PRESCRIPTION MONITORING PROGRAM MODEL ACT 2010 Revision

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

The purposes of this act are:

1. To enhance patient care by providing prescription monitoring information that will assure legitimate use of controlled substances in health care, including palliative care, research and other medical and pharmacological uses.
2. To help curtail the misuse and abuse of controlled substances.
3. To assist in combating illegal trade in and diversion of controlled substances.
4. To enable the access to prescription information by practitioners, pharmacists, law enforcement, researchers and regulatory and other authorized individuals and agencies, and to make this information available to the same entities in other states.

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) "Dispense" means to deliver a controlled substance or other drug required to be submitted under Section 5 of this Act to an ultimate user or research subject by lawful means and includes the packaging, labeling, or compounding necessary to prepare the substance for such delivery.

(d) "Dispenser" means a person who is lawfully authorized to deliver a Schedule II, III, IV and/or V controlled substance, as defined in subsection (k), or other drug required to be submitted under Section 5 of this Act to the ultimate user, but does not include:

(I) A licensed hospital or institutional facility 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, III, IV and/or V controlled substance or other drug required to be submitted under Section 5 of this Act.

(e) "Interoperability" means, with respect to a state prescription monitoring program, the ability of that program to share electronically reported prescription information with another State's prescription monitoring program.

(f) "Patient" means the person or animal who is the ultimate user of a controlled substance or other drug required to be submitted under Section 5 of this Act for whom a lawful prescription is issued and/or for whom a controlled substance or such other drug is lawfully dispensed.

(g) "Practitioner" means a physician, dentist, podiatrist, veterinarian, or other person licensed or otherwise permitted to prescribe, dispense, or administer a controlled substance or other drug required to be submitted under Section 5 of this Act in the course of a licensed professional practice.

(h) "Prescribe" means to issue a direction or authorization, by prescription, permitting a patient to obtain lawfully controlled substances.

(i) "Prescriber" means a practitioner or other authorized person who prescribes a Schedule II, III, IV and V controlled substance or other drug required to be submitted under Section 5 of this Act.

(j) "Prescription monitoring program" means a program that collects, manages, analyzes, and provides information regarding Schedule II, III, IV and V controlled substances or other drug required to be submitted under Section 5 of this Act or program established by a similar act in another state, district or territory of the United States.

(k) "Schedule II, III, IV and V controlled substances" means drugs or drug products that are included in or assigned to Schedules II, III, IV and V as provided under [insert

section of the state controlled substances act] or the Federal Controlled Substances Act.

(l) "State" means state, district or territory of the United States.

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, IV and V controlled substances [and, if selected by the state, additional drugs identified by the designated state agency as demonstrating a potential for abuse] by all prescribers or dispensers in this state.

(b) Each dispenser shall submit to the [designated state agency] information regarding each prescription dispensed for a controlled substance or other drug included under subsection (a) of this section. Any dispenser located outside the boundaries of [name of state] and is licensed and registered by the [insert name of state board of registration/licensure in pharmacy] shall submit information regarding each prescription dispensed to an ultimate user who resides within [name of state].

(c) Each dispenser required to report under subsection (b) of this section shall submit to the [designated state agency] by electronic means information that 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) Days' supply dispensed
(VIII) Number of refills ordered
(IX) Patient identification number.
(X) Patient name.
(XI) Patient address.
(XII) Patient date of birth.
(XIII) Patient gender
(XIV) Prescriber identification number.
(XV) Date prescription issued by prescriber.
(XVI) Person who receives the prescription from the dispenser, if other than the patient.
(XVII) Source of payment for prescription.

(XVIII) State issued serial number [if state chooses to establish a serialized prescription system].

(d) Each dispenser shall submit the required information in accordance with transmission methods and frequency established by the [designated state agency]; but no more than seven days from the date each prescription was dispensed.

(e) 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 subsection (c) of this section is submitted in this alternative format.

[Note: the following subsections, (f) – (i), are intended for those states that choose to establish a serialized prescription form system as part of the prescription monitoring program.]

(f) 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 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.

(g) Each prescriber shall only prescribe [Schedule II, III, IV and V] controlled substances on official serialized prescription forms issued by the [designated state agency].

(h) Each dispenser shall only dispense [Schedule II, III, IV and V] controlled substances on such official serialized prescription forms.

(i) The [designated state agency] may 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 choose to use an alternative method other than paragraph (i) to pay the cost of their serialized prescription forms and monitoring system, for example, through controlled substances registration fees. In such instances, subsection (i) can be deleted.]

Section 6. Confidentiality.

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 section 7.

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

b) The [designated state agency] shall establish and enforce policies and procedures to ensure that the privacy and confidentiality of patients are maintained and that patient information collected, recorded, transmitted, and stored is protected and not disclosed to persons except as in section 7.

c) The PMP shall establish and maintain a process for verifying the credentials and authorizing the use of prescription information by those individuals and agencies listed in subsections (b) and (c) of section 7 of this Act.

Section 7, Providing Prescription Monitoring Information

(a) The [designated state agency or entity] should review the prescription information. Such reviews should include but not be limited to:

(I) A review to identify information that appears to indicate if a person may be obtaining prescriptions in a manner that may represent misuse or abuse of controlled substances. When such information is identified, the [designated state agency] should notify the practitioners and dispensers who prescribed or dispensed the prescriptions.

(II) A review to identify information that appears to indicate if a violation of law or breach of professional standards may have occurred. Whenever such information is identified, the [designated state agency] should notify the appropriate law enforcement and/or professional licensing, certification or regulatory agency or entity, and provide prescription information necessary for an investigation.

(b) The [designated state agency] is authorized to provide information in the prescription monitoring program upon request only to the following persons.

(I) Persons authorized to prescribe or dispense controlled substances or other drug required to be submitted under Section 5 of this Act, for the purpose of providing medical or pharmaceutical care for their patients or for reviewing information regarding prescriptions that are recorded as having been issued or dispensed by the requester.

(II) A patient who requests the patient's own prescription monitoring information, or of the parent or legal guardian of a minor child, in accordance with procedures

established under [insert state statute granting individuals access to state held information 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 or other drug required to be submitted under Section 5 of this Act activity] if the request is pursuant to an investigation or is pursuant to the agency's official duties and responsibilities.

(IV) Local, state and federal law enforcement or prosecutorial officials engaged in the administration, investigation or enforcement of the laws governing controlled substances or other drug required to be submitted under Section 5 of this Act pursuant to the agency's official duties and responsibilities.

(V) [Insert state Medicaid agency's unit(s) with legal authority to conduct investigations and utilization review of program services] regarding Medicaid program recipients or Medicaid program providers.

(VI) [Insert titles of medical examiners, coroners or others authorized under law to investigate causes of deaths] for cases under investigation pursuant to their official duties and responsibilities.

(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].

[Note: A state may determine to authorize additional agencies to request and receive prescription information including substance abuse treatment providers, worker's compensation board reviewers who are health care professionals, drug court judges, department of corrections' health care professional staff, and probation departments, if they cannot receive information under other provisions already authorized in (I) through (VII)]

(c) The [designated state agency] may provide information to public or private entities for statistical, research, or educational purposes after encrypting or removing the patient name, street name and number, patient ID number, and month and day of birth that could be used to identity individual patients and/or persons who received prescriptions from dispensers.

[Note: A state may choose 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

a) The [designated state agency] may provide prescription monitoring information to other states' prescription monitoring programs and such information may be used by those programs consistent with the provisions of this Act.

b) The [designated state agency] may request and receive prescription monitoring information from other states' prescription monitoring programs and may use such information under provisions of this Act.

c) The [designated state agency] may develop the capability to transmit information to and receive information from other prescription monitoring programs employing the standards of interoperability.

d) The [designated state agency] is authorized to enter into written agreements with other states' prescription monitoring programs for the purpose of describing the terms and conditions for sharing of prescription information under this section.

[Note: Some states have determined that their statute authorizes exchange of prescription monitoring information for individual cases with other PMPs without specific authorization, e.g. their statute lists authorized recipients of prescription monitoring information without regard to the residency of the recipients.]

[Note: Some states have determined that before their PMP begins routine exchange of prescription information with another PMP, their PMP must have a written memorandum of understanding in place with the other states' PMPs and/or there must be an interstate compact for such exchange (a committee is working on drafting such a compact as of February 2010).]

[Note: This section is not intended to interfere with a state's prerogative to provide prescription information directly to authorized persons or entities in other states.]

Section 9. 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 11 of this Act for unlawful acts.

Section 10. Rules and Regulations.

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

Section 11. 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 receive 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 receive 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.]

(d) A person who obtains or attempts to obtain information by fraud or deceit from the prescription monitoring program or from a person authorized to receive prescription monitoring information under this Act shall be subject to [insert appropriate administrative, civil or criminal penalty.]

Section 12. 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.

Section13. Effective Date.

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

Approved by the Alliance of States with Prescription Monitoring Programs at the Annual Business Meeting, June 28, 2010.

Alliance of States with Prescription Monitoring Programs
Promoting Public Health and Safety

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

[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.

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.

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 individual 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 only prescriptions issued or dispensed by the requestor 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:

- *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 Alliance of States with Prescription Monitoring Programs at: assist@pmpalliance.org or calling: 360-556-7152.

Responses to Comments Received Regarding the *Prescription Monitoring Program Model Act* *2010 Revision*

Final 2010-06-28

This document contains the Alliance of States with Prescription Monitoring Programs' responses to comments received from Alliance members and other stakeholders who replied to the Alliance's request for comments regarding the draft *Prescription Monitoring Program Model Act*, 2010 revision.

In 2009, the Alliance, with assistance from the Prescription Drug Monitoring Center of Excellence, established a PMP Model Act Committee to review the *PMP Model Act* which was last revised in 2002. The Committee was charged to examine technological and programmatic changes since the last revision as well as the "Best Practices" currently utilized by PMPs. Based upon this review, the Committee prepared a 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.

In February 2010, the Alliance Executive Board reviewed, revised and approved the draft *PMP Model Act* revisions and the Support Document prepared by the PMP Model Act Committee. These documents were then forwarded to all Alliance members and to other stakeholders for their review and comment.

Multiple comments were received from six parties. This document includes the comments and the Alliance's response to those comments. As noted below, appropriate modifications have been made in the draft documents.

The Alliance Executive Committee has reviewed and approved this "Responses to Comments" document, as well as the modifications made to the *PMP Model Act* and the Support Document.

The next steps are:

- Transmission of the *PMP Model Act, 2010 Revision,* the Support Document and this "Responses to Comments" document to all Alliance Members.
- Final adoption of the *Prescription Monitoring Program Model Act, 2010 Revision,* the Support Document and this "Responses to Comments" document by the Alliance Membership during the 6th National PDMP Meeting in Washington, DC, June 28 to 30, 2010.
- Distribution of the approved *PMP Model Act, 2010 Revision,* the Support Document, and this "Responses to Comments" document to all Alliance members and Stakeholders.
- Placement of these documents on the Alliance website.

Comment 1)
A PMP Administrator recommended a revision in the Support Document, "Section 7. Providing Prescription Monitoring Information." The re-wording would replace the second note regarding Sub-paragraph (b) (1).

Response 1)
Following consultation between the PMP Administrator and certain Committee members, consensus was reached to use the following wording:

> *[Note: Some states may choose ~~not~~ to allow a practitioner or dispenser to request reports of prescriptions issued or dispensed to individual 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 only prescriptions issued or dispensed by the requestor 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.]*

Comment 2)
The National Association of Boards of Pharmacy (NABP) provided several comments. Along with the comments the NABP letter "commends the insightful work that the PMP Model Act Committee put into the revision and agrees with the revised draft, with the following exceptions as denoted by underlines and strikethroughs."

Comment 2.1) The first suggested change is in Section 4, "Definitions." The recommended change is to add "or institutional facility … in order to encompass all in-patient based dispensers."

Response 2.1) The recommended change has been incorporated into the *PMP Model Act* and the proposed change is underlined below:

(d) "Dispenser" means a person who is lawfully authorized to deliver a Schedule II, III, IV, and/or V controlled substance as defined in subsection (d) to the ultimate user, but does not include:

(I) A licensed hospital or institutional facility 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, III, IV and/or V controlled substance.

Comment 2.2) The NABP recommended the reporting of all controlled substances in Schedules II through V as they determined this was required in order to best protect the public health.

Response 2.2) The recommended change has been incorporated into the *PMP Model Act* and the proposed change is underlined below:

> 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, and V 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.

Comment 2.3) The NABP recommended that the clause, [or designated State agency or entity], be removed. NABP "acknowledged that, although a myriad of state agencies administer PMPs (other than boards of pharmacy), this revision was aimed at providing guidance, particularly to those states that have yet to implement PMPs."

Response 2.3) While the Alliance appreciates NABP's desire to assist states that have yet to implement PMPs, the Alliance did not include the recommended change in its *PMP Model Act* for the following reasons:

A) Each state should be encouraged to determine which of its state agencies is most capable of administering its PMP to provide the greatest intervention in the epidemic of prescription controlled substances misuse, abuse, overdoses and deaths.

B) States, given the freedom to choose which agency can best administer their PMPs, have made widely varying choices, resulting in a selection of agencies with multiple skill sets. The types of agencies selected by the 41 states that had authorized PMPs as of January 1, 2010 are:

Consumer Protection Agency	1
Substance Abuse Agency	2
Law Enforcement Agency	6
Professional Licensing Agency	6
Department of Health	11
Pharmacy Board	15

(Source: Alliance/PMP Center of Excellence PMP State Profiles)

C) This multiplicity of agency types gives all PMPs, through the Alliance, access to a broad talent pool of expertise, skills, and models. Examples are:

a. The recently authorized Oregon PMP is going to be administered by the injury prevention staff of the Oregon Department of Health; thus bringing in new capabilities to address the epidemic of unintentional opioid poisoning deaths. Their skills can assist all PMPs.

b. Those PMPs administered by Substance Abuse Agencies are able to develop models for utilizing PMP data to assist in planning for drug treatment programs and in treatment of drug dependent individuals. They are creating a model for other states to follow.

c. Other Department of Health administered PMPs have developed epidemiological analysis and use of PMP data. These epidemiological reports are critical for identifying and intervening in the epidemic of prescription controlled substances misuse, abuse, overdoses and deaths.

D) Contrary to some assertions, prescribers request PMP data from PMPs administered by law enforcement with the same frequency as in states where Boards of Pharmacy administer the PMPs. A recent analysis by the Alliance of reporting by PMPs shows:

Proportion of PDMP Reports to Prescribers and Pharmacists by Type of PMP Agency

# of PDMPs	Type of Agency	% Reports to Prescribers & Pharmacists
3	Boards of Pharmacy	90% - 96%
3	Law Enforcement	90% - 96%

(Source: Alliance of States with Prescription Monitoring Programs, *An Assessment of State Prescription Monitoring Program: Effectiveness and Results Version 1.* November 30, 2007)

E) The presentation by Len Paulozzi, MD of CDC at the NASCSA Annual Educational Conference in 2009 presented data showing that California, Idaho, New York and Texas have rates of unintended drug overdose poisoning fatalities significantly lower than the national average and lower than other states with PMPs. Of these four states, only Idaho's PMP is administered by a Pharmacy Board.

Comment 2.4) "NABP recognizes that the Alliance, whose membership consists of state agencies that are responsible for PMPs, provides a forum for the exchange of information and ideas among state and federal agencies on PMPs. NABP also recognizes that the Alliance members are well versed in the requirements and strengths of PMPs as well as their challenges. The Alliance membership is comprised in part by some NABP member boards, thus we appreciate your request for assistance and hope that you continue to use NABP as a resource in the future."

Response 2.4) The Alliance appreciates this comment and looks forward to working with NABP in the future and invites NABP to use the Alliance's expertise in any future endeavors regarding PMPs and issues surrounding prescription drug abuse and diversion.

Comment 3)
"The Federation of State Medical Board (FSMB) Foundation (the 'Foundation') wishes to be recorded in support of The Alliance of States with Prescription Monitoring Programs Model Prescription Monitoring Act…… "The work of the Foundation is dedicated to providing a forum for the development, sharing, and

exchange of information and ideas for today's health care practitioner. We hope you will consider the Foundation as a resource as The Alliance implements its information sharing infrastructure in 2010 and beyond."

Response 3)
The Alliance appreciates the Federation of State Medical Board Foundation's expression of support for the PMP Model Act and looks forward to future collaborative work.

Comment 4)
The National Association of State Controlled Substances Authorities advises "The Model Act was shared with the NASCSA Executive Committee and no comments were made. The Executive Committee appreciates having had the opportunity to review the documents."

Response 4) The Alliance appreciates NASCSA's Executive Committee's review of the PMP Model Act.

Comment 5)
SAMHSA representatives commented, "We thought that it was very good, and we did not have any comments.

"Thank you for giving us the opportunity to review it before it is finalized."

Response 5)
SAMHSA's comment and support is most appreciated.

Comment 6)
A CDC representative provided a series of comments and questions regarding the Model Act, as follows:

> **Comment 6.1)** The commenter referred to Section 5, paragraph (b), which states: "Each dispenser shall submit to the [designated state agency] information regarding each prescription dispensed for a drug included under subsection (a) of this section. Any dispenser located outside the boundaries of [name of state] and is licensed and registered by the [insert name of state board of registration/licensure in pharmacy] shall submit information regarding each prescription dispensed to an ultimate user who resides within [name of state]."
>
> The commenter asked, regarding the last sentence. "Doesn't each dispenser have to submit data re all nonresidents of the state, too? Otherwise, there is no data to share on cross-border purchases."
>
> **Response 6.1)** The first sentence of the paragraph applies to all dispensers located within the state. The first sentence requires all of them to report all prescriptions dispensed, without regard to the address of the patient or the prescriber.
>
> The second sentence, ending in "[name of state]," only applies to dispensers located outside the state that is enacting this law. This second sentence assures that the PMP receives information it needs

from mail order and retail pharmacies located in other states and when such pharmacies are registered with the state Board of Pharmacy.

For example, the Board of Pharmacy in State A requires mail order and retail pharmacies located outside their state that ship prescriptions into State A to be registered (many states' Boards of Pharmacy have such requirements). The *PMP Model Act* would require that any such registered pharmacy must submit information to State A's PMP when the address of the patient is within State A.

Comment 6.2) The commenter referred to the note following Section 5, paragraph (e): *[Note: the following subsections, (f) – (i), are intended for those states that choose to establish a serialized prescription form system as part of the prescription monitoring program.]*

The commenter asked, "This language is tailored for serialized forms. Why not also include similar language for states that want to require special, tamper-resistant forms w/o serial numbers like CA?"

Response 6.2) The provisions regarding transfer-resistant forms without serial numbers belong in other portions of states' controlled substances laws, not in PMP statutes.

However, the serialized prescription forms need to be included in the *PMP Model Act* because serialized prescriptions are integral parts of PMPs that use them.

Comment 6.3) The commenter referred to Section 7 (b), sub-paragraph (V), "[Insert state Medicaid agency's unit(s) with legal authority to conduct investigations and utilization review of program services] regarding Medicaid program recipients or Medicaid program providers."

The commenter asked, "What about including other state benefits programs? Medicare Part D is becoming a bigger player. Workers compensation programs pay for drugs. Departments of Corrections dispense drugs to inmates. And what of Indian Health Service facilities that report data to the PDMP?"

Response 6.3) Following Section 7, (b), sub-paragraph (VII), the *PMP Model Act* contains a note to advise states that they may wish to authorize other organizations to access PMP data, including workers' compensation programs and departments of corrections. The note indicates that one or more of the listed entities may be authorized to receive data, "*if they cannot receive information under other provisions already authorized in (I) through (VII)."* This qualification is added because some states permit some of the listed organizations to obtain data through other provisions. For example, physicians in department of correction facilities may obtain PMP data under the prescriber provision or through the law enforcement provision. Likewise, Indian Health facilities' physicians may obtain data through the prescriber provision.

The Alliance also concurs that provision should be made for appropriate agencies within the Medicare Part D framework to access PMP data. For this purpose, the Alliance and PMP Center of Excellence will be seeking meetings with CMS to discuss how such access might be provided and the legal language by which to authorize such access within state statutes. When agreement is reached, the PMP Model Act will be amended to include that option.

Comment 6.4) The commenter referred to Section 7, paragraph (c), "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 identity individual patients and/or persons who received prescriptions from dispensers (Commenter highlighted this material).

The commenter asked, "Can you be more specific here? Otherwise a state may remove gender and year of birth, making even basic epidemiologic description of patients impossible. You could say, after removing month and day of birth, address. Also, patient ID number may be important for research to link Rxs to individuals, even if the ID number cannot be linked by the researcher to a person. So retaining patient ID number, if it is not something like SSN would be important."

Response 6.4) The Alliance is clarifying the section cited by the commenter. Paragraph (c) now reads:

> "The [designated state agency] may provide data to public or private entities for statistical, research, or educational purposes after encrypting or removing the patient name, street name and number, patient ID number, and month and day of birth that could be used to identity individual patients and/or persons who received prescriptions from dispensers."

The *PMP Model Act* included the patient number in the list of items to encrypt or remove because that number may be a drivers' license or other number by which a researcher potentially could identify the individual.

In addition, the PMP Center of Excellence is working to develop guidance material for PMPs regarding how to encrypt data in a manner that permits linking of prescriptions dispensed to the same individual but with no way to identify who the individual is. This should substantially assist researchers.

Comment 6.5) The commenter referred to the note following Section 7, paragraph (c) above, i.e. "*[Note: A state may choose to further restrict information released to researchers by removing information that could be used to identify any person. Before deciding to do so, a state may wish to consider if the state's definition of a "person" includes a corporation and, thus, by removing information that could be used to identify any person, information regarding corporations would also be removed.]*

The commenter asked, "I assume this mean identifying prescribers and dispensers, but it could be made more explicit for clarity.

Response 6.5) The note applies to any person who might be identified within a PMP's prescription record, not just prescribers and pharmacies. For example, one PMP also collects an identification number on the person who drops off a prescription at a pharmacy or the person who picks up the dispensed prescription.

For clarity, the Alliance has amended the note to read:

[Note: A state may choose 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.]