

**NATIONAL ASSOCIATION OF STATE
CONTROLLED SUBSTANCES AUTHORITIES**

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**Findings and Recommendations of the
Prescription Monitoring Standards Workgroup**

February 26, 2003

Background:

At the October 2002 Annual Educational Conference of the National Association of State Controlled Substances Authorities (NASCSA) held in Myrtle Beach, SC, the Organization adopted resolution 2002-02 stating its opposition to passage of federal legislation establishing the National All Schedules Prescription Electronic Reporting Act of 2002 (NASPER). The resolution also charged the NASCSA Executive Committee with the task of convening a working group to include the Alliance of States with Prescription Monitoring Programs (Alliance), the U.S. Drug Enforcement Administration, state, federal and industry representatives and others, to make recommendations on prescription monitoring standards and methods to implement such standards. The Resolution also stated that methods should be explored by which data could be shared between states, with the federal government and with prescribing practitioners.

In response to this charge, the NASCSA Executive Committee convened a meeting of the Prescription Monitoring Standards Workgroup in Orlando, Florida on January 23 -25, 2003. The working group was comprised of sixteen individuals representing the constituencies set forth in the resolution. The list of participants is attached to this report (see attachment A).

Recommendations of the Workgroup:

The Workgroup discussed both general concepts and methodology relative to standards for data collection that would facilitate uniformity among states. It also reviewed the specific data elements that comprise the optimal data set identified in the Alliance/NASCSA Prescription Monitoring Program Model Act of 2002, as well as those additional elements that are collected by each of the existing state prescription monitoring programs. Noted below, are the general procedural concepts that the Workgroup recommends as necessary to facilitate optimal data sharing, standards for the data elements recommended in the Model Act and where appropriate a listing of the best sources of that data.

• **General concepts:**

1. While not discouraging the development of "real-time" data collection systems, it was the consensus of the group that the advantages of such systems are presently outweighed by the substantially higher costs associated with their development and operation. Additionally, directing resources at "real-time" data collection would almost certainly siphon funding and other available resources from regulatory and enforcement programs that must accompany a data collection system to ensure its overall

effectiveness. The Workgroup recommends that monitoring programs collect data no less than every thirty days. This collection period, considering available technologies and the ability to provide a timely regulatory response, is believed to be appropriate;

2. Legislative language concerning prescription monitoring programs should be technology neutral to allow for commonly accepted electronic methods of transmitting data as well as the implementation of new technologies. Any specific requirements should be set forth in regulations, rather than statute, to allow for greatest flexibility and adaptability to new technologies. Current technologies include, but are not limited to, secure Internet browsers, modems and hard media including diskettes and tape cartridges. The use of hardcopy reporting is discouraged because it is time consuming and prone to increased rates of errors in data entry;

3. There is much to be gained by each of the participating groups, specifically organizations that set standards, regulatory entities and industry, in agreeing on common standards for data collection. Organizations that set standards can more effectively develop accepted standards among their respective groups, while commonality in the data collected by various state regulatory entities can facilitate interstate sharing of data among these groups in an efficiently and effective manner. Additionally, industry benefits in that they have a single set of standards by which to collect data for all states;

4. It is imperative that data collection programs operating in different states collect universally understood and accepted data elements. Failure to achieve this goal represents a primary barrier to the interstate sharing of data. As an example, if a state uses their own "in-state license number" to identify the pharmacy provider, that number has no meaning in another state. It would be preferable to utilize a universally accepted identifier such as the Drug Enforcement Administration (DEA) registration number that is recognizable across state boundaries. If this isn't feasible, states should at least ensure that they have translation tables to enable states to translate state-specific data elements into standard elements.

- **Recommended Data Elements:**

In its review, the Workgroup utilized the data elements contained in Section 5(b) of the Prescription Monitoring Program Model Act of 2002 (see attachment B) that was jointly adopted by the "Alliance" and "NASCSA", as well as a recent survey that was conducted by NASCSA identifying the data that was being collected by state prescription monitoring programs. The Workgroup recommends that the data elements enumerated in the Model Act as well one additional element specifically, "days supply", be collected by prescription monitoring programs. Where appropriate, the Workgroup has listed what it believes to be the best source of such data. Next best data sources are listed as second and third.

To ensure a full understanding of the Workgroups recommendations it is important that we define the terminology used in our discussions:

- **Data element**– a specific data field that is collected as part of a monitoring program such as the "prescription number"

- **Data source** – where specific data is obtained from, such as the patient’s Social Security number or their motor vehicle operator’s license number
- **“NCPDP number”**- the provider number established by the National Council for Prescription Drug Programs that is used by pharmacies to file claims for services. (This has also been referred to as the NABP number)

The Workgroup recommends that the following standards be applied to the data elements that the Alliance and NASCSA recommend be collected by state prescription monitoring programs:

Data Element	Data Source
1. Dispenser identification number	1. DEA number 2. NCPDP provider number
2. Date prescription filled	
3. Prescription number	1. Pharmacy or dispenser assigned number
4. Prescription is new or is a refill	
5. NDC code for drug dispensed	
6. Quantity of drug dispensed	1. Metric quantities should be used where appropriate (i.e. liquids, injectables)
7. Number of days supply of the drug	1. Indicated on prescription or calculated by the dispenser
8. Patient identification number	1. Government issued ID such as motor vehicle operator’s license number 2. Social Security number (raises confidentiality issues) 3. Universal patient insurance number if it becomes available in future
9. Patient last name	
10. Patient first name	
11. Patient street address	
12. Patient city	
13. Patient state	
14. Patient postal code	1. Allow 9 digit zip codes to be entered
15. Patient date of birth	
16. Prescriber identification number	1. DEA number
17. Date prescription issued by practitioner	
18. Person who receives the prescription from the dispenser, if other than the patient	1. Government issued ID such as motor vehicle operator’s license number 2. Social Security number (raises confidentiality issues) 3. Individual’s name
19. Source of payment for prescription	1. This element should allow for distinction between “Cash” / “Medicaid” / “3 rd party” / “Medicare” or other federal option as it becomes available
20. State issued serial number	If state chooses to establish a serialized prescription system

- **Additional recommendations:**

1. The Workgroup recommends that NASCSA and the Alliance jointly adopt a modification to Section 5 (b) of the Prescription Monitoring Program Model Act of 2002, specifically to add the data element "number of days supply".
2. The Workgroup recommends that NASCSA and the Alliance jointly approve and adopt the findings and recommendations of this report as a means of ensuring that members of both organizations are provided with uniform information concerning prescription monitoring data standards.
3. The Workgroup recommends that all standards organizations modify their present standards, where necessary, to establish the "source of payment" as a standard data element to be collected in a manner that provides for a distinction between the following sources of payment "cash" / "Medicaid" / "3rd party" / "Medicare".
4. Since no state currently requires the reporting of "source of payment for prescription", the Workgroup recommends that states that are considering requiring the reporting of this data element, be aware that there may be a temporary delay in achieving full compliance, as dispensers and software vendors work to modify their data management systems to provide for the capture of this data.

Adoption of the report:

This report was approved by vote of the Executive Committee of the National Association of State Controlled Substances Authorities on March 3, 2003.

Attachment A

**NATIONAL ASSOCIATION OF STATE
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**Prescription Monitoring Program Standards Work Group
January 24-25, 2003 – Orlando, Florida
List of Participants**

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Attachment B

Alliance of States with Prescription Monitoring Programs and National Association of State Controlled Substances Authorities

PRESCRIPTION MONITORING PROGRAM MODEL ACT

October 2002

Section 1. Short Title.

This Act shall be known and may be cited as the "Prescription Monitoring Program Model Act."

Section 2. Legislative Findings

[insert state findings]

Section 3. Purpose

This act is intended to improve the state's ability to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances or other licit drugs of abuse.

Section 4. Definitions

- (a) "Controlled substance" has the meaning given such term in [section of the state controlled substances act].
- (b) [Designated state agency] means the state agency responsible for the functions listed in Section 5.
- (c) "Patient" means the person or animal who is the ultimate user of a drug for whom a prescription is issued and/or for whom a drug is dispensed.
- (d) "Dispenser" means a person who delivers a Schedule II–V controlled substance as defined in subsection (e) to the ultimate user, but does not include:
 - (I) a licensed hospital pharmacy that distributes such substances for the purpose of inpatient hospital care [or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility];
 - (II) a practitioner, or other authorized person who administers such a substance; or

- (III) a wholesale distributor of a Schedule II–V controlled substance.
- (e) “Schedule II, III, IV and/or V controlled substances” mean controlled substances that are listed in Schedules II, III, IV, and V of the Schedules provided under [insert section of the state controlled substances act] or the Federal Controlled Substances Act (21 U.S.C. 812).

Section 5. Requirements for Prescription Monitoring Program.

- (a) The [designated state agency] shall establish and maintain a program for the monitoring of prescribing and dispensing of all Schedule II, III and IV controlled substances [and, if selected by the state, Schedule V controlled substances and/or additional drugs identified by the designated state agency as demonstrating a potential for abuse] by all professionals licensed to prescribe or dispense such substances in this state.
- (b) Each dispenser shall submit to the [designated state agency] by electronic means information regarding each prescription dispensed for a drug included under paragraph (a) of this section. The information submitted for each prescription shall include, but not be limited to:
 - (I) Dispenser identification number.
 - (II) Date prescription filled.
 - (III) Prescription number.
 - (IV) Prescription is new or is a refill.
 - (V) NDC code for drug dispensed.
 - (VI) Quantity dispensed.
 - (VII) Patient identification number.
 - (VIII) Patient name.
 - (IX) Patient address.
 - (X) Patient date of birth.
 - (XI) Prescriber identification number.
 - (XII) Date prescription issued by prescriber.
 - (XIII) Person who receives the prescription from the dispenser, if other than the patient.
 - (XIV) Source of payment for prescription.
 - (XV) State issued serial number [if state chooses to establish a serialized prescription system].
- (c) Each dispenser shall submit the information in accordance with transmission methods and frequency established by the [designated state agency]; but shall report at least every thirty days, between the 1st and the 15th of the month following the month the prescription was dispensed.
- (d) The [designated state agency] may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information by paper form or

other means, provided all information required in paragraph (b) of this section is submitted in this alternative format.

Note: the following paragraphs, (e) - (h), are intended for those states that choose to establish a serialized prescription system as part of the prescription monitoring program.

- (e) A serialized [single copy or multiple copy] prescription form, shall be issued by the [designated state agency] to individual [insert "and institutional" if practitioners in health care institutions issue prescriptions that can be filled in pharmacies outside the institutions] prescribers and shall be used for all prescriptions for drugs in [Schedule II, III, IV and/or V] controlled substances. Each series of prescriptions shall be issued to a specific prescriber [in consecutively numbered blocks of ____] and shall only be used by that prescriber.
- (f) Each prescriber shall only prescribe drugs in [Schedule II, III, IV and/or V] controlled substances on official serialized prescription forms issued by the [designated state agency].
- (g) Each dispenser shall only dispense drugs in [Schedule II, III, IV and/or V] controlled substances on such official serialized prescription forms.
- (h) The [designated state agency] shall charge each prescriber an amount sufficient to cover the costs of processing requests for forms, printing the prescription forms, and operating the prescription monitoring program.

Note: States may chose to use alternative method than paragraph (h) to pay the cost of their serialized prescription forms and monitoring system, for example, through controlled substances registration fees. In such instances, paragraph (h) can be deleted.

Section 6. Access to Prescription Information.

- (a) Prescription information submitted to the [designated state agency] shall be confidential and not subject to public or open records laws, except as provided in paragraphs (c), (d), and (e) of this section.

Note: States may choose to also amend their open record statutes to specifically exclude from disclosure prescription information collected by their prescription monitoring program.

- (b) The [designated state agency] shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained is not disclosed to persons except as in paragraphs (c), (d), and (e) of this section.

- (c) The [designated state agency or entity] shall review the prescription information. If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the [designated state agency] shall notify the appropriate law enforcement or professional licensing, certification or regulatory agency or entity, and provide prescription information required for an investigation.
- (d) The [designated state agency] shall be authorized to provide data in the prescription monitoring program to the following persons.
 - (I) Persons authorized to prescribe or dispense controlled substances, for the purpose of providing medical or pharmaceutical care for their patients.
 - (II) An individual who requests the individual's own prescription monitoring information in accordance with procedures established under [insert state statute granting individuals access to state held data concerning themselves].
 - (III) [insert name or type of state boards and regulatory agencies that supervise or regulate a profession that is authorized for controlled substances activity].
 - (IV) Local, state and federal law enforcement or prosecutorial officials engaged in the administration, investigation or enforcement of the laws governing licit drugs.
 - (V) [insert state Medicaid agency] regarding Medicaid program recipients.
 - (VI) [insert judicial authorities] under grand jury subpoena or court order [or equivalent judicial process in each state].
 - (VII) Personnel of the [designated state agency] for purposes of administration and enforcement of this Act, or [insert state controlled substances act], [if any other state statute is applicable, insert "or" and reference the other statutes].
- (e) The [designated state agency] may provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identify individual patients and/or persons who received prescriptions from dispensers.

Section 7. Authority to Contract

The [designated state agency] is authorized to contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. Any contractor shall be bound to comply with the provisions regarding confidentiality of prescription information

in Section 6 of this Act and shall be subject to the penalties specified in Section 8 of this Act for unlawful acts.

Section 8. Rules and Regulations.

The [designated state agency] shall promulgate rules and regulations setting forth the procedures and methods for implementing this Act.

Section 9. Unlawful Acts and Penalties.

- (a) A dispenser who knowingly fails to submit prescription monitoring information to the [designated state agency or entity] as required by this Act or knowingly submits incorrect prescription information shall be subject to [insert appropriate administrative, civil or criminal penalty].
- (b) A person authorized to have prescription monitoring information pursuant to this Act who knowingly discloses such information in violation of this Act shall be subject to [insert appropriate administrative, civil or criminal penalty.]
- (c) A person authorized to have prescription monitoring information pursuant to this Act who uses such information in a manner or for a purpose in violation of this Act shall be subject to [insert appropriate administrative, civil or criminal penalty.]

Section 10. Severability.

If any provision of this Act or application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act which can be given effect without the invalid provisions or applications, and to this end the provisions of this Act are severable.

Section 11. Effective Date.

This Act shall be effective on [insert specific date or reference to normal state method of determination of the effective date].

**Adopted by *Alliance of States with Prescription Monitoring Programs,*
October 22, 2002.**

**Adopted by National Association of State Controlled Substances
Authorities, October 25, 2002**