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.