



## Report of the Task Force on Standards for the Use of PMP Data

### Members Present:

Joe Fontenot (LA), *chair*; Debra Billingsley (KS); LeeAnn Bundrick (SC); Susan DelMonico (RI); Carl Flansbaum (NM); Mark Hardy (ND); Virginia “Giny” Herold (CA); Ralph Orr (VA); David Schoech (KS); Laura Schwartzwald (MN); Joanne Trifone (MA).

### Others Present:

Jack “Jay” Campbell, *Executive Committee liaison*; Shiri Hickman (FSMB), Maureen Cahill (NCSBN), *guests*; Josh Bolin, Eileen Lewalski, Deborah Zak, Neal Watson, *NABP staff*.

### Introduction:

The Task Force on Standards for the Use of PMP Data met September 9-10, 2014, at NABP Headquarters. This task force was established in response to Resolution 110-4-14, Standards for the Use of PMP Data, which was approved by the NABP membership at the Association’s 110<sup>th</sup> Annual Meeting in May 2014.

### Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review existing current state laws and regulations addressing the use of Prescription Monitoring Program (PMP) data.
2. Review and, if necessary, recommend amending the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* to ensure regular, consistent, and appropriate use of PMP data.

### Recommendation 1: NABP Should Amend the *Model Act*.

The task force recommends the following changes to the *Model Act*, specifically to Appendix G Model Prescription Monitoring Act. The revisions recommended by the task force are denoted by underlines and ~~strikethroughs~~.

## Appendix G

### Model Prescription Monitoring Program Act

#### Section 1. Short Title.

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

#### Section 2. Legislative Findings.

(Insert State-appropriate mission/purposes.)

### Section 3. Purpose.

(Insert State-appropriate mission/purposes.)

### Section 4. Definitions.

- (a) “Dispenser” means a Person authorized in this State to distribute to the ultimate user a substance monitored by the Prescription Monitoring Program, but does not include:
- (1) a licensed hospital or institutional facility Pharmacy that distributes such substances for the purposes of inpatient care;
  - (2) a licensed nurse or medication aide who administers such a substance at the direction of a licensed physician;
- (b) “Drug of Concern” means any prescription or over-the-counter medication that demonstrates a potential for abuse, particularly those identified by Boards of Pharmacy, law enforcement, and addiction treatment professionals.
- (c) “Electronic Health Information Systems” means  
an electronic data intermediary, gateway, or hub that facilitates secure delivery of electronic health information to Practitioners or Dispensers;
- (1) health information exchanges;
  - (2) health Information networks;
  - (3) pharmacy software systems;
  - (4) electronic medical (health) record software applications;
  - (5) emergency department software applications; or
  - (6) electronic prescribing software applications.
- (d) “Interoperability” means the sharing of Prescription Monitoring Program Information with another PMP, or the integration of Prescription Monitoring Program Information into the Electronic Health Information Systems.
- (~~ee~~) “Prescription Monitoring Program Information” means information submitted to and maintained by the Prescription Monitoring Program.
- (~~fd~~) “Prescription Monitoring Program (PMP)” means a program established under Section 5 of this Act.

### Section 5. Establishment Of A Prescription Monitoring Program.

- (a) The Board of Pharmacy shall establish and maintain an electronic system for monitoring all controlled substances in Schedules II through V, all State-specified controlled substances in Schedules II through V, and State-specified Drugs of Concern dispensed to patients in this State.
- (b) The Board of Pharmacy may contract with a vendor to establish and maintain the electronic monitoring system pursuant to guidelines, which the Board of Pharmacy shall promulgate
- (c) The Board of Pharmacy shall promulgate rules or establish policy to include the following:
- (1) using the PMP to improve patient care and to facilitate the goal of reducing misuse, abuse, overdose, addiction to and diversion of controlled substances and drugs of concern;
  - (2) implementing security and safeguards necessary to ensure information is released only to authorized individuals;
  - (3) developing criteria for referring prescription monitoring information to a law enforcement agency, professional licensing agency, licensing board, or other state or

- federal agency charged with the regulation of prescribing, dispensing, or administering a controlled substance or drug of concern;
- (4) designing and implementing training, education, and/or instruction in the appropriate access to and use of the PMP;
  - (5) adopting the most recent version of the ASAP technical standards for electronic reporting of prescription monitoring information; and
  - (6) incorporating technological improvements to facilitate the interoperability of the PMP with other state PMPs and electronic health information systems and to facilitate prescribers' and dispensers' access to and use of the PMP.

## **Section 6. Reporting Of Prescription Monitoring Program Information.**

- (a) Each Dispenser shall submit to the Board of Pharmacy, by electronic means, or other format specified in a waiver granted by the Board of Pharmacy, ~~at a minimum of every seven days~~ within 24 hours, information specified by the Board of Pharmacy, including:
  - (1) ~~Drug Enforcement Administration identification~~ number of the Dispenser;
  - (2) ~~Drug Enforcement Administration identification~~ number of the Prescriber;
  - (3) patient name, address, and telephone number of the ultimate user;
  - (4) patient gender;
  - (5) patient dob;
  - (6) identification of the drug by a national drug code number;
  - (7) quantity dispensed;
  - (8) number of days supplied;
  - (9) number of refills ordered;
  - (10) whether drug was dispensed as a refill or as a new prescription;
  - (11) ~~date of dispensing~~ prescription was dispensed;
  - (12) if a refill, date of the original dispensing; and
  - (13) prescription number;
  - (14) date the prescription was issued by the prescriber;
  - (15) method of payment for the prescription; and
  - (16) such other information as may be required by State law.
- (b) Each Dispenser shall ensure that information reported to the PMP is correct and shall submit corrections when necessary.
- (c) Each Dispenser shall reverse information for any prescription that was not dispensed.

## **Section 7. Access To Prescription Monitoring Program Information/Confidentiality.**

- (a) Except as indicated in paragraphs (b), (c), and (d) of this Section 7, Prescription Monitoring Program Information submitted to the Board of Pharmacy shall be considered Protected Health Information and not subject to public or open records laws.
- (b) The Board of Pharmacy shall review the Prescription Monitoring Program Information. If there is reasonable cause to believe a violation of law (or breach of professional or occupational standards) may have occurred, the Board shall notify the appropriate law enforcement, or professional or occupational licensing, certification, or regulatory agency or entity, and provide Prescription Monitoring Program Information required for an investigation.
- (c) The Board of Pharmacy may provide Prescription Monitoring Program Information for public research, policy or education purposes, to the extent all information has been De-identified.
- (d) The following persons may access the Prescription Monitoring Program Information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar Protected Health Information under federal and State law and regulation

- (1) Practitioners (or agents thereof) or Dispensers (or agents thereof) who certify, under the procedures determined by the State, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient, or verifying PMP information for prescriptions issued by practitioners;
  - (2) Boards of Pharmacy or vendors/contractors for the purpose of establishing and maintaining the Prescription Monitoring Program;
  - (3) other state licensing, certification, or regulatory agencies that license, certify, or regulate health care professionals authorized to prescribe, administer, and dispense controlled substances, which certify, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a reportable substance, and such information will further the purpose of the investigation or assist in the proceeding;
  - (4) local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authorities, which certify, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a reportable substance, and such information will further the purpose of the investigation or assist in the proceeding;
  - (5) other appropriate entities as determined by the Board of Pharmacy; and
  - (6) Patients who certify, under the procedures determined by the State, that the requested information is for the purpose of obtaining and reviewing their own records.
- (e) The Board of Pharmacy shall be immune from civil liability arising from inaccuracy of any of the information submitted to the Board of Pharmacy pursuant to this Act.

### **Section 8 Interoperability**

- (a) The Board of Pharmacy shall execute a memorandum of understanding to participate in a single national hub capable of facilitating interoperability among Prescription Monitoring Programs and between prescription monitoring programs and electronic health information systems.
- (b) The Board of Pharmacy shall ensure that access to Prescription Monitoring Program Information by other state prescription monitoring programs is limited to persons described in Section 7(d).
- (c) The Board of Pharmacy shall establish the technological connectivity and infrastructure to facilitate the secure delivery of Prescription Monitoring Program Information to authorized users of Prescription Monitoring Programs through other states' Prescription Monitoring Programs or Electronic Health Information Systems.
- (d) Any such gateway, hub or any electronic health information system that facilitates the integration of Prescription Monitoring Program Information into a patient's medical record shall:
  - (1) verify the identity of the individual requesting the Information;
  - (2) verify the credential of the individual requesting the Information;
  - (3) provide the Board of Pharmacy with an audit trail for each request; and
  - (4) maintain the security and confidentiality of such information.

### **Section 98. Unlawful Acts And Penalties.**

- (a) A Dispenser who knowingly fails to submit Prescription Monitoring Program Information to the Board of Pharmacy as required by this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

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- (b) A person who knowingly accesses or uses Prescription Monitoring Program Information without authorization in violation of this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).
- (c) A person authorized to have Prescription Monitoring Program 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).
- (d) A person authorized to have Prescription Monitoring Program Information pursuant to this Act who uses such information in a manner or for a purpose in violation of this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

### **Section 109. Evaluation, Data Analysis, And Reporting.**

- (a) The Board of Pharmacy shall design and implement an evaluation component to identify cost benefits of the Prescription Monitoring Program, and other information relevant to policy, research, and education involving substances monitored by the PMP.
- (b) The Board of Pharmacy shall report to the (insert appropriate State decision makers, eg, legislature) on a periodic basis, no less than bi-annually, about the cost-benefits and other information noted in paragraph (a).

### **Section 1140. Rules And Regulations.**

The Board of Pharmacy shall promulgate rules and regulations necessary to implement the provisions of this Act.

### **Section 1244. Severability.**

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

### **Section 1342. Effective Date.**

This Act shall be effective on (insert specific date or reference to normal State method of determination of the effective date).

## Comments

### **Section 4(a)(1). Comment.**

This reporting exception also applies to situations where a patient, who has been dispensed controlled substance medications during a stay in an institutional facility, is allowed to retain any remaining medication upon discharge.

### **Section 6(a)(2). Comment.**

It is recommended that boards of pharmacy consider using practitioners' NPI number for identification purposes

### **Section 7(b). Comment.**

This section is intended to allow boards of pharmacy to evaluate Prescription Monitoring Program information and determine appropriate information to provide to law enforcement entities. It is not intended to allow law enforcement officials open access to all data.

### **Section 7(d)(5). Comment.**

It is recommended that appropriate entities include drug courts, district attorneys' offices, addiction treatment professionals, or other similar entities, and only for the purpose of ensuring appropriate patient treatment, as opposed to efforts to search for information without knowledge of whether such information exists.

### **Background:**

The task force reviewed in detail Appendix G of the *Model Act*, the Model Prescription Monitoring Program Act, and determined that a number of revisions were necessary to address interoperability of state PMPs, to reaffirm the position that the boards of pharmacy should be the entities responsible for overseeing state PMPs, and to add and/or revise information that should be reported. Mainly, members stressed the need for interoperability between state PMPs as sharing PMP information is vital to making sound prescribing and dispensing decisions and curbing prescription drug abuse and diversion. The task force agreed that it was imperative to add language that addressed the facilitation of sharing PMP information between PMPs and/or electronic health systems.

Task force members discussed boards' of pharmacy roles with the state PMPs and agreed that in order to increase uniformity, the boards should be the state entity responsible for overseeing PMPs and promulgating PMP rules or establishing PMP policy. They determined that board oversight could assist with increasing interoperability between state PMPs and ensuring the most effective and appropriate use of PMP information.

Lastly, members reviewed the type of information that should be reported and recommended several revisions. They discussed the timeframe for reporting PMP information and the tenet that the *Model Act* is considered to be the highest standard and decided to increase the reporting frequency from "at a minimum of every 7 days" to "within 24 hours." Additionally, the task force agreed to change "Drug Enforcement Administration" to "identification" number and commented that states should consider using practitioner NPI numbers for identification

purposes. Members decided to add reporting fields for gender, date of birth, prescription number, date of issuance, and method of payment as they agreed this was relevant information that could serve in helping to make prescribing and dispensing decisions. The task force also discussed the problems associated with dispensers submitting incorrect information and determined that a subsection pertaining to correcting erroneous information be added. Along those lines, the members also agreed to add a subsection that requires dispensers to reverse information that was previously reported to a PMP for prescriptions that were ultimately not dispensed.

**Recommendation 2: NABP Should Encourage State Boards of Pharmacy to Mandate That Practice Sites Provide Access to PMP Data and Encourage Use of This Data.**

The task force recommends that NABP should encourage state boards of pharmacy to mandate that practice sites provide access to PMP data and encourage use of this data as part of fulfilling pharmacists' corresponding responsibility, drug utilization review, and counseling duties.

**Background:**

Several task force members shared discussions they had with practicing pharmacists who voiced concern regarding the ease of registering and accessing PMPs at their practice sites, or more aptly stated, the lack thereof. Members further discussed the importance of registering and accessing PMP information and agreed that practitioners should not be mandated to access PMP information for every controlled substance prescription that is presented, but that employers must provide access as part of allowing pharmacist to fulfill their corresponding responsibility, drug utilization review, and counseling duties.

**Recommendation 3: NABP Should Collaborate with State Boards of Pharmacy and Other Stakeholders to Educate Health Care Practitioners and Provide Guidelines on How to Utilize PMP Data.**

The task force recommends that NABP should collaborate with the state boards of pharmacy and other stakeholders to educate health care practitioners and provide guidelines on how to utilize PMP data including how to properly review and analyze the data in order to assist in prescribing and/or dispensing decisions.

**Background:**

Members discussed the issue of practitioners having access to PMP information but then sometimes being unsure as to how to interpret it while incorporating professional judgment when dispensing controlled substance prescriptions. They decided that the best approach would be to provide guidelines that will assist practitioners on how to incorporate PMP information with professional judgment, corresponding responsibility, and standards of care to assist in making prescribing and dispensing decisions.

**Recommendation 4: NABP Should Work with State PMPs and Reporters of PMP Data to Ensure the Accuracy and Timeliness of Reported Data, and that Incorrectly Reported Data Is Corrected and that Information for Undispensed Prescriptions Is Reversed.**

The task force recommends that NABP should work with the state PMP programs and those reporting PMP data to ensure that all reported data is accurate, timely, and that incorrectly

reported data is corrected, as well as any data from prescriptions that were reported but ultimately not dispensed is reversed.

**Background:**

The task force expressed concern over the frequency of incorrect PMP information being reported or undispensed prescription information not being reversed. Several members relayed how problematic the reporting of incorrect Drug Enforcement Administration (DEA) registration numbers has become – errant red flag notices sent to prescribers and prescribers maintaining that prescriptions were forged – all because incorrect DEA number was reported. Members agreed that in order to address the issue of incorrect PMP information, specific language should be added to the reporting section of the *Model Act* and boards of pharmacy should be encouraged to incorporate it into their board regulations. Members agreed that boards should be able to assess fines for providing incorrect and/or incomplete information thereby increasing compliance with reporting requirements.

**Recommendation 5: NABP Should Assist the States in Developing Partnerships and If Necessary, Laws and Regulations, for the State Boards of Pharmacy to Increase the Use and Scope of PMP Data.**

The task force recommends that NABP should assist the states in developing partnerships and if necessary, laws and regulations, for the state boards of pharmacy to allow for research to be conducted on PMP data to identify prescribing and/or dispensing trends in order to decrease misuse, abuse, and diversion of controlled substances and protect the public health and legitimate prescribing and/or dispensing practices.

**Background:**

Task force members discussed the need for further research to be conducted on PMP information to assist in identifying prescribing and dispensing trends. Members agreed that it was good public policy to analyze PMP information, and in particular, to conduct interstate research in order to incorporate geographical information to compare prescribing and dispensing practices, overdose statistics, and distances that patients are traveling to obtain controlled substance medications.

**Recommendation 6: NABP Should Continue to Develop PMP InterConnect and PMP Gateway in Order to Facilitate Secure Interoperability between State PMPs and Electronic Health Information Systems.**

The task force recommends that NABP should continue to develop PMP InterConnect and PMP Gateway in order to facilitate secure interoperability between state PMPs and electronic health information systems.

**Background:**

The task force was provided with an overview of PMP Gateway and how it can facilitate data integration into health care practitioners' workflow, specifically by facilitating the secure transfer of PMP information into electronic health information systems, including pharmacy software. Members agreed that it would be very beneficial to continue the development of PMP Gateway in order to increase the interoperability among state PMPs and electronic health information systems.