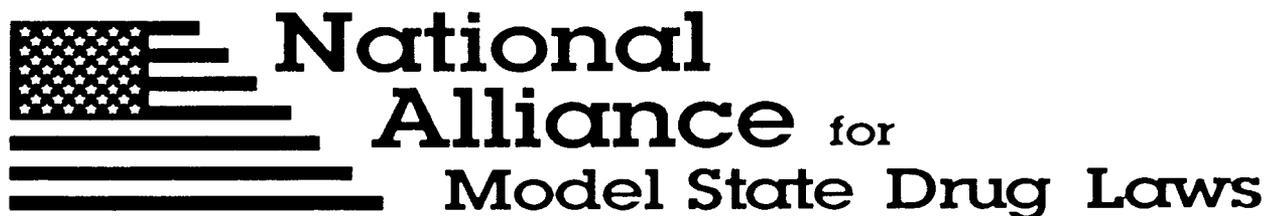


Recommendations for Prescription Monitoring Programs

Prescription Monitoring Work Group
of the
National Alliance for Model State Drug Laws

February 2002



**PRESCRIPTION MONITORING WORK GROUP
OF THE
NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS**

RECOMMENDATIONS FOR PRESCRIPTION MONITORING PROGRAMS

INTRODUCTION

The National Alliance for Model State Drug Laws (the Alliance) offers this report and its accompanying materials to assist states in their efforts to curb the diversion of, abuse of, and addiction to prescription drugs. This document presents the Alliance's Prescription Monitoring Work Group's recommendations regarding key elements for a prescription monitoring program (PMP) and considerations for its design, implementation, and use. A survey of existing state PMP statutes and policies accompanies this report to further guide states' efforts in this important arena (please see Appendix H).

**BACKGROUND OF THE
PRESCRIPTION MONITORING WORK GROUP**

The Virginia Attorney General's Office asked the Alliance to establish a national work group to identify key elements of a model prescription monitoring program (PMP), and to flesh out the numerous issues and perspectives regarding prescription drug monitoring. State legislators, federal agencies, governors, many Attorneys General, and other elected officials at the national, state and local levels are also looking toward this Work Group's recommendations in addressing prescription drug diversion, abuse and addiction.

The Alliance convened and facilitated a work group on October 30-31, 2001 at the Hyatt Regency on Capitol Hill in Washington, D. C. Work Group members represented a variety of professionals involved in this issue, including pain management doctors, addiction treatment professionals, pharmacy board executives, pharmaceutical industry representatives, health professionals, prosecutors, law enforcement officials, state PMP officials, a medical examiner and past consumers of addiction treatment services (see Appendix A for a list of participants).

The group's objectives were (1) to identify key elements of a model prescription monitoring program and (2) to outline considerations for the design, implementation and use of a state PMP.

(For background information about prescription monitoring programs, please see Appendix I for additional resources)

THE WORK GROUP'S PROCESS

Deborah Beck, President of the Drug and Alcohol Providers Organization of Pennsylvania and Sherry Green, Executive Director of the Alliance, facilitated the Work Group meetings. The meetings included two facilitated "brainstorming" sessions, multidisciplinary small group work, and small group presentations. Guidelines for participants included active involvement by everyone, the right of anyone to decline his/her turn to speak, no interruptions of other members as they spoke, and no cross-talking among members during "brainstorming" sessions or small group presentations. These varied sessions and the stringent facilitation were to insure that all participants' perspectives were voiced and heard during the process (please see Appendix C for the meetings' agenda).

Because of the high level of national interest in issues related to prescription drugs, the Alliance invited a select group of special observers to witness and learn from the proceedings. These individuals represented national organizations and associations, federal agencies, advocacy groups, and elected officials at the local, state, and national levels (please see Appendix B for a list of special observers in attendance). While special observers were allowed to interact with Work Group participants during breaks and meals, these guests were not permitted to interject during the group's proceedings.

RECOMMENDATIONS OF THE PRESCRIPTION MONITORING WORK GROUP

MISSION OF A PRESCRIPTION MONITORING PROGRAM

The participants, regardless of background, agreed that PMPs could be effective tools for addressing diversion and abuse of prescription drugs. They quickly focused on the need for a clear mission statement and description of the problem to which the PMP would respond.

The missions listed and widely supported as appropriate for a PMP are as varied as the participants themselves: (1) identify and deter or prevent drug abuse and diversion; (2) provide investigative assistance; (3) support access to legitimate medical use of controlled substances; (4) provide timely information to registrants or other appropriate users of the PMP; (5) facilitate and encourage the identification, intervention with and treatment of persons addicted to prescription drugs; (6) inform public health initiatives, for example, through outlining of use and abuse trends; and (7) educate individuals about PMPs and the use, abuse and diversion of and addiction to prescription drugs. Individuals whom the participants sought to educate include prescribers and other health care professionals, dispensers, patients, prosecutors, law enforcement, patients, state and local policymakers, and the general public.

Participants indicated that an optimal PMP would be proactive and able to accomplish all or most of the missions listed above. However, several people noted that states must decide a PMP's mission in light of a state's particular circumstances. Funding sources available for a PMP, the scope of a state's diversion and abuse problem, and political considerations were all factors participants cited as shaping the structure and operation of a PMP.

CUSTOMIZING A PMP TO A STATE'S INDIVIDUAL NEEDS

The participants sought to balance the desire for guidance offered by a model program with a state's need to do its own problem and resource assessment before undertaking a PMP. They proposed identifying and using the best practices or lessons learned from existing PMPs as a foundation for any program. With this information available, states could then tailor the details of a PMP's development and operation to the needs and requirements of their jurisdictions. The Work Group also conveyed a strong need to honor what was currently in place in states, such as prevention efforts, statutes, enforcement efforts, regulations, and trainings, that could both be enhanced by and support PMPs.

NON-INTRUSIVENESS OF A PMP

Work Group participants believed that the PMP should be non-intrusive in its operation, creating no hardship on patients, prescribers and dispensers (e.g. physicians, pharmacists). The system should be "user friendly" in design, with a mission and operational details that system users could easily understand and implement.

WHICH CONTROLLED SUBSTANCES TO MONITOR

The participants favored being inclusive, rather than limited, with regard to which controlled substances to monitor in a model system. More comprehensive PMPs would allow state officials to respond more quickly to new and future abuse and diversion trends, and to better protect public health and safety. Some participants suggested that monitoring an inclusive list of drugs would also avoid stigmatizing or "chilling" the prescribing of drugs perceived to be targeted through the PMP. However, other Work Group members disputed whether monitoring a controlled substance produces any long-term "chilling" effect on prescribing.

Work Group participants proposed three tiers of program options as to which drugs to monitor. Option 1 would be to monitor the federally scheduled controlled substances (II- IV). Because these drugs are defined for all states, participants believed that this could be the minimal list monitored by a state PMP. Option 2 would include federal schedules and the state's additional scheduled substances (referred to as legend drugs in some states). This would expand the range of monitored drugs and allow for state specificity. Option 3, considered by many participants to be the optimal design, would be to monitor federal schedules, state schedules, and other "drugs of concern" as identified by the state. Participants suggested that "drugs of concern" could be designated

based on input received from law enforcement and treatment providers about substances that have come to their attention due to increased diversion, misuse, and addiction within a state.

The Work Group recognized that available resources might limit states' abilities to monitor the most inclusive range of drugs. Several participants noted that some existing PMPs have evolved to be more inclusive in their monitoring. Therefore, the need to limit the list of drugs monitored should not be seen as a reason to stop a proposed PMP, but rather as a step forward in that the use of some controlled substances would be monitored. Participants did stress the need for creating a mechanism by which to add drugs to the PMP as the system evolves (e.g. advisory committee, designated officials, administrative process, etc.).

METHOD OF MONITORING

Participants preferred electronic monitoring for its efficiency. Individuals stated that an electronic system reduces paperwork, minimizes duplication and facilitates the sharing of information across state lines. One of the small work groups recommended that the American Society for Automation in Pharmacy (ASAP) protocols (see Appendix G for contact information for ASAP and their publications) for entering information into the system. Despite favoring electronic filing, participants acknowledged that a PMP using hard copy prescriptions could be effective, particularly if consecutively numbered, secure forms are used. This style of state-issued script may assist in reducing the likelihood of forgeries. Some individuals also proposed that if cost dissuades state officials from establishing an electronic PMP, the use of hard copy prescriptions should be considered in order to establish the program and to begin reaping the benefits of a monitoring system. However, other participants noted that the actual cost per prescription for paper scripts are often considerably higher for the hosting agency than the cost per electronic record.

The Work Group spent some time discussing whether or not they would recommend "real time" reporting to states considering PMPs. While technology is clearly moving toward the potential for "real time" as the standard in the near future, this option is currently cost-prohibitive for states¹ versus the batch reporting conducted by existing electronic monitoring systems. Therefore, participants did *not* see "real time" as a necessity in order to have an effective, proactive PMP.

CONFIDENTIALITY/WHO HAS ACCESS TO INFORMATION GATHERED AND MAINTAINED BY THE PMP

Safeguarding the confidentiality of the data collected and carefully determining access to the PMP information were priorities for the Work Group. Participants most commonly identified licensing boards, prescribers, dispensers and law enforcement

¹ Potential upgrades for prescribers, dispensers, and states to accommodate "real time" reporting could include high-speed connections, fast processing computers, user software, and personnel to monitor updates as they occur.

officers as categories of individuals who should have access to monitoring system data.² The Work Group stressed that those authorized to access PMP data, not their designees, must both request and receive the information. Recognizing that standard definitions vary from state to state, some members encouraged states to inclusively define “prescriber” and “dispenser” when establishing their PMPs to avoid excluding professionals that may need to provide or receive data. Some participants also specified that physicians affiliated with addiction treatment centers and impaired professionals programs should be included in a state’s definition of “prescriber.” In many cases, PMP data could help to determine patients’ range of addictions. For example, a patient may present as addicted to cocaine, but may also be abusing a prescription drug; PMP data could indicate whether or not the patient had obtained a controlled substance.

Participants recommended that the means of and parameters for access to PMP information be determined by each state based on its existing laws, policies, and procedures. Optimally, advanced notification of emerging issues as shown in the system’s data would be given to prescribers and dispensers. This transfer of information would allow the PMP to be a proactive tool in identifying diversion, abuse, and addiction and making appropriate referrals to law enforcement, addiction treatment, and other related intervention services. In discussing access to the data, the Work Group was careful to note that only the PMP data analyst would view the actual data as it is entered into the system. All others would access PMP data in the form of reports generated by the system. Members believed it was important to clarify this point in order to allay fears regarding the level of information available to those with access to the PMP.

The Work Group agreed that data should be available from a PMP to researchers and public policy analysts in order to better inform drug and alcohol-related research, policies, prevention efforts, enforcement practices, and other public health initiatives. This general statistical information would show trends, mark patterns of use, and suggest outcomes of current efforts. All information that would be reasonably likely to reveal patients or others who are subjects in system entries would be removed from data provided for these purposes.

Individuals suggested that states develop a chain of communication in order to relay information quickly and effectively among those allowed access to the PMP data. Several participants stressed that laws, guidelines and procedures for such communication must comply with Health Insurance Portability and Accountability Act (HIPAA) regulations (see Appendix F for an overview of the HIPAA Privacy Rule). Others recommended that a state should avoid allowing exposure of the data under the Freedom of Information Act (FOIA) or open record laws.

² Patients generally have access to their own medical records through practitioners and/or third party providers, thus would not need to access data from monitoring systems. However in some states, patient access may need to be included in the PMP in order to comply with state law(s).

WHICH AGENCY OR ENTITY SHOULD HOUSE THE PRESCRIPTION MONITORING INFORMATION

Rather than focus on any one agency or site for housing the PMP information, participants emphasized the need for a teamwork approach. Regardless of who maintains the data repository, there should be a mechanism for gathering input from a multidisciplinary, culturally and ethnically diverse group of individuals involved with and affected by the PMP. Participants recognized that a state could not legislate or mandate goodwill. However, they suggested that requiring cross-disciplinary input at least brings key players to the table to begin fostering the necessary partnerships. As identified by the participants, this group would be composed of 1) prescribers, including primary care physicians and other practitioners, 2) dispensers, such as pharmacists, 3) licensing boards or associations such as medical boards or societies, 4) law enforcement, 5) prosecutors, 6) addiction treatment providers, 7) members of the recovering community, 8) state policymakers and agency officials, 9) employers and other payers who may be asked to pay for treatment that results from identifying addicted patients, 10) consumers and 11) others who may initially be inclined to oppose a PMP.

The role of this diverse and multidisciplinary group could range from advisory to governing, depending upon the state's needs. Participants did stress the need to clearly define the role and parameters for this entity. Others heeded that each state would need to consider the representation that this group would need. They also encouraged states to look at their historical use of multidisciplinary boards, committees, etc., in defining the structure and capacity of this group. Some participants cautioned that establishing such a large governing body could lead to a cumbersome process that might impede timely access to the PMP information. Therefore, the Work Group seemed to favor an advisory role for the multidisciplinary team, allowing for the continual input of their expertise. With such varied membership, these advisory groups would bring together states' key stakeholders related to prescription monitoring and could be powerful advocates for creating new PMPs and enhancing existing programs. Participants also suggested that subcommittees of this large group could support a PMP by creating and implementing prevention efforts and other related initiatives.

One of the small work groups did recommend that the PMP be housed by a state agency with a history of successfully handling large, confidential databases. If a state has an agency that already has authority to report and collect data, participants felt that it would not be necessary to create a new entity to host the monitoring system. Reinforcing the teamwork approach, the small work group proposed that the PMP design incorporate a mechanism for the housing agency to incorporate input from the multidisciplinary group. This would allow for a combination of expertise (e.g. law enforcement, clinical, pharmacological) to shape the program and to analyze data reports.

INTERSTATE TRANSACTIONS

Prescription transactions that cross state borders were of paramount concern in the overall and small group discussions. One of the small groups urged that contiguous

states' programs should contain similar elements to facilitate effective transfer of information among states. This seamless system could prevent those behaving inappropriately from using multi-jurisdictional issues to avoid detection or punishment.

SUPPORT FOR EFFECTIVE ESTABLISHMENT AND OPERATION OF A PMP

Education

Participants stressed the integral role that education plays in the success of a PMP. Suggested topics for educational efforts related to monitoring systems included: 1) an overview of the PMP; 2) appropriate pain management, addiction diagnostic, and addiction treatment principles or guidelines; 3) prescription abuse and diversion trends; 4) various "scams" used to obtain drugs; 5) available treatment resources; and 6) proper referral procedures. To deliver these and/or other appropriate topics, Work Group members identified four forms of education that would best support a monitoring system:

1. Orientation Program for the PMP

The Work Group recommended that states, through their relevant licensing boards and other multidisciplinary stakeholders, establish an orientation program during the implementation phase of the PMP. This educational offering would provide an overview of the monitoring system, explanations of the prescribers' and dispensers' roles, system capabilities, and benefits of monitoring.

2. Required class in order to access PMP data

For professionals who are eligible to receive data from the PMP but do not attend an orientation program, Work Group participants recommended that states require these individuals to complete a course that provides an overview of the monitoring system and addresses a selection of the above-suggested topics. The Work Group felt that increased awareness of and training in these areas could prevent the misuse of prescription drugs and delays in identifying addicted individuals.

3. Remedial education for professionals

In addition to applicable penalties and fines under state law, participants recommended a mandatory course for professionals who are found to inappropriately prescribe, divert, or otherwise misuse prescription drugs. This educational requirement would address the above-listed topics.

4. Preparatory and continuing education for professionals

Optimally, the Work Group envisioned pain management, addiction medicine, and effective treatment principles as standard curricula components in medical school, pharmacy school, and other courses of study in health care professions. Participants

strongly encouraged states, their licensing boards, and institutions of higher education to consider expanding their offerings to include the topics proposed in this report. However, they acknowledged the difficulties of adding mandatory elements to existing degree and/or certification requirements.

In addition to these four types of education, the PMP Work Group also recognized the need for increasing awareness and knowledge among law enforcement, legislators, patients, parents, and young people regarding the appropriate use and dangers of misusing prescription drugs. Many participants indicated that too often people view "illegal" drugs, such as heroin, as the only type of drug problem. States may need to consider incorporating this type of education in their PMP design.

Participants also identified the need to publicly highlight the cost benefits of a PMP. Several individuals pointed to the relative low costs of a monitoring system compared to mounting expenses for Medicaid enforcement, investigations and incarceration. Others noted that a PMP could offset costs of untreated addiction and prevent loss of lives and harm to families. The benefits of a PMP may be more widely supported in a state with an understanding of the potential cost savings.

Complementary Systems

A PMP does not operate in a vacuum. A state should provide adequate resources and enhancements for its enforcement, legal, licensing and treatment systems. Numerous participants pointed out that these systems must respond to prescription drug addicts, diverters, improper prescribing practices and other problems identified by the PMP. Several participants suggested that a state's officials should carefully review whether that state's laws provide sufficient remedies and penalties to support the PMP. For example, does a state's laws 1) make "doctor shopping" a crime? 2) impose serious penalties for wrongful conduct related to prescription drugs? 3) give civil liability immunity to prescribers or dispensers when they act in good faith to prevent diversion? 4) prohibit self-prescribing? 5) provide appropriate insurance coverage for pain care, and the treatment of mental health problems, alcohol and other drug (AOD) abuse, and addiction? 6) address the tracking and interstate issues regarding mail-order prescription fulfillment? Several participants proposed that states monitor compliance with and effectiveness of penalties. Many others recommended the establishment of pain management guidelines or distribution of national association standards deemed credible in the state.

Data Analysis and PMP Evaluation

Participants stressed the importance of analyzing the data collected by the PMP to maximize the system's benefits in a state. Data interpretation can help 1) identify trends of abuse, diversion and inappropriate prescribing; 2) efficiently allocate investigative resources; 3) inform pain management and addiction treatment decisions; 4) track cost-benefits of the PMP; 5) outline options for improving the PMP; and 6) educate people about prescription drug diversion, abuse and addiction. Several participants recommended that states include a full-time analyst position (minimally, a part-time

position) in their PMP design in order to maintain, review, and make the best use of the data.

Some participants stated that other entities or agencies in a state might already be collecting some prescription drug information. They recommended that those collection mechanisms be studied for guidance in developing a PMP.

One of the small work groups listed additional types of information a state should collect in order to supplement data from an existing PMP or to illustrate the need for prescription monitoring. These types included 1) DEA theft and loss reports, 2) DAWN/NHSDA statistics, 3) drug task force information, 4) state criminal statistics, and 5) specific case information (e.g. medical examiner reports, doctors arrested and number of units diverted and family tragedies). The small work group members proposed using the information to help educate policymakers and others about the scope and nature of prescription drug diversion, abuse and addiction, and the concomitant need for a PMP.

Incorporation of an evaluation component in the design of a PMP was seen by participants as critical. Ongoing assessment and evaluation of a PMP could identify the program's cost-benefits, thereby justifying continued operation and funding. The Work Group encouraged states to provide routine statistical reports of PMP data to legislatures and other decision-makers in the state in order to inform them of the program's outcomes. However, participants cautioned that a new PMP might initially show an increase in a state's prescription drug diversion statistics, given that a dedicated monitoring mechanism would be in place where only generalized efforts existed previously. This should not discourage states, as it is a common occurrence with new enforcement-related initiatives (e.g. increasing the size of a police force often leads to an initial rise in crime, as more officers are in place to see and report incidents).

FUNDING OF PMPs/FINANCIAL INCENTIVES TO ESTABLISH PROGRAMS

Without money to operate the program, a PMP remains theoretical, never moving from words on paper to actual development. Therefore, participants identified funding of PMPs as a priority. Work Group members identified possible sources of funding for a PMP: 1) controlled substances registration, 2) asset forfeiture proceeds, 3) grants, particularly for start-up costs³, 4) additional or increased fines, 5) victim assistance funds, 6) licensing fees, 7) money or in-kind donations from computer companies that would benefit from long-term customer relationships with electronic monitoring systems, 8) cost-savings gained from offsetting responsibilities of other programs, such as Medicaid enforcement, and 9) federal and/or state incentive grants to implement or enhance a PMP. To reduce problems associated with multi-state prescription drug transactions, this small work group also encouraged the use of financial incentives to help persuade states to implement a PMP that allows for interstate transfers of data.

³ The start-up cost of a prescription monitoring program can often range from \$100,000 to \$500,000. The Work Group identified the following components as potential start-up expenditures: education, vendor fees, computer(s), monitoring software, personnel (including full-time data analyst), and training.

ACCOUNTABILITY

The Work Group identified three categories of professionals and the actions for which they should be held accountable with regard to the prescription monitoring system and its data:

Table 1

Professionals	Action(s)
Prescribers and dispensers	-legitimacy of data reported to the PMP -failure to report data as required -inappropriate use of data received from PMP
Professionals eligible to receive data from PMP (as defined by state)	-unlawful disclosure or other inappropriate use of data received from PMP
Staff of the entity housing the monitoring system	-unlawful disclosure or other inappropriate use of data received for entry into monitoring system

Participants were careful to distinguish violations related to the PMP from the drug diversion, "doctor shopping", and other controlled substance-related violations that the data may suggest. Existing states laws, in most cases, would address the latter. To address the violations outlined in Table 1, each state would need to consider the existing civil, criminal, and administrative laws/policies as well as needed statutes/policies when drafting legislation to establish a PMP.

Several participants viewed enforcement and penalties as keys to putting "teeth" in the PMP to ensure compliance with requirements. One small work group cautioned that administrative penalties are often insufficient to stop people who divert or abuse prescription drugs. Another small work group agreed that a state should enact civil and criminal penalties to deter and address violations of confidentiality laws or rules.

Appendix A

National Alliance for Model State Drug Laws' Prescription Monitoring Work Group *List of Participants*

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Appendix B

National Alliance for Model State Drug Laws' Prescription Monitoring Work Group *List of Special Observers*

The National Alliance for Model State Drug Laws invited a select group of individuals to witness the proceedings of the Prescription Monitoring Work Group. These special observers included federal agency officials, representatives of national organizations, and other individuals interested in issues related to prescription drugs:

Pascal Caputo
Legislative Assistant
Office of Senator Richard Shelby

John M. Little
Legislative Counsel
Office of Senator Jeff Sessions

Brad Cavedo
Deputy Attorney General
Office of the Attorney General –
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Bill Lockwood
American Society of Automation in
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Charlie Cichon
President
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Investigators

Kate Malliarakis
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Ed Munson
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Alice Murphy
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Council on Substance Abuse - National
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Michael Gottlieb
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Jeannie Santos
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Kim Herd
National Association of Attorneys
General

Jaime Vega
Office of National Drug Control Policy

Daniel Lipka
Office of National Drug Control Policy

Mary Ann Wagner
Vice President, Pharmacy Regulatory
Affairs
National Association of Chain Drug
Stores

Appendix C

Agenda for October 30-31, 2001 Prescription Monitoring Work Group meetings at the Hyatt Regency on Capitol Hill

October 30, 2001 Yorktown Room (Ballroom Level)

8:00 a.m. - 8:15 a.m.

Welcome and Overview of Meeting Objectives

Sherry Green, Executive Director, National Alliance for Model State Drug
Laws (co-facilitator)

Deborah Beck, President, Drug and Alcohol Service Providers Association
of Pennsylvania (co-facilitator)

8:15 a.m. - 9:00 a.m.

Introduction of Work Group Participants and Special Observers

9:00 a.m. - 12:00 p.m.

Work Group Discussion Re: Model Prescription Monitoring Program

(The Group will take a break whenever it is appropriate given the discussion)

12:00 p.m. - 1:30 p.m. Regency Foyer (Ballroom Level)

Working Lunch

1:30 p.m. - 4:00 p.m. Yorktown Room

Work Group Discussion Continues

(The Group will take a break whenever it is appropriate given the discussion)

4:00 p.m. - 5:00 p.m.

Summary of Discussion and Identification of Issues for Wednesday's Discussion

October 31, 2001 Yorktown Room

8:00 a.m. - 10:30 a.m.

Work Group Discussion Continues

(The Group will take a break whenever it is appropriate given the discussion)

10:30 a.m. - 11:30 a.m.

Summary of Discussion/Recommendations and Identification of Action Steps to Follow-Up on
Meeting

Appendix D

Work Group Discussion of Key Elements of a Prescription Monitoring Program

With agreement on the need for a clear mission statement and definition of the problem that the program will address, participants began to identify other key elements of a prescription monitoring program. The guidelines for this facilitated “brainstorm” segment of the meeting instructed each participant to speak in turn without interruptions by, challenges from, or questions asked by others in the work group. The purpose of this process was to create a “laundry list” of all elements that should be considered in building a prescription monitoring program, without regard to resources, perceived feasibility, or political realities; participants were not asked to prioritize the elements during the portion of the meeting. The following bulleted lists outline the key elements and the related comments as identified and shared by individual members:

Consideration of the Existing Legislation, Guidelines, and Needs Assessment Findings

- what is the incentive for a state to establish a PMP?
- lay a supportive foundation for and around PMP
- define key terms to be used by participants in the system
- consider state’s drug court legislation when indicating penalties
- determine if “doctor shopping” a crime in the state (it is not in all)
- determine if you will need precursor legislation to implement an effective PMP
- use existing state data, legislation, and related information to determine what issues need to be addressed with the new PMP
- what is the legal status of self-prescribing in the state? may need legislation to make it a criminal offense if PMP is to be effective
- established pain management guidelines need to be part of this or be created (if national association standards are not recognized as adequate legal documentation in state)
- state assessment of what is in place must precede PMP
- given increased Internet access to prescription drugs, state may need separate law to address terms of this access before establishing PMP

Drugs to Monitor and Rationale for Inclusion

- as part of clearly defining the problem to be addressed by a PMP, participants raised the issue of which drugs should be monitored
- participants expressed concern about states establishing new monitoring programs in response to the current drug(s) of concern (“drug du jour” as one participant termed it) rather than as a comprehensive system to protect the public health and well-being
- participants urged states to consider including uncontrolled substances as well as controlled ones, as abuse and diversion trends exist among these drugs as well
- some participants felt that monitoring should be non-drug specific

- monitoring all prescription drugs is often easier on participants in the process (e.g. it creates less confusion, one process for all prescriptions, etc.)
- monitoring all drugs may help to troubleshoot issues as they emerge over time
- overall, participants seem to favor monitoring all or at least multiple schedules of drugs in order to be able to best respond to future trends and needs; some expressed concern with the feasibility to accomplish this in states with limited resources (e.g. personnel to follow-up on what the PMP might show as issues)

Options for states to tailor program to their individual needs

- states are the best qualified to identify or determine their own needs for monitoring systems, policies
- one participant suggested that a matrix be created that placed use, abuse, and diversion on one axis with prevention, intervention, logistics, and transparency down the other to allow each state to choose and work with its own set of elements and how addressing each will be accomplished
- model law is needed that offers states options for customizing programs to their own needs
- use “best practices” from existing state PMPs to start new ones in states
- identify specific elements that can be incorporated into a state PMP
- take key elements back to each state looking to address building or enhancing a PMP
- some states may not yet have prescription monitoring as a priority
- resources are available regarding what states with PMPs have in place, outcomes, and other information (e.g. the Alliance, DEA, NASCSA, Alliance of States)
- resources, needs, populations, and geographic size are different for each state and come into play when designing a PMP
- one participant who suggested the need for state customization made a point to distinguish between state individuality and states’ rights, feeling that the latter suggested a resistance to federal guidance, assistance, or funding for monitoring programs
- each state must go through its own needs assessment process regarding PMP

Balance between states’ needs and uniformity among jurisdictions

- to avoid confusion and to facilitate interstate efforts, it is important to also look at uniformity across existing programs that have been effective, establish these elements as a base, and then let states branch out from there
- is there some uniformity of language that could be achieved, if not uniformity of system, that would assist with interstate issues regarding prescription abuse and diversion?

Strategy for Interstate Diversion and Abuse

- prescription drug issues go across state borders (Ohio River Valley offered by several participants as an example of where diversion issues can easily move from state to state; it is certainly not the only location facing this issue)
- programs should allow for state-to-state transfer of data

- as new programs start, build in the option of interstate integration so that the technology is in place once legal and logistical questions are resolved
- is there some uniformity of language that could be achieved, if not uniformity of system, that would assist with interstate issues?
- states working together on these issues may be more effective than federal mandates and procedures for interstate monitoring (federal guidelines may unwittingly create barriers and/or delays in interstate sharing)

Team work approach

- it will take many disciplines working together to accomplish goals for PMP
- states must create teams across disciplines, not work at cross purposes
- involving key players creates “buy in” and brings concerned parties to the table
- it as important to involve potential or actual opponents (e.g. pharmacists, doctors, consumers, medical society, other advocacy organizations) as it is to include known supporters
- process of establishing a PMP may provide mechanism for minimizing turf issues of those involved in the issue
- participation can be legislated/mandated if good will to work together cannot
- treatment providers must be part of the team
- recovery community must be included
- primary care physicians need to be at the table
- policy makers should be involved in order to help consider existing statutes and programs and/or to plan for needs to address collateral consequences of PMP
- payers/employers need to be involved, as they will be asked to pay for treatment that results from identifying addicted patients and professionals
- bring together a culturally and socioeconomically diverse to team, taking care to include communities which may often be underrepresented on this issue
- bring state agency leaders to table
- many participants favor a multidisciplinary oversight panel to manage PMP; others are concerned that this creates roadblocks to accessing data in a timely manner (i.e. the more people, agencies involved in release of information, the more cumbersome it becomes)
- involve this multidisciplinary collection of stakeholders in both the advocacy for a PMP and in the prep work to establish the system once the state makes the decision to move forward

Multiple approaches and strategies

- PMP is one tool in the tool box for addressing substance abuse and misuse; it is not the end-all, be-all solution

Data collection

- PMP provides a means of documenting that there is a need, via data collection, documentation
- Data should be complete and accurate
- data can be used to educate about problems related to prescription drug abuse and diversion

- data would allow a state to look at the sources of diversion and over-prescribing in order to address these incidents and the individuals involved appropriately and effectively
- states must establish who can access data and for what purposes
- how data is accessed must be determined
- who is collecting data within a state?
- how is data being collected?
- how will data be used
- it may be useful to assess who in a state might currently be collecting prescription drug information (e.g. Attorney General's Office, insurance companies, Medicaid office) and evaluate that model for use in the PMP; this may also help to establish precedents for who can access data and how
- in creating a monitoring system, make provisions for data to be analyzed for trends, spikes in prescribing or consuming, and other patterns; data deemed useless, by some participants, if it is not interpreted
- the translation of data can also help to create solutions
- data collection and analysis help to make enforcement efforts more efficient; knowing where to go to investigate diversion saves officers'/agents' time on the road tracking down sources ("windshield time")
- monitoring can provide useful information for clinical management of patient care
- data can assist law enforcement in detecting prescription fraud, including "doctor shopping" by patients, abuse by individuals, and diversion through theft and/or inappropriate prescribing
- data can also be used to show cost-benefit of program – an important point for legislators and other elected officials
- general statistical information from the monitoring system would be helpful to inform all participants in the process and the state which supports it

Confidentiality

- confidentiality provisions for the program must be established and follow current state statutes, federal law, and HIPAA guidelines
- PMP must balance between confidentiality and getting help for those who need it (e.g. treatment for addicted patients, prescribers, dispensers)
- participants felt that HIPAA regulations will likely influence the way that patient information is handled in the future, so those establishing a monitoring system must understand these guidelines re: confidentiality

Communication

- once it is determined who will have access to data, a chain of communication must be established for relaying information effectively and quickly
- doctors, patients, pharmacists, other prescribers and dispensers, law enforcement, and pharmaceutical industry must be involved in this communication process

Usability of System

- the purpose and logistics of a prescription monitoring program should be easy for all parties involved to understand and utilize

- PMP needs to be “user friendly”

Protection for Patients and Physicians Using and Prescribing Medications for Legitimate Medical Needs

- this element connects to issue of a transparent, invisible system
- monitoring should not deter doctors from prescribing medications appropriately to people who need them
- PMP should not present impediments to appropriate patient care or access to medications that are needed for legitimate medical needs
- PMP should be non-intrusive to the doctor-patient relationship
- PMP must balance ensuring the availability of controlled substances for legitimate medical purposes and the misuse of the same
- state requirements or a “checklist” for physicians to follow and to document adherence when prescribing pain medications may provide “cover” or protection for doctors if misuse occurs
- PMP can also help to identify patients whose pain is sub-optimally managed

Transparency

- prescription monitoring system should be invisible to those involved (e.g. physician, pharmacist, patient)
- system should not burden physicians, pharmacists, other prescribers, other dispensers
- PMP should be non-intrusive
- PMP should ideally be around us and working, but not obvious or intrusive to the participants

Education about prescription drug use, abuse, diversion, and related issues

- mandatory education across health care professions
- awareness and adherence to established guidelines for assessing and treating pain
- utilize existing “profiles of pain” established by professional associations (e.g. Joint Commission on Accreditation of Healthcare Organizations, American Academy of Pain Medicine)
- education and awareness for users of prescriptions
- participants indicated that in several states, most patient complaints of severe pain are presented to primary care physicians; therefore, these professionals should be educated regarding pain management and how to access treatment for addicted patients
- some participants felt that education is not enough, but can be effective in tandem with monitoring and enforcement efforts
- physicians need education re: prescription abuse trends, current attempts and approaches for “scams” to acquire drugs, related issues
- educate physicians who are not pain management specialists re: guidelines for pain, appropriate use of opioids, other pain medications
- cross-disciplinary training, continuing education on prescribing, diversion, abuse, treatment resources, how to make referrals to treatment, and on diagnosing and treating pain for health care professionals

- educating law enforcement re: the importance of addressing prescription drug abuse and diversion; may not be seen as a pressing issue or the exciting one to pursue
- educate decision-makers, such as legislators and other elected officials, as they may be inclined to view only illegal drugs as the concern, may only see selected prescription drugs as problematic, rather than looking to insure safe and appropriate prescribing overall
- education could be a component of PMP, but it is also in place to support a monitoring system
- the meeting's working lunch on 10/30 presented outtakes from public service announcements intended to raise awareness among young people regarding the dangers of misusing prescription drugs; Green invited participants to consider and discuss strategies for providing educational information to teens and other populations that may not be aware of these issues

Allowance for the Collateral Consequences of a Prescription Monitoring Program

- consider implications for law enforcement
- consider related penalties and what they would accomplish
- put policies, penalties, and/or programs in place to support law enforcement efforts (e.g. a first-time offender program that is similar to many states driving under the influence of alcohol provision)
- be prepared to monitor compliance with and effectiveness of penalties, deterrents
- what outcomes are you looking to achieve (include as part of mission statement)?
- what unintended outcomes may occur that state will need to handle? (e.g. increased misuse of uncontrolled substances, increased demand for treatment services, subpoenaing of data for court cases)
- what possible litigation could occur as the result of prescription monitoring (e.g. more diverters entering into the criminal justice system? legal questions about the use of PMP data in court cases? challenges to confidentiality law related to use/release of data?)
- what systems need to be created or enhanced to support PMP (e.g. law enforcement, treatment, judicial, remediation)?

Resources for and Referrals to Treatment

- monitoring program should encourage adequate treatment of addicted patients and professionals
- PMP can provide intervention for participants addicted to medications
- health care professionals need information about what treatment options are available in their areas
- health care professionals also need training and information about how to access treatment for patients
- who will pay for treatment needs resulting from PMP?
- some participants questioned what constitutes "good" or "appropriate" treatment (answer per the treatment professionals in the group: generally, the longer the required stay in treatment program, the better the patient's results)

Appropriate Means to Address Physicians Who Are Diverting Prescription Drugs

- program should help identifying how, where, and why diversion is occurring
- program should encourage adequate treatment for health care professionals who are addicted and who may be self-prescribing
- participants raised the adage of the “Four D’s” as to why physicians may divert prescription drugs – duped, dated, dishonest, drug-addicted

Prevention

- in addition to being a component of a PMP, prevention efforts need to be in place to support a monitoring system

Enforcement

- participants believe that enforcement is an important element in addressing abuse and diversion of prescription drugs; one participant noted a drop in drug related deaths involving certain controlled substances as the result of law enforcement efforts
- enforcement efforts would support a PMP in a state
- in addition to traditional enforcement efforts, incentives for using the process of prescribing medication properly need to be built into the PMP as the “teeth” in the monitoring system

Accountability

- accountability must be in place for all participants involved in a monitoring system, including prescribers, patients, dispensers, data analysts, those with access to data, etc.
- PMP could establish incentives for participants to use process of prescribing medications properly – “teeth” in the system to persuade compliance

Strategy for Addressing Opposition to the Idea of Prescription Monitoring

- PMP and its advocates must have a solid strategy for addressing the political forces that oppose it (e.g. pharmacists who may feel that the burden of labor is on them, consumers who may feel that monitoring invades their privacy, etc.)
- do what is “do-able” given the existing support and opposition in the state

Consideration of All Groups that May Be Affected by PMP

- inclusive definition of prescribers in the state (e.g. physicians, nurse practitioners, veterinarians, dentists, etc.) must be incorporated in the monitoring system
- inclusive definition of dispensers (e.g. individual pharmacists, chain-drug stores, hospital pharmacies, nursing homes, etc.) must be incorporated in the monitoring system
- traditional or presumptive definitions of who these individuals are can lead to loop holes or areas unaddressed by PMP

Willingness to Work Hard to Establish Program

- one participant spoke of entering the tenth year of attempting to get a prescription monitoring program in one state

- constant advocacy may be needed to get supporting legislation or administrative provision
- it takes a great deal of work to coordinate, design, establish, and maintain a monitoring program

Evaluation

- build in an evaluation component for the PMP as it is developed
- carefully determine how and what you will evaluate
- a process for identifying outcomes will assist in the future funding for the program as well as in improving the system
- be able to prove the cost-benefit of PMP

Funding

- consider how you will pay for a monitoring system
- some existing PMPs started with grant funding as seed monies
- some PMPs use registration fees from prescribers and/or dispensers to cover costs
- fines from violators of system could also assist with funding

Appendix E

Multidisciplinary Small Groups' Discussions of PMP Key Elements

During the work group meeting on October 30, 2001, the facilitators divided the participants into three smaller discussion groups. Each small group was intentionally multidisciplinary in its composition; particular care was taken to have existing monitoring programs represented in each subset to allow participants to ask questions of these individuals. The small groups' assignment was to examine the list of elements generated by the individual participants and to prioritize the top five elements. The facilitators and Alliance staff were available to assist the small groups with questions regarding the process or the assignment. However, the subsets largely worked intently to discuss perspectives among themselves and to narrow the large list of elements to their top five.

Each group met with its own struggles to accomplish the assignment of prioritizing five key elements from the extensive "brainstormed" list. Few emerged with a simple list of five elements. However, each subset developed an informed perspective on the intent, structure, and content of a monitoring program to present to the larger group.

Group 1's Priority Elements

Group 1 prioritized the following elements for a PMP:

- 1) What substances to monitor, recommending the Schedules II-V minimally
- 2) Funding for a program, indicating general fund dollars, registration fees, asset forfeiture, grants, additional fines, victim assistance funds, and other creative state-based monies as possible sources
- 3) Access to and confidentiality of the data collection and maintenance
- 4) Clear mission statement for the program, focusing on education, investigative assistance, information for registrants, and encouragement of treatment and prevention
- 5) Addressing interstate issues through a seamless system in which elements of contiguous states' programs are similar enough to facilitate effective transfer of information

In presenting these five elements, Group 1 also indicated that its members preferred an electronic system of monitoring, but not if the cost prevents a state from putting a PMP in place. This group also discussed the interstate issue from the perspective of getting other states to "buy in" to prescription monitoring and sharing information across state lines. Incentives that they identified included creating a preamble among states as to why monitoring is important, the cost benefit that a PMP could bring by offsetting other expenses (e.g. Medicaid enforcement, investigations, incarceration costs), monetary inducements to states to participate. Group 1 also felt strongly that states should be able to design their own PMPs rather than be mandated to follow a national blueprint from the federal government.

Group 2's Priority Elements

Group 2 stated that a model PMP's mission statement would commit to support access to legitimate medical use of prescription drugs, to identify and deter abuse and diversion, respond appropriately with treatment and/or criminal justice options, and to promote education, research and other public health issues related to prescription drug use, abuse, and diversion. The system would include the following key elements:

1. *A team work approach*
2. *Monitor all schedule II – V drugs, plus other drugs of concern*
3. *Ability to communicate why the PMP is needed*
Participants discussed using existing data sources at the state and national levels, medical examiners' reports, and specific, personal cases involving deaths related to the misuse of prescription drugs to "sell" the PMP concept and purpose to dissenters
4. *Determination of who runs the program*
While advocating for an interdisciplinary group comprised of healthcare and law enforcement professionals, group members agreed that the specific composition and physical location of the records should be determined by the state.
5. *Confidentiality*^o
Group 2 believed a specific statute or ruling, including criminal and civil penalties, is needed to identify who can access PMP data. Participants cited HIPAA and Whalen v. Roe as guidelines and precedents to consider.
6. *Limited access to data*
Favoring a computerized monitoring system, this group proposed that every dispenser be required to file electronically. Once the system is established, information should identify individuals via the American Society for Automation in Pharmacy standards, with specific information available by prescriber, dispenser, and patient. Data should be accessible to prescribers and dispensers upon written request, law enforcement via reference or request, patients by right to their own data, and others by court order.

Through their described model PMP, Group 2 hoped to ensure appropriate prescribing, identify individuals in need of addiction treatment, optimal patient care, and education, facilitate successful criminal prosecutions of diverters, and facilitate public health research. Participants also cautioned that states should consider what legal, administrative, and policy changes may be necessary to operate an effective PMP in a state (e.g. "doctor shopping" as a crime, amending insurance laws to better cover

addiction treatment, civil immunity to participants using system in good faith to prevent diversion, etc.)

Group 3's Priority Elements

Group 3 brought forth a PMP model that would positively address four key areas:

- 1) Health care professionals, dispensers, and patients
(system would facilitate communication among those who are treating patients)
- 2) Law enforcement
- 3) Intervention and treatment
- 4) Education and Prevention
(to include research involving collected data)

Structurally, this monitoring system would ideally be electronic for efficiency, although the group agreed that an effective program could be run using handwritten scripts. A state agency with a history of handling large, confidential databases would house the PMP. Law enforcement, clinical, and pharmacological expertise would be utilized to analyze the collected data. In addition to safeguarding confidentiality, another priority that Group 3 identified for the data collection was to provide information back to health care providers to help to prevent misuse and to treat addicted patients.

Group 3 also prioritized the transparency of the system and the need to have a statute to incorporate interstate authority. They also cautioned that administrative penalties are often not enough to deter or stop people who abuse substances and/or the system; group members agreed that people are more likely to respond to law enforcement and criminal penalties for diversion.

Appendix F

The Privacy Rule of Health Insurance Portability and Accountability Act

During Work Group proceedings, members stressed the need for states to consider the potential impact on prescription monitoring programs of the privacy rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA establishes a general rule that when state laws and/or their related standards or implementation specifications conflict with this federal law, the state law is preempted by the federal requirements. However, the statute provides for exceptions, and an application process, to this general rule:

Code of Federal Regulations, Title 45 – Public Welfare, Subtitle A – Department of Health and Human Services, Subchapter C – Administrative Data Standards and Related Requirements, Part 160 – General Administrative Requirements, Subpart B – Preemption of State Law

Current through January 1, 2002; 66 FR 67702

§ 160.203 General rule and exceptions.

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

- (a) A determination is made by the Secretary [of Health and Human Services] under § 160.204 that the provision of State law:
 - (1) Is necessary:
 - (i) To prevent fraud and abuse related to the provision of or payment for health care
 - (ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;
 - (iii) For State reporting on health care delivery or costs; or
 - (iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or
 - (2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.
- (b) The provision of State law relates to the privacy of health information and is more stringent than a standard, requirement, or implementation specification under subpart E of part 164 of this subchapter.
- (c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

- (d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

45 C. F. R. § 160.203

§ 160.204 Process for requesting exception determinations

- (a) A request to except a provision of State law from preemption under § 160.203(a) may be submitted to the Secretary [of Health and Human Services]. A request by a State must be submitted through its chief elected official, or his or her designee. The request must be in writing and include the following information:
 - (1) The State law for which the exception is requested;
 - (2) The particular standard, requirement, or implementation specification for which the exception is requested;
 - (3) The part of the standard or other provision that will not be implemented based on the exception or the additional data to be collected based on the exception, as appropriate;
 - (4) How health care providers, health plans, and other entities would be affected by the exception;
 - (5) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at § 160.203(a); and
 - (6) Any other information the Secretary may request in order to make the determination
- (b) Requests for exception under this section must be submitted to the Secretary at an address that will be published in the Federal Register. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect.
- (c) The Secretary's determination under this section will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at § 160.203(a) has been met,

45 CFR § 160.204

To learn which government legal department in state provides guidance regarding the application of HIPAA, please contact the state's Attorney General's office.

The Office for Civil Rights (OCR) is the component of Health and Human Services that is responsible for implementing and enforcing the privacy regulation. To learn more about OCR and its services, please visit <http://www.hhs.gov/ocr/hipaa>.

Appendix G

Contact Information for the American Society for Automation in Pharmacy

The mission of the American Society for Automation in Pharmacy (ASAP) is to assist its members in advancing the application of computer technology in the pharmacist's role as caregiver and in the efficient operation and management of a pharmacy.

For more information about the voluntary industry guidelines that ASAP recommends, please contact the Society:

American Society for Automation in Pharmacy
Bill Lockwood, Executive Director
492 Norristown Road
Suite 160
Blue Bell, PA 19422
Phone: (610) 825-7783
Fax: (610) 825-7641
E-mail: wal@computertalk.com
Web site: www.asapnet.org

Appendix H

Survey of Existing State Statutes and Policies for Prescription Monitoring Programs

STATE PRESCRIPTION MONITORING STATUTES AND REGULATIONS*

	CA	HI	ID	IL	IN	KY	MA	MI	NV ¹	NM ²	NY	OK	RI	TX	UT	WA ³	WV ⁴
MONITORING																	
Electronic		X	X	X	X	X	X	X ⁶	X		X ⁷	X	X	X ⁵	X		X
Electronic or single form																	
Electronic or triplicate form	X ⁸																
Triplicate form															X		
OVERSEING AGENCY																	
Commerce				X			X						X				
Health									X	X			X				
Pharmacy	X		X						X								X
Law enforcement	X	X			X				X			X		X			
Licensing															X		

¹ NV's statute and regulation does not specify what information shall be submitted to the overseeing/designated state agency. The regulation states that the information to be submitted is set forth in the ASAP Telecommunications Format for Controlled Substances, May 1995 edition, published by the American Society for Automation in Pharmacy.

² NM no longer has an operational prescription monitoring program. The former program is contained in regulation, of which we are awaiting a copy. For comparative purposes, we are including in our analysis, statutory information we have to date and any future information we receive for NM's former program.

³ WA's prescription monitoring program only applies to licensed practitioners and is used for disciplinary purposes or for disciplinary board supervision of a practitioner's practice.

⁴ WV no longer has an operational prescription monitoring program. We are including analysis of WV's former program for comparative purposes.

⁵ TX has switched from a triplicate prescription monitoring program to an electronic monitoring program but still allows the submission of prescription forms until the electronic system is fully implemented.

⁶ MI has recently enacted legislation which will change its prescription monitoring program for Schedule II to an electronic monitoring program for Schedules II, III, IV and V. This legislation will be effective upon the promulgation of required rules and receipt by the secretary of state of written notice from the director of the department of consumer and industry services that the required electronic monitoring system is operational. The department of consumer and industry services will replace the department of commerce as the overseeing agency upon the promulgation of the electronic monitoring rule. This survey reflects information in the statute which remains effective until promulgation of the electronic monitoring rule.

⁷ On January 1, 2002, all official triplicate prescription forms became void and only single part official prescription forms are now valid.

⁸ The CURES program, for electronic monitoring of Schedule II controlled substances, shall become inoperative on July 1, 2003 and shall be repealed on January 1, 2004, unless legislation, which deletes or extends the dates on which it becomes inoperative, is enacted and becomes operative on or before January 1, 2004.

STATE PRESCRIPTION MONITORING STATUTES AND REGULATIONS*

	CA	HI	ID	IL	IN	KY	MA	MI	NV	NM	NY	OK	RI	TX	UT	WA	WV
DRUGS MONITORED																	
Schedule II	X			X	X		X	X			X	X		X			X
Schedules II and III													X				
Schedules II, III and IV			X							X							
Schedules II, III, IV and V						X											X
Benzodiazepines											X						
Determined by overseeing agency		X														X	
Determined by disciplinary authority																	
INFORMATION SUBMITTED																	
Patient/Recipient Information																	
Patient's/Recipient's name	X	X		X	X	X					X	X		X			X
Patient's or animal owner's name								X						X			
If drug dispensed for animal, animal's name																	
Patient's/Recipient's address	X	X		X		X				X	X			X			X
Patient's or animal owner's address								X						X			
Patient's gender	X										X						
Patient's date of birth	X	X			X	X								X ⁹			
Patient's or animal owner's age								X									
Patient's/Recipient's I.D. number		X										X					
Patient's/Recipient's or patient's/recipient's representative's I.D. number					X		X										X
Patient's S.S.N. or I.D. number						X											
Positive I.D. of person receiving RX, including:																	

⁹ A patient's or animal owner's date of birth may also be used.

NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS

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Alliance for Model State Drug Laws.

RESEARCH CURRENT THROUGH 2/4/02

*PLEASE SEE ANATOMY NOTES

STATE PRESCRIPTION MONITORING STATUTES AND REGULATIONS*

	CA	HI	ID	IL	IN	KY	MA	MI	NV	NM	NY	OK	RI	TX	UT	WA	WV
Type of I.D.															X		
Identifying numbers on the I.D.															X		
Drug Information																	
Drug dispensed or prescribed						X		X			X ¹⁰			X	X		X
Date dispensed or filled	X	X		X	X	X	X	X			X	X		X	X		X
Date prescription was written	X	X						X			X ¹¹	X		X	X		X
National drug code number	X	X		X	X	X	X				X ¹¹	X		X			X
Official prescription control number								X						X	X		X
Quantity of drug prescribed														X	X		X
Quantity of drug dispensed	X	X		X	X	X	X	X			X ¹²	X		X	X		X
Dosage of drug								X									X
Dosage quantity and frequency as prescribed																	X
Strength of drug											X ¹³				X		X
Number of refills authorized			X														X
Estimated number of days supply dispensed					X	X	X				X			X			
Intended use of the drug														X			
Instructions for use of the drug														X			
Prescriber Information																	
Prescriber's name						X		X						X	X		X
Prescriber's address								X						X	X		X
DEA registration number	X	X		X	X	X	X	X			X	X		X			X

¹⁰ Name of the drug shall be submitted only if the information is submitted on a departmental form.
¹¹ National drug code number shall be submitted only if the information is submitted electronically.
¹² Dosage of the drug shall be submitted only if the information is submitted on a departmental form.
¹³ Strength of the drug shall be submitted only if the information is submitted on a departmental form.

STATE PRESCRIPTION MONITORING STATUTES AND REGULATIONS*

	CA	HI	ID	IL	IN	KY	MA	MI	NV	NM	NY	OK	RI	TX	UT	WA	WV
Dept. of Public Safety registration number														X			
Practice specialty and subspecialties		X															
State medical license number for those using the DEA number of a government exempt facility	X																
Dispenser/Pharmacy/Pharmacist Information																	
Dispenser's name						X											X
Pharmacy's name														X	X		X
Drug outlet's name															X		
Pharmacist's name																	
Dispenser's location												X					X
Pharmacy's address														X			X
Pharmacy's location		X															
Pharmacist's address								X									
Pharmacy's telephone number							X							X			X
Pharmacy's prescription number	X										X			X			
Pharmacy's license number																	
Pharmacy's national I.D. number											X						
Pharmacist's state license number							X										
NABP number		X							X						X		
DEA registration number				X	X	X						X		X			X
Dept. of Public Safety registration number																	
PERSONS/ENTITIES WHO CAN ACCESS CONFIDENTIAL INFORMATION																	
Appropriate state, local and federal	X																

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persons or public agencies	CA	HI	ID	IL	IN	KY	MA	MI	NV	NM	NY	OK	RI	TX	UT	WA	WV
Agencies or entities determined by the overseeing agency	X																
Public or private entities determined by the overseeing agency	X												X				
Licensing/Regulatory entity or designated representative						X	X					X	X				X
Licensing entity investigator/agent			X									X	X				X
Attorney General or staff		X		X	X							X		X			
Registrants, Practitioners or Pharmacists		X	X			X		X						X	X		
Patients			X				X		X						X		
Patient's attorney			X						X								
State or local prosecutors		X		X	X							X	X	X			
DEA Diversion Group Supervisor												X					
Medicaid agency			X			X											
Medicare agency			X														
Grand Jury						X						X					
Court			X						X								X
Persons with court order or administrative subpoena																	
Public			X											X			X
Investigators/Agents of overseeing agency								X				X		X	X		X
Designated employees of overseeing agency								X									
Authorized personnel analyzing prescription information or researchers								X							X		

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	CA	HI	ID	IL	IN	KY	MA	MI	NV	NM	NY	OK	RI	TX	UT	WA	WV
Person who receives, processes or stores information				X	X												
Contractor who administers prescription monitoring program								X									
Law enforcement/Investigative personnel -			X				X						X				
Federal		X										X					
State		X										X					
Municipal		X										X					
Drug enforcement -																	
Federal				X	X	X		X							X		X
State				X	X	X		X						X	X		X
Municipal						X		X							X		
STATED PURPOSES FOR WHICH CONFIDENTIAL INFORMATION CAN BE USED																	
Disciplinary	X												X				
Civil	X												X				
Criminal	X												X				
Educating practitioners	X												X				
Educational or scholarly endeavors	X			X									X				X
Peer review	X												X				
Statistical	X			X	X			X					X	X			X
Research or analysis	X			X									X				
Public information							X										
Furtherance of an ongoing criminal investigation or prosecution		X										X					
Determination if a violation or possible violation of a controlled		X															

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	CA	HI	ID	IL	IN	KY	MA	MI	NV	NM	NY	OK	RI	TX	UT	WA	WV	
substances act exists																		
Further investigation or other appropriate enforcement or administrative enforcement use			X															
Preventing or avoiding inappropriate use of controlled substances			X															
Investigation, adjudication or prosecution of violation under state or federal controlled substances law				X	X													X
Legitimate licensing, drug enforcement, or regulatory investigation of a designated person						X												
Providing medical or pharmaceutical treatment to a legitimate current patient						X												
Determining the attempt to obtain a controlled substance by fraud, deceit or misrepresentation								X										
Administration, investigation or enforcement of the controlled substances act or another state drug law																		
Pharmacist or practitioner inquiry of recent Schedule II prescription history of specific patient of the practitioner																		X
Pharmacist or practitioner inquiry about his own dispensing or																		X

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prescribing activity	CA	HI	ID	IL	IN	KY	MA	MI	NV	NM	NY	OK	RI	TX	UT	WA	WV
Pharmacist or practitioner inquiry about a current patient to whom he is prescribing or dispensing or considering prescribing or dispensing a controlled substance																X	
Enforcement of federal, state or local controlled substances laws																X	
Investigatory or evidentiary use with specified licensing or regulatory agency																X	
Evidentiary use in the following situations:																	
A proceeding under any state or federal law that involves a Schedule II controlled substance				X													
A criminal proceeding or a proceeding in juvenile court that involves a Schedule II controlled substance																	
A proceeding under any state or federal law that involves a controlled substance					X												
A criminal proceeding or a proceeding in juvenile court that involves a controlled substance					X												
A proceeding under IC 16-42-20 (Drugs: Enforcement of Pharmacy Laws and Rules)					X												

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STATE PRESCRIPTION MONITORING STATUTES AND REGULATIONS*

	CA	HI	ID	IL	IN	KY	MA	MI	NV	NM	NY	OK	RI	TX	UT	WA	WV
PENALTIES FOR FAILURE TO TRANSMIT PRESCRIPTION INFORMATION												X					X
Misdemeanor		X															
Class A misdemeanor					X	X										X	
Civil violation																	
PMP STATUTE(S) DOES NOT LIST PENALTY FOR FAILURE TO TRANSMIT PRESCRIPTION INFORMATION	X		X	X					X	X	X			X		X	
PENALTIES FOR UNAUTHORIZED DISCLOSURE OF PRESCRIPTION INFORMATION																	
Class C Felony			X														
Class D Felony						X									X		
Third degree felony and subject to civil penalties												X					X
Misdemeanor																	
Class A misdemeanor					X												
PMP STATUTE(S) DOES NOT LIST PENALTY FOR UNAUTHORIZED DISCLOSURE OF PRESCRIPTION INFORMATION	X		X	X				X	X		X		X	X		X	

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STATE PRESCRIPTION MONITORING STATUTES AND REGULATIONS*

EXPLANATORY NOTES

Please see attached analysis for more detail about individual state statutes and regulations.

As of February 4, 2002, the following states have introduced bills in the 2002 legislative sessions to establish prescription monitoring programs: FL, MD, NJ, OH, PA, TN and VA.