



MODEL PRESCRIPTION MONITORING PROGRAM (PMP) ACT

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**NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS (NAMSDL)
MODEL PRESCRIPTION MONITORING PROGRAM (PMP) ACT-
REVISED 11-22-13**

SECTION 1. SHORT TITLE.

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

SECTION 2. LEGISLATIVE FINDINGS.

(a) The United States Drug Enforcement Administration reported in 2010 that more than 7 million (more than one out of every 45) Americans abuse prescription medications. The number abusing prescription drugs exceeds the number of people who use cocaine, heroin, hallucinogens, methylenedioxymethamphetamine (ecstasy), and inhalants combined. This increase in prescription drug abuse imposes staggering economic costs and human suffering.

(b) There were four times as many *prescription* drug overdose deaths in 2007 as heroin overdose deaths, and twice as many as cocaine drug overdose deaths. *See Public Health Grand Rounds*, (Center for Disease Control, February 17, 2011). The same report shows that prescription opioid analgesic overdose deaths nearly *quadrupled* between 1999 (2,901 dead) and 2007, when 11,449 people died in America from this cause; there is little indication that the death toll is abating. The 2007 prescription overdose death toll matches the number of Americans killed in Vietnam in 1969.

(c) The proportion of all substance abuse treatment admissions of those aged 12 and older involving abuse of prescription pain relievers more than *quadrupled* from 1998 to 2008. *See Substance Abuse Treatment Admissions Involving Abuse of Pain Relievers: 1998 and 2008 – The TEDS Report*, (Substance Abuse and Mental Health Services Administration (SAMHSA), July 15, 2010).

(d) Prescription drug abuse is particularly threatening the lives and well-being of our children. According to the 2008 National Survey on Drug Use and Health (SAMHSA), every day 2,500 young people between the ages of 12 and 17 abuse a pain reliever for the very first time. More teens abuse prescription drugs than any illicit drug except marijuana. In 2008, more than 2.1 million teens ages 12 to 17 reported abusing prescription drugs. Moreover, the Office of National Drug Control Policy's 2008 Report "Prescription for Danger" reports that one-third of all new abusers of prescription drugs in 2006 were 12- to 17-year-olds. In 2009 52% of 12th graders said they had illegally received or purchased prescription drugs, according to the National Institute for Drug Abuse;

(e) The CDC recently noted that, between 1997 and 2007, drug company distribution of prescription opioid analgesics increased 627%. The CDC states that enough of these

drugs are currently distributed “for every American to take 5 mg. Vicodin every 4 hours for 3 weeks.” *See Public Health Grand Rounds, CDC, February 17, 2011).*

(f) [State statistics mirroring (a) – (e) above.]

(g) The Director of the Office of National Drug Control Policy recently stated that “abuse of prescription drugs is our country's fastest-growing drug problem.”

(h) The diversion of prescription drugs for abuse, costs the entire health insurance industry up to \$72.5 billion a year, including up to \$24.9 billion annually for private health insurers. These huge losses increase health insurance premiums. The bulk of this cost is medical, paying for serious medical complications and injuries that inevitably arise when prescription drugs are abused. But they also include insurance fraud schemes in which health insurers – and therefore payers of insurance premiums – end up paying for abused prescription drugs. *See PRESCRIPTION FOR PERIL – How Insurance Fraud Finances Theft of Addictive Prescription Drugs* (Coalition Against Insurance Fraud, December 2007).

(i) According to a 2011 federal investigation report of the Center for Medicare and Medicaid Services (CMS), the Center in 2007 paid \$20.6 million for 228,000 prescriptions for Schedule II drugs – the most commonly abused prescription drugs – *with invalid or blank identification numbers*. Another investigation a few months before that, revealed that Medicare Part D Plans in 2007 paid \$1.2 billion for drug prescriptions with unlisted or invalid identification numbers. These numbers point to illegal diversion, gross misuse of taxpayers’ dollars and, most importantly, untold human suffering caused by taxpayer-funded prescription drug abuse.

(j) The overall cost of drug abuse to federal, state and local governments was *nearly one-half trillion dollars* in 2005, according to a 2009 report published by The National Center on Addiction and Substance Abuse (CASA) at Columbia University. Although the research cannot establish the precise percentage attributable to *prescription* drug abuse, we know that in 2005 prescription drug abuse and overdose deaths had already far outpaced both cocaine, heroin and other illegal drug abuse and deaths.

(k) Prescription drug abuse presents special challenges not presented by abuse of illegal street (nonprescription drugs), since prescription drugs have an essential and beneficial presence in commerce, are for the most part in the possession of law-abiding patients who are using them under doctors’ orders, and do not have the stigma that is associated with illegal street (nonprescription drugs). Mechanisms for stemming the abuse of prescription drugs must not impinge on their appropriate use.

(l) Doctors are committed to “doing no harm” to their patients. To accomplish this goal, doctors must have full, complete and reliable information about what other drugs have been prescribed to their patients by other doctors; otherwise they can unwittingly harm their patients. Lack of this information can place patients at mortal risk, either through contributing to their drug addiction or through inadvertent, fatal drug interactions.

(m) It is the policy of this state to support doctors, other health care practitioners, dispensers and health care institutions, in their mission to “do no harm” to their patients, and to do so by ensuring that they have the information necessary to make responsible and healthy prescribing decisions.

(n) An effective prescription monitoring program reduces prescription drug abuse and diversion, by identifying potentially inappropriate prescribing, dispensing, and consuming behaviors, referring them for investigation, and where such behaviors prove to be actually inappropriate, referring those involved for ameliorative and corrective remedies.

SECTION 3. PURPOSE.

The purpose of this [Act] is to reduce prescription drug abuse and fraud by providing a tool that will ensure that doctors making prescribing decisions have complete and reliable information about what, if any, other prescription drugs have recently been prescribed to their patients. It is the purpose of this [Act] to provide reporting mechanisms – with full confidentiality protections – in which prescribers, dispensers and other health care practitioners report prescription information to a central repository, in order to identify patient and doctor behavior that gives rise to a reasonable suspicion that prescription drugs are being inappropriately obtained or prescribed, so that appropriate ameliorative and corrective action – treatment for individuals suffering from drug and alcohol addiction – may be taken. This Act is further intended to help detect, refer to law enforcement and regulatory agencies, and deter prescription drug fraud and diversion.

SECTION 4. DEFINITIONS.

For the 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) "Advisory Committee" means the committee established under Section 6 of this Act.

(b) “Alcohol and other drug addiction treatment program” means any facility or treatment program that is [licensed], [certified] or [approved] by the state to provide alcohol and other drug addiction treatment on a hospital, non-hospital residential or outpatient basis.

(c) “Bona fide patient relationship” means a relationship in which the prescriber has ongoing responsibility for the assessment, care and treatment of a patient’s medical condition.

(d) “Controlled substance” means a drug, substance, or immediate precursor in Schedules II-V of [insert citations to state controlled substances law provisions].

(e) “Deliver” means to transfer or to attempt to transfer, a controlled substance or drug of concern, actually or constructively, from one person to another, whether or not there is an agency relationship.

(f) "Dispenser" means a person authorized in the jurisdiction in which the person is practicing to deliver a controlled substance or drug of concern to the ultimate user by or pursuant to the lawful order of a prescriber, but does not include:

(i) a licensed hospital pharmacy that distributes such substances or drugs of concern for the purposes of inpatient hospital care, emergency department care for the immediate use of a controlled substance or drug of concern or when dispensing no more than a [72 hour] supply of a controlled substance or a drug of concern at the time of discharge from such a facility;

(ii) an authorized person who administers a controlled substance or drug of concern upon the lawful order of a prescriber; or

(iii) a wholesale distributor of a controlled substance or drug of concern monitored by the prescription monitoring program.

(g) "Drug" means:

(i) Any substance recognized as a drug in the official compendium, or supplement thereto, designated by the [insert appropriate agency or entity] for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals.

(ii) Any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(iii) Any substance other than food intended to affect the structure or any function of the body of humans or other animals.

(h) "Drug of concern" means a drug other than a controlled substance that is identified by the [insert appropriate agency or entity] as demonstrating a potential for abuse and is designated as a drug of concern in rules and regulations.

(i) "Patient" means the person who is the ultimate user of a controlled substance or drug of concern for whom a prescription is issued or for whom the prescriber directly dispenses a controlled substance or drug of concern.

(j) "Pharmaceutical care" means the responsible provision of drug-related care for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are (i) cure of a disease; (ii) elimination or reduction of a patient's symptomatology; (iii) arresting or slowing of a disease process; or (iv) preventing a disease or symptomatology.

(k) "Prescribe" means to direct, designate or order the use of a formula for the preparation of a controlled substance or drug of concern for a disease or illness and the manner of using the substance or drug of concern.

(l) "Prescriber" means a health care professional authorized in the jurisdiction in which the professional is practicing to prescribe a controlled substance or drug of concern.

(m) "Prescription monitoring information" means information collected, recorded transmitted and maintained by the Prescription Monitoring Program.

(n) "Prescription Monitoring Program" or "PMP" means a program established under Section 5 of this Act.

(o) "Ultimate user" means an individual who lawfully possesses a controlled substance or drug of concern monitored by the PMP for the individual's own use or for the use of a member of the individual's household or for administering to an animal owned by the individual or by a member of the individual's household.

SECTION 5. ESTABLISHMENT OF A PRESCRIPTION MONITORING PROGRAM.

(a) The [designated state agency or entity] shall establish and maintain, in consultation with the Advisory Committee, an electronic system for the monitoring of controlled substances and drugs of concern dispensed in the state or dispensed to an address in the state.

(b) The [designated state agency or entity] may contract with another state agency or a private vendor to establish and maintain the electronic monitoring system pursuant to guidelines promulgated by the [designated state agency or entity]. A contractor shall comply with the provisions regarding confidentiality of prescription monitoring information in this Act and is subject to the penalties specified in this Act for unlawful acts.

SECTION 6. ADVISORY COMMITTEE.

(a)(i) An Advisory Committee is established to provide input and advice to the [designated state agency or entity] regarding the establishment and maintenance of the PMP, including but not limited to:

- (A) use of the PMP to improve patient care, to identify and address addiction, and to facilitate the goal of reducing misuse, abuse, overdose, addiction to and diversion of controlled substances and drugs of concern;
- (B) potential safeguards for the release of information to authorized users;
- (C) the confidentiality of prescription monitoring information and the integrity of the patient's relationship with the patient's health care provider;
- (D) development of criteria for referring prescription monitoring information to a law enforcement or professional licensing agency;
- (E) development of criteria for referring a prescriber or dispenser to a professional licensing agency or impaired professionals association;
- (F) the design and implementation of training, education or instruction identified in Section 9;
- (G) the provision of assessment and referral to alcohol and other drug addiction treatment as part of any other requirements of this Act;

- (H) technical standards for electronic reporting of prescription monitoring information;
- (I) technological improvements to facilitate the interoperability of the PMP with other state PMPs and electronic health information systems, and to facilitate prescribers' and dispensers' access to and use of the PMP;
- (J) the proper analysis and interpretation of prescription monitoring information;
- (K) the design and implementation of an evaluation component; and
- (L) recommended appointments to the Committee.

(ii) For the purpose of providing input and advice pursuant to (a)(i), no Advisory Committee member shall receive prescription monitoring information which identifies, or could reasonably be used to identify, the patient, prescriber, dispenser or other person who is the subject of the information.

(b) Membership.

(i) The Advisory Committee shall have the following members:

- (A) a representative designated by the [state association of addiction treatment programs],
- (B) a representative designated by the [state association of addiction medicine, or where there is no such association, an equivalent organization],
- (C) a representative designated by the [state's impaired lawyers organization],
- (D) an individual in recovery from prescription drug and other drug addictions designated by the [state association of addiction treatment programs],
- (E) a representative designated by [the state association of medical examiners or county coroners or other appropriate association],
- (F) a representative designated by [each appropriate state association of prescribing professionals],
- (G) a representative designated by [each appropriate state association representing pharmacists, including independent pharmacists], and
- (H) a representative designated by [each state professional licensing or certification agency or board for prescribers and dispensers].

(ii) The Advisory Committee may also have the following members:

[insert one or more professionals or community representatives whose membership is deemed necessary to help undertake the duties and responsibilities outlined in Section 6(a)(i). Examples of such additional members include:]

- (A) a representative designated by a consumer or patients' rights

- organization selected by the Secretary of the [department responsible for public health matters],
- (B) a representative designated by the [state hospital association],
- (C) a representative designated by the [state association of pain management],
- (D) a representative designated by the state Office of the Attorney General,
- (E) a representative designated by the [state district attorneys or prosecuting attorneys association],
- (F) a representative designated by the [state police or state bureau of investigation],
- (G) a representative designated by the [state sheriffs' association],
- (H) a representative designated by the [state chiefs of police association],
- (I) a representative designated by the [state department responsible for public health matters], and
- (J) a representative designated by the [single state authority for drug and alcohol programs].

(iii) The [director/administrator] of the [designated state agency or entity] may also appoint persons with recognized expertise, knowledge and experience in the establishment and maintenance of PMPs, skills and expertise in alcohol and other drug addiction assessment and referral to addiction treatment, or issues involving the misuse, abuse, or diversion of, or the addiction to, controlled substances or drugs of concern.

(c) When an opening on the Advisory Committee occurs, the [designated state agency or entity] shall notify the respective entity set forth in (b)(i) of the vacancy. The entity shall as soon as practicable designate a new representative and notify the [director/administrator] of [the designated state agency or entity] of its decision.

(d) The members of the Advisory Committee shall serve at the pleasure of their respective designating entity. [] members shall constitute a quorum for the transaction of all business. The members shall elect a Chairman and such other officers as deemed necessary whose duties shall be established by the Advisory Committee. The [designated state agency or entity] shall provide at least [60] days written notice to members of the time and place for the regular meetings of the Advisory Committee, which shall meet at least quarterly. The Advisory Committee shall adopt policies and procedures necessary to carry out its duties pursuant to [insert reference to state statute governing reimbursement of expenses and other operational issues].

SECTION 7. REPORTING OF PRESCRIPTION MONITORING INFORMATION.

(a) Each dispenser shall submit to the [designated state agency or entity] by electronic means, except as provided in (c), information required by the [designated state agency or entity]

regarding each prescription dispensed for a controlled substance or drug of concern. Such information may include, but shall not be limited to:

- (i) the dispenser identification number,
- (ii) the date the prescription is filled,
- (iii) the prescription number,
- (iv) whether the prescription is new or is a refill,
- (v) the national drug code for the substance or drug dispensed,
- (vi) the quantity dispensed,
- (vii) the number of days supply of the drug,
- (viii) the patient identification number,
- (ix) the patient's name,
- (x) the patient's address,
- (xi) the patient's date of birth,
- (xii) the prescriber identification number,
- (xiii) the date the prescription was issued by the prescriber, and
- (xiv) the source of payment for the prescription.

(b) Each dispenser shall submit the information required under (a) as frequently as specified by the [designated state agency or entity], but no later than seven days after the dispensing of a controlled substance or drug of concern monitored by the PMP. The [designated state agency or entity] shall implement a real time reporting requirement as expeditiously as possible.

(c) The [designated state agency or entity] may grant a waiver of electronic submission to any dispenser for good cause, including financial hardship, as determined by the [designated state agency or entity]. The waiver shall state the format and frequency with which the dispenser shall submit the required information.

SECTION 8. ACCESS TO AND USE OF THE PRESCRIPTION MONITORING INFORMATION; CONFIDENTIALITY.

(a) Prescription monitoring information submitted to the [designated state agency or entity] shall be confidential, is not subject to public or open records laws, and is not subject to disclosure or use except as provided in this Section.

(b) 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 Section.

(c) The [designated state agency or entity] shall implement technological improvements to facilitate secure access to the PMP through electronic health information systems as expeditiously as possible.

- (d) The [designated state agency or entity] shall review the prescription monitoring information. If the review identifies information that satisfies criteria established by the [designated state agency or entity] in consultation with the Advisory Committee:
 - (i) for referring information about a patient to a prescriber or dispenser, the [designated state agency or entity] shall provide the relevant information to the appropriate prescribers and dispensers.
 - (ii) for referring information to a law enforcement agency or a professional licensing or certification agency or board, the [designated state agency or entity] shall provide the relevant information to the appropriate agency or board for further inquiry and action, as deemed appropriate by that agency or board.

(e) The [designated state agency or entity] may provide prescription monitoring information for statistical, public research, public policy or educational purposes, after removing information which identifies, or could reasonably be used to identify, the patient, prescriber, dispenser or other person who is the subject of the information.

(f) The following persons may access prescription monitoring information after successful completion of the applicable training, education or instruction regarding the PMP identified in Section 9(a) and in accordance with procedures adopted by the [designated state agency or entity]:

- (i) A prescriber, or a representative designated by a prescriber pursuant to criteria established by the PMP, for the purpose of providing medical care to a patient with whom the prescriber has a bona fide patient relationship, or to inquire about the prescriber's own prescribing activity.
- (ii) A dispenser, or a representative designated by a dispenser pursuant to criteria established by the PMP, for the purpose of providing pharmaceutical care to a bona fide patient, or to inquire about the dispenser's own dispensing activity.
- (iii) A law enforcement or prosecutorial official engaged in the administration, investigation, or enforcement of the laws governing controlled substances or drugs of concern who is involved in a bona fide investigation or prosecution.
- (iv) A designated representative from an agency or board responsible for licensing or certifying prescribers or dispensers who is involved in a bona fide investigation of a prescriber or dispenser whose professional practice was or is regulated by that agency or board.
- (v) A designated representative of the [designated state agency or entity] and any vendor or contractor as necessary for the establishment or maintenance of the PMP.
- (vi) A medical examiner or county coroner for the purpose of investigating the death of an individual.
- (vii) A designated physician of an alcohol and other drug addiction treatment program for the purpose of providing medical care to a bona fide patient of the program.

(viii) A member of the Advisory Committee for the purpose of providing advice and input to the [designated state agency entity] pursuant to Section 6(a)(i) and subject to the limitation stated in Section 6(a)(ii).

(g) A judicial authority under grand jury subpoena or court order or equivalent judicial process for investigation of a criminal violation of law governing controlled substances or drugs of concern may access prescription monitoring information.

(h) An individual may access prescription monitoring information, in accordance with procedures established by the [designated state agency or entity], that relates to:

- (i) the receipt of controlled substances or drugs of concern by the individual; or
- (ii) the individual's minor child, or a person for whom the individual is a legal guardian, to the extent consistent with federal and state confidentiality laws and regulations.

(i) A designated prescription monitoring official of a state with which this state has an interoperability agreement may access prescription monitoring information in accordance with procedures adopted by the [designated state agency or entity].

(j) Each of the following professional licensing or certification agencies or boards shall adopt rules and regulations that establish standards and procedures for designated professionals regulated by that agency or board regarding the access and use of patient information available through the PMP:

[list appropriate agencies or boards, e.g., state board of dentistry, state board of nursing, state board of optometry, state medical board]

(k) No one shall knowingly hinder a pharmacist who is eligible to receive information from the PMP from requesting and receiving such information in a timely fashion.

(l) The [designated state agency or entity] shall remove from the PMP all information more than [select period no less than two and no more than seven] years old from the date of collection. Such information shall then be destroyed unless a law enforcement agency or a professional licensing or certification agency or board for prescribers or dispensers has submitted a written request to the [designated state agency or entity] for retention of specific information. All requests shall comply with procedures adopted by the [designated state agency or entity].

SECTION 9. EDUCATION AND TREATMENT.

(a) The [designated state agency or entity] shall, in consultation with the Advisory Committee:

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(i) assist the appropriate agency, board or association for each category of authorized user in Section 8(f) to incorporate the appropriate information regarding the PMP into the training, education or instruction provided to each category of authorized user;

(ii) assist the state or regional chapter of the American Society of Addiction Medicine, or comparable state association, and the state medical society to develop a continuing education course for health care professionals on prescribing practices, pharmacology and identification, referral and treatment of patients addicted to or abusing controlled substances or drugs of concern monitored by the PMP; and

(iii) implement, or assist other appropriate agencies to implement, an educational program to inform the public about the use, diversion and abuse of, addiction to, and treatment for the addiction to the controlled substances or drugs of concern monitored by the PMP.

(b) The [designated state agency or entity], based on criteria established in consultation with the Advisory Committee, shall refer prescribers and dispensers it has reason to believe may be impaired to the appropriate professional licensing or certification agency, and to the appropriate impaired professionals associations, to provide intervention, assessment and referral to alcohol and other drug addiction treatment programs, and ongoing monitoring and follow-up.

(c) The [designated state agency or entity], shall, in consultation with the Advisory Committee, work with the appropriate alcohol and other drug addiction treatment professionals to provide that patients identified through the PMP as potentially addicted to a controlled substance or drug of concern are assessed and referred to alcohol and other drug addiction treatment programs.

SECTION 10. IMMUNITY.

Option 1: [State officials should review their general immunity statutes to determine if immunity issues regarding the PMP are already addressed by those statutes. If so, then this section may be omitted or may include a reference to the legal citation of the appropriate general immunity law.]

Option 2: [If a state wishes to include specific immunity language in its PMP statute, the following language is recommended:

(a) Except as indicated in (b), and unless there is a finding of [insert appropriate state standard, e.g., lack of good faith, gross negligence, malice or criminal intent], the [designated state agency or entity], a prescriber, dispenser, or any other person, agency or entity in proper possession of information pursuant to this Act is not subject to civil liability, administrative action or other legal or equitable relief for any of the following acts or omissions:

(i) Reporting information to the PMP pursuant to this Act.

- (ii) Accessing, using or relying on information pursuant to this Act.
- (iii) Not possessing information that was not furnished to the [designated state agency or entity].
- (iv) Releasing information that was factually incorrect.
- (v) Releasing information to the wrong person or entity.
- (vi) Not referring prescription monitoring information or prescribers or dispensers pursuant to this Act.
- (vii) Failing to purge information from the PMP pursuant to this Act.

(b) If there is a finding of reckless disregard of the requirement in Subsection 8(b), the [designated state agency or entity] may be subject to civil liability, administrative action or other legal or equitable relief for the acts or omissions listed in (a).

SECTION 11. UNLAWFUL ACTS AND PENALTIES.

(a) Administrative Sanctions.

- (i) 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 false information, shall be referred to the appropriate professional licensing or certification agency or board for administrative sanctions as deemed appropriate by that agency or board.
- (ii) A person authorized to have prescription monitoring information pursuant to this Act who knowingly obtains, discloses or uses such information in violation of this Act shall be referred to the appropriate professional licensing or certification agency or board for administrative sanctions as deemed appropriate by that agency or board.

(b) Criminal Sanctions.

- (i) A person authorized to have prescription monitoring information pursuant to this Act who knowingly discloses such information in violation of this Act shall, upon criminal conviction, be fined not more than [] nor imprisoned more than [], or both.
- (ii) A person authorized to have prescription monitoring information pursuant to this Act who knowingly uses such information in violation of this Act shall, upon criminal conviction, be fined not more than [] nor imprisoned more than [], or both.

(iii) A person not authorized to have prescription monitoring information pursuant to this Act who knowingly obtains such information in violation of this Act shall, upon criminal conviction, be fined not more than [] nor imprisoned more than [], or both.

SECTION 12. EVALUATION, DATA ANALYSIS AND REPORTING.

(a) The [designated state agency or entity] shall, in consultation with the Advisory Committee, design and implement an evaluation component to identify:

- (i) cost-benefits of the PMP;
- (ii) any impact on efforts to reduce misuse, abuse, overdose and diversion of, or addiction to, controlled substances and drugs of concern;
- (iii) any impact on prescribing practices for controlled substances and drugs of concern;
- (iv) the number of patients identified through the PMP as potentially addicted to a controlled substance or drug of concern that were assessed for alcohol and other drug addictions;
- (v) the number of patients in (iv) that received alcohol and other drug addiction treatment, and the names of the licensed, certified, or approved alcohol and other drug addiction treatment facilities in which the patients were treated;
- (vi) any progress made in implementing real time reporting; and
- (vii) other information relevant to policy, research and education involving controlled substances and drugs of concern monitored by the PMP.

(b) The [designated state agency or entity] shall annually report the information specified in paragraph (a) to the Advisory Committee members, [insert appropriate state decision makers, e.g. appropriate state legislative committees, Governor], the U.S. Department of Justice (DOJ), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Office of National Drug Control Policy (ONDCP) and members of the state's U.S. Congressional delegation. 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 effect].