)). Members of the survey team must be able to recuse themselves if either they or the OTP believes there is a potential conflict of interest (42 CFR § 8.4(h)(2)). Individuals who participate in accreditation surveys or otherwise participate in the accreditation decision or an appeal of the accreditation decision, as well as their spouses and minor children, shall not have a financial interest in the OTP that is the subject of the accreditation survey or decision (42 CFR § 8.4(g)).

FEDERAL REQUIREMENTS

Federal regulations require that accreditation bodies maintain records of their accreditation activities for at least 5 years from the creation of the record, and such records must contain sufficient detail to support each accreditation decision made by the accreditation body (42 CFR § 8.4(c)(1)).

SAMHSA COULD IMPROVE ITS OVERSIGHT TO ENSURE THAT THE COMMISSION ON ACCREDITATION OF REHABILITATION FACILITIES' RECORDS CONTAIN SUFFICIENT DETAIL TO SUPPORT ACCREDITATION DECISIONS

SAMHSA's oversight generally ensured that CARF verified that OTPs met Federal opioid treatment standards. However, based on our review of 30 judgmentally sampled accreditations, we determined that CARF's records did not contain sufficient detail to support each accreditation decision. Specifically, for all 30 sampled accreditations, the records did not contain sufficient detail to support CARF's rationale for its decisions on whether OTPs complied with Federal opioid treatment standards. CARF's survey team recorded in CARF's proprietary electronic checklist whether an OTP conformed with each accreditation element. For each accreditation element on the checklist, including those associated with Federal opioid treatment standards, surveyors assigned a rating to indicate the level of conformance. However, they did not provide a justification for the given rating.

Specifically, when a surveyor determined that an accreditation element was fully met, there was no information recorded beyond the assigned rating. When a surveyor determined that an accreditation element was not fully met, the surveyor was required to make a recommendation based on his or her observations, interviews with OTP staff and patients, or review of documentation. However, in many of these cases, the recommendation was simply a restatement of the accreditation element and did not document the basis of the surveyor's determination of partial compliance or noncompliance.

After completion of each survey, CARF issued an accreditation decision in an accreditation report, which included only the accreditation elements that were not fully met and the related recommendations.

The following page shows examples of insufficient detail in CARF's records to support surveyors' determinations of full conformance and nonconformance with accreditation elements.

Example of Insufficient Detail To Support a Determination of Full Conformance

Federal regulations (42 CFR § 8.12(f)(2)) and CARF's accreditation elements state that OTPs should require each patient to undergo a complete, fully documented physical evaluation. The full medical examination, including the results of related laboratory tests, must be completed within 14 days following admission.

On CARF's checklist, the surveyor assigned a rating indicating the organization's full conformance with these accreditation elements. Other than the rating, there was no additional information that provided the reasoning behind the surveyor's rating, such as whether the surveyor selected a sample of records for review, whether the surveyor reviewed templates (e.g., for assessments or treatment plans) or actual records, which records were included in the sample, or how many records in the sample were in full conformance with the accreditation elements. In addition, the accreditation report, which was the only survey documentation that SAMHSA reviewed, did not contain any additional information or comments for these accreditation elements when the surveyor determined that there was full conformance.

Example of Insufficient Detail To Support a Determination of Nonconformance

Federal regulations (42 CFR § 8.12(h)(3)) state that OTPs must maintain adequate procedures to ensure that the initial dose of methadone, for each new patient enrolled in a program, must not exceed 30 milligrams and that the total dose for the first day must not exceed 40 milligrams (unless the program physician documents in the patient's record that 40 milligrams did not suppress opioid abstinence symptoms). CARF's accreditation elements state that the initial dose of methadone may not exceed 30 milligrams of methadone or, when applicable, a total dose for the first day may not exceed 40 milligrams.

On CARF's checklist, the surveyor assigned a rating indicating the organization's nonconformance with these accreditation elements and recommended that "the organization's initial dose of methadone not exceed 30 milligrams of methadone or, when applicable, a total dose for the first day that does not exceed 40 milligrams." The surveyor did not record any additional information to support how the surveyor made the determination, such as whether the surveyor reviewed the organization's procedures or a selected sample of patient records, and how many records in the sample did not conform with the accreditation elements.

Other than the accreditation elements and recommendations, the accreditation report, which was the only survey documentation that SAMHSA reviewed, did not contain sufficient detail to explain the basis of the surveyor's decision of nonconformance.

SAMHSA's policies and procedures did not require verification that accreditation bodies' (including CARF's) records contained sufficient detail supporting each accreditation decision. SAMHSA officials said that they would expect the accreditation body to maintain documentation to support any findings, but they had not historically requested internal notes

from accreditation bodies concerning the accreditation decision-making process. SAMHSA stated that CARF surveyors have to assess conformance with hundreds of accreditation elements, sometimes in 1 day, and SAMHSA trusted that the surveyors were conducting and able to conduct the required steps to arrive at their determinations of conformance or nonconformance with the accreditation elements. Not reviewing the accreditation body's records to determine whether they contain sufficient detail could make it difficult for SAMHSA to determine whether accreditation decisions are supported and to effectively evaluate the accreditation body's performance.

RECOMMENDATION

We recommend that the Substance Abuse and Mental Health Services Administration update its policies and procedures to require verification that accreditation bodies maintain records that contain sufficient detail to support each accreditation decision.

SAMHSA COMMENTS

In written comments on our draft report, SAMHSA concurred with our recommendation and stated that it will update its current policies and procedures to ensure that records include sufficient detail to support accreditation bodies' decisions. SAMHSA stated that it anticipates the updated policies and procedures will be in place by January 2022. SAMHSA's comments are included in their entirety as Appendix D.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed SAMHSA's activities in overseeing CARF, including reviewing SAMHSA's policies and procedures. To determine whether SAMHSA's oversight ensured that CARF verified OTPs' compliance with Federal opioid treatment standards, we reviewed: (1) CARF's latest renewal application submitted to SAMHSA, which included CARF's policies and procedures and accreditation elements, and (2) a judgmental sample of 30 accreditations for OTPs that CARF surveyed from September 1, 2019, through February 29, 2020. To determine whether SAMHSA's oversight ensured that CARF's survey teams met Federal requirements, we reviewed CARF's processes for hiring surveyors and selecting them to conduct surveys. For our sample of OTP accreditations, we also reviewed information for surveyors who conducted the surveys, such as the surveyor's role (program or administrative), OTP experience, and credentials.

We did not assess the overall internal control structure of SAMHSA or CARF. Rather, we limited our review to SAMHSA's and CARF's internal controls related to SAMHSA's oversight and CARF's processes for verifying OTPs' compliance with Federal standards and ensuring that survey teams met Federal requirements. To determine the effectiveness of the design and implementation of these internal controls, we interviewed SAMHSA and CARF officials; reviewed SAMHSA's policies and procedures related to their oversight activities; and reviewed CARF's accreditation survey policies and procedures and other guidance related to the accreditation process. Our review of a judgmental sample of 30 accreditations allowed us to evaluate the operating effectiveness of internal controls.

We conducted our audit from August 2020 to August 2021.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal regulations and guidance;
- reviewed SAMHSA's policies and procedures related to its oversight of accreditation bodies;
- interviewed SAMHSA officials to identify SAMHSA's oversight activities and processes related to accreditation bodies that accredited OTPs;
- reviewed CARF's policies and procedures and interviewed CARF officials to identify CARF's accreditation process and the composition of its survey teams;

- reviewed CARF's latest renewal application submitted to SAMHSA (dated March 18, 2019), which included CARF's accreditation elements;

- selected a judgmental sample of 30 accreditations for OTPs that CARF surveyed during our audit period;[14]

- reviewed documentation (e.g., applications to request a survey, accreditation reports, and QIPs) related to the 30 sampled accreditations;

- for the 30 sampled accreditations, reviewed information for the surveyors who conducted the surveys (e.g., the surveyor's role (program or administrative), OTP experience, and credentials); and

- discussed our findings with SAMHSA and CARF 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.

[14] To select accreditations for review, we considered whether a complaint had been filed against the OTP, whether it was a new accreditation or a renewal, the type of accreditation decision, and where the OTP was located.

APPENDIX B: FEDERAL OPIOID TREATMENT STANDARDS

Federal opioid treatment standards established in 42 CFR § 8.12 are used to determine whether an OTP is qualified to engage in opioid treatment. These standards also include standards related to the quantities of opioid drugs that may be provided to patients for unsupervised use. Federal opioid treatment standards cover the following areas:

- OTPs' administrative and organizational structure;
- continuous quality improvement (i.e., OTPs' maintenance of current quality assurance and quality control plans);
- staff credentials;
- patient admission criteria;
- required services, consisting of
    - initial medical examination services,
    - special services for pregnant patients,
    - initial and periodic assessment services,
    - counseling services, and
    - drug abuse testing services;
- recordkeeping and patient confidentiality;
- medication administration, dispensing, and use;
- unsupervised use of opioid treatment medications (e.g., for days that the clinic is closed for business); and
- interim maintenance treatment (provided in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides a comprehensive range of appropriate medical and rehabilitative services).

APPENDIX C: SAMHSA'S OVERSIGHT ACTIVITIES

Within SAMHSA's Center for Substance Abuse Treatment, the Division of Pharmacologic Therapies oversees accreditation bodies that accredited OTPs. The key personnel who are responsible for oversight include the regulatory branch chief, the accreditation body liaison, and multiple compliance officers. (At the time of our audit, there were four compliance officers).

Federal Requirements for SAMHSA's Oversight of Accreditation Bodies

SAMHSA oversees an accreditation body by granting initial approval or renewal of approval if it determines that the accreditation body substantially meets applicable requirements (42 CFR § 8.3(d)(1)). An accreditation body's application should include a set of the accreditation elements and a detailed explanation showing how the proposed elements will ensure that each OTP surveyed by the applicant is qualified to meet or is meeting each of the Federal opioid treatment standards (42 CFR § 8.3(b)(3)).

In addition, SAMHSA evaluates periodically the performance of each accreditation body primarily by inspecting selected OTPs and by evaluating accreditation reports. This evaluation determines whether surveyed and accredited OTPs complied with Federal opioid treatment standards. The SAMHSA evaluation should include a determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the accreditation body's approval (42 CFR § 8.5). If SAMHSA determines that the accreditation body has a major deficiency, SAMHSA should withdraw approval (42 CFR § 8.6(a)). If SAMHSA determines that the accreditation body has minor deficiencies in performing an accreditation function, SAMHSA will notify the accreditation body that it has 90 days to submit a plan of corrective action (42 CFR § 8.6(b)).

SAMHSA's Evaluation of an Accreditation Body's Application and Accreditation Elements

According to SAMHSA's *Oversight of Accreditation Bodies*, SAMHSA's accreditation body liaison is responsible for managing the application process for approval of accreditation bodies. To evaluate an accreditation body's application, which includes the accreditation elements, the accreditation body liaison uses the form "Evaluation Report for Review of Opioid Treatment Programs Accreditation Body Applications" to determine whether the application meets SAMHSA's regulatory requirements and to assess the adequacy of the accreditation elements.

SAMHSA's Inspections of Selected Opioid Treatment Programs

SAMHSA compliance officers conduct site visits of selected OTPs to assess OTPs' compliance with Federal opioid treatment standards. SAMHSA's *Policy on Accrediting Body Oversight* specifies a minimum of 18 inspections per year across all OTPs.

To conduct its inspections of selected OTPs, SAMHSA uses the tools *SAMHSA Performance Assessment of Accreditation Bodies: Site Visit Protocol* and *Patient Chart Review*. SAMHSA officials explained that the compliance officer conducting each inspection prepares reports of the findings, and the accreditation body liaison identifies or is made aware of any deficiencies noted. Final summaries of inspections and findings are reviewed by the branch chief, division directors, and other leaders.

SAMHSA's Review of Accreditation Bodies' Accreditation Reports

Accreditation bodies should make a summary of the results of each accreditation survey available to SAMHSA upon request, and these summaries should contain sufficient detail to justify the accreditation action taken (42 CFR § 8.4(d)(2)).

Federal regulations require that accreditation bodies maintain records of their accreditation activities for at least 5 years from the creation of the record, and such records must contain sufficient detail to support each accreditation decision made by the accreditation body (42 CFR § 8.4(c)(1)).

APPENDIX D: SAMHSA COMMENTS

SAMHSA
Substance Abuse and Mental Health Services Administration
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www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

DATE: September 22, 2021

TO: Assistant Secretary for Legislation

FROM: Assistant Secretary for Mental Health and Substance Use

SUBJECT: U.S. Office of Inspector General Draft Report "*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)

The Substance Abuse and Mental Health Services Administration (SAMHSA) has reviewed the subject document and concurs with the recommendations. SAMHSA offers the attached comments for consideration.

Miriam Delphin-Rittmon

Miriam E. Delphin-Rittmon, Ph.D.

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE OFFICE OF INSPECTOR GENERAL'S DRAFT REPORT ENTITLED 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

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Office of Inspector General (OIG) to review and comment on this draft report.

Recommendation 1

SAMHSA should update its policies and procedures to require verification that accreditation bodies maintain records that contain sufficient detail to support each accreditation decision.

HHS Response

SAMHSA concurs with OIG's recommendation. SAMHSA will update the current policies and procedures to ensure that the records include sufficient detail to support the accreditation bodies' decisions. We anticipate that the updated policies and procedures will be in place by January 2022.