

Department of Health and Human Services
Substance Abuse and Mental Health Services
Administration

**Targeted Capacity Expansion: Medication Assisted
Treatment - Prescription Drug and Opioid Addiction**
(Short Title – MAT-PDOA)
(Initial Announcement)

Funding Opportunity Announcement (FOA) No. TI-16-014

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

PART 1: Programmatic Guidance

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

Key Dates:

Application Deadline	Applications are due by May 31, 2016.
Intergovernmental Review (E.O. 12372)	Applicants must comply with E.O. 12372 if their state(s) participate(s). Review process recommendations from the State Single Point of Contact (SPOC) are due no later than 60 days after application deadline.
Public Health System Impact Statement (PHSIS)/Single State Agency Coordination	Applicants must send the PHSIS to appropriate state and local health agencies by application deadline. Comments from Single State Agency are due no later than 60 days after application deadline.

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EXECUTIVE SUMMARY

The Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment (CSAT), is accepting applications for fiscal year (FY) 2016 Targeted Capacity Expansion: Medication Assisted Treatment - Prescription Drug and Opioid Addiction (MAT-PDOA) grants. The purpose of this program is to expand/enhance access to medication-assisted treatment (MAT) services for persons with opioid use disorder seeking or receiving MAT. This program targets states identified with having the highest rates of primary treatment admissions for heroin and opioids per capita and prioritizes those states with the most dramatic increases for heroin and opioids, based on SAMHSA's Treatment Episode Data Set (TEDS): 2007 – 2013. The desired outcomes include: 1) an increase in the number of admissions for MAT; 2) an increase in the number of clients receiving integrated care/treatment; 3) a decrease in illicit opioid drug use at 6-month follow-up; and 4) a decrease in the use of prescription opioids in a non-prescribed manner at 6-month follow-up.

Funding Opportunity Title:	Targeted Capacity Expansion: Medication Assisted Treatment - Prescription Drug and Opioid Addiction (MAT-PDOA)
Funding Opportunity Number:	TI-16-014
Due Date for Applications:	May 31, 2016
Anticipated Total Available Funding:	\$11,000,000
Estimated Number of Awards:	Up to 11 awards
Estimated Award Amount:	Up to \$1 million per year for eligible states (if using a certified Electronic Health Record (EHR) system or if using a non-certified EHR system but planning to certify) Up to \$950,000 per year for eligible states (if not using a certified EHR system or using a non-certified system with no plan to certify)
Cost Sharing/Match Required	No
Length of Project Period:	Up to three years

Eligible Applicants:	<p>Eligibility is limited to 28 states identified with having the highest rates of primary treatment admissions for heroin and opioids per capita, and prioritizes those states with the most dramatic increases for heroin and opioids, as identified by SAMHSA's Treatment Episode Data Set (TEDS): 2007 – 2013. See Appendix V for a list of eligible states. The application must be submitted by the Single State Agency (SSA) for Substance Abuse within the state.</p> <p>FY 2015 MAT-PDOA grantees funded under announcement TI-15-007 are not eligible to apply for this program.</p> <p>[See Section III-1 of this FOA for complete eligibility information.]</p>
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Be sure to check the SAMHSA website periodically for any updates on this program.

I. FUNDING OPPORTUNITY DESCRIPTION

1. PURPOSE

The Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment (CSAT), is accepting applications for fiscal year (FY) 2016 Targeted Capacity Expansion: Medication Assisted Treatment - Prescription Drug and Opioid Addiction (MAT-PDOA) grants. The purpose of this program is to expand/enhance access to medication-assisted treatment (MAT) services for persons with opioid use disorder seeking or receiving MAT. This program targets states identified with having the highest rates of primary treatment admissions for heroin and opioids per capita, and prioritizes those states with the most dramatic increases for heroin and opioids, based on SAMHSA's Treatment Episode Data Set (TEDS): 2007 - 2013. The desired outcomes include: 1) an increase in the number of admissions for MAT; 2) an increase in the number of clients receiving integrated care/treatment; 3) a decrease in illicit opioid drug use at 6-month follow-up; and 4) a decrease in the use of prescription opioids in a non-prescribed manner at 6-month follow-up.

For the purpose of this FOA, integrated care/treatment is defined as the organized delivery and/or coordination of medical (including the use of Food and Drug Administration (FDA)-approved drugs [buprenorphine, methadone, naltrexone] for addiction), behavioral, social, peer, and other recovery support services provided to individual patients who have multiple healthcare needs in order to produce better overall health outcomes. MAT is defined as the use of FDA-approved opioid agonist medications (e.g., methadone, buprenorphine products, including buprenorphine/naloxone combination formulations and buprenorphine mono-product formulations) for the maintenance treatment of opioid use disorder and opioid antagonist medication (e.g., naltrexone products, including extended-release and oral formulations) in combination with behavioral therapies to prevent relapse to opioid use. MAT includes screening, assessment (which includes determination of severity of opioid use disorder, including presence of physical dependence and appropriateness for MAT), and case management. MAT is to be provided in combination with comprehensive substance use disorder treatment, including but not limited to: counseling, behavioral therapies, other clinically appropriate services in order for individuals to achieve and maintain abstinence from all opioids and heroin, and, when needed, pharmacotherapy for co-occurring alcohol use disorder. MAT is to be provided in a clinically driven, person-centered, and individualized setting.

This program addresses SAMHSA's Strategic Initiative on Health Care and Health Systems Integration. For more information on SAMHSA's six strategic initiatives, you can visit <http://www.samhsa.gov/about-us/strategic-initiatives>. The MAT-PDOA

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

The MAT-PDOA program 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 4th month of the project at the latest.

MAT-PDOA grants are authorized under Section 509 of the Public Health Service Act, as amended. This announcement addresses Healthy People 2020 Substance Abuse Topic Area HP 2020-SA.

2. EXPECTATIONS

SAMHSA expects grantees to provide an array of MAT services, integrated care, peer, and other recovery supports designed to decrease the use of opioids and reduce the risk of overdose among the population(s) of focus. Grantees are expected to prioritize treatment regimens that are less susceptible to diversion for illicit purposes.

MAT services must be provided either by the grantee and/or via sub-awards to domestic public entities (e.g., local health departments), private nonprofit entities (e.g., community-based organizations), and/or for-profit entities that are responsible for administering behavioral health services directly or through contractual agreements. These provider entities may be, but are not limited to, the following: substance use or mental disorder treatment provider agencies, health centers, Federally Qualified Health Centers (FQHCs), primary care, or other agencies that serve the population(s) of focus that can meet the requirements specified in this FOA.

Applicants must identify a minimum of two state-determined high-risk communities and partner with local governments and/or community-based organizations to address the needs in these communities. Applicants are required to use evidence-based practices (EBPs) for all screening, assessment, and interventions. [Note: Grantees are responsible for overseeing all aspects of the EBP implementation including but not limited to: training, certification, monitoring, use of assessment tools, etc.]

Required Activities:

Grantees must ensure that coordinated and integrated care provided to enrolled patients include the following **required** activities:

- Prioritization of treatment regimens that are less susceptible to diversion.

- Outreach and engagement strategies to increase participation in, and access to, MAT for diverse populations at risk for opioid use disorder.
- Assessment to determine diagnostic criteria for opioid use disorders relative to MAT, including determination of opioid dependence, a history of opioid dependence, or high risk of relapse.
- Establish and implement a plan to mitigate the risk of diversion and ensure the appropriate use/dose of medication by patients.
- Direct provision of MAT (the use of FDA-approved medications in combination with behavioral therapies) as defined in this FOA. MAT provided for only medical withdrawal (detoxification) does not qualify for the use of grant funds.
- Providing peer and other recovery support services designed to improve access and retention in MAT. [Note: Grant funds may be used to purchase such services from another provider.]
- Screening and assessment for co-occurring disorders and the coordination, or delivery when not otherwise available and accessible to the individual, of services determined to be necessary for the individual patient to achieve and sustain recovery.
- Use of the state Prescription Drug Monitoring Program (PDMP), where available, for each new patient admission throughout engagement with grant-funded services and in compliance with any relevant state rules or regulations.
- Key staff (Project Director) is expected to contribute to the programmatic development or execution of your project in a substantive and measurable way.

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. In this statement you must propose: (1) the number of individuals to be served during the grant period and identify subpopulations (i.e., racial, ethnic, sexual, and gender minority groups) vulnerable to behavioral health disparities; (2) a quality improvement plan for the use of program data on access, use, and outcomes to support efforts to decrease the differences in access to, use, and outcomes of service activities; and (3) methods for the development of policies and procedures to ensure adherence to the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care. (See PART II: Appendix F – Addressing Behavioral Health Disparities.)

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

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

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 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 disorders 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.

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.

Allowable Activities:

Other **allowable** direct services include the following types of activities:

- Direct provision of MAT and other clinically appropriate services in order for individuals to achieve and maintain abstinence from all opioids and heroin
- Limited outreach and screening to identify incarcerated individuals who are within four months from release and may benefit from MAT services upon release from a jail or detention facility.
- Education, screening, care coordination, risk reduction interventions, and counseling for HIV/AIDS, hepatitis, and other infectious diseases.

The Affordable Care Act (ACA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act place strong emphasis on the widespread adoption and implementation of electronic health record (EHR) technology. Accordingly, all SAMHSA grantees that provide clinical services to individuals are encouraged to demonstrate ongoing use of a certified EHR system in each year of their SAMHSA grant. A certified EHR is an electronic health record system that has been tested and certified by an approved Office of National Coordinator for Health Information Technology's (ONC) certifying body. Applicants may apply for \$1,000,000 annually (rather than \$950,000 annually) if one of the two conditions below is satisfied:

- Use of a certified EHR (an electronic health record system that has been tested and certified by an approved ONC certifying body).
 - You must identify the certified EHR system that you or the primary provider of clinical services associated with the grant (i.e., the grantee, sub-awardee, or sub-contractor that is expected to deliver clinical services) have adopted to manage client-level clinical information; **or**
- If your organization currently is using an EHR system that is **not certified** by ONC, demonstrate the implementation of the plan to gain certification.

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 evidence-based practice (EBP) refers to approaches to prevention or treatment that are validated by some form of documented research evidence. In [Section B](#) of your project narrative, you will need to:

- Identify the evidence-based practice(s) you propose to implement for the specific population(s) of focus.
- If you are proposing to use more than one evidence-based practice, 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.

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

SAMHSA recognizes that EBPs have not been developed for all populations and/or service settings. See [Appendix I](#) of this document for additional information about using 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. In addition to demographic data (gender, age, race, and ethnicity) on all patients served, grantees will be required to report on the following GPRA performance measures: abstinence from use, housing status, employment status, criminal justice system involvement, access to services, retention in services, and social connectedness. This information will be gathered using a uniform data collection tool provided by SAMHSA. Grantees will be required to submit data via SAMHSA's data-entry and reporting system; access will be provided upon award. An example of the type of data collection tool required can be found at <http://www.samhsa-gpra.samhsa.gov> (click 'Click Here to Enter SAIS', then click on 'Data Collection Tools/Instructions', and then click 'Services'), along with instructions for completing it. Data will be collected via a face-to-face interview using this tool at three data collection points: intake to services, six months post-intake, and at discharge. Grantees will be

expected to do a GPRA interview on all patients in their specified unduplicated target number and are also expected to achieve a six-month follow-up rate of 80 percent.

The collection of these data will enable SAMHSA to report on key outcome measures relating to the grant program. In addition to these outcomes, data collected by grantees will be used to demonstrate how SAMHSA's grant programs are reducing disparities in access, service use, and outcomes nationwide.

In addition to these measures, grantees will be expected to report biannually on their progress and performance on achieving the goals and objectives of the grant project.

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

Grantees and sub-awardees will be provided training on the data collection system and its requirements post-award.

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. 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 biannually. The performance assessment report may be included within the regular progress report or as a separate document.

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 durable were the effects?
- Was the intervention effective in maintaining the project outcomes at 6-month follow-up?

As appropriate, describe how the data, including outcome data, will be analyzed by racial/ethnic group or other demographic factors to ensure that appropriate populations are being served and that disparities in services and outcomes are minimized.

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 disparities in access, service use, and outcomes across subpopulations, including the use of the 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)?
- How many individuals were reached through the program?

The performance assessment should be completed and submitted biannually.

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-[2.2](#) and [2.3](#) above. Each sub-awardee may use up to 10 percent of its funds for data collection, performance measurement, and performance assessment (see Sections I-[2.2](#) and [2.3](#)).

2.4 Infrastructure Development (maximum 15 percent of total grant award)

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 15 percent of the total MAT-PDOA grant award for the following types of infrastructure development, if necessary to

support the direct service expansion of the grant project, and you must describe your use of grant funds for these activities in [Section A](#) of the Project Narrative.

- Developing partnerships with other service providers for service delivery.
- 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.
- Training/workforce development to help staff or other providers in the community identify substance abuse or mental health issues, or provide effective services consistent with the purpose of the grant program.

Up to 15 percent of the total grant award may be used for infrastructure expenses. Each sub-awardee may use up to 15 percent of its funds for infrastructure expenses.

2.5 Grantee Meetings

Grantees must plan to send a minimum of two people (including the Project Director) to at least one joint grantee meeting in every other year of the grant. For this grant cohort, grantee meetings will likely be held in 2017 and 2019. You must include a detailed budget and narrative for this travel in your budget. At these meetings, grantees will present the results of their projects and federal staff will provide technical assistance. Each meeting will be up to 3 days. These meetings are usually held in the Washington, D.C., area and attendance is mandatory.

II. AWARD INFORMATION

Funding Mechanism: Grant

Anticipated Total Available Funding: \$11,000,000

Estimated Number of Awards: Up to 11

Estimated Award Amount: Up to \$1 million per year for eligible states (if using a certified Electronic Health Record (EHR) system or if using a non-certified EHR system but planning to certify)

Up to \$950,000 per year for eligible states (if not using a certified EHR system or using a non-certified system with no plan to certify)

Length of Project Period: Up to three years

Proposed budgets cannot exceed \$1,000,000 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

Eligibility is limited to 28 states identified with having the highest rates of primary treatment admissions for heroin and opioids per capita, and prioritizes those states with the most dramatic increases for heroin and opioids, based on SAMHSA's Treatment Episode Data Set (TEDS): 2007 – 2013, (see Appendix V for a list of eligible states). The application must be submitted by the Single State Agency (SSA) for Substance Abuse within the state. Eligibility has been limited to these states because an analysis of TEDS data demonstrates that they represent the highest rates of primary treatment admissions with heroin and opiates per capita. In addition, SAMHSA has identified 11 of these states (see Appendix VI) that have demonstrated a dramatic increase of 40 percent or more in admissions for the treatment of opiates and heroin in recent years and will be given priority for funding. This approach is consistent with the language used to describe the program in the FY 2016 Omnibus language. FY 2015 MAT-PDOA grantees funded under announcement TI-15-007 are not eligible to apply for this program.

2. COST SHARING and MATCH REQUIREMENTS

Cost sharing/match is not required in this program.

3. EVIDENCE OF EXPERIENCE AND CREDENTIALS

SAMHSA believes that only existing, experienced, and appropriately credentialed organizations with demonstrated infrastructure and expertise will be able to provide required services quickly and effectively. You must meet three additional requirements related to the provision of services.

The three requirements are:

- A provider organization for direct client services appropriate to the grant must be involved in the proposed project (e.g., opioid treatment program, substance use disorder treatment facility, community mental health center, rural health center, federally qualified health center). The provider may be the applicant or

another organization committed to the project. More than one provider organization may be involved;

- Each service provider must have at least 2 years' experience (as of the due date of the application) providing relevant services in the geographic area(s) in which services are to be provided (official documents must establish that the organization has provided relevant services for the last 2 years); and
- Each service provider organization must comply with all applicable local (city, county) and state licensing, accreditation, and certification requirements, as of the due date of the application.

[Note: The above requirements apply to all service provider organizations. A license from an individual clinician will not be accepted in lieu of a provider organization's license. See Appendix II, Statement of Assurance, in this document.]

Following application review, if your application's score is within the funding range, the government project officer (GPO) may contact you to request that the following documentation (see Appendix II, Statement of Assurance) be sent by email, or to verify that the documentation you submitted is complete:

- a letter of commitment from every service provider that has agreed to participate in the project that specifies the nature of the participation and the service(s) that will be provided;
- official documentation that all service providers participating in the project have been providing relevant services for a minimum of 2 years prior to the date of the application in the area(s) in which the services are to be provided;
- official documentation that all participating service providers: 1) comply with all applicable 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.

If the GPO does not receive this documentation within the time specified, your application will not be considered for an award.

IV. APPLICATION AND SUBMISSION INFORMATION

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

1. ADDITIONAL REQUIRED APPLICATION COMPONENTS

- **Budget Information Form** – Use SF-424A. Fill out Sections B, C, and E of the SF-424A. A sample budget and justification is included in [Appendix IV](#) of this document. **It is highly recommended that you use the sample budget format in [Appendix IV](#). This will expedite review of your application.**
- **Project Narrative and Supporting Documentation** – The Project Narrative describes your project. It consists of Sections A through F. Sections A-F together may not be longer than 30 pages. (Remember that if your Project Narrative starts on page 5 and ends on page 35, it is 31 pages long, not 30 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 should be provided immediately following your Project Narrative in Sections G and H. Additional instructions for completing these sections and page limitations for Biographical Sketches/Job Descriptions are included in PART II-IV: Supporting Documentation. Supporting documentation should be submitted in black and white (no color).

- **Budget Justification and Narrative** – The budget justification and narrative must be submitted as file BNF when you submit your application into Grants.gov. (See PART II: Appendix B – Guidance for Electronic Submission of Applications.)
- 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>.
- **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 Attachments 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.
 - **Attachment 1:** (1) Identification of at least one experienced, licensed mental health/substance use disorder treatment provider organization; (2) a list of all direct service provider organizations that have agreed to

participate in the proposed project, including the applicant agency, if it is a treatment or prevention service provider organization; (3) letters of commitment from these direct service provider organizations; **(Do not include any letters of support. Reviewers will not consider them if you do.)** (4) the Statement of Assurance (provided in Appendix II of this announcement) signed by the authorized representative of the applicant organization identified on the first page (SF-424) of the application, that assures SAMHSA that all listed providers meet the 2-year experience requirement, are appropriately licensed, accredited and certified, and that if the application is within the funding range for an award, the applicant will send the GPO the required documentation within the specified time.

- **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:** If applying for \$1 million per year, applicants must provide documentation on the use of either a certified EHR or the implementation of a plan to gain certification. Documentation requirements are specified in the Evaluation Criteria, Section C #12. If these documents are not provided, applicants will not be eligible to receive the larger award.
- **Attachment 5:** If applicable, the 11 states listed in Appendix VI must include a statement confirming that their state has a rate of change for primary admission for heroin and non-heroin opiates between the years 2007-2013 equal to or greater than 40 percent. This information must be included to receive 10 points for Section F in the Evaluation Criteria.

2. APPLICATION SUBMISSION REQUIREMENTS

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

3. FUNDING LIMITATIONS/RESTRICTIONS

- No more than 15 percent of the total grant award may be used for developing the infrastructure necessary for expansion of services. Each sub-awardee may use up to 15 percent of its funds for infrastructure expenses.
- No more than 20 percent of the total grant award may be used for data collection, performance measurement, and performance assessment, including incentives

for participating in the required data collection follow-up, e.g., activities required in Sections [1-2.2](#) and [2.3](#) above.

- Each sub-awardee may use up to 10 percent of its funds for data collection, performance measurement, and performance assessment.
- Grant funds may not be used solely for detoxification services.

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 D – Funding Restrictions.

V. APPLICATION REVIEW INFORMATION

1. EVALUATION CRITERIA

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

- In developing the Project Narrative section of your application, use these instructions, which have been tailored to this program.
- The Project Narrative (Sections A-F) together may be no longer than 30 pages.
- You must use the six sections/headings listed below in developing your Project Narrative. **You must indicate the Section letter and number in your response or your application will be screened out, i.e., type “A-1”, “A-2”, etc., before your response to each question.** You may not combine two or more questions or refer to another section of the Project Narrative in your response, such as indicating that the response for B.2 is in C.7. Only information included in the appropriate numbered question will be considered by reviewers. Your application will be scored according to how well you address the requirements for each section of the Project Narrative.
- Although the budget and supporting documentation for the proposed project are not scored review criteria, the Review Group will consider their appropriateness after the merits of the application have been considered. (See PART II: Section IV and Appendix E).
- The number of points after each heading is the maximum number of points a review committee may assign to that section of your Project Narrative. Although scoring weights are not assigned to individual bullets, each bullet is assessed in deriving the overall Section score.

Section A: Population of Focus and Statement of Need (15 points)

1. Identify a minimum of two high-risk communities within your state where you propose implementing programs under this grant. Describe the basis upon which you determined these communities to be high-risk. Describe the nature of the need for services in these communities. Include current prevalence rates or incident data for opioid use disorder, overdose, and other consequences, such as Hepatitis C and HIV.
2. Describe the existing capacity for MAT and document the unmet need. Describe gaps in services instrumental to successful engagement and retention in treatment, and document the extent of the need for these services. 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 quantitative data that could be used are local epidemiologic data, state data from state needs assessments, SAMHSA's National Survey on Drug Use and Health (NSDUH), and/or national data from NSDUH/Centers for Disease Control and Prevention (CDC) reports, and Census data, etc. This list is not exhaustive; applicants may submit other valid data, as appropriate for your program.
3. Provide a comprehensive demographic profile of the individuals with opioid use disorders seeking or receiving MAT in the chosen high-risk communities, including race, ethnicity, sexual, and gender identity minority populations, pregnancy status, age, socioeconomic characteristics, and primary opioid used.
4. Discuss the relationship of the individuals with opioid use disorder seeking or receiving treatment to the overall populations of the selected high-risk communities. Identify sub-population disparities, if any, relating to access/use/outcomes of your provided services, including relevant data citations. Demonstrate how the program you plan to provide will address the unique needs of the high-risk community you have identified and fulfill the intent of this FOA.
5. If you plan to use grant funds for infrastructure development, describe the infrastructure changes you plan to implement, and how they will enhance/improve service effectiveness for the eligible individuals in the selected communities. If you do not plan to use grant funds for infrastructure changes, indicate so in your response.

Section B: Proposed Evidence-Based Service/Practice (20 points)

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

2. Describe your plan to prioritize treatment regimens that are less susceptible to diversion for illicit purposes.
3. Describe the Evidence-Based Practice (EBP) that will be used and justify its use for your population of focus, your proposed program, and the intent of this FOA. Describe how the proposed practice will address the following issues in the population(s) of focus: demographics (race, ethnicity, religion, gender, age, geography, and socioeconomic status); language and literacy; sexual identity (sexual orientation, gender identity); and disability. [See [Appendix I: Using Evidence-Based Practices \(EBPs\)](#).]
3. 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. Describe how the proposed practice will address the following issues in the population(s) of focus: demographics (race, ethnicity, religion, gender, age, geography, and socioeconomic status); language and literacy; sexual identity (sexual orientation, gender identity); and disability.
4. Explain how your choice of an EBP or practice will help you address disparities in service access, use, and outcomes for subpopulations.
5. If applicable, describe any modifications that will be made to the EBP or practice and the reasons the modifications are necessary.

Section C: Proposed Implementation Approach (30 points)

1. Provide a chart or graph depicting a realistic time line for the entire project period showing key activities, milestones, and responsible staff. These key activities should include the requirements outlined in [Section I-2: Expectations](#). Be sure to show that the project can be implemented and service delivery can begin as soon as possible and no later than 4 months after grant award. [Note: The time line should be part of the Project Narrative. It should not be placed in an attachment.]
2. State if the communities selected are final and that they have agreed to participate in the program. Describe how the chosen communities will implement the program and how the state will work with them to achieve the goals of the program.
3. Describe how funding of the program will be structured, i.e., will funds go to domestic public and private nonprofit entities (e.g., local governments or community-based organizations) and/or to for-profit entities (e.g., opioid treatment programs).

4. Describe how the proposed activities will be implemented and how they will adhere to the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care. For additional information go to <http://ThinkCulturalHealth.hhs.gov>.
5. Describe how you will screen and assess patients for the presence of co-occurring medical, mental, and substance use disorders and use the information obtained from the screening and assessment to provide integrated care.
6. Describe how you will provide the appropriate MAT and integrated care/treatment for eligible individuals in the selected communities.
7. Describe your plan to mitigate the risk of diversion and, as appropriate, ensure the appropriate use of medication by patients.
8. Describe how you will identify, engage, and retain eligible individuals in the selected high-risk communities (as described in section A). Discuss how the proposed approach to identify, engage, and retain eligible individuals in the selected communities considers the language, beliefs, norms, values, and socioeconomic factors of this/these population(s).
9. Identify any other organization(s) that will participate in the proposed project. Describe their roles and responsibilities and demonstrate their capacity to fulfill these responsibilities and commitment to the project. Include letters of commitment from these organizations in **Attachment 1** of your application.
10. State the unduplicated number of individuals you propose to serve (annually and over the entire project period) with grant funds, including the types and numbers of services to be provided and anticipated outcomes. Explain how you arrived at this number. You are required to include the numbers to be served by race, ethnicity, gender, and sexual orientation.
11. Provide a per-unit cost for this program. Justify that this per-unit cost is providing high quality services that are cost effective. Describe your plan for maintaining and/or improving the provision of high quality services that are cost effective throughout the life of the grant.

[NOTE: One approach might be to provide a per-person or unit cost of the project to be implemented. You can calculate this figure by: 1) taking the total cost of the project over the lifetime of the grant and subtracting 20 percent for data and performance assessment; 2) dividing this number by the total unduplicated number of persons to be served. Another approach might be to calculate a per-person or unit cost based upon your organization's history of providing a particular service(s). This might entail dividing the organization's annual expenditures on a particular service(s) by the total number of

persons/families who received that service during the year. Another approach might be to deliver a cost per outcome achieved.]

12. If you are applying for \$1 million, document how you are either utilizing a certified EHR system or implementing a plan to gain certification for an existing or new system. In order to be eligible for this award amount, you must provide the documentation identified. If you are using a certified EHR system, you must include a legible copy of a fully executed contract with your EHR vendor in **Attachment 4** of your application and a screenshot of current certification from the ONC available at <http://www.healthit.gov/policy-researchers-implementers/certified-health-it-product-list-chpl>. You must provide the full product name and the Certified Health IT Product List (CHPL) Product Number of the EHR product. If you are using a **non-certified** system, you must demonstrate that you are in the process of implementing a plan to gain certification, and provide a letter of commitment identifying the planned date for certification and a current maintenance and support contract from your EHR vendor in **Attachment 4**.

Section D: Staff and Organizational Experience (10 points)

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. If you are not partnering with any other organizations, indicate so in your response.
3. Provide a complete list of staff positions for the project, including the Project Director and other key personnel, showing the role of each, the number of years in that role, and their level of effort and qualifications. Demonstrate successful project implementation for the level of effort budgeted for the Project Director and key staff.
4. Discuss how key staff have demonstrated experience and are qualified to serve the population(s) of focus and are familiar with their culture(s) and language(s). If key staff 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 of patients in assessing, planning, and implementing your project.

Section E: Data Collection and Performance Measurement (15 points)

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

- data collection,
- management,
- analysis, and
- reporting.

If applicable, specify and justify any additional measures or instruments you plan to use for your grant project. The data collection plan must specify the staff person(s) responsible for tracking the measurable objectives that are identified in your response to question B1.

2. Describe the data-driven quality improvement process by which sub-population disparities in access/use/outcomes will be tracked, assessed, and reduced.
3. Describe your plan for conducting the local performance assessment as specified in [Section I-2.3](#) 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.

Section F: States Identified in Section V (10 points)

1. Priority will be given to states (listed in Appendix V) that have demonstrated a high rate of primary treatment admissions for heroin and opioids per capita, and prioritizes those states with the most dramatic increases for heroin and opioids, based on SAMHSA's Treatment Episode Data Set (TEDS): 2007 – 2013. These states must include a statement confirming that their state has a rate of change for primary admission for heroin and non-heroin opiates between the years 2007-2013 equal to or greater than 40 percent. In order to receive priority, this documentation must be included in **Attachment 5**.

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

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

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

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

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

SUPPORTING DOCUMENTATION

Section G: Biographical Sketches and Job Descriptions

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

Section H: 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 G of your application. See [Appendix III](#) 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 following criteria:

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

VI. ADMINISTRATION INFORMATION

1. REPORTING REQUIREMENTS

In addition to the data reporting requirements listed in Section I-2.2, grantees must comply with the reporting requirements listed on the SAMHSA website at <http://www.samhsa.gov/grants/grants-management/reporting-requirements>. Grantees are required to submit biannual reports.

VII. AGENCY CONTACTS

For questions about program issues contact:

Sherrye C. McManus, Ph.D.
 Senior Public Health Advisor
 Division of Services Improvement, Center for Substance Abuse Treatment
 Substance Abuse and Mental Health Services Administration
 (240) 276-2702
sherrye.mcmanus@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
FOACSAT@samhsa.hhs.gov

Appendix I – 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 evidence that the practice(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 evidence-based practice over other evidence-based practices.
- If applicable, justify the use of multiple evidence-based practices. Discuss how the use of multiple evidence-based practices 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:

You will find information on evidence-based practices 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 evidence-based practices 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.

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

Appendix II – Statement of Assurance

As the authorized representative of [*insert name of applicant organization*]
_____, I assure SAMHSA that all participating service provider organizations listed in this application meet the two-year experience requirement and applicable licensing, accreditation, and certification requirements. If this application is within the funding range for a grant award, 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 abuse treatment provider organizations participating in the project have been providing relevant services for a minimum of 2 years prior to the date of the application in the area(s) in which services are to be provided. Official documents must definitively establish that the organization has provided relevant services for the last 2 years; and
- official documentation that all mental health/substance abuse 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.¹ (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 abuse 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

¹ Tribes and tribal organizations are exempt from these requirements.

Appendix III – 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 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, 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 of an incentive paid for with SAMHSA discretionary grant funds exceed \$30.
- State how volunteer participants will be told that they may receive services intervention even if they do not participate in or complete the data collection component of the project.

4. Data Collection

- Identify from whom you will collect data (e.g., from participants themselves, family members, teachers, others). Describe the data collection procedures and specify the sources for obtaining data (e.g., school records, interviews, psychological assessments, questionnaires, observation or other sources). Where data are to be collected through observational techniques, questionnaires, interviews, or other direct means, describe the data collection setting.
- Identify what type of specimens (e.g., urine, blood) will be used, if any. State if the material will be used just for evaluation or if other use(s) will be made. Also, if needed, describe how the material will be monitored to ensure the safety of participants.

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

5. Privacy and Confidentiality

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

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

6. Adequate Consent Procedures

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

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

- Indicate if you will obtain informed consent from participants or assent from minors along with consent from their parents or legal guardians. Describe how the consent will be documented. For example: Will you read the consent forms? Will you ask prospective participants questions to be sure they understand the forms? Will you give them copies of what they sign?
- Include, as appropriate, sample consent forms that provide for: (1) informed consent for participation in service intervention; (2) informed consent for participation in the data collection component of the project; and (3) informed consent for the exchange (releasing or requesting) of confidential information. The sample forms must be included in **Attachment 3, “Sample Consent Forms”**, of your application. If needed, give English translations.

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

- Describe if separate consents will be obtained for different stages or parts of the project. For example, will they be needed for both participant protection in treatment intervention and for the collection and use of data?
- Additionally, if other consents (e.g., consents to release information to others or gather information from others) will be used in your project, provide a description of the consents. Will individuals who do not consent to having individually identifiable data collected for evaluation purposes be allowed to participate in the project?

7. Risk/Benefit Discussion

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

Protection of Human Subjects Regulations

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

In addition to the elements above, applicants whose projects must comply with the Human Subjects Regulations must fully describe the process for obtaining IRB approval. While IRB approval is not required at the time of grant award, these grantees will be required, as a condition of award, to provide documentation that an Assurance of Compliance is on file with the Office for Human Research Protections (OHRP). IRB approval must be received in these cases prior to enrolling participants in the project.

General information about Human Subjects Regulations can be obtained through OHRP at <http://www.hhs.gov/ohrp> or (240) 453-6900. SAMHSA-specific questions should be directed to the program contact listed in Section VII of this announcement.

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

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

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

FEDERAL REQUEST

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

JUSTIFICATION: Describe the role and responsibilities of each position.

- (1) The Project Director will provide daily oversight of the grant and will be considered key staff.
- (2) The Coordinator will coordinate project services and project activities, including training, communication and information dissemination.
- (3) The Clinical Director will provide necessary medical direction and guidance to staff for 540 clients served under this project.

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

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

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

FEDERAL REQUEST

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

JUSTIFICATION: Fringe reflects current rate for agency.

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

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

FEDERAL REQUEST

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

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

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

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

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

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

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

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

FEDERAL REQUEST

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

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

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

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

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

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

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

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

FEDERAL REQUEST

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

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

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

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

- (2) Treatment services for clients to be served based on organizational history of expenses.
- (3) Case manager is vital to client services related to the program and outcomes.
- (4) Evaluator is provided by an experienced individual (Ph.D. level) with expertise in substance abuse, research and evaluation, is knowledgeable about the population of focus, and will report GPRA data.
- (5) Marketing Coordinator will develop a plan to include public education and outreach efforts to engage clients of the community about grantee activities, and provision of presentations at public meetings and community events to stakeholders, community civic organizations, churches, agencies, family groups and schools.

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

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

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

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

FEDERAL REQUEST

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

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

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

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

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

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

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

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

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

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

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

=====

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

=====

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

Proposed Project Period

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

BUDGET SUMMARY (should include future years and projected total)

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

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

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

***FOR REQUESTED FUTURE YEARS:**

1. Please justify and explain any changes to the budget that differs from the reflected amounts reported in the 01 Year Budget Summary.
2. If a cost of living adjustment (COLA) is included in future years, provide your organization's personnel policy and procedures that state all employees within the organization will receive a COLA.

IN THIS SECTION, REFLECT OTHER FEDERAL AND NON-FEDERAL SOURCES OF FUNDING BY DOLLAR AMOUNT AND NAME OF FUNDER e.g., Applicant, State, Local, Other, Program Income, etc.

Other support is defined as funds or resources, whether federal, non-federal or institutional, in direct support of activities through fellowships, gifts, prizes, in-kind contributions or non-federal means. [Note: Please see PART II: Appendix D, Funding Restrictions, regarding allowable costs.]

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

Infrastructure Development	Year 1	Year 2	Year 3	Year 4	Year 5	Total Infrastructure 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 Infrastructure 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 V – Eligible States for FY 2016 TCE – MAT PDOA

Eligibility for these grants are limited to those states that are experiencing the highest rates of primary treatment admissions for heroin and opioids per capita for treatment of opioid use disorders (both heroin and prescription analgesics). In addition, these 28 states have not received an FY 2015 MAT-PDOA award funded under announcement TI-15-007.

This data is available in the 2014 TEDS report that can be accessed at:
<http://www.samhsa.gov/data/client-level-data-teds/reports>.

Alaska	Nevada
Arizona	New Hampshire
Arkansas	New York
California	North Carolina
Colorado	Ohio
Connecticut	Oklahoma
Delaware	Oregon
Florida	Pennsylvania
Illinois	Rhode Island
Louisiana	South Dakota
Maine	Tennessee
Michigan	Utah
Minnesota	Virginia
Montana	West Virginia

Appendix VI – States with Demonstrated Dramatic Increase in Admission for Treatment of Heroin/Opiates

The following 11 states have demonstrated a dramatic increase in admissions for the treatment of opiates and heroin in recent years based on the percentage of change from 2007 to 2013 (TEDS). These states must submit a statement confirming that their rate of change for primary admission for heroin and non-heroin opiates is equal to or greater than 40 percent to receive the additional 10 points. This information must be included in **Attachment 5** of the application.

Alaska
Arizona
Arkansas
Colorado
Florida
Minnesota
Nevada
New Hampshire
North Carolina
Rhode Island
South Dakota