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This notice is being published less than 15 days prior to the meeting due to scheduling difficulties.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 11, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Proposed Project: New: The Center for Substance Abuse Prevention Online Reporting Tool and Grant Programmatic Progress Report To Replace Division of State Programs—Management Reporting Tool (DSP–MRT) (OMB No. 0930–0354)

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Substance Abuse Prevention (CSAP) is requesting approval from the Office of Management and Budget (OMB) to monitor CSAP discretionary grant programs through administration of a suite of data collection instruments for grant compliance and programmatic performance monitoring. This package describes the data collection activities and proposed instruments. Grant compliance monitoring will be conducted via a single data collection instrument to be completed by all CSAP discretionary grant recipients. Programmatic performance monitoring will be conducted via a suite of data collection instruments with each instrument tailored to a specific CSAP discretionary program. This request for data collection will replace OMB No. 0930–0354: Division of State Programs—Management Reporting Tool.

CSAP intends to monitor six grant programs through this data collection effort:

- *Strategic Prevention Framework—Partnerships for Success (SPF–PFS):* The purpose of the SPF–PFS program is to help reduce the onset and progression of substance misuse and its related problems by supporting the development and delivery of state and community substance misuse prevention and mental health promotion services. This program is intended to promote substance use prevention throughout a state jurisdiction for individuals and families by building and expanding the capacity of local community prevention providers to implement evidence-based programs. In addition, the program is intended to expand and strengthen the capacity of local community prevention providers to implement evidence-based prevention programs. With this program, SAMHSA aims to strengthen state and community level prevention capacity to identify and address local substance use prevention concerns, such as underage drinking, marijuana, tobacco, electronic cigarettes, opioids, methamphetamine, and heroin.
- *Sober Truth on Preventing Underage Drinking (STOP Act):* The purpose of this program is to prevent and reduce alcohol use among youth and young adults ages 12–20 in communities throughout the United States through evidence-based screening, programs and curricula, brief intervention strategies, consistent policy enforcement, and environmental changes that limit underage access to alcohol as authorized by 942 U.S.C. 290bb–25b. The program aims to: (1) address norms regarding alcohol use by youth, (2) reduce opportunities for underage drinking, (3) create changes in underage drinking enforcement efforts, (4) address penalties for underage use, and/or (5) reduce negative consequences associated with underage drinking.
- *Strategic Prevention Framework for Prescription Drugs (SPF Rx):* The purpose of the SPF Rx grant program is to provide resources to help prevent and address prescription drug misuse within a State or locality. The program is designed to raise awareness about the dangers of sharing medications as well as the risks of fake or counterfeit pills purchased over social media or other unknown sources, and work with pharmaceutical and medical communities on the risks of overprescribing. Whether addressed at the state level or by an informed community-based organization, the SPF Rx program will raise community awareness and bring prescription substance misuse prevention activities and education to schools, communities, parents, prescribers, and their patients. In addition, grant recipients will be required to track reductions in opioid related overdoses and incorporate relevant prescription and overdose data into strategic planning and future programming.
- *First Responders—Comprehensive Addiction and Recovery Act (FR CARA):* The purpose of this program is to allow first responders and members of other key community sectors to administer a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.
- *Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths (PDO):* The purpose of this program is to support first responders and members of other key community sectors to administer a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for emergency reversal of known or suspected opioid overdose. Recipients will train and provide resources to first responders and members of other key community sectors at the state, tribal, and local levels on carrying and administering a drug or device approved or cleared under the FD&C Act for emergency treatment of known or suspected opioid overdose.
- *Improving Access to Overdose Treatment (ODTA):* The purpose of this program is to expand access to naloxone and other Food and Drug Administration (FDA) approved overdose reversal medications for emergency treatment of known or suspected opioid overdose. The recipients will collaborate with other prescribers at the community level to implement trainings on policies, procedures, and models of care for prescribing, co-prescribing, and expanding access to naloxone and other FDA-approved overdose reversal medications to the specified population of focus (*i.e.,* rural or urban). With this program SAMHSA aims to expand access to naloxone and other FDA approved overdose reversal medications for emergency treatment of known or suspected opioid overdose.

Grant compliance monitoring: All SAMHSA awards require grantees to submit performance and progress reports through the electronic Research

Administration (eRA) Commons, an end-to-end Grants Management system. The frequency and program-specific instructions for preparation and submission of these reports are identified in the terms and conditions found in the Notice of Award. CSAP discretionary grant compliance monitoring will be conducted through the submission of the Programmatic Progress Report (PPR). The PPR contains fields for grantees to enter information on activities and accomplishments that occurred during the reporting period based on identified goals and objectives. It also contains fields for grantees to share evaluation updates and outcomes as well as planned activities for the upcoming reporting period as well as any challenges that grantees have experienced.

The Center for Substance Abuse Prevention Online Reporting Tool (CORT) is comprised of two components. The first provides fields for grantees to enter annual goals for key programmatic measures. The second provides fields for reporting quarterly progress toward achieving these goals. CSAP intends to have grantees report progress on a quarterly basis to allow for consistent, periodic analyses which will allow for the administration of technical assistance supports when grantees are falling behind in achieving these goals. Quarterly reporting will also allow the Center to review the overall progress of grant programs. Program specific instruments have been developed to ensure optimal alignment with individual grant requirements. These instruments were developed based on instruments approved in OMB 0930–0391: Harm Reduction Grant Program Annual Targets and Quarterly Progress Reports.

Annualized Data Collection Burden

TABLE 1—BURDEN TABLE: ANNUALIZED BURDEN—ANNUAL TARGETS

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Average hourly wage[1]	Total respondent cost
STOP Act	202	1	202	0.5	101	$48.35	$4,883.35
SPF–PFS	315	1	315	0.5	157.5	48.35	7,615.125
FR CARA	87	1	87	0.5	43.5	48.35	2,103.225
PDO	18	1	18	0.5	9	48.35	435.15
ODTA	8	1	8	0.5	4	48.35	193.4
SPF–Rx	27	1	27	0.5	13.5	48.35	652.725
Total (Annual)	657	.....	657	.....	328.5	.....	15,882.98

TABLE 2—BURDEN TABLE: CENTER FOR SUBSTANCE ABUSE PREVENTION ON-LINE REPORT TOOL (CORT)—QUARTERLY PERFORMANCE ANNUALIZED BURDEN

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Average hourly wage[1]	Total respondent cost
STOP Act	202	4	808	0.5	404	$48.35	$19,533.40
SPF–PFS	315	4	1,260	0.5	630	48.35	30,460.50
FR CARA	87	4	348	0.5	174	48.35	8,412.90
PDO	18	4	72	0.5	36	48.35	1,740.60
ODTA	8	4	32	0.5	16	48.35	773.60
SPF–Rx	27	4	108	0.5	54	48.35	2,610.90
Total (Annual)	657	.....	2,628	.....	1,314	.....	63,531.90

[1] Grantee Project Director or Evaluator hourly wage is based on the mean hourly wage for state government managers, as reported in the 2022 Occupational Employment (OES) by the Bureau of Labor Statistics (BLS) found at *https://www.bls.gov/oes/current/naics4_999200.htm#11-0000* Accessed on December 13, 2023.

TABLE 3—ANNUALIZED BURDEN TABLE: CSAP'S GRANT PROGRAMMATIC PROGRESS REPORT

CSAP grant program	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Average hourly wage[1]	Total respondent cost
SPF–PFS	315	1	315	3	945.0	$48.35	$45,690.75
STOP Act	202	1	202	3	606.0	48.35	29,300.10
SPF Rx	27	1	27	3	81.0	48.35	3,916.35
FR CARA	87	1	87	3	261.0	48.35	12,619.35
PDO	18	1	18	3	54.0	48.35	2,610.90
ODTA	8	1	8	3	24.0	48.35	1,160.40
Total (Annual)	657	.....	.....	.....	1,971.00	.....	95,297.85

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fisher Lane, Room 15E57A, Rockville, MD 20852 *OR* email him a copy at *carlos.graham@samhsa.hhs.gov.* Written comments should be received by May 13, 2024.

Alicia Broadus,

Public Health Advisor.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Drug and Alcohol Warning Network (DAWN) (OMB No. 0930–0078)—Reinstatement With Change

Under the Public Health Service Act (42 U.S.C. 290aa–4), SAMHSA is authorized to collect data on the number of individuals admitted to the emergency rooms of hospitals as a result of the abuse of alcohol or other drugs. DAWN is a nationwide public health surveillance system to improve hospital emergency department (ED) monitoring of substance use-related visits. It captures data on ED visits related to recent substance use and misuse directly from the electronic health records (EHR) of participating hospitals. The new DAWN helps SAMHSA and public health professionals, clinicians, and policymakers respond effectively to the opioid and substance misuse crisis in the United States.

SAMHSA is requesting OMB approval of reinstatement with change of the DAWN data collections, to include following changes:

- Revise the data collection title to ''Drug and Alcohol Warning Network'', replacing existing 'abuse' term and including ''alcohol'' in the title.
- Remove drug-related death investigation records review component administered by state medical examiners (MEs) and individual medical examiners/coroners (ME/Cs).
- Revise data collection procedures where participating hospitals can choose the direct chart review option (at the contractor's operation center, home-based abstraction or on site at the hospital). Hospitals will also have the opportunity to select the machine learning with natural language processing (ML with NLP) option. The option for hospitals to use their own staff to abstract DAWN data as they did in the legacy DAWN is no longer offered.
- Revise the hospital selection design of the ED component to a hybrid system that combines sentinel hospitals and probability-based selection of hospitals from high priority suburban/rural areas and from the remaining areas in the United States.
- Change the reporting and publication schedule to further increase the timeliness of the new DAWN data availability and delivery to SAMHSA. The new DAWN data are collected on an ongoing basis and could be available to SAMHSA on demand. The new DAWN data are delivered to SAMHSA and available for analysis at a more frequent intervals than the legacy DAWN.
- Propose following changes to the ED Case Report Form:
  - Add ''Center for Behavioral Health Statistics and Quality'' to specify the center responsible for DAWN data collection.
  - Revise the data collection title to ''Drug and Alcohol Warning Network'' from ''Drug Abuse Warning Network.''
  - Replace prior ''Facility'' data field title with ''Hospital Emergency Department ID'' to provide more precise description and ID number of the DAWN participating hospitals.
  - Q3 ''Age'': replace prior option of ''less than 1 year'' with two detailed options of ''4 weeks (28 days) or younger'' and ''Between 4 weeks and one year old (>4 weeks, <1 year)'' to enable new identification of neonatal substance issues.
  - Q4 ''County of Residence'': revise data field title from prior ''patient's home zip code'' and add more accurate description on what data to be collected and clarify the purpose of data collection. Add new ''Unable to determine county'' option to improve data accuracy and account for geographical variation.
  - Q6 ''Gender Identity'' and Q7 ''Sexual Orientation'': added to provide inclusive measures and to align with SAMHSA's efforts in enhancing behavioral health equities among diverse populations.
  - Q8 ''Ethnicity'' and Q9 ''Race'': revise prior data field ''Race/Ethnicity'' to align with OMB 1997 Standards for Maintaining, Collecting, And Presenting Federal Data on Race and Ethnicity (Statistical Policy Directive No. 15) and to improve data accuracy and comprehensiveness.
  - Q10 ''Case Description'': replace the word ''drug(s)'' with ''substance(s)'' to clarify that the DAWN collects data on all substances including alcohol. Add new instruction language of ''Do not include information that could identify the patient or hospital'' to provide clear instruction and specify the importance of patient and hospital privacy protection.
  - Q11 ''Substance(s) Involved and Route of Administration'': add two new options of ''transdermal'' and ''vaped'' to improve the comprehensiveness of the list on how substance is administered by the patient. Remove ''Mark if confirmed by toxicology test'' and ''alcohol involved?''
  - Q12 ''Diagnosis'': change the question order and move the data field after Q11. Revise prior instruction of ''list up to 4 diagnoses'' to ''list all diagnoses'' to enhances new DAWN's ability to identify novel drug, drug trends, and drug outbreaks.
  - Q13 ''Type of Case'': remove instruction language of ''using the decision tree.'' Revise the existing option of ''seeking detox'' to ''seeking detox and/or substance abuse treatment only'' and remove age restriction for ''Alcohol only'' option to include cases involving alcohol as the only substance of all ages.
  - Q14, Q15, and Q16 ''Was naloxone/buprenorphine/Methadone administered to the patient in the ED'': added to capture new data on the implementation of medication-assisted treatment for opioid use disorder in the emergency department setting and understand why buprenorphine and methadone is administered.