



National Association of State
Controlled Substances Authorities

Model Prescription Monitoring Program Act



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NATIONAL ASSOCIATION OF STATE CONTROLLED SUBSTANCES
AUTHORITIES (NASCSA)
MODEL PRESCRIPTION DRUG MONITORING (PMP) ACT DRAFTING GROUP

PARTICIPANTS

Barbara Carter
Program Manager
MN Prescription Monitoring
Program
MN Board of Pharmacy

Dana Crenshaw, AHFI, CFS
Director
MS Prescription Monitoring Program

Danna E. Droz, JD., RPH
PMP Liaison
National Associations of
Boards of Pharmacy (NABP)

Joe Fontenot
Assistant Executive Director
LA Board of Pharmacy

Bob Twillman, Ph.D., FAPM
Executive Director
American Academy of Pain
Management (AAPM)

Christie Frick
Director
SC Prescription Monitoring Program
Bureau of Drug Control, Dept. of
Health

Aaron Gilson, MS, MSSW, PhD
Research Program Manager
University of Wisconsin-Madison
Pain & Policy Studies Group

Heather Gray
Legislative Director
National Alliance for Model State
Drug Laws (NAMSDL)

Sherry Green
CEO and Manager
Sherry L. Green & Associates, LLC

Lani Ladao
Special Agent
HI Narcotics Enforcement Division
Department of Public Safety

Kathy Zahn
Program Assistant
ND Prescription Monitoring Program

**NATIONAL ASSOCIATION FOR STATE CONTROLLED SUBSTANCES
AUTHORITIES (NASCSA)
MODEL PRESCRIPTION MONITORING PROGRAM (PMP) ACT (2016)**

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 75 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.

SECTION 2. LEGISLATIVE FINDINGS.

[insert state-specific findings]

SECTION 3. PURPOSE.

[insert state-specific purposes of reducing abuse and diversion of monitored drugs and avoiding interference with appropriate professional practice and patient care.]

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) “Audit trail information” means information produced regarding requests for PMP 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.

(b) “De-identified data” means PMP data after removal of information that identifies, or could reasonably be used to identify, the patient, prescriber, and pharmacist or other dispenser.

(c) “Delegate” means an individual who acts as an agent, pursuant to requirements of the [designated state agency], to request PMP data on behalf of an individual [, health care facility or entity] in Section 9 who is authorized to request and receive PMP data. A delegate shall not be

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

(d) “Deliver” means the actual transfer of a monitored drug from an individual or entity to an individual or entity, whether or not there is an agency relationship.

(e) “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.

(f) “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;

(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] 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;

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

(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.]

(g) “Drug of concern” means a non-scheduled drug or substance determined by the [insert appropriate state agency] to be in need of monitoring because it has a potential for abuse or diversion.

(h) “Monitored drug” 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 deemed a drug of concern.

(i) “Patient” means an individual [or animal] for whom a prescription is issued or for whom a prescriber directly dispenses a monitored drug.

(j) “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.

- (k) “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.
- (l) “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.
- (m) “Prescriber” means an individual authorized by any U.S. state to prescribe a monitored drug and includes an individual who is employed by or an agent of a federal agency.
- (n) “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.
- (o) “Prescription monitoring program” or “PMP” means a program established under Section 5 of this Act.
- (p) “PMP data” means data submitted to the [designated state agency] pursuant to Section 7(b) that is maintained, managed, and disclosed pursuant to this Act.
- (q) “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.
- (r) “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 data 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 data,
- (2) identification of patterns of behavior for the review of PMP data pursuant to Section 9(i),
- (3) evaluation of the PMP,
- (4) identification of technological safeguards to protect the security of the PMP data, and
- (5) identification of technological standards for the reporting of PMP data pursuant to Section 7.

(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.

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) Gender.

[(F) Species code, if applicable.]

[(G) Name of animal, if applicable.]

(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 delivered.

(B) Date prescription is written by prescriber.

(C) Prescription number assigned by dispenser.

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

(E) Dose with units.

(F) Days' supply of monitored drug.

(G) Whether monitored drug is delivered as a new or a refilled prescription.

(H) Number of refills authorized.

(I) Method of payment.

(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) Data or information in addition to that listed in subsection (b) that a state statute, rule or regulation requires 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 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)(1) For documented good cause, the [designated state agency] may grant a dispenser a waiver of the reporting requirements in subsection (a).

(2) 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.

(3) 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 DATA AND AUDIT TRAIL INFORMATION.

(a) PMP data submitted to the [designated state agency] and audit trail information 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 data or audit trail information in response to a subpoena or other method of discovery or compelled production in a civil proceeding. PMP data and audit trail 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 data and audit trail 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 data and audit trail information occurs in accordance with this Act.

SECTION 9. ACCESS TO AND USE OF PMP DATA AND AUDIT TRAIL INFORMATION.

(a) The [designated state agency] may disclose PMP data upon request to the individuals [, facilities or entities] identified in paragraphs (1) – (14) [(17)] who have successfully completed all applicable credentialing, registration, education or other requirements regarding the PMP. Mandates in this section apply only to individuals [, facilities or entities] who are subject to state jurisdiction.

(1) A prescriber for the purposes of:

(i) 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];

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

(iii) reviewing the prescriber's own prescribing activity or history of PMP data requests;

or

(iv) reviewing the history of PMP data requests made by the prescriber's delegate.

(2)(A) A pharmacist for the purposes of:

(i) 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];

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

(iii) 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 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 data on behalf of the prescriber or pharmacist; and

(ii) shall be responsible for making all medical and pharmaceutical care decisions based on PMP 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 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 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 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 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] A designated representative, or a representative's delegate, of a state agency with oversight of the Medicaid program for the purpose of investigating fraud [or other inappropriate behavior] by a program recipient.

[B The medical director of a managed care organization may serve as a designated representative or representative's delegate if:

- (i) the managed care organization has entered into an agreement with the state agency,
- (ii) the managed care organization has satisfied all data security requirements of the [designated state agency], and

(iii) the medical director only requests PMP data regarding a program recipient assigned to the managed care organization.]

(9)[A] A designated representative, or a representative's delegate, of the Medicare program for the purpose of investigating fraud [or other inappropriate behavior] by a program recipient.

[B The medical director of a managed care organization may serve as a designated representative or representative's delegate if:

- (i) the managed care organization has entered into an agreement with the state agency,
- (ii) the managed care organization has satisfied all data security requirements of the [designated state agency], and
- (iii) the medical director only requests PMP 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, with which this state has an interoperability agreement for disclosure of this state's PMP data to individuals [, facilities and entities] located in the other state, country, or political subdivision thereof.

[(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:

- (i) prescribers of the facility or entity have prescriber-patient relationships, or
- (ii) pharmacists of the facility or entity have pharmacist-patient relationships.]

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

(c) The [designated state agency] may disclose audit trail information to individuals identified in paragraphs (a)(4) and (5) for use in an active investigation of an individual [, health care facility or entity] who submitted requests for PMP data.

(d) 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.

(e) Prescribers and pharmacists, and their delegates, [health care facilities or entities,] and vendors of health or pharmacy information technology approved pursuant to subsection (b) may store the PMP data in the patient's legal health record or patient profile. The PMP 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 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).

(f) Prescribers and pharmacists, and their delegates, [health care facilities or entities,] and vendors of health or pharmacy information technology approved pursuant to subsection (b):

(1) shall store PMP data in a read only format;

(2) shall not alter, edit or modify the data; and

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

(g) Summaries or interpretations of the PMP data may accompany the PMP data, but shall not be stored or used in lieu of the PMP data except as authorized by the [designated state agency].

(h) The [designated state agency] may provide de-identified data for statistical, public research, public policy, or educational purposes.

(i) The [designated state agency] shall review the PMP data. If the review identifies:

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

(2) 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 for further inquiry and action.

(j) 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 subsection (i).

(k) If the [designated state agency] has reason to believe from a review of the PMP data 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 subsection (i).

COMMENT

Language for paragraphs (a)(5) and (a)(6) regarding access by law enforcement and drug court officials is drawn from LA. REV. STAT ANN. § 40:1007(F) (2016), and LA. ADMIN. CODE tit. 46, § 2921 (2016). 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) Unless there is a finding of lack of good faith, reckless disregard, gross negligence, malice, or criminal intent the [designated state agency] is not subject to civil liability, administrative action, or other legal or equitable relief for the:

(1) failure to possess PMP data that was not reported to the [designated state agency];

(2) release of PMP data or audit trail information that was factually incorrect;

(3) release of PMP data or audit trail information to the wrong person or entity; or

(4) unlawful access to PMP data by an individual [, health care facility or entity], or unlawful disclosure or use of PMP data by an individual [, health care facility or entity] who requested and received PMP data 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 data to the PMP pursuant to Section 7.

(c) A prescriber, dispenser, pharmacist, or other individual, agency, or entity in proper possession of PMP data or audit trail 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 data or audit trail information pursuant to Section 9.

SECTION 11. UNLAWFUL ACTS AND PENALTIES.

Administrative Sanctions.

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

(1) A dispenser who knowingly fails to report PMP data pursuant to Section 7, or who knowingly reports incorrect data.

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

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

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

Criminal Sanctions.

(b) A person authorized to access PMP data pursuant to this Act who knowingly:

(1) requests such data in violation of this Act shall, upon criminal conviction, [be fined not more than [] nor imprisoned more than [], or both.]

(2) discloses such data in violation of this Act shall, upon criminal conviction, [be fined not more than [] nor imprisoned more than [], or both.]

(3) uses such data in violation of this Act shall, upon criminal conviction, [be fined not more than [] nor imprisoned more than [], or both.]

(c) A person not authorized to access PMP data pursuant to this Act who knowingly:

(1) accesses such data in violation of this Act shall, upon criminal conviction, [be fined not more than [] nor imprisoned more than [], or both.]

(2) discloses such data in violation of this Act shall, upon criminal conviction, [be fined not more than [] nor imprisoned more than [], or both.]

(3) uses such data in violation of this Act shall, upon criminal conviction, [be fined not more than [] nor imprisoned more than [], or both.]

SECTION 13. EVALUATION, DATA ANALYSIS, AND REPORTING.

(a) The [designated state agency] shall, in consultation 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 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 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 14. RULES AND REGULATIONS.

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

SECTION 15. 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 16. 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.