NATIONAL ASSOCIATION FOR STATE CONTROLLED SUBSTANCES AUTHORITIES (NASCSA)
MODEL PRESCRIPTION MONITORING PROGRAM (PMP) ACT 2021 (rev.)

SECTION 1. SHORT TITLE.

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

COMMENT

NASCSA provides this Model Act to support and facilitate the enhancements administrators of state prescription drug monitoring programs (PMPs) are making, and will make in the next three-five years, to transform PMPs into optimal public health and safety tools. The Model Act language reflects the collective body of in-depth knowledge and expertise of state PMP administrators developed over the past 80 years.

Some bracketed language is optional language that NASCSA does not specifically endorse for all states. However, NASCSA makes the language available for state officials who believe the language, and underlying policies, serve a particular need of their states.

The Task Force felt that it was important to define that a Prescription Drug Monitoring Program (PDMP) is used interchangeably and synonymously with Prescription Monitoring Program (PMP).

SECTION 2. LEGISLATIVE FINDINGS.

[insert state-specific findings]

SECTION 3. PURPOSE.

[insert state-specific purposes of improving patient care and safety through reducing abuse and diversion of monitored drugs, promoting appropriate professional practice, and public health surveillance.]

SECTION 4. DEFINITIONS.

For the purpose 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. "Act" means the NASCSA Model PMP Act.

B. "Advisory Committee" means the committee established under Section 6 of the Act.

C. "Audit trail information" means information produced regarding requests for PMP dispensation data that the [designated state agency] or others specified by this Act use to help monitor compliance with this Act and other applicable statutes, rules or regulations.

D. "Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V of [insert citations of state controlled substances law provisions].

E. "De-identified data" means PMP information as determined by the [designated state agency] after removal of information that identifies, or could reasonably be used to identify, the patient, the owner if the PMP information is for a veterinary patient, prescriber, and pharmacy or other dispenser.

F. "Delegate" means a person who acts as an agent, pursuant to requirements of the [designated state agency], to request PMP information on behalf of an individual [, health care facility or entity] in Section 9 who is authorized to request and receive PMP information. A delegate shall not include:

1. an individual who is an employee or representative of a software or other vendor or contractor of the PMP,

2. an automated system, or

3. a facility or other entity.

G. "Deliver" means the sale or other actual transfer of a monitored drug from an individual or entity to another individual or entity.

H. "Designee" shall have the same meaning as Delegate.

I. "Dispense" means to deliver in this state or to an address in this state a monitored drug to the ultimate user by or pursuant to the lawful order of a prescriber.

J. "Dispenser" means an individual or entity authorized to dispense a monitored drug, but does not include:

1. an individual or entity employed by or an agent of a federal agency or who is prohibited from reporting under federal law or regulation;

2. a licensed hospital pharmacy that dispenses monitored drugs for the purposes of inpatient hospital care, emergency department care for the immediate use of a monitored drug, or when dispensing no more than [insert specified hours or days] supply of a monitored drug at the time of discharge from such a facility;

3. an individual who is authorized to administer a monitored drug upon the lawful order of a prescriber, [except for an individual who is responsible for the direct administration of a controlled substance for substance use disorder treatment];

4. a long-term care or inpatient hospice facility that dispenses monitored drugs to patients of the facility;

COMMENT

[Even though the long-term care facility is exempt from reporting, the pharmacy which provides dispensed prescription medication to the patients of the facility may not be exempt from reporting based on state law]

5. a wholesale distributor of a monitored drug; or

6. a veterinarian. [Some states may opt to require reporting by a veterinarian who dispenses monitored drugs.]

K. "Drug of concern" [OPTION 1] means a non-scheduled drug or a non-prescribed drug or substance listed in Schedules I, II, III, IV or V as determined by the [insert appropriate state agency] to be in need of monitoring because it has a potential for abuse or diversion or is required to be reported by the [insert appropriate state agency] for public health purposes.

OR

"Drug of concern" [OPTION 2] means a non-prescribed drug as determined by the [insert appropriate state agency] to be in need of monitoring because it has a potential for abuse or diversion or is required to be reported by the [insert appropriate state agency] for public health purposes.

COMMENT

[There are two available options that the agency can select. Option 1 allows for the agency to use the definition in alignment with Monitored Drug [OPTION 1]. Option 2 allows for the agency to use if the agency chooses to monitor all prescribed drugs, both controlled and non-controlled substances. "Drug of concern" may include cannabidiol, marijuana, or other drug or substance which is not prescribed].

L. "Fill" means the constructive preparation of the prescription and when that is complete.

M. "Monitored drug" [OPTION 1] means a prescribed drug or substance listed in Schedules II, III, IV or V of [insert citations to state controlled substances statutes and regulations], or a drug or substance deemed a drug of concern.

OR

"Monitored drug" [OPTION 2] means a prescribed drug or substance, or a non-prescribed drug or substance deemed as a drug of concern.

COMMENT

[There are two available options that the agency can select. Option 1 allows for the agency to use the definition for prescribed controlled substances only as well as drugs of concern. Option 2 allows for the agency to use if the agency chooses to monitor all prescribed drugs, both controlled and non-controlled substances as well as drugs of concern]

N. "Owner" means the owner, client, or person who is responsible for the care of the animal or who arranges for the animal's veterinary care when the prescription is dispensed.

O. "Patient" means an individual [or animal] for whom a prescription is issued or for whom a prescriber directly dispenses a monitored drug.

P. "Pharmacist" means an individual authorized by any U.S. state to engage in the practice of pharmacy and includes an individual who is employed by or an agent of a federal agency.

Q. "Pharmacist-patient relationship" means a consensual relationship in which an individual seeks pharmaceutical care from a pharmacist, and the pharmacist affirmatively acts to provide pharmaceutical care, or agrees to do so. The pharmacist-patient relationship exists when such agreement is entered into explicitly unless state law allows for an implied consent if the patient is unable to provide consent.

R. "Prescribe" means to direct, designate, or order the use of a drug product or formula for the preparation of a monitored drug for a disease or illness and the manner of using the monitored drug.

S. "Prescriber" means an individual authorized by any lawful jurisdiction to prescribe a monitored drug and includes an individual who is employed by or an agent of a federal agency.

T. "Prescriber-patient relationship" means a consensual relationship in which an individual seeks medical care from a prescriber, and the prescriber affirmatively acts to provide medical care, or agrees to do so. The prescriber-patient relationship exists when such agreement is entered into explicitly unless state law allows for an implied consent if the patient is unable to provide consent.

COMMENT

> [Additional information relating to provider-patient relationship is referenced in The AMA Code of Medical Ethics Opinion which can be found at https://www.ama-assn.org/delivering-care/ethics/patient-physician-relationships#:~:text=The%20relationship%20between%20a%20patient,advocate%20for%20their%20patients'%20welfare.]

U. "Prescription monitoring program" or "PMP" means a program established under Section 5 of this Act. Prescription Drug Monitoring Program (PDMP) is used interchangeably and synonymously with Prescription Monitoring Program (PMP).

V. “PMP Information” means PMP dispensation data, PMP-generated analytical data, supplemental data, and audit trail information.

W. “PMP dispensation data” means dispensed prescription data submitted to the [designated state agency] pursuant to Section 7.B that is maintained, managed, and disclosed pursuant to this Act.

X. “PMP-generated analytical data” means the statistical or analytical results of dispensed prescription data generated or produced by the [designated state agency] that is maintained, managed, and disclosed pursuant to this Act.

Y. “Reporting agent” means an individual who acts as an agent, pursuant to requirements of the [designated state agency], to report data to the PMP on behalf of a dispenser.

Z. “Supplemental data” means non-PMP dispensation data that may include, but is not limited to pain management agreements, laboratory results, and information related to fatal and nonfatal overdoses.

AA. “Ultimate user” means a patient or an individual who lawfully possesses a monitored drug on behalf of a patient.

SECTION 5. ESTABLISHMENT OF A PRESCRIPTION MONITORING PROGRAM (PMP).

A. The [designated state agency] shall establish and operate, in consultation with the advisory committee established in Section 6, an electronic system to track the dispensing of monitored drugs.

B. The [designated state agency] may contract with another state agency or a private vendor to establish and operate the PMP pursuant to guidelines issued by the [designated state agency]. A contractor shall comply with the provisions regarding confidentiality of PMP information in this Act, and is subject to the penalties specified in this Act for unlawful acts.

SECTION 6. ADVISORY COMMITTEE.

A. The [designated state agency] shall establish a multidisciplinary advisory committee to provide input and guidance regarding the establishment and operation of the PMP. Committee members shall possess the necessary expertise and experience to assist the [designated state agency] with specified tasks, which shall include, but not be limited to:

1. proper analysis and interpretation of PMP information,

2. identification of patterns of behavior for the review of PMP data pursuant to subsection 9.K,

3. evaluation of the PMP,

4. identification of technological safeguards to protect the security of the PMP information,

5. identification of technological standards for the reporting of PMP dispensation data and supplemental data pursuant to Section 7, and

6. input for reporting specific data elements or information to the PMP

B. The [designated state agency] shall appoint committee members who shall include, at a minimum:

1. a prescriber in active practice and in good standing with the applicable state licensing board or agency,

2. a pharmacist in active practice and in good standing with the state board of pharmacy,

3. a licensed substance abuse addiction counselor providing services for a state licensed substance abuse addiction treatment program,

4. a health care provider with a pain management credential, and

5. a law enforcement official whose duties include the investigation and enforcement of state controlled substances or prescription drug laws.

COMMENT

[The Task Force acknowledged that other individuals or organizations may be appropriate committee members, such as medical examiners, coroners, members of state professional associations, and employees of the state licensing boards, Department of Human Services, Department of Health and Human Services, etc.]

SECTION 7. REPORTING AND RETENTION OF PMP DATA.

A. Unless a waiver is granted under subsection E, each dispenser, or reporting agent, shall electronically submit the data listed in subsection B or a report of no dispensing to the [designated state agency] as frequently as required by the [designated state agency], but no later than the next business day after the dispensing of a monitored drug.

B. For each dispensing of a monitored drug, the following data shall be submitted to the [designated state agency]:

1. Patient
   a. [For human patients,] legal first name; middle name, if applicable; last name; and suffix, if applicable.

b. Date of birth.

c. Physical address, including postal code.

d. Telephone number. If a complete number is unavailable, report "9999999999" or the pharmacy location's area code.

e. [Species code, if applicable.]

f. [For non-human patients, Name of animal, if applicable.]

g. If the patient is an animal, the name, date of birth, and gender should be the information of the owner.

2. Prescriber
   a. DEA number.

   b. National Provider Identification (NPI) number.

   c. State license number if DEA and NPI numbers are unavailable.

3. Dispenser
   a. DEA number.

   b. NPI number.

   c. [National Council for Prescription Drug Programs (NCPDP) number if DEA and NPI numbers are unavailable.]

   d. [State license number if DEA and NPI numbers are unavailable.]

4. Drug
   a. Date monitored drug is filled or prepared by the dispenser.

   b. Date monitored drug is dispensed, sold, or otherwise delivered, if the information is available.

   c. Date prescription is issued by prescriber.

   d. Prescription number assigned by dispenser.

   e. National Drug Code (NDC) number or compound code.

   f. Dose with units.

   g. Days' supply of monitored drug.

h. Number of refills authorized.

i. The refill number of the monitored drug.

j. Method of payment.

COMMENT

[States may determine to modify language for subparagraphs 4.c, 4.d, and 4.e. for data elements on what is reported to the PMP for products such as non-prescribed items (e.g., medical marijuana)]

5. Additional Data
Such additional data as required by the [designated state agency] to effectuate the purposes of this Act.

C. The [designated state agency] shall maintain the data collected under subsection B in a readily retrievable format for a minimum of [insert time frame, e.g., three] years from the date of submission to the [designated state agency], and may establish a procedure for removing the data from the PMP. The [designated state agency] may use removed data for research or analysis purposes after de-identifying the removed data. The [designated state agency] shall retain the de-identified data for a minimum of [insert time frame, e.g., ten years] from the date the data has been de-identified. Removed data that is not used for research or analysis purposes shall be destroyed, except for data the [designated state agency] has authorized a law enforcement or health professionals' licensing or registration agency to retain for use in a specific criminal or administrative investigation.

D. Supplemental data, in addition to that listed in subsection B that a state statute, rule or regulation allows to be reported to the [designated state agency] may be maintained in the PMP database, and shall be accessed, used, or disclosed pursuant to the applicable statute, rule or regulation. Such information may include, but is not limited to reports of controlled substance poisonings or overdoses, convictions for violations of controlled substances or prescription drug laws, stolen controlled substance prescriptions, or blank prescription forms.

E. For documented good cause, the [designated state agency] may grant a dispenser a waiver of the reporting requirements in subsection A.

1. A dispenser shall submit an application for a waiver detailing the circumstances for which a waiver is requested. The application shall contain the signature of the individual in charge. A dispenser shall notify the [designated state agency] of any changes in the application information no later than [insert time frame, e.g., number of days] after the occurrence of such changes.

2. A waiver shall be valid for [insert applicable time period]. A waiver may be extended pursuant to a process specified by the [designated state agency.] Upon notification of

changes to the application information, the [designated state agency] may deny, rescind or modify the waiver.

COMMENT

[Where feasible, NASCSA encourages dispensers to use the most effective commercially available technology, e.g., scanning technology, to collect the data that they submit to the PMP pursuant to this section. Use of such technology helps minimize data collection errors and increases the quality of the data maintained by the PMP.]

SECTION 8. CONFIDENTIALITY OF PMP INFORMATION.

A. PMP information submitted to the [designated state agency] shall be deemed confidential. Such data and information are excluded from public or open records laws, and the [designated state agency] shall disclose the data and information only in accordance with this Act.

B. The [designated state agency] shall not disclose PMP information in response to a subpoena or other method of discovery or compelled production in a civil proceeding. PMP information shall not be admissible as evidence in a civil proceeding.

C. The [designated state agency] shall maintain:

1. standards and safeguards to protect the security of PMP information during the process of collection, maintenance, and disclosure pursuant to this Act; and

2. policies and procedures to ensure that access, disclosure, and use of PMP information occurs in accordance with this Act.

SECTION 9. ACCESS TO AND USE OF PMP INFORMATION.

A. The [designated state agency] may disclose PMP information as applicable, and in accordance with applicable state and federal confidentiality laws, to the individuals [, health care facilities or entities] identified in paragraphs B.1-17 who have successfully completed all applicable credentialing, registration, education or other requirements regarding the PMP. Mandates in this section apply only to individuals [, health care facilities or entities] who are subject to state jurisdiction.

B. The [designated state agency] may disclose PMP dispensation data to:

1. A prescriber for the purposes of:

a. providing, or evaluating the need to provide, medical care to an individual with whom the prescriber has a prescriber-patient relationship [or who seeks medical care for the first time from the prescriber];

[b. providing consultation regarding the medical care of an individual who has a prescriber-patient or pharmacist-patient relationship with another health care professional;]

c. reviewing the prescriber's own prescribing activity or history of PMP data requests; or

d. reviewing the history of PMP data requests made by the prescriber's delegate.

2. A pharmacist for the purposes of:

a. providing, or evaluating the need to provide, pharmaceutical care to an individual with whom the pharmacist has a pharmacist-patient relationship [or who seeks pharmaceutical care for the first time from the pharmacist];

[b. providing consultation regarding the pharmaceutical care of an individual who has a prescriber-patient or pharmacist-patient relationship with another health care professional;]

c. reviewing the pharmacist's own history of PMP data requests; or

d. reviewing the history of PMP data requests made by the pharmacist's delegate.

3.a. A delegate of a prescriber or pharmacist for the purposes of requesting PMP dispensation data on behalf of a prescriber or pharmacist.

b. A prescriber or pharmacist:

i. shall be legally and professionally responsible for a delegate's access, use, and disclosure of PMP dispensation data on behalf of the prescriber or pharmacist; and

ii. shall be responsible for making all medical and pharmaceutical care decisions based on aforementioned data requested by a delegate.

4. A designated representative of a licensing or registration agency that regulates prescribers, pharmacists or other dispensers for the purpose of conducting a good faith administrative investigation of a prescriber's, pharmacist's or other dispenser's professional practice that is or was regulated by that agency.

5.a. A local, state, out-of-state, or federal law enforcement official engaged in the administration, investigation, or enforcement of laws governing monitored drugs who submits:

i. a court order or warrant that relates to a criminal matter,

ii. a subpoena or summons issued by a judicial officer that relates to a criminal matter,

iii. a grand jury subpoena, or

iv. an administrative request that satisfies the criteria outlined in subparagraph b.

b. A law enforcement official shall be appointed by the director or other highest ranking official of a law enforcement agency to request PMP dispensation data on behalf of the agency for an individual under active investigation. The appointed official shall submit to the [designated state agency] a signed request in which the official certifies that:

i. the information sought is relevant and material to a legitimate law enforcement inquiry.

ii. the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought.

iii. de-identified data could not reasonably be used for the inquiry.

c. The director or other highest ranking official of a law enforcement agency shall submit to the [designated state agency] a notarized document identifying the officials appointed to request PMP dispensation data on behalf of the agency. Appointments in effect upon the expiration of the term of the director or other highest ranking official shall expire on the last day of the term. A new director or other highest ranking official shall submit a new notarized document.

6.a. An individual appointed by a judge overseeing a drug court to request PMP dispensation data on behalf of the court for an offender subject to the jurisdiction of the court. The appointed individual shall submit to the [designated state agency] an administrative request that satisfies the criteria outlined in subparagraph b.

b. An appointed individual under subparagraph a shall submit to the [designated state agency] a signed request in which the individual certifies that:

i. the information sought is relevant and material to a legitimate inquiry by the drug court.

ii. the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought.

iii. de-identified data could not reasonably be used for the inquiry.

c. The judge overseeing a drug court shall submit to the [designated state agency] a notarized document identifying the individuals appointed to request

PMP dispensation data on behalf of the court. Appointments in effect upon the expiration of the judge's term overseeing the drug court shall expire on the last day of the term. A new judge overseeing a drug court shall submit a new notarized document.

7. A medical examiner or county coroner, or a delegate thereof, for the purpose of investigating an individual's death.

8. A designated representative, or a representative's delegate, of a state agency with oversight of the Medicaid program. [The medical director of a managed care organization may serve as a designated representative or representative's delegate if:

a. the managed care organization has entered into an agreement with the state agency,

b. the managed care organization has satisfied all data security requirements of the [designated state agency], and

c. the medical director only requests PMP dispensation data regarding a program recipient assigned to the managed care organization.]

9. A designated representative, or a representative's delegate, of the Medicare program. [The medical director of a managed care organization may serve as a designated representative or representative's delegate if:

a. the managed care organization has entered into an agreement with the state agency,

b. the managed care organization has satisfied all data security requirements of the [designated state agency], and

c. the medical director only requests PMP dispensation data regarding a program recipient assigned to the managed care organization.]

10. A probation or parole officer for the purpose of monitoring an offender's compliance with participation in a drug diversion program or with other conditions of probation or parole related to monitored drugs.

11. An individual, or a person with a notarized release form from the individual, for the purposes of reviewing the history of dispensed monitored drugs to the individual.

12. A parent, legal guardian, or legal health care agent, for the purposes of reviewing the history of dispensed monitored drugs to a child or an individual for whom the agent makes health care decisions, to the extent consistent with federal and state confidentiality laws and regulations.

13. A designated representative of the [the designated state agency] and a vendor or contractor for the purpose of operating the PMP.

14. A designated prescription monitoring program official of another state, country, or political subdivision thereof, or territory, federal district, or federal jurisdiction with which this state or jurisdiction has an interoperability agreement for disclosure of this state's or jurisdiction's PMP dispensation data to individuals [, health care facilities or entities] located in the other state, country, or political subdivision thereof, or territory, federal district, or federal jurisdiction.

a. PMP dispensation data made available pursuant to this subsection may be used only consistent with this section.

[15. An executor of a will, or a court-appointed executor of an estate, for the purposes of reviewing the history of dispensed monitored drugs to a deceased individual.]

[16. A licensed substance abuse addiction counselor providing services to a state licensed substance abuse addiction treatment program.]

[17. A health care facility or entity, pursuant to requirements of the [designated state agency], for the purpose of providing medical or pharmaceutical care to individuals with whom:

a. prescribers of the facility or entity have prescriber-patient relationships, or

b. pharmacists of the facility or entity have pharmacist-patient relationships.]

C. The [designated state agency] may disclose supplemental data or PMP-generated analytical data to individuals [, health care facilities or entities] identified in paragraphs [B.1 through B.17, as applicable] in accordance with federal and state laws.

D. The [designated state agency] may disclose audit trail information to individuals:

1. identified in paragraphs B.4 and B.5 for use in an active investigation of an individual [, health care facility or entity] who submitted requests for PMP data;

2. responsible for monitoring compliance with PMP requirements under applicable federal and state laws; or

3. identified in paragraphs B.11 or B.12 for the purpose of determining suspected inappropriateness of the access and use of the PMP dispensation data.

E. Prescribers and pharmacists, and their delegates [, and health care facilities or entities,] may access PMP dispensation data by means of health or pharmacy information technology that the [designated state agency] approves for requesting and receiving PMP data. The individuals [, health care facilities or entities] and vendors of approved health or pharmacy information

technology shall provide the [designated state agency] with audit trail information requested by the [designated state agency].

F. The [designated state agency] may disclose PMP-generated analytical data or supplemental data in accordance with federal and state law.

COMMENT

[Allows for states to have authority to determine what types of data may be released/disclosed in order to reduce incorrect interpretation of the data]

G. Prescribers and pharmacists, and their delegates, shall register to access the PMP. The [designated state agency] shall establish the process and timeline for any mandatory PMP registration.

H. [Option 1.

1. Prescribers and pharmacists, and their delegates, [health care facilities or entities,] and vendors of health or pharmacy information technology approved pursuant to subsection E may store only the PMP dispensation data in the patient's legal health record or patient profile, unless other states authorize the storage of prescription data submitted to the other states' PMPs. The PMP dispensation data shall be subject to disclosure on the same terms and conditions as other information in the patient's legal health record or patient profile. PMP dispensation data stored outside of a patient's legal health record or patient profile shall be subject to disclosure in accordance with applicable state and federal privacy and confidentiality laws. Such laws shall include the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191 (Aug. 21, 1996), 45 C.F.R. parts 160 and 164 (HIPAA Privacy and Security Rules).

2. Prescribers and pharmacists, and their delegates, [health care facilities or entities,] and vendors of health or pharmacy information technology approved pursuant to subsection E:

a. shall store PMP dispensation data in a read only format;

b. shall not alter, edit or modify the data; and

c. shall not copy or incorporate the data into a searchable computer program or database except as authorized by the [designated state agency]].

[Option 2. Prescribers and pharmacists, and their delegates, [health care facilities or entities,] and vendors of health or pharmacy information technology approved pursuant to subsection E shall not store the PMP dispensation data in a patient's legal health record or patient profile. PMP data received pursuant to subsection E may be disclosed for providing, or evaluating the need to provide, medical or pharmaceutical care to the patient.]

I. [Option 1. PMP-generated analytical data and supplemental data may accompany the PMP dispensation data, but shall not be stored or used in lieu of the PMP dispensation data except as authorized by the [designated state agency]].

[Option 2. PMP-generated analytical data and supplemental data may accompany the PMP dispensation data, but shall not be used in lieu of the PMP dispensation data except as authorized by the [designated state agency].]

J. The [designated state agency] may provide de-identified PMP information for statistical, public research, public policy, or educational purposes.

K. The [designated state agency] shall review the PMP information.

1. If the review identifies:
    a. a pattern that indicates inappropriate patient behavior, the [designated agency] [insert shall or may] provide the relevant data to the appropriate prescribers and pharmacists.

    b. a pattern that indicates inappropriate prescriber or pharmacist behavior, the [designated state agency] [insert shall or may] provide the relevant data to the appropriate health professionals' licensing or registration agency.

2. The advisory committee, in consultation with health professionals' licensing or registration agencies and the [insert name of single state authority on drugs and alcohol], shall establish the patterns of behavior for subparagraph 1.a or 1.b, or both.

3. If the [designated state agency] has reason to believe from a review of the PMP information that a violation of laws governing monitored drugs has occurred, the [designated state agency] may notify the appropriate law enforcement agency in addition to the actions taken in paragraph 1.

COMMENT

Language for paragraphs B.5 and B.6 regarding access by law enforcement and drug court officials is drawn from LA. REV. STAT ANN. § 40:1007(F) (2021), and LA. ADMIN. CODE tit. 46, § 2921 (2019). For more information on the implementation history of the Louisiana statutory and regulatory language, please contact Joe Fontenot, Assistant Executive Director, Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, 70809-1700, (225) 922-0094, jfontenot@pharmacy.la.gov

SECTION 10. IMMUNITY.

A. The [designated state agency] is not subject to civil liability, administrative action, or other legal or equitable relief unless there is a finding of lack of good faith, reckless disregard, gross negligence, malice, or criminal intent for the:

1. failure to possess PMP dispensation data or supplemental data that was not reported to the [designated state agency];

2. release of PMP information that was factually incorrect;

3. release of PMP information to the wrong person or entity; or

4. unlawful access to PMP information by an individual [, health care facility or entity], or unlawful disclosure or use of PMP information by an individual [, health care facility or entity] who requested and received PMP information pursuant to Section 9.

B. A dispenser or reporting agent is not subject to civil liability, administrative action, or other legal or equitable relief for reporting PMP dispensation data or supplemental data to the PMP pursuant to Section 7.

C. A prescriber, dispenser, pharmacist, or other individual, agency, or entity in proper possession of PMP information pursuant to this Act is not subject to civil liability, administrative action, or other legal or equitable relief for accessing, using, or disclosing PMP information pursuant to Section 9.

SECTION 11. UNLAWFUL ACTS AND PENALTIES.

A. Administrative Sanctions.

1. The [designated state agency] shall refer the following individuals to the appropriate health professionals' licensing or registration agency for appropriate administrative sanctions:

   a. A dispenser, who knowingly fails to report PMP dispensation data pursuant to Section 7, or who knowingly reports incorrect data.

   b. A dispenser who knowingly fails to correct or amend data after notification by the [designated state agency].

   c. A prescriber, pharmacist, or delegate who knowingly fails to register with the PMP pursuant to Section 9.

   d. A person authorized to request and receive PMP information pursuant to Section 9 who knowingly requests, discloses, or uses such information in violation of this Act.

B. Criminal Sanctions.

1. A person authorized to access PMP information pursuant to this Act who knowingly:

   a. requests such information in violation of this Act, upon criminal conviction, [may be fined not more than [ ] nor imprisoned more than [ ], or both.] [in addition to disciplinary actions as defined in the Act (or state law)].

b. discloses such information in violation of this Act, upon criminal conviction, [may be fined not more than [ ] nor imprisoned more than [ ], or both.] [in addition to disciplinary actions as defined in the Act (or state law)].

c. uses such information in violation of this Act, upon criminal conviction, [may be fined not more than [ ] nor imprisoned more than [ ], or both] [in addition to disciplinary actions as defined in the Act (or state law)]

2. A person listed above may also be subject to fines, penalties, or imprisonment in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191 (Aug. 21, 1996), 45 C.F.R. parts 160 and 164 (HIPAA Privacy and Security Rules).

3. A person not authorized to access PMP information pursuant to this Act who knowingly:

a. accesses such information in violation of this Act, upon criminal conviction, [may be fined not more than [ ] nor imprisoned more than [ ], or both.]

b. discloses such information in violation of this Act, upon criminal conviction, may [be fined not more than [ ] nor imprisoned more than [ ], or both.]

c. uses such information in violation of this Act, upon criminal conviction, [may be fined not more than [ ] nor imprisoned more than [ ], or both.]

SECTION 12. EVALUATION, DATA ANALYSIS, AND REPORTING.

A. The [designated state agency] shall, in consultation or collaboration with the advisory committee, design and implement an evaluation component to identify:

1. costs of PMP operations;

2. any impacts on the misuse, abuse, diversion of, or addiction to, monitored drugs;

3. any impacts on the prescribing or dispensing of monitored drugs, including legitimate prescribing;

4. the availability of PMP dispensation data or supplemental data to prescribers and pharmacists, and any barriers to access by prescribers and pharmacists for every patient; and

5. other information relevant to policy, research, and education involving monitored drugs.

B. The [designated state agency] shall annually [or other designated period] report the information specified in subsection A to the advisory committee members, [insert appropriate state decision makers, e.g., appropriate professional licensing agencies, appropriate state

legislative committees and the Governor]. Additionally, the [designated state agency] shall make the annual report available to the public.

SECTION 13. RULES AND REGULATIONS.

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

SECTION 14. SEVERABILITY.

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

SECTION 15. EFFECTIVE DATE.

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

COMMENT

Where feasible, NASCSA encourages state legislators to consider the time pharmacies need to make programming changes when determining the effective date of this Act.