Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

Strategic Prevention Framework for Prescription Drugs

(Short Title: SPF Rx)

(Initial Announcement)

Funding Opportunity Announcement (FOA) No. SP-16-006

Catalogue of Federal Domestic Assistance (CFDA) No.: 93.243

PART 1: Programmatic Guidance

[Note to Applicants: This document must be used in conjunction with SAMHSA's "Funding Opportunity Announcement (FOA): PART II – General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements". PART I is individually tailored for each FOA. PART II includes requirements that are common to all SAMHSA FOAs. You must use both documents in preparing your application.]

Key Dates:

Application Deadline	**Applications are due by May 31, 2016.**

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EXECUTIVE SUMMARY

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP), is accepting applications for the fiscal year (FY) 2016 Strategic Prevention Framework for Prescription Drugs (SPF Rx) grant program. The SPF Rx grant program provides an opportunity for states, U.S. territories, pacific jurisdictions (herein referred to as "states"), and tribal entities that have completed a Strategic Prevention Framework State Incentive Grant (SPF SIG) to target the priority issue of prescription drug misuse. The program is designed to raise awareness about the dangers of sharing medications and work with pharmaceutical and medical communities on the risks of overprescribing to young adults. SPF Rx will also raise community awareness and bring prescription drug abuse prevention activities and education to schools, communities, parents, prescribers, and their patients. In addition, SAMHSA will track reductions in opioid overdoses and the incorporation of Prescription Drug Monitoring Program (PDMP) data into needs assessments and strategic plans as indicators of the program's success.

The program directly supports the goals of SAMHSA's Strategic Initiative: Prevention of Substance Abuse and Mental Illness.

Funding Opportunity Title:	Strategic Prevention Framework for Prescription Drugs (SPF Rx)
Funding Opportunity Number:	SP-16-006
Due Date for Applications:	May 31, 2016
Anticipated Total Available Funding:	$9,290,395
Estimated Number of Awards:	25
Estimated Award Amount:	Up to $371,616 per year
Cost Sharing/Match Required	No
Length of Project Period:	Up to five years
Eligible Applicants:	Eligibility is limited to states, U.S. territories, pacific jurisdictions (herein referred to as "states") and tribal entities that have completed a Strategic Prevention Framework State Incentive Grant (SPF SIG), and have a state-run PDMP. [See Section III-1 of this FOA for complete eligibility information.]

Be sure to check the SAMHSA website periodically for any updates on this program.

I. FUNDING OPPORTUNITY DESCRIPTION

1. PURPOSE

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP), is accepting applications for the fiscal year (FY) 2016 Strategic Prevention Framework for Prescription Drugs (SPF Rx) grant program. The SPF Rx grant program provides an opportunity for states, U.S. territories, pacific jurisdictions (herein referred to as "states"), and tribal entities that have completed a Strategic Prevention Framework State Incentive Grant (SPF SIG) to target the priority issue of prescription drug misuse. The program is designed to raise awareness about the dangers of sharing medications and work with pharmaceutical and medical communities on the risks of overprescribing to young adults. SPF Rx will also raise community awareness and bring prescription drug abuse prevention activities and education to schools, communities, parents, prescribers, and their patients. In addition, SAMHSA will track reductions in opioid overdoses and the incorporation of Prescription Drug Monitoring Program (PDMP) data into needs assessments and strategic plans as indicators of program success.

The program directly supports the goals of SAMHSA's Strategic Initiative: Prevention of Substance Abuse and Mental Illness.

Prescription opioid-related overdose deaths now outnumber overdose deaths involving all other illicit drugs, including heroin and cocaine.[1] Due to the alarming trends related to prescription drug misuse and opioid overdoses, SAMHSA is prioritizing efforts to address prescription drug misuse.[2] The SPF Rx grant program builds upon the expertise and established SPF-based prevention infrastructures of states/tribes to address one of the nation's top substance abuse prevention priorities, prescription drug misuse among youth ages 12-17 and adults 18 years of age and older. SPF Rx funding for SAMHSA in FY 2016 is part of the Department of Health and Human Services' (HHS) strategic effort to address the non-medical use of prescription drugs and opioid overdoses.

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[1] Centers for Disease Control and Prevention. WONDER [database]. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2013. Available at http://wonder.cdc.gov.

[2] Warner M, Chen LH, Makuc DM, Anderson RN, Miniño AM. Drug poisoning deaths in the United States, 1980– 2008. NCHS data brief, no 81. Hyattsville, MD: National Center for Health Statistics. 2011.

PDMPs are state-run databases used to track the prescribing and dispensing of controlled prescription drugs to patients. They are designed to monitor this information for suspected abuse or diversion (i.e., channeling drugs into illegal use), and can give a prescriber or pharmacist critical information regarding a patient's controlled substance prescription history. State applicants must have a fully operational PDMP in order to apply for the SPF Rx program. Tribes must coordinate with the state run PDMPs to identify opportunities for collaboration that will limit overprescribing in tribal communities.

The SPF Rx grant program is intended to raise awareness about the risks of sharing medications, and promote collaboration between states/tribes and pharmaceutical and medical communities to understand the risks of overprescribing to youth ages 12-17 and adults 18 years of age and older. SAMHSA will track reductions in opioid overdoses and the incorporation of PDMP data into needs assessments and strategic plans as indicators of program success. This grant program complements the effort of the Centers for Disease Control and Prevention which specifically funds the development of PDMPs. CDC's grant program enables an infrastructure development approach at a broad level. The SPF Rx program enables states to work with communities to develop and implement prevention strategies at the local level.

The SPF Rx grant program seeks to address behavioral health disparities among racial and ethnic minorities by encouraging the implementation of strategies to decrease the differences in access, service use, and outcomes among the racial and ethnic minority populations served. (See PART II: Appendix F – Addressing Behavioral Health Disparities).

The SPF Rx grant program is authorized under Section 516 of the Public Health Service Act, as amended. This announcement addresses Healthy People 2020 Substance Abuse Topic Area HP 2020-SA.

2. EXPECTATIONS

The SPF Rx grant program will utilize statewide epidemiological and PDMP data to identify areas where prescription drug misuse is most prevalent. Additionally, grantees will identify areas where there are gaps in PDMP data and implement programs as appropriate. SAMHSA's Opioid Overdose Prevention Toolkit will serve as a resource for grantees to train community partners, families, and prescribers on primary and secondary prevention strategies. Grantees will also be expected to utilize and disseminate the Centers for Disease Control Policy's Guidelines for Prescribing Opioids for Chronic Pain.

The SPF Rx grant program builds upon the Strategic Prevention Framework (SPF). The SPF represents a five-step, data-driven process used to: assess needs (Step 1); build capacity (Step 2); engage in a strategic planning process (Step 3); implement a comprehensive, evidence-based prevention approach (Step 4); and evaluate implementation and related outcomes (Step 5). The guiding principles of cultural

competence and sustainability are included in each of the five steps. The use of the SPF process is critical to ensuring that states/tribes and their communities work together to use data-driven, decision-making processes to develop effective prevention strategies and sustainable prevention infrastructures. To meet the goals of the SPF Rx grant program, SAMHSA expects grantees to use the SPF process at both the state/tribal and community levels. Successful applicants will use the SPF process to describe system needs and plan/implement infrastructure development strategies to meet targeted community needs. Additionally, grantees may use SAMHSA's Opioid Overdose Prevention Toolkit as a resource to provide technical assistance, training, and build capacity in development of programs that address prescription drug misuse and overdose prevention efforts.[3]

Addressing SAMHSA's Prevention Goals:

The SPF Rx grant program directly supports the goals of SAMHSA's Strategic Initiative: Prevention of Substance Abuse and Mental Illness. Accordingly, applicants must ensure that their proposed approach for addressing prescription drug abuse and misuse is aligned with the following goals of this Strategic Initiative:

- Goal 1.1: Promote emotional health and wellness, prevent or delay the onset of and complications from substance abuse and mental illness, and identify and respond to emerging behavioral health issues.

- Goal 1.4: Prevent and reduce prescription drug and illicit opioid misuse and abuse.

States/tribes also must ensure that their proposed approach addresses SAMHSA's goals for prevention with respect to the program requirements below:

- Needs assessment - Assess the current use of PDMP and its components as it relates to accessibility of data, usage by the targeted communities, and outcomes related to previous PDMP use.

- Strategic planning - Conduct continuous strategic planning, including assessment, monitoring, and analysis of the program to meet the desired outcomes.

[3] Substance Abuse and Mental Health Services Administration. SAMHSA Opioid Overdose Prevention Toolkit. HHS Publication No. (SMA) 14-4742. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

- Financing/coordination of funding streams - Coordination of funding streams by leveraging funds from other sources (including, for states, the prevention set-aside of the Substance Abuse Prevention and Treatment Block Grant (SABG)).

- Organizational/structural change (i.e., to create locus of responsibility for specific PDMP issues/populations, address behavioral health disparities, or to increase access to, or efficiency of, services).

- Development of interagency coordination mechanisms - Collaborate to improve the effectiveness of the partnerships between PDMPs; federal, state, regional, and local agencies; private and non-profit organizations; hospitals; pharmacies; and health professional and advocacy groups.

- Policy development to support needed service system improvements (i.e, establishment of standards of care, adherence to the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care, development/revision of credentialing, licensure, or accreditation requirements).[4]

- Quality improvement - Demonstrate measurable quality improvement on all aspects of access to, and usage of the PDMP data, as well as coordination with high need communities to achieve the goals and objectives of the program.

- Performance measure development – The development of performance measures should be directly related to the strategic plan.

- Workforce development - Strengthen workforce development around activities to ensure use of PDMP data (i.e., training, support for licensure, credentialing, and accreditation).

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[4] For purposes of this FOA, "policy" refers to programs and guidelines adopted and implemented by institutions, organizations, and others to inform and establish practices and decisions and to achieve organizational goals. Policy efforts do not include activities designed to influence the enactment of legislation, appropriations, regulations, administrative actions, or Executive Orders ("legislation and other orders") proposed or pending before Congress or any state government, state legislature, or local legislature or legislative body, and awardees may not use federal funds for such activities. This restriction extends to both grassroots lobbying efforts and direct lobbying. However, for state, local, and other governmental grantees, certain activities falling within the normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government are not considered impermissible lobbying activities and may be supported by federal funds.

In year one of the grant, a major portion of planning and administrative activities will take place. **There is no administrative cap on funding during year one. In years two through five, SAMHSA's SPF Rx grants must apply the following administrative cap:**

State Grantees may use up to 15 percent of funds for state-level administrative costs and state-level performance activities, including building capacity or providing training and technical assistance (TA) at the state level to fill gaps in their current prevention infrastructure and systems.

Tribal Grantees may use up to 30 percent of funds for tribal-level administrative costs and tribal-level performance activities, including building capacity or providing training and TA at the tribal level to fill gaps in their current prevention infrastructure and systems.

The key staff for this program will be the Project Director and Evaluator. It is expected that key staff will contribute to the programmatic development and execution of the program.

If your application is funded, you will be expected to develop a behavioral health disparities impact statement no later than 60 days after receiving your award. In this statement, you must propose: (1) the number of individuals to be reached/trained during the grant period and identify subpopulations (i.e., racial, ethnic, sexual, and gender minority groups) vulnerable to behavioral health disparities; (2) a quality improvement plan for the use of program data on access, use, and outcomes to support efforts to decrease the differences in access to, use, and outcomes of grant activities; and (3) methods for the development of policies and procedures to ensure adherence to the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (See PART II: Appendix F – Addressing Behavioral Health Disparities).

SAMHSA strongly encourages all grantees to provide a tobacco-free workplace and to promote abstinence from all tobacco products (except in regard to accepted tribal traditions and practices).

According to the National Survey on Drug Use and Health, individuals who experience mental illness or who use illegal drugs have higher rates of tobacco use than the total population. Data from the National Health Interview Survey, the National Death Index, and other sources indicate earlier mortality among individuals who have mental and substance use disorders than among other individuals. Due to the high prevalence rates of tobacco use and the early mortality of the target population for this grant program, grantees are encouraged to promote abstinence from tobacco products (except with regard to accepted tribal traditional practices) and to integrate tobacco cessation strategies and services in the grant program. Applicants are encouraged to set annual targets for the reduction of past 30-day tobacco use among individuals receiving direct client services under the grant.

SAMHSA encourages all grantees to address the behavioral health needs of returning veterans and their families in designing and developing their programs and to consider prioritizing this population for services, where appropriate. SAMHSA will encourage its grantees to utilize and provide technical assistance regarding locally-customized web portals that assist veterans and their families with finding behavioral health treatment and support.

2.1 Required Activities

The SPF Rx grant program must be used primarily to support infrastructure development and prescription drug prevention efforts, and implement prevention activities designed during the planning phase. Required activiites include the following: 1) raise awareness about the dangers of sharing medications, and work with pharmaceutical and medical communities on the risks of overprescribing to young adults; and 2) raise community awareness by bringing prescription drug abuse prevention activities and education to schools, communities, parents, prescribers, and their patients.

The SPF Rx grant program should increase the capacity of states/tribes to analyze and utilize collected data to identify drug misuse trends, address sources of diversion, and increase the number of users of the PDMP.

SPF Rx grantees must develop a comprehensive plan to strategically address this emergent issue of prescription drug misuse in communities of high need. Through a data driven approach, grantees will use epidemiological data combined with data from the PDMP to identify communities by geography (e.g., city) and high-risk population (e.g., age group), and target communities for primary and secondary prevention activities.

Primary prevention involves the promotion of health and elimination of substance misuse and its consequences through community-wide efforts, such as improving knowledge, altering the environment, and changing the social structure, norms, and value systems. Secondary prevention uses approaches available to individuals and populations for early detection within high-risk groups, and prompt and effective intervention to correct or minimize substance misuse.

Grantees whose state or tribal entity includes SAMHSA Tribal Behavioral Health and/or State-Sponsored Youth Suicide Prevention and Early Intervention grantees must work with them and SPF Rx funded community(ies) to collaborate and coordinate, as appropriate, with local level prevention and clinical service providers trained to assess, manage, and treat youth at risk for suicide. These providers include those working in health, mental health, and substance abuse. **Grantees may take up to one year to strategically plan for a data driven approach to effectively utilize PDMP data and design a plan to evaluate efforts. The subsequent four years of the grant will be used to implement identified strategies and maintain ongoing partnerships.**

In year one of the project, grantees will be required to:

- Hire key staff and identify a structure (i.e., advisory boards, workgroups, task forces) that will provide guidance to the project. These should include participation from the program coordinator, program staff, evaluation staff, partner agencies, elected officials, and other essential community members, including youth and families.

- Develop a strategic plan that:

    - Utilizes a data-driven approach to address prescription drug misuse. States and tribes must use epidemiological and PDMP data to identify communities with high rates of prescription drug use. If available, PDMP data should be utilized to identify communities with high rates of prescription drug misuse (by geography and high-risk population, e.g., age group), and target those communities for primary and secondary prevention activities. These communities may or may not have been a focus of the state's SPF SIG efforts.
    - Focuses on improving PDMP partnerships at the agency level, across state, and state-to-state, wherever possible.
    - Describes approaches to increase use of PDMP data by sub-recipients, tracking data, monitoring usage, and increasing the data collected by the PDMPs. The plan should also identify gaps and areas of need in the data and provide strategies to enhance data collection efforts. Lastly, the plan should address program sustainability.

- Utilize the SPF process to develop an implementation plan that includes a timeline for the entire five years of the project period, showing dates, key activities, responsible staff, and how and when each element of the project will be put into operation and sustained after the life of the grant.

- Utilize the SPF process to actively engage community members, healthcare providers, key stakeholders, adult, youth, young adults, elders, spiritual advisors, and tribal leaders. Grantees may use SAMHSA's resources to increase awareness of the potential risks of sharing and overprescribing medications, as well as provide technical assistance and training on the use of SAMHSA's Opioid Overdose Prevention Toolkit to help prevent opioid overdose-related deaths.

- **For Tribal Applicants:** Tribes must coordinate with the PDMP to identify opportunities for collaboration that will limit overprescribing in tribal communities. Tribes must establish policy and an infrastructure that will ensure tribal participation in the proposed grant activities, and that tribal demographic data are collected. Partnerships should be established with non-native entities that serve tribal populations, such as healthcare organizations, community-based programs, and pharmacies.

- Establish and manage a workgroup with key stakeholders or work with an existing epidemiological workgroup to collect and analyze relevant community indicators and PDMP data. If a needs assessment effort is already in place, work with local, state, or tribal epidemiological outcomes workgroup (SEOW/TEOW) to enhance and supplement the current process and its findings.

During years two through four of the project, grantees will be required to:

- Develop a local evaluation plan and implement evaluation activities based on year one and year two assessment and planning activities. Use the SPF process to identify specific issues of interest to the community related to the goals of the grant project.

- Formalize interagency agreements for collaboration and coordination of services, and develop policies that will increase the use of PDMP data to address prescription drug misuse.

- Ensure that orientation and ongoing training on the SPF approach and PDMP is provided to a wide audience for the purpose of workforce development, through the life of the grant and beyond.

- Develop a community-based social marketing/public education plan to increase awareness of prescription drug misuse issues, the need for a coordinated approach, and promote increased use of PDMP data.

- Conduct an ongoing process evaluation that documents the grant activities, progress, challenges, and lessons learned towards meeting grant goals. This activity must continue through the life of the grant.

- Develop policies, procedures, and other infrastructure changes that will result in system-wide improvements to utilization of PDMP data, and address non-medical use of prescription drugs and opioid overdose.

- Operationalize the strategic plan and revise strategies in existing SPF SIG sub-recipient communities, or identify new communities for program implementation, and increase capacity through expansion of technical assistance and training.

- Describe the data-driven quality improvement process by which health disparities in access/use/outcomes will be tracked, assessed, and reduced.

- Implement the community-based social marketing/public education plan to increase awareness of prescription drug misuse.

- Educate prescribers on the use and benefits of accessing the state's PDMP

database to determine whether a patient is filling the prescriptions provided and/or obtaining prescriptions for the same or similar drug from multiple prescribers.

- Collaborate with pharmacies to ensure timely data input into the PDMP database in an effort to maximize the use of the prescription history data, which has significant implications for patient safety and public health.

- Incorporate PDMPs into a comprehensive prescription drug diversion and prevention strategy that includes education for healthcare providers, patients, and the public on prescription drug misuse.

- Conduct culturally sensitive, environmentally responsible medication disposal programs, and smart law enforcement aimed at reducing pill mills and doctor shopping, to reduce the consequences of prescription drug misuse.

In year five, grantees are required to:

- Review and evaluate program outreach and PDMP data to ensure that targeted communities remain relevant. Assess the program's reach in terms of Institute of Medicine (IOM) category (universal, selective, indicated), six strategies, and demographic group.

- Develop an evaluation report on the SPF Rx program's activities, goals, and objectives.

Additional Requirements

Grantees also will be expected to:

- Utilize the technical assistance provided through SAMHSA's contractors to help meet local programmatic and evaluation goals of the grant, and participate in peer-to-peer learning opportunities with other grantees.

- Coordinate with existing or revitalized Advisory Councils, Evidence-based Practices (EBP) Workgroups, State Epidemiological Outcomes Workgroups (SEOW), or Tribal Epidemiological Outcomes Workgroups (TEOWS) to assist funded communities in building their capacity and addressing their needs.

- Leverage prevention funds and other resources, including the prevention set-aside of the Substance Abuse Prevention and Treatment Block Grant (SABG), at the state, tribal, and community levels to support SPF Rx project goals.

- Coordinate with the PDMP to address high-prevalence areas that are not currently identified within the PDMP data.

- Adhere to local and state laws while planning and implementing the SPF Rx grant program.

- Explain how you plan to coordinate the efforts of your proposed project with any other related federal grants, including those from SAMHSA, Indian Health Service (IHS), Centers for Disease Control and Prevention (CDC), U.S. Department of Justice (DOJ), Office of Justice Programs (OJP), Bureau of Justice Assistance (BJA), and the Health Resources and Services Administration (HRSA).

2.2 Other Allowable Activities

Grantees are encouraged to use grant funds to adopt and/or enhance their computer system, data infrastructure/management information systems (MIS), electronic health records (EHRs)[5], and related activities. Grantees should also increase interoperability between PDMP and EHRs, where possible.

2.3 Data Collection and Performance Measurement

All SAMHSA grantees are required to collect and report certain data so that SAMHSA can meet its obligations under the Government Performance and Results (GPRA) Modernization Act of 2010. You must document your ability to collect and report the required data in Section D: Data Collection and Performance Measurement of your application. For each grant program, SAMHSA will monitor the following required outcomes for GPRA:

- Number of funded states/tribes that incorporate PDMP data into their needs assessments in developing their strategic plans;
- Number of funded states/tribes reporting reductions in opioid overdoses.

In addition to the GPRA measures mentioned above, grantees will be asked to collect data on the following measures:

[5] A certified EHR is an electronic health record system that has been tested and certified by an approved Office of National Coordinator's (ONC) certifying body

- Number of active collaborators/partners supporting the grantee's comprehensive prevention approach;
- Number of people served and/or reached by Institute of Medicine (IOM) category (universal, selected, indicated), six strategies, and demographic group;
- Number and percent of evidence-based programs, policies, and/or practices implemented by sub-recipient communities;
- Number of prevention activities at the sub-recipient level that are supported by collaboration;
- Number, type, and duration of evidence-based interventions by prevention strategy implemented at the community level.

Technical assistance will be provided by SAMHSA, as needed, for collection of the data listed above.

Data will be collected using an online database management system to be provided by SAMHSA. This information will be gathered using SAMHSA's data-entry reporting system; access will be provided upon award. Data are to be reported semi-annually. Grantees also will be expected to participate in a cross-site evaluation.

The collection of these data will enable SAMHSA to report on key outcome measures relating to prevention. In addition to these outcomes, data collected by grantees will be used to demonstrate how SAMHSA's grant programs are reducing behavioral health disparities nationwide.

Performance data will be reported to the public, the Office of Management and Budget (OMB), and Congress as part of SAMHSA's budget request.

2.4 Local Performance Assessment

Grantees must periodically review the performance data they report to SAMHSA (as required above), assess their progress, and use this information to improve management of their grant projects. The assessment should be designed to help you determine whether you are achieving the goals, objectives, and outcomes you intend to achieve, and whether adjustments need to be made to your project. Performance assessments should be used also to determine whether the project is having or will have the intended impact on behavioral health disparities. You will be required to report on your progress achieved, barriers encountered, and efforts to overcome these barriers in a performance assessment report at the end of the grant period interim and annual updates.

Grantee Project Evaluations

All project evaluations should summarize interventions and activities implemented to address the selected prevention priority(ies), and preliminary findings from state/tribal

and/or community level evaluations. Grantees will be required to submit quarterly progress reports related to achievement of their performance assessment objectives. These quarterly progress reports will be submitted through SAMHSA's online reporting platform. Evaluations should include the required performance measures identified above in Section 2.3.

At a minimum, your performance assessment should include the required performance measures identified above. Grantees may also consider outcome and process questions, such as the following:

Outcome questions:

- What was the effect of the intervention on key outcome goals?
- What program/contextual/cultural/linguistic factors were associated with outcomes?
- What individual factors were associated with outcomes, including race/ethnicity/ sexual orientation/gender identity?
- How durable were the effects?

Process Questions:

- How closely did implementation match the plan?
- What types of changes were made to the originally proposed plan?
- What types of changes were made to address behavioral health disparities, including the use of National CLAS Standards?
- What led to the changes in the original plan?
- What effect did the changes have on the planned intervention and performance assessment?
- Who provided (program staff) what services (modality, type, intensity, duration), to whom (individual characteristics), in what context (system, community), and at what cost (facilities, personnel, dollars)?

No more than 20 percent of the total grant award may be used for data collection, performance measurement, and performance assessment, e.g., activities required in Sections I-2.3 and 2.4 above. Be sure to include these costs in your proposed budget (see Appendix II).

2.5 Cross-Site Evaluation

SAMHSA/CSAP's SPF Rx cross-site evaluation is intended to promote understanding of the precursors; environmental, family, and community contextual factors; and characteristics of interventions (alone and in combination) that are most or least effective in contributing to preventing prescription drug misuse. In this context, the cross-site evaluation is designed to assist both SAMHSA/CSAP and SPF Rx grantees in: 1) collecting consistent, complete, and commonly defined data; 2) providing findings related to the SPF Rx evaluation questions and to CSAP's federal reporting requirements; 3) reporting on SPF Rx activities and findings; 4) identifying best practices; and 5) contributing to the formulation of future SPF Rx program and policy directions. **All SPF Rx grantees will be required to comply with the data collection and reporting requirements of SAMHSA/CSAP's cross-site evaluation.**

2.6 Grantee Meetings

Grantees are required to attend a New Grantee Meeting in 2017 to be held in the Washington, DC, area. Each grantee is required to bring two key staff: the Project Director and the Evaluator. For this grant cohort, a grantee meeting will likely be held in 2019, as well. You must include a detailed budget and narrative for this travel in your budget. At these meetings, grantees will present the results of their projects and federal staff will provide technical assistance. Each meeting will be up to three days and attendance is mandatory.

II. AWARD INFORMATION

Funding Mechanism: Cooperative Agreement

Anticipated Total Available Funding: $9,290,395

Estimated Number of Awards: 25

Estimated Award Amount: Up to $371,616

Length of Project Period: Up to five years

Proposed budgets cannot exceed $371,616 in total costs (direct and indirect) in any year of the proposed project. Annual continuation awards will depend on the availability of funds, grantee progress in meeting project goals and objectives, timely submission of required data and reports, and compliance with all terms and conditions of award.

Cooperative Agreement

These awards are being made as cooperative agreements because they require substantial post-award federal programmatic participation in the conduct of the project.

Under this cooperative agreement, the roles and responsibilities of grantees and SAMHSA staff are:

Role of Grantees:

Grantees are expected to participate and collaborate fully with CSAP staff in the conduct and evaluation of this five-year cooperative agreement. Grantees' responsibilities include the following: compliance with all aspects of the terms and conditions of the cooperative agreement; collaboration with CSAP staff in assessment, capacity building, and strategic planning activities; ongoing monitoring, quality improvement, and evaluation tasks; documentation of all system-wide changes stemming from this grant program; and responding to requests for all appropriate program-related data. Grantees also are expected to leverage prevention funds and other resources (including, for states, SABG primary prevention set-aside funds) to support project goals.

Role of SAMHSA Staff:

The SAMHSA Government Project Officer (GPO) will serve as an active participant in the implementation of the grantee's project to provide guidance and TA to help grantees achieve their goals. The GPO's roles and responsibilities include the following: monitoring and reviewing progress of projects; monitoring development and collection of process and outcome data from grantees; ensuring compliance with data/performance measurement requirements; ensuring the project's collaboration with the SEOW/TEOW; consultation on and participation in the redesign or modification of infrastructure or systems changes; providing guidance in defining new strategic directions; providing support services for training, evaluation, and data collection; arrangement of meetings designed to support key grantee activities; and review of key documents central to the project's success, including review and approval of the strategic plan and the state's/tribe's approach and methodology to identify and select communities of high need.

III. ELIGIBILITY INFORMATION

1. ELIGIBLE APPLICANTS

Eligibility is limited to states, U.S. territories, pacific jurisdictions (herein referred to as "states"), and tribal entities that have completed a Strategic Prevention Framework State Incentive Grant (SPF SIG). Applicants also are required to have an operational state run PDMP. (See Table 2 of this document for a list of eligible applicants.) **Applications received from any other entity will be screened out and will not be reviewed.**

Eligibility is limited to these entities because they have the greatest likelihood of achieving success through the SPF Rx grant program. Having completed the SPF process, these entities have the necessary experience and background for

implementation: 1) an established state/tribal infrastructure and system in place—rooted in both the SABG and the SPF prevention model—that allows them to quickly build capacity in communities of need, mobilize those communities, and ensure accurate data collection and reporting at the community level; 2) integration of the SPF-based process into their overall state and tribal prevention systems, ensuring a strong, data-driven focus on identifying, selecting, and implementing effective, evidence-based prevention programs, policies, and practices; 3) experience in working collaboratively with communities to achieve substance misuse prevention goals; 4) familiarity and experience with the alignment of behavioral health with primary prevention; 5) a history of building comprehensive state and tribal level prevention systems over time; and 6) the required state run prescription drug monitoring program.

Table 2 identifies the states and tribal entities eligible to apply.

Table 2: Eligible 2016 SPF Rx Applicants

Grantee Type	Eligible Applicants		
States	Alabama	Louisiana	Oklahoma
	Alaska	Maine	Oregon
	Arizona	Maryland	Pennsylvania
	Arkansas	Massachusetts	Rhode Island
	California	Michigan	South Carolina
	Colorado	Minnesota	South Dakota
	Connecticut	Mississippi	Tennessee
	Delaware	Montana	Texas
	District of Columbia	Nebraska	Utah
	Florida	Nevada	Vermont
	Georgia	New Hampshire	Virginia
	Guam	New Jersey	Washington
	Hawaii	New Mexico	West Virginia
	Illinois	New York	Wisconsin
	Indiana	North Carolina	Wyoming
	Iowa	North Dakota	
	Kansas	Ohio	
	Kentucky		
Tribes	Cherokee Nation		
	Confederated Salish and Kootenai Tribes		
	Cook Inlet Tribal Council		
	First Nations Community Healthsource		
	Grand Traverse Band of Ottawa and Chippewa		
	Great Lakes Inter-Tribal Council		
	Leech Lake Band of Ojibwe		
	Little Traverse Bay Band of Odawa Indians		
	Lower Brule Sioux Tribe		

	Native American Health Center Nooksack Tribal Council Northern Arapaho Tribe Oglala Sioux Oklahoma City Area Inter-tribal Health Board Pueblo of Acoma Rocky Mountain Tribal Leaders Council Tanana Chiefs Conference Winnebago Tribe of Nebraska

2. COST SHARING and MATCH REQUIREMENTS

Cost sharing/match is not required in this program.

IV. APPLICATION AND SUBMISSION INFORMATION

In addition to the application and submission language discussed in PART II: Section I, you must include the following in your application:

1. ADDITIONAL REQUIRED APPLICATION COMPONENTS

- **Budget Information Form** – Use SF-424A. Fill out Sections B, C, and E of the SF-424A. A sample budget and justification is included in Appendix II of this document**. It is highly recommended that you use the sample budget format in Appendix II. This will expedite review of your application.**

- **Project Narrative and Supporting Documentation** – The Project Narrative describes your project. It consists of Sections A through D. Sections A-D together may not be longer than 25 pages. (Remember that if your Project Narrative starts on page 5 and ends on page 30, it is 26 pages long, not 25 pages.) More detailed instructions for completing each section of the Project Narrative are provided in Section V – Application Review Information of this document.

  The Supporting Documentation provides additional information necessary for the review of your application. This supporting documentation should be provided immediately following your Project Narrative in Sections E and F. Additional instructions for completing these sections and page limitations for Biographical Sketches/Job Descriptions are included in PART II – IV: Supporting Documentation. Supporting documentation should be submitted in black and white (no color).

- **Budget Justification and Narrative** – The budget justification and narrative must be submitted as file BNF when you submit your application into

Grants.gov. (See PART II: Appendix B – Guidance for Electronic Submission of Applications.)

- **Attachments 1 through 3** – Use only the attachments listed below. If your application includes any attachments not required in this document, they will be disregarded. Do not use more than a total of 30 pages for Attachments 1 and 3 combined. There are no page limitations for Attachment 2. Do not use attachments to extend or replace any of the sections of the Project Narrative. Reviewers will not consider them if you do. Please label the attachments as: Attachment 1, Attachment 2, etc.

    - **Attachment 1:** Letters of Commitment from any organization(s) participating in the proposed project. **(Do not include any letters of support. Reviewers will not consider them if you do.)**

    - **Attachment 2:** Data Collection Instruments/Interview Protocols – if you are using standardized data collection instruments/interview protocols, you do not need to include these in your application. Instead, provide a web link to the appropriate instrument/protocol. If the data collection instrument(s) or interview protocol(s) is/are not standardized, you must include a copy in Attachment 2.

    - **Attachment 3:** Sample Consent Forms

2. APPLICATION SUBMISSION REQUIREMENTS

Applications are due by **11:59 PM** (Eastern Time) on **May 31, 2016.**

3. FUNDING LIMITATIONS/RESTRICTIONS

- No more than 20 percent of the grant award may be used for data collection, performance measurement, and performance assessment expenses.

- In years three through five, no more than 15/30 percent of the grant award may be used for state/tribal administrative costs, respectively.

SAMHSA grantees also must comply with SAMHSA's standard funding restrictions, which are included in PART II: Appendix D – Funding Restrictions.

V. APPLICATION REVIEW INFORMATION

1. EVALUATION CRITERIA

The Project Narrative describes what you intend to do with your project and includes the Evaluation Criteria in Sections A-D below. Your application will be reviewed and scored according to the quality of your response to the requirements in Sections A-D.

- In developing the Project Narrative section of your application, use these instructions, which have been tailored to this program.

- The Project Narrative (Sections A-D) together may be no longer than 25 pages.

- You must use the four sections/headings listed below in developing your Project Narrative. **You must indicate the Section letter and number in your response or your application will be screened out, i.e., type "A-1", "A-2", etc., before your response to each question.** You may not combine two or more questions or refer to another section of the Project Narrative in your response, such as indicating that the response for B.2 is in C.7. Only information included in the appropriate numbered question will be considered by reviewers. Your application will be scored according to how well you address the requirements for each section of the Project Narrative.

- Although the budget and supporting documentation for the proposed project are not scored review criteria, the Review Group will consider their appropriateness after the merits of the application have been considered. (See PART II: Section IV and Appendix E).

- The number of points after each heading is the maximum number of points a review committee may assign to that section of your Project Narrative. Although scoring weights are not assigned to individual bullets, each bullet is assessed in deriving the overall Section score.

Section A: Statement of Need (15 points)

1. Identify the population(s) that will be the recipients of prevention activities through the targeted systems or agencies, and provide demographic information on the population(s) in terms of race, ethnicity, culture, federally-recognized tribe, language, sex, gender identity, sexual orientation, age, and socioeconomic status.

2. Describe the population(s) in terms of state/tribal and community (sub-recipient) level prevalence rates, consequence data, and risk and protective factor data relevant to prescription drug misuse among youth ages 12 -17 and adults 18 years of age and older. Identify the source of the data. If the data source is not taken from a National Survey (e.g., NSDUH, Youth Risk Behavior Survey (YRBS)), provide sufficient information on how the data were collected so reviewers can assess the reliability and validity of that data. Note: Prevalence rates may come from a variety of quantitative sources such as state needs assessments, SAMHSA's National Survey on Drug Use and Health, and/or other state/national data sources (e.g., state-level health surveys, National Center for Health Statistics/Centers for Disease Control and Prevention reports). This list is not exhaustive; applicants may submit other valid data, as appropriate, for the program.

3. Discuss the current PDMP and its components as it relates to accessibility of data, usage by the targeted communities, and outcomes related to previous PDMP use. Document the need for the state/tribe to develop expertise in the use of PDMP data. Describe the stakeholders and resources that can help implement these increases in capacity. Where possible, provide data comparing those resources to other communities in the state/tribe. Identify all data sources.

4. **For Tribal Applicants:** Explain how you will coordinate with the PDMP to identify opportunities for collaboration, establish policy and an infrastructure that will ensure tribal participation and that tribal demographic data are collected.

5. Describe how the state/tribe will work with the PDMP to carry out such tasks as developing a systematic, ongoing monitoring system to track progress in reducing prescription drug abuse in targeted communities, detect trends, and use such information to redirect resources toward the goals of the SPF Rx program.

6. Describe the process you will use to establish and manage a workgroup with key stakeholders, or work with an existing epidemiological workgroup to collect and analyze relevant community indicators, including PDMP data. If a needs assessment effort is already in place, work with local, state or tribal epidemiological outcomes workgroups (SEOW/TEOW) to enhance and supplement the current process and its findings.

Section B: Proposed Approach (35 points)

1. Describe the purpose of the proposed project, including its goals and measureable objectives. These must relate to the intent of the FOA and performance measures you identify in Section D: Data Collection and Performance Measurement.

2. Identify the proposed prevention priority(ies) to be targeted using SPF Rx funds. Describe the proposed project activities and how they relate to your goals and objectives. Explain why you chose this priority(ies), including how specific data and other information support your choice. Explain how you will provide prevalence data and other information that support your choice of this priority(ies).

3. Provide a brief summary of the state's/tribe's proposed approach and level of effort to carrying out the proposed project that addresses the following components:

    a) A description of how the state/tribe proposes to address the priority(ies) through the work of its sub-recipient community(ies), including its approach for building community infrastructure/capacity to implement effective community-level prevention activities, according to the SPF process and your project goals.

For Tribal Applicants: Describe how you will increase the participation of youth, families, tribal leaders, and spiritual advisors in planning and developing best and/or promising practices, based on the cultural values and practices of the tribal community(ies) to be funded through this grant.

b) Describe how you will develop a community-based social marketing/public education plan to increase awareness of prescription drug misuse issues, the need for a coordinated approach, and promote increased use of PDMP data.

4. Provide a chart or graph depicting a realistic timeline for the entire five years of the project period, showing dates, key activities, and responsible staff. These key activities should include the requirements outlined in Section I-2: Expectations. [Note: The timeline should be part of the Project Narrative. It should not be placed in an attachment.]

5. Briefly describe how the state/tribe will coordinate with the existing or proposed Advisory Council, SEOW/TEOW (or other data driven epidemiological workgroup), and EBP workgroup to assist funded communities to achieve the goals of the proposed project, as new communities or target age groups are identified.

6. **For Tribal Applicants:** Describe the proposed tribal community advisory structure and its membership, roles, and functions; frequency of meetings; how it will relate to existing governing bodies (e.g., tribal council or board of directors); and how it will include representation from youth, families, and other community members.

7. Describe how the proposed activities will adhere to the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (go to http://ThinkCulturalHealth.hhs.gov). Select one element of each of the CLAS Standards: 1) Governance, Leadership and Workforce; 2) Communication and Language Assistance; and 3) Engagement, Continuous Improvement, and Accountability, and specifically describe how these activities will address each element you selected.

8. Briefly describe how the proposed project will address the following issues in your state/tribe:

    - Demographics – race, ethnicity, religion, sexual orientation, gender identity, age, geography, and socioeconomic status;
    - Language and literacy; and
    - Disability.

Section C: Staff, Management, and Relevant Experience (20 points)

1. Discuss the capability and experience of the applicant organization with similar projects and populations, including experience in providing culturally appropriate/competent services.

2. Discuss the capability and experience of other partnering organizations with similar projects and populations, including experience in providing culturally appropriate/competent services.

3. Provide a complete list of staff positions for the project, including the Project Director, Evaluator, and any other key personnel, showing the role of each and their level of effort and qualifications. Demonstrate successful project implementation for the level of effort budgeted for the Project Director and key staff.

4. Discuss how key staff have demonstrated experience and are qualified to develop the infrastructure for the population(s) to engage in activities and are familiar with their culture(s) and language(s).

Section D: Data Collection and Performance Measurement (30 points)

1. Document your ability to collect and report on the required performance measures as specified in Section I-2.3 of this FOA.

2. Describe your specific plan for:

   - data collection,
   - management,
   - analysis, and
   - reporting of data for the population served by your infrastructure program.

   The data collection plan must specify the staff person(s) responsible for tracking the measureable objectives that are identified in your response to question B1.

3. Describe your plan for conducting the local performance assessment, as specified in Section I-2.4 of this FOA, and document your ability to conduct the assessment.

4. Describe how the grantee will use PDMP data to ensure that the goals and objectives are achieved. Goals and objectives of your program should map onto any continuous quality improvement plan, including consideration of behavioral health disparities.

5. Describe the quality improvement process that will be used to track whether your performance measures and objectives are being met, and how any necessary adjustments to the implementation of the project will be made.

6. Discuss the relationship of your population of focus to the overall population in your geographic catchment area and identify sub-population disparities, if any, relating to access/use/outcomes of your provided activities, citing relevant data. Demonstrate an understanding of these populations consistent with the purpose of your program and intent of the FOA.

NOTE: Although the budget for the proposed project is not a scored review criterion, the Review Group will be asked to comment on the appropriateness of the budget after the merits of the application have been considered.

Budget Justification, Existing Resources, Other Support (other federal and non-federal sources)

You must provide a narrative justification for the items included in your proposed budget, as well as a description of existing resources and other support you expect to receive for the proposed project. Other support is defined as funds or resources, whether federal, non-federal, or institutional, in direct support of activities through fellowships, gifts, prizes, in-kind contributions, or non-federal means. (This should correspond to Item #18 on your SF-424, Estimated Funding.) Other sources of funds may be used for unallowable costs, e.g., meals, sporting events, entertainment.

An illustration of a budget and narrative justification is included in Appendix II- Sample Budget and Justification, of this document. **It is highly recommended that you use the Sample Budget format in Appendix II. This will expedite review of your application.**

Be sure that your proposed budget reflects the funding limitations/restrictions specified in Section IV-3. **Specifically identify the items associated with these costs in your budget**.

The budget justification and narrative must be submitted as file BNF when you submit your application into Grants.gov. (See PART II: Appendix B – Guidance for Electronic Submission of Applications.)

SUPPORTING DOCUMENTATION

Section E: Biographical Sketches and Job Descriptions

See PART II: Appendix E – Biographical Sketches and Job Descriptions, for instructions on completing this section.

Section F: Confidentiality and SAMHSA Participant Protection/Human Subjects

You must describe procedures relating to Confidentiality, Participant Protection, and the Protection of Human Subjects Regulations in Section F of your application. See Appendix I of this document for guidelines on these requirements.

2. REVIEW AND SELECTION PROCESS

SAMHSA applications are peer-reviewed according to the evaluation criteria listed above.

Decisions to fund a grant are based on:

- the strengths and weaknesses of the application as identified by peer reviewers;
- when the individual award is over $150,000, approval by the Center for Substance Abuse Prevention's National Advisory Council;
- availability of funds; and
- equitable distribution of awards in terms of geography (including urban, rural, and remote settings) and balance among populations of focus and program size.

VI. ADMINISTRATION INFORMATION

1. REPORTING REQUIREMENTS

In addition to the data reporting requirements listed in Section I-2.3, grantees must comply with the reporting requirements listed on the SAMHSA website at http://www.samhsa.gov/grants/grants-management/reporting-requirements. **Grantees will be required to submit quarterly performance and progress reports.**

VII. AGENCY CONTACTS

For questions about program issues contact:

Kim Nesbitt, MA
Division of State Programs
Center for Substance Abuse Prevention
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane, Room 16E65A
Rockville, MD 20857
(240) 276-1742 Phone
(410) 496-9913 Fax
kim.nesbitt@samhsa.hhs.gov

Kemar Mapp, MPH
Public Health Advisor
SAMHSA/CSAP/DSP
5600 Fishers Lane, Room 16E26D
Rockville, MD 20857
(240) 276-1241 Phone
(301) 480-8480 Fax
Kemar.Mapp@SAMHSA.hhs.gov

For questions on grants management and budget issues contact:

Eileen Bermudez
Office of Financial Resources, Division of Grants Management
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane, Room
Rockville, Maryland 20857
(240) 276-1412 Phone
FOACSAP@samhsa.hhs.gov

Appendix I – Confidentiality and SAMHSA Participant Protection/Human Subjects Guidelines

Confidentiality and Participant Protection:

Because of the confidential nature of the work in which many SAMHSA grantees are involved, it is important to have safeguards protecting individuals from risks associated with their participation in SAMHSA projects. All applicants (including those who plan to obtain IRB approval) must address the seven elements below. If some are not applicable or relevant to the proposed project, simply state that they are not applicable and indicate why. In addition to addressing these seven elements, read the section that follows entitled "Protection of Human Subjects Regulations" to determine if the regulations may apply to your project. If so, you are required to describe the process you will follow for obtaining Institutional Review Board (IRB) approval. While we encourage you to keep your responses brief, there are no page limits for this section and no points will be assigned by the Review Committee. Problems with confidentiality, participant protection, and the protection of human subjects identified during peer review of the application must be resolved prior to funding.

1. Protect Clients and Staff from Potential Risks

    - Identify and describe any foreseeable physical, medical, psychological, social, and legal risks or potential adverse effects as a result of the project itself or any data collection activity.

    - Describe the procedures you will follow to minimize or protect participants against potential risks, including risks to confidentiality.

    - Identify plans to provide guidance and assistance in the event there are adverse effects to participants.

    - Where appropriate, describe alternative treatments and procedures that may be beneficial to the participants. If you choose not to use these other beneficial treatments, provide the reasons for not using them.

2. Fair Selection of Participants

    - Describe the population(s) of focus for the proposed project. Include age, gender, and racial/ethnic background and note if the population includes homeless youth, foster children, and children of substance abusers, pregnant women, LBGT people or other targeted groups.

    - Explain the reasons for including groups of pregnant women, children, people with mental disabilities, people in institutions, prisoners, and individuals who are likely to be particularly vulnerable to HIV/AIDS.

- Explain the reasons for including or excluding participants.

- Explain how you will recruit and select participants. Identify who will select participants.

3. Absence of Coercion

   - Explain if participation in the project is voluntary or required. Identify possible reasons why participation is required, for example, court orders requiring people to participate in a program.

   - If you plan to compensate participants, state how participants will be awarded incentives (e.g., money, gifts, etc.). Provide justification that the use of incentives is appropriate, judicious, and conservative and that incentives do not provide an "undue inducement" which removes the voluntary nature of participation. Incentives should be the minimum amount necessary to meet the programmatic and performance assessment goals of the grant. Applicants should determine the minimum amount that is proven effective by consulting with existing local programs and reviewing the relevant literature. In no case may the value if an incentive paid for with SAMHSA discretionary grant funds exceed $30.

   - State how volunteer participants will be told that they may receive services intervention even if they do not participate in or complete the data collection component of the project.

4. Data Collection

   - Identify from whom you will collect data (e.g., from participants themselves, family members, teachers, others). Describe the data collection procedures and specify the sources for obtaining data (e.g., school records, interviews, psychological assessments, questionnaires, observation, or other sources). Where data are to be collected through observational techniques, questionnaires, interviews, or other direct means, describe the data collection setting.

   - Identify what type of specimens (e.g., urine, blood) will be used, if any. State if the material will be used just for evaluation or if other use(s) will be made. Also, if needed, describe how the material will be monitored to ensure the safety of participants.

   - Provide in **Attachment 2, "Data Collection Instruments/Interview Protocols,"** copies of all available data collection instruments and interview protocols that you plan to use (unless you are providing the web link to the instrument(s)/protocol(s)).

5. Privacy and Confidentiality

- Explain how you will ensure privacy and confidentiality. Include who will collect data and how it will be collected.
- Describe:
  - How you will use data collection instruments.
  - Where data will be stored.
  - Who will or will not have access to information.
  - How the identity of participants will be kept private, for example, through the use of a coding system on data records, limiting access to records, or storing identifiers separately from data.

NOTE: If applicable, grantees must agree to maintain the confidentiality of alcohol and drug abuse client records according to the provisions of **Title 42 of the Code of Federal Regulations, Part II.**

6. Adequate Consent Procedures

- List what information will be given to people who participate in the project. Include the type and purpose of their participation. Identify the data that will be collected, how the data will be used and how you will keep the data private.
- State:
  - Whether or not their participation is voluntary.
  - Their right to leave the project at any time without problems.
  - Possible risks from participation in the project.
  - Plans to protect clients from these risks.
- Explain how you will get consent for youth, the elderly, people with limited reading skills, and people who do not use English as their first language.

NOTE: If the project poses potential physical, medical, psychological, legal, social or other risks, you **must** obtain written informed consent.

- Indicate if you will obtain informed consent from participants or assent from minors along with consent from their parents or legal guardians. Describe how the consent will be documented. For example: Will you read the consent forms? Will you ask prospective participants questions to be sure they understand the forms? Will you give them copies of what they sign?

- Include, as appropriate, sample consent forms that provide for: (1) informed consent for participation in service intervention; (2) informed consent for participation in the data collection component of the project; and (3) informed consent for the exchange (releasing or requesting) of confidential information. The sample forms must be included in **Attachment 3, "Sample Consent Forms",** of your application. If needed, give English translations.

NOTE: Never imply that the participant waives or appears to waive any legal rights, may not end involvement with the project, or releases your project or its agents from liability for negligence.

- Describe if separate consents will be obtained for different stages or parts of the project. For example, will they be needed for both participant protection in treatment intervention and for the collection and use of data?

- Additionally, if other consents (e.g., consents to release information to others or gather information from others) will be used in your project, provide a description of the consents. Will individuals who do not consent to having individually identifiable data collected for evaluation purposes be allowed to participate in the project?

7. Risk/Benefit Discussion

- Discuss why the risks are reasonable compared to expected benefits and importance of the knowledge from the project.

Protection of Human Subjects Regulations

SAMHSA expects that most grantees funded under this announcement will not have to comply with the Protection of Human Subjects Regulations (45 CFR 46), which requires Institutional Review Board (IRB) approval. However, in some instances, the applicant's proposed performance assessment design may meet the regulation's criteria for research involving human subjects.

In addition to the elements above, applicants whose projects must comply with the Human Subjects Regulations must fully describe the process for obtaining IRB approval. While IRB approval is not required at the time of grant award, these grantees will be required, as a condition of award, to provide documentation that an Assurance of Compliance is on file with the Office for Human Research Protections (OHRP). IRB approval must be received in these cases prior to enrolling participants in the project. General information about Human Subjects Regulations can be obtained through OHRP at http://www.hhs.gov/ohrp or (240) 453-6900. SAMHSA–specific questions should be directed to the program contact listed in Section VII of this announcement.

Appendix II – Sample Budget and Justification (no match required)

THIS IS AN ILLUSTRATION OF A SAMPLE DETAILED BUDGET AND NARRATIVE JUSTIFICATION WITH GUIDANCE FOR COMPLETING SF-424A: SECTION B FOR THE BUDGET PERIOD

A. Personnel: Provide employee(s) (including names for each identified position) of the applicant/recipient organization, including in-kind costs for those positions whose work is tied to the grant project.

FEDERAL REQUEST

Position	Name	Annual Salary/Rate	Level of Effort	Cost
(1) Project Director	John Doe	$64,890	10%	$6,489
(2) Grant Coordinator	To be selected	$46,276	100%	$46,276
(3) Clinical Director	Jane Doe	In-kind cost	20%	0
			TOTAL	**$52,765**

JUSTIFICATION: Describe the role and responsibilities of each position.

(1) The Project Director will provide daily oversight of the grant and will be considered key staff.

(2) The Coordinator will coordinate project services and project activities, including training, communication and information dissemination.

(3) The Clinical Director will provide necessary medical direction and guidance to staff for 540 clients served under this project.

Key staff positions require prior approval by SAMHSA after review of credentials of resume and job description.

FEDERAL REQUEST (enter in Section B column 1 line 6a of form S-424A) **$52,765**

B. Fringe Benefits: List all components that make up the fringe benefits rate

FEDERAL REQUEST

Component	Rate	Wage	Cost
FICA	7.65%	$52,765	$4,037
Workers Compensation	2.5%	$52,765	$1,319
Insurance	10.5%	$52,765	$5,540
		TOTAL	**$10,896**

JUSTIFICATION: Fringe reflects current rate for agency.

FEDERAL REQUEST (enter in Section B column 1 line 6b of form SF-424A) $10,896

C. Travel: Explain need for all travel other than that required by this application. Applicants must use their own documented travel policies. If an organization does not have documented travel policies, the federal GSA rates must be used.

FEDERAL REQUEST

Purpose of Travel	Location	Item	Rate	Cost
(1) Grantee Conference	Washington, DC	Airfare	$200/flight x 2 persons	$400
		Hotel	$180/night x 2 persons x 2 nights	$720
		Per Diem (meals and incidentals)	$46/day x 2 persons x 2 days	$184
(2) Local travel		Mileage	3,000 miles@.38/mile	$1,140
			TOTAL	**$2,444**

JUSTIFICATION: Describe the purpose of travel and how costs were determined.

(1) Two staff (Project Director and Evaluator) to attend mandatory grantee meeting in Washington, DC.

(2) Local travel is needed to attend local meetings, project activities, and training events. Local travel rate is based on organization's policies/procedures for privately owned vehicle reimbursement rate. If policy does not have a rate use GSA.

FEDERAL REQUEST (enter in Section B column 1 line 6c of form SF-424A) **$2,444**

D. Equipment: An article of tangible, nonexpendable, personal property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit (federal definition). Organizations should follow their documented capitalization policy thresholds.

FEDERAL REQUEST – (enter in Section B column 1 line 6d of form SF-424A) **$ 0**

E. Supplies: Materials costing less than $5,000 per unit (federal definition) and often having one-time use

FEDERAL REQUEST

Item(s)	**Rate**	**Cost**
General office supplies	$50/mo. x 12 mo.	$600
Postage	$37/mo. x 8 mo.	$296
Laptop Computer	$900	$900
Printer	$300	$300
Projector	$900	$900
Copies	8000 copies x .10/copy	$800
	TOTAL	**$3,796**

JUSTIFICATION: Describe the need and include an adequate justification of how each cost was estimated.

(1) Office supplies, copies and postage are needed for general operation of the project.

(2) The laptop computer and printer are needed for both project work and presentations for Project Director.

(3) The projector is needed for presentations and workshops. All costs were based on retail values at the time the application was written.

FEDERAL REQUEST – (enter in Section B column 1 line 6e of form SF-424A) **$ 3,796**

F. Contract: A contractual arrangement to carry out a portion of the programmatic effort or for the acquisition of routine goods or services under the grant. Such arrangements may be in the form of consortium agreements or contracts. A consultant is an individual retained to provide professional advice or services for a fee. The applicant/grantee must establish written procurement policies and procedures that are consistently applied. All procurement transactions shall be conducted in a manner to provide to the maximum extent practical, open and free competition.

COSTS FOR CONTRACTS MUST BE BROKEN DOWN IN DETAIL AND A NARRATIVE JUSTIFICATION PROVIDED. IF APPLICABLE, NUMBERS OF CLIENTS SHOULD BE INCLUDED IN THE COSTS.

FEDERAL REQUEST

Name	Service	Rate	Other	Cost
(1) State Department of Human Services	Training	$250/individual x 3 staff	5 days	$750
(2) Treatment Services	1040 Clients	$27/client per year		$28,080

Name	Service	Rate	Other	Cost
(3) John Smith (Case Manager)	Treatment Client Services	1FTE @ $27,000 + Fringe Benefits of $6,750 = $33,750	*****Travel at 3,124 @ .50 per mile = $1,562 *****Training course $175 *****Supplies @ $47.54 x 12 months or $570 *****Telephone @ $60 x 12 months = $720 *****Indirect costs = $9,390 (negotiated with contractor)	$46,167
(4) Jane Smith	Evaluator	$40 per hour x 225 hours	12 month period	$9,000
(5) To Be Announced	Marketing Coordinator	Annual salary of $30,000 x 10% level of effort		$3,000
			TOTAL	**$86,997**

JUSTIFICATION: Explain the need for each contractual agreement and how it relates to the overall project.

(1) Certified trainers are necessary to carry out the purpose of the statewide Consumer Network by providing recovery and wellness training, preparing consumer leaders statewide, and educating the public on mental health recovery.

(2) Treatment services for clients to be served based on organizational history of expenses.

(3) Case manager is vital to client services related to the program and outcomes.

(4) Evaluator is provided by an experienced individual (Ph.D. level) with expertise in substance abuse, research and evaluation, is knowledgeable about the population of focus, and will report GPRA data.

(5) Marketing Coordinator will develop a plan to include public education and outreach efforts to engage clients of the community about grantee activities, and provision of presentations at public meetings and community events to stakeholders, community civic organizations, churches, agencies, family groups and schools.

***Represents separate/distinct requested funds by cost category**

FEDERAL REQUEST – (enter in Section B column 1 line 6f of form SF-424A) **$86,997**

G. Construction: NOT ALLOWED – Leave Section B columns 1& 2 line 6g on SF-424A blank.

H. Other: Expenses not covered in any of the previous budget categories

FEDERAL REQUEST

Item	Rate	Cost
(1) Rent*	$15/sq.ft x 700 sq. feet	$10,500
(2) Telephone	$100/mo. x 12 mo.	$1,200
(3) Client Incentives	$10/client follow up x 278 clients	$2,780
(4) Brochures	.89/brochure X 1500 brochures	$1,335
	TOTAL	**$15,815**

JUSTIFICATION: Break down costs into cost/unit (e.g. cost/square foot). Explain the use of each item requested.

(1) Office space is included in the indirect cost rate agreement; however, if other rental costs for service site(s) are necessary for the project, they may be requested as a direct charge. The rent is calculated by square footage or FTE and reflects SAMHSA's fair share of the space.

***If rent is requested (direct or indirect), provide the name of the owner(s) of the space/facility. If anyone related to the project owns the building which is less than an arms length arrangement, provide cost of ownership/use allowance calculations. Additionally, the lease and floor plan (including common areas) are required for all projects allocating rent costs.**

(2) The monthly telephone costs reflect the percent of effort for the personnel listed in this application for the SAMHSA project only.

(3) The $10 incentive is provided to encourage attendance to meet program goals for 278 client follow-ups.

(4) Brochures will be used at various community functions (health fairs and exhibits).

FEDERAL REQUEST – (enter in Section B column 1 line 6h of form SF-424A) **$15,815**

Indirect Cost Rate: Indirect costs can be claimed if your organization has a negotiated indirect cost rate agreement. It is applied only to direct costs to the agency as allowed in the agreement. For information on applying for the indirect rate go to: https://rates.psc.gov/fms/dca/map1.html. **Effective with 45 CFR 75.414(f), any non-federal entity that has never received a negotiated indirect cost rate, except for those non-federal entities described in Appendix VII part 75 (D)(1)(b), may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. If an organization has a federally approved rate of 10%, the approved rate would prevail.**

FEDERAL REQUEST (enter in Section B column 1 line 6j of form SF-424A)

8% of personnel and fringe **(.08 x $63,661)** **$5,093**

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TOTAL DIRECT CHARGES:

FEDERAL REQUEST – (enter in Section B column 1 line 6i of form SF-424A) $172,713

INDIRECT CHARGES:

FEDERAL REQUEST – (enter in Section B column 1 line 6j of form SF-424A) $5,093

TOTAL: (sum of 6i and 6j)

FEDERAL REQUEST – (enter in Section B column 1 line 6k of form SF-424A)
$177,806

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Provide the total proposed project period and federal funding as follows:

Proposed Project Period

a. Start Date: 09/30/2012 b. End Date: 09/29/2017

BUDGET SUMMARY (should include future years and projected total)

Category	**Year 1**	**Year 2***	**Year 3***	**Year 4***	**Year 5***	**Total Project Costs**
Personnel	$52,765	$54,348	$55,978	$57,658	$59,387	$280,136
Fringe	$10,896	$11,223	$11,559	$11,906	$12,263	$57,847
Travel	$2,444	$2,444	$2,444	$2,444	$2,444	$12,220
Equipment	0	0	0	0	0	0
Supplies	$3,796	$3,796	$3,796	$3,796	$3,796	$18,980
Contractual	$86,997	$86,997	$86,997	$86,997	$86,997	$434,985
Other	$15,815	$13,752	$11,629	$9,440	$7,187	$57,823
Total Direct Charges	$172,713	$172,560	$172,403	$172,241	$172,074	$861,991
Indirect Charges	$5,093	$5,246	$5,403	$5,565	$5,732	$27,039
Total Project Costs	**$177,806**	**$177,806**	**$177,806**	**$177,806**	**$177,806**	**$889,030**

TOTAL PROJECT COSTS: Sum of Total Direct Costs and Indirect Costs

FEDERAL REQUEST (enter in Section B column 1 line 6k of form SF-424A) **$889,030**

***FOR REQUESTED FUTURE YEARS:**

1. Please justify and explain any changes to the budget that differs from the reflected amounts reported in the 01 Year Budget Summary.

2. If a cost of living adjustment (COLA) is included in future years, provide your organization's personnel policy and procedures that state all employees within the organization will receive a COLA.

IN THIS SECTION, REFLECT OTHER FEDERAL AND NON-FEDERAL SOURCES OF FUNDING BY DOLLAR AMOUNT AND NAME OF FUNDER e.g., Applicant, State, Local, Other, Program Income, etc.
Other support is defined as funds or resources, whether federal, non-federal or institutional, in direct support of activities through fellowships, gifts, prizes, in-kind contributions or non-federal means. [Note: Please see PART II: Appendix D, Funding Restrictions, regarding allowable costs.]

IN THIS SECTION, include a narrative and separate budget for each year of the grant that shows the percent of the total grant award that will be used for data collection, performance measurement and performance assessment. **Be sure the budget reflects the funding restrictions in Section IV-3 of the** FOA **Part I: Programmatic Guidance.**

Infrastructure Development	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total Infra-structure Costs**
Personnel	$2,250	$2,250	$2,250	$2,250	$2,250	$11,250
Fringe	$558	$558	$558	$558	$558	$2,790
Travel	0	0	0	0	0	0
Equipment	$15,000	0	0	0	0	$15,000
Supplies	$1,575	$1,575	$1,575	$1,575	$1,575	$7,875
Contractual	$5,000	$5,000	$5,000	$5,000	$5,000	$25,000
Other	$1,617	$2,375	$2,375	$2,375	$2,375	$11,117
Total Direct Charges	$6,000	$11,758	$11,758	$11,758	$11,758	**$53,072**

Infrastructure Development	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total Infra-structure Costs**
Indirect Charges	$750	$750	$750	$750	$750	**$3,750**
Total Infrastructure Costs	**$6750**	**$12,508**	**$12,508**	**$12,508**	**$12,508**	**$56,782**

Data Collection & Performance Measurement	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total Data Collection & Performance Measurement Costs**
Personnel	$6,700	$6,700	$6,700	$6,700	$6,700	$33,500
Fringe	$2,400	$2,400	$2,400	$2,400	$2,400	$12,000
Travel	$100	$100	$100	$100	$100	$500
Equipment	0	0	0	0	0	0
Supplies	$750	$750	$750	$750	$750	$3,750
Contractual	$24,950	$24,950	$24,950	$24,950	$24,950	$124,750
Other	0	0	0	0	0	0
Total Direct Charges	$34,300	$34,300	$34,300	$34,300	$34,300	$171,500
Indirect Charges	$698	$698	$698	$698	$698	$3,490
Data Collection & Performance Measurement	**$34,900**	**$34,900**	**$34,900**	**$34,900**	**$34,900**	**$174,500**