

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**SAMHSA'S OVERSIGHT OF
ACCREDITATION BODIES FOR
OPIOID TREATMENT PROGRAMS
DID NOT COMPLY WITH SOME
FEDERAL REQUIREMENTS**

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Office of Inspector General

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Report in Brief

Date: March 2020

Report No. A-09-18-01007

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



Why OIG Did This Audit

The Substance Abuse and Mental Health Services Administration (SAMHSA) estimated that, in 2017, 1.7 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers. Medication-assisted treatment (MAT), provided by opioid treatment programs (OTPs), 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. OTPs must be certified by SAMHSA and accredited by a SAMHSA-approved accreditation body. We reviewed SAMHSA's oversight of the accreditation bodies because the adequacy of that oversight affects the safety of patients and the public.

Our objective was to determine whether SAMHSA's oversight of accreditation bodies complied with Federal requirements.

How OIG Did This Audit

We reviewed SAMHSA's activities in overseeing accreditation bodies. Specifically, we reviewed the results of SAMHSA's inspections performed at selected OTPs from October 2016 through September 2018 (audit period) and a judgmental sample of 30 reports for accreditation surveys conducted by accreditation bodies during our audit period. We also requested documentation of SAMHSA's evaluations of accreditation elements.

SAMHSA's Oversight of Accreditation Bodies for Opioid Treatment Programs Did Not Comply With Some Federal Requirements

What OIG Found

SAMHSA performed inspections at selected OTPs but did not (1) meet its goal for the number of OTPs it would inspect, (2) take actions to address accreditation bodies' noncompliance with survey requirements, or (3) determine whether OTPs complied with the Federal standards when patient charts were incomplete. In addition, SAMHSA reviewed accreditation bodies' survey reports, but the reports were inconsistent and did not contain sufficient information to determine whether the OTPs met the Federal standards. Finally, SAMHSA's evaluations of accreditation bodies' accreditation elements were not documented or retained. (An example of an accreditation element would be accredited OTPs' commitment to continually improving their organizations and service delivery to the people served.) Without improved oversight and proper documentation of its evaluations, SAMHSA may not be able to adequately evaluate the performance of accreditation bodies and ensure that OTPs are meeting the Federal opioid treatment standards.

What OIG Recommends and SAMHSA Comments

We recommend that SAMHSA (1) identify steps it can take and take action to ensure that it meets its goal for the number of OTPs it inspects each year and (2) review the results of its inspections and take action to address accreditation bodies' noncompliance with survey requirements. The report also lists three more procedural recommendations.

SAMHSA concurred with all of our recommendations and provided specific information on actions that it planned to take to address two of our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

According to the Centers for Disease Control and Prevention, opioids were involved in more than 47,000 deaths in 2017, and opioid overdose deaths were 6 times higher in 2017 than in 1999.¹ The Substance Abuse and Mental Health Services Administration (SAMHSA) estimated that, in 2017, 1.7 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.²

Medication-assisted treatment (MAT), provided by opioid treatment programs (OTPs), combines the use of medications with counseling and behavioral therapies to treat opioid use disorders. Federal regulations (42 CFR part 8) established an oversight system for the treatment of substance use disorders with MAT. OTPs must be certified by SAMHSA and accredited by an accreditation body that is approved by SAMHSA.³ We conducted an audit of SAMHSA's oversight of the accreditation bodies that accredited OTPs because the adequacy of that oversight affects the safety of patients and the public.

OBJECTIVE

Our objective was to determine whether SAMHSA's oversight of accreditation bodies complied with Federal requirements.

BACKGROUND

Medication-Assisted Treatment

MAT is the use of medications, with counseling and behavioral therapies, to treat substance use disorders and prevent opioid overdose. It is primarily used to treat addiction to opioids, such as heroin and prescription pain relievers that contain opiates. The prescribed medication normalizes brain chemistry, blocks the euphoric effects of opioids, relieves physiological cravings, and normalizes body functions without the negative effects of the abused drug.

¹ Available at <https://www.cdc.gov/drugoverdose/data/analysis.html>. Accessed on June 27, 2019.

² Available at <https://store.samhsa.gov/system/files/sma18-5068.pdf>. Accessed on July 16, 2019.

³ To become certified, an OTP must successfully complete the certification and accreditation process and meet other requirements outlined in 42 CFR part 8. Accreditation is the accreditation body's acceptance that an OTP has complied with applicable standards. An accreditation body evaluates an OTP using the Federal opioid treatment standards and the accreditation elements or standards developed by SAMHSA-approved accreditation bodies.

Three Food and Drug Administration-approved medications (methadone, buprenorphine, and naltrexone) are used to treat opioid dependence and addiction to opioids. (See the box to the right.) 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 the end of 2018, OTPs were located in every State except Wyoming.⁴ As of November 2018, approximately 1,600 OTPs were in operation.⁵ 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

An accreditation body evaluates an OTP using the Federal opioid treatment standards (found at 42 CFR § 8.12) and the accreditation elements or standards (accreditation elements) developed by SAMHSA-approved accreditation bodies (42 CFR § 8.2).⁶ The accreditation process includes onsite surveys of OTPs by specialists from the accreditation body.

SAMHSA-approved accreditation bodies must be nonprofit accreditation organizations or State governmental entities (42 CFR § 8.3(a)). As of 2017, there were six SAMHSA-approved

Drugs Used in Medication-Assisted Treatment

Methadone reduces cravings and withdrawal symptoms and is usually taken by mouth in liquid form. It is dispensed to addiction treatment clients daily in single doses and only at certified OTPs.

Buprenorphine suppresses and reduces cravings for the abused drug. It comes as a pill or as a tablet that is placed under the tongue. Doctors who complete a training and certification process may prescribe buprenorphine for office-based treatment or at treatment programs.

Naltrexone blocks the ability of opioids to eliminate pain and induce euphoria. This removes the rewarding aspects of opioid use that result in a desire for more. Naltrexone comes as a monthly injection or a daily pill, either of which may be prescribed by any qualified medical professional.

⁴ The District of Columbia and the territories of Puerto Rico and the Virgin Islands also had active OTPs. SAMHSA's website at <https://dpt2.samhsa.gov/treatment/> lists active OTPs in States and territories. Accessed on July 2, 2019.

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 opioid drugs.

⁶ 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.

accreditation bodies. OTPs may choose one of the six accreditation bodies for accreditation, and one accreditation body accredits OTPs located at correctional facilities. The number of OTPs that each accreditation body accredited ranged from 9 to 1,113 (Table 1).

Accreditation bodies (1) accredit OTPs that dispense opioid treatment medications; (2) conduct routine accreditation surveys for initial, renewed, and continued accreditation of each OTP at least every 3 years; and (3) conduct for-cause inspections of OTPs at SAMHSA’s request (42 CFR §§ 8.2 and 8.4(a)).⁷

Federal Requirements for SAMHSA’s Oversight of Accreditation Bodies

In 2001, Federal regulations (42 CFR part 8) established an oversight system for the treatment of substance use disorders with MAT. Federal regulations transferred from the Food and Drug Administration to SAMHSA the administrative responsibility over the use of opioid medications in maintenance and detoxification treatment of substance use disorders and established procedures for an entity to become an approved accrediting body.⁸

Federal regulations (42 CFR part 8) contain requirements for SAMHSA’s oversight of accreditation bodies. SAMHSA oversees an accreditation body by granting an application for initial approval or for 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 for initial approval 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 the accreditation body’s survey reports. This evaluation determines whether the surveyed and accredited OTPs complied with the 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

Table 1: Number of Opioid Treatment Programs Accredited by Accreditation Bodies (as of November 2018)

Accreditation Body	Number of Accredited OTPs
1	1,113
2	387
3	65
4	19
5*	14
6	9
Total	1,607

* Accredits OTPs located at correctional facilities.

⁷ A for-cause inspection is “an inspection of an [OTP] by the Secretary [of Health and Human Services (HHS)], or by an accreditation body, that may be operating in violation of Federal opioid treatment standards, may be providing substandard treatment, or may be serving as a possible source of diverted medications” (42 CFR § 8.2).

⁸ “Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction,” Final Rule, 66 Fed. Reg. 4076 (Jan. 17, 2001).

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 Oversight Activities

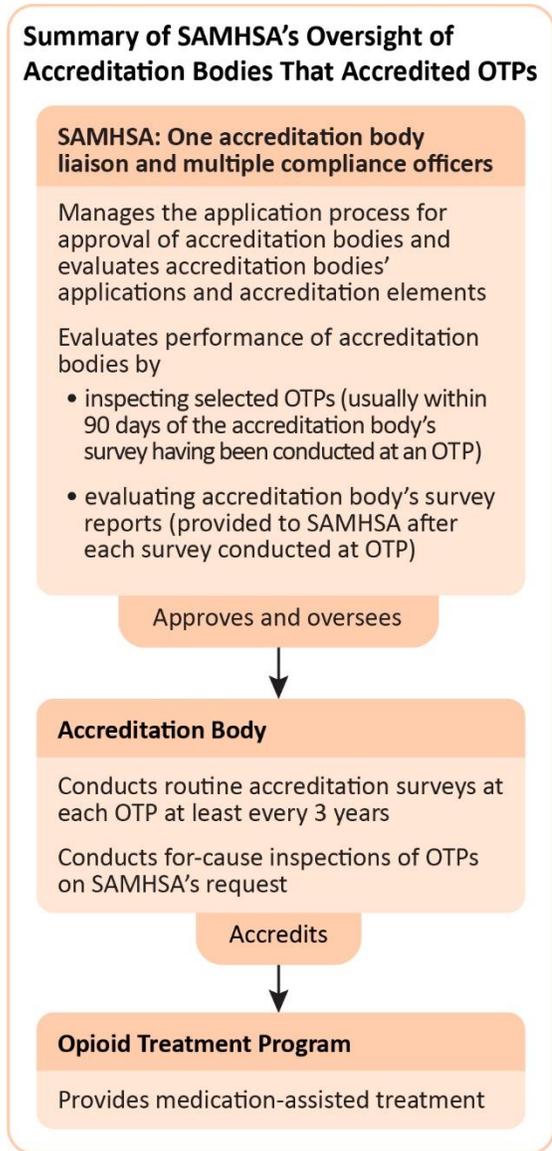
Within SAMHSA's Center for Substance Abuse Treatment, the Division of Pharmacologic Therapies (DPT) oversees accreditation bodies and certification processes for OTPs. The key personnel who are responsible for oversight include the regulatory branch chief, the accreditation body liaison, and multiple compliance officers. (See the box to the right for a summary of SAMHSA's oversight activities.)

SAMHSA's Evaluation of Accreditation Elements

According to SAMHSA's *Oversight of Accreditation Bodies* (policies and procedures), SAMHSA's accreditation body liaison is responsible for managing the application process for approval of accreditation bodies. To evaluate an 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 Review of Accreditation Bodies' Survey Reports

SAMHSA's policies and procedures state that an accreditation body should provide to SAMHSA a survey report at the conclusion of each survey the accreditation body performs and before granting an initial accreditation of an OTP or renewing an OTP's accreditation. The report should contain sufficient detail to justify the accreditation action taken. SAMHSA evaluates an accreditation body's performance by evaluating the survey report to determine whether the surveyed and accredited OTP complied with the Federal opioid treatment standards (42 CFR § 8.5).



SAMHSA's Inspections of Opioid Treatment Programs

To assess the accreditation body's process of accrediting OTPs and to evaluate the OTPs' compliance with the Federal opioid treatment standards, DPT's accreditation body liaison and compliance officers conduct inspections of selected OTPs that have recently been surveyed and accredited by an accreditation body.

SAMHSA's Conducting a Compliance Audit of Opioid Treatment Programs (Compliance Audit Guidance) states that as part of the inspection, the compliance officer asks the OTP about the accreditation process (e.g., by asking about the number of surveyors), reviews the OTP's documents (e.g., organization structure, staffing, and admission and discharge criteria), and reviews selected patient charts (containing information related to a patient's admission and discharge, treatment, and services). The compliance officer records the results of the inspection in the inspection instruments⁹ and reviews the results with the OTP at the end of the inspection.

The compliance officer shares the results with the accreditation body liaison, who compares the deficiencies with the most recent accreditation survey report. If any deficiencies identified at the inspection had already been identified in the survey report, SAMHSA does not intervene, because it expects the OTP to resolve the deficiencies with the accreditation body. If deficiencies identified from the inspection were not identified in the survey report, the accreditation body liaison meets with the accreditation body to discuss the deficiencies.

HOW WE CONDUCTED THIS AUDIT

We reviewed SAMHSA's activities in overseeing accreditation bodies. To determine whether SAMHSA's oversight of accreditation bodies complied with Federal requirements, we reviewed (1) the results of SAMHSA's inspections performed at selected OTPs from October 1, 2016, through September 30, 2018 (audit period) and (2) a judgmental sample of 30 reports for accreditation surveys conducted by accreditation bodies during our audit period.¹⁰ We also requested documentation of SAMHSA's evaluations of accreditation elements.

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.

⁹ The inspection instruments are *SAMHSA Performance Assessment of Accreditation Bodies: Site Visit Protocol* and *SAMHSA Performance Assessment of Accreditation Bodies: Patient Chart Review*.

¹⁰ To select survey reports for review, we considered the number of surveys that each of the six accreditation bodies conducted during our audit period. Specifically, we selected 12 survey reports from the largest accreditation body, 6 from the second largest accreditation body, and 3 from each of the 4 smaller accreditation bodies.

Appendix A contains the details of our audit scope and methodology.

FINDINGS

SAMHSA's oversight of accreditation bodies did not comply with some Federal requirements. Specifically, we found the following:

- SAMHSA performed inspections at selected OTPs but did not (1) meet its goal for the number of OTPs it would inspect, (2) take actions to address accreditation bodies' noncompliance with survey requirements, or (3) determine whether OTPs complied with the Federal opioid treatment standards when patient charts were incomplete. SAMHSA did not dedicate sufficient resources (e.g., staffing) to ensure that it met its inspection goal or took actions to address accreditation bodies' noncompliance, and SAMHSA did not follow its Compliance Audit Guidance.
- SAMHSA reviewed accreditation bodies' survey reports, but the reports were inconsistent and did not contain sufficient information to determine whether the OTPs met the Federal opioid treatment standards. SAMHSA officials said that they did not want to put an additional burden on the accreditation bodies by creating a standard report format.
- SAMHSA's evaluations of accreditation bodies' accreditation elements were not documented or retained. As a result, we were unable to determine whether SAMHSA completed evaluations of accreditation bodies. SAMHSA did not provide us with any completed evaluations of the accreditation elements because, according to SAMHSA officials, the evaluations were completed before any of SAMHSA's current leadership was in place, and the documentation of the evaluations could not be found.

Without improved oversight and proper documentation of its evaluations, SAMHSA may not be able to adequately evaluate the performance of accreditation bodies and ensure that OTPs are meeting the Federal opioid treatment standards.

SAMHSA'S INSPECTIONS OF OPIOID TREATMENT PROGRAMS NEED IMPROVEMENTS

As part of evaluating the performance of accreditation bodies, SAMHSA performed inspections at selected OTPs, but SAMHSA did not (1) meet its goal for inspecting OTPs, (2) take actions to address accreditation bodies' noncompliance with survey requirements, or (3) determine whether OTPs complied with the Federal opioid treatment standards when patient charts were incomplete.

SAMHSA Did Not Meet Its Internal Goal for Inspecting Opioid Treatment Programs

Federal regulations state that SAMHSA must periodically evaluate the performance of accreditation bodies primarily by inspecting a selected sample of the OTPs accredited by an

accrediting body and evaluating the accreditation body’s survey reports to determine whether the surveyed and accredited OTPs complied with the Federal opioid treatment standards (42 CFR § 8.5). According to SAMHSA officials, their internal goal, since 2001, had been to inspect 25 to 30 OTPs each year.¹¹

SAMHSA inspected 14 OTPs in calendar year (CY) 2017 and 23 OTPs in CY 2018,¹² which did not meet its internal goal for the number of OTPs it would inspect. (See Table 2.) For CY 2017, SAMHSA officials could not explain why the inspection goal was not met, because the previous management had not documented the reason for not meeting the goal. For CY 2018, SAMHSA officials said that because of a shortage of staff, they were not able to meet the inspection goal.

Table 2: Number of OTPs Inspected by SAMHSA

Accreditation Body	2017	2018
1	8	14
2	5	6
3	0	1
4	1	1
5	0	0
6	0	1
Total	14	23

If SAMHSA inspects fewer than the targeted number of OTPs, the inspections, collectively, may not be sufficient to evaluate the performance of accreditation bodies in determining whether the surveyed and accredited OTPs complied with the Federal opioid treatment standards.

SAMHSA Did Not Take Actions To Address Accreditation Bodies’ Noncompliance With Survey Requirements

SAMHSA will evaluate periodically the performance of an accreditation body primarily by inspecting a selected sample of the OTPs accredited by the accrediting body and by evaluating the accreditation body’s reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the accreditation body are in compliance with Federal regulations (42 CFR § 8.5). If SAMHSA determines that an accreditation body is not in substantial compliance with Federal regulations, SAMHSA shall take appropriate action (42 CFR § 8.6). Federal regulations require that, at a minimum, an accreditation body’s survey team consist of at least two healthcare professionals with expertise in drug abuse treatment and, in particular, opioid treatment (42 CFR § 8.4(h)(1)).

SAMHSA did not take actions to address accreditation bodies’ noncompliance with survey requirements. Specifically, for 12 OTPs at which SAMHSA performed inspections, SAMHSA determined that the accreditation body’s survey team consisted of only 1 surveyor. SAMHSA officials said that SAMHSA’s compliance officers recorded this deficiency in the inspection

¹¹ During our audit period, SAMHSA’s policies and procedures did not indicate the number of OTPs it would inspect. During our fieldwork, in January 2019, SAMHSA added to its written policies and procedures its goal to inspect at least 25 OTPs each year.

¹² Although our audit period was based on the Federal fiscal year, SAMHSA counted the numbers of inspected OTPs based on the calendar year, and these inspections were performed within our audit period.

instruments but did not take actions to address it because the branch chief and accreditation body liaison positions were vacant in 2017 and part of 2018.

If SAMHSA does not address accreditation bodies' noncompliance with the requirement to conduct surveys with two surveyors, survey teams may not have the opioid treatment expertise to perform the surveys.¹³

SAMHSA Did Not Determine Opioid Treatment Programs' Compliance With Certain Federal Requirements When Patient Charts Were Incomplete

Federal regulations state that OTPs must operate in accordance with the Federal opioid treatment standards (42 CFR § 8.11(f)(7)). SAMHSA's Compliance Audit Guidance states that as part of the inspection at an OTP, the compliance officer should review three to five patients' charts to determine an OTP's compliance with these standards. While reviewing a chart, if portions of the chart are not available, the compliance officer should request an alternative patient's chart with the same or similar characteristics (i.e., a chart from a different patient).

SAMHSA did not determine whether OTPs complied with some of the Federal opioid treatment standards in 42 CFR § 8.12 when patient charts (containing information related to a patient's admission and discharge, treatment, and services) were incomplete. For CYs 2017 and 2018, the compliance officers reviewed three patients' charts at each of the selected OTPs, which complied with SAMHSA's Compliance Audit Guidance. However, in some cases, part of a patient chart was unavailable for various reasons. For example, one OTP switched from using paper files for patient records to using an electronic system and did not have access to all portions of patients' charts because they had been sent to an outside vendor for scanning into the new system. In each case, the compliance officer indicated in the inspection instrument that part of the chart was unavailable but did not review an alternative patient chart as required. Therefore, the compliance officers did not follow SAMHSA's Compliance Audit Guidance to determine whether OTPs complied with all the Federal opioid treatment standards.

If parts of the patient charts are unavailable and the compliance officers do not review alternative patient charts, SAMHSA cannot evaluate the performance of accreditation bodies in determining whether the surveyed and accredited OTPs complied with the Federal opioid treatment standards.

¹³ During our fieldwork in February 2019, SAMHSA had a conference call with all the accreditation bodies and discussed the requirement that the accreditation survey team consist of at least two healthcare professionals with the requisite credentials and experience.

ACCREDITATION SURVEY REPORTS WERE INCONSISTENT AND DID NOT CONTAIN SUFFICIENT INFORMATION

Federal regulations state that accreditation bodies should make available to SAMHSA on request a summary of the results of each accreditation survey. These summaries should contain sufficient detail to justify the accreditation action taken (42 CFR § 8.4(d)(2)). SAMHSA evaluates an accreditation body's performance by evaluating its survey reports to determine whether the OTPs surveyed and accredited by the accreditation body complied with the Federal opioid treatment standards (42 CFR § 8.5).

Although SAMHSA reviewed the accreditation bodies' survey reports, the report contents were inconsistent and did not contain sufficient information to determine whether the OTPs met all of the Federal opioid treatment standards. For example, some survey reports did not contain any information about the survey team (e.g., the names and number of surveyors), and some reports contained only the accreditation elements, with no reference to the Federal opioid treatment standards. SAMHSA officials said that they did not want to put an additional burden on the accreditation bodies by creating a standard report format because some of the accreditation bodies also accredit other programs (besides OTPs) and used their report format for all their accreditations.

If the contents of accreditation bodies' survey reports are inconsistent and do not contain sufficient information, it may be difficult for SAMHSA to evaluate the performance of accreditation bodies in determining whether the surveyed and accredited OTPs complied with the Federal opioid treatment standards.¹⁴

SAMHSA'S EVALUATIONS OF ACCREDITATION ELEMENTS WERE NOT DOCUMENTED OR RETAINED

Federal regulations state that SAMHSA oversees an accreditation body by granting an application for initial approval or for renewal of approval if it determines that the accreditation body substantially meets applicable requirements (42 CFR § 8.3(d)(1)). An accreditation body's term of approval is for a period not to exceed 5 years (42 CFR § 8.3(g)). The accreditation body must provide a set of the accreditation elements and a detailed explanation showing how the proposed elements will ensure that each OTP surveyed by the accreditation body is qualified to meet or is meeting each of the Federal opioid treatment standards (42 CFR § 8.3(b)(3)). As part of the evaluation process, SAMHSA officials stated that they used an evaluation chart to review each accreditation body's proposed accreditation elements.

¹⁴ After our audit period, SAMHSA officials stated that the accreditation body liaison had started working with the accreditation bodies to standardize the survey reports.

In addition, Federal regulations require that each Federal agency “make and preserve records¹⁵ containing adequate and proper documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the agency” (36 CFR § 1220.30(a)). HHS policy is to preserve all official records in accordance with applicable statutory and regulatory requirements and to promote access to information by staff, partners, and the public, as appropriate (*HHS Policy for Records Management* § 5). Each office within HHS is required to establish and maintain a records management program to create, receive, and maintain official records that provide adequate and proper documentation as evidence of HHS’s activities.

SAMHSA’s evaluations of accreditation elements were not documented or retained, as required by Federal regulations and the HHS policy for records management. Specifically, SAMHSA did not provide us with any completed evaluations of the accreditation bodies’ accreditation elements but instead provided a template that it used. SAMHSA officials said that the evaluations were completed before any of SAMHSA’s current leadership was in place, and they could not find documentation of the evaluations.¹⁶

Without proper documentation and retention of SAMHSA’s evaluation of the accreditation elements, we cannot determine whether SAMHSA met its requirement to ensure that an accreditation body meets Federal requirements and each surveyed OTP is qualified to meet or is meeting each of the Federal opioid treatment standards.

CONCLUSION

Federal regulations (42 CFR part 8) describe 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. Therefore, if SAMHSA does not provide adequate oversight of accreditation bodies and proper documentation of its evaluations, it cannot adequately evaluate the performance of accreditation bodies to ensure that OTPs are meeting those minimum acceptable standards and, to the greatest extent possible, the safety of patients and the public.

¹⁵ A record is a unit of information, generated or received by an entity on behalf of the organization, that acts as evidence and provides a history of activities (*HHS Policy for Records Management*, Attachment 1).

¹⁶ According to SAMHSA officials, they approved five of the six accreditation bodies’ renewal applications in 2015, and their next renewals will be in 2020. The officials said that they approved the remaining accreditation body’s renewal application in 2016.

RECOMMENDATIONS

We recommend that the Substance Abuse and Mental Health Services Administration:

- identify steps it can take and take action to ensure that it meets its goal for the number of OTPs it inspects each year,
- review the results of its inspections and take action to address accreditation bodies' noncompliance with survey requirements,
- ensure that its compliance officers follow the Compliance Audit Guidance by reviewing alternative patients' charts when parts of a chart are unavailable to determine an OTP's compliance with the Federal opioid treatment standards,
- work with the accreditation bodies to standardize the survey reports to include not only surveyor teams' information but also OTPs' compliance with each of the Federal opioid treatment standards, and
- comply with Federal regulations and the HHS policy for documenting and retaining its evaluations of accreditation elements.

SAMHSA COMMENTS

In written comments on our draft report, SAMHSA concurred with all of our recommendations and provided specific information on actions that it planned to take to address our first and third recommendations:

- Regarding our first recommendation, SAMHSA stated that each year, it would develop a plan for the selection of OTPs to receive compliance visits. SAMHSA also stated that it would include in the plan the number of site visits that would take place by September 30, 2020, and the OTPs that would be visited.
- Regarding our third recommendation, SAMHSA stated that all compliance officers would receive training on the Compliance Audit Guidance to ensure understanding and compliance with the site-review procedures.

SAMHSA's comments are included in their entirety as Appendix B.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed SAMHSA's activities in overseeing accreditation bodies. To determine whether SAMHSA's oversight of accreditation bodies complied with Federal requirements, we reviewed (1) the results of SAMHSA's inspections performed at selected OTPs from October 1, 2016, through September 30, 2018, and (2) a judgmental sample of 30 reports for accreditation surveys conducted by accreditation bodies during our audit period. To select survey reports for review, we considered the number of surveys that each of the six accreditation bodies conducted during our audit period. We also requested documentation of SAMHSA's evaluations of accreditation elements.

We did not review SAMHSA's overall internal control structure. Rather, we limited our review to determining whether SAMHSA's oversight of accreditation bodies that accredited OTPs complied with Federal requirements.

We performed our fieldwork from January through October 2019, which included visits to SAMHSA's office in Rockville, Maryland.

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,
- identified the dates of each active OTP's latest accreditation survey,
- reviewed the results of SAMHSA's inspections performed at selected OTPs during our audit period,
- selected and reviewed a judgmental sample of 30 reports for accreditation surveys conducted during our audit period,¹⁷
- requested documentation for SAMHSA's evaluations of accreditation elements, and

¹⁷ We selected 12 survey reports from the largest accreditation body, 6 from the second largest accreditation body, and 3 from each of the 4 smaller accreditation bodies.

- discussed our findings with SAMHSA 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.

APPENDIX B: SAMHSA COMMENTS



Substance Abuse and Mental Health
Services Administration

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FEB 25 2020

TO: Amy J. Frontz
Deputy Inspector General for Audit Services
Office of Inspector General

FROM: Elinore F. McCance-Katz, M.D., Ph.D.
Assistant Secretary for Mental Health and Substance Use

SUBJECT: OIG Draft Report "*SAMHSA's Oversight of Accreditation Bodies for Opioid Treatment Programs Did Not Comply with Some Federal Requirements*" A-09-18-01007

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.

A handwritten signature in black ink, appearing to read "Elinore F. McCance-Katz", with a date "2/25/20" written to the right.

Elinore F. McCance-Katz, M.D., Ph.D.

Attachment

GENERAL COMMENTS FROM THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION ON THE OFFICE OF INSPECTOR GENERAL'S DRAFT REPORT ENTITLED –SAMHSA's OVERSIGHT OF ACCREDITATION BODIES FOR OPIOID TREATMENT PROGRAMS DID NOT COMPLY WITH SOME FEDERAL REQUIREMENTS A-09-18-01007

The Substance Abuse and Mental Health Services Administration appreciates the opportunity from the Office of Inspector General (OIG) to review and comment on this draft report. SAMHSA's Division of Pharmacological Therapies is in a rebuilding phase. SAMHSA believes strongly in the use of all medication-assisted treatment and understands the need to ensure Opioid Treatment Programs (OTPs) are complying with all regulations. SAMHSA will continue to strengthen its processes around this issue.

Recommendation 1

SAMHSA should identify steps it can take and take action to ensure that it meets its goal for the number of OTPs it inspects each year.

SAMHSA Response

SAMHSA concurs with this recommendation. Each year, SAMHSA will develop a plan for the selection of OTPs to receive compliance visits per 42 CFR part 8.5 Periodic evaluation of accreditation bodies by inspecting a selected sample of the OTPs accredited by the accrediting body. This plan will include the number of site visits that will take place by September 30, 2020 and the OTPs that will be visited.

Recommendation 2

SAMHSA should review the results of its inspections and take action to address accreditation bodies' noncompliance with survey requirements.

SAMHSA Response

SAMHSA concurs with this recommendation.

Recommendation 3

SAMHSA should ensure that its compliance officers follow the Compliance Audit Guidance by reviewing alternative patients' charts when parts of a chart are unavailable to determine an OTP's compliance with the Federal opioid treatment standards.

SAMHSA Response

SAMHSA concurs with this recommendation. To ensure understanding and compliance with site review procedures, all compliance officers will receive training on the compliance audit guidance.

Recommendation 4

SAMHSA should work with the accreditation bodies to standardize the survey reports to include not only surveyor teams' information but also OTPs' compliance with each of the Federal opioid treatment standards.

SAMHSA Response

SAMHSA concurs with this recommendation.

GENERAL COMMENTS FROM THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION ON THE OFFICE OF INSPECTOR GENERAL'S DRAFT REPORT ENTITLED –SAMHSA's OVERSIGHT OF ACCREDITATION BODIES FOR OPIOID TREATMENT PROGRAMS DID NOT COMPLY WITH SOME FEDERAL REQUIREMENTS A-09-18-01007

Recommendation 5

SAMHSA should comply with Federal regulations and the HHS policy for documenting and retaining its evaluations of accreditation elements.

SAMHSA Response

SAMHSAS concurs with this recommendation.