SUPPORTING STATEMENT FOR THE CENTER FOR SUBSTANCE ABUSE PREVENTION (CSAP) HARM REDUCTION GRANT PROGRAM TARGET SETTING AND QUARTERLY AGGREGATE REPORTING INTRUMENT

JUSTIFICATION

A1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting approval from the Office of Management and Budget (OMB) for the Center for Substance Abuse Prevention (CSAP) Harm Reduction Grant Program Target Setting and Quarterly Aggregate Reporting Instrument (OMB No. 0930–XXXX). The instrument in this package is comprised of two parts: 1) the Harm Reduction Grant Annual Data section to be used to report annual programmatic goals, and 2) the Harm Reduction Grant Quarterly Data section to be used to report grant outputs and activities. Data collected through this instrument are necessary to ensure SAMHSA and grantees comply with requirements under the Government Performance and Results Act Modernization Act of 2010 (GPRMA) that requires regular reporting of performance measures.

In developing the Harm Reduction Grant Program Target Setting and Quarterly Aggregate Reporting Instrument, we sought the ability to elicit programmatic information that demonstrates impact at the program aggregate level. In this way, data from the tool can be used to assess resource allocation and to delineate who we serve and how we served them across quarters. The tool reflects CSAP's desire to elicit pertinent program level data that can be used to not only guide future programs and practice, but to also respond to stakeholder, congressional and agency inquiries.

This information is collected using the target setting and aggregate-level data collection instrument that provides SAMHSA with the capacity to report on the performance and outcomes for all of its discretionary programs, including demographic characteristics of individuals served, receipt of services, numbers of individuals served; and to be fully accountable for the spending of federal funds, SAMHSA requires all discretionary programs to collect and report program data to ensure program goals and objectives are being met. Data collected as part of this package will be used to monitor performance through the grant period and to ensure appropriate spending of federal funds. Approval of this information collection will allow SAMHSA to continue to meet GPRMA reporting requirements that quantify the effects and accomplishments of its discretionary grant programs which are consistent with OMB guidance. To carry out section 1105(a) (29) of the GPRA, SAMHSA is required to prepare a performance plan for its major programs of activity.

SAMHSA's legislative mandate is to increase access to high quality prevention and treatment services and to improve outcomes. Its mission is to reduce the impact of substance use and mental illness on our communities. All SAMHSA's programs and activities are geared toward the achievement of goals related to reducing the impact of substance use and mental health disorders. GPRA performance monitoring is a collaborative and cooperative aspect of this process. This request represents a first step in SAMHSA's efforts to improve its ability to assess

the impact of its programs, and to use data collected from its discretionary grant portfolio to enhance grantee performance and to improve the lives of Americans with mental health and substance use disorders. To help accomplish these goals, SAMHSA is undertaking an effort to enhance and modernize its data collection efforts over the next three years. The current request seeks approval for the Harm Reduction Grant Program Target Setting and Quarterly Aggregate Reporting Instrument.

Background

Harm reduction is a proactive approach that aims to reduce the negative personal and public health impacts of alcohol and other substance use or misuse and other high-risk behaviors at both the individual and community levels. Harm reduction is part of a comprehensive approach to prevention, treatment, and recovery where individuals set their own goals. Harm reduction services *meet people where they are* and may serve as a pathway to prevention, treatment, and recovery. Harm reduction also works by addressing broader health and social issues through improved policies, programs, and practices. This includes empowering individuals by equipping them with accurate information and resources.
Specifically, harm reduction can:

- Reduce overdose deaths, promote linkages into care, facilitate co-location of services as part of a comprehensive, integrated approach, reduce stigma associated with substance misuse and addiction,
- Lessen harms associated with drug use and related behaviors that increase the risk of infectious diseases, including HIV, viral hepatitis, and bacterial and fungal infections,
- Reduce infectious disease transmission among people who use drugs, including those who inject drugs, and
- Lessen harms associated with other substance use.

As documented in the American Rescue Plan Act of 2021, Sec. 2706 (b)(2), the goals of SAMHSA's harm reduction efforts include preventing and controlling the spread of infectious diseases and the consequences of such diseases for individuals with a substance use disorder. In Fiscal Year (FY) 2022, SAMHSA intends to award up to up to $400,000 per year for up to three years to 23 grants to state, local, tribal, and territorial governments, tribal organizations, non-profit community-based organizations, and primary and behavioral health organizations through the Harm Reduction Program grant.

The purpose of the program is to support community-based overdose prevention programs, syringe services programs, and other harm reduction services. Funding will be used to prevent and control the spread of infectious diseases and the consequences of such diseases for individuals with, or at risk of developing substance use disorders (SUD), support distribution of opioid overdose reversal medication to individuals at risk of overdose, connect individuals at risk for, or with, a SUD to overdose education, counseling, and health education, refer individuals to treatment for infectious diseases such as HIV, sexually transmitted infections (STIs), and viral hepatitis, and encourage such individuals to take steps to reduce the negative personal and public health impacts of substance use or misuse.

Harm reduction plays a significant role in the prevention of risky behaviors that cause or are linked to SUDs, such as HIV/STIs/Viral Hepatitis rates, opioid overdoses, alcohol use, suicide rates, substance-involved auto accidents, substance-involved community costs, sexual assault, high risk sexual behaviors, and trauma. Harm Reduction grant funds are to be used to decrease barriers to harm reduction programs, which will be achieved by promoting widespread dissemination and implementation of harm reduction activities, including stigma.

The priority populations for this program are rural communities, LGBTQ+ and/or racial and ethnic minorities. Grant recipients will focus activities on "meeting people where they're at" within the context of harm reduction through integrating trauma informed care and facilitating the use of peer support specialists/coaches in programming. The Harm Reduction grant program is authorized under Section 516 of the PHS Act, as amended.

A2. Purposes and Use of Information

The information is used by individuals at three different levels: 1) the Assistant Secretary for Mental Health and Substance Use, HHS, and SAMHSA leadership, 2) program-level SAMHSA staff, including CSAP leadership and Government Project Officers (GPOs), and 3) grantees:

> **Assistant Secretary Level** – The information is used to inform the Assistant Secretary for Mental Health and Substance Use of the performance and outcomes of the programs funded through the Agency. The performance is based on the goals of the grant program. This information serves as the basis of the annual GPRA report to Congress contained in the Justifications of Budget Estimates.
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> **Center Level** – In addition to providing information about the performance of the various 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.
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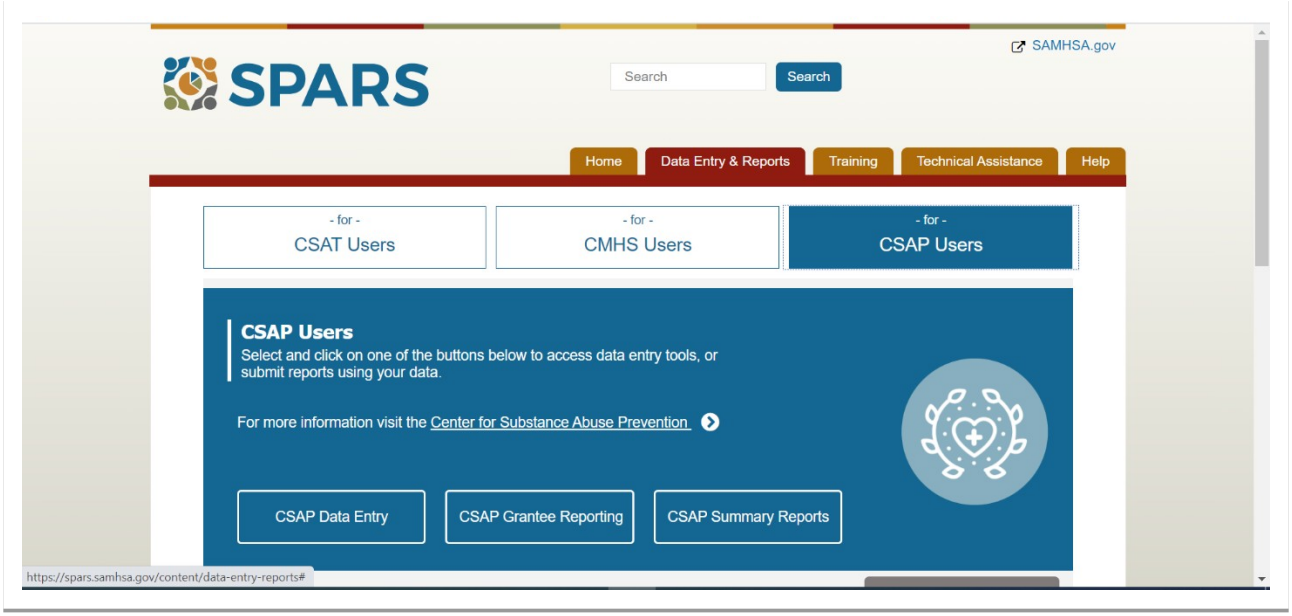
> **Grantee Level** – In addition to monitoring performance and outcomes, the grantee staff use the information to improve the quality of harm reduction services provided within their projects.

SAMHSA and its Centers will use the data for annual reporting required by GPRA to describe and understand changes across quarters. GPRA requires that SAMHSA's report for each fiscal year include actual results of performance monitoring for the three preceding fiscal years. The information collected through this revised data collection process allows SAMHSA to report on the results of performance and outcomes in a manner that is consistent with SAMHSA specific performance domains, and to assess the accountability and performance of its discretionary and formula grant programs.

A3. Use of Improved Information Technology

Programs collect 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 collection. 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:



Programs may submit their data electronically through an upload process. This facilitates the submission of data while avoiding duplication of the data entry process. Thus, programs that collect these data for other purposes are spared an additional collection burden.

Electronic submission of the data promotes enhanced data quality. With built-in data quality checks, 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 the data are put into the web-based system, it is available for access, review, and reporting by all those with access to the system from Center staff to the grantee staff.

A4. Efforts to Identify Duplication

The items collected are necessary in order to assess grantee performance. CSAP is promoting the use of consistent performance and outcomes measures across all Harm Reduction Program grantees; 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.

SAMHSA will work closely with the grantees to identify whether other data are being collected by the grantee, which may be redundant to the Harm Reduction GPRA instrument. When duplication is identified, SAMHSA and the grantees will identify a priority action plan to reduce the duplicative efforts and streamline the data items to reduce burden.

A5. Involvement of Small Entities

Individual grantees vary from small entities to large provider organizations. Every effort has been made to minimize the number of data items collected from all programs down to the least number of items necessary to accomplish the objectives described within and meet GPRA reporting requirements. Therefore, there is no significant impact to small entities.

A6. Consequences if Information Collected Less Frequently

The Harm Reduction grant program collects data annually for target setting purposes as well as performance data reporting on a quarterly basis. These time points are part of regular program activity.

These data collection points are generally accepted intervals for monitoring and the grantees will be asked to respond to the items according to this schedule. The data will be reported out to SAMHSA on an annual basis in keeping with the GPRA requirements for annual reporting; however, the grantees can enter the data into SPARS on an earlier schedule if they so choose.

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 February 14, 2022 (87 FR 8269). Three public comments were received. No other consultations were conducted outside the agency.

A9. Payment to Respondents

Grantees are asked to budget for data collection in their grant applications. There is no expectation for payment to respondents as the unit of analysis is the grantee and not the individual.

A10. Assurance of Confidentiality

The information from grantees and all other potential respondents will be kept private through all points in the data collection and reporting processes. However, SAMHSA cannot ensure complete confidentiality of programmatic data. SAMHSA will work with each grantee to prepare an impact assessment protocol. All data will be closely safeguarded, and no institutional or

individual identifiers will be used in reports. Only aggregated data will be reported. SAMHSA and its contractors will not receive identifiable client records. Provider-level information will be aggregated to, at least, the level of the grant/cooperative agreement-funding announcement.

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 abuse treatment providers are subject to the federal regulations for alcohol and substance abuse patient records (42 CFR Part 2) (OMB No.0925-0404) 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 improve the quality and availability of prevention, early intervention, treatment, and rehabilitation services for mental and substance use disorders, including co-occurring disorders, to improve health and reduce illness, death, disability, and cost to society. For the harm reduction program, the tools used to report on performance is at the aggregate level. There are no questions of a sensitive nature that are asked of individuals as the data collection is focused at the grantee level and not the individual participant level.

A12. Estimates of Annualized Hour Burden

The time to complete the instruments is estimated in Table 1. These estimates are based on current funding and planned fiscal year 2022; the amount of time required to complete the new questions is based on an informal pilot and prior SAMHSA/CSAP experience in collecting similar data.

Table 1: Estimates of Annualized Hour Burden

SAMHSA Tool	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden Hours per Response	Total Burden Hours	Hourly Wage[1]	Total Hour Cost
Target Setting Tool	23	1	23	0.6	13.8	$24.78	$342
Aggregate Program Level Tool[2]	23	4	92	0.6	55.2	$24.78	$1,368
Total	**23**		**115**		**72**		**$1,710**

[1] The hourly wage estimate is $24.78 based on the Occupational Employment and Wages, Mean Hourly Wage

Rate for 21-1011 Substance Abuse and Behavioral Disorder Counselors = $24.78/hr. as of May 11, 2021. (http://www.bls.gov/oes/current/oes211011.htm. Accessed on May 11, 2021.)
(2) This is an aggregate tool and collection is based on encounters.

The estimates in this table reflect the maximum annual burden for proposed discretionary harm reduction services program. The number of grants in following years is estimated to be the same assuming level funding of the Harm Reduction Grant 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 the cost of a contract to collect the data from the various programs and to conduct analyses, which generate routine reports from the data collected. The reports examine baseline characteristics and changes between baseline, discharge, and each of the follow-up periods. It is the responsibility of the contractor to work with the GPO when preparing reports that combine the services data with the annual reports of the project.

The estimated annualized cost for a contract for the GPRA mandate is $7.2 million and the cost of one full-time equivalent staff (25% for the midpoint of one GS-14 $34,372.75 and 75% for one GS-12 $73,386) responsible for the CSAP data collection effort is approximately $107,758.00/year.

A15. Changes in Burden

This is a new activity and this there is no change in burden

A16. Time Schedule, Publication and Analysis Plans

Time Schedule for Data Collection

Activity	**Time Schedule**
Obtain OMB approval for data collection	April 2022
Collect data	April 2022 – September 2025
Analyze data --Quantitative data submitted quarterly	June 2022 – September 2025
Disseminate of findings --Annual reports	Ongoing for monitoring purposes

Data for the annual GPRA plan/report are needed by SAMHSA by September of each year. The discretionary services program data are readily available through the web-based system. Data are provided for the most recently completed calendar year to SAMHSA in May in order to assure analysis in time for the annual GPRA report. The annual GPRA report must be submitted to the

U.S. Department of Health and Human Services and to OMB by September and is included in the President's annual budget request which is released to the public February 1st. Data may be refined and added to the final Presidential budget request after the Department submits its initial GPRA report.

Analysis/Publication Plans

Program monitoring and outcome data will be collected through the web site. Data will be used to report to Congress regarding GPRA as specified in the SAMHSA Annual Justifications of Budget Estimates. The data might also be used for specific comparisons relative to the Office of National Drug Control Policy's National Drug Control Strategic Goals.

SAMHSA and each of its Centers specifically will use the grant program data for annual reporting required by GPRA on the previously stated items. The GPRA dataset will consist of each element coded into the reporting categories as seen in Attachment 1. These data are at the aggregate program level. The SAMHSA GPRA performance outcome data will be aggregated at the following levels: Project/Grantee, Program/Division, and Activity. The analyses will be organized around SAMHSA's Harm Reduction Program Grant measures. Baseline level analyses involves using frequency distributions and measures of central tendency to describe the populations across the various demographic groups (e.g., gender, race, ethnicity). The data items collected will be analyzed and presented in reports using basic descriptive statistics.

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.