Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

Improving Access to Overdose Treatment

Short Title: OD Treatment Access

(Initial Announcement)

Funding Opportunity Announcement (FOA) No. SP-17-006

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

PART 1: Programmatic Requirements

Note to Applicants: This document MUST be used in conjunction with SAMHSA's "Funding Opportunity Announcement (FOA) PART II: Administrative and Application Submission Requirements 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 July 31, 2017.**

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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 fiscal year (FY) 2017 Improving Access to Overdose Treatment (Short Title: OD Treatment Access). SAMHSA will award OD Treatment Access funds to a Federally Qualified Health Center (FQHC), Opioid Treatment Program, or practioner who has a waiver to prescribe buprenorphine to expand access to Food and Drug Administration (FDA)-approved drugs or devices for emergency treatment of known or suspected opioid overdose. The grantee will partner with other prescribers at the community level to develop best practices for prescribing and co-prescribing FDA-approved overdose reversal drugs. After developing best practices, the grantee will train other prescribers in key community sectors as well as individuals who support persons at high risk for overdose.

Funding Opportunity Title:	Improving Access to Overdose Treatment
Funding Opportunity Number:	SP-17-006
Due Date for Applications:	July 31, 2017
Anticipated Total Available Funding:	Up to $1,000,000
Estimated Number of Awards:	1
Estimated Award Amount:	Up to $1,000,000 per year
Cost Sharing/Match Required	No [See Section III-2 of this FOA for cost sharing/match requirements.]
Length of Project Period:	Up to 5 years

Eligible Applicants:	SAMHSA is limiting eligibility to Federally Qualified Health Centers (FQHC) as identified *(as defined in section 1861(aa) of the Social Security Act), opioid treatment programs under part 8 of title 42, Code of Federal Regulations, and practitioners dispensing narcotic drugs pursuant to section 303(g) of the Controlled Substances Act.* The eligibility for this grant program is statutorily defined in Section 544 of the Public Health Service Act. [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.

IMPORTANT APPLICATION INFORMATION: SAMHSA's application procedures have changed. **All applicants must register with NIH's eRA Commons in order to submit an application. This process takes up to six weeks. If you believe you are interested in applying for this opportunity, you MUST start the registration process immediately. Do not wait to start this process. SAMHSA will not be able to accept applications from applicants that do not complete the registration process. No exceptions will be made.** Applicants also must register with the System for Award Management (SAM) and Grants.gov (see PART II: Section I-1 and Section II-1 for all registration requirements). Due to the new registration and application requirements, it is strongly recommended that applicants start the registration process **six (6) weeks in advance** of the application due date.

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 fiscal year (FY) 2017 Improving Access to Overdose Treatment (Short Title: OD Treatment Access). SAMHSA will award OD Treatment Access funds to a Federally Qualified Health Center (FQHC), Opioid Treatment Program, or practioner who has a waiver to prescribe buprenorphine to expand access to Food and Drug Administration (FDA)-approved drugs or devices for emergency treatment of known or suspected opioid overdose. The grantee will partner with other prescribers at the community level to develop best practices for prescribing and co-prescribing FDA-approved overdose reversal drugs. After developing best practices, the grantee will train other prescribers in key community sectors as well as individuals who support persons at high risk for overdose.

Drug overdose deaths and opioid-involved deaths continue to increase in the United States. The majority of drug overdose deaths (more than six out of ten) involve an

opioid.[1] From 2000 to 2015 more than half a million people died from drug overdoses. 91 Americans die every day from an opioid overdose.[2]

In 2013, SAMHSA released the Opioid Overdose Prevention Toolkit to help reduce the number of opioid-related overdose deaths and adverse events. The OD Treatment Access grant program will utilize this toolkit and other resources to help the grantee train and provide resources for health care providers and pharmacists on the prescribing of drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose

The OD Treatment Access grant program will also ensure the grantee establishes protocols to connect patients who have experienced a drug overdose with appropriate treatment, including medication-assisted treatment and appropriate counseling and behavioral therapies. The OD Treatment Access grant program supports SAMHSA's Strategic Initiative: Prevention of Substance Abuse and Mental Illness.

OD Treatment Access grants are authorized under section 546 of the Public Health Service Act. This announcement addresses Healthy People 2020 Substance Abuse Topic Area HP 2020-SA.

2. EXPECTATIONS

The grantee may use up to 10 percent of funds for administrative costs and activities, including building capacity or providing training and technical assistance (TA).

No more than 20 percent of funds may be used to 1) purchase drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, for distribution under the program, and, 2) offset the co-payments and other cost sharing associated with drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

It is expected that the key staff will contribute to the programmatic development or execution of the grantee's project in a measurable way. The key staff for this program will be the Project Director and the Lead Evaluator.

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[1] Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep. ePub: 16 December 2016. DOI: http://dx.doi.org/10.15585/mmwr.mm6550e1.

[2] CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at http://wonder.cdc.gov.

Required Activities

OD Treatment Access grant funds must be used primarily to support the following activities:

- Establish a program for prescribing a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

- Train and provide resources for health care providers and pharmacists on the prescribing of drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

- Establish protocols to connect patients who have experienced a drug overdose with appropriate treatment, including medication-assisted treatment, and appropriate counseling and behavioral therapies.

- Develop a plan for sustaining the program after Federal support for the program has ended.

- Use SAMHSA's Opioid Overdose Prevention Toolkit as a guide to develop and implement a comprehensive prevention program to reduce the number of prescription drug/opioid overdose-related deaths and adverse events among cases of known or suspected opioid overdose.

No more than 20 percent of the grant award may be used for the following:

- Purchase drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, for distribution under the program.

- Offset the co-payments and other cost sharing associated with drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

Allowable Activities

SAMHSA's OD Treatment Access grant may also support the following types of activities:

- Collaboration with healthcare providers and pharmacists to educate them on overdose dangers, and to recommend that they consider providing standing orders for FDA-approved overdose reversal drugs to patients and individuals who support person at high-risk for overdose.

- Collaboration with pharmacies to distribute FDA-approved overdose reversal drugs, if permitted by state law.

- Public education on any state "Good Samaritan" laws, such as those that permit bystanders to alert emergency responders to an overdose or to administer FDA-approved overdose reversal drugs without fear of civil or criminal penalties.

Other Expectations

If your application is funded, you will be expected to develop a behavioral health disparities impact statement no later than 60 days after your award. (See PART II-Appendix E, Addressing Behavioral Health Disparities.)

Although people with behavioral health conditions represent about 25 percent of the U.S. adult population, these individuals account for nearly 40 percent[3] of all cigarettes smoked and can experience serious health consequences[4]. 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).

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

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[3] 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

[4] 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.

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 is intended to advance recovery opportunities for all Americans 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.

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 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. Examples of some of the key performance measures that the grantee may be asked to report on include:

1. Total amount of OD Treatment Access grant funds spent on purchase of FDA-approved overdose reversal drugs.

2. Number of health care providers and pharmacists on the prescribing of drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

3. Total amount of OD Treatment Access grant funds spent on co-payments and other cost sharing associate with drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

4. Number of patients who have experienced a drug overdose that are connected with appropriate treatment, including medication-assisted treatment and appropriate counseling and behavioral therapies.

This information will be gathered electronically using SAMHSA's Performance Accountability and Reporting System (SPARS); access will be provided upon award. The frequency of data reporting will be determined and communicated to the grantee following the award.

Data collection activities will help the grantee develop tracking systems to follow up with high-risk populations and increase prevention capacity. The data will be used to understand the impact of grant activities on overdose deaths and reversals and on opioid-related drug poisoning.

Performance data will be reported to the public as part of SAMHSA's Congressional Justification.

In addition to conducting performance monitoring, the grantee could be asked to participate in a cross-site evaluation of the OD Treatment Access program, and the grantee must comply with the data collection and reporting requirements mandated by SAMHSA for such an evaluation. Details regarding participation in the cross-site evaluation will be communicated only if participation is required.

2.2 Local Performance Assessment

The grantee 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 also should be used to determine whether your project is having/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 to be submitted at least biannually. Progress reports will be submitted online to your project officer for feedback/approval. In addition, the grantee will be required to submit an evaluation plan to their project officer.

At a minimum, your performance assessment should include the required performance measures identified above. You 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 sustainable 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-2.1 and 2.2 above. Be sure to include these costs in your proposed budget (see Appendix B).

2.3 Virtual Grantee Meetings

The grantee must plan to have a minimum of two people (including the Project Director and the Lead Evaluator) attend at least one joint grantee meeting in every other year of the grant. For this grant cohort, grantee meetings will likely be held in years two and four of the grant. At these meetings, the grantee will present the results of their projects and federal staff will provide technical assistance.

II. AWARD INFORMATION

Funding Mechanism: Grants

Anticipated Total Available Funding: Up to $1,000,000

Estimated Number of Awards: 1

Estimated Award Amount: Up to $1,000,000

Length of Project Period: Up to 5 years

Proposed budgets cannot exceed the amount awarded 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.

III. ELIGIBILITY INFORMATION

1. ELIGIBLE APPLICANTS

SAMHSA is limiting eligibility to FQHCs *(as defined in section 1861(aa) of the Social Security Act), opioid treatment programs as defined under part 8 of title 42, Code of Federal Regulations, and practitioners dispensing narcotic drugs pursuant to section 303(g) of the Controlled Substances Act.*

The eligibility for this grant program is statutorily defined in Section 544 of the Public Health Service Act.

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 <u>all</u> Sections of the SF-424A. Please note the following:
    - **In Line #17 of the SF-424** please input the following information: (Proposed Project: a. Start Date: 9/30/2017; b. End Date: 9/29/2022).
    - **Section A** – Budget Information – Non-Construction Programs: Use the first row only (Line 1) to report the total federal funds and non-federal funds requested for the 1st year of your project only.
    - **Section B** – Budget Categories: Use the first column only (Column 1) to report the budget category breakouts (Lines 6a through 6h) and indirect charges (Line 6j) for the total funding requested for the 1st year of your project only.

- **Section D** – Forecasted Cash Needs: Use the first column "*Total for 1st Year*" only to enter the amount requested (federal and non-federal) for Year 1 of the project period

- **Section E** – Budget Estimates of Federal Funds Needed for Balance of the Project is for the amount requested for Year 2 and Year 3.

A sample budget and justification is included in Appendix B of this document**. It is highly recommended that you use the sample budget format in Appendix B. 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 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 II-3.1, Required Application Components, and Appendix D, Biographical Sketches and Position 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 II-3.1, Required Application Components.)

- **Attachments 1 through 5**– 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, 3 and 4 combined. There are no page limitations for Attachment 2 and 5. 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. Use the Other Attachments Form from Grants.gov to upload the attachments.

  - **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

- **Attachment 4:** Letter to the SSA (if applicable; see PART II: Appendix B, Intergovernmental Review (E.O. 12372) Requirements).

- **Attachment 5:** Documentation certifying that you meet the eligibility requirements as noted in Section III and a signed Statement of Assurance as noted in Appendix C.

2. APPLICATION SUBMISSION REQUIREMENTS

Applications are due by **11:59 PM** (Eastern Time) on **July 31, 2017.**

IMPORTANT APPLICATION INFORMATION: SAMHSA's application procedures have changed. **All applicants must register with NIH's eRA Commons in order to submit an application. This process takes up to six weeks. If you believe you are interested in applying for this opportunity, you MUST start the registration process immediately. Do not wait to start this process. SAMHSA will not be able to accept applications from applicants that do not complete the registration process. No exceptions will be made.** Applicants also must register with the System for Award Management (SAM) and Grants.gov (see PART II: Section I-1 and Section II-1 for all registration requirements).

Due to the new registration and application requirements, it is strongly recommended that applicants start the registration process **six (6) weeks in advance** of the application due date.

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.

- No more than 10 percent of the grant award may be used for grantee administrative costs.

- No more than 20 percent of the grant award may be used for the purchase of drugs or devices approved or cleared under the Federal Food, Drug, and

Cosmetic Act for emergency treatment of known or suspected opioid overdose, for distribution or to offse co-payments and other cost sharing associated with the provision of FDA-approved overdose reversal drugs.

- Only FDA-approved drugs and devices may be purchased with OD Treatment Access funds.

- SAMHSA grant award funds must not be used for the same activities that are funded by HRSA, CDC, or other SAMHSA programs.

Be sure to identify these expenses in your proposed budget.

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

4. INTERGOVERNMENTAL REVIEW (E.O. 12372) REQUIREMENTS

All SAMHSA grant programs are covered under Executive Order (EO) 12372, as implemented through Department of Health and Human Services (HHS) regulation at 45 CFR Part 100. Under this Order, states may design their own processes for reviewing and commenting on proposed federal assistance under covered programs. See PART II: Appendix B for additional information on these requirements as well as requirements for the Public Health System Impact Statement.

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, 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.

- 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 (25 points)

1. Describe the projects and initiatives currently being implemented related to the prevention of overdose deaths.

2. Describe the extent to which the area to which the entity will furnish services through use of the grant is experiencing significant morbidity and mortality caused by opioid abuse. Note: Data may come from a variety of quantitative sources such as needs assessments, SAMHSA's state estimates from the 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/ CDC reports). This list is not exhaustive; applicants may submit other valid data, as appropriate for their program.

3. Describe the criteria that will be used to identify eligible patients to participate in this program.

4. Discuss the process you will use to identify sub-population disparities, if any, relating to access/use/outcomes of your provided activities, citing relevant data.

5. Document the need for an enhanced infrastructure to increase the capacity to implement, sustain, and improve effective overdose prevention and intervention services that is consistent with the purpose of the program and intent of the FOA. Include the service gaps and other problems related to the need for infrastructure development. Identify the source of the data. Documentation of need may come from a variety of qualitative and quantitative sources. Examples of data sources for the qualitative data that could be used include interviews with community stakeholders, focus groups, and case studies. Examples of data sources for the quantitative data that could be used are local epidemiologic data, state data (e.g., from needs assessments,), and/or national data (e.g., from SAMHSA's National Survey on Drug Use and Health or from National Center for Health Statistics/CDC reports, and Census data). This list is not exhaustive; applicants may submit other valid data, as appropriate for your program.

Section B: Proposed Approach (35 points)

1. Describe the purpose of the proposed project, including its goals and measurable objectives. These must relate to the intent of the FOA, SAMHSA's Strategic

Initiative: Prevention of Substance Abuse and Mental Illness, and the performance measures identified in Section D: Data Collection and Performance Measurement.

2. Describe how achievement of goals will increase system capacity to support the prevention of prescription drug/opioid overdose-related deaths.

3. Provide a chart or graph depicting a realistic timeline for the entire five (5) 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.]

4. Describe how the key activities in your timeline will be implemented, including how they will meet your infrastructure needs and improve outcomes.

5. Describe the relevant barriers and challenges you expect to encounter in the implementation of the project and how the project will work to overcome these anticipated barriers and challenges.

6. Describe the stakeholders, including agencies responsible for the applicant's substance abuse treatment system, treatment providers, and entities currently engaged in FDA-approved overdose reversal drugs prescribing, training, or distribution, and resources, including existing FDA-approved overdose reversal drugs funding sources in the catchment area that can help implement the needed infrastructure development. Describe the roles and responsibilities of these stakeholders and demonstrate their commitment to the project. Include letters of commitment from these organizations in **Attachment 1** of your application.

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. Describe how you plan to establish a program for prescribing a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

9. Discuss how you plan to develop and implement a training program for health care providers and pharmacists on the prescribing of drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

10. Describe the process you will use to purchase drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, for distribution.

11. Describe how you plan to determine which patients will need funding to offset co-payments and other cost sharing associated with drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

12. Describe how you plan to establish protocols to connect patients who have experienced a drug overdose with appropriate treatment, including medication-assisted treatment and appropriate counseling and behavioral therapies.

Section C: Staff, Management, and Relevant Experience (10 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 and Lead Evaluator, 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 Lead Evaluator.

4. Discuss how key staff has demonstrated experience and are qualified to develop the infrastructure for the population(s) to engage in activities.

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(s) 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-2.2 of this FOA and document your ability to conduct the assessment.

4. 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.

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 B – Sample Budget and Justification of this document. **It is highly recommended that you use the Sample Budget format in Appendix B. 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: Section II-3.1, Required Application Components.)

REQUIRED SUPPORTING DOCUMENTATION

Section E: Biographical Sketches and Job Descriptions

See PART II: Appendix D, 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. **Failure to include these procedures will impact the review of your application.** See Appendix A 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 CSAP National Advisory Council;
- availability of funds;
- equitable distribution of awards in terms of geography (including urban, rural, and remote settings) and balance among populations of focus and program size; and
- In accordance with 45 CFR 75.212, SAMHSA reserves the right not to make an award to an entity if that entity does not meet the minimum qualification standards as described in section 75.205(a)(2). If SAMHSA chooses not to award a fundable application, SAMHSA must report that determination to the designated integrity and performance system accessible through the System for Award Management (SAM) [currently the Federal Awardee Performance and Integrity Information System (FAPIIS)].

VI. ADMINISTRATION INFORMATION

1. REPORTING REQUIREMENTS

In addition to the data reporting requirements listed in Section I-2.3, the grantee must comply with the reporting requirements listed on the SAMHSA website at http://www.samhsa.gov/grants/grants-management/reporting-requirements. The frequency of data reporting will be determined and communicated to the grantee following the award.

VII. AGENCY CONTACTS

For questions about program issues contact:

Tonia F. Gray, MPH
Division of State Programs, Center for Substance Abuse Prevention
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane, Room 16E25B
Rockville, MD 20857
(240) 276-2492 Phone
(240) 276-2560 Fax

tonia.gray@samhsa.hhs.gov

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

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
(240) 276-1412
FOACSAP@samhsa.hhs.gov

Appendix A – 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, and 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, individuals who support persons at high risk for overdose, 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 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?

- 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 the grantee 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 B – 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 × 2 persons	$400
		Hotel	$180/night × 2 persons × 2 nights	$720
		Per Diem (meals and incidentals)	$46/day × 2 persons × 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. × 12 mo.	$600
Postage	$37/mo. × 8 mo.	$296
Laptop Computer	$900	$900
Printer	$300	$300
Projector	$900	$900
Copies	8000 copies × .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 × 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 × 12 months or $570 *Telephone @ $60 × 12 months = $720 *Indirect costs = $9,390 (negotiated with contractor)	$46,167
(4) Jane Smith	Evaluator	$40 per hour × 225 hours	12 month period	$9,000
(5) To Be Announced	Marketing Coordinator	Annual salary of $30,000 × 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. × 700 sq. ft.	$10,500
(2) Telephone	$100/mo. × 12 mo.	$1,200
(3) Client Incentives	$10/client follow up × 278 clients	$2,780
(4) Brochures	.89/brochure × 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 arm's 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 × $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 Appendix G, Standard 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-5 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**

Appendix C – Statement of Assurance

An authorized representative of the applicant organization (whose signature appears on the Face Page of the application, SF-424) must complete and sign this Assurance.

All applicant organizations must meet one of the three following eligible entities: 1) Federally Qualified Health Centers (FQHC) *(as defined in section 1861(aa) of the Social Security Act); 2) opioid treatment programs as defined under part 8 of title 42, Code of Federal Regulations; OR, 3) practitioners dispensing narcotic drugs pursuant to section 303(g) of the Controlled Substances Act.*

Please check the appropriate box below:

- ☐ FQHC) (as defined in section 1861(aa) of the Social Security Act)
- ☐ Opioid treatment programs as defined under part 8 of title 42, Code of Federal Regulations
- ☐ Practitioners dispensing narcotic drugs pursuant to section 303(g) of the Controlled Substances Act

This form must be signed and dated by an authorized representative of the applicant organization certifying that the aforementioned statement is accurate.

_____

Type or Print Name and Title

_____ _____

Signature of Individual Certifying Validity of All Information Contained in this Document

Date of Signature