

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

Background information on the
PRESCRIPTION MONITORING PROGRAM MODEL ACT

October 2002

Introduction

The Alliance of States with Prescription Monitoring Programs (Alliance) and the National Association of State Controlled Substances Authorities (NASCSA) adopted the *Prescription Monitoring Program Model Act* in October 2002. The Model Act provides a statutory framework for establishing and operating a prescription monitoring program (PMP). Both organizations recommend that states use the Model Act to establish new and update existing PMPs. This document summarizes the provisions of the Model Act as well as the basis and rationale for those provisions.

Basis for the Model Act

The Model Act is a consensus document that reflects the best practices of the states that currently run PMPs as well as the knowledge of many other states that have a longstanding interest in PMPs. The prescription monitoring states cover half the U.S. individual and practitioner populations and have over 100 years of combined experience in operating PMPs.

The Alliance is an organization of representatives of twenty-eight states that have adopted or are considering adoption of PMPs, including all eighteen states that currently have such programs. NASCSA is an organization of forty-three states and is comprised of agencies responsible for prescription controlled substances in each of those states.

PMPs provide a highly efficient means of collecting the prescribing and dispensing information that has been routinely collected as part of investigations into prescription drug diversion. States that operate PMPs have found that they are an effective tool for enforcement, education and prevention that does not interfere with legitimate prescribing and dispensing of pharmaceuticals.¹

¹ Alliance of States with Prescription Monitoring Programs. *The Goals of Prescription Monitoring*. 1999. (available at www.nascsa.org/monitoring.htm)

The Alliance/NASCSA Model Act builds upon many years of work by the Alliance and NASCSA and by many individual states. Its foundation lies in the Model Prescription Accountability Act adopted by NASCSA in 1995 and revised in 1996, and in the Consensus Statement on Data Elements for Electronic Submission of Controlled Substances Prescriptions, adopted by the Alliance in 1996.²

The Model Act also incorporates concepts contributed by states, based upon their recent experiences operating PMPs. Provisions are included from a resolution adopted at the 2001 NASCSA annual conference.³ In addition, several points from a model act that was drafted by the National Alliance of Model State Drug Laws in 2001 have been incorporated, with adjustments, into the Alliance/NASCSA Model Act.

Provisions of the Model Act

The Model Act provides the following essential elements:

- Establishes, as a minimum standard, the collection of information for all prescriptions issued for Schedule II - IV controlled substances.
- Provides the option for states to also collect information on Schedule V controlled substances and on drugs that have a potential for abuse but are not currently scheduled.
- Requires the submission of the minimum essential data elements to be collected for each prescription, and maintains an option for states to collect additional data elements, if needed. The entire list of data elements are considered essential for the optimal operation of a PMP.
- Mandates that pharmacies submit data electronically, since the use of computers is now the standard in pharmacy practice.
- Permits a waiver to be issued for paper submission of information if a particular pharmacy is unable to submit information electronically.
- Provides an option for states to also use state issued serialized prescription forms, if they so choose.
- Ensures the privacy and confidentiality of information collected by a PMP.

² The American Society for Automation of Pharmacy (ASAP) used this Consensus Statement to revise its protocols so that the national ASAP standards for electronic transmission of prescription information now conform to the Consensus Statement.

³ NASCSA Resolution 2001-04

- Identifies the persons and agencies to which information may be released, with appropriate restrictions on data requests and limitations on information use. This section specifically permits patients to access their own prescription information.
- Requires that the prescription information be reviewed to determine if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, in which case, the appropriate law enforcement or professional licensing agency will be notified and given necessary information.
- Ensures that the state agency responsible for operating the PMP can maintain currency with advancing information technology by authorizing the agency to promulgate implementing regulations.
- Authorizes contracts with another state agency or private vendor to help operate the PMP, and makes them subject to the confidentiality requirements.
- Provides for penalties for any breaches of confidentiality requirements.
- Establishes penalties for knowing failure to submit required information to the PMP.

ADDITIONAL COMMENTS

Serialized prescription forms

The Alliance/NASCSA Model Act provides for a comprehensive PMP that uses advances in computer and electronic information transmission technologies to establish efficient, cost-effective programs. In addition, states are given statutory language to establish an official serialized prescription system, if they wish to do so. The prescription monitoring states that currently utilize serialized prescription forms (California, New York and Texas) find them to be an effective deterrent to prescription forgery and counterfeiting. Note that states that elect to include a serialized prescription system may wish to consider including all Schedule II -IV prescription controlled substances in the electronic monitoring process, while limiting the serialized prescriptions to those drugs with the highest potential for abuse.

Oversight boards

The Model Act does not provide for an oversight board of stakeholders specifically designed to oversee the PMP. Most states with PMPs do not have such boards and their PMPs are accountable as part of the operating agencies' normal reporting system. Nothing in the Model Act precludes a state from establishing an advisory group to make recommendations on the establishment or operation of a PMP.

Education provisions

The Model Act does not contain a section on education because such a section would be redundant. Current state controlled substances laws, and health care professional licensing and practice statutes contain sufficient authority for states to educate health care professionals and other parties who may review prescription information.

Many states already provide some training and communications regarding professional practice with controlled substances and how to review prescription monitoring information. While there is room for expansion of these activities, states can do this by management decision rather than through additional statutory language.

Treatment provisions

The Model Act does not contain a section regarding substance abuse treatment. States that operate PMPs recognize the importance of referring into treatment persons who are identified as having potential substance abuse problems. One of the great assets of PMPs is that use of PMP information enables physicians and pharmacists to identify such persons so they can be referred to appropriate treatment.

However, it is unnecessary to include such language in the Model Act because appropriate statutes already exist for the referral and treatment of persons who abuse substances and for the treatment of impaired health care professionals.

Use of PMP information

This Model Act provides a statutory framework for implementing and operating PMPs so they may collect, analyze and refer information; it does not attempt to identify the multitude of ways in which the information may be utilized. Substantial state laws and regulations already exist to govern the manner in which the parties who may access prescription information may carry out their separate responsibilities. Thus it is inappropriate for this Model Act to include sections delineating specific uses, such as education and treatment.

To place this in context, the same prescription information has been available for decades to the parties that can access the PMPs' information. The difference is that to examine the information without a PMP, each party must go through thousands of prescriptions to manually compile the information. The PMPs simply utilize new technology to make the information more readily accessible and analyzable. The information users will need to adjust their approaches to deal with this greater accessibility, but that is an issue for the information users, not for the agency that operates the PMP and compiles the information.

Having said this, the sponsors of this Model Act recognize that each state will adapt it to specific local circumstances and concerns. Nothing precludes individual states from amending this and other appropriate statutes to address new concerns as well as any or all of the ancillary areas, above.

FURTHER INFORMATION

Further information regarding the Prescription Monitoring Model Act or any of the issues discussed in this document is available from the Alliance of States with Prescription Monitoring Programs and the National Association of Controlled Substances Authorities at www.nascsa.org.