

**Department of Health and Human Services**

**Substance Abuse and Mental Health Services Administration**

**National All Schedules Prescription Electronic Reporting of 2005 Act  
Program Grants**

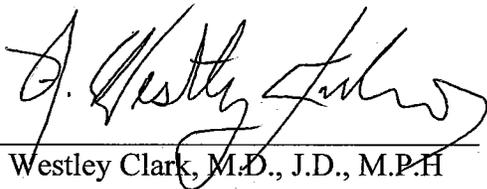
**Short Title: NASPER**

**Request for Applications (RFA) No. TI-09-F1**

**Catalogue of Federal Domestic Assistance (CFDA) No.: 93.975**

**Key Date:**

<b>Application Deadline</b>	<b>Applications are requested as soon as possible, but must be received by July 27, 2009.</b>
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## Table of Contents

I.	FUNDING OPPORTUNITY DESCRIPTION .....	4
1.	INTRODUCTION .....	4
2.	EXPECTATIONS .....	4
II.	AWARD INFORMATION.....	9
III.	ELIGIBILITY INFORMATION .....	9
1.	ELIGIBLE APPLICANTS .....	9
2.	COST SHARING and MATCH REQUIREMENTS.....	10
3.	OTHER .....	10
IV.	APPLICATION AND SUBMISSION INFORMATION.....	10
1.	ADDRESS TO REQUEST APPLICATION PACKAGE .....	10
2.	CONTENT AND FORM OF APPLICATION SUBMISSION .....	10
3.	SUBMISSION DATES AND TIMES .....	12
4.	INTERGOVERNMENTAL REVIEW (E.O. 12372) REQUIREMENTS .....	13
5.	FUNDING LIMITATIONS/RESTRICTIONS.....	13
6.	OTHER SUBMISSION REQUIREMENTS .....	14
V.	APPLICATION REVIEW INFORMATION .....	15
1.	EVALUATION CRITERIA .....	15
2.	REVIEW AND SELECTION PROCESS .....	18
VI.	AWARD ADMINISTRATION INFORMATION .....	18
1.	AWARD NOTICES.....	18
2.	ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS.....	18
3.	REPORTING REQUIREMENTS .....	19
VII.	AGENCY CONTACTS.....	20
	Appendix A – Checklist for Formatting Requirements and Screenout Criteria for SAMHSA Grant Applications .....	21
	Appendix B – Guidance for Electronic Submission of Applications .....	23
	Appendix C – Assurance of Compliance with Provisions of NASPER .....	25
	Appendix D – Funding Restrictions.....	26
	Appendix E – Sample Budget and Justification (no match required).....	27
	Appendix F – Minimum Requirements for Security of the Database.....	31
	Appendix G – Minimum Requirements for Authentication and Certification .....	32

## **EXECUTIVE SUMMARY:**

As authorized by Public Law 109-60 of the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER), the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) announces the availability of FY 2009 funds for National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) Program grants. The NASPER program provides funding for the establishment and implementation or improvement of a State controlled substance monitoring program.

**Funding Opportunity Title:** National All Schedules Prescription Electronic Reporting Act of 2005 Program

**Funding Opportunity Number:** TI-09-F1

**Due Date for Applications:** July 27, 2009

**Anticipated Total Available Funding:** \$2 million

**Estimated Award Amount:** \$21,467-\$113,129 (Based on the assumption that all 50 States and the District of Columbia are approved for a NASPER grant; the award range will increase if fewer States apply).

**Length of Project Period:** Up to 1 year

**Eligible Applicants:** Eligible applicants are immediate office of the Chief Executive (e.g., Governor) in the States and the District of Columbia.  
[See Section III-1 of this RFA for complete eligibility information.]

# I. FUNDING OPPORTUNITY DESCRIPTION

## 1. INTRODUCTION

As authorized by Public Law 109-60 of the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER), the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) announces the availability of Fiscal Year 2009 funds for National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) Program grants. The NASPER program provides funding for the establishment and implementation or improvement of a State controlled substance monitoring program.

## 2. EXPECTATIONS

The National All Schedules Prescription Electronic Reporting Act of 2005, enacted on August 11, 2005, created a formula grant program under the authority of Secretary for Health and Human Services for State controlled substance monitoring programs (PMPs). The intent of this authorization is to foster the establishment or enhancement of State-administered PMPs in order to ensure that health care providers and law enforcement officials have access to accurate, timely prescription history information. In addition, the expansion and establishment of PMPs has the potential for assisting in the early identification of patients at risk for addiction.

NASPER establishes the authority for a grant program with the Secretary, HHS, where a State may submit an application to establish and implement a new controlled substance monitoring program or to make improvements upon an existing State controlled substance monitoring program. In addition, the legislation includes provisions for standardization that will enable and require the sharing of information between States with programs. The State application for a grant must include measures to prevent unauthorized disclosures. This is important as State PMPs include patient health information on both individuals who receive and fill controlled substance prescriptions.

In order to satisfy the minimum requirements of NASPER, applicants who are applying to **improve** a State PMP must:

- Provide a budget cost estimate for establishment or enhancement of the controlled substance monitoring program;
- Comply with established criteria for security for information handling and for the database maintained by the State;
- Provide an agreement to adopt health information interoperability standards, including health vocabulary and messaging standards;
- Establish criteria for meeting uniform electronic format requirements;
- Comply with established criteria for availability of information and limitation on access to program personnel;

- Comply with established criteria for access to the database, and procedures to ensure that information in the database is accurate;
- Comply with established criteria for the use and disclosure of information, including a description of the certification process to be applied to requests for information;
- Describe the penalties for the unauthorized use and disclosure of information maintained in the State controlled substance monitoring program in violation of applicable State law or regulation;
- Provide assurances of compliance with all other requirements of NASPER or a Statement describing why such compliance is not feasible or is contrary to the best interests of public health in your State (See Appendix C of this RFA). This assurance must be provided in **Appendix 1** of your application; and
- Provide a plan that will enable the State PMP to achieve interoperability with at least one other State PMP.

Applicants who are applying to **establish and implement** a State PMP must address the first eight bullets above in addition to the following two bullets:

- Provide information on the relevant State laws, policies, and procedures, if any, regarding purging of information from the database; and
- Provide assurances of compliance with all other requirements of NASPER in **Appendix 1** of your application (See Appendix C of this RFA).

## 2.1 Database Requirements

State PMPs contain personal patient health information on both individuals who receive and fill controlled substance prescriptions and those who have had a controlled substance dispensed to them beyond a 48-hour supply. PMPs must collect identification information on prescribers and dispensers, as well as the types and quantities of the prescribed/dispensed substances. Security for information handling and for the database maintained by the State must be in place to prevent unauthorized access and disclosure of this information. Minimum requirements for the security of the database can be found in Appendix F.

To ensure the accuracy of the information in the database, **existing** PMPs must adopt the 1995 or higher version of the American Society for Automation in Pharmacy (ASAP) standard for electronic prescription formatting. PMPs that are being **established and implemented** must adopt the most current ASAP version (i.e., ASAP 2007). This will help ensure that gross formatting errors in identification numbers, NDC codes, etc., are minimized. PMPs must also have a mechanism for correcting inaccuracies by physicians, pharmacists, patients, and others. As it would be difficult for PMP 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.

## 2.2 Interoperability

States must adopt health information interoperability standards that are consistent with the Integrated Justice Information System's NIEM XML standard. In addition, States that are improving their existing PMP through the NASPER grant must also provide a plan on how to achieve interoperability with at least one other State PMP including geographically bordering States. A letter of agreement to adopt these standards must be included in **Appendix 2** of your application.

## 2.3 Reporting Requirements

States receiving NASPER grants must adopt the 1995 or higher version of ASAP for existing PMPs or the most current ASAP version (i.e., ASAP 2007) for new PMPs as the electronic format for reporting, sharing, and disclosure of information and must require dispensers to report to their State the following information:

- Drug Enforcement Administration (DEA) Registration Number (or other identifying number used in lieu of such Registration Number) of the dispenser;
- DEA Registration Number (or other identifying number used in lieu of such Registration Number) and name of the practitioner who prescribed the drug;
- Name and address of the ultimate user;
- Identification of the drug by a national drug code (NDC) number;
- Quantity dispensed;
- Number of refills ordered;
- Whether the drug was dispensed as a refill of a prescription or as a first-time request;
- Date of the dispensing;
- Date of origin of the prescription; and
- Other information as may be required by State law.

This information must be reported from the dispenser to the State after each dispensing of a controlled substance in the State to an ultimate user not later than 1 week after the date of dispensing. However, a State is not required to report this information in the following cases:

- The direct administration of a controlled substance to the body of an ultimate user
- The dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less

If a State has an existing PMP that cannot comply with the above requirements, a statement must be provided in **Appendix 1** detailing why such compliance is not feasible or is contrary to the best interests of public health in the State (See Appendix C of this RFA).

## 2.4 Use and Disclosure of Information

Disclosures from a State PMP are to be limited to purposes of public health and law enforcement. A State may voluntarily disclose information from the PMP only in response to a request from one of the following five entities<sup>1,2</sup>:

- 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 the Department of Health and Human Services, a State Medicaid program, a State health department, or the Drug Enforcement Administration (DEA)
- An agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's PMP

The individual or entity requesting information from the PMP 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 G of this RFA.

In addition, States receiving a grant must establish a program to notify practitioners and dispensers of information that will help identify and prevent unlawful diversion or misuse of controlled substances. At a minimum, States must establish and articulate thresholds for notifying prescribers and dispensers. For example, one possible threshold for notifying prescribers and dispensers is when an individual has filled five or more controlled substance prescriptions from five different prescribers or five different dispensers in the State within a six month period. NASPER may permit States to disseminate other forms of information from their systems. Some States have developed screening tools for prescribers to screen for patients in need of an intervention. A State PMP may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines the information in their PMP database indicates unlawful diversion or abuse of a controlled substance.

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<sup>1</sup> Even though NASPER 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.

<sup>2</sup> 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 NASPER and any other applicable laws.

Each PMP must have a Master Administrator, an individual with the responsibility of controlling and monitoring access to the PMP database. This individual has the responsibility for assigning usernames and passwords to those who are granted access to PMP data (both State employees and non-State employees who are certified to receive PMP 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 PMP database. This required log would need to detail who accessed the system, but not necessarily each record received. Background checks or security clearance must be conducted on the Master Administrator and any other individual with similar access to the database.

## **2.5 Advisory Council**

A State may establish an advisory council to assist in the establishment, implementation, or improvement of a State PMP. In establishing this advisory council, a State should consult with appropriate professional boards and other interested parties. However, funds received under this grant cannot be used for the operations of the advisory council.

## **2.6 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 Act (GPRA). You must document your ability to collect and report the required data in "Section K: Performance Assessment and Data" of your application. A limited subset of the data required in "Section I-2.3 Reporting Requirements" of this RFA will be collected in compliance with GPRA.

## **2.7 Performance Assessment**

Grantees must also periodically review the performance data they report to SAMHSA 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 semi-annually.

Suggested areas for assessment include:

- Number of licensed prescribers, dispensers, individuals authorized to conduct investigations, researchers, and other individuals of the State agency or entity of another State agency that were trained in the use of the State controlled substance monitoring program;
- Number of licensed prescribers and dispensers trained formally in coordinating and sharing data;

- Number of reports generated for each type of requester (solicited) and non-requester (unsolicited); and
- Number of individuals that filled prescriptions from 5 or more pharmacies and/or 5 or more prescribers.

## II. AWARD INFORMATION

<b>Funding Mechanism:</b>	Grant
<b>Anticipated Total Available Funding:</b>	\$ 2 million
<b>Estimated Award Amount<sup>3</sup>:</b>	\$21,467-\$113,129
<b>Length of Project Period:</b>	Up to 1 year

The allocation formula allots to each State approved for an award a minimum amount equal to 1 percent of the funds appropriated for grants. From the remaining funds, each State approved for an award shall receive an additional amount that is proportional to the number of pharmacies in the State divided by the total number of pharmacies in all approved States.

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>).

## III. ELIGIBILITY INFORMATION

### 1. ELIGIBLE APPLICANTS

Eligible applicants are the immediate office of the Chief Executive (e.g., Governor) in the States and the District of Columbia, that have enacted legislation or regulations that permit the following:

- Implementation of a State controlled substance monitoring program; and
- Imposition of appropriate penalties for the unauthorized use and disclosure of information maintained in the program.

**NOTE: The aforementioned legislation or regulations must be enacted by the time of submission of this grant application.**

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<sup>3</sup> Based on the assumption that all States and the District of Columbia will be approved for a NASPER grant.

## 2. COST SHARING and MATCH REQUIREMENTS

Cost sharing/match is not required in this program.

## 3. OTHER

### 3.1 Additional Eligibility Requirements

**You must comply with the following requirements, or your application will be screened out and will not be reviewed:** use of the PHS-5161-1 application form; application submission requirements in Section IV-3 of this document; and 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 kit from the SAMHSA Health Information Network 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 v2.

### 2. CONTENT AND FORM OF APPLICATION SUBMISSION

#### 2.1 Application Kit

SAMHSA application kits include the following documents:

- PHS-5161-1 – Includes the face page (SF 424 v2), budget forms, assurances, certification, and checklist. You must use the PHS-5161-1. **Applications that are not submitted on the required application form 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 CSAT Division of Pharmacologic Therapies Web site (<http://www.dpt.samhsa.gov/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 required ten application components (Face Page, Abstract, Table of Contents, Budget Form, Project Narrative and Supporting Documentation, Appendices, Assurances, Certifications, Disclosure of Lobbying Activities, and Checklist).

- **Face Page** – SF 424 v2 is the face page. This form is part of the PHS-5161-1. [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.]
- **Abstract** – Your total abstract should not be longer than 35 lines. In the first five lines or less of your abstract, clearly state if the application is to establish and implement or improve a PMP and provide 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 appendix.
- **Budget Form** – Use SF 424A, which is part of the PHS-5161-1. 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** – The Project Narrative describes your project. It consists of Sections A through K. Sections A-K 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.
- **Appendices** – Use only the appendices listed below. If your application includes any appendices not required in this document, they will be disregarded. Do not use the appendices to extend or replace any of the sections of the Project Narrative. Reviewers will not consider them if you do. Please label the appendix.
  - *Appendix 1*: Assurance of Compliance with Provisions of NASPER

○ *Appendix 2: Letter of Agreement to Adopt Health Information Interoperability Standards*

- **Assurances** – Non-Construction Programs. You must read the list of assurances provided on the SAMHSA Web site or in the application kit before signing the face page (SF 424 v2) of the application.
- **Certifications** – You must read the list of certifications provided on the SAMHSA Web site or in the application kit before signing the face page (SF 424 v2) of the application.
- **Disclosure of Lobbying Activities** – You must submit Standard Form LLL found in the PHS-5161-1. 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. If no lobbying is to be disclosed, mark N/A on the form.
- **Checklist** – Use the Checklist found in PHS-5161-1. 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.

### 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. SUBMISSION DATES AND TIMES

Applications are due by close of business on **July 27, 2009**. Hard copy applications are due by 5:00 PM (EST). Electronic applications are due by 11:59 PM (EST). **Hand carried applications will not be accepted. 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.

**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 will not accept or consider any applications sent by facsimile.

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

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

This program is not subject to the intergovernmental review requirements of E.O. 12372, as implemented through DHHS regulations at 45 CFR Part 100. However, individual States may require coordination procedures similar to those specified in E.O. 12372.

Under E.O. 12372, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs. Certain jurisdictions have elected to participate in the EO process and have established State Single Points of Contact (SPOCs). A current listing of SPOCs is included in the application kit and can be downloaded from the Office of Management and Budget (OMB) Web site at [www.whitehouse.gov/omb/grants/spoc.html](http://www.whitehouse.gov/omb/grants/spoc.html).

- Check the list to determine whether your State participates in this program.
- If your State participates, contact your SPOC as early as possible to alert him/her to the prospective application(s) and to receive any necessary instructions on the State's review process.
- For proposed projects serving more than one State, you are advised to contact the SPOC of each affiliated State.

The SPOC should send any State review process recommendations to the following address within 60 days of the application deadline. **For United States Postal Service:** Barbara Orlando, Division of Grants Management, Substance Abuse and Mental Health Services Administration 1 Choke Cherry Road, Room 7-1109, Rockville, MD **20857**. ATTN: SPOC – Funding Announcement No. **TI-09-F1**. Change the zip code to **20850** if you are using another delivery service.

#### **5. 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>:

- Institutions of Higher Education: OMB Circular A-21

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- State and Local Governments and federally Recognized Indian Tribal Governments: OMB Circular A-87
- Nonprofit Organizations: OMB Circular A-122
- Hospitals: 45 CFR Part 74, Appendix E

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

- Grant funds must be used for purposes supported by the program.
- Any lease arrangements in association with the proposed project utilizing NASPER funds may not be funded by NASPER beyond the project period nor may the portion of the space leased with NASPER funds be used for purposes not supported by the grant.
- Grant funds may not be used to pay for the purchase or construction of any building or structure to house any part of the grant program.

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

## **6. OTHER SUBMISSION REQUIREMENTS**

You may submit your application in either electronic or paper format:

### **Submission of Electronic Applications**

SAMHSA accepts electronic submission of applications through <http://www.Grants.gov>. Electronic submission is voluntary. No review points will be added or deducted, regardless of whether you use the electronic or paper format.

To submit an application electronically, you must use the <http://www.Grants.gov> apply site. You will be able to download a copy of the application package from <http://www.Grants.gov>, complete it off-line, and then upload and submit the application via the Grants.gov site. E-mail submissions will not be accepted.

**Please refer to Appendix B for detailed instructions on submitting your application electronically.**

## **Submission of Paper Applications**

You must submit an original application and 2 copies (including appendices). The original and copies must not be bound. Do not use staples, paper clips, or fasteners. Nothing should be attached, stapled, folded, or pasted.

Send applications to the address below:

### **For United States Postal Service:**

Barbara Orlando  
Division of Grants Management  
Substance Abuse and Mental Health Services Administration  
One Choke Cherry Road  
Room 7-1091  
Rockville, MD 20857  
**Attn: NASPER Formula Grant**

Change the zip code to 20850 if you are using another delivery service.

Do not send applications to other agency contacts, as this could delay receipt. Be sure to include "NASPER and TI-09-F1" in item number 12 on the face page (SF 424 v2) of any paper applications. If you require a phone number for delivery, you may use (240) 276-1422.

**SAMHSA will not accept or consider any applications sent by facsimile.**

## **V. APPLICATION REVIEW INFORMATION**

### **1. EVALUATION CRITERIA**

Applications for the State controlled substance monitoring program will be reviewed against the requirements listed below for developing the Project Narrative (Sections A-K). **These are to be used instead of the "Program Narrative" instructions found in the PHS-5161-1.** Reviewers will review the applications on the quality of responses to the requirements listed below. Deficiencies may delay or prevent grant award.

- Your responses should be as brief as possible, but must convey the requested information. Some information may best be presented in tabular format.
- The Project Narrative (Sections A-K) together may be no longer than 25 pages.
- The Documentation you provide in Appendices 1 and 2 will be considered by reviewers in assessing your response, along with the material in the Project Narrative.

**Section A: Overview of Proposed Controlled Substance Monitoring Program (PMP)**

- Clearly state whether you are proposing to establish and implement or improve upon an existing PMP.
- Describe your plan to establish and implement a PMP or the improvements you propose to make to an existing PMP.

**Section B: Budget Cost Estimate**

- Provide a budget cost estimate for the proposed project. For additional information on preparing Budget Cost Estimate, please refer to Appendix E in Section B.

**Section C: Security**

- Describe your plan to meet established criteria for security (see Appendix F of the RFA) for information handling and for the database maintained by the State, including appropriate encryption technology or other appropriate technology to protect the security of information.

**Section D: Interoperability**

- Describe how you will adopt health information interoperability standards, including health vocabulary and messaging standards. States must adopt health information interoperability standards that are consistent with the IJIS project NIEM XML standard. Include a letter of agreement to adopt these standards in **Appendix 2** of your application.
- If you are proposing to **improve** upon an existing PMP, provide a plan that will enable your State PMP to achieve interoperability with at least one other State PMP.

**Section E: Uniform Electronic Format**

- Describe your plan to meet established criteria for uniform electronic format requirements as described in Section I-2.3 Reporting Requirements of this RFA.

**Section F: Availability of Information and Access**

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

**Section G: Access to Database and Quality Control**

- Describe your processes and criteria for granting access to the substance monitoring database, and describe procedures that will ensure information in the database is accurate.
- Describe the roles and responsibilities of any PMP staff including the Master Administrator.

## **Section H: Use and Disclosure of Information**

- Describe your guidelines and policies for the use and disclosure of information to: practitioners; 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 the Department of Health and Human Services, a State Medicaid program, a State health department, or the Drug Enforcement Administration; and an agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's controlled substance monitoring program.
- Describe the certification procedures for authorized requestors of information from the database.
- Describe your plan to establish a program to notify practitioners and dispensers of information that will help identify and prevent unlawful diversion or misuse of controlled substances.
- Provide a plan to establish and articulate thresholds for notifying prescribers and dispensers.

## **Section I: Penalties**

- Describe the penalties for the unauthorized use and disclosure of information maintained in the State controlled substance monitoring program in violation of applicable State law or regulation.

## **Section J: Additional Requirements for Applicants Proposing to Establish and Implement a PMP**

- Provide information on relevant State laws, policies, and procedures, if any, regarding purging of information from the database.

## **Section K: Performance Assessment and Data**

- Describe your plan to collect and report Government Performance and Results Act (GPRA) data. Remember to include evaluation and data collection costs in your requested budget.
- Describe your plan for conducting the performance assessment as specified in Section I-2.7 of this RFA and document your ability to conduct the assessment.

## **2. REVIEW AND SELECTION PROCESS**

### **AWARD CRITERIA**

Decisions to award State allotments will be based on a determination that all of the documents and attachments described under "Required Application Components" have been included and meet program requirements.

## **VI. AWARD ADMINISTRATION INFORMATION**

### **1. AWARD NOTICES**

After your application has been reviewed, your Government Project Officer (GPO) and/or your Grants Management Specialist will contact you to discuss the results of the review and obtain any additional information in writing. After all outstanding issues/concerns have been successfully addressed, a Notice of Award (NoA) will be issued. The NoA is the sole obligated document that allows the grantee to receive Federal funding for work on the grant project. It is sent by postal mail and is addressed to the contact person listed on the face page of the application.

### **2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS**

- 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 at <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.
- 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.

### **3. REPORTING REQUIREMENTS**

#### **3.1 Progress and Financial Reports**

As a SAMHSA grantee, you will be required to submit semi-annual and final progress and financial reports. The format and requirements for completing and submitting the reports will be provided to you by your Government Project Officer (GPO).

OMB Circular A-133 provides audit requirements for all entities. An audit is required for all entities which expend \$500,000 or more of Federal funds in each fiscal year. For questions and information concerning the submission process, please visit <http://harvester.census.gov/sac/> or you may call the Federal Audit Clearinghouse (888-222-9907).

#### **3.2 Publications**

If you are funded under this grant program, you are required to notify your GPO and SAMHSA's Publication Clearance Officer (240-276-1884) of any materials based on the SAMHSA-funded grant project that are accepted for publication.

In addition, SAMHSA requests that grantees:

- Provide the GPO and SAMHSA Publications Clearance Officer with advance copies of publications.
- Include acknowledgment of the SAMHSA grant program as the source of funding for the project.
- Include a disclaimer stating that the views and opinions contained in the publication do not necessarily reflect those of SAMHSA or the U.S. Department of Health and Human Services and should not be construed as such.

SAMHSA reserves the right to issue a press release about any publication deemed by SAMHSA to contain information of program or policy significance to the substance abuse treatment/substance abuse prevention/mental health services community.

## VII. AGENCY CONTACTS

For questions regarding grants management and budget issues, contact:

Barbara Orlando  
Division of Grants Management  
Substance Abuse and Mental Health Services Administration  
1 Choke Cherry Road  
Room 7-1091  
Rockville, MD 20857  
(240) 276-1422  
[barbara.orlando@samhsa.hhs.gov](mailto:barbara.orlando@samhsa.hhs.gov)

For questions regarding program issues, contact:

Jennifer Fan  
Project Officer  
1 Choke Cherry Road  
Room 2-1084  
Rockville, Maryland 20857  
(240) 276-1759  
[jennifer.fan@samhsa.hhs.gov](mailto:jennifer.fan@samhsa.hhs.gov)

Nicholas Reuter  
1 Choke Cherry Road  
Room 2-1063  
Rockville, Maryland 20857  
(240) 276-2716  
[nicholas.reuter@samhsa.hhs.gov](mailto:nicholas.reuter@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 PHS-5161-1 application form.
- Applications must be received by the application due date and time, as detailed in Section IV-3 of this grant announcement.
- 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 Section IV-6 of this announcement under "Submission of Electronic 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.*

- The application components required for SAMHSA applications should be included and submitted in the following order.
  - Face Page (Standard Form 424 v2, which is in PHS-5161-1)
  - Abstract
  - Table of Contents
  - Budget Form (Standard Form 424A, which is in PHS-5161-1)
  - Project Narrative and Supporting Documentation
  - Appendices
  - Disclosure of Lobbying Activities (Standard Form LLL, which is in PHS-5161-1)
  - Checklist (a form in PHS-5161-1)

- Applications should comply with the following requirements:
  - Provisions specified in Section V-1 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 PHS-5161-1.
- Pages should be typed single-spaced in black ink with one column per page. Pages should not have printing on both sides.
- 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 Standard form 424 v2 are not to be numbered. Appendices should be labeled and separated from the Project Narrative and budget section, and the pages should be numbered to continue the sequence.
- Send the original application and two copies to the mailing address in Section IV-6 of this document. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. 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 help:

- **By e-mail:** [support@Grants.gov](mailto:support@Grants.gov)
- **By phone:** 1-800-518-4726 (1-800-518-GRANTS). The Customer Support Center is open from 7:00 a.m. to 9:00 p.m. Eastern Time, Monday through Friday, excluding Federal holidays.

**If this is the first time you have submitted an application through Grants.gov, you must complete four 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; 3) Credential Provider registration; and 4) Grants.gov registration. **REMINDER: CCR registration expires each year and must be updated annually.**

**It is strongly recommended that you submit your grant application using Microsoft Office 2003 products (e.g., Microsoft Word 2003, Microsoft Excel, etc.). The new Microsoft Vista operating system and Microsoft Word 2007 products are not currently accepted by Grants.gov.** If you do not have access to Microsoft Office 2003 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 or PDF may result in your file being unreadable by our staff.

The Project Narrative must be a separate document in the electronic submission. 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.

**Keep the Project Narrative as a separate document. Please consolidate all other materials in your application to ensure the fewest possible number of attachments. Be sure to label each file according to its contents, e.g., "Appendices 1-3", "Appendices 4-5."**

Ensure all pages in your application are numbered consecutively, with the exception of the standard forms in the PHS-5161-1 application package. **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.**

If you are submitting any documentation that cannot be submitted electronically, please send a hard copy to the address below. [SAMHSA no longer requires submission of a signed paper original of the face page (SF 424 v2) or the assurances (SF 424B)] **You must include the Grants.gov tracking number for your application on these documents. The documents must be received at the following address within 5 business days after your electronic submission.** Delays in receipt of these documents may impact the score your application receives or the ability of your application to be funded.

**For United States Postal Service:**

Barbara Orlando  
Division of Grants Management  
Substance Abuse and Mental Health Services Administration  
One Choke Cherry Road  
Room 7-1091  
Rockville, MD 20857  
**Attn: NASPER Formula Grant**

**For other delivery services, change the zip code to 20850.**

If you require a phone number for delivery, you may use (240) 276-1422.

## Appendix C – Assurance of Compliance with Provisions of NASPER

As the authorized representative of [*insert name of applicant organization*]  
\_\_\_\_\_, I assure SAMHSA that we will  
comply with all the provisions of the National All Schedules Prescription Electronic Reporting  
Act of 2005 (42 U.S.C. 280g-3).

**For existing PMPs proposing improvements ONLY:** Please provide a Statement below if  
compliance with all the provisions of NASPER is not feasible or contrary to the best interests of  
public health in your State.

I understand that compliance with this assurance throughout the period of the project is a term  
and condition of the grant award.

\_\_\_\_\_  
Signature of Authorized Representative

\_\_\_\_\_  
Date

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

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

## Appendix E – Sample Budget and Justification (no match required)

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

**A. Personnel:** an employee of the applying agency whose work is tied to the application

### FEDERAL REQUEST

Position	Name	Annual Salary/Rate	Level of Effort	Cost
Project Director	John Doe	\$64,890	10%	\$ 6,489
Coordinator	To be selected	\$46,276	100%	\$46,276
			TOTAL	\$52,765

**JUSTIFICATION: Describe the role and responsibilities of each position.**

The Project Director will provide daily oversight of the grant and will be considered a key staff position. The coordinator will coordinate project services and project activities, including training, communication and information dissemination. Key staff positions requires prior approval of resume and job description.

**FEDERAL REQUEST** (enter in Section B column 1 line 6a of form SF424A) **\$52,765**

**B. Fringe Benefits:** List all components of 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 SF424A) **\$10,896**

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

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

Cost for two staff to attend a grantee meeting in Washington, DC. Local travel is needed to attend local meetings, project activities, and training events. (Be as specific as possible regarding events and conference names and locations.) Local travel rate is based on the grantee organization's policies and procedures privately owned vehicle (POV) reimbursement rate.

**FEDERAL REQUEST** (enter in Section B column 1 line 6c of form SF424A) **\$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.

**FEDERAL REQUEST** – (enter in Section B column 1 line 6d of form SF424A) **\$ 0**

**E. Supplies:** materials costing less than \$5,000 per unit 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
<b>TOTAL</b>		<b>\$3,796</b>

**JUSTIFICATION: Describe need and include explanation of how costs were estimated.**

Office supplies, copies and postage are needed for general operation of the project. The laptop computer is needed for both project work and presentations. The projector is needed for presentations and workshops. All costs were based on retail values at the time the application was written.

\*Provide adequate justification and need for purchases.

**FEDERAL REQUEST** – (enter in Section B column 1 line 6e of form SF424A) **\$ 3,796**

**F. Contract:** A consultant is an individual retained to provide professional advice for a fee. A contract provides services for a fee. The grantee must have procurement policies and procedures governing their use of consultants and contracts that are consistently applied among all the organization's projects.

**FEDERAL REQUEST**

Name	Service	Rate	Other	Cost
Joan Doe	Training staff	\$150/day	15 days	\$2,250
	Travel	.38/mile	360 miles	\$137
			<b>TOTAL</b>	<b>\$2,387</b>

**JUSTIFICATION: Explain the need for each agreement and how they relate to the overall project.**

This person will advise staff on ways to increase the number clients and client services. Consultant is expected to make up to 6 trips (each trip a total of 60 miles) to meet with staff and other local and government experts. Mileage rate is based on grantee's POV reimbursement rate.

**FEDERAL REQUEST**

Entity	Product/Service	Cost
To Be Announced	Marketing Coordinator \$25/hour x 115 hours	\$2,300
ABC, Inc.	Evaluation \$65/hr x 70 days	\$4,500
<b>TOTAL</b>		<b>\$6,800</b>

**JUSTIFICATION: Explain the need for each agreement and how they relate to the overall project.**

The Marketing Coordinator will development a marketing plan to include public education and outreach efforts to engage clients of the community about grantee activities, provision of presentations at public meetings and community events to stakeholders, community civic organizations, churches, agencies, family groups and schools. Information disseminated by written or oral communication, electronic resources, etc. A local evaluator will be contracted to produce the outcomes and report input of GPRA data.

**FEDERAL REQUEST** – (enter in Section B column 1 line 6f of form SF424A) **\$ 9,187**  
 (combine the total of consultant and contact)

**G. Construction: NOT ALLOWED** – Leave Section B columns 1&2 line 6g on SF424A blank.

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

**FEDERAL REQUEST**

Item	Rate	Cost
Rent*	\$15/sq.ft x 700 sq. feet	\$10,500
Telephone	\$100/mo. x 12 mo.	\$1,200
Client Incentives	\$10/client follow up x 278 clients	\$2,784
Brochures	.89/brochure X 1500 brochures	\$1,335
TOTAL		\$15,819

**JUSTIFICATION: Break down costs into cost/unit, i.e. cost/square foot. Explain the use of each item requested.**

Office space is included in the indirect cost rate agreement; however, other service site rental costs are necessary for the project as well as telephone service to operate the project. The rent is calculated by square footage and reflects SAMHSA's share of the space. The monthly telephone costs reflect the % of effort for the personnel listed in this application for the SAMHSA project only. Brochures will be used at various community functions (health fairs and exhibits) once per month throughout the service area.

\*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 since mortgage costs are unallowable.

**FEDERAL REQUEST** – (enter in Section B column 1 line 6h of form SF424A) **\$ 15,819**

**Indirect cost rate:** Indirect costs can only 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 indirect cost rate agreement.

For information on applying for the indirect rate go to: [samhsa.gov](http://samhsa.gov) then click on Grants – Grants Management – HHS Division of Cost Allocation – Regional Offices.

**FEDERAL REQUEST** (enter in Section B column 1 line 6j of form SF424A)  
 8% of salaries and wages and fringe benefits (.08 x \$63,661) **\$5,093**

**BUDGET SUMMARY: (identical to SF-424A)**

Category	Federal Request
Salaries & Wages	\$52,765
Fringe Benefits	\$10,896
Travel	\$2,444
Equipment	0
Supplies	\$3,796
Contractual	\$9,187
Other	\$15,819
Total Direct Costs*	\$94,907
Indirect Costs	\$5,093
Total Project Costs	\$100,000

**\* TOTAL DIRECT COSTS:**

FEDERAL REQUEST – (enter in Section B column 1 line 6i of form SF424A) **\$94,907**

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

FEDERAL REQUEST (enter in Section B column 1 line 6k of form SF424A) **\$100,000**

## Appendix F – Minimum Requirements for Security of the Database

Information from the PMPs 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, NASPER 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, PMP 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 entities upon request (solicited), or without request (unsolicited). 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.

The following questions that can be useful in examining the existing level of security of the program:

- 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 PMP-supporting systems up to date in enforcing those requirements?
- What additional steps are needed to protect Protected Health Information (PHI)?

## Appendix G – Minimum Requirements for Authentication and Certification<sup>4, 5</sup>

1. A practitioner (or the agent thereof, including pharmacist) 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 practitioner's name and date of birth, a corresponding DEA registration number, and State medical license number. In soliciting information from the State PMP 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 web-based procedures. This minimum requirement procedure must be utilized at the time of funding by States that are establishing and implementing a PMP. If States that receive funding for improving their existing PMP cannot comply with this minimum requirement, they must certify that they will modify their procedures to conform to this minimum requirement and have established procedures for grandfathering or reapplication for already authenticated users by September 30, 2010.
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 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 controlled substance monitoring program 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. Any interoperability agreements that meet the requirements of the individual State PMPs, and the general requirements should be acceptable. This means, for example, that if the

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<sup>4</sup> Although NASPER 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.

<sup>5</sup> 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 NASPER authentication and certification procedures and any other applicable laws.

ultimate information requester is a law enforcement entity, each State PMP 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 PMP that identifies the summary statistics sought. 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.
5. An agent of the State agency or entity of another State that is responsible for the **establishment and maintenance** of the State's controlled substance monitoring program must submit a written request on Agency letterhead that identifies the requestor as the person responsible for that State's PMP. After authentication by the disclosing State PMP, the requesting State certifies that the State has a PMP application approved by SAMHSA and the requested information is for the purpose of implementing the State's PMP. This category applies to States that do not have an interoperability agreement. In addition, both States must have an approved NASPER grant.