

Role of the State Opioid Treatment Authority (SOTA)

Core and Common Responsibilities under Current Federal Regulations
May 2023

BACKGROUND

In most states, the authority to oversee opioid treatment programs (OTPs) is granted to the Director of the State alcohol and drug agency, also known as the Single State Agency (SSA) for alcohol and other drugs. The specific responsibilities for overseeing OTPs are designated to a position that has come to be known as the State Opioid Treatment Authority, or the "SOTA."

SOTAs play a key role in ensuring accessible, high quality, and safe opioid use disorder treatment in opioid treatment programs.

The Code of Federal Regulations Title 42, Part 8, Medication Assisted Treatment for Opioid Use Disorders, specifies the rules by which OTPs must abide to legally operate. The same federal regulation outlines key responsibilities of a State agency in its oversight role of OTPs. In particular, the regulation designates this "State Authority" as "the agency designated to exercise the responsibility and authority within the State or Territory for governing the treatment of opioid addiction with an opioid drug."

The Substance Abuse and Mental Health Services Administration (SAMHSA) certifies OTPs, approves accrediting bodies, and supports education and training efforts to promote quality treatment services. The U.S. Drug Enforcement Administration (DEA) regulates controlled substances to prevent the diversion and misuse of medication provided in OTPs², and plays a role in regulating OTPs.

CORE RESPONSIBILITIES

The core responsibilities of the SOTA are outlined below.

- 1. Monitor OTPs' operations to ensure quality and regulatory compliance. SOTAs oversee OTPs to ensure compliance with relevant federal and State laws and regulations, including conducting announced and unannounced visits. They provide technical assistance to assist OTPs in complying with federal and State requirements.
- 2.Serve as liaison between the OTPs and SAMHSA. SOTAs collaborate closely with SAMHSA and the State licensing authority in processing applications for new OTPs. SAMHSA relies on the SOTAs to review and provide feedback on the ability of applicants for new OTPs to adhere to State and federal requirements. SOTAs help to inform OTPs about changes in federal policy, such as those generated by the COVID-19 Public Health Emergency. SOTAs also facilitate requests by OTPs to SAMHSA.
- 3. Serve as liaisons between the OTPs and the DEA. SOTAs verifies information to the DEA when an OTP applies for a new application, changes addresses, or when the DEA is reviewing an application for a medication unit.
- 4. Consult with and make recommendations to SAMHSA concerning new and renewing applications for OTPs and medication units, and on patient complaints. SOTAs meet with OTP applicants and visit the proposed site of the OTP to determine acceptability of the program. The SOTA advises the OTP leadership about the roles of the DEA, SAMHSA, the SOTA and other relevant State and local entities.

¹ 42 CFR Part 8.

² 21 CFR Parts 1300 to End.



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- 5. Review and approve or deny exception requests for SAMHSA approval, including requests to implement interim maintenance. SOTAs are responsible for approving "exception requests" for take home medications or other operational variances, based on the needs of the patients served by the OTP.
- 6. Educate partners about OTP services and medications for opioid use disorder. In collaboration with State Directors, SOTAs are responsible for educating partners and stakeholders on the benefits of and operation of OTPs. This may include working closely with the State licensing staff, providing consultation regarding financial resources (such as Medicaid, insurance coverage or grant applications), and educating local government officials.
- 7. Oversee closure of OTPs to ensure regulatory compliance and continuity of care for patients. SOTAs instruct OTPs that are terminating operations about federal and State regulations governing the closing of an OTP, including transfer of patient records to ensure that each patient impacted by the closing has a clear plan for continuity of care.
- 8. Act as a liaison for emergency and disaster planning. SOTAs, in the case of emergencies and disasters, connect OTPs to the State's emergency preparedness agency for resources, as well as make the agency aware of the needs of the OTPs. The SOTA assures that OTPs have continuity of operations plan in place and are prepared to implement it should the need arise. SOTAs inform OTPs of their communication responsibilities in emergencies.

CONCLUSION

In conclusion, the SOTA plays a critical role in providing oversight of OTPs to ensure high quality services. This document is designed to clarify the many complex responsibilities of the SOTA. While this document lists essential responsibilities, it is not exhaustive. Depending on conditions unique to each State, SOTAs may also be responsible for additional functions.

ABOUT NASADAD

The National Association of State Alcohol and Drug Abuse Directors (NASADAD) represents State alcohol and drug agency directors from the fifty States, the District of Columbia, and Territories. States work with counties and local communities to ensure that public dollars are dedicated to effective prevention, treatment, and recovery programs using tools such as: performance data management and reporting, contract monitoring, corrective action planning, onsite reviews, and technical assistance.