PDMP TTAC

Prescription Drug Monitoring Program Training and Technical Assistance Center

Explanation for 2010 Amendments to:
PRESCRIPTION MONITORING PROGRAM MODEL ACT

FINAL 6/28/2010

Introduction

The Alliance of States with Prescription Monitoring Programs (Alliance) and the Prescription Drug Monitoring Center of Excellence have prepared this revision to the *Prescription Monitoring Program Model Act* to provide a statutory framework for establishing and operating a prescription monitoring program (PMP). It also provides a framework for states with existing PMPs to update their statutes. This document summarizes the provisions of the Model Act, the basis for those provisions, and recommended amendments to update the Act.

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 other states that have a long standing interest in PMPs. Forty states and the Territory of Guam have legislation authorizing a PMP and several others are considering legislation at the time this report is written.

The Alliance is an organization of representatives of states with Prescription Monitoring Programs (PMPs) and includes those states considering implementing such a program. Most if not all representatives are Managers or Administrators of their state's PMP programs or individuals leading the effort to establish or implement a PMP.

The Alliance of States with Prescription Monitoring Programs is an organization dedicated to providing a forum for the development, sharing, and exchange of information and ideas regarding all aspects of prescription monitoring programs to state and federal agencies that seek to curtail drug diversion and abuse while simultaneously ensuring patient care. The Alliance provides its expertise and support for establishing, operating and enhancing prescription monitoring programs, sharing information to enhance drug intervention and prevention programs, and conducting research and education in the use of prescription controlled substances to improve patient care and protect public health and safety.

The PDMP Center of Excellence is an organization based at Brandeis University and supported by the Federal Bureau of Justice Assistance to provide support to states, including assistance in developing Best Practices such as this Model Act.

[Note: A Prescription Monitoring Program (PMP) is sometimes referred to as a Prescription Drug Monitoring Program (PDMP).These terms, as used in this document, are synonymous.]

PMPs provide a highly efficient means of facilitating the collection of 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 to assist prescribers and dispensers care for their patients and to assist regulatory and law enforcement with their investigations while not interfering with legitimate prescribing and dispensing of pharmaceuticals.

This revision of the Model Act builds upon many years of work by the Alliance and by many individual states and organizations. Its direct predecessor was the Prescription Monitoring Program Model Act that was completed in 2002. Its foundation lies earlier in the Model Prescription Accountability Act adopted by the National Association of State Controlled Substance Authorities (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 and NASCSA in 1996.[1]

This revision of the Model Act also incorporates concepts contributed by states, based upon their recent experiences operating PMPs. In addition, several points from a Model Act that was published by the President's Commission on Model State Drug Laws in 1993 are incorporated; the President's Commission was the predecessor to the National Alliance for Model State Drug Laws.

Reasons for Modifying the Model Act in 2010

In the eight years since the Model Act was last revised many changes have occurred.

- In response to the needs of prescribers and other prescription monitoring information users to obtain information on controlled substances prescriptions dispensed in other states, a major effort has been launched to establish a method for exchanging information between PMPs. This effort is a collaborative effort of the Alliance of States with Prescription Monitoring Programs, the Federal Bureau of Justice Assistance and the IJIS Institute. An information sharing infrastructure through which PMP information may be exchanged is expected to become operational during 2010.
- Information technology advances have made possible more rapid and larger volume collection, management and transmission of data, enabling PMPs to provide data through web portals to users. In 2002, only 2 PMPs used web portals (Kentucky and Utah). By 2010, 30 PMPs do so.
- States have identified new types of users who should have access to their PMP information.

Provisions of the Model Act and 2010 Modifications

Following are the sections of the Model Act that have been amended in 2010. *Information in italics explains the essential content of each section. Italics are also used for notes.* The changes made in 2010, are in standard font.

[1] 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 issued in 1995 conformed to the Consensus Statement.

Section 3. Purpose

This section explains the purposes for establishing a PMP.

The purpose statement has been rewritten to reflect new and enhanced goals and objectives of Prescription Monitoring Programs (PMPs).

Section 4. Definitions

This section includes definitions of terms used in the Model Act.

To make the Model Act and its provisions more usable, terms have been added to the definition section:

- "Dispense" – added to clarify its meaning throughout the Model Act.
- "Dispenser" – modified to exclude an institutional facility pharmacy as well as a hospital pharmacy.
- "Interoperability"-- added to clarify the intent of new Section 8 regarding exchange of PMP data between states.
- "Practitioner" – added to assure that practitioners who dispense controlled substances can request and receive prescription monitoring information, as well as those who prescribe; i.e. health care professionals who prescribe controlled substances are not the only ones who should be able to access PMP information.
- "Prescribe"-- added to clarify its meaning throughout the Model Act.
- "Prescriber" -- added to the definitions to clarify its distinction from the term "Practitioner.
- "Prescription Monitoring Program"— added to clarify the intent of new Section 8.
- "State"-- added to clarify that this term also incorporates territories and districts of the United States that may establish prescription monitoring programs.

Section 5. Requirements for Prescription Monitoring Program

Section 5 provides the following essential elements:

- *Establishes, as a minimum standard, the collection of information for all prescriptions issued for Schedule II - V controlled substances.*
- *Provides the option for states to also collect information on drugs that have a potential for abuse but are not currently scheduled.*
- *Requires the submission of essential information to be collected for each prescription, and maintains an option for states to collect additional information, if needed. The entire list of data elements is considered essential for the optimal operation of a PMP.*
- *Mandates that pharmacies submit data electronically.*
- *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 use state issued serialized prescription forms.*

Paragraph (b) has been amended to require:

- A dispenser located in a PMP state to submit information for all prescriptions, including those delivered by mail or other means to ultimate users located in other states.
- A dispenser licensed/registered by but not located in a PMP state to submit information regarding shipments to ultimate users within the state of licensure / registration, i.e. if a Pharmacy Board requires out-of-state pharmacies to register, the pharmacies must report to the PMP. This applies to mail order or retail pharmacies located in other states that ship controlled substances prescriptions into the PMP's state, provided the PMP state's Board of Pharmacy requires the mail order or retail pharmacies to register.

Paragraph (c) has been amended to require dispensers to submit prescription information within 7 days of dispensing.

The list of data elements has been updated by the addition of:

- Days' supply dispensed
- Number of refills ordered
- Patient Gender

[Note: In response to inquiries, it should be noted if a PMP requires dispensers other than pharmacies to submit prescription information, e.g. physicians in rural areas, then all dispensers, including veterinarians, who dispense controlled substances should also be required to submit information.]

[Note: Section 5 provides 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 (New York and Texas) find them to be an effective deterrent to prescription forgery and counterfeiting. 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.]

Previous Section 6. Access to Prescription Information

This Section has been divided into two sections with new titles for each.

Section 6. Confidentiality

This section ensures the privacy and confidentiality of information collected by a PMP.

The new Section 6 has been named "Confidentiality" and it contains what were paragraphs (a) and (b) of Section 6 in the 2002 version of the Model Act.

The remaining paragraphs in Section 6 have been placed into a new Section 7.

Section 7. Providing Prescription Monitoring Information

This section contains important provisions that:

- *Require that prescription information be reviewed and, if potential problems are identified, information may be forward to the appropriate parties.*
- *Identify the persons and agencies to which information may be released, with appropriate restrictions on data requests and limitations on information use.*
- *Specifically permit patients to access their own prescription information.*

Paragraph (a) of the new Section 7 contains two sub-paragraphs to require PMPs to proactively analyze PMP data:

- Sub-paragraph (I) - When evaluation of data indicates a person is obtaining prescriptions in a manner that appears to represent misuse, abuse or diversion of controlled substances, e.g. obtaining prescriptions for the same or similar drugs from multiple prescribers and dispensers during the same time period, the PMP may provide this information to prescribers and dispensers.
- Sub-paragraph (II) - When evaluation of data identifies what appears to represent a violation of law or breach of professional standards the PMP shall provide the information to a law enforcement agency or a licensing board, as appropriate [this is taken from the current Section 6 (c)].

Paragraph (b) contains the list of parties to whom PMPs may provide requested prescription information [i.e. solicited reports]. This paragraph has been re-worded to make clear that 1) the information provided under this paragraph is "upon request," and 2) the individuals and entities authorized to receive information upon request are limited to those on this list.

The list of the individuals and entities has been amended from the list in the 2002 version:

- Sub-paragraph (I) regarding prescribers and dispensers expressly authorizes PMPs to provide information upon request regarding the prescribers' and dispensers' patients and regarding prescriptions in the PMP database attributed to each prescriber or dispenser.

  [Note: Substance abuse programs' medical staff who conduct medical evaluations of persons in treatment may use sub-paragraph (I) to request prescription information regarding persons they are evaluating or to assure compliance with treatment protocols.]

  [Note: Some states may choose to allow a practitioner or dispenser to request reports of prescriptions issued or dispensed to <u>individual</u> patients, one patient at a time, but not allow him/her to request a report containing all the prescription information for all of the practitioner's or dispenser's patients. In such instances, the state may interpret the statute such that a report of <u>only prescriptions issued or dispensed by the requestor</u> does not constitute the provision of medical or pharmaceutical care since it is retrospective in nature and not proximate in time to the treatment decisions for a particular patient.]

- Sub-paragraphs (III) and (IV), regarding regulatory and law enforcement agencies, have been modified to clarify that PMPs may provide data upon request pursuant to an open investigation or to other assurance that the request is pursuant to the agency's official duties and responsibilities.

  [Note: Some states may prefer to further restrict such access by including a requirement that the agency may only request a report on an individual and may require some evidence of that investigation such as a case number, affidavit, or subpoena.]

- Sub-paragraph (V), regarding Medicaid agencies, has been amended to clarify that PMPs may provide information specifically to Medicaid staff with legal authority to conduct investigations or utilization review of program services.

  [Note that Medicaid fraud units that have law enforcement authority may ~~to~~ have access through provisions for law enforcement].

- New sub-paragraph(VI) authorize PMPs to provide information to Medical Examiners, coroners, or others authorized under law to investigate causes of deaths, for cases under investigation.

- The old sub-paragraph (VII) regarding PMP information to judicial authorities under grand jury subpoena or court order has been removed because these uses are already covered under sub-paragraph (IV) which includes local, state and federal law enforcement or prosecutorial officials engaged in the administration, investigation or enforcement of the laws governing controlled substances

  [Note: The Committee considered the use of PMP information in criminal and civil proceedings. The Committee determined that the information has some important legitimate uses in such proceedings. Some states have blocked subpoenas for inappropriate uses, e.g. divorces or custody suits, by restricting the provision of information only to those specified in statute.]

- A note has been included in the Model Act advising states that they may wish to consider adding to the list:
  - Worker's Compensation Boards' medical reviewers
  - Drug Court Judges
  - Department of Corrections' medical staff
  - Probation Departments, if they cannot receive information under law enforcement provisions.

Paragraph (c) has been amended regarding the authority to provide data to researchers. The previous version called for protection of patients' identity by removal of information. This has been modified to permit either encryption or removal of the identifying information and a specification that patient name, street name and number, patient ID, and month and day of birth are the data fields to be encrypted or removed. These changes will permit epidemiological research to be done while protecting patients' identity.

A note has been added regarding paragraph (c), the authority to provide data to researchers. The note indicates that some states may wish to further restrict information released to researchers by encrypting or removing information that could be used to identify a prescriber, a pharmacy or any other person.

Section 8. Information exchange with other prescription monitoring programs

Section 8 provides authority for PMPs to share data with other states' PMPs and to receive information from them.

A new Section 8 has been added to authorize sharing of prescription monitoring between states so states that need specific statutory authority for interstate exchange of prescription monitoring information may use the suggested language.

> *[Note: Section 8 is drafted broadly enough that states wishing share prescription monitoring information in bulk with other PMPs should be able to do so. This would permit states, particularly those that have common borders, to send prescription information in bulk regarding patients and/or prescribers whose addresses are in the other states, rather than having to reply to thousands of individual requests.]*

Section 10. Rules and Regulations.

This section ensures that the state agency responsible for operating the PMP can maintain currency by authorizing the agency to promulgate implementing regulations.

While no changes have been made in this section, states may wish to know that they can add specific rule making authority into each section of the Model Act, if that is the preferred statutory drafting convention in their state.

> *[Note: Examples of the types of rules and regulations that PMPs may develop include:*
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> - *A means of identifying each patient, prescriber, and dispenser about which information is transmitted;*
> - *The requirements for the transmission of information from the dispenser to [designated state agency] including frequency and format of the transmission;*
> - *The procedure to issue a waiver to a dispenser that is unable to submit prescription information by electronic means;*
> - *Specific drug(s) other than controlled substances that must be included (if a state provides for inclusion of a drug that is not a controlled substance); and*
> - *The procedure whereby a person or government entity to which the [designated state agency] is authorized to provide information may submit a request to the [designated state agency] for the information and the [designated state agency] may verify the identity of the requestor; and*
> - *The procedure whereby an individual may request the individual's own database information and the board may verify the identity of the individual.]*

Section 11. Unlawful Acts and Penalties

This section establishes penalties for knowing failure to submit required information to the PMP. It also provides for penalties for any breaches of confidentiality requirements.

A new paragraph (d) has been added to assure that penalties can be assessed against persons who obtain or attempt to obtain prescription or any other information by fraud and deceit from the prescription monitoring program or from a person authorized to have such information.

[Note: The Committee recommends to all states, including those with enacted statutes, that they should apply strong penalties to any:

- *Persons authorized to receive PMP information but who use the information in an unauthorized manner or who disclose the information to unauthorized persons.*
- *Persons not authorized to receive information but who obtain information.*
- *Persons who obtain or attempt to obtain data or any information from the prescription monitoring program or other person authorized to have such information by fraud or deceit.]*

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.

Assistance

Assistance in understanding or using the Model Act is available by contacting the PDMP Training and Technical Assistance Center at: info@pdmpassist.org or calling: 781-609-7741.