

**Department of Health and Human Services**

**Substance Abuse and Mental Health Services Administration**

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

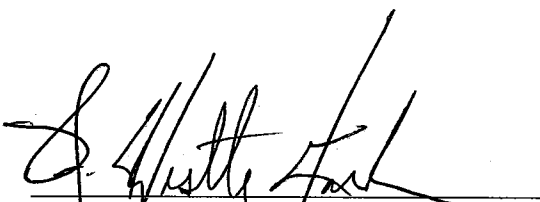
**Short Title: NASPER**

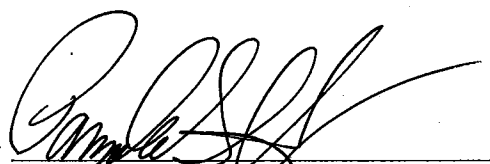
**Request for Applications (RFA) No. TI-10-F1**

**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 August 10, 2010.</b>
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## **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 2010 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-10-F1

**Due Date for Applications:** August 10, 2010

**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 2010 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.

The Substance Abuse and Mental Health Services Administration's (SAMHSA) mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA, in collaboration with other Federal agencies, States, Tribes, local organizations, and individuals including consumers and the recovery community, has demonstrated again and again in research and practice - prevention works, treatment is effective, and people recover from mental and substance use disorders. Behavioral health is an essential part of health service systems and community-wide strategies that work to improve health status and lower costs for families, businesses, and governments. Through continued improvement in the delivery and financing of prevention, treatment, and recovery support services SAMHSA with its partners can advance and protect the Nation's health. In order to achieve this goal SAMHSA has identified ten Strategic Initiatives to focus the Agency's work on improving lives and capitalizing on emerging opportunities. The NASPER program addresses the Prevention of Substance Abuse and Mental Illness Strategic Initiative. One of the goals of this Initiative, which is consistent with the intent of NASPER, is to 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.

More information is available at the SAMHSA website:  
<http://www.samhsa.gov/About/strategy.aspx>.

## **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 **Attachment 1** of your application; and
- Provide a plan that will enable the State PMP to achieve interoperability with at least one other State PMP. In addition, if a State PMP has not achieved interoperability with a geographically bordering State that is a NASPER PMP grantee at the time of application, the 2010 application must include a description of the manner in which the State PMP will achieve interoperability with the geographically bordering State.

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 **Attachment 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, **all** PMPs must adopt the 4.1 or higher version of the American Society for Automation in Pharmacy (ASAP) standard for electronic prescription formatting by September 30, 2010 or, if legislation change must be made, provide documentation formally requesting legislation change or regulation amendment permitting the use of ASAP 4.1 or higher. 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. If a State PMP has not achieved interoperability with a geographically bordering State that is a NASPER grantee at the time of application, include a description of the manner in which the State PMP will achieve interoperability with the geographically bordering State. A letter of agreement to adopt these standards must be included in **Attachment 2** of your application.

## 2.3 Reporting Requirements

States receiving NASPER grants must adopt the 4.1 or higher version of ASAP as the electronic format for reporting, sharing, and disclosure of information by September 30, 2010 or, if legislation change must be made, provide documentation formally requesting legislation change or regulation amendment permitting the use of ASAP 4.1 or higher 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 **Attachment 1** of your application 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)

<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.

- 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.

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 the NASPER 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 PMP 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.

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. SAMHSA suggests that States provide unsolicited disclosures to prescribers and pharmacies when an individual has filled six or more controlled substance prescriptions of the same drug class, from six or more different prescribers, or, six or more different pharmacies in the State within a one-month period (i.e., "6/6/1 threshold"). PMPs should at least evaluate their data on a quarterly basis. Electronic reports and notifications are permissible and must comply with HIPAA and other confidentiality laws. For example, some States provide notifications to practitioners that do not contain patient health information, but instead request the practitioner to obtain a report. Notifications or reports must be sent to at least 5% of the registered prescribers and pharmacies in the State in one calendar year. In lieu of the "6/6/1 threshold" cited above, States may propose an alternate plan for unsolicited disclosures, but must also provide an evaluation plan demonstrating the effectiveness of the program, and must send notifications or reports to at least 5% of the prescribers and pharmacies in the State in one calendar year. 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.

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.

