Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

PPHF-2012-Cooperative Agreements for Prescription Drug Monitoring Program (PDMP) Electronic Health Record (EHR) Integration and Interoperability Expansion (PPHF-2012)

(Short Title: PDMP EHR Integration and Interoperability)

(Initial Announcement)

Request for Applications (RFA) No. TI-12-011

Catalogue of Federal Domestic Assistance (CFDA) No.: 93.748

Key Dates:

Application Deadline	**Applications are due by July 31, 2012.**

Table of Contents

EXECUTIVE SUMMARY:

The Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment is accepting applications for fiscal year (FY) 2012 PPHF-2012-Cooperative Agreements for Prescription Drug Monitoring Program (PDMP) Electronic Health Record (EHR) Integration and Interoperability Expansion (PPHF-2012). The purpose of this program is to: 1) improve real-time access to PDMP data by integrating PDMPs into existing technologies, like EHRs, in order to improve the ability of State PDMPs to reduce the nature, scope, and extent of prescription drug abuse; and 2) strengthen State PDMPs that are currently operational by providing resources to make the changes necessary to increase interoperability of State PDMPs. Grant funds will enable States to integrate their PDMPs into EHR and other health information technology systems to expand utilization by increasing the production and distribution of unsolicited reports and alerts to prescribers and dispensers of prescription data. Grant funds will also be used by States for modification of their systems to expand interoperability. This grant program will be complemented by an evaluation program conducted by the Centers for Disease Control and Prevention (CDC).

Funding Opportunity Title:	PPHF-2012-Cooperative Agreements for Prescription Drug Monitoring Program EHR Integration and Interoperability Expansion
Funding Opportunity Number:	TI-12-011
Due Date for Applications:	July 31, 2012
Anticipated Total Available Funding:	$3.6 million
Estimated Number of Awards:	Up to 8
Estimated Award Amount:	Up to $225,000 per year
Cost Sharing/Match Required	No
Length of Project Period:	2 years
Eligible Applicants:	Eligible applicants are the immediate office of the Chief Executive (e.g. Governor) in the States and U.S. Territories in the 49 States and 1 U.S. territory with existing PDMP legislation**.** [See Section III-1 of this RFA for complete eligibility information.]

I. FUNDING OPPORTUNITY DESCRIPTION

1. PURPOSE

The Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment is accepting applications for fiscal year (FY) 2012 PPHF-2012-Cooperative Agreements for Prescription Drug Monitoring Program (PDMP) Electronic Health Record (EHR) Integration and Interoperability Expansion (PPHF-2012). The purpose of this program is to: 1) improve real-time access to PDMP data by integrating PDMPs into existing technologies like EHRs, in order to improve the ability of State PDMPs to reduce the nature, scope, and extent of prescription drug abuse; and 2) strengthen State PDMPs that are currently operational by providing resources to make the changes necessary to increase interoperability of State PDMPs. Grant funds will enable States to integrate their PDMPs into EHR and other health information technology systems to expand utilization of PDMP data by increasing the production and distribution of unsolicited reports and alerts to prescribers and dispensers of prescription data. Grant funds will also be used by States to allow for modification of their systems to expand interoperability. This grant program will be complemented by an evaluation program conducted by the Centers for Disease Control and Prevention (CDC).

A Federal Expanded Interoperability and EHR Integration program is expected to produce immediate and measurable outcomes in the number of States that are able to share information. In addition, resources to States to enable their PDMPs to link electronically to Emergency Department EHRs, outpatient facility EHRs, and retail pharmacy chain dispensing systems hold the possibility to expand utilization dramatically. CDC will systematically evaluate how both measures have affected prescription drug abuse and utilization of PDMPs.

The Centers for Disease Control and Prevention (CDC) Injury Center's prescription drug overdose team will develop metrics that are consistent across the States to ensure a robust and systematic evaluation and identify appropriate data sources to support the evaluation.

<u>Background</u>

PDMPs support States' efforts to reduce abuse of controlled prescription drugs by collecting, monitoring, and analyzing electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners. PDMPs support public health and enforcement efforts and are managed under the auspices of a State, District, Commonwealth, or Territory of the United States.

PDMPs have been shown to affect practitioner opioid dosing and prescribing patterns. A 2012 study found that PDMPs mitigated opioid abuse and misuse trends. Without a PDMP in place, intentional opioid exposures reported to Poison Control Centers increased, on average, 1.9% per quarter, whereas intentional opioid exposures

increased 0.2% (P = 0.036) per quarter in States with a PDMP in place.[1] Another study showed that after Wyoming's PDMP implemented an unsolicited reporting initiative that did not require significant resources, it saw reductions in the number of people meeting criteria for filling multiple controlled substance prescriptions from different prescribers or in different pharmacies over a short period (sometimes referred to as doctor shopping) and increases in providers utilizing the PDMP.[2] Unsolicited reporting (also known as proactive reporting) is a product of a PDMP where the prescription information is analyzed by PDMP staff and questionable activities are then reported to appropriate personnel based on thresholds established by the PDMP.[3] In addition, a study in Ohio found that use of Ohio's PDMP data helped guide clinicians to prescribe more appropriate doses of opioids for patients.[4] Currently, 49 States have authorization to establish and operate a PDMP and 42 are operational. Since the inception of the Department of Justice Harold Roger's Prescription Drug Monitoring Program grant program in FY 2002, forty-seven states and 1 U.S. Territory have received support through this grant program.[5] The PDMP programs receive technical assistance support through the Alliance of States with Prescription Drug Monitoring Programs, a membership organization, and the PDMP Center of Excellence at Brandeis University which is supported by the Bureau of Justice Assistance, U.S. Department of Justice. Many stakeholders have pointed to the need to expand utilization of PDMPs and promote the appropriate sharing of information among States through system interoperability.

The PDMP EHR Integration and Interoperability Expansion grant program aims to help reduce prescription drug misuse and abuse through the education of current and future prescribers regarding appropriate prescribing practices for pain and other medications subject to abuse and misuse. Likewise, it also seeks to enhance the capacity for the exchange and analysis of EHR data to assess quality of care and improve patient outcomes.

---

[1] Reifler LM et al. Do prescription monitoring programs impact state trends in opioids abuse/misuse? Pain Medicine. 13(3):434-442. 2012

[2] PDMP Center of Excellence at Brandeis Univeristy. Trends in Wyoming PDMP Prescription History Reporting: Evidence for a Decrease in Doctor Shopping? http://www.PDMPexcellence.org/sites/all/pdfs/NFF_wyoming_rev_11_16_10.pdf. Accessed May 13, 2012.

[3] The Alliance fo States with Prescription Monitoring Programs. PMP Acronyms and Terms. http://www.pmpalliance.org/content/pmp-acronyms-terms

[4] Baehren DF, Marco, CA, Droz DE, et al. A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing Behaviors. Annals of Emergency Medicine. 56(1):19-23. 2010.

[5] U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, State Prescription Drug Monitoring Programs Questions and Answers. http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm#10

Access to PDMP data is governed by State law. In general, practitioners and pharmacists are allowed access to the data to inform their prescribing practice. Opportunities to enhance practitioner and pharmacist utilization of PDMP data include making the appropriate data more accessible by integrating the PDMP into existing systems like EHRs and pharmacy dispensing systems, with appropriate privacy protections.

Integration will allow the healthcare provider to access the PDMP data without disturbing their regular workflow and will allow the information to be accessed in as timely a manner as possible. For example, some prescribers have commented that creating a "single login" for their EHR systems and the State PDMP system would make them more likely to access PDMP data. Moreover, PDMP integration expands utilization by increasing the production and distribution of unsolicited reports and alerts to prescribers and dispensers of prescription data.

Another opportunity to enhance the utility of PDMPs is State interoperability. While 42 States have operational PDMPs, most do not have State-to-State interoperability in place. While a physician in State A can obtain prescription information on a patient in State A, that physician cannot readily obtain a patient's prescription history in State B. This limitation can be especially problematic in States that border each other since patients who are drug-seeking may try to avoid detection by crossing State lines. Providing a national network of PDMPs that are able to link to one another would help mitigate prescription drug misuse and abuse.

This initiative aligns with two of SAMHSA's Strategic Initiatives, Prevention and Health Information Technology. More information on SAMHSA's Strategic Initiatives is available at the SAMHSA website: http://www.samhsa.gov/About/strategy.aspx. It also aligns with the Administration's plan to prevent prescription drug abuse released in April 2011. In addition, this grant initiative relates to the Center for Medicare and Medicaid Services EHR Incentive Program for Stage 2 and/or Stage 3 of Meaningful Use. Specifically, the Office of the National Coordinator for Health Information Technology (ONC) and SAMHSA are developing electronic specifications and tools and developing behavioral health-related clinical quality measure specifications and standards.

PDMP EHR Integration and Interoperability cooperative agreements are authorized under Section 509 of the Public Health Service Act, as amended, and are financed by 2012 Prevention and Public Health Funds (PPHF-2012). This announcement addresses Healthy People 2020 Substance Abuse Topic Area HP 2020-SA.

2. EXPECTATIONS

Applicants that have not yet established interoperability or integration of PDMP into EHR systems must propose **implementation** of both systems to improve the State's ability to reduce prescription drug abuse. **Applicants must have an existing PDMP or have an operational PDMP by September 30, 2012, in order to receive an award under this program. An operational PDMP is one that is collecting data and responding to authorized requests for reports. If you do not currently have an operational PDMP, you must submit an assurance in Attachment 2 of your application that you will have one by September 30, 2012. (See Appendix I.)**

Applicants that do not have an operational PDMP by September 30, 2012, will not be considered for an award. Applicants that have already established interoperability with at least one State or have integrated their PDMP into an EHR system must propose **expanding** interoperability to multiple State PDMPs and **improving** real-time access to PDMP data by integrating PDMPs into existing technologies.

All grantees will be expected to be interoperable with at least eight other State PDMPs including two geographically bordering States by the end of the grant period. Moreover, all grantees will be expected to integrate their PDMP into at least one emergency room EHR, one primary care EHR, and one pharmacy system. If a grantee already has interoperability in place with at least eight other State PDMPs, then the grantee is expected to increase interoperability by at least 50%.

SAMHSA recommends that grantees notify and coordinate activities under this grant with their Single State Agency (SSA) and State Health Information Technology (HIT) Coordinator (as applicable). SAMHSA also recommends that grantees coordinate activities under this grant with other relevant EHR and HIT activities within their State, including the SAMHSA/Health Resources and Services Administration (HRSA) funded Center for Integrated Health Solutions cooperative agreements in KY, IL, ME, OK, and RI.

2.1 Required Activities

PDMP EHR integration and Interoperability Expansion grant funds must be used to support integrating PDMPs into EHRs and expanding interoperability, including but not limited to the following types of activities:

- Adopting the National Information Exchange Model (NIEM) Prescription Monitoring Program (PDMP) specification as the common specification for exchanging PDMP reports with prescriber and dispenser organizations. Applicants should adhere to the PMIX Architecture, which was supported by the Alliance for States with PMPs during the Alliance Annual Conference on June 5, 2012. In addition, grantees may use any existing hub system for interoperability, as long as it conforms with the PMIX Architecture;

- Adopting the 4.2 or higher version of American Society for Automation in Pharmacy (ASAP) standard as the electronic format for reporting, sharing, and disclosure of information. This will help ensure that gross formatting errors in identification numbers, National Drug Codes (NDC), etc., are minimized;

- Ensuring that PDMPs have a mechanism for correcting inaccuracies by physicians, pharmacists, patients, and others. As it would be difficult for PDMP staff to determine data accuracy based on a telephone call or letter from a physician or patient, a mechanism must be in place to permit error corrections when notified by dispensers and prescribers;

- Developing system-level access (application programming interface [API], Web services) to support computer-to-computer integration with Statewide PDMPs;

- Developing a common set of Data Elements and definitions, including human-readable view of the data. The Data Elements are needed to:
    - Configure a query that uniquely identifies prescribers, dispensers, and patients
    - Specify the kind of data being requested from these systems
- Developing a generic and reusable Data Element Exchange Standard that explains how to electronically define and exchange the Data Elements;
- Developing a Cross Reference between the Data Elements and other data specifications to eliminate any ambiguity in the correlation of different data definitions used by different systems;
- Ensuring that PDMP data are updated at least weekly, with the goal that the data will be updated at the point that the user requests a PDMP report so that the data reflect all prescription activity in as close to real time as possible;
- Enabling authorized dispensers and prescribers, with appropriate privacy protections, to access a minimum of six months of a patient's controlled substance prescription history;
- Enabling PDMP users to automatically sign on to the PDMP system based on their User System. Authentication should not interfere with the User's workflow;
- Developing capability of PDMP data to be integrated into EHR pharmacy dispensing systems, and other health information technologies, with appropriate privacy protections so that PDMP information is presented to users within their normal workflow;
- Providing a plan on how to achieve interoperability with at least eight other State PDMPs including two geographically bordering States Achieving interoperability with other State PDMPs;
- Providing a plan on how the PDMP will be integrated into an emergency department's EHR, a provider's EHR, and a pharmacy dispensing system and implementing the plan; and
- Modifying the PDMP system to alert dispensers and prescribers of information that will help identify and prevent misuse or unlawful diversion of controlled substances. Dispensers and prescribers could create a threshold within their EHR/HIE that would alert them when patients receive a certain number of prescriptions for controlled substances.

Since oversight of evaluation activities resides within the CDCs National Center for Injury Prevention and Control, States must be able to provide PDMP data (de-identified or anonymized) to CDC for the evaluation and participate in evaluation-related assessments and interviews.

2.2 Database Requirements

Security for PDMP information handling and for the database maintained by the State must be in place to prevent unauthorized access and disclosure of prescription and dispensing information. Minimum requirements for the security of the database can be found in Appendix G of this document.

To ensure the accuracy of the information in the database, the PDMPs of all awardees of this funding opportunity must adopt the 4.2 or higher version of the American Society for Automation in Pharmacy (ASAP) standard for electronic prescription formatting. This will help ensure that gross formatting errors in identification numbers, National Drug Codes (NDC), etc., are minimized. PDMPs must also have a mechanism for correcting inaccuracies by physicians, pharmacists, patients, and others. As it would be difficult for PDMP staff to determine data accuracy based on a telephone call or letter from a physician or patient, a mechanism must be in place to permit error corrections when notified by dispensers and prescribers.

2.3 Use and Disclosure of Information

To be eligible for funding under this announcement, State PDMP disclosures must be limited to purposes of public health and law enforcement. A State may voluntarily disclose information from the PDMP only in response to a request from one of the following five entities[6,7].

- A practitioner (or the agent thereof)
- Any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority
- The controlled substance monitoring program of another State or group of States with whom the State has established an interoperability agreement
- Any agent of HHS, a State Medicaid program, a State health department, or the DEA
- An agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's PDMP

The individual or entity requesting information from the PDMP must be authorized ("authentication") to receive the information, and the authorized individual or entity must provide a need ("certification") for the requested information. Minimum requirements for authentication and certification can be found in Appendix H of this RFA.

---

[6] Even though this grant does not specifically designate disclosures to patients as a category for minimum requirements, State disclosure to patients would depend on whether there is a law that requires the State (as opposed to the dispensers) to disclose such information to the patients. If disclosure to the patient is permissible, the patient must submit a written notarized request with the name, address, phone number, and a copy of a Government issued photo identification. The request must be submitted in person.

[7] If there are requests for information from an authority other than the ones listed and such request is made to enable the authority to perform functions authorized by law, States may disclose the information consistent with this grant and any other applicable laws.

SAMHSA recognizes that a number of States allow practitioners to enlist the assistance of agents who can retrieve patient information on behalf of the practitioner. Under this grant program, prescriber and dispenser sub-accounts are permissible; however, the master account holder (practitioner or dispenser) must be accountable for the sub-accounts, have a means to monitor the PDMP activities of all sub-accounts (e.g., documenting access by sub-account holders, audit trails, etc.), and periodically verify that the sub-account holder is still under his/her supervision.

Each PDMP must have a Master Administrator, an individual with the responsibility of controlling and monitoring access to the PDMP database. Background checks or security clearance must be conducted on the Master Administrator and any other individual with similar access to the database. The Master Administrator has the responsibility for assigning usernames and passwords to those who are granted access to PDMP data (both State employees and non-State employees who are certified to receive PDMP data notices). In addition, the Master Administrator has the ability to maintain a log that accurately details those who have accessed and received data from the PDMP database.

2.4 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 Modernization Act of 2010 (GPRA). You must document your ability to collect and report the required data in "Section E: Performance Assessment and Data" of your application. SAMHSA expects information gathered through the CDC evaluation will include but not be limited to the following:

The following GPRA measures have been established for this program:

- Number of providers registered with the PDMP;
- Number of physicians, pharmacists, and other healthcare providers using the PDMP, i.e., requesting reports;
- Number of providers from other States requesting PDMP reports;
- Number of unsolicited reports sent to licensure boards and law enforcement (where applicable);
- An increase in the number of referrals to substance abuse treatment providers as a result of using the State PDMP;
- Percentage of professional partnerships with other healthcare providers that are established (i.e., with substance abuse treatment providers and primary care providers) as a result of using the State PDMP;
- Number of unsolicited (proactive) reports sent to practitioners; and

- Number of EHR or other health information technology systems that have incorporated PDMP data

2.5 Performance Assessment

Grantees must periodically review the performance data they report to SAMHSA (as required above) and 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. 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 annually. At a minimum, your performance assessment should include the required performance measures identified above.

Outcome Questions:

- What was the effect of intervention on key outcome goals?
- What program/contextual/cultural factors were associated with outcomes?
- What individual factors were associated with outcomes?
- How durable were the effects?

Process Questions:

- How closely did implementation match the plan?
- What types of changes were made to the originally proposed plan?
- What led to the changes in the original plan?
- What effect did the changes have on the planned intervention and performance assessment?

No more than 10% of the total grant award may be used for data collection, performance measurement, and performance assessment, e.g., activities required in Sections I-2.4 and 2.5 above.

2.6 Grantee Meetings

Grantees must plan to send a minimum of one person to at least one grantee meeting in each year of the grant. You must include a detailed budget and narrative for this travel in your budget. At these meetings, the grantee will present the results of its project, and Federal staff will provide technical assistance. Each meeting will be no more than 1 day. These meetings are usually held in the Washington, D.C. area and attendance is mandatory.

II. AWARD INFORMATION

Proposed budgets cannot exceed $225,000 in total costs (direct and indirect) in each year of the proposed two-year project. Multi-year funding will depend on grantee progress in meeting project goals and objectives, timely submission of required data and reports, and compliance with all terms and conditions of award. This program is financed by 2012 Prevention and Public Health Funds (PPHF-2012).

These awards will be made as Cooperative Agreements

These awards will be made as cooperative agreements because they require substantial post-award Federal programmatic participation in the conduct of the project, including a CDC evaluation. Under these cooperative agreements, the roles and responsibilities of the grantee and SAMHSA staff are:

Role of Grantee:

- Implement and assess the program in full cooperation with SAMHSA staff members and contractors;

- Comply with all aspects of the terms and conditions of the cooperative agreement (to be issued with the award);

- Provide required reports semi-annually or as needed, including those related to the Government Performance and Results Modernization Act of 2010 (GPRA) and those required in Section VI-3 regarding PPHF funds;

- Respond to requests by the Government Project Officer for information or data related to the program; and

- Provide PDMP data (de-identified or anonymized) to CDC for evaluation purposes and provide these data and results when requested. PDMP staff must also be available for interviews related to implementation to better understand the challenges and successes related to interoperability. Examples of the information the grantee is expected to provide for evaluation purposes include:

    - Information on Patterns of PDMP Use
    - PDMP Data to Determine Prescribing and Use Patterns of Controlled Prescription Drugs that are not personally identifiable but that use common research tools and strategies to identify longitudinal trends
    - Information on Successes Related to Implementation
    - Information on Challenges with Implementation
    - Costs Associated with Implementation

- Health Outcomes[8] as a Result of Implementation

Role of SAMHSA Staff:

- Ensure that consultation services are provided to the States and regions of the country with the greatest need;
- Provide advice and assistance in developing the performance assessment
- Foster learning, collaboration and coordination with other SAMHSA-funded activities;
- Provide assistance in identifying treatment referral resources
- Provide CDC evaluation data as appropriate.
- Provide coordination with ONC and the Department of Justice.

III. ELIGIBILITY INFORMATION

1. ELIGIBLE APPLICANTS

Eligible applicants are the immediate office of the Chief Executive (e.g., Governor) in the 49 States and 1 U.S. territory (i.e., Guam) that have **enacted** legislation or regulations that permit the following:

- Implementation of a State PDMP;
- Imposition of appropriate penalties for the unauthorized use and disclosure of information maintained in the program; and
- Ability to share PDMP data (de-identified or anonymized) with CDC for evaluation purposes.

Eligibility is limited to States/Territory with enacted PDMP legislation because only these States/Territory have the capability to collect the required information and make that information available to prescribers, dispensers, and under controls, other States. PDMPs that are not actively collecting information cannot link their systems to EHRs or share information with other State PMDPs. Due to State laws establishing PDMPs, privacy, confidentiality, security, and other limitations on PDMPs, PDMP EHR

[8] Because the grant funds are only for two years, it may not be possible to see changes in nonmedical use, Emergency Department visits, substance abuse treatment admissions, or overdose deaths. Often changes in prescribing and use patterns, as captured in the PDMP, will be seen several years before changes in morbidity and mortality. In addition, data on these outcomes may not be timely enough for the evaluation period.

Integration and Interoperability grants are limited to State and applicable territorial government entities.

2. COST SHARING and MATCH REQUIREMENTS

Cost sharing/match are not required in this program.

3. OTHER

You must comply with the following three requirements, or your application will be screened out and will not be reviewed: 1) use of the SF-424 Application form; Budget Information form SF-424A; Project/Performance Site Location(s) form; Disclosure of Lobbying Activities, if applicable; and Checklist. 2) application submission requirements in Section IV-3 of this document; and 3) formatting requirements provided in Appendix A of this document.

IV. APPLICATION AND SUBMISSION INFORMATION

1. ADDRESS TO REQUEST APPLICATION PACKAGE

You may request a complete application package from SAMHSA at 1-877-SAMHSA7 [TDD: 1-800-487-4889].

You also may download the required documents from the SAMHSA Web site at http://www.samhsa.gov/grants/apply.aspx.

Additional materials available on this Web site include:

- a grant writing technical assistance manual for potential applicants;
- standard terms and conditions for SAMHSA grants;
- guidelines and policies that relate to SAMHSA grants (e.g., guidelines on cultural competence, consumer and family participation, and evaluation); and
- a list of certifications and assurances referenced in item 21 of the SF-424.

2. CONTENT AND GRANT APPLICATION SUBMISSION

2.1 Application Package

A complete list of documents included in the application package is available at http://www.samhsa.gov/Grants/ApplicationKit.aspx. This includes:

- The Face Page (SF-424); Budget Information form (SF-424A); Project/Performance Site Location(s) form; Disclosure of Lobbying Activities, if applicable; and Checklist. **Applications that do not include the required forms will be screened out and will not be reviewed.**

- Request for Applications (RFA) – Provides a description of the program, specific information about the availability of funds, and instructions for completing the grant application. This document is the RFA. The RFA will be available on the SAMHSA Web site (http://www.samhsa.gov/grants/index.aspx) and a synopsis of the RFA is available on the Federal grants Web site (http://www.Grants.gov).

You must use all of the above documents in completing your application.

2.2 Required Application Components

Applications must include the following 12 required application components:

- **Face Page** – SF-424 is the face page. [Note: Applicants must provide a Dun and Bradstreet (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. SAMHSA applicants are required to provide their DUNS number on the face page of the application. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access the Dun and Bradstreet Web site at http://www.dunandbradstreet.com or call 1-866-705-5711. To expedite the process, let Dun and Bradstreet know that you are a public/private nonprofit organization getting ready to submit a Federal grant application. In addition, you must be registered in the Central Contractor Registration (CCR) prior to submitting an application and maintain an active CCR registration during the grant funding period. **REMINDER: CCR registration expires each year and must be updated annually. It can take 24 hours or more for updates to take effect, so check for active registration well before your grant deadline. Grants.gov will not accept your application if you do not have current CCR registration. If you do not have an active CCR registration prior to submitting your paper application, it will be screened out and returned to you without review. The DUNS number you use on your application must be registered and active in the CCR. You can view your CCR registration status at http://www.bpn.gov/CCRSearch/Search.aspx and search by your organization's DUNS number. Additional information on the Central Contractor Registration (CCR) is available at https://www.bpn.gov/ccr/default.aspx].**

- **Abstract** – Your total abstract must not be longer than 35 lines. It should include the project name, population to be served (demographics and clinical characteristics), strategies/interventions, project goals and measurable objectives, including the number of people to be served annually and throughout the lifetime of the project, etc. In the first five lines or less of your abstract, write a summary of your project that can be used, if your project is funded, in publications, reporting to Congress, or press releases.

- **Table of Contents** – Include page numbers for each of the major sections of your application and for each attachment.

- **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 E of this document.

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

  The Supporting Documentation provides additional information necessary for the review of your application. This supporting documentation should be provided immediately following your Project Narrative in Sections F through I. There are no page limits for these sections, except for Section H, Biographical Sketches/Job Descriptions. Additional instructions for completing these sections are included in Section V under "Supporting Documentation." Supporting documentation should be submitted in black and white (no color).

- **Attachments 1 and 2** – 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 your Attachments. 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 and Attachment 2.

  - *Attachment 1:* Letters of Commitment/Coordination/Support

  - Attachment 2: The Statement of Assurance (provided in Appendix I of this announcement) signed by the authorized representative identified on the face page of the application, that assures SAMHSA that, if you do not currently have an operational PDMP, you will have one by September 30, 2012.

- **Project/Performance Site Location(s) Form** – The purpose of this form is to collect location information on the site(s) where work funded under this grant announcement will be performed. This form will be posted on SAMHSA's Web site with the RFA and provided in the application package.

- **Assurances** – Non-Construction Programs. You must read the list of assurances provided on the SAMHSA Web site **and check the box marked 'I Agree'** before signing the face page (SF-424) of the application. You are also required to complete the Assurance of Compliance with SAMHSA Charitable Choice Statutes and Regulations Form SMA 170. This form will be posted on SAMHSA's Web site with the RFA and provided in the application package.

- **Certifications** – You must read the list of certifications provided on the SAMHSA Web site **and check the box marked 'I Agree'** before signing the face page (SF-424) of the application.

- **Disclosure of Lobbying Activities** – Federal law prohibits the use of appropriated funds for publicity or propaganda purposes or for the preparation, distribution, or use of the information designed to support or defeat legislation pending before the Congress or State legislatures. This includes "grass roots" lobbying, which consists of appeals to members of the public suggesting that they contact their elected representatives to indicate their support for or opposition to pending legislation or to urge those representatives to vote in a particular way. You must sign and submit this form

  Additionally, Public Law 112-74 requires the following:

  a) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation of the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government itself.

  b) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than normal and recognized executive-legislative relationships or participation by an agency or officer of an State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

  c) The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending, or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale of marketing, including but not limited to the advocacy or promotion of gun control.

- **Checklist** – The Checklist ensures that you have obtained the proper signatures, assurances and certifications. If you are submitting a paper application, the Checklist should be the last page.

- **Documentation of nonprofit status** as required in the Checklist.

2.3 Application Formatting Requirements

Please refer to Appendix A, *Checklist for Formatting Requirements and Screenout Criteria for SAMHSA Grant Applications,* for SAMHSA's basic application formatting requirements. Applications that do not comply with these requirements will be screened out and will not be reviewed.

3. APPLICATION SUBMISSION REQUIREMENTS

Applications are due by **July 31, 2012**. SAMHSA provides two options for submission of grant applications: 1) electronic submission, **or** 2) paper submission. You are encouraged to apply electronically. Hard copy applications are due by **5:00 PM** (Eastern Time). Electronic applications are due by **11:59 PM** (Eastern Time). **Applications may be shipped using only Federal Express (FedEx), United Parcel Service (UPS), or the United States Postal Service (USPS).** You will be notified by postal mail that your application has been received.

Note: If you use the USPS, you must use Express Mail.

SAMHSA will not accept or consider any applications that are hand carried or sent by facsimile.

Submission of Electronic Applications

If you plan to submit electronically through Grants.gov it is very important that you read thoroughly the application information provided in Appendix B, "Guidance for Electronic Submission of Applications."

Submission of Paper Applications

If you are submitting a paper application, you must submit an original application and 2 copies (including attachments). The original and copies must not be bound and nothing should be attached, stapled, folded, or pasted. Do not use staples, paper clips, or fasteners. You may use rubber bands.

Send applications to the address below:

For United States Postal Service:

Diane Abbate, Director of Grant Review

Office of Financial Resources

Substance Abuse and Mental Health Services Administration

Room 3-1044

1 Choke Cherry Road

Rockville, MD **20857**

Change the zip code to **20850** if you are using FedEx or UPS.

Do not send applications to other agency contacts, as this could delay receipt. Be sure to include "**PDMP**" and **"RFA #TI-12-011**" in item number 12 on the face page (SF-424) of any paper applications. If you require a phone number for delivery, you may use (240) 276-1199.

Your application must be received by the application deadline or it will not be considered for review. Please remember that mail sent to Federal facilities undergoes a security screening prior to delivery. You are responsible for ensuring that you submit your application so that it will arrive by the application due date and time.

If an application is mailed to a location or office (including room number) that is not designated for receipt of the application and, as a result, the designated office does not receive your application by the deadline, your application will be considered late and ineligible for review.

SAMHSA accepts electronic submission of applications through http://www.Grants.gov. Please refer to Appendix B for "Guidance for Electronic Submission of Applications."

4. FUNDING LIMITATIONS/RESTRICTIONS

Cost principles describing allowable and unallowable expenditures for Federal grantees, including SAMHSA grantees, are provided in the following documents, which are available at http://www.samhsa.gov/grants/management.aspx:

- Educational Institutions: 2 CFR Part 220 and OMB Circular A-21
- State, Local and Indian Tribal Governments: 2 CFR Part 225 (OMB Circular A-87)
- Nonprofit Organizations: 2 CFR Part 230 (OMB Circular A-122)
- Hospitals: 45 CFR Part 74, Appendix E

In addition, SAMHSA's grant recipients for this program must comply with the following funding restrictions:

- No more than 10% of the grant award may be used for data collection, performance measurement, and performance assessment expenses.

SAMHSA grantees must also comply with SAMHSA's standard funding restrictions, which are included in Appendix C.

V. APPLICATION REVIEW INFORMATION

1. EVALUATION CRITERIA

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

- In developing the Project Narrative section of your application, use these instructions, which have been tailored to this program.
- The Project Narrative (Sections A-E) together may be no longer than 25 pages.
- You must use the five sections/headings listed below in developing your Project Narrative. You must place the required information in the correct section, **or it will not be considered.** Your application will be scored according to how well you address the requirements for each section of the Project Narrative.
- Reviewers will be looking for evidence of cultural competence in each section of the Project Narrative, and will consider how well you address the cultural competence aspects of the evaluation criteria when scoring your application. SAMHSA's guidelines for cultural competence can be found on the SAMHSA Web site at http://www.samhsa.gov/grants/apply.aspx at the bottom of the page under "Resources for Grant Writing."
- The Supporting Documentation you provide in Sections F-I and Attachments 1 and 2 will be considered by reviewers in assessing your response, along with the material in 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 (10 points)

- Indicate if your State has established interoperability or integration of your PDMP into EHR systems.
- If it has not, discuss the need to implement either system to improve your State's ability to reduce prescription drug use. Explain why interoperability is needed and how use and effectiveness will be improved by linking to EHR systems.
- Describe the service gaps, barriers, and other problems related to the need for enhanced interoperability and EHR integration.

Section B: Proposed Approach (30 points)

- Describe the purpose of the proposed project, including a clear statement of its goals and objectives. These must relate to the performance measures you identify in Section E, Performance Assessment and Data.

- Describe how achievement of goals will expand interoperability and enable PDMP integration into EHR.

- Describe the proposed project activities, how they meet your PDMP needs, and how they relate to your goals and objectives. These should align with Section I-2, Expectations.

- Provide a chart or graph depicting a realistic time line for the entire project period showing key activities, milestones, and responsible staff. [Note: The time line should be part of the Project Narrative. It should not be placed in an attachment.]

- Describe any other organizations that will participate and their roles and responsibilities. Demonstrate their commitment to the project. Include letters from these community organizations in **Attachment 1** of your application.

- Describe the potential barriers to successful conduct of the proposed project and how you will overcome them.

- Describe your plan to continue the project after the funding period ends. Also describe how program continuity will be maintained when there is a change in the operational environment (e.g., staff turnover, change in project leadership) to ensure stability over time.

- Describe your plan to analyze other similar initiatives and propose how the activities under this grant may complement and not duplicate these other initiatives, including initiatives supported by the Department of Justice and the Office of the National Coordinator for Health Information Technology at HHS.

- Attest that activities supported by awards received through this funding opportunity will comply with the Database Requirements found in Section I-2.2 and Appendix G.

Section C: Interoperability and EHR Integration (30 points)

- Describe how you will adopt the NIEM PMP specification as the common specification for exchanging PDMP reports with prescriber and dispenser organizations.

- Describe how you will adopt ASAP 4.2 or higher as the electronic format for reporting, sharing, and disclosure of information.

- Describe how the use of grant funds will expand interoperability to at least eight other State PDMPs, including two geographically bordering States. Include a description of the manner in which the State PDMP will achieve interoperability with other State PDMPs. If you plan on enhancing your systems to provide real-time access or other system upgrades, please specify in your proposal.

- Describe how you will integrate PDMPs into emergency department EHRs, primary care EHRs and pharmacy dispensing systems with appropriate privacy protections.

- Describe your plan to meet established criteria for the availability of information and limitation on access to program personnel.

- Describe your processes and criteria for granting access to the PDMP, and describe procedures that will ensure information in the database is accurate.

Section D: Staff, Management, and Relevant Experience (15 points)

- Discuss the capability and experience of the applicant organization and other participating organizations with similar projects and populations.

- Provide a complete list of staff positions for the project, including the Project Director and other key personnel, showing the role of each and their level of effort and qualifications.

- Discuss how key staff have demonstrated experience and are qualified to carry out grant activities.

- Describe the resources available for the proposed project (e.g., facilities, equipment).

Section E: Performance Assessment and Data (15 points)

- Document your ability to collect and report on the required performance measures as specified in Section I-2.4 of this RFA. Describe your plan for data collection, management, analysis and reporting. Specify and justify any additional measures you plan to use for your grant project.

- Describe how data will be used to manage the project and assure continuous quality improvement. Describe how information related to process and outcomes will be routinely communicated to program staff.

- Describe your plan for conducting the performance assessment as specified in Section I-2.5 of this RFA and document your ability to conduct the assessment.

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.

SUPPORTING DOCUMENTATION

Section F: Literature Citations. This section must contain complete citations, including titles and all authors, for any literature you cite in your application.

Section G: Budget Justification, Existing Resources, Other Support. 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. Be sure to show that no more than 10% of the total grant award will be used for data collection, performance measurement, and performance assessment. **Specifically identify the items associated with these costs in your budget**. An illustration of a budget and narrative justification is included in Appendix E of this document.

Section H: Biographical Sketches and Job Descriptions.

- Include a biographical sketch for the Project Director and other key positions. Each sketch should be 2 pages or less. If the person has not been hired, include a position description and/or a letter of commitment with a current biographical sketch from the individual.

- Include job descriptions for key personnel. Job descriptions should be no longer than 1 page each.

- Information on what you should include in your biographical sketches and job descriptions can be found in Appendix D of this document.

Section I: 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 I of your application. See Appendix F for guidelines on these requirements.

2. REVIEW AND SELECTION PROCESS

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

Decisions to fund a grant are based on:

- the strengths and weaknesses of the application as identified by peer reviewers;

- when the individual award is over $150,000, approval by the Center for, Substance Abuse Treatment's National Advisory Council;

- availability of funds; and

- distribution of awards in terms of geography

VI. ADMINISTRATION INFORMATION

1. AWARD NOTICES

You will receive a letter from SAMHSA through postal mail that describes the general results of the review of your application, including the score that your application received.

If you are approved for funding, you will receive an **additional** notice through postal mail, the Notice of Award (NoA), signed by SAMHSA's Grants Management Officer. The Notice of Award is the sole obligating document that allows you to receive Federal funding for work on the grant project.

If you are not funded, you will receive notification from SAMHSA.

2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

- In order for your application to be funded, you must have an operational PDMP by September 30, 2012. An operational PDMP is one that is collecting data and responding to authorized requests for reports. If you do not currently have an operational PDMP, you must submit an assurance in **Attachment 2** of your application that you will have one by September 30, 2012. (See Appendix I.) Applicants that do not have an operational PDMP by September 30, 2012, will not be considered for an award.

- If your application is funded, you must comply with all terms and conditions of the grant award. SAMHSA's standard terms and conditions are available on the SAMHSA Web site at http://www.samhsa.gov/grants/management.aspx.

- If your application is funded, you must also comply with the administrative requirements outlined in 45 CFR Part 74 or 45 CFR Part 92, as appropriate. For more information see the SAMHSA Web site (http://www.samhsa.gov/grants/management.aspx).

- Depending on the nature of the specific funding opportunity and/or your proposed project as identified during review, SAMHSA may negotiate additional terms and conditions with you prior to grant award. These may include, for example:

  - actions required to be in compliance with confidentiality and participant protection/human subjects requirements;

  - requirements relating to additional data collection and reporting;

  - requirements relating to participation in a cross-site evaluation;

  - requirements to address problems identified in review of the application; or

  - revised budget and narrative justification.

- If your application is funded, you will be held accountable for the information provided in the application relating to performance targets. SAMHSA program officials will consider your progress in meeting goals and objectives, as well as your failures and strategies for overcoming them, when making an annual recommendation to continue the grant and the amount of any continuation award. Failure to meet stated goals and objectives may result in suspension or termination of the grant award, or in reduction or withholding of continuation awards.

- Grant funds cannot be used to supplant current funding of existing activities. "Supplant" is defined as replacing funding of a recipient's existing program with funds from a Federal grant.

- In an effort to improve access to funding opportunities for applicants, SAMHSA is participating in the U.S. Department of Health and Human Services "Survey on Ensuring Equal Opportunity for Applicants." This survey is included in the application package for SAMHSA grants and is posted on the SAMHSA Web site at http://www.samhsa.gov/grants/downloads/SurveyEnsuringEqualOpp.pdf. You are encouraged to complete the survey and return it, using the instructions provided on the survey form.

3. 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 Web site at http://www.samhsa.gov/Grants/ApplicationKit.aspx. Recipients are responsible for contacting their HHS grant/program managers for any needed clarifications.

Responsibilities for Informing Sub-recipients:

- Recipients agree to separately identify to each sub-recipient and document at the time of sub-award and at the time of disbursement of funds, the Federal award number, any special CFDA number assigned for 2012 PPHF fund purposes, and amount of PPHF funds.

Reporting Requirements under Section 201 of the 2012 Enacted Appropriations Bill for the Prevention and Public Health Fund, Public Law 112-74:

This award requires the recipient to complete projects or activities which are funded under the 2012 PPHF and to report on use of PPHF funds provided through this award. Information from these reports will be made available to the public.

Recipients awarded a grant, cooperative agreement, or contract from such funds with a value of $25,000 or more shall produce reports on a semi-annual basis with a reporting cycle of January 1 – June 30 and July 1 – December 31; and e-mail such reports (in 508 compliant format) to the HHS grants management official assigned to the grant or cooperative agreement no later than 20 calendar days after the end of each reporting period (i.e. July 20 and January 20, respectively). Recipient reports shall reference the

notice of award number and title of the grant or cooperative agreement, and include a summary of activities undertaken and identify any sub-grants or sub-contracts awarded (including the purpose of the award and the identity of the [sub] recipient).

VII. AGENCY CONTACTS

For questions about program issues contact:

Jinhee J. Lee, Pharm.D.
Project Officer
Division of Pharmacologic Therapies
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road
Room 7 -1028
Rockville, Maryland 20857
(240) 276-0545
jinhee.lee@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
1 Choke Cherry Road
Room 7-1079
Rockville, Maryland 20857
(240) 276-1412
eileen.bermudez@samhsa.hhs.gov

Appendix A – Checklist for Formatting Requirements and Screenout Criteria for SAMHSA Grant Applications

SAMHSA's goal is to review all applications submitted for grant funding. However, this goal must be balanced against SAMHSA's obligation to ensure equitable treatment of applications. For this reason, SAMHSA has established certain formatting requirements for its applications. **If you do not adhere to these requirements, your application will be screened out and returned to you without review.**

- Use the SF-424 Application form; Budget Information form SF-424A; Project/Performance Site Location(s) form; Disclosure of Lobbying Activities, if applicable; and Checklist.
- Applications must be received by the application due date and time, as detailed in Section IV-3 of this grant announcement.
- You must be registered in the Central Contractor Registration (CCR) prior to submitting your application. The DUNS number used on your application must be registered and active in the CCR prior to submitting your application.
- Information provided must be sufficient for review.
- Text must be legible. Pages must be typed in black ink, single-spaced, using a font of Times New Roman 12, with all margins (left, right, top, bottom) at least one inch each.
- (For Project Narratives submitted electronically, see separate requirements in Appendix B, "Guidance for Electronic Submission of Applications.")
- To ensure equity among applications, page limits for the Project Narrative cannot be exceeded.
- Paper must be white paper and 8.5 inches by 11.0 inches in size.

To facilitate review of your application, follow these additional guidelines. Failure to adhere to the following guidelines will not, in itself, result in your application being screened out and returned without review. However, the information provided in your application must be sufficient for review. Following these guidelines will help ensure your application is complete, and will help reviewers to consider your application.

- If you are submitting a paper application, the application components required for SAMHSA applications should be submitted in the following order:
  - Face Page (SF-424)
  - Abstract
  - Table of Contents

- Budget Information Form (SF-424A)
- Project Narrative and Supporting Documentation
- Attachments
- Project/Performance Site Location(s) Form
- Disclosure of Lobbying Activities (Standard Form LLL, if applicable)
- Checklist
- Documentation of nonprofit status as required in the Checklist

- Applications should comply with the following requirements:
  - Provisions relating to confidentiality and participant protection specified in Appendix F of this announcement.
  - Budgetary limitations as specified in Sections I, II, and IV-5 of this announcement.
  - Documentation of nonprofit status as required in the Checklist.

- Black ink should be used throughout your application, including charts and graphs. Pages should be typed single-spaced with one column per page. Pages should not have printing on both sides. Pages with printing on both sides run the risk of an incomplete application going to peer reviewers, since scanning and copying may not duplicate the second side. **Materials with printing on both sides will be excluded from the application and not sent to peer reviewers.**

- Pages should be numbered consecutively from beginning to end so that information can be located easily during review of the application. The abstract page should be page 1, the table of contents should be page 2, etc. The four pages of SF-424 are not to be numbered. Attachments should be labeled and separated from the Project Narrative and budget section, and the pages should be numbered to continue the sequence.

- The page limits for Attachments stated in Section IV-2.2 of this announcement should not be exceeded.

- Send the original application and two copies to the mailing address in Section IV-3 of this document. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. You may use rubber bands. Do not use heavy or lightweight paper or any material that cannot be copied using automatic copying machines. Odd-sized and oversized attachments such as posters will not be copied or sent to reviewers. Do not include videotapes, audiotapes, or CD-ROMs.

Appendix B – Guidance for Electronic Submission of Applications

If you would like to submit your application electronically, you may search http://www.Grants.gov for the downloadable application package by the funding announcement number (called the opportunity number) or by the Catalogue of Federal Domestic Assistance (CFDA) number. You can find the CFDA number on the first page of the funding announcement.

You must follow the instructions in the User Guide available at the http://www.Grants.gov apply site, on the Help page. In addition to the User Guide, you may wish to use the following sources for technical (IT) help:

- By e-mail: support@Grants.gov
- By phone: 1-800-518-4726 (1-800-518-GRANTS). The Grants.gov Contact Center is available 24 hours a day, 7 days a week, excluding Federal holidays.

If this is the first time you have submitted an application through Grants.gov, you must complete three separate registration processes before you can submit your application. Allow at least two weeks (10 business days) for these registration processes, prior to submitting your application. The processes are: 1) DUNS Number registration; 2) Central Contractor Registry (CCR) registration; and 3) Grants.gov registration (Get username and password.). REMINDER: CCR registration expires each year and must be updated annually. It can take 24 hours or more for updates to take effect, so check for active registration well before your grant deadline. Grants.gov will not accept your application if you do not have active CCR registration. The DUNS number you use on your application must be registered and active in the CCR. You can view your CCR registration status at **https://www.bpn.gov/CCRSearch/Search.aspx** and search by your organization's DUNS number. Additional information on the Central Contractor Registration (CCR) is available at **https://www.bpn.gov/ccr/default.aspx**. Be sure the person submitting your application is properly registered with Grants.gov as the Authorized Organization Representative (AOR) for the specific DUNS number cited on the SF-424 (face page). See the Organization Registration User Guide for details at the following Grants.gov link: http://www.grants.gov/applicants/get_registered.jsp.

Please also allow sufficient time for enter your application into Grants.gov. When you submit your application you will receive a notice that your application is being processed and that you will receive two e-mails from Grants.gov. within the next 24-48 hours. One will confirm receipt of the application in Grants.gov and the other will indicate that the application was either successfully validated by the system (with a tracking number) or rejected due to errors. It will also provide instructions that if you do not receive a receipt confirmation **and** a validation confirmation or a rejection e-mail within 48 hours, you must contact Grants.gov directly. Please note that it is incumbent on the applicant to monitor their application to ensure that it is successfully received and validated by

Grants.gov. **If your application is not successfully validated by Grants.gov it will not be forwarded to SAMHSA as the receiving institution.**

It is strongly recommended that you prepare your Project Narrative and other attached documents using Microsoft Office 2007 products (e.g., Microsoft Word 2007, Microsoft Excel 2007, etc.). If you do not have access to Microsoft Office 2007 products, you may submit PDF files. Directions for creating PDF files can be found on the Grants.gov Web site. Use of file formats other than Microsoft Office 2007 or PDF may result in your file being unreadable by our staff.

The Abstract, Table of Contents, Project Narrative, Supporting Documentation, Budget Justification, and Attachments must be combined into 4 separate files in the electronic submission. **If the number of files exceeds 4, the electronic application will not convey properly to SAMHSA.**

Formatting requirements for SAMHSA e-Grant application files are as follows:

- Project Narrative File (PNF): The PNF consists of the Abstract, Table of Contents, and Project Narrative (Sections A-E) in this order and numbered consecutively.
- Budget Narrative File (BNF): The BNF consists of only the budget justification narrative.
- Other Attachment File 1: The first Other Attachment file will consist of the Supporting Documentation (Sections F- I) in this order and lettered consecutively.
- Other Attachment File 2: The second Other Attachment file will consist of the Attachments (Attachment 1and 2) in this order and numbered consecutively.

  Scanned images must be scanned at 75 dpi/ppi resolution and saved as a jpeg or pdf file. Using a higher resolution setting or different file type could result in a rejection of application.

Formatting requirements for SAMHSA grant applications are described in Appendix A of this announcement. These requirements also apply to applications submitted electronically, with the following exceptions only for Project Narratives submitted electronically in Microsoft Word. These requirements help ensure the accurate transmission and equitable treatment of applications.

- Text legibility: Use a font of Times New Roman 12, line spacing of single space, and all margins (left, right, top, bottom) of at least one inch each. Adhering to these standards will help to ensure the accurate transmission of your document.

- Amount of space allowed for Project Narrative: The Project Narrative for an electronic submission may not exceed **12,875** words. **If the Project Narrative for an electronic submission exceeds the word limit, the application will be**

screened out and will not be reviewed. To determine the number of words in your Project Narrative document in Microsoft Word, select file/properties/statistics.

Be sure to scan all images at 75 dpi and save as a jpeg or pdf file. Also, be sure to label each file according to its contents, e.g., "Project Narrative", "Budget Narrative", "Other Attachment 1", and "Other Attachment 2". **If the number of files exceeds the 4 allowable files, the electronic application will not convey properly to SAMHSA.**

With the exception of standard forms in the application package, all pages in your application should be numbered consecutively. **Documents containing scanned images must also contain page numbers to continue the sequence.** Failure to comply with these requirements may affect the successful transmission and consideration of your application.

Applicants are strongly encouraged to submit their applications to Grants.gov early enough to resolve any unanticipated difficulties prior to the deadline. After you electronically submit your application, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number. It is important that you retain this number. **Receipt of the tracking number is the only indication that Grants.gov has successfully received and validated your application. If you do not receive a Grants.gov tracking number, you may want to contact the Grants.gov help desk for assistance.**

Appendix C – Funding Restrictions

SAMHSA grant funds must be used for purposes supported by the program and may not be used to:

- Pay for any lease beyond the project period.
- Provide services to incarcerated populations (defined as those persons in jail, prison, detention facilities, or in custody where they are not free to move about in the community).
- Pay for the purchase or construction of any building or structure to house any part of the program. (Applicants may request up to $75,000 for renovations and alterations of existing facilities, if necessary and appropriate to the project.)
- Provide residential or outpatient treatment services when the facility has not yet been acquired, sited, approved, and met all requirements for human habitation and services provision. (Expansion or enhancement of existing residential services is permissible.)
- Pay for housing other than residential mental health and/or substance abuse treatment.
- Provide inpatient treatment or hospital-based detoxification services. Residential services are not considered to be inpatient or hospital-based services.
- Make direct payments to individuals to induce them to enter prevention or treatment services. However, SAMHSA discretionary grant funds may be used for non-clinical support services (e.g., bus tokens, child care) designed to improve access to and retention in prevention and treatment programs.
- Make direct payments to individuals to encourage attendance and/or attainment of prevention or treatment goals. However, SAMHSA discretionary grant funds may be used for non-cash incentives of up to $20 to encourage attendance and/or attainment of prevention or treatment goals when the incentives are built into the program design and when the incentives are the minimum amount that is deemed necessary to meet program goals. SAMHSA policy allows an individual participant to receive more than one incentive over the course of the program. However, non-cash incentives should be limited to the minimum number of times deemed necessary to achieve program outcomes. A grantee or treatment or prevention provider may also provide up to $20 cash or equivalent (coupons, bus tokens, gifts, child care, and vouchers) to individuals as incentives to participate in required data collection follow up. This amount may be paid for participation in each required interview.

- Food is generally unallowable unless it's an integral part of a conference grant or program specific, e.g., children's program, residential.

- Funds may not be used to distribute sterile needles or syringes for the hypodermic injection of any illegal drug.

- Pay for pharmacologies for HIV antiretroviral therapy, sexually transmitted diseases (STD)/sexually transmitted illnesses (STI), TB, and hepatitis B and C, or for psychotropic drugs.

SAMHSA will not accept a "research" indirect cost rate. The grantee must use the "other sponsored program rate" or the lowest rate available.

Additionally, Public Law 112-74 requires the following:

a) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation of the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government itself.

b) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than normal and recognized executive-legislative relationships or participation by an agency or officer of an State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

c) The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending, or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale of marketing, including but not limited to the advocacy or promotion of gun control.

Appendix D – Biographical Sketches and Job Descriptions

Biographical Sketch

Existing curricula vitae of project staff members may be used if they are updated and contain all items of information requested below. You may add any information items listed below to complete existing documents. For development of new curricula vitae include items below in the most suitable format:

1. Name of staff member
2. Educational background: school(s), location, dates attended, degrees earned (specify year), major field of study
3. Professional experience
4. Honors received and dates
5. Recent relevant publications
6. Other sources of support [Other support is defined as all funds or resources, whether Federal, non-federal, or institutional, available to the Project Director/Program Director (and other key personnel named in the application) in direct support of their activities through grants, cooperative agreements, contracts, fellowships, gifts, prizes, and other means.]

Job Description

1. Title of position
2. Description of duties and responsibilities
3. Qualifications for position
4. Supervisory relationships
5. Skills and knowledge required
6. Personal qualities
7. Amount of travel and any other special conditions or requirements
8. Salary range
9. Hours per day or week

Appendix E– 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				
(2) Grant Coordinator				
(3) Clinical Director				

JUSTIFICATION: Describe the role and responsibilities of each position.

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)

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

FEDERAL REQUEST

Component	Rate	Wage	Cost
FICA			
Workers Compensation			
Insurance			

JUSTIFICATION: Fringe reflects current rate for agency.

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

C. Travel: Explain need for all travel other than that required by this application. Local travel policies prevail.

FEDERAL REQUEST

Purpose of Travel	Location	Item	Rate	Cost

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

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

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).

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

FEDERAL REQUEST

Item(s)	Rate	Cost
General office supplies		
Postage		
Laptop Computer		
Printer		
Projector		
Copies		

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

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

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

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

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

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*		
(2) Telephone		

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) is required for all projects allocating rent costs.**

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

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: http://www.samhsa.gov then click on Grants – Grants Management – Contact Information – Important Offices at SAMHSA and DHHS - HHS Division of Cost Allocation – Regional Offices.

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

8% of personnel and fringe

==========

TOTAL DIRECT CHARGES:

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

INDIRECT CHARGES:

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

TOTALS: (sum of 6i and 6j)

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

==========

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

Provide the total proposed Project Period and Federal funding as follows**:**

Proposed Project Period

a. Start Date:	**09/30/2012**	b. End Date:	**09/29/2014**

BUDGET SUMMARY (should include future years and projected total)

Category	Year 1	Year 2*				Total Project Costs
Personnel						
Fringe						
Travel						
Supplies						
Contractual						
Other						
Total Direct Charges						
Indirect Charges						
Total Project Costs						

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)

*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.

Appendix F – 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 must address the two elements below. If one or both is not applicable or relevant to your proposed project, simply state that they are not applicable and indicate why.

1. 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.

2. 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.**

Appendix G – Minimum Requirements for Security of the Database

Information from the PDMPs must be stored and protected in an electronic manner and must, at a minimum, be equivalent to the standards set forth in regulations promulgated under section 262 of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191; 110 Stat. 2033). This would include the technical safeguards standards of the HIPAA Security Rule under 45 CFR 164.312. In addition, this grant does not supersede the requirements of the Federal substance abuse confidentiality law (42 U.S.C. 290dd-2) and regulations under 42 CFR Part 2.

At a minimum, PDMP databases must be stored on separate servers that are physically secured with firewall protections or use of other technology and/or system architecture that is certified to provide the same or more protection as databases which are stored on separate servers or separate networks, physically secured with firewall protection. These databases must provide for backup and restore needs in the event of disasters. These backup systems must also conform to the same security requirements.

The information from these electronic databases is released to certain approved entities. The transmission of this information must also be secure to prevent inadvertent disclosure. The Administrator understands that many of these releases are conducted by web-based applications. At a minimum, such web-based releases are encrypted with 128-bit Secure Socket Logic technology. In examining the existing level of security of the program, programs should consider the factors below when evaluating the security level of their PDMP:

- What individuals or organizations have direct access to the internal data systems? Is such access monitored or audited to ensure accountability?
- What kind of encryption, authentication, and access control mechanisms are used? Are they adequate?
- Are regular, encrypted database backups performed to external media and stored in an offsite location?
- Is sensitive data contained in systems that are accessible via the Internet? If so, are appropriate measures in place to prevent outside access?
- Have penetration tests or other security validation assessments been conducted?
- Are security and privacy protection policies adequate? Are the PDMP-supporting systems up to date in enforcing those requirements?
- What additional steps are needed to protect Protected Health Information (PHI)?

Appendix H – Minimum Requirements for Authentication and Certification[9,10]

1. As part of the authentication process, a practitioner (or the agent thereof, including pharmacist) must initially submit a hard copy written, signed and notarized request to the designated State agency, which in turn, verifies the information before providing a username and password to the practitioner. The request must include the practitioner's name and date of birth, a corresponding DEA registration number, and State medical license number. States may propose an alternate plan for authentication. This alternate authentication plan must provide a reasonable assurance that the applicant is properly identified before the username and password is assigned. For example, some States cross reference the PDMP application information against information provided by practitioners as part of the State license and registration process. Practitioners must undergo a renewal process at least every three years. States may submit an alternate plan to ensure that the practitioner information is valid and accurate for renewal purposes. In soliciting information from the State PDMP database, the practitioner must certify that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient. Such requests/certifications can be conducted by secure web-based procedures. This minimum requirement procedure must be utilized at the time of funding by States that are establishing and implementing a PDMP. Procedures for grandfathering or reapplication for already authenticated users must be in place.

2. A local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority must submit a hard copy written signed and notarized request to the designated State agency, which in turn, verifies the information before providing a username and password to the practitioner. The request must include the agency name and the individuals who will be authorized to request access within the agency. The requestor must certify for each disclosure that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV

[9] Although this grant does not specifically designate disclosures to patients as a category for minimum requirements, State disclosure to patients would depend on whether there is a law that requires the State (as opposed to the dispensers) to disclose such information to the patients. If disclosure to the patient is permissible, the patient must submit a written notarized request with the name, address, phone number, and a copy of a Government issued photo identification. The request must be submitted in person.

[10] If there are requests for information from an authority other than the ones listed and such request is made to enable the authority to perform functions authorized by law, States may disclose the information consistent with this grant authentication and certification procedures and any other applicable laws.

substance, and that such information will further the purpose of the investigation or assist in the proceeding. Such requests shall include an active case number or provide other assurance that the request is pursuant to the law enforcement agency's official duties and responsibilities.

3. The PDMP of another State or group of States must have an established, signed interoperability agreement in place before interstate patient information sharing (but not anonymous, aggregate data) can proceed. Interoperability agreements that meet the requirements of the individual State PDMPs and the general requirements should be acceptable. This means, for example, that if the ultimate information requester is a law enforcement entity, each State PDMP must meet the authentication and certification requirements listed in item 2.

4. Any agent of the Department of Health and Human Services, a State Medicaid program, a State health department, or the DEA must submit a written request to the State PDMP that identifies the summary statistics sought; such entities can only request aggregate, non-individually identifiable data. The requesting Department, program, administration, etc., must certify that the requested information is necessary for research to be conducted by such department, program, or administration, respectively, and the intended purposes of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature. In addition, aggregate data requests must be a State-wide summary for at least a three-month period.

Appendix I – Statement of Assurance

As the authorized representative of [*insert name of applicant organization*] _____, I assure SAMHSA that the State PDMP will be operational prior to or at the time of the grant award (September 30, 2012) **and** the State PDMP will meet all of the expectations listed in Section I-2 of the RFA. I understand that if these requirements are not met 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.

_____ _____

Signature of Authorized Representative Date