PDMP TTAC

Prescription Drug Monitoring Program Training and Technical Assistance Center

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.]