

STATE TARGETED RESPONSE TO THE OPIOID CRISIS (OPIOID STR) PROGRAM DATA COLLECTION AND PERFORMANCE MEASUREMENT

SUPPORTING STATEMENT

A. Justification

A.1 Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment is requesting approval from the Office of Management and Budget (OMB) for data collection activities associated with its State Targeted Response to the Opioid Crisis (Opioid STR) grant program. The data collection was previously approved; however one data collection table was omitted from the original submission, thus this data collection is currently in use without OMB approval. SAMHSA recently became aware of this violation and is submitting this OMB package as a corrective action. Furthermore, SAMHSA is in the process of identifying and implementing policies and procedures to mitigate the risk of future Paperwork Reduction Act violations.

SAMHSA received approval from OMB in September 2017 to collect performance data from Opioid STR grantees (OMB No. 0930-0378). However, SAMHSA omitted a data collection table (Table E) in the original OMB request. This data table is currently in use by Opioid STR grantees, who are reporting Table E data to SAMHSA on a semi-annual basis. In order to correct this violation, SAMHSA is now seeking OMB approval for a new data collection package that includes not only the instruments originally approved by OMB in September 2017, but also this additional data collection table. It is important for SAMHSA to continue to collect this information in order to assess the impact of funding from the Opioid STR program on increasing access to prevention strategies and treatment and recovery services to address the opioid crisis. Additionally, this data will provide SAMHSA with critical information to effectively manage the Opioid STR program, to help states and territories adopt, or scale-up, effective practices and policies, and to help prepare to implement the new State Opioid Response grant program.

The federal fiscal year (FY) Justification of Estimates for the Appropriations Committees <https://www.samhsa.gov/sites/default/files/samhsa-fy-2017-congressional-justification.pdf> included a State Targeted Response proposal and the 21st Century Cures Act (P.L. 114-255) enacted December 13, 2016, authorized a grant program for the states in response to the illicit and prescription opioid crisis. The statute authorized \$1 billion to be made available over the course of FY 2017 and FY 2018. The Funding Opportunity Announcement (FOA # TI-17-014) requires the Opioid STR grant recipients to prepare and submit mid- and end-year reports.

As of 2016, approximately 2.1 million people in the United States had an opioid use disorder.ⁱ The number of opioid overdose deaths were five times higher in 2016 than 1999, and opioids were involved in 42,249 deaths in 2016.ⁱⁱ In 2017, the Department of Health and Human Services declared a public health emergency for the Opioid Crisis.ⁱⁱⁱ Due to the rise in the number of

opioid users and overdose deaths, SAMHSA is committed to addressing and combating this issue.

A.2 Purpose and Use of Information

Opioid STR Data Collection and Performance Measurement grant recipients' progress in addressing the opioid epidemic will be addressed through the submission of data in compliance with the Substance Abuse Prevention and Treatment Block Grant (SABG) standard reporting requirements. SAMHSA is required to collect on the following performance measures specific to the Opioid STR program: number of persons and demographic information (i.e., age, gender, race/ethnicity, pregnancy status) who receive opioid use disorder (OUD) prevention, treatment and recovery services; details on types of Medication Assisted Treatment offered, type of prevention treatment, and recovery services and settings (including admission; number of providers implementing medication assisted treatment (MAT); and non-direct services and systems development information including the number of OUD prevention and treatment providers trained. These data are collected twice per grant year via mid-year and end of year reporting.

A.3 Use of Improved Information Technology

The SABG recipients, i.e., states and jurisdictions, prepare biennial plans and annual reports to SAMHSA in accordance with section 1932(b) of Title XIX, Part B, Subpart II of the Public Health Service Act (42 U.S.C. 300x-32(b)) and 45 CFR 96.122(g) and section 1942(a) of Title XIX, Part B, Subpart III of the Public Health Service Act (42 U.S.C. 300x-52(a)) and 45 CFR 96.122(f), respectively. To fulfill the requirements described in the authorizing legislation and implementing regulation, the states and jurisdictions submit their respective plans and reports through SAMHSA's Web Block Grant Application System (BGAS). SAMHSA amended the block grant application (0930-0168) to include data collection tables that correspond to the performance measures described in section 2.2 of the Funding Opportunity Announcement (TI-17-014).

A.4 Efforts to Avoid Duplication

A review was conducted of opioid use disorder data collected by SAMHSA and other federal agencies; there is not a duplication of this information.

A.5 Involvement of Small Businesses

This does not directly affect small entities.

A.6 Consequences if Information Collected Less Frequently

This is a two (2) year data collection. However, if the language contained in Section 1004 of the 21st Century Cures Act is included in a subsequent Labor-HHS-ED and Related Agencies appropriation bill or an omnibus bill, the data collection will be applicable to a subsequent fiscal year's funds or extended via no-cost extensions. If data is collected less frequently, government

project officers may be unable to adequately monitor state and jurisdiction performance as each responds to the existing opioid crisis.

A.7 Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

The data collection efforts will be consistent with the guidelines at 5 CFR 1320.5(d)(2).

A.8 Federal Register Notice

As required by 5 CFR 1320.8(d), the 60-Day FRN was published in the *Federal Register* on August 10, 2018 (83 FR 39765).

A.9 Payments/Gifts to Respondents

The respondents do not receive payments.

A.10 Assurance of Confidentiality

Health information data protection standards are taken to protect the information shared. Assurance of confidentiality will not be provided to respondents, as there is no personally identifiable client-level information being reported to SAMHSA for this program. Once the data is collected, the data is protected in a file server that is password protected.

A.11 Questions of a Sensitive Nature

The SABG and Opioid STR reporting requirements do not solicit information of a sensitive nature.

A.12 Estimates of Burden Hours

Table 1 shows the estimated annualized burden hours for the respondents’ time to participate in each data collection activity. Across the instruments, the total burden is estimated to be 969 hours. The total cost burden is estimated to be \$43,605.

Table 1. Estimate of Annualized Hour Burden

Data Collection Tool	Number of respondents	Responses per respondent	Total responses	Average burden per response (in hours)	Total burden (in hours)	Hourly Wage Cost	Total Wage Cost
Performance reporting	57	2	114	8.5	969	\$45	\$43,605

A.13 Estimates of Annualized Respondent Capital and Maintenance Costs

There are neither capital nor startup costs, nor are there any operations or maintenance costs.

A.14 Estimates of Annualized Cost to the Federal Government

SAMHSA has planned and allocated resources for the management, processing, and use of the collected information in a manner that will enhance its utility to the federal government, as well as award recipients. The Web BGAS contract modification to cover the task order expansion of the current data collection system accommodating this data collection is \$636,439 over a 24-month period, where the contract modification cost for year one is \$289,944 and the cost for year two is \$346,495. It is estimated that one SAMHSA employee will be involved for 5% of their time, at an estimated annualized cost of \$4,407 to the government. The total estimated average cost to the government for year one is \$294,351, and \$350,902 for year two.

The annualized cost to the government is \$322,626.50.

A.15 Change in Burden

Currently there are 912 burden hours in the OMB inventory. SAMHSA is requesting 969 total burden hours. The request to increase the burden by 57 hours is due to the inclusion of Table E which was omitted from the original submission.

A.16 Time Schedule, Publication and Analysis Plan

The Web Block Grant Application System (BGAS) includes this addendum, which includes Table E, for states and jurisdictions to submit data electronically. The schedule anticipates a conclusion of data collection in May 2021.

Activity	Tentative Timeline
Receive OMB clearance Notice of Action (NOA) for data collection	Anticipated October/November 2018
Notification letter to states and jurisdictions regarding NOA, Provide access to amendment via Web BGAS	October/November 2018
Data collection via mid-year progress reporting	November/December 2018
Begin processing and analyzing data	January 2019
Data collection via annual progress reporting	May 2019 Through May 2021
Recurring mid-year and annual progress reporting	

Data from the Opioid STR recipients' responses, i.e., mid-year and annual progress reports, will be accessed by the federal government to generate routine and ad hoc administrative reports to describe award recipients' efforts to address the illicit and prescription opioid crisis. Further, Opioid STR recipients' data may be used for a wide variety of other oversight, administrative, and statistical purposes of the federal government, state governments, and Congress (e.g., budget preparation, performance analysis). Data will be tabulated and analyzed using standard descriptive and statistical analytic techniques and may be published through the mechanisms noted above, as well as through the publication of special analytic studies.

A.17 Exemption for Display of Expiration Date

The OMB expiration date will be displayed.

A.18 Exceptions to Certification Statement

The certifications are included in this submission and fully comply with 5 CFR 1320.9.

ⁱ Substance Abuse and Mental Health Services Administration (2017). Key Substance Use and Mental Health Indicators in the United States: Results from the 2016 National Survey on Drug Use and Health. Retrieved from Department of Health and Human Services. (2018, March). What is the U.S. Opioid Epidemic? Retrieved from <https://www.hhs.gov/opioids/about-the-epidemic/index.html>

ⁱⁱ Centers for Disease Control and Prevention (2017). Drug Overdose Death Data. Retrieved from <https://www.cdc.gov/drugoverdose/data/statedeaths.html>

ⁱⁱⁱ Department of Health and Human Services. (2018, March). What is the U.S. Opioid Epidemic? Retrieved from <https://www.hhs.gov/opioids/about-the-epidemic/index.html>