



Prescription Drug Monitoring Program

PDMP Model Act 2020

August 2020

In 2010, the Prescription Drug Monitoring Program Training and Technical Assistance Center (TTAC) collaborated with prescription drug monitoring program (PDMP) Administrators to develop a PDMP Model Act. Since then, there have been substantial changes in the operations and capabilities of PDMPs. To address those changes and update the PDMP Model Act, TTAC convened a workgroup consisting of PDMP representatives to provide PDMP Administrators with an optimal public health and safety framework for adding new functionality or programs to the PDMP. The Model Act language reflects the collective body of in-depth knowledge and experience of PDMP Administrators over the years. The Model Act is a consensus document that reflects PDMP best practices from the PDMP Administrators' perspectives. The suggested language in this document should be used by states as guidance to draft their own legislation or regulations.

The PDMP Training and Technical Assistance Center (TTAC), based at the Institute for Intergovernmental Research (IIR) and supported by the Bureau of Justice Assistance (BJA), 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. TTAC 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.

This revision of the Model Act builds upon many years of collaborative work by TTAC and by many individual states and organizations. This revised and updated Model Act incorporates proposed language of best practices and initiatives undertaken by PDMPs over the years. It also is a product of various concepts contributed by many PDMP Administrators, based on their experiences operating PDMPs, and by PDMP Administrators from Alabama, California, Florida, Kentucky, and Pennsylvania who made up the workgroup that revised the Model Act. In addition, all PDMP Administrators were presented with a draft PDMP Model Act in April 2020 and given the opportunity to provide comments on any of the sections. The following contains finalized PDMP Model Act 2020 and the comments that were received from several PDMP Administrators, as well as further suggestions from the workgroup and responses for addressing them.

The Prescription Drug Monitoring Program (PDMP) Model Act 2020 provides state administrators with model language that PDMPs may use when considering developing state laws to ensure that health care practitioners have complete and reliable information regarding their patients' controlled substance histories and to assist law enforcement in combating drug diversion. The Act includes sections on establishment of advisory boards or committees, reporting, access and use, incorporating alternate data sources, interstate data sharing, audit trail information and transmission audit logs, integration, confidentiality, practitioner activity reports, mandatory registration and query requirements, immunity, data analysis, rules and regulations, unlawful acts, and penalties and severability.

Prescription Drug Monitoring Program Model Act 2020

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Section 1. Short Title.

This Act shall be known and may be cited as the “Prescription Drug Monitoring Program (PDMP) Act.”

Section 2. Legislative Findings.

[Insert findings here]

Section 3. Scope and Purpose.

The purpose of this Act is to provide a tool that will ensure that health care practitioners making prescribing and dispensing decisions have complete and reliable information regarding their patients’ controlled substance and other monitored drug history to help curtail misuse and abuse and to assist law enforcement in combating drug diversion.

Section 4. Definitions.

For purposes of this Act, unless the context clearly indicates otherwise, the following words and phrases shall have the meanings given to them in this Section:

- (a) “Administer/Administration” means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means;
- (b) “Administering agency/Board/Department [designated state agency or entity]” means the agency responsible for maintenance and operation of the PDMP;
- (c) “Advisory Committee” means the entity established under Section 6 of this Act;
- (d) “Audit trail information” means any query-based information resulting from an authorized prescription monitoring program user’s request for a PDMP report, which could include the user’s name, date and time of query, or other related information;
- (e) “Bona fide patient relationship” means an established relationship in which the practitioner has ongoing responsibility for the assessment, care, and treatment of a patient;
- (f) “Data integration” means the linking of the PDMP into health information technology systems to allow health systems, pharmacies, or health information exchanges to seamlessly access PDMP data;

- (g) “Date prescription filled” means the date a prescription is prepared and ready for delivery to a patient;
- (h) “Date prescription dispensed/sold” means the date a prescription is delivered to the patient or the patient’s legal guardian or agent on behalf of the patient, provided that, for prescriptions delivered by mail or other common carrier, it is the date placed in the mail or for delivery;
- (i) “De-identified data/information” means information that is not individually identifiable information or direct identifiers and specified demographic information have been removed in a manner consistent with State law and 45 CFR 164.514 ;
- (j) “Deliver” or “delivery” means the actual, constructive, or attempted transfer of a controlled substance or other drug from one person to another;
- (k) “Designee/Delegate/Agent” means an individual designated by and who reports to a prescriber, dispenser, or chief medical examiner/coroner who is employed by or under contract with the prescriber, dispenser, or chief medical examiner/coroner, to access the PDMP for the purpose of clinical care of bona fide current patients of the authorizing prescriber or dispenser, or related to a bona fide investigation or inquiry into an individual’s death by the chief medical examiner/coroner. The prescriber, dispenser, or chief medical examiner/coroner shall be accountable for the delegate’s actions;
- (l) “Dispense” means to deliver a controlled substance or other monitored drug to a bona fide patient by lawful means and includes the packaging, labeling, or compounding necessary to prepare the medication for such delivery, with the intent that it be consumed away from the premises on which it was dispensed. For purposes of this Act, physical delivery includes mailing monitored substances into this state;
- (m) “Dispenser” means a practitioner who dispenses a controlled substance or other monitored drug to an ultimate user, or his or her agent, but does not include:
 - i. A licensed hospital pharmacy that distributes controlled substances or other monitored drugs for the purpose of inpatient hospital care, or at the time of discharge from such a facility, except for a pharmacy owned by a hospital that has a retail pharmacy permit when the pharmacy is distributing controlled substances or other monitored drugs directly to the public;
 - ii. An institutional pharmacy that serves only a health care facility, including, but not limited to, a nursing home, an intermediate care home, a personal care home, or a hospice program, which provides patient care and which pharmacy dispenses controlled substances or other monitored drugs to be administered and used by the patient on the premises of the facility;

- iii. A practitioner or other authorized person who administers a monitored substance/ covered substance;
 - iv. A pharmacy operated by, or on behalf of, or under contract with, the Department of Corrections for the sole and exclusive purpose of providing services in a secure environment to prisoners within a penal institution, penitentiary, prison, detention center, or other secure correctional institution, including correctional institutions operated by private entities in this state which house inmates under authority of the Department of Corrections;
 - v. A manufacturer or wholesale distributor of controlled substances or other monitored drugs; or
 - vi. A clinical researcher providing a controlled substance or other monitored drug to research subjects as part of a research study approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protections programs;
- (n) “Drug” means any of the following:
- i. Any substance recognized as a drug, medicine, or medicinal chemical in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, or official Veterinary Medicine Compendium, or other official drug compendium or supplements thereto;
 - ii. Any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal;
 - iii. Any chemical substance, other than food, intended to affect the structure or any function of the body of man or other animal; and
 - iv. Any substance intended for use as a component of any items specified in subparagraphs (a), (b), or (c) of this paragraph, but does not include medical devices or their components, parts, or accessories;
- (o) “Drug of concern” means a drug, other than a controlled substance, as defined by rule which demonstrates a potential for abuse or diversion;
- (p) “Electronic health record” or “EHR” means the electronic version of a patient’s medical history, that is maintained by a provider over time, and may include all of the key administrative clinical data relevant to that patient’s care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports;
- (q) “Health care system” means an organization of people, institutions, and resources that deliver health care services to meet the health needs of target populations;
- (r) “Health information exchange” or “HIE” is the mobilization of health care information electronically across organizations within a region, community, or hospital system. In practice, the term HIE may also refer to the organization that facilitates the exchange;

- (s) “Health information system or health information technology system” refers to a system designed to manage healthcare data. This includes systems that collect, store, manage, and transmit a patient’s electronic health record, a hospital’s operational management, or a system to support healthcare policy decisions;
- (t) “Interoperability/Exchangeability” means, with respect to [this state] or another state’s prescription drug monitoring program, the ability of that program to share electronically reported prescription information with another state, district, or territory of the United States’ prescription drug monitoring program or a third party, approved by the [administering agency], that operates interstate prescription drug monitoring exchanges;
- (u) “Law enforcement personnel” means agents of the [state] bureau of investigation, federal Drug Enforcement Administration agents, and other state, local, and federal law enforcement officers and law enforcement officers of other states;
- (v) “Licensing/regulatory board” means an entity authorized by law to license, regulate, or discipline a prescriber or dispenser;
- (w) “Monitored drug” means all controlled substances included in Schedules II, III, IV, and V of the federal or state Controlled Substances Act [statutory references], prescription drugs, and any other drug(s) of concern, as specified by rulemaking, that is required to be reported to the PDMP pursuant to this Act;
- (x) “Nonresident pharmacy or mail order pharmacy” means a pharmacy located outside of [state] in any state in the United States or any province or territory of Canada that ships, mails, or delivers prescription drugs and/or devices to a patient or person in [state];
- (y) “Office based opioid treatment” or “OBOT” means opioid treatment within a healthcare provider’s practice for prescribing, dispensing or administering buprenorphine as established by the Drug Abuse and Treatment Act of 2000;
- (z) “Opioid treatment program” or “OTP” means a specialty addiction treatment program for dispensing and administering opioid-replacement medication including methadone and buprenorphine under carefully controlled and observed conditions as defined and regulated by federal regulation 42 CFR, Part 8;
- (aa) “Patient” means:
 - i. The person or animal who is the ultimate user of a controlled substance or other monitored drug required to be submitted to the PDMP for whom a lawful prescription is issued and for whom a controlled substance or such other monitored drug is lawfully dispensed; or

- ii. A person or animal with whom a practitioner has a bona fide patient relationship.
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- (bb) “Patient identification number” means the unique number contained on a valid passport, military identification card, driver’s license, or identification card issued to a recipient pursuant to State law or similar law of another state if the recipient is not a resident of the State of [state], or if the recipient is less than 18 years old and has no such identification, the unique number contained on a valid passport, military identification card, driver’s license, or identification card issued to the recipient’s parent or guardian, or if the monitored drug is obtained for an animal, the unique number contained on the animal owner’s valid driver’s license or identification card. Nonresident drug outlets registered pursuant to the [State Pharmacy Act] and resident drug outlets as defined by law are exempt from the picture identification requirement if the nonresident and resident drug outlets have obtained the identification of the patient through the prescription benefit plan of the patient;
 - (cc) “Person” means an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture, or any legal or commercial entity;
 - (dd) “Personally identifiable information” means information that can be associated with a particular person through one or more identifiers or other information or circumstances;
 - (ee) “Pharmacy” means an established location, either physical or electronic, licensed or registered by the [designated state agency or entity] where drugs or devices are dispensed;
 - (ff) “Pharmacy dispensing system” means a system that automatically performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, and labeling for dispensing and delivery of medications, and that collects, controls, and maintains all transaction information;
 - (gg) “Pharmacist” means an individual licensed under state law [insert citation here] to dispense a monitored drug;
 - (hh) “Practitioner” means any of the following:
 - i. A physician, dentist, podiatrist, veterinarian, advanced practice registered nurse, physician assistant, pharmacist, naturopath, optometrist, scientific investigator, or other person licensed, registered, or otherwise permitted to prescribe, dispense, conduct research with respect to, or to administer a monitored drug in the course of professional practice or research in this state;
 - ii. A pharmacy, including a nonresident pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to dispense, conduct research with

- respect to, or to administer a monitored drug in the course of professional practice or research in this state;
- iii. Individuals with a federal license to prescribe, administer, or dispense controlled substances;
 - (ii) “Prescribe” means to issue a direction or authorization, by prescription, permitting a bona fide patient to lawfully obtain a controlled substance or other monitored drug from any person authorized by law to dispense a monitored drug;
 - (jj) “Prescriber” means a licensed health care professional with the authority to write and issue prescriptions:
 - (kk) “Prescription” means an order transmitted orally, electronically, or in writing by a prescriber for a monitored drug for a particular patient;
 - (ll) “Prescription drug” means a drug that cannot be dispensed without the written, oral, or electronic prescription of a prescriber;
 - (mm) “PDMP/PMP/program” means a program that collects, manages, analyzes, and provides information regarding Schedules II, III, IV, and V controlled substances and other monitored drugs required to be submitted to the PDMP under this Act or a program established by a similar Act in the United States, another state, district, or territory of the United States, or any subdivision thereof;
 - (nn) “Prescription monitoring information” means data submitted to and maintained by the PDMP established under this Act;
 - (oo) “Proactive notification/Unsolicited report” means a notification by the administering agency/board/department, generated based on factors determined by the administering agency/board/department and issued to a specific practitioner or pharmacist, indicating that a patient may be practitioner shopping or pharmacy shopping or at risk of abusing or misusing a controlled substance or other monitored drug;
 - (pp) “Prospective patient” means an individual who:
 - i. Is seeking medical advice, medical treatment, or medical services from a practitioner; and
 - ii. The practitioner is considering accepting as a patient;
 - (qq) “Public health surveillance” means the continuous, systematic collection, analysis, and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice. Public health surveillance may be used for all of the following purposes:

- i. as an early warning system for impending public health emergencies;
 - ii. to document the impact of an intervention;
 - iii. to track progress towards specified goals;
 - iv. to monitor and clarify the epidemiology of health problems;
 - v. to establish public health priorities; and
 - vi. to inform public health policy and strategies;
- (rr) “Reciprocal agreements” means a written agreement that provides for the exchange of information requests and responses of PDMP data between data-sharing partners if access under such agreements is consistent the privacy, security, and disclosure protections under applicable laws and regulations;
- (ss) “Replacement prescription” means an unscheduled prescription request in the event the document on which a patient’s prescription was written has been lost or stolen, or the patient’s prescribed medication is reported to the prescriber as having been lost or stolen;
- (tt) “Controlled substance/Schedules II – V controlled substances” means a controlled substance included in Schedules II, III, IV, or V of 21 United States Code, Section 812 or 21 CFR, Section 1308, or the Controlled Substances Act of this state [statutory reference];
- (uu) “State” means any state, territory, or possession of the United States, any subdivision thereof, or the District of Columbia;
- (vv) “Transmission audit log” means a report created by the PDMP of all monitored drugs reported to the PDMP by a dispenser;
- (ww) “Ultimate user” means a person who lawfully possesses a controlled substance or other monitored drug for:
- i. the person’s own use;
 - ii. the use of a member of the person’s household; or
 - iii. administering to an animal owned by a person or by a member of the person’s household;
- (xx) “Zero report” means a report that indicates that a dispenser has not dispensed a monitored drug since the previous submission of dispensing data or zero report;

Section 5. Establishment of Prescription Drug Monitoring Program.

- (a) The [designated state agency or entity] shall establish, maintain, and administer, [in consultation with the Advisory Committee,] an electronic system to monitor the prescribing and dispensing of all Schedule II – V controlled substances and other monitored drugs prescribed and dispensed in this state or dispensed to an address in this state.
- (b) The [designated state agency or entity] may contract with another state agency or a private vendor as may be necessary for the implementation and maintenance of the PDMP. Any such contractor shall be bound to comply with the provisions regarding confidentiality of data in this Act and shall be subject to the penalties specified in this Act.

Section 6. Advisory Committee. [Optional]

- (a) The [designated state agency or entity] shall establish a multi-disciplinary advisory committee which shall function under the [designated state agency or entity] to advise in the implementation, maintenance, and administration of the PDMP, and to make recommendations to the [designated state agency or entity].
- (b) The advisory committee shall consist of [n] members. The members of the committee may include the following:
 - i. The [Director/Secretary/Commissioner] of the [designated state agency or entity], or his or her designee;
 - ii. At least two representatives from the PDMP, one of whom shall be the person responsible for administration of the PDMP, or his or her designee, and one of whom may be an epidemiologist or data analyst;
 - iii. At least three representatives of the Board of Medicine, at least one of whom shall be a pain medicine specialist and one of whom shall be a physician assistant, appointed by such board;
 - iv. A representative of the Board of Pharmacy, appointed by such board;
 - v. A representative of the [Dental Board/Board of Dental Examiners/Board of Dentistry], appointed by such board;
 - vi. A representative of the Board of Nursing who shall be an advanced practice registered nurse, appointed by such board;
 - vii. A representative of the Board of Veterinary Medicine, appointed by such board;
 - viii. [Any additional licensing or regulatory board representatives should be included here]
 - ix. The Chief Medical Examiner, or his or her designee;
 - x. The Attorney General, or his or her designee;
 - xi. The Commissioner of the Department of Health, or his or her designee;

- xii. A representative of the [state] police;
 - xiii. A representative of local law enforcement, appointed by the [state] Chiefs of Police Association or the [state] Sheriff's Association;
 - xiv. [A state prosecutor, appointed by the [state] Prosecutor's Association];
 - xv. [A public defender, appointed by the [state] Public Defender's Association];
 - xvi. [A certified addiction specialist, appointed by the appropriate licensing board or agency;
 - xvii. [A certified recovery specialist, appointed by the (state association of addiction treatment programs)];
 - xviii. [Two/three] members of the public who represent the perspective of patients, appointed by the [governor/secretary of the department of health];
- (c) The [Director/Secretary/Commissioner] of the [designated state agency or entity] shall designate the Chair of the Committee.
- (d) The members of the Committee shall serve at the pleasure of their respective designating entity. The term of a member appointed to the Committee is [n] years. If a vacancy occurs during the term of an appointed member, the [Director/Secretary/Commissioner] of the [designated state agency or entity] shall appoint a successor who shall serve until the term expires.
- (e) A majority of the members of the Committee shall constitute a quorum.
- (f) Members of the Committee shall not receive compensation for their services as members of the Committee [however, members may be reimbursed for actual expenses incurred in carrying out their duties as members of the Advisory Committee pursuant to (statutory reference)].
- (g) The Advisory Committee shall convene at least [n] times per year.
- (h) The Advisory Committee shall:
- i. Evaluate and recommend changes to the [state] administrative rules regarding the PDMP;
 - ii. Evaluate and recommend changes to this Act;
 - iii. Review opportunities for federal grants and other forms of public or private funding to support projects to increase data integration;
 - iv. Recommend and periodically review criteria for reviewing the prescribing and dispensing information collected;
 - v. Recommend and periodically review criteria for reporting matters to the applicable licensing or regulatory board for further investigation;
 - vi. Recommend and periodically review criteria for notifying practitioners of patients who are engaged in obtaining monitored drugs from multiple prescribers and/or dispensers;

- vii. Recommend and periodically review criteria for referring prescription monitoring information to law enforcement officials;
 - viii. Collect information on the outcomes and impact of the PDMP;
 - ix. Provide ongoing advice and consultation on the implementation and operation of the PDMP, including recommendations relating to:
 - 1. Changes in the PDMP to reflect advances in technology and best practices in the field of electronic health records and electronic prescription monitoring;
 - 2. Interoperability with other PDMPs and electronic health information systems;
 - 3. Improvements in prescriber and dispenser access to and use of the PDMP;
 - x. Recommend drugs of concern that should be monitored by the PDMP;
 - xi. Advise in the implementation of online educational courses for persons authorized to access PDMP information; and
 - xii. Make recommendations regarding the proper analysis and interpretation of PDMP information.
- (i) The Advisory Committee shall not have access to any personally identifiable information from the PDMP.

Section 7. Reporting of Prescription Monitoring Information.

- (a) Each dispenser, or his or her designee, shall submit to the [designated state agency or entity] by electronic means, except as provided in subsection (d) below, information required by the [designated state agency or entity] regarding each prescription dispensed for a monitored prescription drug. Such information shall include, but not be limited to, the following:
- i. Dispenser identification number;
 - ii. Date prescription filled;
 - iii. Date prescription sold;
 - iv. Prescription number;
 - v. Whether the prescription is new or a refill;
 - vi. National Drug Code (NDC);
 - vii. Quantity dispensed;
 - viii. Days' supply;
 - ix. Number of refills;
 - x. Patient identification number;
 - xi. Patient name, address, date of birth, and gender;
 - xii. Patient telephone number;
 - xiii. Patient email address;
 - xiv. Species code, if applicable;
 - xv. Name of animal, if applicable;
 - xvi. Prescriber identification number;

- xvii. Date prescription issued by prescriber;
- xviii. If the prescription is picked up by an individual other than the person for whom the prescription was written, the name, address, and identification number for the individual picking up the prescription;
- xix. Method of payment; and
- xx. Such additional information as the [designated state agency or entity] may require by rule.

[Comment: Per the ONC, states may wish to add the following additional fields as data elements required to be reported to help with patient matching: (1) previous name; (2) race; (3) ethnic group; (4) previous address; and (5) telephone number designation (work/home/cell).]

- (b) Each dispenser shall submit the required information in accordance with the transmission methods and frequency established by the [designated state agency or entity], but no later than [24 hours/one calendar day] from the date the prescription was dispensed.
- (c) If no monitored drugs are dispensed, the dispenser must transmit a zero report to the PDMP once every [24 hours/one calendar day].
- (d) The [designated state agency or entity] may issue a waiver to a dispenser who is unable to submit prescription information by electronic means. The waiver shall state the format and frequency with which the dispenser shall submit the required information. Such waiver shall be valid for a period of not more than [one year/two years] at which time the dispenser shall be required to reapply for the waiver.
- (e) The [designated state agency or entity] may grant an extension of time within which to submit prescription monitoring information if:
 - i. The dispenser suffers a mechanical failure, or cannot meet the submission frequency established by the [designated state agency or entity] for other reasons beyond the dispenser's control and the dispenser submits a written application for an extension to the [designated state agency or entity] within [24 hours/72 hours] of the discovery of the circumstance necessitating the extension request or on the next day the [designated state agency or entity]'s office is open for business; or
 - ii. The [designated state agency or entity] is unable to receive electronic submission;
- (f) Prescription monitoring information submitted to the [designated state agency or entity] shall be retained in a readily retrievable format for a minimum of [n] years from the date such information is received by the [designated state agency or entity]. The [designated state agency or entity] may retain prescription monitoring information that has been deidentified for no more than [n] years. The [designated state agency or

entity] shall promulgate regulations and procedures that will ensure that any identifying information received from any dispensing or reporting entity that is more than [n] years old is deleted or destroyed on an ongoing basis in a timely and secure manner.

- (g) A law enforcement agency or an [agency, board, department] charged with administrative oversight of those persons engaged in the prescribing or dispensing of monitored prescription drugs may submit a written request to the [designated state agency or entity] requesting that specific prescription monitoring information, related to an open investigation or prosecution, be retained beyond the [n] year retention period.
- (h) The [designated state agency or entity] shall notify a dispenser of an error in data reporting. Upon receiving notification of an error in data reporting, the dispenser shall take appropriate measures to correct the error and transmit the corrected data to the [designated state agency or entity] within [n] calendar days of being notified of the error.
- (i) A patient who identifies an error in his or her prescription monitoring information shall notify the dispenser responsible for submitting such information. The dispenser shall take all steps necessary to verify the information and make any corrections necessary.

Section 8. Access to and Use of Prescription Monitoring Information.

- (a) The [designated state agency or entity] or its designee shall review the prescription monitoring information collected pursuant to this Act. If the [designated state agency or entity] has reason to believe that a violation of law or breach of professional standards may have occurred, the [designated state agency or entity] or its designee shall notify the appropriate licensing or regulatory board or law enforcement agency in the form of a proactive notification/unsolicited report and provide them with the prescription information required for an investigation.
- (b) The [designated state agency or entity] or its designee shall further review the prescription monitoring information to identify information that appears to indicate that a patient may be obtaining prescriptions in a manner that may represent misuse, abuse, or diversion of monitored prescription drugs. If the information appears to indicate that misuse, abuse, or diversion has occurred, the [designated state agency or entity] shall notify the prescribers and dispensers who have prescribed or dispensed for that patient and provide them with the prescription information relevant to that patient in the form of a proactive notification/unsolicited report.
- (c) The [designated state agency or entity] is authorized to provide prescription monitoring information upon request to the following:

- i. A prescriber for the purpose of providing medical care to a current bona fide or prospective patient, or to inquire about the prescriber's own prescribing activity;
- ii. A dispenser for the purpose of providing pharmaceutical care to a current bona fide or prospective patient, or to inquire about the dispenser's own dispensing activity;
- iii. A delegate appointed by a prescriber or dispenser for the purposes of requesting prescription monitoring information on a specific patient and at the request of the delegating prescriber or dispenser. The prescriber or dispenser shall be legally and professionally responsible for a delegate's access, use, and disclosure of PDMP data on behalf of the prescriber or dispenser.
- iv. [Local, state, and federal law enforcement or prosecutorial officials engaged in the administration, investigation, or enforcement of the laws governing monitored prescription drugs and who are involved in an investigation or prosecution of a specific patient, prescriber, or dispenser;]

[Local, state, and federal law enforcement or prosecutorial officials with a subpoena, search warrant, court order, or other form of judicial process who are engaged in the administration, investigation, or enforcement of the laws governing monitored prescription drugs and who are involved in an investigation or prosecution of a specific patient, prescriber, or dispenser;]
- v. A licensing or regulatory board responsible for licensing or certifying prescribers or dispensers if the request is pursuant to an administrative/regulatory investigation of a specific prescriber or dispenser licensed by that licensing or regulatory board or is pursuant to the board's official duties and responsibilities;
- vi. A patient who requests the patient's own prescription monitoring information; the parent or legal guardian of a minor child; an individual designated by the patient with a properly executed and notarized release of health information form, power of attorney, or durable power of attorney for healthcare form; or a person appointed by a duly authorized court to act as guardian or conservator for an incapacitated adult;
- vii. A [medical examiner/coroner], or his or her designee, for the purpose of investigating the death of an individual;
- viii. A designated representative of the [state] Medicaid or other state administered health insurance program regarding program recipients, prescribers, or dispensers for the purpose of investigating fraud, waste, or abuse of the [state] Medicaid or other state administered health insurance program;

- ix. The presiding judge, or his or her designee, of a drug court to the extent the information requested relates specifically to a current participant in the drug court treatment program;
 - x. A probation or parole officer for the purpose of monitoring an individual's compliance with the terms and conditions of a diversion program, probation, or parole;
 - xi. A licensed or certified addiction counselor for the purpose of providing treatment services to a patient;
 - xii. Personnel of the [designated state agency or entity] for purposes of administration and enforcement of this Act and any vendor or contractor, as authorized by the [designated state agency or entity] as necessary for the operation and maintenance of the PDMP;
 - xiii. Personnel of the State [agency responsible for investigation of child welfare cases] whose job it is to investigate child welfare cases to the extent the information requested relates specifically to an individual currently under investigation by the [agency responsible for investigation of child welfare cases] or the child who is the subject of the investigation;
 - xiv. A practitioner to the extent the request relates to the birth parent of an infant who is currently being treated by the practitioner for neonatal abstinence syndrome or has symptoms that suggest prenatal drug exposure;
 - xv. Any health insurer for persons, enrolled in or covered by their program, regarding the utilization of controlled substances for purposes of ensuring patient safety or investigating fraud and abuse;
 - xvi. Personnel of the [designated local or state health agency or entity] for any of the following purposes:(A) Developing education programs or public health interventions relating to specific prescribing practices, controlled substances and the prevention of fraud and abuse.(B) Conducting analyses on prescribing trends in their respective jurisdictions;
 - xvi. Personnel of the [designated local or state agency or entity] established to examine circumstances surrounding drug-related deaths in the [state] for the purposes of promoting safety and reducing drug-related deaths.
- (d) The [designated state agency or entity] may provide de-identified prescription monitoring information for statistical, research, educational, or public health surveillance purposes provided that all data elements that would reasonably identify a

specific patient, prescriber, or dispenser shall be deleted or redacted from the information before disclosure.

Section 9. Alternate Data Sources.

[This section is intended to provide options for states seeking to include or link to data sources beyond monitored prescription drugs.]

Medical Marijuana

[Option 1 – include medical marijuana in the definition of “Monitored prescription drug,” in Section 4 so that it reads:

“Monitored prescription drug” means all controlled substances included in Schedules II, III, IV, and V of the federal or state Controlled Substances Act [statutory references], medical marijuana, drug(s) of concern, and other prescription drugs, as specified by rulemaking, that are required to be reported to the PDMP pursuant to this Act.]

[Option 2 – reporting of medical marijuana directly to the PDMP by dispensaries]

[At least once per day/No later than chosen data reporting interval], a dispensary shall transmit electronically to the PDMP the information set forth in Section 7, Reporting of Prescription Monitoring Information, for all medical marijuana dispensed.

[Option 3 – reporting of medical marijuana to the PDMP by the agency responsible for oversight of the medical marijuana program within the state for situations where dispensing information is already being submitted to that department by dispensaries as a condition of their licensure or registration]

Pursuant to [cross-reference applicable state law], the [agency responsible for oversight of medical marijuana program] shall maintain a database of all medical marijuana dispensed to a qualifying patient or caregiver on behalf of a qualifying patient in this state. That system is intended to serve the same purpose as, and shall be cross-referenced with, the PDMP.

Opioid Antagonist/Naloxone Reporting

[Option 1 – include opioid antagonists/Naloxone in the definition of “Monitored prescription drug,” in Section 4 so that it reads:

“Monitored prescription drug” means all controlled substances included in Schedules II, III, IV, and V of the federal or state Controlled Substances Act [statutory references], opioid antagonists/Naloxone, drug(s) of concern, and other prescription drugs, as specified by rulemaking, that are required to be reported to the PDMP pursuant to this Act.]

[Option 2 – reporting of the dispensing of opioid antagonists/Naloxone]

Opioid antagonists, including, but not limited to, naloxone, which are dispensed shall be transmitted to the PDMP in the same format and with the same frequency as other monitored prescription drugs.

[Option 3 – reporting of the dispensing of opioid antagonists/Naloxone, not for inclusion in patient’s PDMP report]

Opioid antagonists, including, but not limited to, naloxone, shall be transmitted to the PDMP in the same format and with the same frequency as other monitored prescription drugs. Provided, however, that information collected regarding the dispensing of opioid antagonists shall be for statistical, research, educational, or public health surveillance purposes only and shall not be included in a patient’s prescription monitoring information report.

[Option 4 – reporting of the administration of opioid antagonists/Naloxone directly to the PDMP]

- (a) The administration of an opioid antagonist/Naloxone by a first responder, practitioner, or other licensed individual authorized to administer monitored prescription drugs shall be reported to the PDMP within [chosen data reporting interval] of such administration.
- (b) The first responder, practitioner, or other licensed individual shall submit the following data elements for each administration:
 - 1. The name, address, and date of birth of the person to whom the opioid antagonist was administered;
 - 2. Identification of the person who administered the opioid antagonist/Naloxone;
 - 3. The date of the administration;
 - 4. The quantity of opioid antagonists administered;
 - 5. The outcome of the administration (whether the individual survived, was transported to the hospital, or suffered a fatal overdose); and
 - 6. Any other information required by rule.
- (c) The information submitted shall be included in a patient’s PDMP report.
- (d) As used in this section, “first responder” means an emergency medical services (EMS) provider, or a firefighter or peace officer trained and authorized to administer an opioid antagonist.

[Option 5 – reporting of the administration of opioid antagonists/Naloxone to the PDMP by the agency responsible for oversight of EMS personnel]

- (a) A first responder who administers an opioid antagonist shall report to the [agency with oversight of EMS personnel] information regarding the opioid antagonist administered for inclusion in the PDMP. The information submitted must include:
 - 1. The name, address, and date of birth of the person to whom the opioid antagonist was administered, if available;
 - 2. Identification of the person who administered the opioid antagonist;
 - 3. The date of the administration;
 - 4. The quantity administered;
 - 5. The outcome of the administration (whether the individual survived, was transported to the hospital, or suffered a fatal overdose); and
 - 6. Any other information required by rule.
- (b) The information must be submitted within [chosen data reporting interval] of the date the opioid antagonist was administered.
- (c) The [agency with oversight of EMS personnel] shall transmit the information to the [designated state agency or entity] for inclusion in the PDMP.

Fatal and Non-fatal Overdose Reporting to the PDMP

- (a) If a medical examiner/coroner determines that the cause of death of a person resulted from poisoning or overdose involving a monitored prescription drug, the medical examiner/coroner shall, within [chosen data reporting interval] after the date on which the medical examiner/coroner determines the cause of death, submit the following information to the PDMP:
 - 1. The decedent’s name, address at time of death, and date of birth;
 - 2. Each drug or other substance found in the decedent’s system that may have caused or contributed to the poisoning or overdose, if known; and
 - 3. Any other information required by rule.
- (b) If a person is treated at or admitted to a hospital or other medical facility for poisoning or overdose involving a monitored prescription drug, the hospital or other facility shall, within [chosen data reporting interval] after the date on which the person is treated or admitted, submit the following information to the PDMP:
 - 1. The patient’s name, address, and date of birth;
 - 2. Each drug or other substance found in the person’s system that may have contributed to the poisoning or overdose, if known;
 - 3. The name of the hospital or other medical facility;
 - 4. The date of treatment or admission; and
 - 5. Any other information required by rule.
- (c) Information regarding fatal and non-fatal overdoses shall be made available to authorized recipients of prescription monitoring information through the PDMP.

Drug-related Arrest and Conviction Data

- (a) The Administrative Office of the Courts shall, on at least a [weekly/monthly/bi-monthly/quarterly] basis, submit to the [designated state agency or entity] a report containing the name, address, date of birth, and case number of each person convicted of or who plead guilty to a violation of the State Controlled Substances Act involving a monitored prescription drug during the preceding reporting period.
- (b) The [designated state agency or entity] shall:
 - 1. Enter such information into the PDMP;
 - 2. Attempt to identify, through the PDMP, each practitioner who may have prescribed a monitored prescription drug to the person; and
 - 3. Provide each practitioner so identified with:
 - i. A copy of the information provided by the court; and
 - ii. The information obtained from the PDMP that led the [designated state agency or entity] to determine that the practitioner may have prescribed a monitored prescription drug to the person.
- (c) This information shall be provided for the purpose of assisting the practitioner in discussions with the person regarding their use of monitored prescription drugs and making decisions regarding future prescriptions written for the person.
- (d) If a law enforcement officer, while acting in his or her official capacity and in the regular course of an investigation, encounters a situation in which the law enforcement officer has [probable cause/a reasonable belief] that a violation of the State Controlled Substances Act involving a monitored prescription drug is occurring or has occurred, the officer shall submit the following information to the law enforcement agency that employs the officer:
 - 1. The name, address, if known, and date of birth of the individual suspected the violation;
 - 2. The name of the person to whom the monitored prescription drug involved in the suspected violation is or was prescribed;
 - 3. If a prescription container for the monitored prescription drug is found in the vicinity of the location of the suspected violation:
 - i. The name of the prescriber;
 - ii. The prescription number; and
 - iii. The name of the monitored prescription drug as it appears on the prescription container.
- (e) The law enforcement agency that employs the officer who submits the information in subsection (d) shall, within [chosen data reporting interval], upload to the PDMP notice of the suspected violation and the information received pursuant to subsection (d). The law enforcement agency shall ensure that only a person who is authorized by law to access the PDMP uploads such information.
- (f) If the law enforcement agency determines that uploading any information to the PDMP will interfere with an active criminal investigation, the agency may postpone uploading such information until the conclusion of the investigation.

Lost or Stolen Prescription or Medication

- (a) If a law enforcement officer, while acting in his or her official capacity, receives a report of a stolen prescription order for a monitored prescription drug or a stolen monitored prescription drug, the officer shall submit the following information to the law enforcement agency that employs the officer:
 - 1. The name, address, and date of birth of the individual who filed the report of a stolen prescription order or stolen monitored prescription drug;
 - 2. The name of the person to whom the monitored prescription drug was prescribed;
 - 3. The name of the prescriber;
 - 4. The prescription number, if known; and
 - 5. The name of the monitored prescription drug as it appeared on the prescription order or prescription container.
- (b) The law enforcement agency that employs the officer who submits the information in subsection (a) shall, within [chosen data reporting interval], upload to the PDMP the information received pursuant to subsection (a). The law enforcement agency shall ensure that only a person who is authorized by law to access the PDMP uploads such information.
- (c) If the law enforcement agency determines that uploading any information to the PDMP will interfere with an active criminal investigation, the agency may postpone uploading such information until the conclusion of the investigation.
- (d) If a prescriber or dispenser receives a report from a patient that a prescription order issued for the patient has been lost or stolen, or receives a report from a patient that the patient's previously dispensed monitored prescription drug has been lost or stolen, the prescriber or dispenser shall report the following information to the PDMP:
 - 1. The name, address, and date of birth of the patient who made the report;
 - 2. The name of the person to whom the monitored prescription drug was prescribed or dispensed, if different;
 - 3. The name of the prescriber and/or dispenser;
 - 4. The prescription number, if known; and
 - 5. The name of the monitored prescription drug as it appeared on the prescription order.

Pain Management Agreements

The PDMP shall include a mechanism by which a practitioner can indicate that a patient is subject to a pain management agreement for the purpose of notifying the patient's other treating practitioners and dispensers that the patient is subject to the terms of a pain management agreement. The PDMP shall also include a mechanism by which a practitioner can remove the pain management agreement designation from the patient's prescription monitoring information.

Voluntary Non-opioid Directive Form

The PDMP shall include a mechanism by which a practitioner can record the execution of a voluntary non-opioid directive form by a patient in the PDMP which shall indicate to all practitioners that the patient shall not be administered, offered, prescribed, or dispensed an opioid drug.

Medicaid Lock-in Program

- (a) The PDMP shall include a mechanism to indicate that a patient is currently enrolled in a Medicaid Lock-in Program which shall include the following information:
 - 1. The name, address, and date of birth of the patient;
 - 2. The name(s) of the authorized lock-in prescribers; and
 - 3. The name(s) of the authorized lock-in dispensers. If the patient is limited to a chain pharmacy, the practitioner can indicate the name of the chain.
- (b) If the patient changes his or her primary physician or pharmacy, the change shall be noted in the patient's PDMP record.

Reporting by Manufacturers and Distributors

Each manufacturer or wholesale distributor of monitored prescription drugs that delivers drugs to practitioners shall submit to the [designated state agency or entity] the following purchase information:

- (a) Wholesaler's or manufacturer's DEA registration number or other mutually acceptable identifier;
- (b) Purchaser's DEA registration number or other mutually acceptable identifier;
- (c) NDC number of the actual drug sold;
- (d) Date of the sale;
- (e) Quantity of the drug sold; and
- (f) Transaction or invoice number.

Report of Licensee Discipline to PDMP

- (a) If a professional licensing or regulatory board takes administrative action against a licensee for:
 - 1. A violation of law or regulation related to the prescribing or dispensing of monitored prescription drugs;
 - 2. A violation of law or regulation related to the PDMP; or
 - 3. A violation of patient privacy laws or regulations

which results in discipline against the licensee by the board, the board shall report the following information to the [designated state agency or entity]:

1. The name of the licensee who was the subject of the administrative action;
 2. The licensee's DEA registration number, if applicable;
 3. The nature of the violation for which administrative action was taken against the licensee;
 4. The discipline imposed by the board; and
 5. The date of the violation.
- (b) Upon receipt of a report from a licensing or regulatory board regarding discipline taken against a licensee for a violation listed in subsection (a), the [designated state agency or entity] shall ...

Section 10. Interstate Data Sharing.

- (a) The [designated state agency or entity] may provide prescription monitoring information to authorized users of other PDMPs through a secure system and such information may be used by those programs consistent with the provisions of this Act;
- (b) The authorized users of [designated state agency or entity] PDMP may request and receive prescription monitoring information from other PDMPs through a secure system and may use such information consistent with the provisions of this Act;
- (c) The [designated state agency or entity] may develop the capability to transmit information to and receive information from other PDMPs;
- (d) The [designated state agency or entity] is authorized to enter into written reciprocal agreements with other prescription monitoring programs for the purpose of describing the terms and conditions for sharing of prescription monitoring information under this section.

Section 11. Audit Trail Information and Transmission Audit Logs.

- (a) The [designated state agency or entity] is authorized to provide audit trail information upon request only to the following:
 - i. A prescriber or dispenser who is requesting his or her own audit trail information;
 - ii. A prescriber or dispenser requesting audit trail information for transactions executed by a delegate on behalf of the requesting prescriber or dispenser;
 - iii. An authorized representative of a licensing or regulatory board responsible for licensing or certifying prescribers or dispensers requesting audit trail information

for one of their licensees who is currently the subject of an active administrative/regulatory investigation or pursuant to the board's official duties and responsibilities;

- iv. Local, state, or federal law enforcement or prosecutorial officials engaged in the administration, investigation, or enforcement of the laws governing monitored prescription drugs requesting audit trail information for a specific prescriber or dispenser who is currently the subject of an active criminal investigation or prosecution.

(b) The [designated state agency or entity] is authorized to provide transmission audit logs upon request only to the following:

- i. An authorized representative of the [state board] responsible for the licensure of dispensers requesting transmission audit logs for a specific dispenser, including an out-of-state or mail order pharmacy, licensed, certified, or registered by the Board of Pharmacy who is currently the subject of an active investigation or pursuant to the board's official duties and responsibilities;
- ii. Local, state, or federal law enforcement or prosecutorial officials engaged in the administration, investigation, or enforcement of the laws governing monitored prescription drugs requesting transmission audit logs related to a specific pharmacy, including an out-of-state or mail order pharmacy, who is currently the subject of an active investigation or prosecution.

(c) Audit trail information and transmission audit logs provided to a licensing or regulatory board or law enforcement or prosecutorial official may be shared with the prescriber, dispenser, or pharmacy that is the subject of the audit trail or transmission audit log unless otherwise prohibited by law.

Section 12. PDMP Data Integration.

(a) A practitioner or health care system may integrate its electronic health record system or a pharmacy may integrate its automated data processing system with the PDMP using an application programming interface. Use of an integrated system shall comply with all of the following:

- i. The integrated system shall log each user's access to PDMP information. Audit trail information logs shall be retained by the practitioner, health care system, or pharmacy for a minimum of [] years from the date of access and shall be provided to the [designated state agency or entity] upon request.
- ii. If the user identified in the logs is not the practitioner, the integrated system shall clearly identify on which practitioner's behalf the user was accessing PDMP

information. [A practitioner's delegate using an integrated system is required to maintain an active PDMP registration.]

- iii. The integrated system shall maintain appropriate administrative, technical, and physical security measures to safeguard against unauthorized access, disclosure, or theft of PDMP information and shall meet all HIPAA requirements for safeguarding protected health information.
- iv. The practitioner, health care system, or pharmacy shall notify the PDMP administrator of any breach in the electronic health record system that may have included PDMP information within [] hours of making the determination that a breach occurred.
- v. Unless authorized by the [designated state agency or entity], the integrated system shall not:
 - 1. Store PDMP information in other than a read-only format;
 - 2. Alter, edit, or modify PDMP data; or
 - 3. Copy or incorporate PDMP data into a searchable computer program or database.

(b) The [designated state agency or entity] shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements of this Section to retrieve information from the PDMP on behalf of an authorized prescriber or dispenser.

(c) The [designated state agency or entity] shall not access patient-identifiable information in an entity's health information technology system.

(d) The [designated state agency or entity] may prohibit integration or terminate a health information technology system's ability to retrieve information from the PDMP if the health information technology system fails to meet the requirements of this Section, or the entity operating the health information technology system does not fulfill its obligations under this Section.

(e) Authorized users of PDMPs in other states may access PDMP information in this state through a secure interstate data exchange system or health information exchange system approved by the [designated state agency or entity].

Section 13. Confidentiality.

(a) Prescription monitoring information submitted to the [designated state agency or entity], audit trail information compiled by the [designated state agency or entity], and transmission audit logs shall be confidential, are not subject to public or open records laws, and are not subject to disclosure or use except as provided in this Act.

- (b) Prescription monitoring information, audit trail information, and transmission audit logs shall not be subject to subpoena in a civil action, nor shall such records be disclosed, discoverable, or compelled to be produced in any civil proceeding.
- (c) The [designated state agency or entity] shall maintain procedures to protect the privacy and confidentiality of patients and to ensure that information collected, recorded, transmitted, and maintained pursuant to this Act is not obtained, disclosed, or used except as provided in this Act.
- (d) The [designated state agency or entity] shall establish and maintain a process for verifying the credentials and authorizing the use of prescription monitoring information by those persons, entities, and agencies authorized by this Act.

Section 14. Practitioner Activity Reports.

- (a) Beginning [date], and at least [monthly/quarterly/annually] thereafter, the [designated state agency or entity] shall issue each practitioner who has prescribed or dispensed a monitored prescription drug as reflected in the PDMP for the previous [month/quarter/year] a practitioner activity report which shall include, but not be limited to, the following information:
 - i. A summary of the practitioner’s history of prescribing or dispensing monitored prescription drugs;
 - ii. A comparison of the practitioner’s history of prescribing or dispensing monitored prescription drugs with the history of other practitioners of the same profession or specialty;
 - iii. The total number of patients receiving 90 morphine milligram equivalents (MMEs) or more per day;
 - iv. The total number of patients receiving opioid medications for 30 days or more;
 - v. The total number of patients receiving opioid and benzodiazepine medications concurrently;
 - vi. The total number of patients issued prescriptions from multiple practitioners;
 - vii. The total number of patients filling prescriptions at multiple pharmacies;
 - viii. The total number of patients with monitored prescription drug prescriptions whose dispensing dates overlap;
 - ix. The total number of patients obtaining refills of their prescriptions more than [one week early];
 - x. The total number of program queries made by the practitioner and the ratio of queries to the number of patients or monitored prescription drug prescriptions issued or dispensed;
 - xi. General patient risk factors;
 - xii. [Educational updates]; and

- xiii. Other pertinent information identified by the [designated state agency or entity] by rule.

(b) Information provided to a practitioner in an activity report shall not:

- i. Constitute a public record;
- ii. Be admissible as evidence in a civil or criminal proceeding; and
- iii. Be the sole basis for investigation by a licensure board.

Section 15. Mandatory Registration.

Practitioners authorized to prescribe or dispense monitored prescription drugs shall register as data requestors with the PDMP and shall maintain such registration continuously during the term of the prescriber's or dispenser's term of licensure.

Section 16. Mandatory Query Requirements.

- (a) [Option 1] A prescriber, or his or her delegate, shall query the PDMP prior to initially prescribing a monitored prescription drug for a patient. If the course of treatment with that monitored prescription drug continues for more than three (3) months after the date of the initial prescription, the prescriber, or his or her delegate, shall query the PDMP no less frequently than once every three (3) months thereafter until the course of treatment with that monitored prescription drug has ended.

[Option 2] A prescriber, or his or her delegate, shall query the PDMP each time he or she issues a prescription for a monitored prescription drug for a patient.

- (b) [Option 1] A dispenser, or his or her delegate, shall query the PDMP prior to initially dispensing a monitored prescription drug to a patient and shall query the PDMP no less frequently than once every three (3) months thereafter until the course of treatment with that monitored prescription drug has ended.

[Option 2] A dispenser, or his or her delegate, shall query the PDMP each time he or she dispenses a monitored prescription drug for a patient.

- (c) [Only applies if Option 1 is chosen] A prescriber, or his or her delegate, shall query the PDMP prior to issuing a replacement prescription for monitored prescription drug to a patient.

- (d) The requirement to query the PDMP under subsections (a) and (b) above does not apply in the following circumstances:

- i. The monitored prescription drug is prescribed or dispensed to a patient currently receiving hospice or palliative care for a serious or chronic illness;
- ii. The monitored prescription drug is prescribed or dispensed to a patient currently a resident of a nursing care facility, assisted living facility, correctional facility, or mental health facility;
- iii. The monitored prescription drug is prescribed or dispensed to a patient currently receiving treatment for cancer or a cancer-related illness or condition;
- iv. The monitored prescription drug is prescribed or dispensed to a patient currently receiving treatment in an inpatient setting in a hospital or licensed health care facility;
- v. The monitored prescription drug is prescribed or dispensed to a patient immediately before or within [3/7/14] days following a surgical procedure and such prescription is non-refillable;
- vi. The quantity of the controlled substance prescribed or dispensed does not exceed an amount sufficient to treat the patient for a period of [3/5/7] days and does not allow a refill, and no subsequent prescriptions are written or dispensed within fifteen (15) days of the initial prescription;
- vii. When the monitored prescription drug is necessary for the treatment of a patient in an emergency situation at the scene of an emergency or in a licensed ground or air ambulance;
- viii. The monitored prescription drug is directly administered to the patient by the prescriber or other person authorized to administer a monitored prescription drug;
- ix. If all of the following circumstances are satisfied:
 - 1. It is not reasonably possible for the practitioner to access the PDMP in a timely manner;
 - 2. Another person is not reasonably available to query the PDMP on the practitioner's behalf; and
 - 3. The quantity of the substance does not exceed a non-refillable [3/5] day supply;
- x. If consultation of the PDMP would result in the patient's inability to obtain the prescription in a timely manner and would thereby adversely impact the patient's medical condition, provided the quantity does not exceed a non-refillable [3/5/7] day supply; or
- xi. The PDMP is not operational or cannot be accessed due to a temporary technological or electrical failure. The practitioner shall document the attempt to query the PDMP in the patient's medical record.

(e) The mandatory query provisions of this section are not satisfied if a prescriber or dispenser has integrated PDMP information into a patient's electronic health records or health information exchange, and the information provided by the system is limited to a patient risk score. Prescribers and dispensers must review a patient's complete PDMP report and make an independent decision whether to prescribe or dispense to a patient based on that information.

- (f) [A prescriber or dispenser practicing in an opioid treatment program, including an office based opioid treatment program, shall query the PDMP in the following circumstances:
- i. Upon admission of the patient to the program;
 - ii. At the initiation of medication assisted treatment;
 - iii. After the initial 30 days of treatment and every 90 days thereafter;
 - iv. Prior to any take-home medication being granted, excluding any take-home medication for program closure and federal holidays;
 - v. When the number of take-home doses is increased;
 - vi. If a patient refuses to participate in a drug screen; and
 - vii. After any positive drug screen.]
- (g) [A prescriber recommending [medical marijuana/medical cannabis/low-THC oil/cannabidiol oil] shall query the PDMP in the following circumstances:
- i. Prior to certifying a patient as being diagnosed with a specific condition that requires the use of [medical marijuana/medical cannabis/low-THC oil/cannabidiol oil];
 - ii. Prior to issuing a recommendation for the use of [medical marijuana/medical cannabis/low-THC oil/cannabidiol oil];
 - iii. Every three months thereafter; and
 - iv. Prior to recommending a change in the form or amount of [medical marijuana/medical cannabis/low-THC oil/cannabidiol oil].]

Section 17. Immunity.

- (a) Except as otherwise provided in this Act, and unless there is a finding of [gross negligence, malice, criminal intent, or lack of good faith], the [designated state agency or entity], a prescriber, dispenser, or other person, agency, or entity in proper possession of prescription monitoring information, audit trail information, or transmission audit logs pursuant to this Act is not subject to civil liability, administrative action, or other legal or equitable relief for any of the following acts:
- i. Reporting information to the PDMP pursuant to this Act;
 - ii. Accessing, using, or relying on information pursuant to this Act;
 - iii. Releasing information that was factually incorrect; or
 - iv. Releasing information to the wrong person, agency, or entity.
- (b) If there is a finding of reckless disregard for the privacy and confidentiality provisions of this Act, the [designated state agency or entity], a prescriber, dispenser, or other person, agency, or entity may be subject to civil liability, administrative actions, or other legal or equitable relief.

Section 18. Evaluation, Data Analysis, and Reporting.

- (a) The [designated state agency or entity] shall design and implement an evaluation component of the PDMP to identify:
- i. Costs of PDMP operations;
 - ii. Any impact on the misuse, abuse, or diversion of monitored prescription drugs;
 - iii. Any impact on the prescribing or dispensing of monitored prescription drugs;
 - iv. Progress made toward integrating PDMP data with other health information systems, including, but not limited to, HIEs and EHRs;
 - v. Other information relevant to policy, research, and education related to monitored prescription drugs.
- (b) The [designated state agency or entity] shall annually submit a report to the [appropriate state legislative committees] which shall include the results of the evaluation of the PDMP and may include any recommendations for legislation related to the operation of the PDMP.

Section 19. Rules and Regulations.

The [designated state agency or entity] shall promulgate rules and regulations necessary to implement the provisions of this Act.

Section 20. 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 who knowingly submits incorrect prescription information, shall be referred to the appropriate professional licensing or regulatory board for administrative sanctions and may be subject to an administrative penalty levied by the [designated state agency or entity] of no more than \$_____ per violation. Each such failure to submit prescription monitoring information shall count as a separate violation.
- (b) A dispenser who knowingly fails to correct or amend prescription monitoring information submitted to the [designated state agency or entity] after notification by the [designated state agency or entity] shall be referred to the appropriate licensing or regulatory board for administrative sanctions and may be subject to an administrative penalty levied by the [designated state agency or entity] of no more than \$_____ per violation. Each such failure to correct or amend prescription monitoring information shall count as a separate violation.

- (c) A prescriber, dispenser, or delegate who knowingly fails to register with the PDMP as required by this Act shall be referred to the appropriate licensing or regulatory board for administrative sanctions and may be subject to an administrative penalty levied by the [designated state agency or entity] of no more than \$_____.
- (d) A prescriber or dispenser who knowingly fails to query the PDMP as required by this Act shall be referred to the appropriate licensing or regulatory board for administrative sanctions and may be subject to an administrative penalty levied by the [designated state agency or entity] of no more than \$_____ per violation. Each such failure to query the PDMP shall count as a separate violation.
- (e) A person, agency, or entity authorized to receive prescription monitoring information, audit trail information, or transmission audit logs 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].
- (f) A person, agency, or entity authorized to receive prescription monitoring information, audit trail information, or transmission audit logs pursuant to this Act who knowingly 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].
- (g) A person, agency, or entity authorized to receive prescription monitoring information, audit trail information, or transmission audit logs pursuant to this Act who knowingly requests such information in violation of this Act shall be subject to [insert appropriate administrative, civil, or criminal penalty].
- (h) A person, agency, or entity not authorized to receive prescription monitoring information, audit trail information, or transmission audit logs pursuant to this Act who obtains or attempts to obtain such information by fraud or deceit from the PDMP or from a person authorized to receive such information under this Act shall be subject to [insert appropriate administrative, civil, or criminal penalty].
- (i) A person, agency, or entity not authorized to receive prescription monitoring information, audit trail information, or transmission audit logs pursuant to this Act knowingly discloses or uses such information in violation of this Act shall be subject to [insert appropriate administrative, civil, or criminal penalty].

Section 21. Severability.

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

Section 22. Effective Date.

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

Comments and Responses

Section 3. Scope and Purpose.

The purpose of this Act is to provide a tool that will ensure that health care practitioners making prescribing and dispensing decisions have complete and reliable information regarding their patients' controlled substance and other monitored drug history to help curtail misuse and abuse. In addition, this Act is intended to assist law enforcement in combating diversion and the resultant abuse of controlled substances and other monitored drugs.

Comment(s)—Change wording:

The purpose of this Act is to provide a tool that will ensure that health care practitioners making prescribing and dispensing decisions have complete and reliable information regarding their patients' controlled substance and other monitored drug history to help curtail misuse and abuse and to assist law enforcement in combating drug diversion.

Response from workgroup: accepted change

Section 4. Definitions.

- (g) "Date prescription filled" means the date a prescription is prepared and ready for delivery;

Comment(s)—Change wording:

- (g) "Date prescription filled" means the date a prescription is prepared and ready for delivery to a patient;

Response from workgroup: accepted change

- (i) "De-identified data/information" means information that is not individually identifiable information consistent with State law and 45 CFR 164.514, or direct identifiers and specified demographic information have been removed in accordance with the requirements of that section;

Comment(s)—Change wording:

- (i) "De-identified data/information" means information that is not individually identifiable information or direct identifiers and specified demographic information have been removed in a manner consistent with consistent with State law and 45 CFR 164.514;

Response from workgroup: accepted change

- (x) “Office based opioid treatment” or “OBOT” means an office based opioid treatment physician practice for prescribing buprenorphine as established by the Drug Abuse and Treatment Act of 2000. An OBOT may be a preferred provider, an individual physician practice, or several physicians practicing as a group;

Comment(s)—Change wording:

- (x) “Office based opioid treatment” or “OBOT” opioid treatment within a health care provider’s practice for prescribing, dispensing, or administering buprenorphine as established by the Drug Abuse and Treatment Act of 2000;

Response from workgroup: accepted change

- (y) “Opioid treatment program” or “OTP” means an opioid treatment program as defined and regulated by federal regulation 42 CFR, Part 8, and DEA regulations related to safe storage and dispensing at OTPs. OTPs are specialty addiction treatment programs for dispensing opioid-replacement medication, including methadone and buprenorphine, under carefully controlled and observed conditions. OTPs offer onsite ancillary services;

Comment(s)—Change wording:

- (y) “Opioid treatment program” or “OTP” means a specialty addiction treatment program for dispensing and administering opioid-replacement medication, including methadone and buprenorphine, under carefully controlled and observed conditions as defined and regulated by federal regulation 42 CFR, Part 8;

Response from workgroup: accepted change

- (dd) “Pharmacy” means an established location, either physical or electronic, registered by the Board of Pharmacy where drugs or devices are dispensed;

Comment(s)—Change wording:

- (dd) “Pharmacy” means an established location, either physical or electronic, licensed or registered by the [designated state agency or entity] where drugs or devices are dispensed;

Response from workgroup: accepted change

- (ll) “PDMP/PMP/program” means a program that collects, manages, analyzes, and provides information regarding Schedules II, III, IV, and V controlled substances and other monitored drugs required to be submitted to the PDMP under this Act or a program established by a similar Act in another state, district, or territory of the United States;

Comment(s)—Change wording:

(ll) “PDMP/PMP/program” means a program that collects, manages, analyzes, and provides information regarding Schedules II, III, IV, and V controlled substances and other monitored drugs required to be submitted to the PDMP under this Act or a program established by a similar Act in the United States, another state, district, or territory of the United States, or any subdivision thereof;

Response from workgroup: accepted change

(qq) “Reciprocal agreements” means a written agreement that provides for the exchange of information requests and responses of PDMP data between state data-sharing partners if access under such agreements is consistent the privacy, security, and disclosure protections under state laws and regulations;

Comment(s)—Change wording:

(qq) “Reciprocal agreements” means a written agreement that provides for the exchange of information requests and responses of PDMP data between data-sharing partners if access under such agreements is consistent the privacy, security, and disclosure protections under applicable laws and regulations;

Response from workgroup: accepted change

(ss) “Controlled substance/Schedules II – V controlled substances” means a controlled substance included in Schedules II, III, IV, or V of 21 United States Code, Section 812 or 21 Code of Federal Regulations, Section 1308, or the Controlled Substances Act of this state [statutory reference];

Comment(s)—Change wording:

(ss) “Schedules II – V controlled substances/Controlled Substances” means a controlled substance included in Schedules II, III, IV, or V of 21 United States Code, Section 812 or 21 CFR Section 1308, or the Controlled Substances Act of this state [statutory reference];

Response from workgroup: accepted change

(tt) “State” means any state, territory, or possession of the United States, the District of Columbia, or foreign nation;

Comment(s)—Change wording:

(tt) “State,” as used in the context of this document, means any state, territory, or possession of the United States, any subdivision thereof, or the District of Columbia;

Response from workgroup: accepted change

Comment(s)—Add new definition:

(q) “Health care system” means an organization of people, institutions, and resources that deliver health care services to meet the health needs of target populations;

Response from workgroup: accepted change; Note: Addition will renumber subsequent definitions, a change reflected in the final copy of the 2020 PDMP Model Act.

Section 5. Establishment of Prescription Drug Monitoring Program.

(c) The [designated state agency or entity] shall establish, maintain, and administer, [in consultation with the Advisory Committee,] an electronic system to monitor the prescribing and dispensing of all Schedule II – V controlled substances and other monitored drugs prescribed and dispensed in this state or dispensed to an address in this state. The PDMP must not interfere with the legal use of a monitored drug.

Comment(s)—Change wording:

(a) The [designated state agency or entity] shall establish, maintain, and administer [in consultation with the Advisory Committee] an electronic system to monitor the prescribing and dispensing of all Schedule II – V controlled substances and other monitored drugs prescribed and dispensed in this state or dispensed to an address in this state.

Response from workgroup: accepted change

Section 6. Advisory Committee. [Optional]

(j) The [designated state agency or entity] shall establish a multi-disciplinary advisory committee which shall function under the [designated state agency or entity] to assist in the implementation, maintenance, and administration of the PDMP, and to advise and make recommendations to the [designated state agency or entity] regarding the operation of the PDMP.

Comment(s)—Change wording:

- (a) The [designated state agency or entity] shall establish a multidisciplinary advisory committee, which shall function under the [designated state agency or entity] to advise in the implementation, maintenance, and administration of the PDMP and to make recommendations to the [designated state agency or entity].

Response from workgroup: accepted change

- (h) The Advisory Committee shall:
 - x. Identify drugs of concern that should be monitored by the PDMP;
 - xi. Design and implement online educational courses for persons authorized to access PDMP information; and

Comment(s)—Change wording:

- (h) The Advisory Committee shall:
 - x. Recommend drugs of concern that should be monitored by the PDMP;
 - xi. Advise in the implementation of online educational courses for persons authorized to access PDMP information; and

Response from workgroup: accepted change

Section 7. Reporting of Prescription Monitoring Information.

- (f) Prescription monitoring information submitted to the [designated state agency or entity] shall be retained in a readily retrievable format for a minimum of [n] years from the date such information is received by the [designated state agency or entity]. The [designated state agency or entity] may retain prescription monitoring information that has been deidentified for more than [n] years but shall promulgate regulations and procedures that will ensure that any identifying information the [designated state agency or entity] receives from any dispensing or reporting entity that is more than [n] years old or older is deleted or destroyed on an ongoing basis in a timely and secure manner.

Comment(s)—Change wording:

- (f) Prescription monitoring information submitted to the [designated state agency or entity] shall be retained in a readily retrievable format for a minimum of [n] years from the date such information is received by the [designated state agency or entity]. The [designated state agency or entity] may retain prescription monitoring information that has been deidentified for no more than [n] years. The [designated state agency or entity] shall promulgate regulations and procedures that will ensure that any identifying

information received from any dispensing or reporting entity that is more than [n] years old is deleted or destroyed on an ongoing basis in a timely and secure manner.

Response from workgroup: accepted change

Section 8. Access to and Use of Prescription Monitoring Information.

- (c) The [designated state agency or entity] is authorized to provide prescription monitoring information upon request to the following:
- ii. A dispenser for the purpose of providing pharmaceutical care to a current bona fide patient, or to inquire about the dispenser’s own dispensing activity;

Comment(s)—Change wording:

- ii. A dispenser for the purpose of providing pharmaceutical care to a current bona fide or prospective patient, or to inquire about the dispenser’s own dispensing activity;

Response from workgroup: accepted change

- xi. The presiding judge, or his or her designee, of a drug court, to the extent the information requested relates specifically to a current participant in the drug court treatment program;

Comment(s)—“There is a potential ethical issue as to the judge in a case getting the information as opposed to the probation office. That would violate model rules, but each state may have differences in its ethics rules for judges.

Response from workgroup: Differences in judicial ethic rules were not researched for this project. States should determine the appropriate language.

- xii. Personnel of the [designated state agency or entity] and any vendor or contractor, as authorized by the [designated state agency or entity] for purposes of administration and enforcement of this Act and as necessary for the operation and maintenance of the PDMP;

Comment(s)—Change wording:

- xii. Personnel of the [designated state agency or entity] for purposes of administration and enforcement of this Act and any vendor or contractor, as authorized by the [designated state agency or entity] as necessary for the operation and maintenance of the PDMP;

Response from workgroup: accepted change

- xiii. Personnel of the State [agency responsible for investigation of child welfare cases] whose job it is to investigate child welfare cases to the extent the information requested relates specifically to an individual currently under investigation by the [agency responsible for investigation of child welfare cases] or the child who is the subject of the investigation;

Comment(s)—“. . .This could be a problem if the use of legitimately needed prescriptions is stigmatized and causes parents to lose custody of children.”

Response from workgroup: Both the need for access by this user type and risk of stigmatization are valid. States should determine the appropriate language.

Comment(s)—Add private insurance, health departments, and overdose fatality review teams (OFRs) to the list of user types:

Response from workgroup: accepted suggestion and will add the following to this subsection:

- xv. Any health insurer for persons, enrolled in or covered by their program, regarding the utilization of controlled substances for purposes of ensuring patient safety or investigating fraud and abuse;
- xvi. Personnel of the [designated local or state health agency or entity] for any of the following purposes: (A) Developing education programs or public health interventions relating to specific prescribing practices, controlled substances, and the prevention of fraud and abuse. (B) Conducting analyses on prescribing trends in their respective jurisdictions;
- xvii. Personnel of the [designated local or state agency or entity] established to examine circumstances surrounding drug-related deaths in the [state] for the purposes of promoting safety and reducing drug-related deaths.

Section 9. Alternate Data Sources.

Opioid Antagonist/Naloxone Reporting

[Option 4—reporting of the administration of opioid antagonists/naloxone directly to the PDMP]

- (e) The administration of an opioid antagonist/naloxone by a first responder, practitioner, or other individual authorized to administer monitored prescription drugs shall be reported to the PDMP within [chosen data reporting interval] of such administration.
- (f) The first responder, practitioner, or other individual shall submit the following data elements for each administration:

Comment(s)—Change wording:

- (a) The administration of an opioid antagonist/naloxone by a first responder, practitioner, or other licensed individual authorized to administer monitored prescription drugs shall be reported to the PDMP within [chosen data reporting interval] of such administration.
- (b) The first responder, practitioner, or other licensed individual shall submit the following data elements for each administration:

Response from workgroup: accepted change

Medicaid Lock-in Program

- (c) The PDMP shall include a mechanism by which a practitioner can indicate that a patient is currently enrolled in a Medicaid Lock-in Program which shall include the following information:

Comment(s)—“. . .this is impractical and will result in bad data being entered into the system. . .“lock-in” information is entered by the Medicaid program as opposed to by practitioners.”

Change wording:

- (a) The PDMP shall include a mechanism to indicate that a patient is currently enrolled in a Medicaid lock-in program, which shall include the following information:

Response from workgroup: accepted change

Reporting by Manufacturers and Distributors

Each manufacturer or wholesale distributor of monitored prescription drugs that delivers drugs to prescribers or terminal distributors of dangerous drugs shall submit to the [designated state agency or entity] the following purchase information:

Comment(s)—Change wording:

Each manufacturer or wholesale distributor of monitored prescription drugs that delivers drugs to practitioners shall submit to the [designated state agency or entity] the following purchase information:

Response from workgroup: accepted change

Section 10. Interstate Data Sharing.

- (e) The [designated state agency or entity] may provide prescription monitoring information to authorized users of other state PDMPs through a secure system and such information may be used by those programs consistent with the provisions of this Act;

- (f) The authorized users of [designated state agency or entity] PDMP may request and receive prescription monitoring information from other states' PDMPs through a secure system and may use such information consistent with the provisions of this Act;
- (g) The [designated state agency or entity] may develop the capability to transmit information to and receive information from other PDMPs employing the Prescription Monitoring Information eXchange (PMIX) standards of interoperability;
- (h) The [designated state agency or entity] is authorized to enter into written reciprocal agreements with other states' prescription monitoring programs for the purpose of describing the terms and conditions for sharing of prescription monitoring information under this section.

Comment(s)—“This change is meant to allow flexibility with potential new technologies.”

Change wording:

- (a) The [designated state agency or entity] may provide prescription monitoring information to authorized users of other PDMPs through a secure system, and such information may be used by those programs consistent with the provisions of this Act;
- (b) The authorized users of [designated state agency or entity] PDMP may request and receive prescription monitoring information from other PDMPs through a secure system and may use such information consistent with the provisions of this Act;
- (c) The [designated state agency or entity] may develop the capability to transmit information to and receive information from other PDMPs;
- (d) The [designated state agency or entity] is authorized to enter into written reciprocal agreements with other prescription monitoring programs for the purpose of describing the terms and conditions for sharing of prescription monitoring information under this section.

Response from workgroup: accepted change

Section 11. Audit Trail Information and Transmission Audit Logs.

- (c) Audit trail information and transmission audit logs provided to a licensing or regulatory board or law enforcement or prosecutorial official may be shared with the prescriber, dispenser, or pharmacy that is the subject of the audit trail or transmission audit log unless otherwise prohibited by law. Otherwise, all information contained in audit trail information and transmission audit logs is confidential and not subject to public records laws. Further, audit trail information and transmission audit logs may not be used as evidence in any civil proceeding.

Comment(s)—Change wording:

- (c) Audit trail information and transmission audit logs provided to a licensing or regulatory board or law enforcement or prosecutorial official may be shared with the prescriber, dispenser, or pharmacy that is the subject of the audit trail or transmission audit log unless otherwise prohibited by law.

Response from workgroup: accepted change

Section 12. PDMP Data Integration.

- (f) A practitioner or health care system may integrate its electronic health record system or a pharmacy may integrate its automated data processing system with the PDMP using an application programming interface. Use of an integrated system shall comply with all of the following:
 - i. The integrated system shall log each user’s access to PDMP information. Access logs shall be retained by the practitioner, health care system, or pharmacy for a minimum of [] years from the date of access and shall be provided to the [designated state agency or entity] upon request.

Comment(s)—“health care system is a new term not used previously and not in definitions

- (a) A practitioner or health care system may integrate its electronic health record system or a pharmacy may integrate its automated data processing system with the PDMP using an application programming interface. Use of an integrated system shall comply with all of the following:
 - i. The integrated system shall log each user’s access to PDMP information. Audit trail information shall be retained by the practitioner, health care system, or pharmacy for a minimum of [] years from the date of access and shall be provided to the [designated state agency or entity] upon request.

Response from workgroup: accepted change and added definition of “health care system to Section 4 Definitions

Section 14. Practitioner Activity Reports.

- (c) Beginning [date], and at least [monthly/quarterly/annually] thereafter, the [designated state agency or entity] shall issue each practitioner who has prescribed or dispensed a monitored prescription drug as reflected in the PDMP for the previous [month/quarter/year] a practitioner activity report which shall include, but not be limited to, the following information:

Comment(s)—“It would seem this section should only be for prescriber and not dispenser reports and that those reports should be handled separately.”

Response from workgroup: This section details a general practitioner activity report that applies to both prescribers and dispensers. However, if a state prefers, this section can be separated into two (2) sections listing the appropriate items for each.