HOUSE BILL 2730

INTERAGENCY COUNCIL

REPORT TO THE 82nd TEXAS LEGISLATURE

December 31, 2010

House Bill 2730
Interagency Council
Report to the 82nd Texas Legislature

Table of Contents

H.B. 2730 Charge to the Interagency Council

Article 22 of H.B. 2730 created an interagency Council composed of the Director of the Department of Public Safety and the Executive Directors of the Texas State Board of Pharmacy and the Texas Medical Board or their designees.

The Interagency Council was charged to develop a transition plan for the orderly transfer from the Department of Public Safety to the Texas State Board of Pharmacy of certain records and regulatory functions relating to dispensing controlled substances by prescription under Chapter 481, Health and Safety Code. In developing the transition plan, the council shall:

(1) consult with the Health and Human Services Commission, the Department of State Health Services, and other health and human services agencies that contract with a third party for data collection;

(2) specify the records and regulatory functions to be transferred;

(3) create a time frame within which the specified records and functions will be transferred;

(4) ensure the Department of Public Safety's continued access for law enforcement purposes to prescription drug information obtained under Chapter 481, Health and Safety Code;

(5) develop a plan for the transfer of relevant database information;

(6) make recommendations for improvements to data transmission, including examining the feasibility of implementing an electronic data transmission system for use by registrants and the Department of Public Safety or the Texas State Board of Pharmacy;

(7) estimate the fiscal impact of the transfer, including an estimate of the costs associated with any necessary staff increase;

(8) minimize disruptions to the professions affected by the transfer;

(9) identify any obstacles to the transfer and make recommendations to address those obstacles; and

(10) address any other consideration the council determines is appropriate.

REPORT OF THE H.B. 2730 INTERAGENCY COUNCIL

The H.B. 2730 Interagency Council (Council) is composed of the following individuals;

Gay Dodson, R.Ph., Executive Director/Secretary, Texas State Board of Pharmacy;

Johnny Hatcher, Manager, Audit and Investigations Bureau, Compliance and Enforcement Service, Regulatory Services Division, Texas Department of Public Safety; and

Mari Robinson, J.D., Executive Director, Texas Medical Board.

At the first meeting of the Council, the members all agreed that the Council will develop and recommend a transition plan for the for the orderly transfer of the Prescription Monitoring Program (PMP) from the Department of Public Safety (DPS) to the Texas State Board of Pharmacy (TSBP) and address the additional items mentioned in the charge. The members also agreed that since the decision to move the PMP would be made by the Legislature and not this Council, the Council should focus on suggestions to improve the PMP whether the program remains at the DPS or moves to the TSBP. In addition, the Council agreed that The PMP should not hinder a patient's ability to obtain needed prescriptions but should prevent those individuals from attempting to obtain prescription drugs for diversion or abuse.

Over the next few meetings, the Council agreed to the following recommendations for improvements to the PMP. We believe these recommendations will increase the effectiveness of the program and potentially reduce the numbers of controlled substances obtained by persons seeking the drugs not for a legitimate medical purpose, but rather for illegal distribution and use.

RECOMMENDATIONS

(1) Improvements to the Texas Prescription Monitoring Program

(A) A secure Web Site should be established to allow practitioners and other authorized users easy and quick access to the data in the prescription monitoring system so that:

- prescribers and pharmacies can make better decision when prescribing and dispensing controlled substances; and
- regulatory agencies and law enforcement can identify licensees and individuals who are attempting to prescribe, dispense, or obtain controlled substances for illegal use.

(B) To make the data more useful and up to date, pharmacies should be required to submit prescription data to the program at least every seven days rather than the current requirement to submit no more than the 15th day after the end of the month in which the prescription was dispensed or up to 45-days after the prescription was dispensed so that the data is more up to date and useful to all who access the system.

(C) The Texas PMP should adopt those requirements in the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) that will allow the Texas PMP to share data with other states that operate a prescription monitoring program.

(D) The portion of the Texas Controlled Substances Act that deals with the PMP should be amended based on certain agreed upon provisions of the Prescription Monitoring Program Model Act developed by the Alliance of States with Prescription Monitoring Programs.

(E) The current requirement for a practitioner's DPS and DEA controlled substance registration numbers to be on all prescriptions for controlled substances in Texas should be modified to require only the DEA controlled substance registration number.

(F) All licensing boards for health care professionals allowed to prescribe controlled substances should be allowed to access to data collected by the PMP.

(2) <u>Funding Requirements</u>

The Council recommends that both the PMP and CSR be administered by the same agency. In addition, the council also recommends that to accomplish the recommended changes to the prescription monitoring program, the program should be fully funded with all fees collected by the CSR and PMP.

TRANSITION PLANS

The charge to the Interagency Council requires the Council to develop a transition plan for the orderly transfer from the Department of Public Safety (DPS) to the Texas State Board of Pharmacy (TSBP) of certain records and regulatory functions relating to dispensing controlled substances by prescription under Chapter 481, Health and Safety Code. The Council is submitting two transition plans as follows. Please note that the members of the Interagency Council agreed that since the decision to move the PMP would be made by the Legislature and not this Council, the Council is not making a recommendation on whether the Prescription Monitoring Program (PMP) remains at the DPS or moves to the TSBP.

Transition Plan #1 – Move the Prescription Monitoring Program and the Controlled Substance Registration Program

This transition plan will implement all of the recommendations of the Interagency Council for improvements to the Prescription Monitoring Program (PMP) and will move the PMP and the Controlled Substance Registration program (CSR) from the DPS to the TSBP. This plan is being submitted because one of the recommendations of the Interagency Council is to keep the PMP and the CSR at the same agency since the CSR generates revenue that could be used to fund both programs.

Transition Plan #2 – Move the Prescription Monitoring Program

This transition plan will implement all of the recommendations of the Interagency Council for improvements to the Prescription Monitoring Program (PMP) and will move only the PMP from the DPS to the TSBP. If the legislature chooses this transition plan, a method of funding will have to be created to operate the PMP at the TSBP.

DISCUSSION

In developing these plans, each item in the charge was studied and is addressed in these plans. The first item in the charge directed the Interagency Council to consult with the Health and Human Services Commission (HHSC), the Department of State Health Services, and other health and human services agencies that contract with a third party for data collection. HHSC currently has contracts for data collection and/or management of different phases of the Medicaid Vendor Drug Program with three third party contractors. These contractors:

(1) process approximately 30 million claims per year and generate reports for the Vendor Drug Program;

(2) maintain the preferred drug list, negotiate contracts for the list, report cost effective drugs, collect data regarding the savings to the state, and look at market shifts, and

(3) handle prior approvals including collecting data, performing clinical edits, and looking at the cost savings.

Our research has indicated that there are numerous companies that contract with states to support the operation of prescription monitoring programs. These vendors collect the data from pharmacies, maintain secure websites that allow authorized persons to access this data, and provide customer and technical support.

ASSUMPTIONS

The following assumptions are applicable for both transition plans.

(1) Fiscal Year 2012 will be used for planning, contracting, setup, etc of the PMP and/or CSR program at the Texas State Board of Pharmacy while the actual transfer of the programs/program will occur on September 1, 2012.

(2) TSBP intends to contract with a vendor to support the operation of the Texas PMP. In discussions with a number of these venders, TSBP has determined the following regarding costs for such a contract.

- Costs for implementation and conversion of data ranges from $100,000 to $250,000 depending on how many years of data will need to be converted. TSBP has determined that two to three years of data should be maintained on-line with the remaining data archived in the TSBP office.

- Annual costs for operating the program range from $210,000 to $360,000.

Actual cost for the contract cannot be determined until a bid process is completed. However, after discussions with several vendors, TSBP estimates that a reasonable cost for the biennium is $500,000.

(3) TSBP is a self-funded agency, and all expenses are funded through fees charged by the agency. Therefore, it is assumed that if the PMP or the PMP and CSR programs are transferred to TSBP, these programs will also be self-funded through fees paid to the agency.

(4) Whether one or both programs are transferred, TSBP will gain additional employees and will need space to house these employees. If space for these employees cannot be found in a state owned facility such as our current home, the William P. Hobby, Jr. State Office Building, the agency will have to lease space for these employees in a privately owned building. In August 2010, the Texas Facilities Commission estimated that each employee would need approximately 200 square feet of space at a cost of $20 per square foot for a full-service lease. Each of the plans presents the cost to run the program/programs if housed in state owned facilities or private leased space.

(5) TSBP currently has a total of 72 FTEs. The transfer of both or one of these programs will add from 25 – 43 employees to operate the new program/programs. The addition of this large number of employees will increase the size of the agency by 35%-60% and the agency will need to add a number of administrative staff to support this increase. Actual numbers of administrative staff needed are outlined in each of the plans.

(6) TSBP will hire a project manager to plan, execute, and finalize the transition plan according to strict deadlines. We anticipate that the project manager will be employed only during FY2012.

(7) Two federal grants are available for state PMP programs: one from the U.S. Department of Justice, Office of Justice Programs' Bureau of Justice Assistance, the Harold Rogers Prescription Drug Monitoring Program grant; and one from the Department of Health and Human Services Substance Abuse and Mental Health Services Administration, the National All Schedules Prescription Electronic Reporting (NASPER) grant. Texas should be eligible to receive one or both of these grants. For the purpose of the Transition Plan, we assume Texas will receive at least one grant for $400,000.

Transition Plan #1 – Move the Prescription Monitoring Program and the Controlled Substance Registration Program

DISCUSSION

According to information received from the Department of Public Safety (DPS), for the last two fiscal years (FY2009 – FY2010), DPS expended approximately $4,248,009 ($4,950,925 if matching benefits are included) to operate the Controlled Substance Registration Program (CSR) (including precursor chemicals and the laboratory apparatus registration), the Prescription Monitoring Program (PMP), and the Narcotic Regulatory/Investigative Unit Program. DPS employs a total of 39 FTEs to operate these programs. It's important to note that the costs DPS provided to TSBP do not include any figures for administrative support of these programs (e.g., Information Technology, Human Resources, Accounting, Rent, etc.). As indicated above in assumption #5, TSBP will need to add administrative staff to support the addition of these employees and this cost is included in our estimates.

After reviewing the current staffing pattern at DPS, TSBP has determined that we can plan and prepare for the transfer of the programs with one additional employee (a Project Manager) in FY2012 and then operate the Controlled Substance Registration Program, Prescription Monitoring Program, and the Narcotic Regulatory/Investigative Unit Program with a total 43 additional employees in FY2013.

In planning for this transition, TSBP has determined that we can introduce several improvements to the system that should increase the efficiency of the CSR. TSBP has operated with these improvements for our registration programs for pharmacists, pharmacies, and pharmacy technicians for many years. The improvements we plan to introduce are:

- establish on-line programs to allow individuals to apply for initial registrations and to renew existing registrations (this will eliminate most of the paper applications and renewals). The on-line programs will also allow individuals to verify existing registrations.

- begin issuing registrations for a two-year period rather than the one-year currently used by DPS.

Our experience in implementing the above improvements show that:

- on-line initial applications and renewals reduce the work load of employees by eliminating the mailing and processing of paper applications. In addition, experience has shown that acceptance rates for use of the on-line programs are very high as indicated by our current use rates for pharmacy technicians (99%) and for pharmacists (83%).

- conversion to a two-year license period is more efficient for staff in that it allows the workload for the renewal of registrations to be spread over two-years rather than one-year.

EXPENSE ESTIMATES

Estimates for expenses to move both programs from DPS to TSBP are indicated in Table 1 and Table 2 below. The first scenario (Table 1) assumes that space can be located for the additional employees necessary to operate the PMP and CSR in the William P. Hobby, Jr. Office Building. The second scenario (Table 2) assumes that space will not be available and the agency will need to find lease space for 38 of these new employees. As you can see the costs for operating the two programs using lease space is approximately $2,000,000 more per year than housing the employees in state owned buildings.

TABLE 1
ESTIMATED EXPENSES TO MOVE BOTH PROGRAMS FROM DPS TO TSBP
SCENARIO #1 (State Office Space)

	FY2012	FY2013
Expenses	$354,724	$3,195,310
Matching benefits	20,039	458,619
Remolding, Rent, etc.	222,900	0
Indirect Costs-Bond Debt and Utilities	0	39,271
Estimated Totals in State Office Space	**$597,663**	**$3,693,200**
# FTEs	1	43

TABLE 2
ESTIMATED EXPENSES TO MOVE BOTH PROGRAMS FROM DPS TO TSBP
SCENARIO #2 (Private Leased Space)

	FY2012	FY2013
Expenses	$354,724	$3,175,056
Matching benefits	20,039	458,619
Outside rent, moving expenses, etc.	22,900	2,005,718
Estimated Totals in Private Leased Space	**$397,663**	**$5,639,393**
# FTEs	1	43

REVENUE ESTIMATES

TSBP will generate revenue to support the above estimated expenses. Again this information is presented as two scenarios. The first scenario (Table 3) assumes that space can be located for the additional employees necessary to operate the PMP and CSR program in the William P. Hobby, Jr. Office Building. The second scenario (Table 4) assumes that space will not be available in a state facility and the agency will need to find lease space for 38 of these new employees. As you can see, the agency projects that the current $25 per year fee for controlled substance registrations could be lowered from $25 per year to $17 per year (an $8 decrease per year) if space is available in a state owned facility. If space is not available in a state facility, fees would have to be increased to $27 per year (a $2 per year increase).

TABLE 3 REVENUE ESTIMATE TO SUPPORT TO MOVING BOTH PROGRAMS TO TSBP SCENARIO #1 (State Office Space)		
	FY2012	**FY2013**
Fees from Controlled Substance Registration at $17 per year or $34 for a two year renewal (Note: this is an $8 per year decrease in fees from the current $25 per year fees)	$0	$1,700,000
Transferred portion of fees collected by DPS in FY2012 for the FY2013 time period (Note: the fees are prorated to be used in FY2012 and FY2013)	397,663	661,087
Additional fees collected during FY2013 from the transition to biennial renewal	0	850,000
Revenue from Sale of Official Prescriptions		563,400
Projection of Federal Grant Award Amount	200,000	200,000
Estimated Totals in State Office Space	**$597,663**	**$3,974,487**

TABLE 4 REVENUE ESTIMATE TO SUPPORT TO MOVING BOTH PROGRAMS TO TSBP SCENARIO #2 (Private Leased Space)		
	FY2012	**FY2013**
Fees from Controlled Substance Registration at $27 per year or $54 for a two year renewal (Note: This is a $2 per year increase in fees from the current $25 per year fee)	$0	$2,700,000
Transferred of the portion of fees collected by DPS in FY2012 for the FY2013 time period (Note: the fees are prorated to be used in FY2012 and FY2013)	197,633	861,087
Additional fees collected during FY2013 from the transition to biennial renewal	$0	1,350,000
Revenue from Sale of Official Prescriptions	$0	563,400
Projection of Federal Grant Award Amount	200,000	200,000
Estimated Totals in Private Leased Space	**$397,663**	**$5,674,487**

Transition Plan #2 – Move the Prescription Monitoring Program Only

DISCUSSION

According to information received from the Department of Public Safety (DPS), for the last two fiscal years (FY2009 – FY2010), DPS expended an average of approximately $2,124,005 ($2,475,463 if matching benefits are included) to operate the Prescription Monitoring Program (PMP). DPS employed a total of 20 FTEs to operate this program. It's important to note that the costs DPS provided to TSBP do not include any figures for administrative support of the program (e.g., Information Technology, Human Resources, Accounting, Rent, etc.) As indicated above in assumption #5, TSBP will need to add administrative staff to support the addition of these employees and this cost is included in our estimates. TSBP anticipates we will need to add 26 employees to operate the program and provide administrative support the program

Because TSBP has no experience operating a program like the PMP, TSBP has no basis to suggest improvements that may increase the efficiency of the program. TSBP has determined that we can plan and prepare for the transfer of the programs with one additional employee (a Project Manager) in FY2012 and then operate the PMP with a total 25 additional employees in FY2013.

EXPENSE ESTIMATES

Estimates for expenses to move only the PMP from DPS to TSBP are indicated in Table 5 and Table 6 below. The first scenario (Table 5) assumes that space can be located for the additional employees necessary to operate the PMP and CSR in the William P. Hobby, Jr. Office Building. The second scenario (Table 6) assumes that space will not be available and the agency will need to find lease space for 22 new employees. As you can see the costs for operating the two programs using lease space is approximately $1,200,000 more per year than housing the employees in state owned buildings.

TABLE 5
ESTIMATED EXPENSES TO MOVE ONLY THE PMP FROM DPS TO TSBP
SCENARIO #1 (State Office Space)

	FY2012	FY2013
Expenses	$104,724	$2,131,335
Matching benefits	20,038	249,255
Remodeling, Rent, etc.	123,100	0
Indirect Costs-Bond Debt and Utilities	0	34,601
Estimated Totals in State Office Space	**$247,862**	**$2,415,191**
# FTEs	1	25

TABLE 6 ESTIMATED EXPENSES TO MOVE ONLY THE PMP FROM DPS TO TSBP SCENARIO #2 (Private Leased Space)		
	FY2012	**FY2013**
Expenses	$104,724	$2,131,335
Matching benefits	20,038	$249,255
Outside rent, moving expenses, etc.	23,100	$1,223,958
Estimated Totals in Private Leased Space	**$147,862**	**$3,604,548**
# FTEs	1	25

REVENUE ESTIMATES

TSBP will generate revenue to support the above estimated expenses. Again this information is presented as two scenarios. The first scenario (Table 7) assumes that space can be located for the additional employees necessary to operate the PMP and CSR in the William P. Hobby, Jr. Office Building. The second scenario (Table 8) assumes that space will not be available in a state facility and the agency will need to find lease space for 22 of these new employees. In this scenario, the CSR will not be moved to TSBP. The CSR generates the majority of the revenue in the scenario that moves both programs; therefore, a revenue source will have to be created to fund the PMP program if the CSR is not moved.

Some other states have funded their PMP programs with a surcharge on each individual/entity that is registered to prescribe, dispense, or distribute controlled substances. The following revenue estimates apply such a surcharge. This surcharge will be collected by DPS from their CSR registrants and the collected funds will be passed through to TSBP.

TABLE 7 REVENUE ESTIMATE TO SUPPORT MOVING ONLY THE PMP FROM DPS TO TSBP SCENARIO #1 (State Office Space)		
	FY2012	**FY2013**
Surcharge of $20 on all CSR registrants	$0	$2,000,000
Revenue from Sale of Official Prescriptions	0	563,400
Projection of Federal Grant Award Amount	247,862	152,138
Estimated Totals in State Office Space	**$247,862**	**$2,715,538**

TABLE 8 REVENUE ESTIMATE TO SUPPORT MOVING ONLY THE PMP FROM DPS TO TSBP SCENARIO #2 (Private Leased Space)		
	FY2012	**FY2013**
Surcharge of $29 on all CSR registrants	$0	$2,900,000
Revenue from Sale of Official Prescriptions	0	563,400
Projection of Federal Grant Award Amount	$147,862	252,138
Estimated Totals in Private Leased Space	**$147,862**	**$3,715,538**

As you can see from the above revenue estimates, CSR registrants would be required to pay an additional significant surcharge ($20 – $29 per year) in addition to the $25 annual CSR registration fee to fund the PMP if it is moved to TSBP.

TIMELINE

DATE	ACTIVITY
9/1/11	Project Manager Starts
12/1/11	1. Iron Data begins work on modifying TSBP's data processing system for licensing application for the Controlled Substance Registration Program 2. Begin planning for the transfer of the Controlled Substance Registration Program paper files to TSBP 3. Begin planning for the transfer of the historical data files of the Prescription Monitoring Program to TSBP.
3/1/12	1. Request for bid published for the contract for the Prescription Monitoring Program 2. Request for bid published for outside leased space (if necessary)
3/1/12 – 9/1/12	1. Transfer Controlled Substance microfilmed records to TSBP scan system.
	2. Transfer Prescription Monitoring Program historical data files to TSBP
4/1/12	Application due for the Harold Rogers Grant
7/1/12	1. Notice to registrants regarding the moving of the Controlled Substance Registration Program to TSBP. 2. Notice to pharmacies/physicians regarding the move of the Prescription Monitoring Program to TSBP.
6/1/12 – 8/31/12	Post, interview and hire for new positions to start 9/1/12
7/1/12-8/31/12	Remodeling of new space, including IT cable drops, etc. and furniture and equipment set-up.
8/10/12	Application due for the NASPER Grant
9/1/12	First day of operation of the Controlled Substance Registration and Prescription Monitoring Program at TSBP.

ARTICLE 22. TRANSFER OF REGULATORY PROGRAMS RELATING TO DISPENSING CONTROLLED SUBSTANCES BY PRESCRIPTION

SECTION 22.01. (a) The director of the Department of Public Safety or the director's designee, the executive director of the Texas State Board of Pharmacy or the executive director's designee, and the executive director of the Texas Medical Board or the executive director's designee shall meet as an interagency council to develop a transition plan for the orderly transfer from the Department of Public Safety to the Texas State Board of Pharmacy of certain records and regulatory functions relating to dispensing controlled substances by prescription under Chapter 481, Health and Safety Code.

(b) In developing the transition plan, the council shall:

(1) consult with the Health and Human Services Commission, the Department of State Health Services, and other health and human services agencies that contract with a third party for data collection;

(2) specify the records and regulatory functions to be transferred;

(3) create a time frame within which the specified records and functions will be transferred;

(4) ensure the Department of Public Safety's continued access for law enforcement purposes to prescription drug information obtained under Chapter 481, Health and Safety Code;

(5) develop a plan for the transfer of relevant database information;

(6) make recommendations for improvements to data transmission, including examining the feasibility of implementing an electronic data transmission system for use by registrants and the Department of Public Safety or the Texas State Board of Pharmacy;

(7) estimate the fiscal impact of the transfer, including an estimate of the costs associated with any necessary staff increase;

(8) minimize disruptions to the professions affected by the transfer;

(9) identify any obstacles to the transfer and make recommendations to address those obstacles; and

(10) address any other consideration the council determines is appropriate.

(c) Not later than January 1, 2011, the council shall submit its recommendations to the legislature on the transition plan developed by the council.

(d) The Department of Public Safety may not enter into any contract or otherwise take any action that would prevent, delay, or hinder a potential transfer to the Texas State Board of Pharmacy occurring on or after September 1, 2011, of certain records and regulatory functions relating to dispensing controlled substances by prescription.

(e) This section expires September 1, 2011.

TEXAS STATE BOARD OF PHARMACY

INTERAGENCY COUNCIL ESTABLISHED BY HOUSE BILL 2730 TO DEVELOP A TRANSITION PLAN FOR THE TRANSFER OF THE PRESCRIPTION MONITORING PROGRAM FROM DPSTO TSBP ORGANIZATIONAL MEETING

William P. Hobby Building
333 Guadalupe Street
Tower III, 8th Floor Conference Room
Austin, Texas
January 20, 2010

MINUTES

The meeting was called to order at approximately 1:00 p.m. Members present were Gay Dodson, R.Ph., Executive Director/Secretary, Texas State Board of Pharmacy (TSBP); Johnny Hatcher, Manager, Narcotics Regulatory Program, Texas Department of Public Safety (DPS); and Mari Robinson, J.D., Executive Director, Texas Medical Board. Others present were Kerstin Arnold, General Counsel (TSBP); Allison Benz, R.Ph., M.S., Director of Professional Services (TSBP); Pat Knue, Program Administrator, Texas Prescription Program (DPS); Sarah Carnes-Lemp, Attorney Narcotics Regulatory Program, (DPS).

Committee members discussed H.B. 2730 regarding the transition plan to move the Texas Department of Public Safety Prescription Monitoring Program to the Texas State Board of Pharmacy including strategies, methods and timelines for development of the plan. The committee proposed to send out a letter requesting input on changes/improvements to the Prescription Monitoring Program to stakeholders including the following organizations: Texas Medical Association, Texas Pharmacy Association, Texas Pain Society, Texas Osteopathic Medical Association, Texas Academy of Physician Assistants, Texas Nurses Association, Texas Federation of Drug Stores, Texas Society of Health-System Pharmacists, Texas Dental Association, and Texas Optometric Association. Gay Dodson will draft the letter and route it to the other members for review. Another meeting will be scheduled once the responses to the letter have been received.

The meeting was adjourned at approximately 2:30 p.m.

TEXAS STATE BOARD OF PHARMACY

INTERAGENCY COUNCIL ESTABLISHED BY HOUSE BILL 2730 TO DEVELOP A TRANSITION PLAN FOR THE TRANSFER OF THE PRESCRIPTION MONITORING PROGRAM FROM DPSTO TSBP
ORGANIZATIONAL MEETING

William P. Hobby Building
333 Guadalupe Street
Tower III, 8th Floor Conference Room
Austin, Texas
May 13, 2010

MINUTES

The meeting was called to order at approximately 10:00 a.m. Members present were Gay Dodson, R.Ph., Executive Director/Secretary, Texas State Board of Pharmacy (TSBP); and Johnny Hatcher, Manager, Narcotics Regulatory Program, Texas Department of Public Safety (DPS). Others present were Kerstin Arnold, General Counsel (TSBP); Allison Benz, R.Ph., M.S., Director of Professional Services (TSBP); Pat Knue, Program Administrator, Texas Prescription Program (DPS); and Sarah Carnes-Lemp, Attorney Narcotics Regulatory Program, (DPS). Member Mari Robinson, J.D., Executive Director, Texas Medical Board was not present.

Following discussion, the committee members approved the minutes of the meeting held on January 20, 2010.

The committee discussed the results of the letter sent out requesting input on changes/improvements to the Prescription Monitoring Program. Responses were received from the Texas Pain Society, Texas Medical Association, Texas Federation of Drug Stores, Texas Optometric Association, National Association of Chain Drug Stores, Texas Hospital Association, and Houston Police Department. After discussion, the committee asked staff from DPS and TSBP to review the current provisions of the Texas Controlled Substance Act that deals with the Prescription Monitoring Program and draft amendments based on the responses received. The members also suggested that, if possible, staff obtain a copy of the Model Rules for Prescription Drug Programs being drafted by Alliance of States with Prescription Monitoring Programs.

The committee set a deadline of October 31, 2010, for completing the report to the Texas Legislature to allow time for legislation to be drafted before the next session. The members agreed the next meeting will be held on Wednesday, June 23, 2010,

The meeting was adjourned at approximately 11:00 a.m.

TEXAS STATE BOARD OF PHARMACY

INTERAGENCY COUNCIL ESTABLISHED BY HOUSE BILL 2730 TO DEVELOP A TRANSITION PLAN FOR THE TRANSFER OF THE PRESCRIPTION MONITORING PROGRAM FROM DPSTO TSBP

William P. Hobby Building
333 Guadalupe Street
Tower III, 8th Floor Conference Room
Austin, Texas

June 23, 2010

MINUTES

The meeting was called to order at approximately 9:35 a.m. Members present were Gay Dodson, R.Ph., Executive Director/Secretary, Texas State Board of Pharmacy (TSBP); Johnny Hatcher, Manager, Narcotics Regulatory Program, Texas Department of Public Safety (DPS); and Mari Robinson, J.D., Executive Director, Texas Medical Board (TMB). Others present were Kerstin Arnold, General Counsel (TSBP); Allison Benz, R.Ph., M.S., Director of Professional Services (TSBP); and Pat Knue, Program Administrator, Texas Prescription Program (DPS).

Following discussion, the council members approved the minutes of the meeting held on May 13, 2010.

The council reviewed a draft of the Texas Controlled Substances Act and agreed with the changes. The council recommended including references to patient's agent and requiring pharmacies to backout prescriptions if the prescription is not picked up. The council also reviewed a draft of the new Prescription Monitoring Program Model Act (Model Act) from the Alliance of States with Prescription Monitoring Programs. The Model Act includes the patient in the list of individuals authorized to access prescription monitoring information. The council recommended that the patient/patient's agent not be included in the list. The council discussed recommendations for the plan to transfer the prescription monitoring program from DPS to TSBP. The council will continue to study the costs, and transfer of data. The members agreed the next meeting will be held on Thursday, August 5, 2010,

The meeting was adjourned at approximately 11:00 a.m.

TEXAS STATE BOARD OF PHARMACY

INTERAGENCY COUNCIL ESTABLISHED BY HOUSE BILL 2730 TO DEVELOP A TRANSITION PLAN FOR THE TRANSFER OF THE PRESCRIPTION MONITORING PROGRAM FROM DPSTO TSBP

William P. Hobby Building
333 Guadalupe Street
Tower III, 8th Floor Conference Room
Austin, Texas

August 5, 2010

MINUTES

The meeting was called to order at approximately 1:35 p.m. Members present were Gay Dodson, R.Ph., Executive Director/Secretary, Texas State Board of Pharmacy (TSBP); and Mari Robinson, J.D., Executive Director, Texas Medical Board (TMB). Others present were Kerstin Arnold, General Counsel (TSBP); Allison Benz, R.Ph., M.S., Director of Professional Services (TSBP); Pat Knue, Program Administrator, Texas Prescription Program (DPS); and Sarah Carnes-Lemp, Attorney Narcotics Regulatory Program, (DPS). Johnny Hatcher, Manager, Narcotics Regulatory Program, Texas Department of Public Safety (DPS) was not present.

Following discussion, the council members approved the minutes of the meeting held on June 23, 2010.

The council reviewed a revised draft of the Texas Controlled Substances Act. The council agreed to draft one version of the Act leaving the program in the CSA and another version in the Texas Pharmacy Act. The council discussed recommendations for the plan to transfer the prescription monitoring program from DPS to TSBP. TSBP will draft a plan with regard to the transition for the next meeting. The members agreed the next meeting will be held on October 7, 2010.

The meeting was adjourned at approximately 3:00 p.m.

APPENDIX C

March 10, 2010, E-Mail:
Prescription Monitoring Program – Request for Input

List of Organizations Asked to Provide Input/Suggestions for Improvement of the Prescription Monitoring Program

From: Gay Dodson [mailto:gay.dodson@tsbp.state.tx.us]
Sent: Wednesday, March 10, 2010 4:46 PM
To: Interested Parties
Subject: Prescription Monitoring Program - Request for Input

H.B. 2730 Interagency Council
Texas Department of Public Safety – Texas Medical Board –
Texas State Board of Pharmacy

M E M O

DATE: March 10, 2010
TO: Interested Parties
FROM: House Bill 2730 Interagency Council
Gay Dodson, R.Ph., Texas State Board of Pharmacy
Johnny Hatcher, Texas Department of Public Safety
Mari Robinson, J.D., Texas Medical Board
RE: Prescription Monitoring Program – Request for Input **Please give us your response by Friday, March 26, 2010.**

H.B. 2730 passed by the 2009 Texas Legislature established an Interagency Council composed of representatives of the Department of Public Safety, the Texas Medical Board, and the Texas State Board of Pharmacy. This Council is charged with developing a transition plan for the orderly transfer of the Prescription Monitoring Program from the Department of Public Safety to the Texas State Board of Pharmacy. The Interagency Council is required to submit a report to the Legislature by January 1, 2011. A copy of the portion of H.B. 2730 containing the charge to the Council is attached for your information.

As a part of this report to the legislature, the Interagency Council plans to submit recommendations for changes to the Texas Controlled Substances Act to improve the Prescription Monitoring Program whether or not the program is moved. We ask your assistance in this task. Please provide us with your suggestions to make the Prescription Monitoring Program more useful to prescribers, pharmacies, and law enforcement. To assist you in making suggestions, following are some suggestions and issues that surfaced during the last legislative session.

1. Texas should establish Web access to the data in the prescription monitoring system that will allow prescribers, pharmacies, and law enforcement to query the system.

2. Pharmacies should be required to submit prescription data to the program more often so that the data is more up to date and useful. Currently Texas pharmacies are required to send data "no later than the 15th day after the month in which the prescription was dispensed." This means that the data may be up to 45-days old before it is submitted. To make the data more up-to-date, how often should pharmacies be required to submit prescription data?

3. Over the last few years, several additional practitioners have been given the authority to prescribe controlled substances, e.g., Advanced Nurse Practitioners (APN) and Therapeutic Optometrist. These individuals are allowed to access information in the Prescription Monitoring Program but the Controlled Substances Act has not been amended to allow the Board of Nursing or the Texas Optometry Board to access the information. Should the Texas Controlled Substances Act be amended to allow the licensing boards for all healthcare professionals allowed to prescribe controlled substances to access data on their licensees?

You're not limited to the three items above, please give us your input on any area you believe will make the Prescription Monitoring Program more effective in helping reduce the diversion of controlled substances. In addition, if you know others who are interested in this issue, please provide them a copy of this memo. You may send your responses by e-mail to gay.dodson@tsbp.state.tx.us or by mail to the address below.

Please give us your response by Friday, March 26, 2010.

==========
Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
333 Guadalupe Street, #3-600
Austin, Texas 78701
phone: 512/305-8026
fax: 512/305-8082
e-mail: gay.dodson@tsbp.state.tx.us
Web-site: www.tsbp.state.tx.us
==========

LIST OF ORGANIZATIONS ASKED TO PROVIDE INPUT/SUGGESTIONS FOR IMPROVEMENT OF THE PRESCRIPTION MONITORING PROGRAM

PROFESSIONAL ASSOCIATIONS

American Pharmacies
Richard Beck

National Association of Chain Drug Stores

Texas Dental Association
Mary Kay Linn, Executive Director

Texas Federation of Drug Stores
Kathy Barber, Executive Director

Texas Hospital Association
Matthew T. Wall, Associate General Counsel

Texas Medical Association
Dan Finch, Legislative Affairs Director

Texas Nurses Association
Clair Jordon, MSN, RN, Executive Director
Jim Willmann, J.D., General Counsel & Government Affairs Director

Texas Optometric Association
Bj Avery, Executive Director

Texas Osteopathic Medical Association
Sam Tesson, Executive Director

Texas Pain Society
Krista R. Crockett, Executive Director

Texas Pharmacy Association
Joe A. DaSilva FACHE CAE
Executive Director/CEO

Texas Society of Health-System Pharmacists
Paul Davis, Executive Director

CITY, STATE, AND FEDERAL AGENCIES

Austin Police Department
Richard Burns, Sergeant

Brazos County Sheriff's Office
Michael Welch, Assistant Commander

Calcasieu Parish, Louisiana
John DeRosier, District Attorney

Dallas Police Department
Paul Turbyfill, Sergeant

Drug Enforcement Administration
Mark Caverly, Chief Liasion and Policy

Michael T. DellaCorte, Group Supervisor

Lisa Sullivan, Program Manager, Dallas

William Massey, Acting Program Manager, El Paso

Judett Black, Program Manager, Houston

Texas Dental Board
Sherry Sanders Meek, Executive Director

Harris County District Attorney's Office

Houston Police Department
Troy Gamble, Sergeant

Texas Board of Nursing
Katherine Thomas, MN, RN, Executive Director

Oklahoma Bureau of Narcotics
Don Vogt, Program Manager

Texas Optometry Board
Chris Kloeris, Executive Director

OTHERS

Hance Scarborough, LLP
Cheri Brimberry Huddleston, Legislative Consultant

Walgreen
Karen Reagan

Hilco Partners
Martha Jones

APPENDIX D

Suggestions for Improvement to the Texas Prescription Monitoring Program from:

Austin Police Department

Houston Police Department

Drug Enforcement Administration

National Association of Chain Drug Stores

Texas Federation of Drug Stores

Texas Hospital Association

Texas Medical Association

Texas Optometric Association

Texas Pain Society

AUSTIN POLICE DEPARTMENT

From: Richard Burns
Sent: Thursday, March 18, 2010 4:11 PM
To: Gay Dodson
Subject: RE: Prescription Monitoring Program - Request for Input

---

From: Nichols, Joe
Sent: Thursday, March 11, 2010 3:52 PM
To: Burns, Richard
Cc: Woodfin, Michele
Subject: RE: Prescription Monitoring Program - Request for Input

The current system works well for our office. The request form is easy to complete and fax to DPS. In most cases DPS will email the results of our request on the same day. The idea to set up a web access database would obviously make it much easier, as long as we have access to the database.

The 45 day delay on reporting has not been too much of a problem. Cutting down the delay by any amount would be desirable.

HOUSTON POLICE DEPARTMENT

From: John Kowal
Sent: Thu, 3/25/2010 1:20 PM
To: Gay Dodson
Subject: PMP RESPONSE; SEE ATTACHED

THANK YOU IN ADVANCE FOR YOU EFFORTS IN REGARD TO IMPROVING THE CURRENT PMP. IT HAS ALWAYS BEEN A GREAT TOOL FOR LAW ENFORCEMENT. PLEASE DO NOT HESITATE TO CALL IF THERE IS ANYTHING WE AT THE HOUSTON POLICE DEPARTMENT NARCOTICS DIVISION CAN DO TO HELP IN YOUR EFFORTS.

THANK YOU
JOHN KOWAL
HPD NARCOTICS DIVISION

RESPONSE TO IMPROVEMENTS FOR THE PMP

The existing PMP in its current form operated by the Texas Department of Public Safety (DPS) has been an invaluable tool for investigators within the Houston Police Department. The successful PMP for schedule II controlled substances administered by the DPS most probably accounted for the limited Oxycontin problem the Houston area encountered while parts of the country were overrun with an epidemic of Oxycontin due to no PMP.

The current PMP has always been easily accessed by law enforcement to enhance investigations. Information within the PMP is presorted, reviewed, and quantified by the DPS prior to dissemination to law enforcement saving valuable time and man hours.

Not too fully fund the current PMP run by the DPS would hinder future prescription drug investigations. The current statistics generated by the Houston Police Department in regard to prescription drug seizures shows the magnitude of the problem. A fully funded PMP with real time tracking carefully monitored by the DPS, with instant access to law enforcement, medical providers, and pharmacists would help in the fight against prescription drug abuse.

In summation a fully funded PMP administered by the DPS would prevent any “time loss” due to a transition to a new agency. A DPS administered program would seem all encompassing to all parties as opposed to a program that is administered by only one segment of the prescription drug chain.

DRUG ENFORCEMENT ADMINISTRATION
HOUSTON FIELD DIVISION

From: Latimore, Sharnett
Sent: Thu, 3/25/2010 11:24 AM
To: Gay Dodson
Subject: RE: Prescription Monitoring Program - Request for Input

Gay:

Good Morning!

I wanted to let you know that unfortunately, DEA will be unable to provide any comments in this matter, as directed from our Congressional Affairs department. Lisa, Bill, Michael and I do wish you all the success in this endeavor, and regret that we could not offer more in the way of support.

Take care.

Sharnett Y. Latimore, Acting
Diversion Program Manager
Houston Field Division
713/693-3645 (O)
713/693-3388 (F)
713/539-1715 (C)

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

March 26, 2010

HB 2730 Interagency Council
Johnny Hatcher, Texas Department of Public Safety
Mari Robinson, Texas Medical Board
Gay Dodson, Texas State Board of Pharmacy

RE: Interagency Council – Request for Input

Dear Council Members:

On behalf of the approximately 2,561 chain pharmacies operating in the state of Texas, the National Association of Chain Drug Stores (NACDS) thanks the members of the Interagency Council ("Council") for requesting our input on recommended changes to the Texas Controlled Substances Act to improve the Texas Prescription Program. We commend the Council for using this process to seek improvements to the prescription monitoring program and we welcome the opportunity to convey our viewpoints on this matter.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

NACDS members believe that prescription monitoring programs can be effective tools for identifying and curbing instances of prescription drug diversion and abuse. Chain pharmacy supports programs that are aptly designed to collect dispensing data that identifies specific individuals who may be misusing or diverting controlled substances without impeding the delivery of pharmaceutical care or creating administrative burdens on the dispensers that report data to the program. With respect to the current Texas Prescription Program, we believe that several changes to the program should be made to help meet this aim more effectively and efficiently.

- **Eliminate requirement to report the prescriber's DPS number.**

Currently, dispensers must report the prescriber's Department of Public Safety ("DPS") issued registration number for each controlled substance prescription dispensed. Compliance with this requirement presents the greatest administrative challenge for pharmacies. Notably, the majority of data rejections are for errors associated with the DPS number field, which can be especially challenging to report in the required format for prescriptions issued by out-of-state prescribers without a DPS number. Considering that records flagged with errors do not get uploaded to the state's database until the error gets corrected, this problem can delay the availability of that record in the system.

While we appreciate the necessity of uniformly identifying the issuer of a prescription, there are other, more effective ways of accomplishing this. Both the Drug Enforcement Administration ("DEA") registration number and the NPI number, which any in-state and out-of-state prescriber issuing a controlled substance prescription will have, could be used for this purpose. Accordingly, we urge the Council to move to adopt one of these

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

alternative identifiers and to discontinue use of the DPS number. *Eliminating the DPS number reporting requirement is the number one way in which the Council could improve program efficiencies.*

- **Transition of the Texas Prescription Program from DPS to TSBP.**

NACDS supports the transition of the Texas Prescription Program from DPS to the Texas State Board of Pharmacy ("TSBP") as specified in HB 2730 (2009). As the agency overseeing the practice of pharmacy and general pharmacy operations, TSBP is well-suited to manage the Texas Prescription Program. Further, this change would bring the Texas program in line with the majority of other states operating prescription monitoring programs. To facilitate smooth transition of the program, the Council should pursue statutory revisions to ensure that the program funding, including the funds currently collected through registration fees paid to DPS, is appropriated to the TSBP budget. Additionally, TSBP should be authorized to apply for the various federal and private grants that are available to states with prescription monitoring programs.

- **Ease process to allow practitioner access to program data.**

Texas Health and Safety Code §481.076 authorizes pharmacists and practitioners to obtain information from the prescription monitoring program to evaluate the prescription history of a particular patient being treated or to inquire about their own dispensing or prescribing activity *if* "proper need" need has been shown. Requiring individuals to show "proper need" may actually deter health care professionals from seeking information from within the prescription monitoring program database, which seems contrary to the intent of the program. To promote greater use of the program for its intended purpose, we ask the Council to seek a revision to the law that will ease the process by which authorized health care professionals can obtain information for a specific patient being treated or the healthcare provider's own information from within the program.

- **Establish important liability protections for pharmacists and prescribers who access the prescription monitoring program database.**

A number of states have liability protections in their laws for prescribers and dispensers who report and access prescription information under the prescription monitoring program.[1,2] These important liability protections promote greater use of prescription monitoring program data amongst practitioners by creating an environment wherein prescribers and dispensers are able to report and access program data without fear of legal repercussions for any information they would act on or fail to act on. We believe that the

[1] The following states have statutory liability protections in place: AL, AK, ID, IL, IN, IA, KS, MN, NJ, NC, ND, OH, OK, OR, SC, TN, VT, VA, WA, WY

[2] Following is an example of the liability protections in the Alaska law -- AS § 17.30.200 (h):
"An individual who has submitted information to the database in accordance with this section may not be held civilly liable for having submitted the information. Nothing in this section requires or obligates a dispenser or practitioner to access or check the database before dispensing, prescribing, or administering a medication, or providing medical care to a person. Dispensers or practitioners may not be held civilly liable for damages for accessing or failing to access the information in the database."

Texas Prescription Program could be further enhanced if similar liability protections were enacted into law in the state of Texas.

- **Concerns with establishing web-based access to PMP database information.**

In the notice soliciting stakeholder input on potential improvements to Texas Prescription Program, the Council posed the question as to whether or not Texas should establish internet access to the prescription monitoring system so that prescribers, pharmacies, and law enforcement may perform an online query of data in the system. NACDS urges the Council not to pursue this change, as it could create the risk for a security data breach to occur that could expose sensitive patient records. This would not be an unprecedented event; in April 2009, hackers breached the online Virginia Prescription Monitoring Program database and exposed various records in the database. If the Council decides, in spite of this risk, to pursue program changes allowing online access to the program database, we urge the Council to allow this only as an *additional* method (not the sole method) for obtaining information from the prescription monitoring program. Doing so will provide pharmacies and other practitioners who do not want to risk exposing their own pharmacy records to an online data breach, with an alternative method for checking the program database. Pharmacies and practitioners should not be required to have internet access in order to obtain data from the prescription monitoring program.

- **Weekly reporting would provide practitioners with up-to-date dispensing information that would be sufficient to look for trends of abuse and diversion.**

Another question posed by the Council to stakeholders was whether prescription reporting frequency should be increased from "no later than the 15th day after the month in which the prescription was dispensed" to a more frequent interval. We would conditionally support increasing the reporting frequency up to a weekly basis if the program discontinues use of the DPS number as the prescriber identifier and instead allows pharmacies to report the prescriber's DEA or NPI number. As discussed earlier in our comments, there are administrative challenges associated with reporting the DPS number. Accordingly, pharmacies need the current allotted timeframe to identify, research, correct, and re-submit the numerous rejections typically associated with the DPS number.

If pharmacies were not required to report the DPS number, a weekly reporting schedule would be adequate to otherwise address rejection errors. Further, this timeframe would be sufficient for individuals with access to the database to be able to determine whether or not a particular patient is exhibiting possible patterns of abuse or diversion. Notably, if the state of Texas intends to seek a federal grant through the National All Schedules Prescription Electronic Reporting ("NASPER") grant program, it must require dispensers to report controlled substances dispensing information on a weekly basis.

In Conclusion

NACDS thanks the Council for considering our comments. Please do not hesitate to contact me with any questions or for further assistance. I can be reached at: 817-442-1155 or mstaples@nacds.org.

Sincerely,

Mary Staples
Regional Director, State Government Affairs

TEXAS FEDERATION OF DRUG STORES

"The Voice of Chain Pharmacy in the State of Texas"

DATE: March 26, 2010

TO: HB 2730 Interagency Council
Johnny Hatcher, Texas Department of Public Safety
Mari Robinson, Texas Medical Board
Gay Dodson, Texas State Board of Pharmacy

FROM: Texas Federation of Drug Stores

RE: Prescription Drug Monitoring Program – Request for Input

The Texas Federation of Drugs Stores represents fourteen chain pharmacies located in over 2,500 neighborhoods throughout the state of Texas. We thank you for the opportunity to provide our thoughts regarding a transition plan for the Prescription Monitoring Program from its current agency, the Texas Department of Public Safety (DPS), to the Texas State Board of Pharmacy (TSBP).

The Texas Federation of Drug Stores (Federation) supports an efficient and effective prescription monitoring program that does not inhibit the prescribing or dispensing of prescription drugs. We support providing the Texas Department of Public Safety, the Texas Medical Board and the Texas Board of Pharmacy the tools necessary to ensure illegal diversion of drugs is detected and eliminated. In addition, the Federation supports a program that ensures patient safety and ready access to medication while identifying those individuals who are seeking controlled substances for diversion purposes. We also believe that a prescription monitoring program should in no manner impede the ability of a patient to receive needed medications for a legitimate purpose.

The Federation supports the transition of the program from the DPS to the TSBP. The majority of states that have enacted prescription monitoring programs house the programs at their pharmacy regulatory agency and provide access to program data to law enforcement. Regulatory boards overseeing the practice of pharmacy are well-suited to manage the program because of their in-depth knowledge of how pharmacies operate and prescriber/pharmacists professional responsibilities. If the transition of the program to the Board of Pharmacy were to occur, the funding for the program must also follow. Currently, the program is funded through registration fees paid to the DPS registrants. The funding stream should remain with the program to offset operational costs. The Federation would also recommend the TSBP apply for available federal and private grants for use in operating prescription monitoring programs.

The Federation supports discontinuing the use of a DPS number in conjunction with the prescription monitoring program. The DPS-issued number does not enhance the system in either efficiency or effectiveness. Prescribers are required to register for each practice location resulting in the issuance of multiple DPS numbers for one practitioner. This increases the likelihood of unintended reporting errors in reporting information to the data base. Practitioner

identifiers, such as the Drug Enforcement Agency (DEA) identifier and National Provider Identification (NPI) identifier which are issued nationally follow the prescriber not the location and would be a more suitable identifier.

The Council has asked for input regarding frequency of reporting to the data base. Currently, pharmacies are required to provide prescription information to DPS using an electronic format "no later than the 15th day after the month in which the prescription was dispensed". All pharmacies dispensing CII through CV drugs, with the exception of inpatient hospital pharmacies filling inpatient prescriptions, must report to the program. The Federation would consider increasing the number of times per month data is reported to the program. Any changes in reporting requirements must take into consideration the different number of pharmacy computer systems in use and any additional programming, software changes, cost or workload increases.

The Federation would not support the use of a web-based application for the purposes of making a query. Pharmacies often restrict access to the internet by their employees to create a more controlled environment regarding their computer systems. Pharmacies take great lengths to ensure the security of their system and do not want to create a portal subject to intrusion by outside individuals.

In conclusion, the Federation supports a robust prescription monitoring program that is accessible to law enforcement to detect abuse and diversion of controlled substances. The program should not hinder a patient's ability to obtain needed prescription but should prevent those individuals attempting to obtain prescription drugs for diversion or abuse.

If you require additional information or have any questions regarding the Texas Federation of Drug Stores' position on this matter, please feel free to contact me at (512)472-8261 or at kbarber@txretailers.org.

Sincerely,

Kathy Barber
Executive Director
Texas Federation of Drug Stores

TEXAS HOSPITAL ASSOCIATION

From: Matt Wall
Sent: Fri, 3/26/2010 3:39 PM
To: Gay Dodson
Subject: RE: Prescription Monitoring Program - Request for Input

Hi, Gay,
Thanks for the opportunity to provide input. In THA's view, regarding #2, increasing prescription-data submittal frequency may be a burden, especially for rural hospitals. Some consideration should be given to exempting rural hospitals from any increase in reporting frequency. A possible consideration would be tying the current reporting volume to the definition used for rural hospitals recently in the tech supervision rules. As you know, in these rural hospitals the volume of prescriptions is small, they are rarely schedule I and II, and there is not a full time pharmacist.

Please let me know if you have any questions –
Matt

Matthew T. Wall, J.D.
Associate General Counsel
Texas Hospital Association
Phone: 512/465-1538
Fax: 512/692-2800
Mailing: P. O. Box 679010, Austin, Texas 78767-9010
Physical: 1108 Lavaca, Suite 700, Austin, Texas 78701

Physicians Caring for Texans

March 26, 2010

Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
333 Guadalupe Street, #3-600
Austin, Texas 78701
E-mail: gay.dodson@tsbp.state.tx.us

Re: House Bill 2730 Interagency Council; Prescription Monitoring Program – Request for Input.

Dear Ms. Dodson,

The Texas Medical Association ("TMA") is a private, voluntary, nonprofit association of Texas physicians and medical students. TMA was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, our maxim continues in the same direction: "Physicians Caring for Texans." TMA's diverse physician members practice in all fields of medical specialization.

On behalf of our nearly 45,000 member physicians, the Texas Medical Association (TMA) strongly supports electronic prescription drug monitoring and the transfer of this function to the Texas State Board of Pharmacy. We are pleased to offer the following comments and observations.

1. The federal National All Schedules Prescription Electronic Reporting System (NASPERS) has emerged as a national model. TMA believes adoption of that model or one based on this model would greatly benefit physicians, patients, licensing agencies and law enforcement. Because the heart of such a system is dependent on data provided by pharmacies and pharmacists, we support placing such a function with the Texas State Board of Pharmacy with appropriate access to law enforcement, other licensing agencies and the practitioners who are permitted by law to prescribe controlled substances.
2. Such a system should serve not only law enforcement, but also the health licensing agencies that are legislatively mandated to protect the public through the establishment and enforcement of standards for their licensees. Both are essential

elements to ensure public safety. The diversion of controlled substances has both criminal law and civil law components and the system should conveniently support queries by both law enforcement agencies and the appropriate state licensing agencies.

3. An electronic monitoring system, as envisioned for Texas, could bring about efficiencies in the secure collection, timeliness and appropriate use of data related to prescriptions for controlled substances. Most pharmacies in the state are already utilizing electronic submission of data for billing purposes. Tapping into a portion of this data stream to collect data on prescriptions for controlled substances is possible. The system should accommodate individual queries by all licensees with prescribing privileges, including those with delegated prescriptive authority, and licensing agencies which govern their practice. We believe this can be accomplished through a secure web based access. Among the benefits that will result from access are: each practitioner may monitor his/her own prescribing patterns; each practitioner can determine when a fraudulent prescription may have been written under his/her license, and facilitate appropriate action; for physicians, being able to access the system would serve as the beginnings of a convenient medication audit process for their patients for the purposes of monitoring potential drug interactions of prescriptions written by other practitioners; and the capability to flag individuals who may be "doctor shopping" or engaging in drug seeking efforts. In addition, each pharmacy may monitor its filled prescriptions and may detect early signs of diversion in their own communities.

We thank you for the opportunity to share our perspectives. We believe there are many benefits related to a robust electronic prescription drug monitoring system and we appreciate the thoughtful examination of this by the State Board of Pharmacy and the cooperation among law enforcement and professional licensing agencies in its implementation.

Sincerely,

William H. Fleming III, MD
President

WHF:df

Cc: Mari Robinson, JD
Texas Medical Board

Texas Optometric Association

"Doctors of Optometry working together to advance excellence in eyecare for every Texan."

1104 West Avenue, Austin, TX 78701 Ph: (512)707-2020 Fax: (512)326-8504 TexOp@aol.com http://texas.aoa.org

APPENDIX D

DATE: March 16, 2010

TO: House Bill 2730 Interagency Council
Gay Dodson, R.Ph., Texas State Board of Pharmacy
Johnny Hatcher, Texas Department of Public Safety
Mari Robinson, J.D., Texas Medical Board

FROM: Stanley Woo, O.D., M.S., F.A.A.O.; President, Texas Optometric Association
Bruce Onofrey, R.Ph., O.D., F.A.A.O.
Larry Gunnell, O.D.; DSHS Medical Advisory Board Physician

RE: Prescription Monitoring Program – Request for Input

We are writing in response to the request for input dated March 10, 2010 from the H.B. 2730 Interagency Council. We appreciate the opportunity to provide some background about optometry and our role as stakeholders in the Prescription Monitoring Program.

Doctors of Optometry (ODs) are the independent, primary health care professionals for the eye. We examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures as well as identify related systemic conditions affecting the eye.

Reducing the diversion of controlled substances is an important issue, and optometrists can play a role. However, in order to do so the Controlled Substances Act should be updated to reflect a standard of practice that has been in place for over 29 years. In doing so, the Texas Optometry Board would have access to licensee data, that would help them fulfill their mission to promote, preserve, and protect the health, safety and welfare needs of the people of Texas.

Lastly, we would hope that as independent prescribers, ODs would have the same access to data as fellow prescribers, pharmacies, and law enforcement regardless of the information technology platform selected.

Thank you for your consideration.

Stanley Woo, OD, MS, FAAO
President, TOA

Doctors on the Frontline of Eye and Vision Care

March 26, 2010

House Bill 2730 Interagency Council
Gay Dodson, R.Ph., Texas State Board of Pharmacy
Johnny Hatcher, Texas Department of Public Safety
Mari Robinson, J.D., Texas Medical Board

Re: Prescription Monitoring Program – Request for Input

Submit recommendations electronically to: gay.dodson@tsbp.state.tx.us

Dear House Bill 2730 Interagency Council:

Thank you for the opportunity to comment on recommendations for changes to the Texas Controlled Substances Act to improve the Prescription Monitoring Program and whether or not the program is moved.

With regards to your published questions, the TPS would like to provide the following thoughts and comments:

1. Texas should establish web access to the data in the prescription monitoring system that will allow prescribers, pharmacies, and law enforcement to query the system.

Yes, physicians will use the program more frequently and need to use it frequently because they are the individuals responsible for writing prescriptions. It is extremely important that they be able to access the information in real time (ie web access) –the current method of requesting a report in writing is not as effective. By the time you receive the results it is too late, either a patient who needs the prescription doesn't get it while awaiting the report, or a patient does get the prescription but they abuse and divert the drugs. Both ways are equally bad.

Real time access would allow physicians to check patients prescription history if they are suspected of doctor shopping or giving false information to a physician. It would also serve as a patient safety mechanism for physicians to look up other current medication and avoid possible drug – drug interactions. A very successful program is Kentucky's eKASPER program, where over 90% of all inquiries made are by physicians.

According to the Drug Enforcement Agency (DEA) as of January 2010, 34 states have operational PDMPs that have the capacity to receive and distribute controlled substance prescription information to authorized users. Five states (Alaska, Florida, Kansas, Oregon, and New Jersey) and one U.S. territory (Guam) have enacted legislation to establish a PDMP, but are not fully operational. (http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm#4)

2. Pharmacies should be required to submit prescription data to the program more often so that the data is more up to date and useful. Currently Texas pharmacies are required to send data "no later than the 15th day after the month in which the prescription was dispensed." This means that the data may be up to 45-days old before it is submitted. To make the data more up-to-date, how often should pharmacies be required to submit prescription data?

As a practical matter weekly reporting would be ideal, but every two weeks is good, however monthly is acceptable. We need to thoroughly consider what is cost effective and practical – patients that are doctor shopping will continue to shop week after week because they need the revenue. Therefore the question is how quickly do you want to catch them and at what cost.

3. Over the last few years, several additional practitioners have been given the authority to prescribe controlled substances, e.g., Advanced Nurse Practitioners (APN) and Therapeutic Optometrist. These individuals are allowed to access information in the Prescription Monitoring Program but the Controlled Substances Act has not been amended to allow the Board of Nursing or the Texas Optometry Board to access the information. Should the Texas Controlled Substances Act be amended to allow the licensing boards for all healthcare professionals allowed to prescribe controlled substances to access data on their licensees?

Absolutely, all licensing boards for healthcare professionals allowed to prescribe controlled substances should be able to access the data. Abuse can occur in all areas, across all socioeconomic groups, and across all professions, therefore the regulating boards and agencies need access to ensure proper oversight of licensees.

Additionally, the TPS strongly recommends that the National All Schedules Prescription Electronic Reporting (NASPER) Act, HR 1132 that was signed into law on August 12 2005, be used as the model for the Texas Electronic Prescription Program because:

1) it would increase the state's access to funding under the NASPER Act & Harold Rogers Prescription Drug Monitoring Program (HRPDM). Currently for FY2010 there is $7 million in funding from the HRPDMP (www.ojp.usdoj.gov/BJA/grant/prescripdrugs.html) and $2 million in funding from the NASPER Act.

2) pill mills flourish by operating close to state lines and its paramount that we be able to exchange data across state lines to combat prescription diversion. The standardization of the nomenclature and electronic systems is necessary to accomplish this goal.

3) in order to conform with national nomenclature we strongly recommend the Texas program be referred to as Texas All Schedules Prescription Electronic Reporting (TASPER).

Kentucky is an excellent example of a state that has successfully followed the NASPER model and implemented KASPER (Kentucky All Schedules Prescription Electronic Reporting). Their website is a wealth of information (http://chfs.ky.gov/os/oig/KASPER.htm and additional information at http://pmp.relayhealth.com/KY/).

More information on other state programs (including funding) is available from the Alliance of States with Prescription Monitoring Programs (http://www.pmpalliance.org/).

The TPS strongly supports a reliable, accessible, accurate, robust and real time electronic prescription monitoring program for Texas. We appreciate your consideration of our recommendation for the benefit of Texas patients. It is our hope that together we can work out a system that will provide a solution that establishes a meaningful **BALANCE** between **ACCESS** to care and preventing **DIVERSION** and abuse of medications.

If you have any questions or if we can provide any further explanation or expertise, please do not hesitate to contact us.

Sincerely,

Allen. W. Burton, MD
Texas Pain Society
President

C.M. Schade, MD, PhD
Texas Pain Society
TMA Delegate & TPS Board Emeritus

enclosure

P.O. Box 201413 · Austin, Texas 78720-1413 · Ph 512.535.0010 · Toll Free 866.324.7922 · Fax 866.235.2557 · www.texaspain.org

The mission of the TPS is to be the organization of pain medicine practitioners that represents the interests of patients, the public, physicians, and others involved in the care of Texans who suffer from pain.

Alliance of States with Prescription Monitoring Programs
Promoting Public Health and Safety

PRESCRIPTION MONITORING PROGRAM MODEL ACT 2010 Revision

Section 1. Short Title.

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

Section 2. Legislative Findings

[Insert state findings]

Section 3. Purpose

The purposes of this act are:

1. To enhance patient care by providing prescription monitoring information that will assure legitimate use of controlled substances in health care, including palliative care, research and other medical and pharmacological uses.
2. To help curtail the misuse and abuse of controlled substances.
3. To assist in combating illegal trade in and diversion of controlled substances.
4. To enable the access to prescription information by practitioners, pharmacists, law enforcement, researchers and regulatory and other authorized individuals and agencies, and to make this information available to the same entities in other states.

Section 4. Definitions

(a) "Controlled substance" has the meaning given such term in [section of the state controlled substances act].

(b) [Designated state agency] means the state agency responsible for the functions listed in Section 5.

(c) "Dispense" means to deliver a controlled substance or other drug required to be submitted under Section 5 of this Act to an ultimate user or research subject by lawful means and includes the packaging, labeling, or compounding necessary to prepare the substance for such delivery.

(d) "Dispenser" means a person who is lawfully authorized to deliver a Schedule II, III, IV and/or V controlled substance, as defined in subsection (k), or other drug required to be submitted under Section 5 of this Act to the ultimate user, but does not include:

(I) A licensed hospital or institutional facility pharmacy that distributes such substances for the purpose of inpatient hospital care [or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility];

(II) A practitioner, or other authorized person who administers such a substance; or

(III) A wholesale distributor of a Schedule II, III, IV and/or V controlled substance or other drug required to be submitted under Section 5 of this Act.

(e) "Interoperability" means, with respect to a state prescription monitoring program, the ability of that program to share electronically reported prescription information with another State's prescription monitoring program.

(f) "Patient" means the person or animal who is the ultimate user of a controlled substance or other drug required to be submitted under Section 5 of this Act for whom a lawful prescription is issued and/or for whom a controlled substance or such other drug is lawfully dispensed.

(g) "Practitioner" means a physician, dentist, podiatrist, veterinarian, or other person licensed or otherwise permitted to prescribe, dispense, or administer a controlled substance or other drug required to be submitted under Section 5 of this Act in the course of a licensed professional practice.

(h) "Prescribe" means to issue a direction or authorization, by prescription, permitting a patient to obtain lawfully controlled substances.

(i) "Prescriber" means a practitioner or other authorized person who prescribes a Schedule II, III, IV and V controlled substance or other drug required to be submitted under Section 5 of this Act.

(j) "Prescription monitoring program" means a program that collects, manages, analyzes, and provides information regarding Schedule II, III, IV and V controlled substances or other drug required to be submitted under Section 5 of this Act or program established by a similar act in another state, district or territory of the United States.

(k) "Schedule II, III, IV and V controlled substances" means drugs or drug products that are included in or assigned to Schedules II, III, IV and V as provided under [insert

section of the state controlled substances act] or the Federal Controlled Substances Act.

(l) "State" means state, district or territory of the United States.

Section 5. Requirements for Prescription Monitoring Program.

(a) The [designated state agency] shall establish and maintain a program for the monitoring of prescribing and dispensing of all Schedule II, III, IV and V controlled substances [and, if selected by the state, additional drugs identified by the designated state agency as demonstrating a potential for abuse] by all prescribers or dispensers in this state.

(b) Each dispenser shall submit to the [designated state agency] information regarding each prescription dispensed for a controlled substance or other drug included under subsection (a) of this section. Any dispenser located outside the boundaries of [name of state] and is licensed and registered by the [insert name of state board of registration/licensure in pharmacy] shall submit information regarding each prescription dispensed to an ultimate user who resides within [name of state].

(c) Each dispenser required to report under subsection (b) of this section shall submit to the [designated state agency] by electronic means information that shall include, but not be limited to:

(I) Dispenser identification number.
(II) Date prescription filled.
(III) Prescription number.
(IV) Prescription is new or is a refill.
(V) NDC code for drug dispensed.
(VI) Quantity dispensed.
(VII) Days' supply dispensed
(VIII) Number of refills ordered
(IX) Patient identification number.
(X) Patient name.
(XI) Patient address.
(XII) Patient date of birth.
(XIII) Patient gender
(XIV) Prescriber identification number.
(XV) Date prescription issued by prescriber.
(XVI) Person who receives the prescription from the dispenser, if other than the patient.
(XVII) Source of payment for prescription.

(XVIII) State issued serial number [if state chooses to establish a serialized prescription system].

(d) Each dispenser shall submit the required information in accordance with transmission methods and frequency established by the [designated state agency]; but no more than seven days from the date each prescription was dispensed.

(e) The [designated state agency] may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information by paper form or other means, provided all information required in subsection (c) of this section is submitted in this alternative format.

[Note: the following subsections, (f) – (i), are intended for those states that choose to establish a serialized prescription form system as part of the prescription monitoring program.]

(f) A serialized [single copy or multiple copy] prescription form, shall be issued by the [designated state agency] to individual [insert "and institutional" if practitioners in health care institutions issue prescriptions that can be filled in pharmacies outside the institutions] prescribers and shall be used for all prescriptions for drugs in [Schedule II, III, IV and V] controlled substances. Each series of prescriptions shall be issued to a specific prescriber [in consecutively numbered blocks of ____] and shall only be used by that prescriber.

(g) Each prescriber shall only prescribe [Schedule II, III, IV and V] controlled substances on official serialized prescription forms issued by the [designated state agency].

(h) Each dispenser shall only dispense [Schedule II, III, IV and V] controlled substances on such official serialized prescription forms.

(i) The [designated state agency] may charge each prescriber an amount sufficient to cover the costs of processing requests for forms, printing the prescription forms, and operating the prescription monitoring program.

[Note: States may choose to use an alternative method other than paragraph (i) to pay the cost of their serialized prescription forms and monitoring system, for example, through controlled substances registration fees. In such instances, subsection (i) can be deleted.]

Section 6. Confidentiality.

a) Prescription information submitted to the [designated state agency] shall be confidential and not subject to public or open records laws, except as provided in section 7.

[Note: States may choose to also amend their open record statutes to exclude specifically from disclosure prescription information collected by their prescription monitoring program.]

b) The [designated state agency] shall establish and enforce policies and procedures to ensure that the privacy and confidentiality of patients are maintained and that patient information collected, recorded, transmitted, and stored is protected and not disclosed to persons except as in section 7.

c) The PMP shall establish and maintain a process for verifying the credentials and authorizing the use of prescription information by those individuals and agencies listed in subsections (b) and (c) of section 7 of this Act.

Section 7, Providing Prescription Monitoring Information

(a) The [designated state agency or entity] should review the prescription information. Such reviews should include but not be limited to:

(I) A review to identify information that appears to indicate if a person may be obtaining prescriptions in a manner that may represent misuse or abuse of controlled substances. When such information is identified, the [designated state agency] should notify the practitioners and dispensers who prescribed or dispensed the prescriptions.

(II) A review to identify information that appears to indicate if a violation of law or breach of professional standards may have occurred. Whenever such information is identified, the [designated state agency] should notify the appropriate law enforcement and/or professional licensing, certification or regulatory agency or entity, and provide prescription information necessary for an investigation.

(b) The [designated state agency] is authorized to provide information in the prescription monitoring program upon request only to the following persons.

(I) Persons authorized to prescribe or dispense controlled substances or other drug required to be submitted under Section 5 of this Act, for the purpose of providing medical or pharmaceutical care for their patients or for reviewing information regarding prescriptions that are recorded as having been issued or dispensed by the requester.

(II) A patient who requests the patient's own prescription monitoring information, or of the parent or legal guardian of a minor child, in accordance with procedures

established under [insert state statute granting individuals access to state held information concerning themselves].

(III) [Insert name or type of state boards and regulatory agencies that supervise or regulate a profession that is authorized for controlled substances or other drug required to be submitted under Section 5 of this Act activity] if the request is pursuant to an investigation or is pursuant to the agency's official duties and responsibilities.

(IV) Local, state and federal law enforcement or prosecutorial officials engaged in the administration, investigation or enforcement of the laws governing controlled substances or other drug required to be submitted under Section 5 of this Act pursuant to the agency's official duties and responsibilities.

(V) [Insert state Medicaid agency's unit(s) with legal authority to conduct investigations and utilization review of program services] regarding Medicaid program recipients or Medicaid program providers.

(VI) [Insert titles of medical examiners, coroners or others authorized under law to investigate causes of deaths] for cases under investigation pursuant to their official duties and responsibilities.

(VII) Personnel of the [designated state agency] for purposes of administration and enforcement of this Act, or [insert state controlled substances act], [if any other state statute is applicable, insert "or" and reference the other statutes].

[Note: A state may determine to authorize additional agencies to request and receive prescription information including substance abuse treatment providers, worker's compensation board reviewers who are health care professionals, drug court judges, department of corrections' health care professional staff, and probation departments, if they cannot receive information under other provisions already authorized in (I) through (VII)]

(c) The [designated state agency] may provide information to public or private entities for statistical, research, or educational purposes after encrypting or removing the patient name, street name and number, patient ID number, and month and day of birth that could be used to identity individual patients and/or persons who received prescriptions from dispensers.

[Note: A state may choose to further restrict information released to researchers by encrypting or removing information that could be used to identify a prescriber, a pharmacy, or any other person.]

Section 8. Information exchange with other prescription monitoring programs

a) The [designated state agency] may provide prescription monitoring information to other states' prescription monitoring programs and such information may be used by those programs consistent with the provisions of this Act.

b) The [designated state agency] may request and receive prescription monitoring information from other states' prescription monitoring programs and may use such information under provisions of this Act.

c) The [designated state agency] may develop the capability to transmit information to and receive information from other prescription monitoring programs employing the standards of interoperability.

d) The [designated state agency] is authorized to enter into written agreements with other states' prescription monitoring programs for the purpose of describing the terms and conditions for sharing of prescription information under this section.

[Note: Some states have determined that their statute authorizes exchange of prescription monitoring information for individual cases with other PMPs without specific authorization, e.g. their statute lists authorized recipients of prescription monitoring information without regard to the residency of the recipients.]

[Note: Some states have determined that before their PMP begins routine exchange of prescription information with another PMP, their PMP must have a written memorandum of understanding in place with the other states' PMPs and/or there must be an interstate compact for such exchange (a committee is working on drafting such a compact as of February 2010).]

[Note: This section is not intended to interfere with a state's prerogative to provide prescription information directly to authorized persons or entities in other states.]

Section 9. Authority to Contract

The [designated state agency] is authorized to contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. Any contractor shall be bound to comply with the provisions regarding confidentiality of prescription information in Section 6 of this Act and shall be subject to the penalties specified in Section 11 of this Act for unlawful acts.

Section 10. Rules and Regulations.

The [designated state agency] shall promulgate rules and regulations setting forth the procedures and methods for implementing this Act.

Section 11. Unlawful Acts and Penalties.

(a) A dispenser who knowingly fails to submit prescription monitoring information to the [designated state agency or entity] as required by this Act or knowingly submits incorrect prescription information shall be subject to [insert appropriate administrative, civil or criminal penalty].

(b) A person authorized to receive prescription monitoring information pursuant to this Act who knowingly discloses such information in violation of this Act shall be subject to [insert appropriate administrative, civil or criminal penalty.]

(c) A person authorized to receive prescription monitoring information pursuant to this Act who uses such information in a manner or for a purpose in violation of this Act shall be subject to [insert appropriate administrative, civil or criminal penalty.]

(d) A person who obtains or attempts to obtain information by fraud or deceit from the prescription monitoring program or from a person authorized to receive prescription monitoring information under this Act shall be subject to [insert appropriate administrative, civil or criminal penalty.]

Section 12. Severability.

If any provision of this Act or application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act which can be given effect without the invalid provisions or applications, and to this end the provisions of this Act are severable.

Section13. Effective Date.

This Act shall be effective on [insert specific date or reference to normal state method of determination of the effective date].

Approved by the Alliance of States with Prescription Monitoring Programs at the Annual Business Meeting, June 28, 2010.

APPENDIX F

ASIPP ADVOCACY

Home

Members Only
About ASIPP
Join Us
Journal
Health Policy
Fee Schedules
Advocacy
Meetings
Publications

· AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS ·

" The Voice Of Interventional Pain Management "

PROMOTING THE DEVELOPMENT AND PRACTICE
OF SAFE, HIGH QUALITY, COST-EFFECTIVE
INTERVENTIONAL PAIN MANAGEMENT TECHNIQUES

National All Schedules Prescription Electronic Reporting Act of 2005

(Enrolled as Agreed to or Passed by Both House and Senate)
--H.R.1132--
H.R.1132
One Hundred Ninth Congress of the United States of America

AT THE FIRST SESSION
Begun and held at the City of Washington on Tuesday, the fourth day of January, two thousand and five
An Act yo provide for the establishment of a controlled substance monitoring program in each State.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `National All Schedules Prescription Electronic Reporting Act of 2005'.

SEC. 2. PURPOSE.

It is the purpose of this Act to--

(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

(2) establish, based on the experiences of existing State controlled substance monitoring programs, a set of best practices to guide the establishment of new State programs and the improvement of existing programs.

SEC. 3. CONTROLLED SUBSTANCE MONITORING PROGRAM.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding after section 399N the following:

SEC. 399O. CONTROLLED SUBSTANCE MONITORING PROGRAM.

`(a) Grants-

`(1) IN GENERAL- Each fiscal year, the Secretary shall award a grant to each State with an application approved under this section to enable the State--

`(A) to establish and implement a State controlled substance monitoring program; or

`(B) to make improvements to an existing State controlled substance monitoring program.

`(2) DETERMINATION OF AMOUNT-

`(A) MINIMUM AMOUNT- In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount that equals 1.0 percent of the amount appropriated to carry out this section for that fiscal year.

`(B) ADDITIONAL AMOUNTS- In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an additional amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year and remaining after amounts are made available under subparagraph (A) as the number of pharmacies of the State bears to the number of pharmacies of all States with applications approved under this section (as determined by the Secretary), except that the Secretary may adjust the amount allocated to a State under this subparagraph after taking into consideration the budget cost estimate for the State's controlled substance monitoring program.

`(3) TERM OF GRANTS- Grants awarded under this section shall be obligated in the year in which funds are allotted.

`(b) Development of Minimum Requirements- Prior to awarding a grant under this section, and not later than 6 months after the date on which funds are first appropriated to carry out this section, after seeking consultation with States and other interested parties, the Secretary shall, after publishing in the Federal Register proposed minimum requirements and receiving public comments, establish minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).

`(c) Application Approval Process-

`(1) IN GENERAL- To be eligible to receive a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such assurances and information as the Secretary may reasonably require. Each such application shall include--

`(A) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(A)--

`(i) a budget cost estimate for the controlled substance monitoring program to be implemented under the grant;

`(ii) criteria for security for information handling and for the database maintained by the State under subsection (e) generally including efforts to use appropriate encryption technology or other appropriate technology to protect the security of such information;

`(iii) an agreement to adopt health information interoperability standards, including health vocabulary and messaging standards, that are consistent with any such standards generated or identified by the Secretary or his or her designee;

`(iv) criteria for meeting the uniform electronic format requirement of subsection (h);

`(v) criteria for availability of information and limitation on access to program personnel;

`(vi) criteria for access to the database, and procedures to ensure that information in the database is accurate;

`(vii) criteria for the use and disclosure of information, including a description of the certification process to be applied to requests for information under subsection (f);

`(viii) penalties for the unauthorized use and disclosure of information maintained in the State controlled substance monitoring program in violation of applicable State law or regulation;

`(ix) information on the relevant State laws, policies, and procedures, if any, regarding purging of information from the database; and

`(x) assurances of compliance with all other requirements of this section; or

`(B) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(B)--

`(i) a budget cost estimate for the controlled substance monitoring program to be improved under the grant;

`(ii) a plan for ensuring that the State controlled substance monitoring program is in compliance with the criteria and penalty requirements described in clauses (ii) through (viii) of subparagraph (A);

`(iii) a plan to enable the State controlled substance monitoring program to achieve interoperability with at least one other State controlled substance monitoring program; and

`(iv) assurances of compliance with all other requirements of this section or a statement describing why such compliance is not feasible or is contrary to the best interests of public health in such State.

`(2) STATE LEGISLATION- As part of an application under paragraph (1), the Secretary shall require a State to demonstrate that the State has enacted legislation or regulations to permit the implementation of the State controlled substance monitoring program and the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained in such program.

`(3) INTEROPERABILITY- If a State that submits an application under this subsection geographically borders another State that is operating a controlled substance monitoring program under subsection (a)(1) on the date of submission of such application, and such applicant State has not achieved interoperability for purposes of information sharing between its monitoring program and the monitoring program of such border State, such applicant State shall, as part of the plan under paragraph (1)(B)(iii), describe the manner in which the applicant State will achieve interoperability between the monitoring programs of such States.

`(4) APPROVAL- If a State submits an application in accordance with this subsection, the Secretary shall approve such application.

`(5) RETURN OF FUNDS- If the Secretary withdraws approval of a State's application under this section, or the State chooses to cease to implement or improve a controlled substance monitoring program under this section, a funding agreement for the receipt of a grant under this section is that the State will return to the Secretary an amount which bears the same ratio to the overall grant as the remaining time period for expending the grant funds bears to the overall time period for expending the grant (as specified by the Secretary at the time of the grant).

`(d) Reporting Requirements- In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B) submit to the Secretary for approval a statement of why such compliance is not feasible or is contrary to the best interests of public health in such State, with the following:

`(1) The State shall require dispensers to report to such State each dispensing in the State of a controlled substance to an ultimate user not later than 1 week after the date of such dispensing.

`(2) The State may exclude from the reporting requirement of this subsection--

`(A) the direct administration of a controlled substance to the body of an ultimate user;

`(B) the dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less; or

`(C) the administration or dispensing of a controlled substance in accordance with any other exclusion identified by the Secretary for purposes of this paragraph.

`(3) The information to be reported under this subsection with respect to the dispensing of a controlled substance shall include the following:

`(A) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) of the dispenser.

`(B) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) and name of the practitioner who prescribed the drug.

`(C) Name, address, and telephone number of the ultimate user or such contact information of the ultimate user as the Secretary determines appropriate.

`(D) Identification of the drug by a national drug code number.

`(E) Quantity dispensed.

`(F) Number of refills ordered.

`(G) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

`(H) Date of the dispensing.

`(I) Date of origin of the prescription.

`(J) Such other information as may be required by State law to be reported under this subsection.

`(4) The State shall require dispensers to report information under this section in accordance with the electronic format specified by the Secretary under subsection (h), except that the State may waive the requirement of such format with respect to an individual dispenser that is unable to submit such information by electronic means.

`(e) Database- In implementing or improving a controlled substance monitoring program under this section, a State shall comply with the following:

`(1) The State shall establish and maintain an electronic database containing the information reported to the State under subsection (d).

`(2) The database must be searchable by any field or combination of fields.

`(3) The State shall include reported information in the database in a manner consistent with criteria established by the Secretary, with appropriate safeguards for ensuring the accuracy and completeness of the database.

`(4) The State shall take appropriate security measures to protect the integrity of, and access to, the database.

`(f) Use and Disclosure of Information-

`(1) IN GENERAL- Subject to subsection (g), in implementing or improving a controlled substance monitoring program under this section, a State may disclose information from the database established under subsection (e) and, in the case of a request under subparagraph (D), summary statistics of such information, only in response to a request by--

`(A) a practitioner (or the agent thereof) who certifies, under the procedures determined by the State, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;

`(B) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding;

`(C) the controlled substance monitoring program of another State or group of States with whom the State has established an interoperability agreement;

`(D) any agent of the Department of Health and Human Services, a State medicaid program, a State health department, or the Drug Enforcement Administration who certifies that the requested information is necessary for research to be conducted by such department, program, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature; or

`(E) an agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's controlled substance monitoring program, who

certifies that--

`(i) the State has an application approved under this section; and

`(ii) the requested information is for the purpose of implementing the State's controlled substance monitoring program under this section.

`(2) DRUG DIVERSION- In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving a grant under subsection (a)--

`(A) shall establish a program to notify practitioners and dispensers of information that will help identify and prevent the unlawful diversion or misuse of controlled substances; and

`(B) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the database maintained by the State under subsection (e) indicates an unlawful diversion or abuse of a controlled substance.

`(g) Limitations- In implementing or improving a controlled substance monitoring program under this section, a State--

`(1) shall limit the information provided pursuant to a valid request under subsection (f)(1) to the minimum necessary to accomplish the intended purpose of the request; and

`(2) shall limit information provided in response to a request under subsection (f)(1)(D) to nonidentifiable information.

`(h) Electronic Format- The Secretary shall specify a uniform electronic format for the reporting, sharing, and disclosure of information under this section.

`(i) Rules of Construction-

`(1) FUNCTIONS OTHERWISE AUTHORIZED BY LAW- Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

`(2) NO PREEMPTION- Nothing in this section shall be construed as preempting any State law, except that no such law may relieve any person of a requirement otherwise applicable under this Act.

`(3) ADDITIONAL PRIVACY PROTECTIONS- Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

`(4) FEDERAL PRIVACY REQUIREMENTS- Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191; 110 Stat. 2033) and section 543 of the Public Health Service Act.

`(5) NO FEDERAL PRIVATE CAUSE OF ACTION- Nothing in this section shall be construed to create a Federal private cause of action.

`(j) Studies and Reports-

`(1) IMPLEMENTATION REPORT-

`(A) IN GENERAL- Not later than 180 days after the date of enactment of this section, the Secretary, based on a review of existing State controlled substance monitoring programs and other relevant information, shall determine whether the implementation of such programs has had a substantial negative impact on--

`(i) patient access to treatment, including therapy for pain or controlled substance abuse;

`(ii) pediatric patient access to treatment; or

`(iii) patient enrollment in research or clinical trials in which, following the protocol that has been approved by the relevant institutional review board for the research or clinical trial, the patient has obtained a controlled substance from either the scientific investigator conducting such research or clinical trial or the agent thereof.

`(B) ADDITIONAL CATEGORIES OF EXCLUSION- If the Secretary determines under subparagraph (A) that a substantial negative impact has been demonstrated with regard to one or more of the categories of patients described in such subparagraph, the Secretary shall identify additional appropriate categories of exclusion from reporting as authorized under subsection (d)(2)(C).

`(2) PROGRESS REPORT- Not later than 3 years after the date on which funds are first appropriated under this section, the Secretary shall--

`(A) complete a study that--

`(i) determines the progress of States in establishing and implementing controlled substance monitoring programs under this section;

`(ii) provides an analysis of the extent to which the operation of controlled substance

monitoring programs have reduced inappropriate use, abuse, or diversion of controlled substances or affected patient access to appropriate pain care in States operating such programs;

`(iii) determines the progress of States in achieving interoperability between controlled substance monitoring programs, including an assessment of technical and legal barriers to such activities and recommendations for addressing these barriers;

`(iv) determines the feasibility of implementing a real-time electronic controlled substance monitoring program, including the costs associated with establishing such a program;

`(v) provides an analysis of the privacy protections in place for the information reported to the controlled substance monitoring program in each State receiving a grant for the establishment or operation of such program, and any recommendations for additional requirements for protection of this information;

`(vi) determines the feasibility of implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in controlled substance monitoring programs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

`(vii) evaluates the penalties that States have enacted for the unauthorized use and disclosure of information maintained in the controlled substance monitoring program, and reports on the criteria used by the Secretary to determine whether such penalties qualify as appropriate pursuant to this section; and

`(B) submit a report to the Congress on the results of the study.

`(k) Preference- Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) and for which only States are eligible to apply, shall give preference to any State with an application approved under this section. The Secretary shall have the discretion to apply such preference to States with existing controlled substance monitoring programs that meet minimum requirements under this section or to States that put forth a good faith effort to meet those requirements (as determined by the Secretary).

`(l) Advisory Council-

`(1) ESTABLISHMENT- A State may establish an advisory council to assist in the establishment, implementation, or improvement of a controlled substance monitoring program under this section.

`(2) LIMITATION- A State may not use amounts received under a grant under this section for the operations of an advisory council established under paragraph (1).

`(3) SENSE OF CONGRESS- It is the sense of the Congress that, in establishing an advisory council under this subsection, a State should consult with appropriate professional boards and other interested parties.

`(m) Definitions- For purposes of this section:

`(1) The term `bona fide patient' means an individual who is a patient of the practitioner involved.

`(2) The term `controlled substance' means a drug that is included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act.

`(3) The term `dispense' means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

`(4) The term `dispenser' means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

`(5) The term `interoperability' with respect to a State controlled substance monitoring program means the ability of the program to electronically share reported information, including each of the required report components described in subsection (d), with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

`(6) The term `nonidentifiable information' means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

`(7) The term `practitioner' means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he or she practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

`(8) The term `State' means each of the 50 States and the District of Columbia.

`(9) The term `ultimate user' means a person who has obtained from a dispenser, and who possesses, a controlled substance for his or her own use, for the use of a member of his or her household, or for the use of an animal owned by him or her or by a member of his or her household.

APPENDIX F

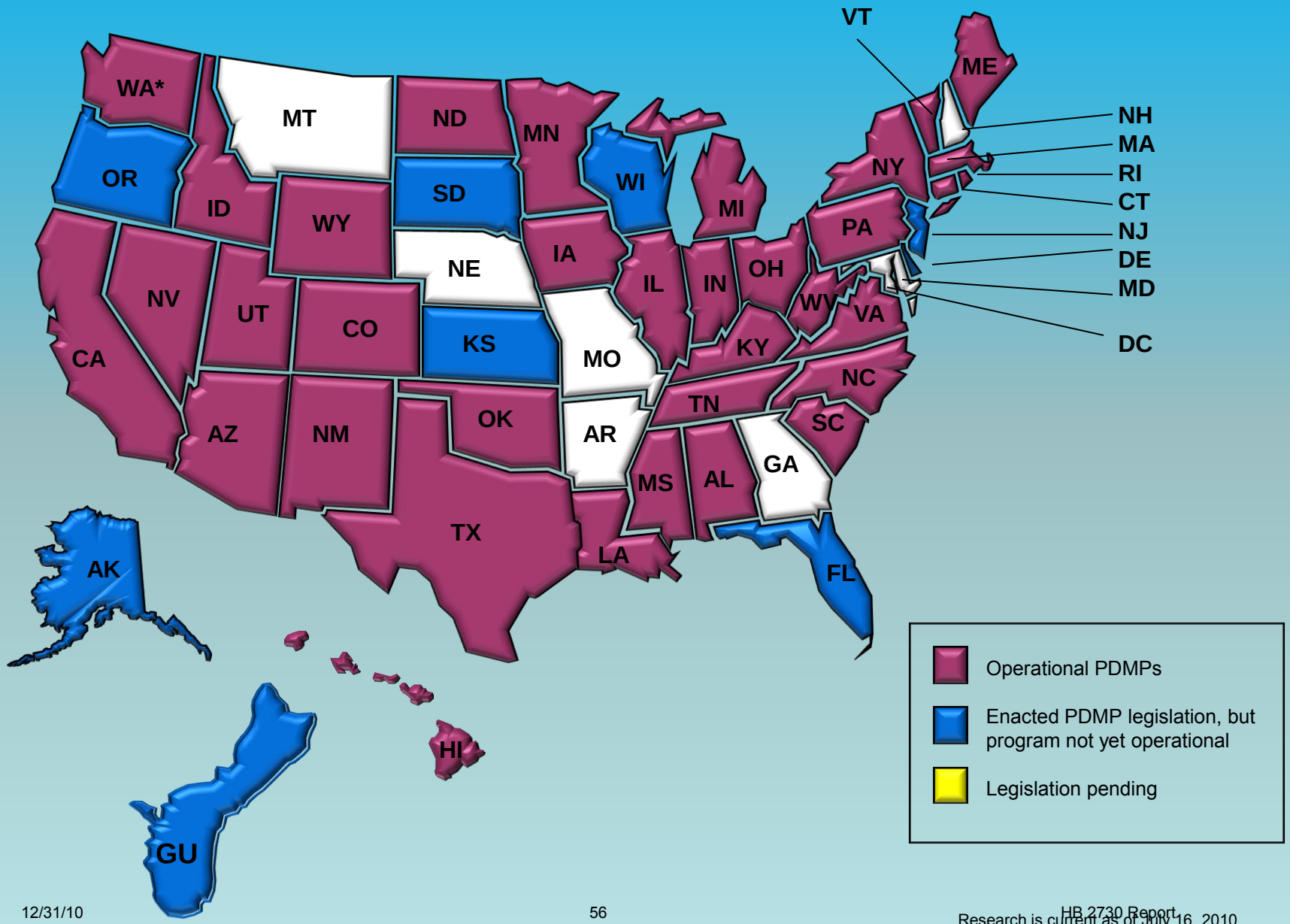
`(n) Authorization of Appropriations- To carry out this section, there are authorized to be appropriated--

`(1) $15,000,000 for each of fiscal years 2006 and 2007; and

`(2) $10,000,000 for each of fiscal years 2008, 2009, and 2010.'.

Speaker of the House of Representatives.
Vice President of the United States and
President of the Senate.

Status of Prescription Drug Monitoring Programs (PDMPs)



*Washington has temporarily suspended its PMP operations due to budgetary constraints.

Research is current as of July 16, 2010

Alliance of States with Prescription Monitoring Programs

Promoting Public Health and Safety

Prescription Monitoring Frequently Asked Questions (FAQ)

What is a Prescription Monitoring Program?
Prescription Monitoring Programs (PMPs) are highly effective tools utilized by government officials for reducing prescription drug abuse and diversion. PMPs collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners. The data are used to support states' efforts in education, research, enforcement and abuse prevention. PMPs are managed under the auspices of a state, district, commonwealth, or territory of the United States.

States recognize the medical need for controlled substances and, therefore, PMPs do not interfere with appropriate, medical use. Prescription data is provided ***only*** to entities authorized by state law to access the program, such as health care practitioners, pharmacists, regulatory boards and law enforcement agencies.

PMPs are proactive in safeguarding public health and safety while supporting the legitimate use of controlled substances. PMPs do not infringe on the legitimate prescribing of a controlled substance by a practitioner acting in good faith and in the course of a professional practice.

How many States have a PMP?
Currently 43 states and one territory have legislation authorizing the creation and operation of a PMP. Thirty-four States currently have a PMP that is operational (meaning collecting data from dispensers and reporting information from the database to authorized users). For more information, visit the Alliance website at www.pmpalliance.org where you can view our PMP Program Status Map or Table. To learn more about a specific state PMP, please also visit our State Profile Section.

How do I find State Laws and Rules that govern a PMP in my state?
The State Profiles have a link to each state's laws and rules governing their PMPs on our website at www.pmpalliance.org.

What agency administers the PMP in each State?
A variety of state agencies administer the PDMP:

Consumer Protection	1
Substance Abuse	2
Law Enforcement	6
Professional Licensing	7
Departments of Health	11
Boards of Pharmacy	16
TOTAL	**43**

Information about which agency is responsible for the PMP in a specific state is available on our website at www.pmpalliance.org on our State Profiles. You may also view our state agency map to see a nation-wide look.

PO Box 438, Voorheesville, NY 12186 | Phone: 360.556.7152 | Fax: 888.705.8053
Email: assist@pmpalliance.org | Website: *www.pmpalliance.org*

Alliance of States with Prescription Monitoring Programs

Promoting Public Health and Safety

What drugs are monitored by PMPs?
Per state law, PMPs monitor controlled substances as defined by Federal and State Controlled Substances Laws. Most PMPs collect federal schedules II-IV which contain narcotics like hydrocodone, tranquilizers like alprazolam and diazepam, and stimulants like methylphenidate. Some PMPs also monitor additional drugs of concern such as carisoprodol. To find out which drugs are monitored by a specific state we again direct you to our State Profiles on our website at www.pmpalliance.org.

- 1 PMP collects only schedule II: PA
- 2 PMPs collect only Schedule II & III: RI, WI
- 17 PMPs collect Schedules II - IV: AZ, CA, FL, IA, KS, ME, MN, NV, NJ, NM, OR, SC, SD, VT, VA, WV, WY
- 24 PMPs collect Schedules II - V: AK, AL, CO, CT, DE, Guam, HI, ID, IL, IN, KY, LA, MA, MI, MS, NY, NC, ND, OH, OK, TN, TX, UT, WA

Who is typically provided access to PMP information?
Access to PMP information is determined by state law. Most States allow practitioners and pharmacists to obtain PMP reports on patients under their care.

Many states also provide PMP information to other authorized groups that may include:

- Law Enforcement for drug investigations (open investigations and sometimes court orders are required)
- Licensing and Regulatory Boards for investigating health care professionals who prescribe or dispense prescription controlled substances
- State Medicaid Programs for Medicaid member or provider reviews
- State medical examiners or coroners for cause of death investigations
- Research organizations that may be provided de-identified data for analysis and research

Who do I contact in my state/territory for questions about my local PMP?
A contact list is maintained on our website that has contacts for each PMP as well as other partner agencies and organizations.

What type of Training and Technical Assistance is available and how do I request assistance?
Made possible through the partnership of three groups – The Bureau of Justice Assistance (BJA), The Schneider Institutes for Health Policy at Brandeis University, and The Alliance – the Training and Technical Assistance Center is helping BJA grantees and others in planning, implementing and enhancing prescription monitoring programs.

More information on the types of assistance available and how to make requests may be found on our Training and Technical Assistance Page at www.pmpalliance.org.

PO Box 438, Voorheesville, NY 12186 | Phone: 360.556.7152 | Fax: 888.705.8053
Email: assist@pmpalliance.org | Website: *www.pmpalliance.org*