Prescription drug monitoring programs

Introduction

According to a 2007 study conducted by the Substance Abuse and Mental Health Services Administration, prescription drugs follow marijuana as the most commonly abused substance (excluding alcohol). Another study completed by the CDC found a 97 percent increase in prescription opioid analgesic-related deaths from 1997 to 2002 in 28 metropolitan areas. In comparison, during the study period deaths from cocaine overdoses rose by 13 percent and deaths from heroin or morphine actually fell by three percent. As CDC epidemiologist, Dr. Len Paulozzi succinctly states, "Drug overdoses are now the second leading cause of unintentional injury death in the United States, exceeded only by motor vehicle fatalities."[1]

Prescription drug abuse also has financial implications. A 2006 study determined that, in 2001 dollars, the costs for opioid abuse totaled $8.6 billion. Of this amount, direct health care costs and lost productivity contributed $2.6 billion and $4.6 billion, respectively. Criminal justice costs accounted for the remaining $1.4 billion.[2] In 2005 dollars, the total fiscal cost would be $9.5 billion. Considering the continued increase in drug overdoses, in 2010 dollars this amount would likely be substantially more. In order to combat these trends, state legislatures have taken action. Along with creating Drug Awareness months and regulating pain clinics, many have also created prescription drug monitoring programs (PMPs).[3]

PMP overview

The National Alliance for Model State Drug Laws (NAMSDL) defines a PMP as "a statewide electronic database which collects designated data on substances dispensed in the state. The PMP is housed by a specified statewide regulatory, administrative or law enforcement agency. The housing agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession."[4] The NAMSDL also describes the goals of PMPs:

- To support access to legitimate medical use of controlled substances,
- To help identify and deter or prevent drug abuse and diversion,
- To facilitate and encourage the identification, intervention with and treatment of persons addicted to prescription drugs,
- To help inform public health initiatives through outlining of use and abuse trends, and

[1] http://www.ncsl.org/default.aspx?tabid=19735
[2] Birnbaum, Howard G., et al. "Estimated costs of prescription opioid analgesic abuse in the U.S. in 2001." *Clinical Journal of Pain* 22 (2006): 667–76.
[3] Association of State and Territorial Health Officials. "Prescription Drug Overdose – State Agencies Respond." *Centers for Disease Control and Prevention* (2008).
[4] http://www.namsdl.org/documents/PMPsBriefOverview8-17-2010.pdf

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- To help educate individuals about PMPs and the use, abuse and diversion of and addiction to prescription drugs.[5]

PMPs may be proactive or reactive. Reactive PMPs "generate solicited reports only in response to a specific inquiry made by a prescriber, dispenser, or other party with appropriate authority."[6] In addition to providing requested reports, proactive PMPs also "identify and investigate cases, generating unsolicited reports whenever suspicious behavior is detected."[7] States with proactive PMPs are more inclined to focus on law enforcement than those with reactive PMPs (as contrast, refer to Section 5 of H-95.947 below).[8] These states that allow law enforcement to access PMP data, however, tightly control the dissemination of confidential information. In other words, law enforcement officials cannot engage in fishing expeditions to comb through all PMP data. As an example, Illinois requires law enforcement officials to complete a written request explaining why they need to access PMP data.[9]

AMA policy

The AMA has adapted policy regarding PMPs. The text of the relevant AMA policy follows:

H-95.947 Prescription Drug Monitoring to Prevent Abuse of Controlled Substances

Our AMA:

- Supports the refinement of state-based prescription drug monitoring programs and development and implementation of appropriate technology to allow for Health Insurance Portability and Accountability Act (HIPAA)-compliant sharing of information on prescriptions for controlled substances among states;
- Policy is that the sharing of information on prescriptions for controlled substance with out-of-state entities should be subject to same criteria and penalties for unauthorized use as in-state entities;
- Actively supports the funding of the National All Schedules Prescription Electronic Reporting Act of 2005 which would allow federally funded, interaoperative, state based prescription drug monitoring programs as a tool for addressing patient misuse and diversion of controlled substances;
- Encourages and supports the prompt development of, with appropriate privacy safeguards, treating physician's real time access to their patient's controlled substances prescriptions; and
- Advocates that any information obtained through these programs be used first for education of the specific physicians involved prior to any civil action against these physicians. (BOT Rep. 3, A-08)

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[5] *Id.*
[6] http://www.ojp.gov/BJA/pdf/PDMPExecSumm.pdf
[7] *Id.*
[8] *Id.*
[9] https://www.ilpmp.org/law_request_process.pdf

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AMA recommendations for policymakers

Further, state medical associations involved in establishing PMPs may want to consider the following recommendations:

- **House the program in a health or human services department or in a board of pharmacy;**
  Choosing to house the program in one of these places versus a law enforcement agency will allow it to be used in an educational, rather than punitive, manner. Without fear of repercussions, more dispensers will be encouraged to input and review PMP data.
- **Enable the program to run in real time, and if that is not possible, allow the turnaround time to the information requestor to be no longer than a week;**
  This will allow physicians to access up-to-date information when making prescribing decisions and thus choose the most medically appropriate treatment for their patients. It may also help both physicians and dispensers avoid liability for writing/filling prescriptions based on incomplete PMP data.
- **Allow PMP access to a limited set of individuals; and**
  This will help protect the security of patients' health information. Also, by allowing limited access to law enforcement agencies, the data will be used more for educational purposes.
- **Use the data collected from the PMP in an educational, rather than punitive, manner.**
  This goal can also be achieved through the steps outlined above. Using the data in an educational manner will encourage more accurate reporting of drug dispensing, thereby aiding the ultimate goal of reducing prescription drug abuse.

Current PMP use

As of August 2010, 43 states have enacted legislation to create PMPs. Of those, 34 states are currently operating (i.e. collecting and distributing data to one or more authorized users) PMPs. Washington has suspended its PMP due to insufficient financial resources.[10] For a detailed breakdown by state, refer to the following map, created by NAMSDL.[11]

[10] http://www.namsdl.org/documents/PMPsBriefOverview8-17-2010.pdf
[11] http://www.namsdl.org/documents/PMPProgramStatusJuly2010.pdf

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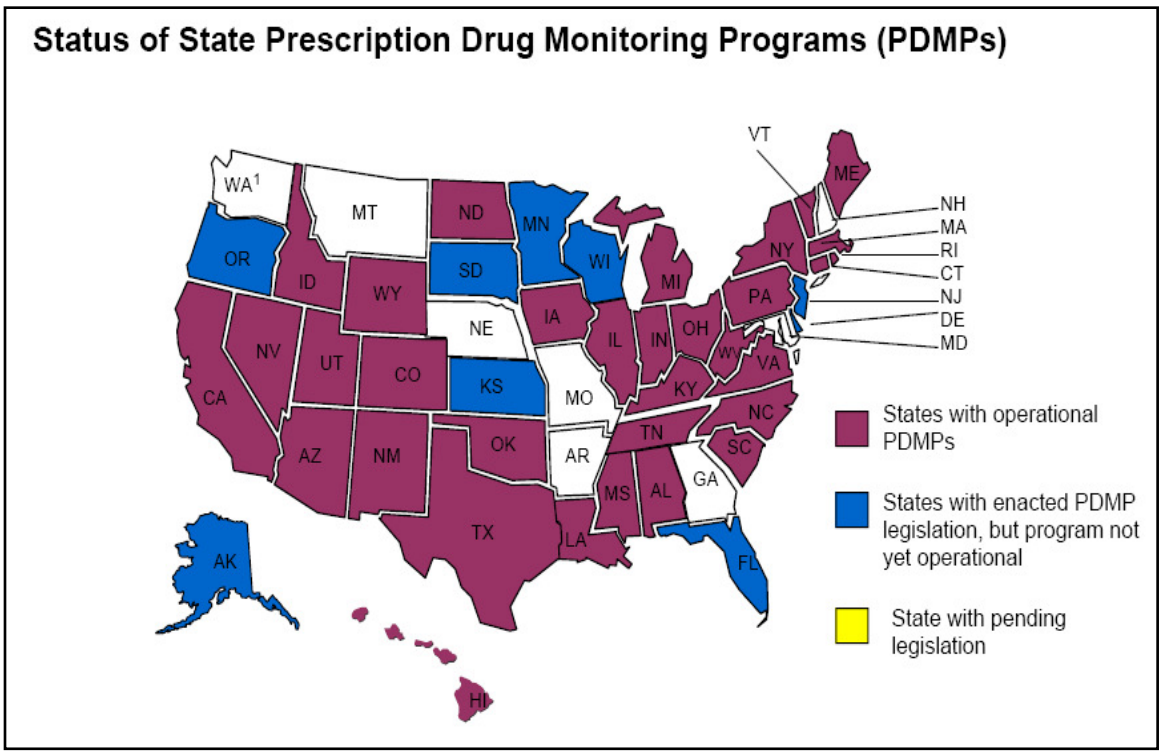


PMP costs and funding

Although implementation costs vary by state, the average start-up cost for a PMP is $300,000 (based on 2004 information). Annual operating costs also differ. In 2002, it cost Utah $150,000 to run its PMP and Nevada $112,000. [12] Kentucky's operating costs were significantly higher at $500,000.[13]

In addition to using state money to develop PMPs, states can also apply for two types of federal funding: the Harold Rogers Prescription Drug Monitoring Program (HRPDMP) and the National All Schedules Prescription Electronic Reporting Act (NASPER). HRPDMP is administered by the Bureau of Justice Assistance (BJA), which is housed in the U.S. Department of Justice's Office of Justice Programs. According to the BJA, "Applicants…[must have] legislation or regulations, either pending or in place, that (1) require the submission of dispensing data to a centralized database and (2) authorize or designate a state agency to implement and administer the program. State governments that want to improve an existing prescription drug monitoring program may apply for an enhancement award. States that want to apply for a planning grant do not need to have

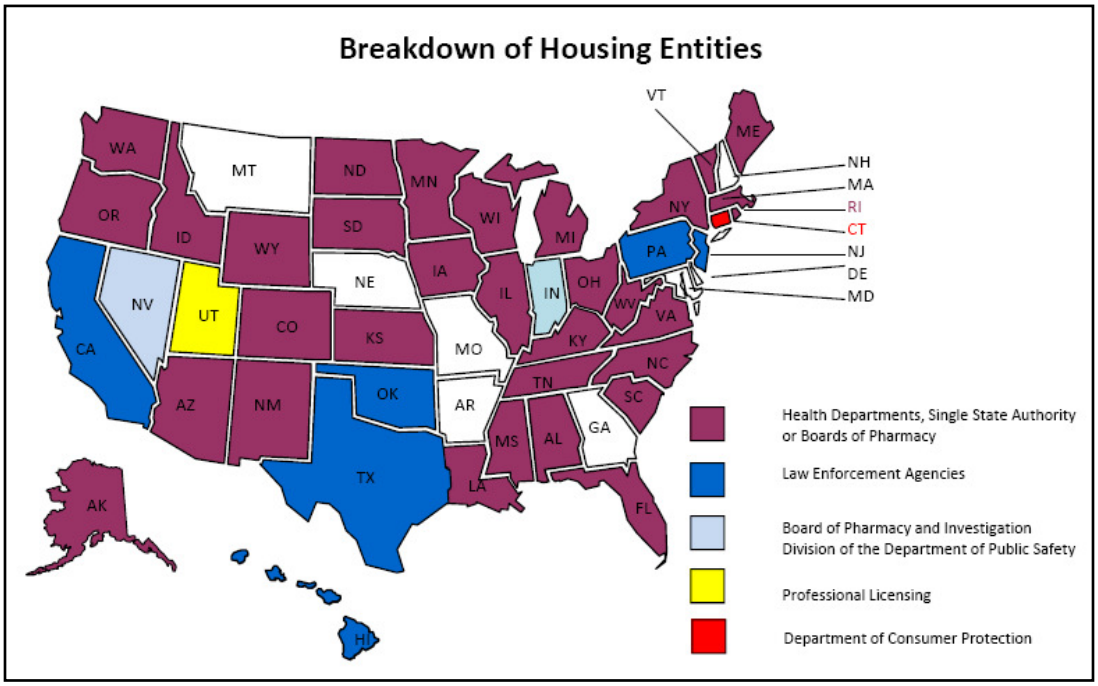
[12] http://www.ncsl.org/default.aspx?tabid=14428

[13] This higher amount may be explained by several facts. First, at the time of data compilation, Kentucky's population was twice that of Nevada and Utah. It also had about 1,000 more pharmacies. Finally, Kentucky received 400 daily requests for PMP information (versus 20 in Nevada and 130 – 150 in Utah) and employed more staff. (http://www.ncsl.org/default.aspx?tabid=14428)

legislation or a regulation in place or pending."[14] HRPDMP has awarded over 100 grants, totaling $48 million in funds, since its creation in 2002. For fiscal year 2010, the program has a $7 million budget. NASPER, developed in 2009, is administered by the U.S. Department of Health and Human Services. States that wish to create new PMPs or enhance their existing PMPs are eligible to apply for this federal grant. In 2009, NASPER awarded $2 million in grant money. It has a 2010 appropriation of $2 million.[15]

PMP logistics

PMP programs may be housed in (1) a health or human services department, single state authority on drugs and alcohol, or board of pharmacy, (2) a law enforcement agency, (3) a professional licensing agency, or (4) a consumer protection agency. Of the 43 existing PMPs, 33 are in health departments, single state authorities, or boards of pharmacy; six are in law enforcement agencies; two are in professional licensing agencies; one is in a board of pharmacy; and one is in a consumer protection agency.[16] For a detailed breakdown by state, refer to the map below, created by NAMSDL.[17]



PMPs also vary in the substances they monitor. One state monitors only Schedule II substances, two states monitor Schedule II and III substances, and 40 states monitor Schedule II – IV substances. Additionally, 23 states monitor Schedule V substances and 12 monitor noncontrolled/nonscheduled

[14] http://www.ojp.usdoj.gov/BJA/grant/prescripdrugs.html
[15] http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm
[16] http://www.namsdl.org/documents/PMPsBriefOverview8-17-2010.pdf
[17] http://www.namsdl.org/documents/BreakdownofHousingEntitiesRev.pdf

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substances as defined by state laws and regulations. Refer to the chart below for a breakdown by state. [18] For more information on the distinctions among schedule categories and examples of drugs that fall in each category, visit the DEA website.

Monitored substances by state

	Schedule II	Schedule III	Schedule IV	Schedule V	Noncontrolled
Alabama	Yes	Yes	Yes	Yes	
Alaska	Yes	Yes	Yes	Yes	
Arizona	Yes	Yes	Yes		
Arkansas					
California	Yes	Yes	Yes		
Colorado	Yes	Yes	Yes	Yes	
Connecticut	Yes	Yes	Yes	Yes	
Delaware	Yes	Yes	Yes	Yes	Yes
Florida	Yes	Yes	Yes		
Georgia					
Hawaii	Yes	Yes	Yes	Yes	
Idaho	Yes	Yes	Yes		Yes
Illinois	Yes	Yes	Yes	Yes	
Indiana	Yes	Yes	Yes	Yes	
Iowa	Yes	Yes	Yes		
Kansas	Yes	Yes	Yes		Yes
Kentucky	Yes	Yes	Yes	Yes	
Louisiana	Yes	Yes	Yes	Yes	Yes
Maine	Yes	Yes	Yes		
Maryland					
Massachusetts	Yes	Yes	Yes	Yes	Yes
Michigan	Yes	Yes	Yes	Yes	
Minnesota	Yes	Yes	Yes		
Mississippi	Yes	Yes	Yes	Yes	Yes
Missouri					
Montana					
Nebraska					
Nevada	Yes	Yes	Yes		
New Hampshire					
New Jersey	Yes	Yes	Yes	Yes	Yes
New Mexico	Yes	Yes	Yes		
New York	Yes	Yes	Yes	Yes	
North Carolina	Yes	Yes	Yes	Yes	
North Dakota	Yes	Yes	Yes	Yes	Yes
Ohio	Yes	Yes	Yes	Yes	Yes
Oklahoma	Yes	Yes	Yes	Yes	
Oregon	Yes	Yes	Yes		
Pennsylvania	Yes				
Rhode Island	Yes	Yes			
South Carolina	Yes	Yes	Yes		
South Dakota	Yes	Yes	Yes		

[18] http://www.namsdl.org/documents/PMPsBriefOverview8-17-2010.pdf

Tennessee	Yes	Yes	Yes	Yes	
Texas	Yes	Yes	Yes	Yes	
Utah	Yes	Yes	Yes	Yes	
Vermont	Yes	Yes	Yes		
Virginia	Yes	Yes	Yes		
Washington	Yes	Yes	Yes	Yes	Yes
West Virginia	Yes	Yes	Yes		
Wisconsin	Yes	Yes			Yes
Wyoming	Yes	Yes	Yes		Yes
Total States	43	42	40	23	12

Depending on the state, pharmacies and/or physicians that sell controlled (and noncontrolled in some states) substances will report dispensing of Schedule II, III, IV, and/or V drugs to the state PMP. In Illinois, for instance, retail pharmacies are required to report their sales.[19] Virginia's requirements are more detailed: "Pharmacies, non-resident pharmacies, permitted physicians, and physicians holding a permit to sell controlled substances are required to report all dispensing of any Schedule II, III, and IV controlled substances to the PMP. There is a limited list of reporting exemptions such as dispensing of manufacturers' samples."[20]

Several groups of individuals may access PMP data. These include:

- Licensed physicians/practitioners with the authority to prescribe substances;
- Pharmacists with the authority to dispense substances;
- Designated federal, state, and local law enforcement;
- Representatives of professional or occupational licensing, certification, or regulatory boards, commissions, or agencies; and/or
- Individuals whose receipt of prescriptions has been included in the PMP database.[21]

People who may access PMP data under the last category may include state-authorized outside vendors that analyze PMP data and advisory groups that consult with the entity housing the PMP. Eighteen states actually mandate participation of advisory groups and/or task forces in the creation of a PMP, and several others require PMP officials to consult with professionals or other agencies (but do not require the formation of a committee or council for this process).[22]

Although licensed prescribers are encouraged to access PMP data, under the laws of 19 states they have no duty to access the information. Nevada and Delaware, in contrast, mandate that prescribers access PMP data in certain circumstances to determine whether a prescription is medically necessary.[23]

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[19] https://www.ilpmp.org/QandA.php
[20] http://www.dhp.state.va.us/dhp_programs/pmp/pmp_desc.asp#required
[21] http://www.namsdl.org/documents/PMPsBriefOverview8-17-2010.pdf
[22] *Id.*
[23] *Id.*

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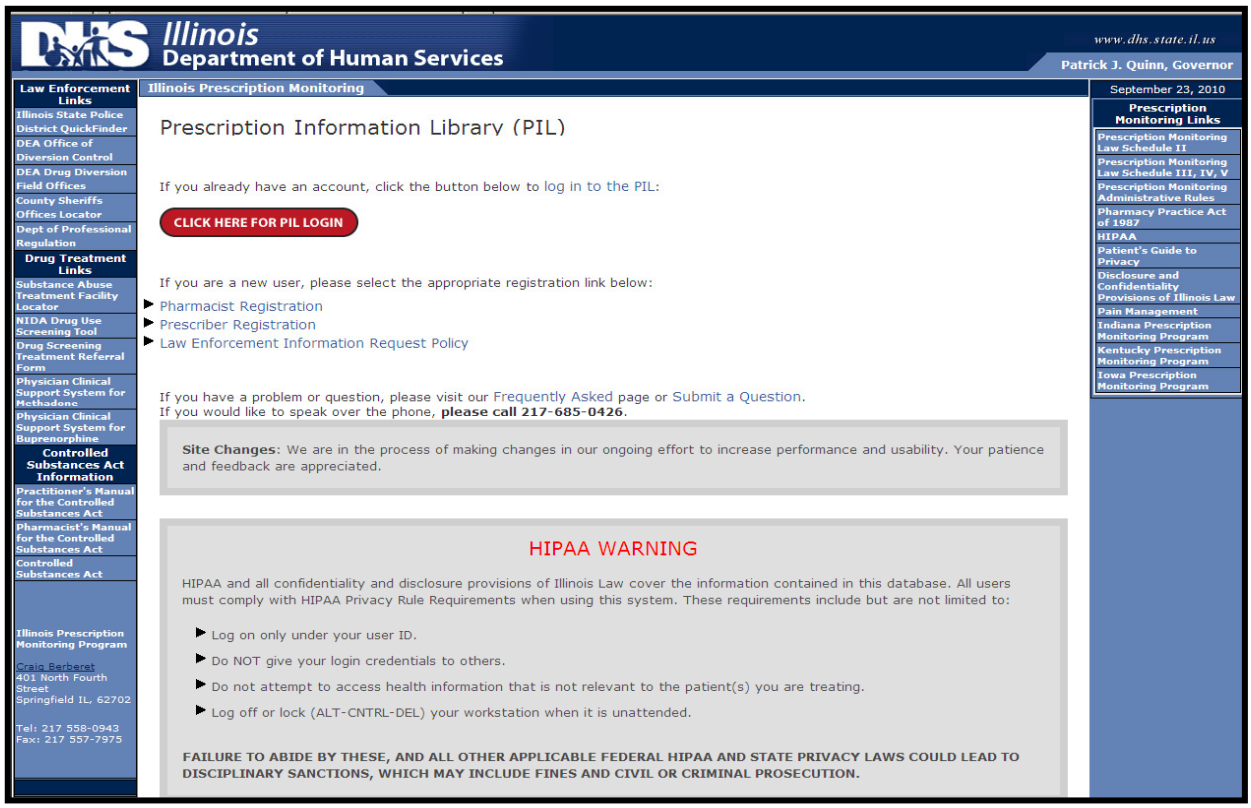
In order to protect PMP data, states may institute safeguards. Common options include:

- Exempting PMP data from public records or open record laws;
- Classifying PMP data as confidential or protected health information;
- Carefully specifying who has access to the PMP;
- Carefully specifying the criteria for access to and use of the PMP data;
- Requiring the entity housing the PMP to comply with relevant state and federal privacy and confidentiality laws, and perhaps develop its own procedures to protect the information; and
- Penalizing the unlawful access and/or disclosure of PMP data.[24]

PMP portal example



Barriers to PMP implementation/use

Financing is a fundamental barrier to both the creation and utilization of a PMP. Because a state may not have enough funding in its own coffers to develop a PMP, it may turn to the federal grant opportunities. To review more information about the Harold Rogers Prescription Drug Monitoring Program federal grant, visit the BJA website. To review more

[24] *Id.*

information about the National All Schedules Prescription Electronic Reporting Act federal grant, visit *www.grants.gov*. Last year's application is available online as well. Even if a state receives grant funds to develop a program, it may not have sufficient funds to operate the program. This is what happened in Washington state; although they have a PMP, with the state's tight budget, the program has been suspended.

Other common concerns with PMP use include privacy and liability. Regarding privacy, patients have expressed fears that their prescription records may be viewed by people who are not health care providers. Since the PMP is online, there must also be sufficient safeguards in place to prevent unauthorized access (e.g. by hacking into) to the database. In a report compiled by the Association of State and Territorial Health Officials (ASTHO) for the CDC, state and territorial health officials in nine states commented that "stringent privacy protections are implemented at [their] state health associations" and the "state health associations have the appropriate education, policy, and technical infrastructure to be responsible data stewards."[25]

Regarding liability, in most states, health care providers have no duty to access PMP data. Still, the ASTHO report found "health care providers are concerned that their medical decisions will be second-guessed by law enforcement or by malpractice attorneys."[26] To avoid such liability, doctors may cut back on prescribing opioid painkillers, thereby under-treating their patients' pain. Also, because PMPs do not typically have real time reporting, it is possible that a patient may doctor-shop and have several prescriptions filled before the information appears in the PMP. Consequently, there is a fear that a dispenser may be liable for filling a prescription even if he or she did so before being able to access the PMP data and realize that the patient had a potential drug abuse problem.

Finally, the ASTHO report noted the challenge of convincing pharmacists that the burden of reporting controlled drug prescription data "was small and justified" considering the importance of preventing prescription drug abuse.[27]

Conclusion

The AMA favors the development of appropriate state-based prescription drug monitoring programs. Currently, the majority of states do have functioning PMPs. The next step, which is already being tested through pilot programs, is establishing a system for prescribers to share information across states. In both their present design and any future iterations, for maximum efficacy PMPs must (1) keep their data secure and (2) limit the number of individuals who have access. With their continued use and improvement, PMPs will ideally help prevent prescription drug abuse without impeding upon health care practitioners' ability to prescribe controlled substances for legitimate medical purposes.

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[25] Association of State and Territorial Health Officials. "Prescription Drug Overdose – State Agencies Respond." *Centers for Disease Control and Prevention* (2008).
[26] *Id.*
[27] *Id.*