

**SUPPORTING STATEMENT FOR THE
STATE OPIOID RESPONSE (SOR) AND TRIBAL OPIOID RESPONSE (TOR)
PROGRAM DATA COLLECTION AND PERFORMANCE MEASUREMENT**

Check off which applies:

- ☐ New
- ☒ Revision
- ☐ Reinstatement with Change
- ☐ Reinstatement without Change
- ☐ Extension
- ☐ Emergency
- ☐ Existing

JUSTIFICATION

A1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) is requesting approval from the Office of Management and Budget (OMB) for revisions to the previously approved program instrument and data collection activities associated with the State Opioid Response (SOR) and Tribal Opioid Response (TOR) grant programs (OMB No. 0930–0384). SAMHSA is requesting approval to modify its existing CSAT SOR/TOR Program Instrument by (1) broadening language from ‘naloxone’ to ‘naloxone and other opioid overdose reversal medications’ due to the availability of new FDA-approved non-naloxone opioid overdose reversal medications; (2) broadening language from ‘fentanyl test strips’ to ‘drug checking technologies as directed by SAMHSA’ due to the availability of new drug checking technology, including test strips for other emerging substances; (3) adding five questions to collect treatment and recovery support data that were previously reported biannually in the performance progress reports; (4) adding one question to collect data on clients who received contingency management for the treatment of stimulant use disorder; (5) adding a sub-recipient entity inventory table to collect expenditure data for each grant sub-recipient in response to the Consolidated Appropriations Act, 2023 (42 U.S.C. § 300x–52(a)); (6) combining four questions with similar themes into two questions for clarity; (7) removing question 12 because it is comprised of more than one question with several different ideas, making it unsuited for this instrument; and (8) adding one question at the request of the Office of National Drug Control Policy (ONDCP) to collect information on Congressionally mandated and programmatic activities and comply with reporting requirements.

The SOR/TOR programs are authorized under the Further Consolidated Appropriations Act, 2024, Division D, Title II, and section 1003 of the 21st Century Cures Act [Public Law 114-255] (42 USC 290ee–3a), as amended.

This information is collected using a grantee-level (state/territory or tribal entity) tool that provides CSAT with prevention, education, harm reduction, treatment, and recovery support information about all SOR/TOR grantees, including data on:

- Reported overdose reversals;
- The purchase and distribution of naloxone and other opioid overdose reversal medications;
- Training on the administration of naloxone and other opioid overdose reversal medications;
- Implementation of prevention and education activities;
- The purchase and distribution of drug checking technologies as directed by SAMHSA;
- Treatment services for opioid use disorder (OUD), and stimulant use disorder;
- The types of recovery support services; and
- Expenditure amounts for each SOR and TOR grant sub-recipient.

This program level information is collected quarterly for questions 1 to 13b, and annually for the sub-recipient entity inventory table. To be fully accountable for the spending of federal funds, SAMHSA/CSAT requires all SOR/TOR grantees to collect and report data to ensure that program goals and objectives are met. Data collected as part of this package are used as a tool to monitor performance through the grant period. All data under this request will be collected electronically in SAMHSA's Performance and Accountability Reporting System (SPARS).

Approval of this information collection will allow SAMHSA to continue to meet the Government Performance and Results Modernization Act (GPRA) of 2010 reporting requirements that quantify the effects and accomplishments of its discretionary grant programs, which are consistent with OMB guidance, as well as legislative mandates.

To carry out section 1105(a) (29) of the GPRA, SAMHSA is required to prepare a performance plan for its major program activities.

SAMHSA's legislative mandate includes increasing access to high quality services and to improve outcomes. Its mission is to reduce the impact of substance use and mental illness on our communities.

A2. Purposes and Use of Information

SAMHSA uses this information to report on the performance and outcomes of its SOR/TOR programs. The information is used by individuals at different levels: the Assistant Secretary and SAMHSA staff, the Center administrators, Government Project Officers (GPOs), and grantees:

Assistant Secretary Level – The information is used to inform the administration of the performance of the SOR/TOR programs.

Center Level – In addition to providing information about the performance of the SOR/TOR programs, the information is used to monitor and manage individual grant projects within each program. The information is used by GPOs to identify program strengths and weaknesses, to provide an informed basis for providing technical assistance and other support to grantees, to inform funding decisions, and to identify potential issues for additional evaluation.

Grantee Level – In addition to monitoring performance and outcomes, the grantee staff uses the information to improve the quality of prevention, education, harm reduction, treatment, and recovery support services provided to clients within their projects.

SAMHSA and CSAT will use these data to better assess grantee accountability and performance on the required prevention, education, harm reduction, treatment, and recovery support activities for the SOR/TOR programs. The revisions will assist SAMHSA in providing comprehensive data on the full range of required activities to inform Congressionally mandated reports for the SOR program.

Proposed Changes to Data Collection Tool

SAMHSA is proposing to revise the SOR/TOR Program Instrument data collection instrument (OMB No. 0930-0384), to collect information on Congressionally mandated and programmatic activities and comply with reporting requirements.

SOR/TOR grantees are required to engage in the following prevention and education activities: (1) train peers, first responders, and other key community sectors on the recognition of opioid overdose and appropriate use of naloxone and other opioid overdose reversal medications; (2) develop evidence-based community prevention efforts such as strategic messaging on the consequences of opioid and stimulant misuse; (3) implement evidence-based prevention interventions, involving schools, parents, and community programs; and (4) purchase and distribute naloxone and other opioid overdose reversal medications based on the naloxone distribution and saturation plan. Additionally, grantees are required to implement service delivery models that enable the full spectrum of treatment and recovery support services that facilitate positive treatment outcomes and long-term recovery from opioid and stimulant use disorders.

The revised tool will continue to allow SAMHSA to collect data on the required prevention education, and harm reduction, treatment, and recovery support activities, and better assess grantee performance on these activities. Modifications were made to the program instrument to address the mandates included in Consolidated Appropriations Act, 2023 (42 U.S.C. § 300x–52(a)). Grantees must provide a description of the sub-recipients of SOR and TOR grant funds and expenditure data, as mandated by the statute. The revised tool will include the sub-recipient entity inventory table that will collect information annually on the list of SOR/TOR grant sub-recipients, expenditure amounts for each sub-recipient, and the types of services provided by each sub-recipient. Treatment and recovery services questions were previously reported by the grantees biannually in the performance progress reports. Adding these questions to the instrument will enable SAMHSA to provide comprehensive data on the full range of required activities to inform Congressionally mandated reports for the SOR and TOR programs quarterly in a structured format.

Summary of Proposed Changes:

The current SOR/TOR program instrument has 12 questions. SAMHSA is proposing to (1) broaden language from ‘naloxone’ to ‘naloxone and other opioid overdose reversal medications’

due to availability of new FDA-approved non-naloxone opioid overdose reversal medications; (2) broaden language from ‘fentanyl test strips’ to ‘drug checking technologies as directed by SAMHSA due to the availability of new drug checking technology, including test strips for other emerging substances; (3) add five questions to collect treatment and recovery support data that was previously reported biannually in the performance progress reports; (4) add one question to collect data on clients who received contingency management for the treatment of stimulant use disorder; (5) add a sub-recipient entity inventory table to collect expenditure data for each sub-recipient in response to the Consolidated Appropriations Act, 2023 (42 U.S.C. § 300x–52(a)); (6) combine four questions with similar themes into two questions for clarity; (7) remove question 12 because it is comprised of more than one question that has several different ideas, making it unsuited for this instrument; and (8) add one question at the request of ONDCP to collect information on Congressionally mandated and programmatic activities and comply with reporting requirements. The revised instrument will collect data on new medications and technologies, and provide clarification on prevention, education, harm reduction, treatment, and recovery support activities. Additionally, the revised instrument will continue to improve SAMHSA’s ability to assess grantee accountability and performance on the required prevention, education, harm reduction, treatment, and recovery support activities for the SOR/TOR programs; and provide comprehensive data on the full range of required activities, to inform Congressionally mandated reports for the SOR program.

As a result of the revisions, SOR/TOR grantees will submit data on the following outcome measures:

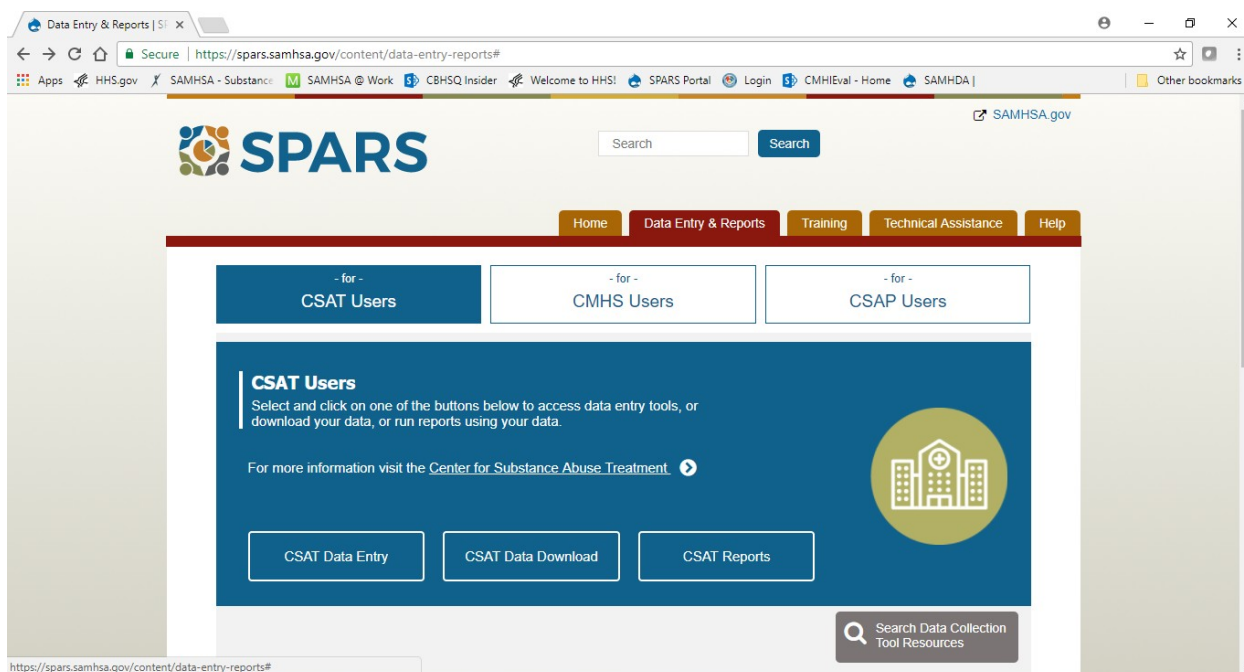
- Purchase and distribution of naloxone and other opioid overdose reversal medications;
- Types of entities that distribute naloxone and other opioid overdose reversal medications;
- Purchase and distribution of drug checking technologies as directed by SAMHSA;
- Train first responders and individuals in key community sectors on recognizing an opioid overdose and appropriate use of naloxone and other opioid overdose reversal medications;
- Educate individuals on the consequences of opioid and/or stimulant misuse, using strategic messaging, and prevention and education activities;
- Educate school-aged children on the consequences of opioid and/or stimulant misuse, using school-based prevention and education activities;
- Treatment services provided for OUD, and the types of medications provided;
- Contingency management provided for the treatment of stimulant use disorder;
- Types of recovery support services provided; and
- Expenditure amounts for each SOR and TOR grant sub-recipient.

All SOR/TOR data collection activities are intended to promote the use of consistent measures among SOR/TOR grantees. These measures are a result of extensive examination and recommendations, using consistent criteria, by panels of staff who have knowledge of and experience with the SOR/TOR programs. Wherever feasible, the measures are consistent with or build upon previous data development efforts within CSAT. These data collection activities are organized to reflect, and support required SOR/TOR prevention, education, harm reduction, treatment, and recovery support services.

A3. Use of Improved Information Technology

Grantees collect program-level information using a variety of methods, including paper-and-pencil and electronic methods. This project will not interfere with ongoing program collection operations that facilitate information collection at each site.

A web-based data collection and entry system, SAMHSA's Performance Accountability and Reporting System (SPARS), has been developed, and is currently used and available to all programs for data submission. This web-based system allows for easy data entry, submission, and reporting to all those who have access to the system. Levels of access have been defined for users based on their authority and responsibilities regarding the data and reports. Access to the data and reports is limited to those individuals with a username and password. A screenshot of the data entry screen on SPARS is below:



Electronic submission of the data promotes enhanced data quality. With built-in data quality checks and easy access to data outputs and reports, users of the data can feel confident about the quality of the output. The electronic submission also promotes immediate access to the dataset. Once data are entered in the web-based system, they are available for access, review, and reporting by all those with access to the system, both Center and grantee staff.

A4. Efforts to Identify Duplication

The items collected are necessary in order to assess grantee performance. SAMHSA is promoting the use of consistent performance and outcomes measures across SOR and TOR programs; this effort will result in less overlap and duplication and will substantially reduce the burden on grantees that results from data demands associated with individual programs.

A program-level review of current measures and methods of data collection was conducted with the goal of creating questions for more precise monitoring of grantee performance. Each proposed question was reviewed and approved by CSAT senior leadership as meeting the performance monitoring and management needs of the SOR/TOR program.

A5. Involvement of Small Entities

Individual grantees vary from tribal entities to tribes and states. Every effort has been made to minimize the number of data items collected from grantees, requiring responses to only the items necessary to accomplish the objectives described in the GPRA reporting requirements. Therefore, there is no significant impact to small entities.

A6. Consequences if Information Collected Less Frequently

SOR/TOR grant programs report program level data to SAMHSA quarterly for questions 1 to 13b, and annually for the sub-recipient entity inventory table. These points in time are part of regular program monitoring. If these data are collected less frequently, changes in program services will be difficult to measure.

These data will be reported by SAMHSA in Congressionally mandated SOR reports.

A7. Consistency with the Guidelines in 5 CFR1320.5(d)(2)

This information collection fully complies with 5 CFR 1320.5(d) (2).

A8. Consultation Outside the Agency

The notice required by 5 CFR 1320.8(d) was published in the *Federal Register* on June 24, 2024 (89 FR 52483). Comments were received from the public and are available on the attached Public Comment Matrix.

A9. Payment to Respondents

The respondents do not receive payments.

A10. Assurance of Confidentiality

Data will be kept private to the extent allowed by law. The information from grantees and all other potential respondents will be kept private through all steps in the data collection and reporting processes. However, SAMHSA cannot ensure complete confidentiality of the program level data. Only aggregated data will be reported. SAMHSA has statutory authority to collect data under the GPRA (Public Law 1103(a), Title 31), and is subject to the Privacy Act for the protection of data. Federally assisted substance use disorder treatment providers are subject to the federal regulations for alcohol and substance abuse patient records (42 CFR Part 2) (OMB No. 0930-0092), which govern the protection of patient identifying data. In some cases, these same providers meet the definition of a Health Insurance Portability and Accountability Act

covered entity and are additionally subject to the Privacy Rule (45 CFR Parts 160 and 164) for the protection of individually identifiable data.

A11. Questions of a Sensitive Nature

SAMHSA’s mission is to lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and better outcomes. The data submitted by each grantee primarily include aggregate data on reported overdose reversals; the purchase and distribution of naloxone and opioid overdose reversal medications; types of entities that distribute naloxone and opioid overdose reversal medications; training on naloxone and opioid overdose reversal medications administration; implementation of prevention and education activities; the purchase and distribution of drug checking technologies as directed by SAMHSA; treatment services for OUD, and stimulant use disorder; types of recovery support services; and expenditure amounts for each SOR and TOR grant sub-recipient.

A12. Estimates of Annualized Hour Burden

The estimated time to complete the instruments is given in Table 1. These estimates are based on current funding and planned funding and the number of consumers served in recent years. The amount of time required to complete the new questions is based on an informal pilot and prior SAMHSA/CSAT experience in collecting similar data.

Table 1: Estimates of Annualized Hour Burden for SOR/TOR Grantees

SAMHSA Data Collection	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden Hours per Response	Total Burden Hours	Hourly Wage¹	Total Wage Cost
Grantee-Level Instrument	189	4	756	.30	226.80	\$28.89	\$6,552.25
Grantee-Level Instrument	189	1	189	.25	47.25	\$28.89	\$1,365.05
Total	378	5	945		274.05	\$28.89	\$7,917.30

^[2] The hourly wage estimate is \$28.89 based on the Occupational Employment and Wages, Mean Hourly Wage Rate for 21-1018 Substance Abuse, Behavioral Disorder, and Mental Health Counselors= \$28.89 /hr. as of May 2023 (<https://www.bls.gov/oes/current/oes211018.htm> Accessed on September 23, 2024.)

The estimates in this table reflect the maximum annual burden for currently funded SOR/TOR programs. The number of clients served in future years is estimated to be the same, assuming unchanged funding of the SOR/TOR program, resulting in the same annual burden estimate for those years.

A13. Estimates of Annualized Cost Burden to Respondents

There are no capital or startup costs, nor are there any operation and maintenance costs.

A14. Estimates of Annualized Cost to the Government

The principal additional cost to the government for this project is a contract to collect data from the various programs and conduct analyses for routine reports. The reports will examine program level data quarterly. It will be the responsibility of the contractor to work with the GPO when preparing reports that combine program level data with the project annual reports.

The cost of one full-time equivalent staff (25% for one GS-14 Step 5, \$39,495.50 and 75% for one GS-12 Step 5, \$84,318.75) responsible for the CSAT data collection effort is approximately \$371,442.75 over 3 years.

The annualized cost to the government is \$123,814.25.

A15. Changes in Burden

The number of questions were increased from 12 to 17. Four questions with similar themes were combined into two questions for clarity; one question was removed because it is comprised of more than one question that has several different ideas, making it unsuited for this instrument; one question was added at the request of ONDCP; six questions were added to collect data on treatment and recovery support activities, and an expenditure table was added to collect data on each grant sub-recipient to collect information on Congressionally mandated and programmatic activities and comply with reporting requirements. Therefore, the burden hours per response increased from 0.30 to 0.55 hours, which increased the total burden hours from 226.80 to 274.05 hours.

A16. Time Schedule, Publication and Analysis Plans

Data for the SOR/TOR programs are needed by SAMHSA to prepare Congressionally mandated reports. The SOR/TOR program data are readily available through the web-based system. Depending on the question, data are provided quarterly and annually to SAMHSA, to assure timely analysis, and to submit the required Congressional reports.

There will also be program-specific analyses of these data because each program has unique programmatic and performance goals. The data items collected will be analyzed and presented in GPRA reports using basic descriptive statistics. Key outcomes that will be calculated and aggregated at the program level include: reported overdose reversals; the purchase and distribution of naloxone and opioid overdose reversal medications; types of entities that distribute naloxone and opioid overdose reversal medications; training on the administration of naloxone and opioid overdose reversal medications; implementation of prevention and education activities; purchase and distribution of drug checking technologies as directed by SAMHSA; treatment services for OUD, and stimulant use disorder; types of recovery support services; and

expenditure amounts for each SOR and TOR sub-recipient. If deemed necessary for CSAT specific issues, the data will be examined at the individual activity level.

A17. Display of Expiration Date

The expiration date for OMB approval will be displayed on all data collection instruments.

A18. Exceptions to Certification Statement

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions. The certifications are included in this submission.