

Prescription Drug Abuse and Diversion: The Role of Prescription Drug Monitoring Programs

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Sherry Green

National Alliance for Model State Drug Laws, Alexandria, VA

Executive Director

Testimony

Chairman Gregg, Senator Sessions, members of the Committee, and staff, thank you for this opportunity to appear before you today to offer an overview of state prescription drug monitoring programs (PMPs). I am honored to be here to discuss this issue at a time when federal support for these programs and states' efforts to establish and enhance them has never been stronger.

Definition and Intent of Prescription Drug Monitoring Programs (PMP)

For those unfamiliar with prescription monitoring programs, I offer the following definition. A prescription monitoring program (PMP) is system into which prescription data for designated schedules of controlled substances are reported dispensers to a central location (e.g. a state agency) where the information is entered into an electronic database. A PMP can perform three primary functions: 1) data collection, 2) respond to requests for reports by those authorized by statute/regulation/rule to make such requests, and 3) optimally, data would be analyzed to spot trends and identify diversion and addiction issues early with reports going proactively to those who could respond (e.g. physicians, pharmacists, occupational licensing, certification and regulatory personnel, law enforcement).

State PMPs can optimally accomplish a variety of goals related to safeguarding public health and safety. These purposes could include: to support the legitimate medical use of controlled substances; to facilitate and encourage the identification, intervention with and treatment of individuals addicted to prescription drugs; to identify and prevent drug diversion; to provide assistance to those investigating cases of diversion or other misuse; and to inform the public, including health care professionals and policy makers, of use and abuse trends related to prescription drugs (for more information regarding the possible missions of state prescription monitoring programs, please see Prescription Monitoring Work Group of the National Alliance for Model State Drug Laws: Recommendations for State Prescription Monitoring Programs, submitted with this testimony).

The data collected in the monitoring system is not "new" information – in other words, information that was previously unavailable to those investigating diversion cases. With or without a PMP in place, prescription information is accessible to regulatory and/or law enforcement personnel with open cases involving suspected diversion of prescription drugs. What the PMP does by serving as a central point of collecting this data and

responding to authorized requests is to save the already limited resources of state regulatory boards and law enforcement by eliminating the need for their staff to go to individual pharmacies throughout the state in order to view the specific prescription data needed for diversion investigations.

NAMSDL's History Assisting States re: PMPs

As a Congressionally-funded 501(c)(3) nonprofit organization, the National Alliance for Model State Drug Laws (NAMSDL) has worked with states to address alcohol and other drug problems through laws, policies, and programs, using the model laws created by NAMSDL's predecessor – the President's Commission on Model State Drug Laws – as a menu of options. Prescription drug misuse, abuse, diversion, and addiction have been among the issues on which states have sought NAMSDL's assistance since our inception in 1993, including information and guidance in planning, establishing, and enhancing state PMPs. NAMSDL's Congressional funding through the Transportation, Treasury, and General Government (formerly Treasury, Postal, and General Government) appropriations has permitted us to work with states on these issues, as well as over 70 other alcohol and other drug-related problems. Through a grant from the Bureau Justice Assistance (BJA), Office of Justice Programs, awarded in fiscal year 2003 (supplemented in fiscal year 2004), NAMSDL has been able to intensify efforts to assist states' efforts to establish PMPs and to provide opportunities and instruments for planning for the interstate sharing of PMP data. Additionally, NAMSDL is now able to make outreach to states which have not historically pursued the possibility of a PMP as a tool for addressing the misuse of, abuse of, diversion of, and addiction to prescription drugs and for safeguarding the availability of these controlled substances to individuals with bona fide medical needs.

PMPs in the States

States Currently Operating Programs

As I testify before you today, nineteen states are currently operating PMPs (i.e., these states have monitoring system is in place that is both collecting reports of the designated prescription data and responding to requests for information from those authorized to do so). These states are:

- California
- Hawaii
- Idaho
- Illinois
- Indiana
- Kentucky
- Maine
- Massachusetts
- Michigan

- Nevada
- New York
- Oklahoma
- Pennsylvania
- Rhode Island
- Texas
- Utah
- Virginia
- Washington
- West Virginia

A variety of state agencies house and operate these programs in the states, based on the resources, capabilities, purview, and other state-specific considerations as to where the PMP would be best suited in each state (for more discussion of factors states consider in determining which agency should house and operate a PMP, please see the report of NAMSDL's national working group on state PMPs, submitted with this testimony). Of the 19 state PMPs currently in place, nine are housed and operated by state agencies responsible for public health, five by law enforcement/public safety departments, four by Boards of Pharmacy, and one – Maine – by the single state authority for substance abuse (a listing of the 19 current state PMPs and their overseeing agencies is provided with this testimony).

Projected Growth of State PMPs

In an effort to better address prescription drug misuse, abuse, diversion, and addiction, a significant number of states are mobilizing to establish PMPs. Wyoming and New Mexico are currently on track to being operating state PMPs by the end of calendar year 2004. With legislation in place, Alabama and Tennessee could be operating PMPs by early 2005. Iowa and Mississippi have determined that they can, per their Controlled Substances Act, establish PMPs through rule changes by their Boards of Pharmacy; these changes are currently being pursued to ready these states to being operating monitoring systems. Additionally, the following 18 states are actively pursuing legislation/regulations/rules and/or planning the structure necessary to begin these programs: Colorado, Connecticut, Florida, Georgia, Kansas, Louisiana, New Jersey, Ohio, Oregon, Missouri, Montana, New Hampshire, North Carolina, North Dakota, South Carolina, South Dakota, Vermont, and Wisconsin. NAMSDL continues to reach out with information and offers of technical assistance to the states that have not taken steps toward establishing PMPs or that are in the very nascent stages of planning.

Funding for State PMPs

Prior to fiscal year 2002, there were 15 states operating PMPs. States funded these programs as part of state agency budgets, fees from regulatory and/or licensing boards, private funding, or some combination of these funding streams. In fiscal year 2002, the

Harold Rogers Prescription Drug Monitoring Program, a competitive grant program administered since fiscal year 2002 by the Bureau of Justice Assistance, Office of Justice Programs, was established to support state efforts to plan for, establish, and enhance PMPs. Since its inception, this funding opportunity has resulted in 14 states receiving new program grants and 6 states netting planning grants (a listing of states receiving these grants is provided with this testimony). To date, eight states have asked NAMSDDL staff about the possibility and timing of fiscal year 2005 federal funding to assist in moving their efforts to establish programs forward. As we continue our outreach to states to engage them in planning efforts, this interest in federal assistance is likely to rise.

Understanding that current federal assistance is not intended to be used as operating or sustaining funding, states with planning and new program grants as well as those intending to apply for any fiscal year 2005 opportunities continue to develop options for funding the operations of state PMPs overtime. Private funding, pharmacy licensing fees, state appropriations, and state controlled substances registration fees are alternatives being considered by states for the continuing operation of new programs. Individuals working closely with existing PMPs and efforts to establish new monitoring systems are confident that evaluation of these programs will show cost benefits such as reducing Medicaid and healthcare fraud, diversion investigation time, and consequences related to untreated addiction to prescription drugs; these savings could result in an offset of funds being available to operate state PMPs and the continuation of these anticipated savings.

Components of a Strong Prescription Monitoring Program

I want to share NAMSDDL's observations of what appear to be key components of PMPs and their related enabling legislation and/or regulations/rules. While further formal evaluation of existing state PMPs across the nation is needed, I hope that our anecdotal findings will be helpful in understanding the types of considerations that states may undertake in setting up these programs.

Schedules of Drugs Monitored

Drugs monitored optimally would include federal controlled substances, additional specified controlled substances regulated by the state, and drugs of concern documented to demonstrate a potential for abuse, particularly those identified by law enforcement and addiction treatment professionals. While not officially scheduled, some substances can still be highly abused and require immediate attention. In a state which requires a legislative action to schedule substances, the prescription drug monitoring official will need the authority through the monitoring system to immediately address the problem. If the monitoring program only tracks controlled substances, the officials will have to wait perhaps six months or more for the legislature to pass a bill placing the abused substance on a controlled substances schedule.

Proactive Provision of Information

The monitoring system should proactively provide information to law enforcement, occupational licensing and other appropriate individuals. The prescription drug monitoring official should review the information in the system and if there is reasonable cause to believe there has been a violation of law or a breach of occupational standards, the official should notify the appropriate agency.

Additionally, the statute should allow the program to provide information for public research, policy and education purposes to the extent all information reasonably likely to reveal the patient or other person who is the subject of the information has been removed.

Individuals Allowed to Request Information from State PMPs

Dispensers and prescribers, law enforcement officials and occupational licensing officials should be included among the individuals or officials allowed to request specific information from the program.

Training for Individuals Utilizing State PMPs

Requestors of program information must demonstrate that they have the training necessary to responsibly and properly use the information they receive from the program. All requestors should be required to prove that they have received training on the purpose and operation of the program, and how to properly use the program. Additionally, health professionals should be required to receive training on proper prescribing practices, pharmacology and identification, treatment and referral of patients addicted to or abusing substances monitored by the program. This training can help physicians better assess whether the marketing and sales information they are given about a prescription drug's effects appears to be accurate.

Evaluation of State PMPs

An evaluation component is necessary to identify cost benefits of the program and any recommended improvements. As part of the ongoing assessment process, an advisory board or council should provide advice and input regarding the development and operation of the prescription drug monitoring system. The board or council should address issues such as (1) what drugs of concern to be monitored, (2) what specific state controlled substances to be monitored, (3) what constitutes diversion and proper prescribing, (4) the content and implementation of educational courses, (5) the interpretation of prescription monitoring information.

Confidentiality Provisions for PMP Data

Confidentiality protections from improper use of the system or of information from the system are important statutory provisions. Prescription monitoring information should not be subject to public or open records laws. Additionally, the law creating the prescription drug monitoring program should include penalties for knowingly disclosing or using information other than as authorized by the law.

Addressing Interstate Issues

Interstate misuse and abuse of prescription drugs is an issue each state with a prescription drug monitoring program should attempt to address. By statute, regulation or interstate agreement, the state should speak to the following circumstances:

- pharmacies or other dispensers located in the state with a prescription drug monitoring program which dispense or deliver to an address of an ultimate user in another state;
- pharmacies or other dispensers located in another state which dispense or deliver to an address of an ultimate user in the state with a prescription drug monitoring program;
- pharmacies or other dispensers located in another state which dispense or deliver to an ultimate user with an official address in the state with a prescription drug monitoring program.

Progress on Interstate Issues

An acknowledged challenge for states is addressing the diversion that can occur from state to state. In enhancing existing PMPs and in establishing new programs, states are working to include provisions for information sharing among states with monitoring systems in order to reduce interstate diversion. Here are several examples of current efforts:

Provisions for Mail Order Pharmacies

In a survey conducted by NAMSDL of existing state PMPs, 12 of the 19 existing PMPs indicated that they require out-of-state mail order pharmacies delivering or dispensing drugs into their states to report data to their states' PMPs (HI, ID, IL, IN, KY, ME, MI, NY, OK, RI, UT, WV). The reporting requirement is based on the license or registration which the mail order pharmacies must obtain to conduct business or dispense in their states. These measures can help reduce the incidents of "doctor shopping" across state lines in an effort to avoid detection by the monitoring system. A summary of NAMSDL's survey re: how state PMPs are addressing mail order pharmacies is submitted with this testimony.

Western States Network

Initiated by Nevada, the Western States Network is a plan to share PMP data among the states with PMPs in the Western U.S. (currently Nevada, Idaho, California, Oklahoma, and Texas) and Hawaii through a secure e-mail exchange. Nevada is currently "beta" testing the online technology required before working with the other states in the region to establish legal agreements and then technology structures to begin the proposed data exchange.

Common Data Elements to be Collected by State PMPs

To facilitate interstate sharing of PMP data, common data elements must be collected by each state with a monitoring system. This will allow for consistency in reporting as well as, from a technological standpoint, a cleaner transfer of data. The National Association of State Controlled Substances Authorities (NASCSA) and the Alliance of States with Prescription Monitoring Programs, based in part on a 2003 NASCSA survey of data that was being collected by state PMPs, convened a Prescription Monitoring Standards Working Group that recommended that states with and developing prescription monitoring systems include the following set of data elements:

- Dispenser identification number
- Date prescription filled
- Prescription number
- Whether the prescription is new or a refill
- NDC code for Controlled Substance dispensed
- Quantity of Controlled Substance dispensed
- Number of days' supply of the Controlled Substance
- Patient identification number
- Patient last name
- Patient first name
- Patient street address
- Patient city
- Patient state
- Patient postal code
- Patient date of birth
- Prescriber identification number
- Date prescription issued by practitioner
- Person who receives the prescription from the dispenser, if other than the patient
- Source of payment for prescription
- State issued serial number, if applicable.

NAMSDL has widely distributed these recommendations to states working to establish monitoring systems in an effort to encourage consistency among programs that will better facilitate interstate sharing. Additionally, NAMSDL includes members from NASCSA and Alliance of States members in our regional planning, topical working groups, and national meetings to keep all involved informed re: efforts in this area.

Legal Agreements among States

In addition to establishing accommodating technology structures among states, legal agreements must be in place to allow the exchange of PMP data across state lines and among the entities housing the PMP and the entities requesting the information. Legal counsel working with NAMSDL on these issues suggests that these arrangements may resemble interstate commerce compacts that states currently utilize. NAMSDL has convened a national working group comprised of state administrators of PMPs, representatives from state attorneys general's offices, public health officials, addiction

treatment professionals, law enforcement officials, and physicians (including a pain management specialist) to offer their expertise and recommendations toward our drafting a model interstate compact. This model will offer a guide for states to use in establishing these legal agreements for sharing PMP data.

Internet Pharmacies

To date, three states (Arkansas, Nevada, and Florida) have state statutes in place addressing Internet pharmacies. Only one of these states – Nevada – currently has a PMP; NV's Internet pharmacy law requires Internet pharmacies to report to the state's PMP for controlled substances delivered into the state.

Most state PMP administrators agree that as important as it is to have legitimate Internet pharmacies report into state PMPs, the legal sites are not the primary issue. Illegal Internet sites that acquire and deliver controlled substances to individuals without prescriptions for these prescription drugs are of greater concern. Federal assistance on this issue, such as that proposed by Senator Gregg, will be appreciated by states to alleviate the misuse, abuse, diversion, and addiction to which these illegal sites contribute.

Technical Assistance Provided to States by NAMSDL re: PMPs

NAMSDL provides a variety of technical assistance to states as they plan for, establish, operate, and enhance prescription monitoring programs. In broad terms, the overarching goals of our services to states are 1) to engage states in efforts to establish PMPs, 2) to provide information, tools (e.g. model law, samples of grant applications, etc.), and referrals to minimize the state resources needed to begin efforts to implement monitoring systems, and 3) to maximize the federal and state resources going toward state efforts by coordinating information and state-to-state assistance to eliminate inadvertent "reinvention of the wheel" as states implement, operate, or enhance these programs.

Specific services include:

- Assistance in drafting enabling legislation
- Facilitating regional planning session to further interstate planning
- Providing information on current PMPs efforts to states planning to establish programs
- Contacting states which have not yet mobilized to create PMPs and providing them start-up information
- Bill status updates on states' legislative efforts
- Serving as a central point for articles, materials, and updates re: state PMPs
- Bimonthly updates re: state efforts, materials available, related Congressional news, and other relevant information
- Connecting key constituencies groups within and among the states to work on establishing PMPs
- Holding an annual conference on PMPs
- Convening topical working groups to develop model acts, reports, or other resources as needed by states to address issues related to PMPs

While our current grant from BJA has allowed us to intensify our technical assistance to states, NAMSDL has worked with states re: PMPs and the related issues since our inception. If prescription drug diversion, misuse, abuse, and addiction continue to be priority areas for states, NAMSDL – as it has historically – will continue to include these issues in our work with states beyond the life of any grant or grant program.

Opportunities for Congressional, Federal Support

I want to conclude by briefly outlining some possible opportunities for Congress and/or the Federal Government to support states in their efforts to create, sustain, and enhance prescription monitoring programs. These suggestions come from feedback that NAMSDL has received from our state colleagues as we work with them on these programs.

Funding

Given the record budget deficits in many states at this time, it is unlikely that states will be able to establish new monitoring systems without the assistance of outside funding. Over the past few years, several state legislatures have actually passed the enabling legislation for state PMPs with fiscal notes attached, indicating that they recognized the need for and usefulness of these programs but cannot fund them through state budgets. The timing of the fiscal year 2004 grant solicitation and state pre-filing deadlines coincided, allowing a significant increase in the number of eligible states to apply and receive awards. Congressional support for similar grant opportunities will continue to facilitate the growth of these programs.

Internet Pharmacies

As I have previously mentioned in this testimony, states are concerned about the diversion of prescription drugs via illegal Internet sites. Federal assistance – specifically federal-state partnerships – will be needed to effectively address this concern.

Federal Entities not Reporting to State PMPs

In NAMSDL's work with states, they have alerted us to the dispensers of prescription drugs that are under federal jurisdiction and thus not required to report to state PMPs: Veterans' Administration hospitals and medical facilities, facilities on military bases, and tribal nations. While these entities are housed in states, they are not required to report designated prescription data to state PMPs. States have indicated that it would be helpful toward further curbing diversion and intervening early with people who may need appropriate addiction treatment to have dispensers from these entities to report data to these programs.

Evaluation

Earlier in my remarks, I mentioned that there has not yet been a formal, science-based

national evaluation of state PMPs. My understanding is that an evaluation design is being developed in conjunction with the BJA grant program. As more states consider establishing programs and the existing 19 states plan for sustaining their current monitoring systems, objective, concrete results from this national evaluation re: the effectiveness of PMPs will greatly help states justify the expenditure for these programs. Currently, states must focus on the need for reducing prescription diversion and addiction as well as anecdotal findings/experiences from other states' monitoring systems when working with decision makers to establish or sustain state PMPs. With federal resources also facilitating the start-up and enhancement of PMPs, this national evaluation will be instructive as to the best uses of these funds in the future (e.g. continued enhancements? technology project related to the PMPs? support to corollary systems such as addiction treatment?).

Thank you once again for the opportunity to share this information with you. I would be happy to answer any questions that you have as the hearing proceeds.