Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

State Targeted Response to the Opioid Crisis Grants

Short Title: Opioid STR

(Initial Announcement)

Funding Opportunity Announcement (FOA) No. TI-17-014

Catalogue of Federal Domestic Assistance (CFDA) No.: 93.788

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".

Key Dates:

Application Deadline	**Applications are due by February 17, 2017.**

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EXECUTIVE SUMMARY

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) and Center for Substance Abuse Prevention (CSAP)**,** are accepting applications for fiscal year (FY) 2017 State Targeted Response to the Opioid Crisis Grants (Short Title: Opioid STR). The program aims to address the opioid crisis by increasing access to treatment, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of prevention, treatment and recovery activities for opioid use disorder (OUD) (including prescription opioids as well as illicit drugs such as heroin). These grants will be awarded to states and territories via formula based on unmet need for opioid use disorder treatment and drug poisoning deaths.

Funding Opportunity Title:	State Targeted Response to the Opioid Crisis Grants
Funding Opportunity Number:	TI-17-014
Due Date for Applications:	February 17, 2017
Anticipated Total Available Funding:	Up to $485,000,000 per year
Estimated Number of Awards:	59 awards
Cost Sharing/Match Required	No
Length of Project Period:	Up to 2 years
Eligible Applicants:	Eligibility is limited to Single State Agencies (SSAs). See Section III-1 of this FOA for complete eligibility information.

I. FUNDING OPPORTUNITY DESCRIPTION

1. PURPOSE

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) and Center for Substance Abuse Prevention (CSAP)**,** are accepting applications for fiscal year (FY) 2017 State Targeted Response to the Opioid Crisis Grants (Short Title: Opioid STR). The program aims to address the opioid crisis by increasing access to treatment, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of prevention, treatment and recovery activities for opioid use disorder (OUD) (including prescription opioids as well as illicit drugs such as heroin). These grants will be awarded to states and territories via formula based on unmet need for opioid use disorder treatment and drug poisoning deaths.

Grantees will be required to do the following: use epidemiological data to demonstrate the critical gaps in availability of treatment for OUDs in geographic, demographic, and service level terms; utilize evidence-based implementation strategies to identify which system design models will most rapidly address the gaps in their systems of care; deliver evidence based treatment interventions including medication and psychosocial interventions; and report progress toward increasing availability of treatment for OUD and reducing opioid-related overdose deaths based upon measures developed in collaboration with the Department of Health and Human Services (DHHS).

The program supplements activities pertaining to opioids currently undertaken by the state agency or territory and will support a comprehensive response to the opioid epidemic using a strategic planning process to conduct needs and capacity assessments. The results of the assessments will identify gaps and resources from which to build upon existing substance use prevention and treatment activities. Grantees will be required to describe how they will expand access to treatment and recovery. Grantees will also be required to describe how they will advance substance misuse prevention in coordination with other federal efforts such as those funded by the Centers for Disease Control and Prevention (CDC). Grantees must use funding to supplement and not supplant existing opioid prevention, treatment, and recovery activities in their state. Grantees are required to describe how they will improve retention in care, using a chronic care model. To the extent applicable, grantees should align STR prevention efforts with CDC's State's Opioid Program.

Opioid STR is one of SAMHSA's services grant programs. SAMHSA intends that its services grants result in the delivery of services as soon as possible after award. Service delivery should begin by the fourth month of the project <u>at the latest.</u>

Opioid STR grants are authorized under Section 1003 of the 21st Century Cures Act, as amended. This announcement addresses Healthy People 2020, Substance Abuse Topic Area HP 2020-SA.

2. EXPECTATIONS

Grantees will develop and provide opioid misuse prevention, treatment, and recovery support services for the purposes of addressing the opioid abuse crisis within the states and territories. This service array should be based on needs identified in the State's strategic plan. Opioid STR grantees will be permitted to use up to five percent of their grant award on administrative/infrastructure costs to administer the grant. At least eighty percent of the remaining award must be spent on opioid use disorder treatment and recovery support services. Grantees are expected to assess the needs of their tribal communities and include them in their strategic plan. Grantees will be required to report expenditures for all activities. Further details will be provided at time of award. Grantees should ensure all available resources for services within the state or territory are leveraged for substance use prevention, treatment, and recovery services and coordinate activities with other funding sources such as other SAMHSA or CDC funding for States and providers of these services to avoid duplication of efforts.

Key staff for this program will be the Project Director.

Required Activities:

You must use SAMHSA's Opioid STR grant funds primarily to support prevention, treatment, and recovery support activities. This includes the following required activities:

- Develop a needs assessment using statewide epidemiological data (where available if a needs assessment effort is already in place, work with the local, state, or tribal epidemiological outcomes workgroup to enhance and supplement the current process and its findings). The needs assessment should identify:
    - areas where opioid misuse and related harms are most prevalent.
    - the number and location of opioid treatment providers in the state, including providers that offer opioid use disorder services.
    - all existing activities and their funding sources in the state that address opioid use prevention, treatment, and recovery activities and remaining gaps in these activities.

- Develop a comprehensive state strategic plan to address the gaps in prevention, treatment, and recovery identified in the needs assessment.

- Design, implement, enhance, and evaluate primary and secondary prevention using evidence-based methods defined by SAMHSA or CDC proven to reduce the number of persons with OUDs and OUD associated deaths.

- Implement or expand access to clinically appropriate evidence-based practices (EBPs) for OUD treatment, particularly, the use of medication assisted treatment (MAT), i.e., the use of FDA-approved medications (e.g., methadone, buprenorphine products including buprenorphine/naloxone combination formulations and buprenorphine monoproduct formulations, naltrexone products including extended-release and oral formulations or implantable buprenorphine) in combination with psychosocial interventions. (For more relevant resources: https://www.samhsa.gov/medication-assisted-treatment.)

- Provide assistance to patients with treatment costs and develop other strategies to eliminate or reduce treatment costs for under- and uninsured patients.

- Provide treatment transition and coverage for patients reentering communities from criminal justice settings or other rehabilitative settings.

- Enhance or support the provision of peer and other recovery support services designed to improve treatment access and retention and support long-term recovery.

Allowable Activities:

- Train substance use and mental health care practitioners, on topics such as best practices for prescribing opioids, pain management, recognizing potential cases of substance use disorder, referral of patients to treatment programs, and overdose prevention including CDC's opioid prescribing guidelines.

- Support access to healthcare services, including services provided by Federally certified opioid treatment programs or other appropriate healthcare providers to treat substance use disorders.

- Address barriers to receiving treatment by reducing the cost of treatment, developing systems of care to expand access to treatment, engaging and retaining patients in treatment, and addressing discrimination associated with accessing treatment, including discrimination that limits access to MAT.

- Train OUD prevention and treatment providers, such as physicians, nurses, NPs, PAs, counselors, social workers, care coordinators and case managers. SAMHSA's Opioid Overdose Prevention Toolkit must be used when developing training that addresses opioid overdose as well as CDC's prescribing guidelines.

- Support innovative telehealth in rural and underserved areas to increase the capacity of communities to support OUD prevention and treatment.

- Integrate health information technology programs, including enhancing clinical decision tools, to support identification of patients with OUD and engage them in treatment.

- Purchase naloxone for distribution in high need communities, if necessary, and training first responders, substance use prevention and treatment providers, and others on the use of naloxone.

- Enhance the State Prescription Drug Monitoring Program (PDMP), working with CDC grantees where applicable, to increase use of PDMP data (where appropriate).

- Establish and/or enhance statewide and community-based recovery support systems, networks, and organizations to develop capacity at the state and local levels to design and implement peer and other recovery support services as vital components of recovery-oriented continuum of care.

Other Expectations:

If you currently receive opioid-related funding from other Federal programs, you must coordinate activities to eliminate duplication of services and programs (e.g. MAT-PDOA, SPF-Rx, PDO, SABG, CDC's PDMP, etc.).

Although people with behavioral health conditions represent about 25 percent of the U.S. adult population, these individuals account for nearly 40 percent[1] of all cigarettes smoked and can experience serious health consequences[2]. A growing body of research shows that quitting smoking can improve mental health and addiction recovery outcomes. Research shows that many smokers with behavioral health conditions want to quit, can quit, and benefit from proven smoking cessation treatments. SAMHSA strongly encourages all grantees to adopt a tobacco-free facility/grounds policy and to promote abstinence from all tobacco products (except in regard to accepted tribal traditions and practices).

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[1] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (March 20, 2013). *The NSDUH Report: Adults with Mental Illness or Substance Use Disorder Account for 40 Percent of All Cigarettes Smoked.* Rockville, MD. http://media.samhsa.gov/data/spotlight/spot104-cigarettes-mental-illness-substance-use-disorder.pdf

[2] U.S. Department of Health and Human Services. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

Grantees must utilize third party and other revenue realized from provision of services to the extent possible and use SAMHSA grant funds only for services to individuals who are not covered by public or commercial health insurance programs, individuals for whom coverage has been formally determined to be unaffordable, or for services that are not sufficiently covered by an individual's health insurance plan. Grantees are also expected to facilitate the health insurance application and enrollment process for eligible uninsured clients. Grantees should also consider other systems from which a potential service recipient may be eligible for services (for example, the Veterans Health Administration or senior services), if appropriate for and desired by that individual to meet his/her needs. In addition, grantees are required to implement policies and procedures that ensure other sources of funding are utilized first when available for that individual.

Recovery from mental and/or substance use disorders has been identified as a primary goal for behavioral health care. SAMHSA's Recovery Support Strategic Initiative is leading efforts to advance the understanding of recovery and ensure that vital recovery supports and services are available and accessible to all who need and want them. Building on research, practice, and the lived experiences of individuals in recovery from mental and/or substance use disorders, SAMHSA has developed the following working definition of recovery: *A process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential.* See http://store.samhsa.gov/product/SAMHSA-s-Working-Definition-of-Recovery/PEP12-RECDEF for further information, including the four dimensions of recovery, and 10 guiding principles. Programs and services that incorporate a recovery approach fully involve people with lived experience (including consumers/peers/people in recovery, youth, and family members) in program/service design, development, implementation, and evaluation.

SAMHSA's standard, unified working definition of recovery is intended to advance recovery opportunities for all Americans, particularly in the context of health reform, and to help clarify these concepts for peers/persons in recovery, families, funders, providers and others. The definition is to be used to assist in the planning, delivery, financing, and evaluation of behavioral health services. SAMHSA grantees are expected to integrate the definition and principles of recovery into their programs to the greatest extent possible. For the purposes of this grant, prospective grantees must ensure that no program receiving support from this award will deny access to any patient, client or participant or consider him/her "not in recovery" based solely on his/her use of FDA approved pharmacotherapy furnished for opioid use disorder treatment.

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 Using Evidence-Based Practices

SAMHSA's services grants are intended to fund services or practices that have a demonstrated evidence base and that are appropriate for the population(s) of focus. An EBP refers to approaches to prevention or treatment that are validated by some form of documented research evidence. However, SAMHSA recognizes that EBPs have not been developed for all populations and/or service settings. See Appendix A of this document for additional information about using EBPs. In your project narrative, based on PDMP and epidemiological data, you will need to:

- Identify the EBPs you propose to implement for the specific population(s) of focus. If an EBP does not exist/apply for your program/population(s) of focus, describe the service/practice you plan to implement as an appropriate alternative.

- If you are proposing to use more than one EBP, provide a justification for doing so and clearly identify which service modality and population of focus each practice will support.

- Discuss the population(s) for which the practice(s) has (have) been shown to be effective and show that it (they) is (are) appropriate for your population(s) of focus. Indicate whether/how the practice(s) will be adapted for a specific population. SAMHSA encourages you to consult with an expert or the program developer to complete any modifications to the chosen EBP. This is especially important when adapting EBPs for specific underserved populations for whom there are fewer EBPs.

In selecting an EBP, be mindful of how your choice of an EBP or practice may impact disparities in service access, use, and outcomes for your population(s) of focus. While this is important in providing services to all populations, it is especially critical for those working with underserved and minority populations.

[Note: See PART II: Appendix C - Funding Restrictions, regarding allowable costs for EBPs.]

2.2 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 E: Data Collection and Performance Measurement of your application. Grantees' progress in addressing the opioid epidemic will be partially assessed through the submission of data in compliance with the Substance Abuse

Prevention and Treatment Block Grant (SABG) standard reporting requirements. Additionally, grantees will be required to report performance on the following performance measures specific to this program:

- Number of people who receive OUD treatment.
- Number of people who receive OUD recovery services.
- Number of providers implementing MAT.
- Number of OUD prevention and treatment providers trained, to include NPs, PAs, as well as physicians, nurses, counselors, social workers, case managers, etc.
- Numbers and rates of opioid use.
- Numbers and rates of opioid overdose-related deaths.

More information will be provided on performance data requirements upon award. Performance data will be reported to the public as part of SAMHSA's Congressional Justification. Grantees will also be expected to participate in a national evaluation.

2.3 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. All grantees receiving the Opioid STR grant are required to create a final annual report at the conclusion of each year related to substance use pursuant to section 1942 of the Public Health Service (PHS) Act (42 U.S.C. 300x52) which must include. The performance data required above and:

- The purposes for which the grant funds received by the grantee were expended and a description of the activities under the program; and
- The ultimate recipients of amounts provided to the grantee in the grants.

Grantees will also submit a progress report at the midpoint of each grant year with the same information. The report required under this program is in addition to the report submitted pursuant to section 1942 of the PHS Act.

2.4 Infrastructure Development/Administrative Costs (maximum 5 percent of total grant award)

NOTE: These costs are those specific to administering the grant program at the SSA level.

Although services grant funds must be used primarily for direct services, SAMHSA recognizes that infrastructure changes may be needed to implement the services or improve their effectiveness. You may use no more than 5 percent of the total grant award for the following types of infrastructure development, if necessary to support the direct service expansion of the grant project, and describe your use of grant funds for these activities in Section B of the Project Narrative.

- Adopting and/or enhancing your computer system, management information system (MIS), electronic health records (EHRs), etc., to document and manage client needs, care process, integration with related support services, and outcomes.

- Data Collection and Reporting.

- Training/workforce development to help your staff administer the grant program (NOTE: THIS IS TRAINING SPECIFIC TO ADMINISTERING THE GRANT; THIS IS DIFFERENT FROM THE WORKFORCE DEVELOPMENT ACTIVITY REFERENCED IN THE REQUIRED ACTIVITIES SECTION).

- Policy development to support needed service system improvements (e.g., rate-setting activities, establishment of standards of care, adherence to the National CLAS Standards in Health and Health Care, development/revision of credentialing, licensure, or accreditation requirements)[3].

- Evaluation of grant activities.

II. AWARD INFORMATION

Funding Mechanism: Grant

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[3] 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 the 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 grass-roots 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.

Anticipated Total Available Funding:	Up to $485,000,000 per year
Estimated Number of Awards:	59 awards
Length of Project Period:	Up to 2 years

State allocations for the Opioid STR grants are calculated by a formula based on the number of people with abuse or dependence on opioids with unmet treatment needs (NSDUH, 2011-2014) and the number of drug poisoning deaths (CDC Surveillance System). See Appendix E for more information.

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.

III. ELIGIBILITY INFORMATION

1. ELIGIBLE APPLICANTS

Eligible applicants are the Single State Agencies (SSAs).

IV. APPLICATION AND SUBMISSION INFORMATION

In addition to the application requirements noted in PART II; 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 D of this document**. It is highly recommended that you use the sample budget format in Appendix D. This will expedite review of your application.**

- **Project Narrative and Supporting Documentation** – The Project Narrative describes your project. It consists of Sections A through E. Sections A-E together may not be longer than 60 pages. (Remember that if your Project Narrative starts on page 5 and ends on page 65, it is 61 pages long, not 60 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 section provides additional information necessary for the review of your application. This supporting documentation must be attached to your application using the Other Attachments Form from the Grants.gov application package. Additional instructions for completing these sections and page limitations for Biographical Sketches/Position Descriptions are included in PART II: Section III and Appendix D, Biographical Sketches and Job Descriptions. 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: Section I-3.1, Required Application Components.)

- Applicants for this program are required to complete the Assurance of Compliance with SAMHSA Charitable Choice Statutes and Regulations Form SMA 170**.** This form is posted on SAMHSA's website at http://www.samhsa.gov/grants/applying/forms-resources.

- The following attachment must be included with your application. If your application includes any other attachments they will be disregarded. Do not use the attachment to extend or replace any of the sections of the Project Narrative. Reviewers will not consider the information if you do. Please label the attachment as Attachment 1. Use the Other Attachments Form from Grants.gov to upload the attachment.

    - **Attachment 1**: 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 1.

2. APPLICATION SUBMISSION REQUIREMENTS

Applications are due by **11:59 PM** (Eastern Time) on **February 17, 2017.**

3. FUNDING LIMITATIONS/RESTRICTIONS (All budgets will be reviewed in conjunction with program objectives and will be approved prior to award)

- No more than 5 percent of the total grant award may be used for administrative and infrastructure development costs.

- Not less than 80 percent of the remaining total grant award (after administrative/infrastructure costs) must be used for opioid treatment services.

- Only U.S. Food and Drug Administration (FDA) –approved products can be purchased with Opioid STR grant funds.

- Funds may not be expended through the grant or a subaward by any agency which would deny any eligible client, patient or individual access to their program because of their use of FDA-approved medications for the treatment of substance use disorders (e.g., methadone, buprenorphine products including buprenorphine/naloxone combination formulations and buprenorphine monoproduct formulations, naltrexone products including extended-release and oral formulations or implantable buprenorphine.) Specifically, patients must be allowed to participate in methadone treatment rendered in accordance with current federal and state methadone dispensing regulations from an Opioid Treatment Program and ordered by a physician who has evaluated the client and determined that methadone is an appropriate medication treatment for the individual's opioid use disorder. Similarly, medications available by prescription or office-based implantation must be permitted if it is appropriately authorized through prescription by a licensed prescriber or provider. In all cases, MAT must be permitted to be continued for as long as the prescriber or treatment provider determines that the medication is clinically beneficial. Grantees must assure that clients will not be compelled to no longer use MAT as part of the conditions of any programming if stopping is inconsistent with a licensed prescriber's recommendation or valid prescription.

Be sure to identify all expenses in your proposed budget.

SAMHSA grantees and subgrantees also must comply with SAMHSA's funding restrictions, which are included in PART II: Appendix C, 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-E below. Your application will be reviewed and scored according to the quality of your response to the requirements in Sections A-E.

In developing the Project Narrative section of your application, use these instructions. **You must indicate the Section letter and number in your response,** 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.** Your application will be

scored according to how well you address the requirements for each section of the Project Narrative.

Section A: Population of Focus and Statement of Need

1. Identify your communities of focus at highest risk for OUD. Provide a comprehensive demographic profile of this population in your local area in terms of race, ethnicity, federally recognized tribe (if applicable), language, sex, gender identity, sexual orientation, age, rural/urban population, and socioeconomic (including insurance) status.

2. Discuss the differences in access, service use, and outcomes for your population of focus in comparison with the general population in the local service area, citing relevant data. Describe how the proposed project will improve these disparities in access, service use, and outcomes.

3. Describe the nature of the OUD problem, including currently available resources and service gaps. Document the extent of the need (i.e., current prevalence rates or incidence data) for the population(s) of focus identified in your response to question A.1. To the extent available, use local data to describe need and service gaps, supplemented with state and/or national data. Identify the source of the data.

Section B: Proposed Implementation Approach

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 E: Data Collection and Performance Measurement.

2. If applicable, describe other state and Federal resources, such as CDC resources, that address the objectives of the proposed projects and how Opioid STR funds will work synergistically with these activities to enhance and not duplicate existing efforts.

3. Provide a chart or graph depicting a realistic time line for the two (2) 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: Be sure to show that the project can be implemented and service delivery can begin as soon as possible and no later than four months after grant award. The time line should be part of the Project Narrative. It should not be placed in an attachment.]

4. Describe clearly your administrative and infrastructure costs (up to 5 percent of the award) and how these will lead to your program's success.

5. Describe the prevention activities that will be implemented as part of your comprehensive approach to address the opioid crisis. Please clearly identify strategies to accomplish the required activities and any other activities you plan to undertake.

6. Describe the treatment/recovery support services (not less than 80 percent of award after administrative costs) that will be implemented as part of your comprehensive plan to address the opioid crisis. Please clearly identify strategies to accomplish the required activities and any other activities you plan to undertake.

7. Describe how you will identify, recruit, and retain the population(s) of focus, and how this approach will take into consideration the language, beliefs, norms, values, and socioeconomic factors of this/these population(s).

8. State the unduplicated number of individuals to which you propose to provide treatment and recovery support services (annually and over the entire project period) with grant funds. Include the types and numbers of other services to be provided and anticipated outcomes. Explain how you arrived at this number and that it is reasonable given your budget request.

Section C: Proposed Evidence-Based Service/Practice

1. Describe the system design and implementation models that you will use to increase availability of services to prevent and treat OUD.

2. Describe the Opioid Use Prevention and Treatment EBP(s) that will be used. Document how each EBP chosen is appropriate for the outcomes you want to achieve. Justify the use of each EBP for your population of focus. Explain how the chosen EBP(s) meet SAMHSA's goals for this program. If an EBP does not exist/apply for your program, fully describe the practice you plan to implement, explain why it is appropriate for the population of focus, and justify its use compared to an appropriate existing EBP.

3. Explain how your choice of an EBP or practice will help you address disparities in service access, use, and outcomes for your population(s) of focus.

4. Describe any modifications that will be made to the EBP or practice and the reasons the modifications are necessary. If you are not proposing any modifications, indicate so in your response.

5. Explain how you will monitor the delivery of the EBPs to ensure that they are implemented according to the EBP guidelines.

Section D: Staff and Organizational Experience

1. Discuss the capability and experience of the applicant organization with similar projects and populations. Demonstrate that the applicant organization has linkages to the population(s) of focus and ties to grassroots/community-based organizations that are rooted in the culture(s) and language(s) of the population(s) of focus.

2. Discuss the capability and experience of other partnering organizations with similar projects and populations. Demonstrate that other partnering organizations have linkages to the population(s) of focus and ties to grassroots/community-based organizations that are rooted in the culture(s) and language(s) of the population(s) of focus

3. Provide a complete list of staff positions for the project, including the Project Director and 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 members have demonstrated experience and are qualified to serve the population(s) of focus and are familiar with their culture(s) and language(s). If key staff members are to be hired, discuss the credentials and experience the new staff must possess to work effectively with the population of focus.

5. Describe how your staff will ensure the input gathered from consumers, clients, and families in assessing, planning and implementing your project.

Section E: Data Collection and Performance Measurement

1. Document your ability to collect and report on the required performance measures as specified in Section I-2.2 of this FOA.

2. Describe your specific plan for:
   - data collection,
   - management,
   - analysis, and
   - reporting.

   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 the quality improvement process that will be used to track whether your performance measures and objectives are being met, and how these data will inform the ongoing implementation of the project.

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

You must provide a narrative justification of 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 D - Sample Budget and Justification, of this document. **It is highly recommended that you use the Sample Budget format in Appendix D. This will expedite review of your application.**

Be sure 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.)

REQUIRED SUPPORTING DOCUMENTATION

Section F: Biographical Sketches and Position Descriptions.

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

Section G: 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. **Failure to include these procedures will impact the review of your application.** See Appendix C of this document for guidelines on these requirements.

VI. ADMINISTRATION INFORMATION

1. REPORTING REQUIREMENTS

In addition to the programmatic data reporting requirements listed in Section I-2.2, grantees must comply with the grants management reporting requirements listed on the

SAMHSA website at http://www.samhsa.gov/grants/grants-management/reporting-requirements.

VII. AGENCY CONTACTS

For questions about program issues contact:

Donna Hillman
Center for Substance Abuse Treatment
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Donna.Hillman@samhsa.hhs.gov

Tonia Gray
Center for Substance Abuse Prevention
Substance Abuse and Mental Health Services Administration
(240) 276-2492
Tonia.Gray@samhsa.hhs.gov

For questions on grants management and budget issues contact:

Odessa Crocker
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Appendix A – Using Evidence-Based Practices (EBPs)

SAMHSA recognizes that EBPs have not been developed for all populations and/or service settings. For example, certain practices for American Indians/Alaska Natives, rural or isolated communities, or recent immigrant communities may not have been formally evaluated and, therefore, have a limited or nonexistent evidence base. In addition, other practices that have an established evidence base for certain populations or in certain settings may not have been formally evaluated with other subpopulations or within other settings. Applicants proposing to serve a population with a practice that has not been formally evaluated with that population are required to provide other forms of evidence that the practice(s) they propose is appropriate for the population(s) of focus. Evidence for these practices may include unpublished studies, preliminary evaluation results, clinical (or other professional association) guidelines, findings from focus groups with community members, etc. You may describe your experience either with the population(s) of focus or in managing similar programs. Information in support of your proposed practice needs to be sufficient to demonstrate the appropriateness of your practice to the individuals reviewing your application.

- Document the EBP(s) you have chosen is appropriate for the outcomes you want to achieve.

- Explain how the practice you have chosen meets SAMHSA's goals for this grant program.

- Describe any modifications/adaptations you will need to make to your proposed practice(s) to meet the goals of your project and why you believe the changes will improve the outcomes. We expect that you will implement your evidence-based service(s)/practice(s) in a way that is as close as possible to the original service(s)/practice(s). However, SAMHSA understands that you may need to make minor changes to the service(s)/practice(s) to meet the needs of your population(s) of focus or your program, or to allow you to use resources more efficiently. You must describe any changes to the proposed service(s)/practice(s) that you believe are necessary for these purposes. You may describe your own experience either with the population(s) of focus or in managing similar programs. However, you will need to convince the people reviewing your application that the changes you propose are justified.

- Explain why you chose this EBP over other evidence-based practices.

- If applicable, justify the use of multiple EBPs. Discuss how the use of multiple EBPs will be integrated into the program. Describe how the effectiveness of each evidence-based practice will be quantified in the performance assessment of the project.

- Discuss training needs or plans for training to successfully implement the proposed evidence-based practice(s).

Resources for Evidence-Based Practices (EBPs):

You will find information on EBPs at http://store.samhsa.gov/resources/term/Evidence-Based-Practice-Resource-Library. SAMHSA has developed this website to provide a simple and direct connection to websites with information about evidence-based interventions to prevent and/or treat mental and substance use disorders. The *Resource Library* provides a short description and a link to dozens of websites with relevant EBPs information – either specific interventions or comprehensive reviews of research findings.

In addition to the website noted above, you may provide information on research studies to show that the services/practices you plan to implement are evidence-based. This information is usually published in research journals, including those that focus on minority populations. If this type of information is not available, you may provide information from other sources, such as unpublished studies or documents describing formal consensus among recognized experts.

Other Federal Resources that should be addressed in the State Funding application as applicable

- CDC's Prevention for States Program (state funding): http://www.cdc.gov/drugoverdose/states/state_prevention.html
- CDC's Data-Driven Prevention Initiative (state funding): http://www.cdc.gov/drugoverdose/foa/ddpi.html
- CDC's Enhance State Surveillance of Opioid-Involved Morbidity and Mortality (state funding):http://www.cdc.gov/drugoverdose/foa/state-opioid-mm.html

Prescribing Guideline

- CDC Guideline for Prescribing Opioids for Chronic Pain: http://www.cdc.gov/drugoverdose/prescribing/guideline.html
- Guideline information for patients: http://www.cdc.gov/drugoverdose/prescribing/patients.html
- Guideline information for providers: http://www.cdc.gov/drugoverdose/prescribing/providers.html
- Other Guideline resources: http://www.cdc.gov/drugoverdose/prescribing/resources.html

[Note: Please see PART II: Appendix C – Funding Restrictions, regarding allowable costs for EBPs.]

Appendix B – Statement of Assurance

As the authorized representative of [*insert name of applicant organization*] _____, I assure SAMHSA that all participating service provider organizations meet the applicable licensing, accreditation, and certification requirements. I also attest that no program will receive funds if it denies patients the opportunity to receive services or care based on use of pharmacotherapy for opioid use disorder supplied through a qualified provider or valid prescription. If this application is funded, we will provide the SAMHSA Government Project Officer (GPO) with the following documents. I understand that if this documentation is not received by the GPO within the specified timeframe, the application will be removed from consideration for an award and the funds will be provided to another applicant meeting these requirements.

- official documentation that all mental health/substance use treatment provider organizations: 1) comply with all local (city, county) and state requirements for licensing, accreditation and certification; **OR** 2) official documentation from the appropriate agency of the applicable state, county, or other governmental unit that licensing, accreditation, and certification requirements do not exist.[4] (Official documentation is a copy of each service provider organization's license, accreditation, and certification. Documentation of accreditation will not be accepted in lieu of an organization's license. A statement by, or letter from, the applicant organization or from a provider organization attesting to compliance with licensing, accreditation, and certification or that no licensing, accreditation, certification requirements exist does not constitute adequate documentation.)

- for tribes and tribal organizations only, official documentation that all participating mental health/substance use treatment provider organizations: 1) comply with all applicable tribal requirements for licensing, accreditation, and certification; OR 2) documentation from the tribe or other tribal governmental unit that licensing, accreditation, and certification requirements do not exist.

_____ _____

Signature of Authorized Representative Date

[4] Tribes and tribal organizations are exempt from these requirements.

Appendix C – 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. Be sure to discuss these elements as they pertain to on-line counseling (i.e., telehealth) if they are applicable to your program. 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 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, children of substance abusers, pregnant women 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 1**, "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 obtain 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?

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 D – 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. These are not exhaustive but reflect types of activities and costs expected depending on community needs.

FEDERAL REQUEST

Activity	**Amount**
Personnel (SSA Level)	
MIS System	
Data Collection	
Other (to be specified)	

JUSTIFICATION: Describe the role and responsibilities of each position. Clearly describe each activity and the proposed cost.

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

FEDERAL REQUEST (TREATMENT COSTS: MUST BE AT LEAST 80% OF REMAINING AWARD AFTER ADMINISTRATIVE COSTS)

Activity	**Amount**
Outpatient Services	
Individual and Family Support	

Activity	Amount
MAT	
Peer Recovery Support Services	
Provider Training	

Please list each treatment activity along with the proposed budget for each. Some examples of allowable activities are provided.

JUSTIFICATION: Provide a detailed justification of each activity along with a proposed cost for each.

FEDERAL REQUEST PREVENTION COSTS

Please list each prevention activity along with the proposed budget for each. Some examples of allowable activities are provided.

Activity	Amount
Education	
Media Campaigns	
Training	
Naloxone Purchase	

***FOR REQUESTED FUTURE YEAR:**

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 a future year, provide your organization's personnel policy and procedures that state all employees within the organization will receive a COLA.

Appendix E – Annual Formula Based Allocation of State Targeted Response Grants

(Note: If all states/territories do not apply, funds remaining will be redistributed to all grantees proportionally based on the same formula)

State/Territory	Annual Award Amount
California	$44,749,771
Texas	$27,362,357
Florida	$27,150,403
Pennsylvania	$26,507,559
Ohio	$26,060,502
New York	$25,260,676
Michigan	$16,372,680
Illinois	$16,328,583
North Carolina	$15,586,724
Tennessee	$13,815,132
New Jersey	$12,995,621
Arizona	$12,171,518
Washington	$11,790,256
Georgia	$11,782,710
Massachusetts	$11,742,924
Indiana	$10,925,992
Kentucky	$10,528,093
Maryland	$10,036,845
Missouri	$10,015,898
Virginia	$9,762,332
Louisiana	$8,167,971
Alabama	$7,967,873
Colorado	$7,869,651
Wisconsin	$7,636,938
Oklahoma	$7,283,229
South Carolina	$6,575,623
Oregon	$6,564,425
West Virginia	$5,881,983
Nevada	$5,663,328
Utah	$5,537,458
Connecticut	$5,500,157
Minnesota	$5,379,349
New Mexico	$4,792,551
Arkansas	$3,901,297
Mississippi	$3,584,702
New Hampshire	$3,128,366

Kansas	$3,114,402
Iowa	$2,728,077
Rhode Island	$2,167,007
Maine	$2,039,029
Idaho	$2,000,000
Delaware	$2,000,000
Hawaii	$2,000,000
Nebraska	$2,000,000
Montana	$2,000,000
Alaska	$2,000,000
Wyoming	$2,000,000
Vermont	$2,000,000
District of Columbia	$2,000,000
South Dakota	$2,000,000
North Dakota	$2,000,000
Puerto Rico	$4,811,962
Guam	$258,048
Micronesia	$250,000
Virgin Islands	$250,000
Marshall Islands	$250,000
American Samoa	$250,000
Northern Marianas	$250,000
Palau	$250,000

*The Formula is based on the number of people who meet criteria for dependence or abuse of heroin or pain relievers who have not received any treatment (NSDUH 2011-2014; 70% weight) and the number of drug poisoning deaths (CDC Surveillance System; 30% weight).