

**Maryland Advisory Council on
Prescription Drug Monitoring
Legislative Report**



Prepared by the
**Maryland Advisory Council on
Prescription Drug Monitoring
December 31, 2009**

Table of Contents

Executive Summary	4
Preamble	5
<i>States that have enacted programs and information available nationally:</i>	6
<i>The “Curran” Report and the 2006 Legislation enacted and vetoed:</i>	6
<i>Definitions not included in this recommendation:</i>	7
The Recommendations of the Advisory Council	10
Recommendation No. 1: Drugs included	10
Recommendation No. 2: Advisory Board.....	10
<i>Composition of the Advisory Board</i>	10
<i>Chair of the Advisory Board</i>	11
<i>Duties of the Advisory Board</i>	11
Recommendation No. 3: Who should be required to submit information to the data base.	13
<i>Dispensers</i>	13
<i>Recommended exclusions from the reporting requirements</i>	13
Recommendation No. 4: Information submitted.....	14
Recommendation No. 5: How Information is to be submitted–The Data Base	14
Recommendation No. 6: Access to the PDMP Data Base	14
<i>Who may have access to data base? Confidentiality</i>	14
Recommendation No. 7: Patient Access to Data Base.....	15
Recommendation No. 8: Confidentiality and Security	16
<i>How to best insure that information in data base remain confidential?</i>	16
Recommendation No. 9: Housing of Data Base	17
Recommendation No. 10: Funding.....	17
Recommendation No. 11: Immunity.....	17
Recommendation No. 12: Technical Review Committee.....	18
Recommendation No. 13: Public Policy	18
Recommendation No. 14: Education	18
Recommendation No. 15: Outcome.....	19
Recommendation No. 16: Data Mining	19
The Recommendations of the Advisory Council with Commentary	20
Recommendation No. 1: Drugs to be monitored.	20
<i>The alternatives</i>	20
<i>The best patient care</i>	20

<i>Cost and practicality dictate the recommendation for only CDS drugs to be monitored at this time</i>	21
<i>Prior Maryland and other state inclusions stating the drugs to be monitored:</i>	21
Recommendation No. 2: Advisory Board	22
<i>Commentary</i>	25
Recommendation No. 3: Who should be required to submit information to the data base.	28
<i>Commentary</i>	29
<i>Prior Maryland [HB1287-2006] and other state inclusions in the drugs to be monitored</i>	30
Recommendation No. 4: Data information to be submitted	34
<i>Commentary</i>	34
<i>As to patient consent</i>	37
<i>Software used by pharmacies</i>	39
<i>Kentucky and Virginia provisions for information sharing with other states</i>	39
Recommendation No. 5 : How submission of data information is to be made	40
<i>Commentary</i>	40
<i>The stand-alone program and funding</i>	41
<i>The Maryland Health Care Commission position</i>	42
<i>How Information is to be Submitted—through the Statewide Health Information Exchange</i>	44
<i>How Information is Submitted</i>	44
<i>Another possible approach</i>	46
<i>Providers</i>	47
<i>Dispensers</i>	48
<i>State of Maryland</i>	48
<i>The cost of the programs and the money available or not available</i>	48
Recommendation No. 6: Who may have access to data base? Confidentiality	49
<i>Commentary</i>	50
1. <i>Some Maryland statutes protecting against the disclosure of patient health care records</i>	50
2. <i>Extracted provisions from selected statutes</i>	51
3. <i>The Practitioners and Dispensers</i>	52
4. <i>Law enforcement</i>	53
5. <i>Health Care Boards</i>	55
6. <i>A Multiciplinary Team</i>	57
7. <i>Statutory excerpts</i>	58
8. <i>The Health Information Exchange and the Maryland Health Care Commission</i>	64
9. <i>Concern from some in the Medical Community</i>	65

Recommendation No. 7: Patient Access to Data Base.....	66
<i>Commentary</i>	66
<i>The Maryland provisions concerning patient access and changes to medical records</i>	66
<i>Patient access statutory provisions</i>	67
Recommendation No. 8: Confidentiality and Security.....	68
<i>How to best insure that information in data base remain confidential?</i>	68
<i>Commentary</i>	69
<i>Penalties</i>	70
<i>Provisions from other states addressing this issue of penalties include</i>	71
<i>From the Maryland Health Care Commission (MHCC)</i>	72
<i>Confidentiality and Security</i>	72
Recommendation No. 9. Housing of Data Base.....	74
<i>Commentary</i>	74
Recommendation No. 10: Funding.....	76
<i>Commentary</i>	76
<i>Federal grant funds</i>	77
<i>State settlement money</i>	78
<i>Appropriated State Funds</i>	78
Recommendation No. 11: Immunity.....	79
<i>Commentary</i>	79
<i>Criminal penalties and disciplinary action</i>	79
<i>Civil liability and good faith for failing to access the data-base</i>	80
<i>Immunity</i>	81
<i>Other states' statutory provisions</i>	81
Recommendation No. 12: Technical Review Committee.....	84
<i>Commentary</i>	84
Recommendation No. 13: Public Policy.....	86
Recommendation No. 14: Education.....	86
<i>Commentary</i>	87
Recommendation No. 15: Outcome.....	88
<i>Commentary</i>	88
Recommendation No. 16: Data Mining.....	89
<i>Commentary</i>	89
List of Exhibits and availability.....	92

Executive Summary:

The Maryland Advisory Council on Prescription Drug Monitoring (the Advisory Council or Council) was established within the Department of Health and Mental Hygiene (the Department) in October 2008, by Health-General Article, §21-2A-01, Annotated Code of Maryland. The Council consists of a multi-disciplinary group of stakeholders who would be affected by the establishment and operation of a prescription drug monitoring program (PDMP). The purpose of the Advisory Council is to study establishing a PDMP that electronically collects and stores monitored prescription drug data.

The majority of the PDM Advisory Council sees the need for the PDMP and Council members support establishing a PDMP for two broad purposes. From a public health perspective the Council's view is that a PDMP can be a useful tool for both prescribers and dispensers to better coordinate effective treatment of patients among multiple providers and dispensers. From law enforcement perspective the PDMP is seen as a tool to reduce illegal prescription drug abuse and diversion by providing documented evidence of doctor shopping. A PDMP would also be useful to establish statistical bases on prescription drug for use by the Department for public health program and policy development.

During 2008-09, the Advisory Council explored other states' PDMP programs, and the issues and challenges states face in administering their PDMPs. This report details the work of the Advisory Council with information obtained from other state PDMPs, including in-depth information from interviews with several other states, and presentations and feedback from external stakeholder groups.

Finally, based on the research and study completed by the Advisory Council, this report provides the recommendations to the Secretary on the implementation, administration, maintenance, and funding for a PDMP for Maryland. In its study and formulation of recommendations to the Secretary for establishing a PDMP for Maryland, the Advisory Council was required to consider the following:

- (1) Identify the prescription drugs to be monitored;
- (2) Identify the types of dispensers that shall be required to submit information to a prescription drug monitoring program;
- (3) Determine the data a dispenser must submit to a prescription drug monitoring program for a monitored prescription drug;
- (4) Determine the process for submitting prescription drug monitoring data to a prescription drug monitoring program;

- (5) Specify recipients authorized to receive prescription drug monitoring data from a prescription drug monitoring program;
- (6) Identify the circumstances under which prescription drug monitoring data are provided to an authorized recipient;
- (7) Identify the circumstances under which an authorized recipient may disclose prescription drug monitoring data provided by a prescription drug monitoring program;
- (8) Determine how to ensure that confidential or privileged patient information is kept confidential;
- (9) Define the process for interpreting prescription drug monitoring data for disciplinary or law enforcement purposes;
- (10) Determine the most efficient and effective operation of a prescription drug monitoring program;
- (11) Determine the cost of and sources of funds for establishing and operating a prescription drug monitoring program, including the cost of and sources of funds for submitting and receiving prescription drug monitoring data to and from the program;
- (12) Determine whether the establishment and operation of a prescription drug monitoring program is feasible without additional cost to dispensers and authorized recipients;
- (13) Determine a time line for establishing and implementing a prescription drug monitoring program;
- (14) Identify the types of education and training needed to implement a prescription drug monitoring program;
- (15) Determine the need for immunity from liability in connection with the submission or receipt of prescription drug monitoring data; and
- (16) Determine the need for penalties for improper submission or use of prescription drug monitoring data.

Preamble

This is the report of the Advisory Council on Prescription Drug Monitoring appointed by the Secretary of Health and Mental Hygiene of Maryland pursuant to an enactment by the Maryland Legislature in 2008. **Exhibit O** is a copy of the 2008 Legislation enacted as HG §21-2A-01.

States that have enacted programs and information available nationally:

At the end of 2009 some 33 states have some form of an operational prescription drug monitoring program (PDMP), and 40 states have enacted enabling statutes for establishing and operating a PDMP. The reason for this is to further the police power of the states in the protection of public health and to attempt to stem drug abuse and drug diversion. However, given the years of other states' experience in operating PDMPs and the voluminous amount of information available, there remains some controversy as to whether these programs are working. No concrete statistics are available to show the programs work; no concrete statistics are available to show the programs do not work.

There is so much information available on drug diversion and existing PDMPs from which to choose for study and to analyze, that it was sometimes overwhelming. **Exhibit B** is a compilation from the National Alliance for Model State Drug Laws–Prescription Drug Monitoring Program. One can easily get lost in the voluminous material available. Whether it is an Advisory Council making a recommendation or the Legislature enacting legislation, decisions have to be made as to the drugs to be monitored, who shall be required to submit data, what information is to be submitted, the content of the data base, access to the data base, security of the data base, etc., in accord with the culture of a particular State regulatory effort and preference as to the content of a Program.

There is much information, much assistance and much camaraderie of purpose regarding PDMPs. A National Harold Rogers Prescription Drug Monitoring Program conference is held each year and was attended in September of 2009 by a number of members of the Advisory Council.¹

The “Curran” Report and the 2006 Legislation enacted and vetoed:

In 2006, spurred by an effort initiated by The Honorable Joseph J. Curran, the Office of the Attorney General of Maryland produced an excellent report entitled “Prescription for Disaster.” (**EXHIBIT I**) The report and subsequent efforts by Attorney General Curran resulted in a bill being enacted by the 2006 Maryland Legislature to establish a PDMP in Maryland. The proposed statutory enactment was vetoed by Governor Ehrlich. There is much to say for both the Bill enacted and for some of the reasons it was vetoed. **Exhibit A** is a compilation of HB1287-2006, some legislative history, the Fiscal and Policy Note to the Bill, the text of the bill as passed, and the veto message.

¹ The 2009 meeting – The 5th National Harold Rogers Prescription Drug Monitoring Program held on September 24-25, 2009 at the Liaison Capitol Hill Hotel, Washington, D.C. Coordinating this program was Chris Baumgartner – ASPMP, 3134 83rd Avenue SW, Olympia, Washington 98512 assist@pmpalliance.org Phone: 360-556-7152

Definitions not included in this recommendation:

Not included in the recommendations made by the Advisory Council are definitions because HB1287-2006 contained definitions attendant to the content of the provisions of the legislation. Exhibit A, pp. 11-13. Statutes from other states may be helpful to the Legislature for additional definitions to be included in a statute to be enacted depending on the provisions of that statute. **EXHIBIT G:** Oklahoma, p 13; Florida, p. 7; Virginia, p. 14; and Vermont, p. 19. These statutes were chosen for exhibit because the programs each represents are operationally mature and appear compatible with the original intent of the 2006 Maryland legislation.

Web site information from a number of the PDMPs is listed in **EXHIBIT K**. Information from the Florida PDMP is contained in **EXHIBIT L** and from the Virginia PDMP is in **EXHIBIT J**.

There is Advisory Council consensus that a PDMP is needed in Maryland, but it must be a secure program that is state of the art with real time access to achieve maximum utility. Though the material submitted in this report is voluminous, the Advisory Council is of the opinion that greatest challenge in legislative decision making may only be seen with Recommendation No. 5—the data base vehicle to be utilized. Because of the lack of money available in the current “bad” economy and the amount of money needed to start a PDMP (up to \$1,000,000 based on some estimates) for a State the size of Maryland, this challenge becomes even more pronounced.

Respectfully submitted:

Judge John F. Fader, II, B.S. Pharm.

Chair, Secretary’s Designee

Linda M. Bethman, M.A., J.D.

Attorney General Designee

Dorcas Ann Taylor, PharmD, J.D.

Designee for the President of the Maryland Board of Pharmacy, member through 6/5/09

Donald Taylor, RPh

President of the Maryland Board of Pharmacy

J. Ramsay Farah, M.D.

Secretary of the Maryland Board of Physicians

Nancy D. Adams, R.N., MBA

President of the Maryland Board of Nursing Designee

Health System Executive, Western Maryland Health System

Bruce Kozlowski, B.S.

Chair of the Maryland Health Care Commission Designee
Director of the Center for Health Care Financing and Health Policy
Director of the Center for Long-Term Care and Community Based Services

Devang H. Gandhi, M.D.

Physician representative, member of the Society of Addiction Medicine

Marcia D. Wolf, M.D.

Physician representative, Medical Director MidAtlantic Pain Medicine Center

Ira Kornbluth, M.D.

Physician representative
Founder of Spine Medicine and Rehabilitation Therapies, Westminster, MD
ABPMR Pain Management Board Certified

Robert L. Lyles, Jr., M.D., Ph.D.

Physician representative, Board Certified in Anesthesiology and Critical Care Medicine
Medical Director of LifeStream Health Center
President of Anne Arundel Medical Society

Nicholette Martin-Davis, M.D.

Physician representative
Board Certified - American Board of Physical Medicine & Rehabilitation

Jeannette Quigley, MS.,CRNP.

Nurse practitioner representative, Pain Management Med. Institute

Janet Getzey Hart, RPh

Pharmacist representative
Director of Government Affairs and Trade Relations RiteAid
Responsible for reporting data to PDMPs for 20+ states

Toni T. Carter-Radden, Licensed Pharmacist

Pharmacist representative, Outpatient Pharmacy Manager, Johns Hopkins Hospital

Karen Thompson, RPh

Pharmacist representative, Chief Pharmacist, Tidewater Pharmacy
Mechanicsville, St. Mary's County, MD

Stephen L. Disharoon, B.S. Pharm.

Pharmacist representative, Self-employed community pharmacist, The Drug Store

John J. Mooney

State law enforcement representative–Maryland State Police Trooper

Henry S. “Tim” Clark, III, B.S.

Local Law Enforcement Official representative

Currently with Maryland DPSCS, Internal Investigation Unit

Retired U.S. Department of Justice Special Agent

LaRai Forrest Everett, Esquire

Prosecutor representative–Maryland State’s Attorneys’ Association

Mandy David, PA-C

Maryland citizen representing the perspective of pain patients

Gwenn Herman, LCSW-C, DCSW

Maryland citizen representing the perspective of pain patients

Gail Amalia B. Katz, MHS-Health Policy and Management

Health Care Administration at the American Cancer Society, Nottingham, MD

Vice President, Patient Resources Navigation

The Recommendations of the Advisory Council

Recommendation No. 1: Drugs included.

It is the recommendation of the Advisory Council that the prescription drugs to be monitored by a PDMP are those included in Schedules II through V. (“monitored prescription drug means a prescription drug that contains a substance listed in Schedule II through Schedule V.”)

Recommendation No. 2: Advisory Board.

It is the recommendation of the Advisory Council that an Advisory Board on Prescription Drug Monitoring be Established within the Department of Health and Mental Hygiene of the State of Maryland with a statutory designation of specific duties and membership.

It is further recommended:

Composition of the Advisory Board:

The following members constitute the Advisory Board on Prescription Drug monitoring:²

1. The Secretary, or the Secretary’s Designee;
2. The President of the Maryland Board of Pharmacy, or the President’s Designee;
3. The Chairman of the Maryland Board of Physicians, or the Chairman’s Designee;
4. The President of the Maryland Board of Nursing, or the President’s Designee;
5. The Chairman of the Maryland Health Care Commission or the Chairman’s Designee;
6. Four Physicians and One Nurse Practitioner with Expertise in Areas of Clinical Practice that Involve Pain Management, Substance Abuse, and Addiction Treatment appointed by the Secretary upon nomination by:
 - i. The Medical and Chirurgical Faculty of Maryland, the Maryland State Medical Society, Maryland Society of Physical Medicine and Rehabilitation Society, Maryland Society of Anesthesiologists, and the Maryland Society of Addition Medicine;³ and
 - ii. The Maryland Nurse Practitioners Association of Maryland.⁴

² HB1287/2006Bill has the Attorney General of Maryland or the Attorney General’s Designee to be one of the permanent members of the Advisory Board on Prescription Drug Monitoring. Because the Attorney General’s Office would assign an Assistant Attorney General to provide advice and counsel to the Advisory Board in the same manner that it currently provides counsel to the Department of Health and Mental Hygiene, it was felt unnecessary to specifically designate the Attorney General’s Office as a member of an already expansive Advisory Board. The final vote of Advisory Council was 6 in favor of this deletion to 4 against.

³ The Maryland Society of Addiction Medicine is an addition for consultation by the Secretary to what was included in the HB1287-2006.

⁴ The HB1287-2006 had recommended that consultation by the Secretary be with the Maryland Nurses Association.

7. Four Pharmacists appointed by the Secretary upon nomination by the Maryland Pharmacists Association, The Maryland Association of Chain Drug Stores, Epic Pharmacies, and any Other Appropriate Organization:
 - i. Three of whom represent the perspective of independent, chain pharmacies and pharmacists, and group model health maintenance organization pharmacies and pharmacists⁵: and
 - ii. One of whom represents the perspective of hospital outpatient pharmacies;
8. A federal Law Enforcement Official, appointed by the Secretary after consultation with the United States Department of Justice Drug Enforcement Administration;
9. A State Law Enforcement Official, appointed by the Secretary after consultation with the Maryland State Police;
10. A local Law Enforcement Official, appointed by the Secretary after consultation with the Maryland Chiefs of Police Association;
11. A Prosecutor, appointed by the Secretary after consultation with the Maryland State's Attorneys Association; and
12. Three Maryland citizens who represent the perspective of pain patients, appointed by the Secretary from a list submitted by the Maryland Pain Initiative, one of whom is to be a Caregiver.⁶

Chair of the Advisory Board:

The Secretary shall designate the Chair of the Board

Duties of the Advisory Board:

The duties of the Advisory Board should include:

1. Meet no less than three times annually;⁷

⁵ The HB1287-2006 called for the selection of pharmacists from independent, chain and out-patient hospital pharmacies. To that the Advisory Council has added Group Model Health Maintenance Organization pharmacies and pharmacists in recognition of Kaiser Permanente and other Group Model Health Maintenance Organizations who are most important in what they have to offer, both from the professional pharmacist input and the technical input attendant to processing prescriptions in those organizations.

⁶ The Advisory Council asks the Legislature to consider whether it would not be helpful or even essential to appoint individuals to the Advisory Board with experience that can reflect advances in technology and best practices in the field of electronic health records, electronic monitoring, and electronic records maintained other than health records. Newspaper, magazine and other news sources contain articles from time to time on how different people with technology backgrounds working for different companies form societies and groups to keep abreast of what is occurring in a particular field. Reportedly, application in some settings can be most helpful in working out problems and formulating applications in other setting.

⁷ The Advisory Council is in agreement that the number of meetings at the beginning of the process are going to be more numerous than as the Advisory Board settles in its advisory role for future years.

2. Make recommendations to the Secretary regarding the design and implementation of a prescription drug monitoring program in accordance with the provisions of this subtitle, including recommendations about:
 - i. Regulations and the need for any further legislation concerning the program; and
 - ii. Sources of funding, including grant funds under the Harold Rogers Prescription Drug Monitoring Program and other sources of federal, private, or State funds:
3. Submit reports:
 - i. Provide within 180 days after its first meeting, in accordance with § 2-1246 of the State Government Article, an interim report to the General Assembly setting forth the Advisory Board's analysis and recommendations regarding the design, implementation, and funding of the program; and
4. Provide annually to the Governor and, in accordance with § 2-1246 of the State Government Article, the General Assembly an analysis of the impact of the Program on Patient Access to Pharmaceutical Care and on Curbing Prescription Drug Diversion in the State, including any recommendations relating to modification or continuation of the program;
5. Provide ongoing advice and consultation on the implementation and operation of the program, including recommendations regarding:
 - i. Changes in the program to reflect advances in technology and best practices in the field of electronic health records and electronic prescription monitoring; and
 - ii. The design and implementation of an ongoing evaluation component of the program.

The Advisory Council strongly recommends that the Advisory Board on Prescription Drug Monitoring have the duty to recommend to the Secretary impact drugs to be included as part of the monitoring process. Note that a somewhat similar provision was struck from the 2006 PDMP legislation (HB1287-2006).

It is recommended that the terms of the Advisory Board Members and the process for filling vacancies should be left to the regulatory process. It is our understanding that most boards and councils under the cabinet position of Secretary of Health and Mental Hygiene have a somewhat standard appointment schedule for staggered terms so that there is experience in the group when there are replacements.

Recommendation No. 3: Who should be required to submit information to the data base.

Dispensers:

It is recommended by the Advisory Council that all pharmacies dispensing prescriptions to patients, and all practitioners who are authorized to dispense, be required to timely report certain prescription information to the PDMP data base in a form to be determined by the Secretary in regulations.⁸

Recommended exclusions from the reporting requirements:

The Council recommends that there be certain categorical exemptions to the PDMP reporting requirements.

- First, healthcare practitioners directly administering controlled substances to patients should be exempt from reporting requirements.⁹ Dispensing a controlled substance should be distinguished from the administration of a controlled substance, wherein a healthcare practitioner personally administers a drug to a patient by, for example, oral, intravenous, or intramuscular means.
- Second, the dispensing of samples¹⁰ and drugs that are part of clinical trial programs should be exempt from reporting requirements.¹¹
- Third, licensed opioid maintenance treatment programs¹² should be exempt.
- Fourth, the Council recommends that pharmacies providing in-patient hospital services be exempted from reporting requirements. The rationale is that these pharmacies are located within the institutions and the medications are provided directly to a healthcare practitioner who then administers them to the patients in the hospital beds. In addition, the medications are typically prescribed through chart orders, not prescriptions. Medications are not “dispensed” in this setting. Therefore, conduct intended to be tracked by the PDMP data base (e.g., doctor-shopping, falsifying prescriptions, illegal

⁸ It is noted that there is a definition of “dispense” in the Criminal Law Article. Title 5 of the Criminal Law Article is entitled: Controlled Dangerous Substances, Prescriptions, and Other Substances. CR §5-101 is a definition section:

CR 5 -101 (k) Dispense - (1) “Dispense” means to deliver to the ultimate user or the human research subject by or in accordance with the lawful order of an authorized provider.

(2) “Dispense” includes to prescribe, administer, package label, or compound a substance for delivery.

⁹ Dr. Robert L. Lyles, Jr., a Member of the Advisory Council, informs that anesthesiologists, CRNA, surgeons, and proceduralists are required to record their administration to patients in hospital and out-patient settings and are usually exempt from reporting, but the data is readily available in the pharmacy and medical records of the patient.

¹⁰ Dr. Lyles informs that manufacturers samples are not usually a problem because they are limited in number and schedule class.

¹¹ Dr. Marcia D. Wolf, a Member of the Advisory Council points out the fact that in clinical trials, dispensing is blinded most of the time and it is not known whether a placebo or the real prescription medication is dispensed. She states that there are already so many oversights and counts needed for these trials and that if medication is going to be lost or stolen it will be from a university setting not an outpatient setting.

¹² Dr. Lyles, Jr. informs that some licensed drug maintenance programs are a potential source for problems. To the extent, the patients at these facilities receive medication other than through a prescription, the activity would not be recorded. However, if this medication is received through a prescription, the dispenser would be required to report.

prescribing of controlled substances) is not generally going to be captured by requiring in-patient hospital pharmacies to report.¹³ However, hospital pharmacies that also provide outpatient pharmacy services would have to report the controlled substances dispensed to outpatients.

Recommendation No. 4: Information submitted.

It is the recommendation of the Advisory Council that the data to be submitted as part of the PDMP should be determined by the Secretary upon consultation with the Advisory Board. (See Recommendation No. 2). The Advisory Council recommends that there be no inclusion in the statute for a patient opt out provision by patients and that all defined dispensing data be submitted through the PDMP be reported.

Recommendation No. 5: How Information is to be submitted–The Data Base.

The Advisory Council recommends that data required to be submitted should be electronically submitted in a form as determined by the Secretary upon advice and recommendation from the Advisory Board. For good cause the Secretary may authorize a dispenser to submit data by an alternative form of submission or omit one or more elements of prescription monitoring data.¹⁴ It is the recommendation of the Advisory Council that the system used for submitting data should not be a stand-alone system. Rather, it is recommended that the data base for collection of information be developed in connection with the Maryland Health Care Commission (MHCC) Health Information Exchange (HIE).¹⁵

Recommendation No. 6: Access to the PDMP Data Base.

Who may have access to data base? Confidentiality.

The Advisory Council recommends that access to the data base should be available to the following individuals and entities. The parameters of this access shall be determined by regulations to be adopted by the Secretary upon consultation with the Advisory Board on

¹³ The Council received comments stating that hospitals and other such settings had significant problems with diversion and pilferage of controlled substances by staff. While the Council agrees that diversion in hospitals has been a documented issue, staff diversion and pilferage would not be captured by the PDMP data base even if inpatient pharmacies were required to report.

¹⁴ P 6 of the October 1, 2009 report on Statewide Health Information Exchange through the Maryland Health Care Commission notes that the statewide HIE intends to benefit all Marylanders and to recognize the challenges of uninsured and underserved populations. There are going to be a few dispensers who are not technologically sufficiently proficient that will have to be allowed a time to submit data in a form other than electronically.

¹⁵ The vote by the Advisory Council was 13 in favor of this recommendation with 3 members in favor of a stand alone system.

Prescription Drug Monitoring to be established within the Department of Health and Mental Hygiene:

1. A prescribing practitioner in connection with the medical care of a patient;
2. A dispenser in connection with the dispensing of a monitored prescription drug;
3. To Federal, State, and local law enforcement, upon issuance of a subpoena for the purpose of furthering an existing bona fide individual investigation;
4. To certain health care regulatory boards (Physicians, Pharmacy, Nursing, Dental, Podiatric), upon the issuance of a subpoena;
5. To the Secretary for calculating performance measures and fulfilling his/her responsibility to report to the Governor, the President of the Senate and the Leader of the House; and for information for the purpose of bona fide research, analysis, and public reporting or education by qualified personnel approved by the Secretary; and
6. To individual patients whose data has been submitted to the data base.

For security and privacy, information from the PDMP to be used for reports to the Governor and the Legislature and to evaluate performance of the program, as well for bona fide research, analysis, and public reporting or education, shall not contain any information that could identify a patient, prescriber or dispenser. Information from the PDMP shall not be discoverable, subject to a subpoena, or admissible in a civil, criminal, or administrative action except as is specifically authorized by the legislation to be enacted establishing a Prescription Drug Monitoring Program.

Further, it is recommended that there be established a Multidisciplinary Consultation Team to assist federal, State or local law enforcement or a Health Care Licensing Board in the interpretation of data and considering whether the data, in the context of the nature of a prescriber's or a dispenser's practice, a patient's medical condition, or any other relevant facts, suggests the need for further investigation or a practice not in conformity with the existing standard of care and responsibility of the practitioner in dispensing CDS.

Recommendation No. 7: Patient Access to Data Base

It is the recommendation of the Advisory Council that the Legislature provide for patient access to their own personal PDMP information. Many states allow this access and it seems only fair that the patient knows what records there are concerning him/her and what those records say. As to any patient correction of the records, we recommend that the patient be allowed to make comments and to state corrections that should be made but that the PDMP record should not be changed. This is consistent with the provisions of the Maryland Confidentiality of Medical Records Act.

Recommendation No. 8: Confidentiality and Security

How to best insure that information in data base remain confidential?

The Advisory Council recommends a number of provisions toward assuring confidentiality of the data collected by a PDMP in Maryland and against the dissemination of that information by individuals who have access to the data base or, otherwise, obtain the data for a purpose other than allowed by statute and regulation:

- (1) The data system utilized must be of the highest quality to restrict access other than allowed by statute;
- (2) Unauthorized access should be punishable by disciplinary action against health care professionals; and
- (3) Unauthorized access and unauthorized disclosure of data base information should be punishable by criminal penalties (misdemeanor) and a system of civil penalties and attorneys fees that can be obtained by a patient whose confidentiality has been compromised.

Data collected should statutorily be pronounced as confidential, privileged, and not subject to discovery, subpoena, or other means of legal compulsion in civil litigation. It should be specifically noted that access other than provided by the statute creating the PDMP is prohibited. A specific provision should be added that no information collected is subject to disclosure under the *Maryland Public Information Act*. (SG §10-611, et seq.) Injunctive authority should be given to the Office of the Attorney General to carry out the provisions of the law to maintain confidentiality.

Individuals allowed to have access to the system must be credentialed. All data should be encrypted.

Though the systems employed by the PDMPs are difficult to hack into, there was a breach early in 2009 of the Virginia PDMP system which caused the system to be shut down for a period of time. The etiology of the breach and the extent of the breach have not been determined but Virginia took immediate steps to notify users of the problem and to assure them and inform them concerning the steps that were taken to seal off the system. It is to be noted that Virginia utilizes a system of gathering and storing of data that is less than the state of the art utilized by the newer systems.

One of the duties of the Advisory Board on Prescription Drug Monitoring recommended to be established within the Department of Health and Mental Hygiene of the State of Maryland should be to keep abreast of the technology in the field with systems available and utilized by other States.

Recommendation No. 9: Housing of Data Base

The Advisory Council recommends that the operations of the Prescription Drug Monitoring Program be housed in the Division of Drug Control, in the Department of Health and Mental Hygiene.

Recommendation No. 10: Funding

The Advisory Council recommends that the Department apply for funds through the Harold Rogers PDMP Grants Program and other federal grants to implement a PDMP with a data base to be developed and is consistent with the Maryland Health Care Commission Health Information Exchange.

Recommendation No. 11: Immunity

The Advisory Council recommends that there should be a criminal and administrative penalty (disciplinary action) against any Dispenser who willfully fails to report the dispensing of a monitored substance required by the PDMP. However, it is also recommended that notwithstanding the provisions of the law assessing penalties for a “willful” violation of statutory responsibility, that the statute enacted should make it clear that Practitioners and Dispensers shall have no requirement or obligation to access or check the information in the central data base prior to prescribing, dispensing or administering medications as part of a professional practice.

A separate statutory provision should make it clear that a Prescriber and Dispenser shall not be liable to any person for any claim of damages as a result of accessing or failing to access the information in the central data base and that no lawsuit may be predicated thereon.

Also, a Prescriber or Dispenser acting in good faith should be immune from any civil, criminal, or disciplinary liability that might otherwise be incurred or imposed for receiving or using information from the PDMP.

There should also be a provision to the effect that the Secretary, the Advisory Board, and employees of the Secretary, and anyone authorized by the Secretary to access PDMP data are not liable and are immune from any civil damages resulting from the accuracy or inaccuracy of any information reported to and complied pursuant to the statute.

Recommendation No. 12: Technical Review Committee

In accord with what is enacted by the legislature as to who shall have access to the data base, it is recommended by the Advisory Council that a Professional Technical Review Committee be a part of the statutory framework for enactment of a PDMP. Earmarking CDS problems and practice by experts in the field will be important for education, law enforcement, disciplinary boards, and most important, the individual practitioners and dispensers.

The members of this Technical Review Committee will have to be paid a stipend or per diem and be clinicians in active practice.

Regulations should be promulgated to effectuate implementation and operations of this Committee so as to what functions are to be performed by the Committee.

Recommendation No. 13: Public Policy

It is the recommendation of the Advisory Council that the Legislature state as strongly as it can the Legislative Purpose for the enactment of a PDMP.

Recommendation No. 14: Education

The Advisory Council recommendation on education is more by way of information to the Legislature and a recommendation to the PDMP once it is established. Information concerning the workings of the program and the need for the program should include:

- (1) A Web site containing easy access to virtually all information concerning the program;
- (2) Initial contact by letter to dispensers and practitioners concerning the program accompanied by forms for registration;
- (3) A manual for software manufacturers setting forth requirements needed to comply with the reporting provisions of the program;
- (4) A personal initiative for visits to hospitals and medical societies throughout the State of Maryland to present information and field questions concerning the PDMP;¹⁶

¹⁶ Meika Zilberberg, MS, Program Coordinator, Vermont Prescription Monitoring System, Vermont Department of Health {phone} 802-652-4147 {email} mzilber@vdh.state.vt.us <http://healthvermont.gov/adap/VPMS.aspx> emphasized the importance of this initiative. Vermont is a smaller state which probably added to the ability to make this initiative successful. Ms. Zilberberg said the individuals accompanying her on the visits are the Medical Director of the Vermont PDMP, the Attorney for the Vermont Medical Society and a detective Specialist involved with Drug Control. These presenters talk about drug abuse and the program and answer questions. Following these visits, they ask those in attendance to fill out a survey as to the helpfulness of the visit and invite contact with the program for any questions that may arise.

It should be noted that the Vermont program has no connection with law enforcement and allows no access by law enforcement personnel.

- (5) Pamphlets and frequently asked questions (FAQ) to educate the public, dispensers, practitioners, and patients concerning the program;
- (6) Procedural manuals for the program;¹⁷ and
- (7) Availability of a help desk help to assist individuals in need of assistance regarding all aspects of the program.

Recommendation No. 15: Outcome

The Advisory Council recommends that the legislation to be enacted for a PDMP provide for future analysis of the effectiveness of the PDMP. Recommendation No. 2 states that the Advisory Board created be responsible for implementing procedures to evaluate the effectiveness of the PDMP. We consider this evaluation responsibility and the responsibility to be kept advised of advancements in the field of prescription drug monitoring essential to the proper working of a PDMP.

Recommendation No. 16: Data Mining

As part of the “access to information” section of the report, the Advisory Council recommends that state agencies and academic institutions be allowed to request data extracts from the PDMP governing body for the purpose of data analysis to support public health and public reporting as defined in statute or regulation for the requesting agency.

Requestors should be required to submit an abstract to the administrative agency outlining the purpose and scope of the intended analysis. Data will be extracted should be provided to requestors as de-identified information unless the data is supporting a bona fide public health emergency.

The importance of this tool makes it important for a separate recommendation to the Legislature concerning the use of data mining.

¹⁷ The Advisory Council emphasizes the need for the implementation of a system that is not difficult to use. Manuals vary in the amount of information they contain. For instance, the Optimum Technology manual for the Oklahoma PDMP consists of 240 pages as opposed to Vermont where the manual does not exceed 30 pages.

The Recommendations of the Advisory Council with Commentary

Recommendation No. 1: Drugs to be monitored.

It is the recommendation of the Advisory Council that the drugs to be monitored by a PDMP are those included in Schedules II through V. (“monitored prescription drug means a prescription drug that contains a substance listed in Schedule II through Schedule V.”)

Commentary

The alternatives:

Determine if, or ensure that, consumers are not receiving controlled substances from multiple prescribers, doctor shopping, or over-utilizing controlled substances. The statewide HIE is capable of allowing providers to access data that verifies consumers have not previously filled a prescription, or are not visiting numerous The Advisory Council considered three separate possibilities focusing on what drugs should be monitored: (1) Scheduled Drugs, (2) Scheduled Drugs plus medication for anxiety, not a scheduled drug, which have synergistic and augmentation therapy effects (i.e., a “drug of concern” or “impact drug”), and (3) all prescription medication.¹⁸ The final vote of the Council was for the first alternative: “monitored prescription drug means a prescription drug that contains a substance listed in Schedules II through V.” Maryland’s CDS law are found in CR §5-401 through §5-406.¹⁹

The best patient care

The most effective plan of care for treating individuals in pain will be developed when the practitioner has a complete view of all medication that is being taken by a patient. A member of the Advisory Council appointed to represent the perspective of the pain patient felt strongly that all drugs should therefore be included as part of the PDMP. Considering the objectives of Prescription Drug Monitoring Legislation to curtail abuse and foreclose diversion while providing for the proper treatment of patients in pain, the best alternative for the future is going to be a system where the physician treating pain has the ability to view a complete list all of the prescription medication a patient is and has been taking.²⁰ This may be especially true for patients who are being treated for pain but also suffer from depression and other mental disorders. There is now research to develop gene specific medication.

¹⁸ Dr. Lyles states that the EMR systems all have the capacity for this and the information available is often beneficial for the establishment of a proper treatment regimen for patients in pain.

¹⁹ CR §5-401. In general; CR §5-402. Schedule I; CR §5-403. Schedule II; CR §5-404. Schedule III; CR § 5-405. Schedule IV and CR §5-406. Schedule V.

²⁰ There was discussion by the Advisory Council that we have not had the input of the mental health experts as to what additions to the drugs to be monitored would be deemed advisable for “best” patient treatment.

Driven by the opportunities to improve health care quality and reduce health care spending, Maryland is consistent with many other states in its effort to expand the adoption of electronic health records and implement a statewide health information exchange (HIE). After several years of planning, Maryland began the implementation of a statewide HIE. The statewide HIE, which is being built on sound privacy and security principles, is well positioned to assist legitimate prescribers by providing them with data to pharmacies with similar prescriptions from multiple physicians. Appropriately authorized and authenticated providers who use the statewide HIE could have access to data before prescribing or dispensing controlled substances. The data could also prevent or stop criminal activity related to controlled substance abuse. This approach would improve access to timely and accurate information in a private and secure environment, and minimal costs and workflow disruption to pharmacies.

Cost and practicality dictate the recommendation for only CDS drugs to be monitored at this time:

If current technology is used, the cost of the initial Maryland Prescription Drug Monitoring Program is going to be dependent to a significant extent by the number of drugs monitored. That fact is considered as a “given” from all information reviewed by the Advisory Council. Most PDMP systems up and running in the United States (and most commercial software available) are keyed only to scheduled drugs being monitored. Therefore, a practical approach dictates the recommendation of alternative one – limiting the monitoring of scheduled drugs only. It should be pointed out that when the Maryland Health Care Commission Health Information Exchange is up and running, one of the utilities of that system will be the availability and real time accessibility of all prescription medication dispensed to every patient.

Prior Maryland and other state inclusions stating the drugs to be monitored:

HB1287-2006	<p>21-2A-01.</p> <p>(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.</p> <p>(+) (H) “MONITORED PRESCRIPTION DRUG” MEANS A PRESCRIPTION DRUG THAT:</p> <p>(+) CONTAINS A SUBSTANCE LISTED IN SCHEDULE II THROUGH SCHEDULE IV; OR</p> <p>(2) IS A DRUG OF CONCERN.</p> <p>21-2A-02.</p> <p>(A) THE DEPARTMENT SHALL ESTABLISH AND MAINTAIN, IN CONSULTATION WITH THE BOARD, A PRESCRIPTION DRUG MONITORING PROGRAM THAT ELECTRONICALLY COLLECTS AND STORES DATA CONCERNING MONITORED PRESCRIPTION DRUGS.</p>
Oklahoma	<p>Okla. Stat. §2-309C.</p> <p>A. A dispenser of a Schedule II, III, IV or V controlled dangerous substance, except Schedule V substances that contain any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers shall transmit to a central repository</p>
Florida	<p>Fla. Stat. § 893.055. Prescription drug monitoring program</p> <p>(1) As used in this section, the term:</p> <p>(b) “Controlled substance” means a controlled substance listed in Schedule II, Schedule III, or Schedule IV in s. 893.03.</p>

Virginia	Va. Code. Ann. § 54.1-2520. Program establishment; Director’s regulatory authority A. The Director shall establish, maintain, and administer an electronic system to monitor the dispensing of covered substances to be known as the Prescription Monitoring Program. Covered substances shall include all Schedule II, III, and IV controlled substances, as defined in the Drug Control Act (§ 54.1-3400 et seq.).
Kentucky	KRS 218A.202. Electronic system for monitoring controlled substances -- (1) The Cabinet for Health and Family Services shall establish an electronic system for monitoring Schedules II, III, IV, and V controlled substances that are dispensed within the Commonwealth by a practitioner or pharmacist or dispensed to an address within the Commonwealth by a pharmacy that has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy.
Vermont	Chapter 84A. § 4283. Creation; implementation (b) As required by the department, every dispenser who is licensed by the Vermont board of pharmacy shall report to the department in a timely manner data for each controlled substance in Schedules II, III, and IV, as amended and as may be amended, dispensed to a patient within Vermont. Reporting shall not be required for:...

Recommendation No. 2: Advisory Board

Establishment of an Advisory Board on Prescription Drug Monitoring in the Department of Health and Mental Hygiene

It is the recommendation of the Advisory Council that an Advisory Board on Prescription drug Monitoring be Established within the Department of Health and Mental Hygiene of the State of Maryland with a statutory designation of specific duties and membership.

It is further recommended:

Composition of the Advisory Board:

The following members constitute the composition of the Advisory Board on Prescription Drug monitoring:²¹

1. The Secretary, or the Secretary’s Designee;
2. The President of the Maryland Board of Pharmacy, or the President’s Designee;
3. The Chairman of the Maryland Board of Physicians, Or the Chairman’s Designee;
4. The President of the Maryland Board of Nursing, or the President’s Designee;
5. The Chairman of the Maryland Health Care Commission or the Chairman’s Designee;

²¹ HB1287/2006Bill has the Attorney General of Maryland or the Attorney General’s Designee to be one of the permanent members of the Advisory Board on Prescription Drug Monitoring. Because the Attorney General’s Office would assign an Assistant Attorney General to provide advice and counsel to the Advisory Board in the same manner that it currently provides counsel to the Department of Health and Mental Hygiene, it was felt unnecessary to specifically designate the Attorney General’s Office as a member of an already expansive Advisory Board. The final vote of Advisory Council was 6 in favor of this deletion to 4 against.

6. Four Physicians and One Nurse Practitioner with Expertise in Areas Clinical of Practice that Involve Pain Management, and Substance Abuse and Addiction Treatment appointed by the Secretary upon nomination by with:
 - iii. The Medical and Chirurgical Faculty of Maryland, the Maryland State Medical Society, the Maryland Society of Physical Medicine and Rehabilitation Society, and the Maryland Society of Anesthesiologists, and the Maryland Society of Addition Medicine²² with Respect to the Physician Appointments; and
 - iv. The Maryland Nurse Practitioners Association of Maryland.²³
7. Four Pharmacists Appointed by the Secretary upon nomination by the Maryland Pharmacists Association, The Maryland Association of Chain Drug Stores, Epic Pharmacies, and any Other Appropriate Organization:
 - iii. Three of whom Represent the Perspective of Independent, Chain Pharmacies and Pharmacists, and Group Model Health Maintenance Organization pharmacies and pharmacists²⁴: and
 - iv. One of Whom Represents the Perspective of Hospital Outpatient Pharmacies;
8. A Federal law Enforcement Official, Appointed By the Secretary After Consultation with the Drug Enforcement Administration of the United States Department of Justice;
9. A State Law Enforcement Official, Appointed by the Secretary After Consultation with the Maryland State Police;
10. A Local Law Enforcement Official, Appointed by the Secretary After Consultation with the Maryland Chiefs of Police Association;
11. A Prosecutor, Appointed by the Secretary After Consultation with the Maryland State's Attorneys Association; and
12. Three Maryland Citizens Who Represent the Perspective of Pain Patients, Appointed by the Secretary From a List Submitted by the Maryland Pain Initiative, one of whom is recommended to be a Caregiver.²⁵

²² The Maryland Society of Addiction Medicine is an addition for consultation by the Secretary to what was included in the HB1287-2006.

²³ The HB1287-2006 had recommended that consultation by the Secretary be with the Maryland Nurses Association.

²⁴ The HB1287-2006 called for the selection of pharmacists from independent, chain and out-patient hospital pharmacies. To that the Advisory Council has added Group Model Health Maintenance Organization pharmacies and pharmacists in recognition of Kaiser Permanente and other Group Model Health Maintenance Organizations who are most important in what they have to offer, both from the professional pharmacist input and the technical input attendant to processing prescriptions in those organizations.

²⁵ The Advisory Council asks the Legislature to consider whether it would not be helpful or even essential to appoint individuals to the Advisory Board with experience that can reflect advances in technology and best practices in the field of electronic health records, electronic monitoring, and electronic records maintained other than health records. Newspaper, magazine and other news sources contain articles from time to time on how different people with technology backgrounds working for different companies form societies and groups to keep abreast of what is occurring in a particular field. Reportedly, application in some settings can be most helpful in working out problems and formulating applications in other setting.

CHAIR OF THE ADVISORY BOARD:

The Secretary shall designate the Chair of the Board

DUTIES OF THE ADVISORY BOARD:

The duties of the Advisory Board should include:

1. Meet no less than three times annually;²⁶
2. Make recommendations to the Secretary regarding the design and implementation of a prescription monitoring program in accordance with the provisions of this subtitle, including recommendations about:
 - iii. Regulations and the need for any further legislation concerning the program; and
 - iv. Sources of funding, including grant funds under the Harold Rogers Prescription Drug Monitoring Program and other sources of federal, private, or state funds:
3. Submit reports:
 - ii. Provide within 180 days after its first meeting, in accordance with § 2-1246 of the State Government Article, an interim report to the General Assembly setting forth the Advisory Board's analysis and recommendations regarding the design, implementation, and funding of the program; and
4. Provide annually to the Governor and, in accordance with § 2-1246 of the State Government Article, the General Assembly an analysis of the impact of the Program on Patient Access to Pharmaceutical Care and on Curbing Prescription Drug Diversion in the State, including any Recommendations relating to modification or continuation of the program;
5. Provide ongoing advice and consultation on the implementation and operation of the program, including recommendations regarding:
 - iii. Changes in the program to reflect advances in technology and best practices in the field of electronic health records and electronic prescription monitoring; and
 - iv. The design and implementation of an ongoing evaluation component of the program; and

The Advisory Council strongly recommends that the Advisory Board on Prescription Drug Monitoring have the continuing duty to recommend to the Secretary impact drugs to be included

²⁶ The Advisory Council is in agreement that the number of meetings at the beginning of the process are going to be more numerous than as the Advisory Board settles in its advisory role for future years.

as part of the monitoring process. A somewhat similar provision was struck from the 2006 Legislation.

It is recommended that the terms of the Advisory Board Members and how vacancies are filled should be left to the regulatory process. It is our understanding that most Boards under the cabinet position of Secretary of Health and Mental Hygiene have a somewhat standard appointment schedule for staggered terms so that there is experience in the group when there are replacements.

Commentary

HB1287-2006 made the following recommendations as to the members, the chair and the duties of the Advisory Board:

Members of the Advisory Board	<p>21-2A-03.</p> <p>(A) THERE IS AN ADVISORY BOARD ON PRESCRIPTION DRUG MONITORING IN THE DEPARTMENT.</p> <p>(B) THE BOARD CONSISTS OF THE FOLLOWING 15 <u>21</u> MEMBERS:</p> <p>(1) THE ATTORNEY GENERAL, OR THE ATTORNEY GENERAL'S DESIGNEE;</p> <p>(2) THE SECRETARY, OR THE SECRETARY'S DESIGNEE;</p> <p>(3) THE PRESIDENT OF THE MARYLAND BOARD OF PHARMACY, OR THE PRESIDENT'S DESIGNEE;</p> <p>(4) THE CHAIRMAN OF THE MARYLAND BOARD OF PHYSICIANS, OR THE CHAIRMAN'S DESIGNEE;</p> <p><u>(5) THE PRESIDENT OF THE MARYLAND BOARD OF NURSING, OR THE PRESIDENT'S DESIGNEE;</u></p> <p>(5) <u>(6) THE CHAIRMAN OF THE MARYLAND HEALTH CARE COMMISSION, OR THE CHAIRMAN'S DESIGNEE;</u></p> <p>(6) <u>(7) TWO FOUR PHYSICIANS AND ONE NURSE PRACTITIONER WITH EXPERTISE IN PHYSICAL MEDICINE AND REHABILITATION AREAS OF PRACTICE THAT INVOLVE PAIN MANAGEMENT AND SUBSTANCE ABUSE AND ADDICTION TREATMENT, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH:</u></p> <p><u>(i) THE MEDICAL AND CHIRURGICAL FACULTY OF MARYLAND, THE MARYLAND STATE MEDICAL SOCIETY, THE MARYLAND PHYSICAL MEDICINE AND REHABILITATION SOCIETY, AND THE MARYLAND SOCIETY OF ANESTHESIOLOGISTS WITH RESPECT TO THE PHYSICIAN APPOINTMENTS; AND</u></p> <p><u>(ii) THE MARYLAND NURSES ASSOCIATION WITH RESPECT TO THE NURSE PRACTITIONER APPOINTMENT;</u></p> <p>(7) <u>(8) TWO FOUR PHARMACISTS WHO REPRESENT THE PERSPECTIVE OF INDEPENDENT AND CHAIN PHARMACIES AND PHARMACISTS, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH THE MARYLAND PHARMACISTS ASSOCIATION,</u></p>
--	---

THE MARYLAND ASSOCIATION OF CHAIN DRUG STORES, EPIC PHARMACIES, AND ANY OTHER APPROPRIATE ORGANIZATION;

(1) THREE OF WHOM REPRESENT THE PERSPECTIVE OF INDEPENDENT AND CHAIN PHARMACIES AND PHARMACISTS; AND

(II) ONE OF WHOM REPRESENTS THE PERSPECTIVE OF HOSPITAL OUTPATIENT PHARMACIES;

~~(8)~~ (9) A FEDERAL LAW ENFORCEMENT OFFICIAL, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH THE DRUG ENFORCEMENT ADMINISTRATION OF THE UNITED STATES DEPARTMENT OF JUSTICE;

~~(9)~~ (10) A STATE LAW ENFORCEMENT OFFICIAL, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH THE MARYLAND STATE POLICE;

~~(10)~~ (11) A LOCAL LAW ENFORCEMENT OFFICIAL, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH THE MARYLAND CHIEFS OF POLICE ASSOCIATION;

~~(11)~~ (12) A PROSECUTOR, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH THE MARYLAND STATE'S ATTORNEYS ASSOCIATION; AND

~~(12)~~ (13) TWO MARYLAND CITIZENS WHO REPRESENT THE PERSPECTIVE OF PAIN PATIENTS, APPOINTED BY THE SECRETARY FROM A LIST SUBMITTED BY THE MARYLAND PAIN INITIATIVE.

(C) THE SECRETARY SHALL DESIGNATE THE CHAIR OF THE BOARD.

(D) (1) THE TERM OF A MEMBER APPOINTED BY THE SECRETARY IS 3 YEARS.

(2) IF A VACANCY OCCURS DURING THE TERM OF AN APPOINTED MEMBER, THE SECRETARY SHALL APPOINT A SUCCESSOR WHO SHALL SERVE UNTIL THE TERM EXPIRES.

(E) THE BOARD SHALL:

(1) MEET NOT FEWER THAN THREE TIMES ANNUALLY;

(2) MAKE RECOMMENDATIONS TO THE SECRETARY REGARDING THE DESIGN AND IMPLEMENTATION OF A PRESCRIPTION MONITORING PROGRAM, IN ACCORDANCE WITH THE PROVISIONS OF THIS SUBTITLE, INCLUDING RECOMMENDATIONS ABOUT:

(i) REGULATIONS AND THE NEED FOR ANY FURTHER LEGISLATION CONCERNING THE PROGRAM; AND

(ii) SOURCES OF FUNDING, INCLUDING GRANT FUNDS UNDER THE HAROLD ROGERS PRESCRIPTION DRUG MONITORING PROGRAM AND OTHER SOURCES OF FEDERAL, PRIVATE, OR STATE PROGRAMS FUNDS;

(3) (i) PROVIDE WITHIN 180 DAYS AFTER ITS FIRST MEETING, IN ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, AN INTERIM REPORT TO THE GENERAL ASSEMBLY SETTING FORTH THE BOARD'S ANALYSIS AND RECOMMENDATIONS UNDER ITEM (2) OF THIS SUBSECTION REGARDING THE DESIGN, IMPLEMENTATION, AND FUNDING OF THE PROGRAM; AND

Chair of the
Advisory Board

Vacancy on
Advisory Board

(II) PROVIDE ANNUALLY TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY AN ANALYSIS OF THE IMPACT OF THE PROGRAM ON PATIENT ACCESS TO PHARMACEUTICAL CARE AND ON CURBING PRESCRIPTION DRUG DIVERSION IN THE STATE, INCLUDING ANY RECOMMENDATIONS RELATED TO MODIFICATION OR CONTINUATION OF THE PROGRAM; AND

(4) PROVIDE ONGOING ADVICE AND CONSULTATION ON THE IMPLEMENTATION AND OPERATION OF THE PROGRAM, INCLUDING RECOMMENDATIONS REGARDING:

(I) CHANGES IN THE PROGRAM TO REFLECT ADVANCES IN TECHNOLOGY AND BEST PRACTICES IN THE FIELD OF ELECTRONIC HEALTH RECORDS AND ELECTRONIC PRESCRIPTION MONITORING; AND

~~(II) EMERGING DRUGS OF CONCERN THAT SHOULD BE IDENTIFIED AS MONITORED PRESCRIPTION DRUGS; AND~~

Duties of the
Advisory Board

~~(III)~~ (II) THE DESIGN AND IMPLEMENTATION OF AN ONGOING EVALUATION COMPONENT OF THE PROGRAM.

EXHIBIT C provides a list of States that Statutorily mandate that the PDMP Use/Work with an Advisory Committee or Council, Task Force or Working Group, and the data listed was collected through August 2009. This exhibit C was compiled by the National Alliance for Model State Drug Laws (NAMSDL) 703-836-7496 and furnished to the Advisory Council by Ms. Sherry Green, the CEO for NAMSDL. sgreen@namsdl.org

Exhibit C sets forth the composition of the PDMP Advisory Board and the directive as to the duties of these Boards as enacted in various States. It should be noted:

- The recommendation for the role of the Advisory Board to consider “changes in the program to reflect advances in technology and best practices” is very encompassing and we feel “all” encompassing. Other states have been more specific as to what is required for an Advisory Board, i.e.: (1) Alabama: “matters related to the establishment, maintenance, and operation of the data base, access to the data base information, how access is to be regulated, and security of information;” (2) Colorado: “with the development, operation, and maintenance of the...program; and with the development of access and security protocols for the program;” (3) Florida: “to monitor the implementation and safeguarding of the electronic system...and to ensure privacy, protection of individual medication history, and the electronic system’s appropriate use by physicians, dispensers, pharmacies, law enforcement agencies, and those authorized to requires information from the electronic system.”

Provisions are also made in Illinois, Indiana, Iowa, Kansas, Louisiana, Massachusetts, Michigan, Minnesota, North Dakota, Oregon, Tennessee, Vermont and Virginia for an Advisory Board under different names. Statutory excerpts are set forth in EXHIBIT C.

- EXHIBIT C sets forth 17 different statutory forms for membership on an Advisory Board, some with significantly more specificity as to the makeup of the members than others.

Recommendation No. 3: Who should be required to submit information to the data base.

Dispensers:

It is recommended by the Advisory Council that all pharmacies dispensing prescriptions to patients, and all practitioners who are authorized to dispense, be required to timely report certain prescription information to the PDMP data base in a form to be determined by the Secretary in regulations.²⁷

Recommended exclusions from the reporting requirements:

The Council recommends that there be certain categorical exemptions to the PDMP reporting requirements.

- First, healthcare practitioners directly administering controlled substances to patients should be exempt from reporting requirements.²⁸ Dispensing a controlled substance should be distinguished from the administration of a controlled substance, wherein a healthcare practitioner personally administers a drug to a patient by, for example, oral, intravenous, or intramuscular means.
- Second, the dispensing of samples²⁹ and drugs that are part of clinical trial programs should be exempt from reporting requirements.³⁰
- Third, licensed opioid maintenance treatment programs³¹ should be exempt.

²⁷ It is noted that there is a definition of “dispense” in the Criminal Law Article. Title 5 of the Criminal Law Article is entitled: Controlled Dangerous Substances, Prescriptions, and Other Substances. CR §5-101 is a definition section:

CR 5 -101 (k) Dispense - (1) “Dispense” means to deliver to the ultimate user or the human research subject by or in accordance with the lawful order of an authorized provider.

(2) “Dispense” includes to prescribe, administer, package label, or compound a substance for delivery.

²⁸ Dr. Robert L. Lyles, Jr., a Member of the Advisory Council, informs that anesthesiologists, CRNA, surgeons, and procedurists are required to record their administration to patients in hospital and out-patient settings and are usually exempt from reporting, but the data is readily available in the pharmacy and medical records of the patient.

²⁹ Dr. Lyles informs that manufacturers samples are not usually a problem because they are limited in number and schedule class.

³⁰ Dr. Marcia D. Wolf, a Member of the Advisory Council points out the fact that in clinical trials, dispensing is blinded most of the time and it is not known whether a placebo or the real prescription medication is dispensed. She states that there are already so many oversights and counts needed for these trials and that if medication is going to be lost or stolen it will be from a university setting not an outpatient setting.

³¹ Dr. Lyles, Jr. informs that some licensed drug maintenance programs are a potential source for problems. To the extent, the patients at these facilities receive medication other than through a prescription, the activity would not be recorded. However, if this medication is received through a prescription, the dispenser would be required to report.

- Fourth, the Council recommends that pharmacies providing in-patient hospital services be exempted from reporting requirements. The rationale is that these pharmacies are located within the institutions and the medications are provided directly to a healthcare practitioner who then administers them to the patients in the hospital beds. In addition, the medications are typically prescribed through chart orders, not prescriptions. Medications are not “dispensed” in this setting. Therefore, conduct intended to be tracked by the PDMP data base (e.g., doctor-shopping, falsifying prescriptions, illegal prescribing of controlled substances) is not generally going to be captured by requiring in-patient hospital pharmacies to report.³² However, hospital pharmacies that also provide outpatient pharmacy services would have to report the controlled substances dispensed to outpatients.

Commentary

Pharmacies located outside the State that service Maryland patients either through mail order, the internet, or other means are included as “dispensers” to submit reports. These out-of-state pharmacies are required to be licensed in Maryland under HO § 12-403 as “non-resident pharmacies.” A non-resident pharmacy means “a pharmacy located outside this State that, in the normal course of business, as determined by the Board, ships, mails, or delivers drugs or devices to a person in this State pursuant to a prescription.” Comity among states, the full faith and credit clause of the U.S. Constitution and the general police power of Maryland together necessitate that both resident and non-resident pharmacies should be required to report to the PDMP data base. This is an important part of a PDMP, particularly as the proliferation of internet pharmacies continues to grow and allow for an easily accessible means of obtaining controlled substances.

Aware of the fact that nursing homes, assisted living, and hospice facilities have sometimes been reported as having fallen victim to theft of CDS in large quantities, the Advisory Council sees this as a problem that has to otherwise be regulated. The Maryland Board of Pharmacy reports that CDS medication furnished to patients in these facilities are through prescriptions written. That means that upon dispensing CDS medication to a patient in one of these facilities a reporting incident will occur. Difficulties that may be experienced with diversion or theft within one of these institutions following the dispensing of medication is not within the charge of the Advisory Council. It is the responsibility of the Pharmacist filling prescriptions for these institutions to monitor the dispensing with a view to calling the prescribers attention to the fact that there is a request for prescription medication to be filled or refilled in excess of the dose amount prescribed.

³² The Council received comments stating that hospitals and other such settings had significant problems with diversion and pilferage of controlled substances by staff. While the Council agrees that diversion in hospitals has been a documented issue, staff diversion and pilferage would not be captured by the PDMP data base even if inpatient pharmacies were required to report.

Delora R. Sanchez, J.D, Assistant Director, State Affairs, Johns Hopkins Institutions reports that the exclusion of inpatient pharmacies from the reach of the HB 1287-2006 and later HB 525-2008 was as a result of testimony given by the Maryland Hospital Association on the bill on behalf of Maryland hospitals. She states that it was the consensus from hospitals that the amount of reporting would create a substantial administrative and cost burden and that the General Assembly recognized that in these times of increasing costs for health care, the burden created could not effectively be minimized. Therefore the Legislature decided not to include hospitals in the definition of “Dispenser.” Denise M. Matricciani, Vice President, Government Relations, Maryland Hospital Association (MHA) submitted a statement to the Advisory Council that MHA fully supports the comments made by Delora Sanchez and added that prescription drug volume is vastly different in an inpatient hospital setting and hospitals are subject to much more rigorous oversight than in other settings.

Michael N. Souranis, P.D., a Member of the Maryland Board of Pharmacy has expressed some concern with this exemption. He believes that a case can be made for a tendency for both abuse and diversion in the hospital setting. There is no data or studies on this subject. Discussions between Mr. Souranis and hospital pharmacists are reported by him to show problems with nurses, pharmacy technicians, physicians, and health care personnel who have abused and diverted CDS in the hospital setting. CDS medication dispensed by a hospital pharmacy is billed by the central pharmacy and could therefore be reported. Unit Dose medication as well as emergency supplies at stations within the hospital are tabulated by the hospital pharmacy. Mr. Souranis questions the strength of the factual basis of the Maryland Hospital Association’s statement that there would be a substantial administrative and cost burden. He notes that hospitals are mostly not-for-profit entities and do not pay taxes. Mr. Souranis notes with emphasis that out-patient hospital pharmacies should not be exempt from reporting. Prescriptions are filled in these out-patient pharmacies, not orders. A different permit is issued for an out-patient pharmacy than for an in-patient hospital pharmacy.

Specifically not excluded from the definition of a “dispenser” are veterinarians. Though the profession is controlled through the Agriculture Article, they are required to be registered as dispensers for the medication they give to the owners of animals they treat which are not filled through a prescription. There have been instances when CDS medication meant for “Fluffy” has found itself diverted to the owners of “Fluffy” and others.

Prior Maryland [HB1287-2006] and other state inclusions in the drugs to be monitored:

HB1287-2006	<p>21-2A-05.</p> <p style="text-align: center;">(A) FOR EACH MONITORED PRESCRIPTION DRUG THAT IS DISPENSED, A DISPENSER SHALL SUBMIT TO THE PROGRAM INFORMATION</p> <p>21-2A-01.</p> <p style="text-align: center;">(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS</p>
-------------	--

	<p>INDICATED.</p> <p style="text-align: center;">* * *</p> <p>(D) (1) “DISPENSER” MEANS A PERSON WHO DISPENSES A MONITORED PRESCRIPTION DRUG TO A PATIENT OR THE PATIENT’S AGENT IN THE STATE.</p> <p>(2) “DISPENSER” INCLUDES A PERSON OPERATING BY MAIL OR OTHER MEANS FROM A PLACE OF BUSINESS OUTSIDE THE STATE.</p> <p>(3) “DISPENSER” DOES NOT INCLUDE A LICENSED HOSPITAL PHARMACY THAT DISPENSES A MONITORED PRESCRIPTION DRUG FOR INPATIENT HOSPITAL CARE.</p> <p>(E) “DISPENSES” HAS THE MEANING STATED IN § 12-101³³ OF THE HEALTH OCCUPATIONS ARTICLE.</p>
<p>Oklahoma</p>	<p>Okla. Stat. § 2-309C. Dispensers of Schedule II, III, IV or V controlled dangerous substances--Transmittal of certain information to central repository--</p> <p>A. A dispenser of a Schedule II, III, IV or V controlled dangerous substance, except Schedule V substances that contain any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers shall transmit to a central repository</p> <p>§ 2-309B. Definitions</p> <p>For the purposes of the Anti-Drug Diversion Act:</p> <p style="text-align: center;">* * *</p> <p>2. “Dispenser” means a person who distributes a Schedule II controlled dangerous substance, but does not include a licensed hospital pharmacy or a licensed nurse or medication aide who administers such a substance at the direction of a licensed physician...</p>
<p>Florida</p>	<p>Fla Stat. § 893.055. Prescription drug monitoring program</p> <p>(3) The pharmacy dispensing the controlled substance and each prescriber who directly dispenses a controlled substance shall submit to the electronic system, by a procedure and in a format established by the department and consistent with an ASAP-approved format, the</p>

³³ **HO §12-101. Definitions.**

(a) *In general.*- In this title the following words have the meanings indicated.

* * *

(h) *Dispense or dispensing.*- “Dispense” or “dispensing” means the procedure which results in the receipt of a prescription or nonprescription drug or device by a patient or the patient’s agent and which entails the:

- (1) Interpretation of an authorized prescriber’s prescription for a drug or device;
- (2) Selection and labeling of the drug or device prescribed pursuant to that prescription; and
- (3) Measuring and packaging of the prescribed drug or device in accordance with State and federal laws.

	<p>following information for inclusion in the data base:</p> <p>(4) Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system...</p> <p>(5) When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:</p> <p>(a) A health care practitioner when administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.</p> <p>(b) A pharmacist or health care practitioner when administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.</p> <p>(c) A practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections.</p> <p>(d) A practitioner when administering a controlled substance in the emergency room of a licensed hospital.</p> <p>(e) A health care practitioner when administering or dispensing a controlled substance to a person under the age of 16.</p> <p>(f) A pharmacist or a dispensing practitioner when dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.</p>
<p>Virginia</p>	<p>Va Code Ann. § 54.1-2521. Reporting requirements</p> <p>A. The failure by any person subject to the reporting requirements set forth in this section and the Department’s regulations to report the dispensing of covered substances shall constitute grounds for disciplinary action by the relevant health regulatory board.</p> <p>B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information:</p> <p>§ 54.1-2519. Definitions</p> <p>“Dispenser” means a person or entity that (i) is authorized by law to dispense a covered substance or to maintain a stock of covered substances for the purpose of dispensing, and (ii) dispenses the covered substance to a citizen of the Commonwealth regardless of the location of the dispenser, or who dispenses such covered substance from a location in Virginia regardless of the location of the recipient.</p> <p>§ 54.1-2522. Reporting exemptions</p> <p>The dispensing of covered substances under the following circumstances shall be exempt from the reporting requirements set forth in § 54.1-2521:</p> <ol style="list-style-type: none"> 1. Dispensing of manufacturers’ samples of such covered substances or of covered substances dispensed pursuant to an indigent patient program offered by a pharmaceutical manufacturer. 2. Dispensing of covered substances by a practitioner of the healing arts to his patient in a bona fide medical emergency or when pharmaceutical services are not available.

	<p>3. Administering of covered substances.</p> <p>4. Dispensing of covered substances within an appropriately licensed narcotic maintenance treatment program.</p> <p>5. Dispensing of covered substances to inpatients in hospitals or nursing facilities licensed by the Board of Health or facilities that are otherwise authorized by law to operate as hospitals or nursing homes in the Commonwealth.</p> <p>6. Dispensing of covered substances to inpatients in hospices licensed by the Board of Health.</p> <p>7. Dispensing of covered substances by veterinarians to animals within the usual course of their professional practice.</p> <p>8. Dispensing of covered substances as otherwise provided in the Department's regulations.</p>
<p>Vermont</p>	<p>Chapter 84 A § 4283. Creation; implementation</p> <p style="text-align: center;">* * *</p> <p>(b) As required by the department, every dispenser who is licensed by the Vermont board of pharmacy shall report to the department in a timely manner data for each controlled substance in Schedules II, III, and IV, as amended and as may be amended, dispensed to a patient within Vermont. Reporting shall not be required for:</p> <p>(1) a drug administered directly to a patient; or</p> <p>(2) a drug dispensed by a health care provider at a facility licensed by the department, provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of 48 hours.</p>
<p>Kentucky</p>	<p>KRS 218A.202. Electronic system for monitoring controlled substances -- Penalty for illegal use of system -- Pilot project -- Continuing education programs.</p> <p>(3) Every dispenser within the Commonwealth or any other dispenser who has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy shall report to the Cabinet for Health and Family Services the data required by this section in a timely manner as prescribed by the cabinet except that reporting shall not be required for:</p> <p>(a) A drug administered directly to a patient; or</p> <p>(b) A drug dispensed by a practitioner at a facility licensed by the cabinet provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours.</p>

Another consideration focuses on the fact that there is a realization that cooperation between jurisdictions are beneficial, if not essential, to the proper working of the system. To that effect, Virginia provides:

Va Stat. Ann. § 54.1-2523. Confidentiality of data; disclosure of information; discretionary authority of Director

D. The Director may enter into agreements for mutual exchange of information among prescription monitoring programs in other jurisdictions, which shall use the information only for purposes allowed by this chapter.

Dr. Robert L. Lyles, Jr., reports that data bases presently exist and are fully functional covering 99 % of the approximately 61,000 pharmacies in the US including mail order pharmacies. Pharmacies already submit the pharmacy information for the industry for eligibility, level of benefits, etc. This data base is presently collected by the pharmacies and is entered into the SureScripts data base network, An important requirement should be that since self pay prescriptions are not presently in the SureScripts data network, the self pay prescriptions would be additional required effort as part of the Prescription Drug Monitoring Program. No self pay data is reported presently and this self pay prescription data would not be captured without a special requirement and is estimated to constitute 1 to 3 % of all prescriptions prescriptions. Self pay records are presently maintained on a local basis as required by State and Federal laws. The costs the dispenser should essentially be the same with the addition of a self-pay inclusion.

Recommendation No. 4: Data information to be submitted

It is the recommendation of the Advisory Council that the data to be submitted as part of the PDMP should be determined by the Secretary upon consultation with the Advisory Board. (See Recommendation No. 2). The Advisory Council recommends that there be no inclusion in the statute for a patient opt out provision by patients and that all defined dispensing data be submitted through the PDMP be reported.

Commentary

Some states such as Virginia have legislatively provided for specific data to be submitted to the PDMP. The Advisory Council feels that with changing technology, data base systems in-place and in the process of being updated, and the need for cooperation among states for the exchange of information, that it is best left to the Secretary to determine what should be included upon consultation with and a recommendation received from the Advisory Board.

Information designated to be included in the data base in the previously proposed Maryland Legislation and some other states are as follows:

HB1287-2006

21-2A-05.

(A) FOR EACH MONITORED PRESCRIPTION DRUG THAT IS DISPENSED, A DISPENSER SHALL SUBMIT TO THE PROGRAM INFORMATION SPECIFIED BY THE SECRETARY, INCLUDING:

- (1) A PATIENT IDENTIFIER;**
- (2) THE PRESCRIPTION DRUG DISPENSED;**

	<p>(3) THE DATE OF DISPENSING;</p> <p>(4) THE QUANTITY DISPENSED;</p> <p>(5) THE PRESCRIBER; <u>AND</u></p> <p>(6) THE PHARMACY FROM WHICH THE DRUG IS DISPENSED; AND</p> <p>(7) THE PRESCRIBER'S DIAGNOSIS CODE, IF SUCH CODE IS PART OF THE ELECTRONIC RECORD CREATED BY THE DISPENSER.</p>
<p>Oklahoma</p>	<p>Okla Stat. § 2-309C. Dispensers of Schedule II, III, IV or V controlled dangerous substances--Transmittal of certain information to central repository--...</p> <p>A. A dispenser of a Schedule II, III, IV or V controlled dangerous substance, except Schedule V substances that contain any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers shall transmit to a central repository designated by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control using the American Society for Automation in Pharmacy's (ASAP) Telecommunications Format for Controlled Substances version designated in rules by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control, the following information for each dispensation:</p> <ol style="list-style-type: none"> 1. Recipient's name, when feasible to submit; 2. Recipient's identification number; 3. National Drug Code number of the substance dispensed; 4. Date of the dispensation; 5. Quantity of the substance dispensed; 6. Prescriber's United States Drug Enforcement Agency registration number; and 7. Dispenser's registration number.
<p>Florida</p>	<p>§ 893.055. Prescription drug monitoring program</p> <p>(3) The pharmacy dispensing the controlled substance and each prescriber who directly dispenses a controlled substance shall submit to the electronic system, by a procedure and in a format established by the department and consistent with an ASAP-approved format, the following information for inclusion in the data base:</p> <p>(a) The name of the prescribing practitioner, the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription.</p> <p>(b) The date the prescription was filled and the method of payment, such as cash by an individual, insurance coverage through a third party, or Medicaid payment. This paragraph does not authorize the department to include individual credit card numbers or other account numbers in the data base.</p> <p>(c) The full name, address, and date of birth of the person for whom the prescription was written.</p> <p>(d) The name, national drug code, quantity, and strength of the controlled substance dispensed.</p>

(e) The full name, federal Drug Enforcement Administration registration number, and address of the pharmacy or other location from which the controlled substance was dispensed. If the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, federal Drug Enforcement Administration registration number, and address.

(f) The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's National Provider Identification (NPI).

(g) Other appropriate identifying information as determined by department rule.

Virginia

Va. Code Ann. § 54.1-2521. Reporting requirements

A. The failure by any person subject to the reporting requirements set forth in this section and the Department's regulations to report the dispensing of covered substances shall constitute grounds for disciplinary action by the relevant health regulatory board.

B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information:

1. The recipient's name and address.
2. The recipient's date of birth.
3. The covered substance that was dispensed to the recipient.
4. The quantity of the covered substance that was dispensed.
5. The date of the dispensing.
6. The prescriber's identifier number.
7. The dispenser's identifier number.

8. Any other non-clinical information that is designated by the Director as necessary for the implementation of this chapter in accordance with the Department's regulations.

9. Any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds.

Vermont

Chapter 84 A. § 4283. Creation; implementation

(b) As required by the department, every dispenser who is licensed by the Vermont board of pharmacy shall report to the department in a timely manner data for each controlled substance in Schedules II, III, and IV, as amended and as may be amended, dispensed to a patient within Vermont. Reporting shall not be required for:

(1) a drug administered directly to a patient; or

(2) a drug dispensed by a health care provider at a facility licensed by the department, provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of 48 hours.

(c) Data for each controlled substance that is dispensed shall include the following:

(1) patient identifier, which may include the patient's name and date of birth;

(2) drug dispensed;

- (3) date of dispensing;
- (4) quantity and dosage dispensed;
- (5) the number of days' supply;
- (6) health care provider; and
- (7) dispenser.

Kansas

KRS § 218A.202 (2009)

(3) Every dispenser within the Commonwealth or any other dispenser who has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy shall report to the Cabinet for Health and Family Services the data required by this section in a timely manner as prescribed by the cabinet except that reporting shall not be required for:

(a) A drug administered directly to a patient; or

(b) A drug dispensed by a practitioner at a facility licensed by the cabinet provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours.

(4) Data for each controlled substance that is dispensed shall include but not be limited to the following:

- (a) Patient identifier;
- (b) Drug dispensed;
- (c) Date of dispensing;
- (d) Quantity dispensed;
- (e) Prescriber; and
- (f) Dispenser.

As to patient consent:

The Maryland Health Care Commission (MHCC) Technology to Support a PDMP in Maryland, October 1, 2009 Report calls attention to the fact that the Maryland Confidentiality of Medical Records Act is consistent with HIPAA regarding implicit consent of patients. The Report also notes that there is an opt out provision for patients in some instances regarding the confidentiality of their medical records being included in information that is available to providers and able to be exchanged among providers with only implicit consent for treatment purposes. MHCC has called out attention at p. 10 of their Report to the fact that a 2007 opinion from the Attorney General of Maryland addressed the requirement of an opt-in versus opt-out policy in an electronic health records system. The Attorney General's opinion that a consumer does not have the right to an opt-out under the Act of a Health Information Exchange (HIE).

To keep the PMP Program operational and effective, as stated above, the Advisory Council, recommends that there be no patient opt-out or opt-in provision and that the Legislation

providing for the Program specifically address this fact. It would be surprising if some of the patients most likely to opt-out were not those for whom there is a necessity of a PDMP.

The HIE initiative of the MHCC states that patient record information is to be collected in a health record bank of personal health records that exist on an individual. The record will not constitute a central record but rather a system that allows records to be looked at throughout the system by both Health Care Providers and dispensers. See p. 5 of the October, 1, 2009, Report to the Advisory Council. While the HIE will inform consumers of their right not to participate through a public awareness campaign, this right not to participate should not apply to drugs required to be reported through the PDMP. The HIE will only implement a program that meets federal enforced statutes.

In general, services are rendered with the agreement, amounting to consent from the consumer whose information is being exchanged. The statewide HIE will notify consumers about its existence and the consumer's ability to opt-out of all exchange participation, meaning that they will have the choice to prohibit all of their health information from flowing through the HIE. The notice will describe the statewide HIE, its purpose and its functions. In effect, opting out will be the equivalent of placing one's self on a do not call or global suppression list. However, some information will remain in the statewide HIE for consumers that choose to opt-out. Pharmacy data is an example of the data that will continue to flow through the exchange even if a consumer opts out of the exchange. In practice this means that the statewide HIE will include all consumers by default unless they request not to be included. For those consumers that participate, the statewide HIE will be available for a variety of purposes, some of which will require additional consumer consent or authorization under the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) Administrative Simplification Provisions and the *Maryland Confidentiality of Medical Records Act* (MCMRA), and some of which will operate without explicit patient approvals.³⁴ For instance, under most circumstances, a hospital emergency department will ask verbal approval from any consumer capable of indicating consent before they use the statewide HIE to query external sources for health information. The Attorney General has concluded that the MCMRA permits an HIE in which health records are held by certain providers and referenced in the MPI facilitating other providers access to the records as needed without the authorization of the consumer.³⁵ This function is a critical element of the approach in Maryland.)

Statutes enacted to provide for a PDMP more recently contain provisions that allow cooperation between states and an exchange of information among states relating to the programs. It is recorded that abuse and diversion readily occur in situations where an individual may go from state to state to have physicians write prescriptions and to have pharmacies dispense medication for CDS medication. Statutorily mandating information to be included in the data collected may

³⁴ Maryland's Confidentiality of Medical Records Act, codified at Health-General § 4-301 *et seq.*, has been operative since 1991.

³⁵ *Ibid.*

very well have a negative and limiting effect on the cooperation that Maryland may need in the near for an exchange of information with its sister jurisdictions of Virginia, Delaware, the District of Columbia and Pennsylvania.

Software used by pharmacies:

Janet M. Hart, P.D., a pharmacist member of the Advisory Council reports that there are a number of vendors who offer software for reporting information: McKesson, RelayHealth, HID, Optimum Technologies and Atlantic Associates. These vendors contract with States to gather the data and then process that data. States use various standards for reporting data. ASAP standards (American Society for Automation in Pharmacy) are used. Each vendor has minor differences, however, each vendor is used by several states. Vendor prices vary depending on what the state requires, the number of pharmacies, reporting. To the best of her knowledge, the starting price for this software and processing is around \$100,000 or greater per year. Some states gather the data themselves, the way Maryland intends to gather its data with the Health Exchange Initiative in progress through the Maryland Health Care Commission.

Ms. Hart is correct in stating it is going to be essential to have a pharmacist on the Advisory Board with knowledge of vendors and standards. The basis data elements reported can be identified for reporting. There is concern that when data is not available to the pharmacist, such as diagnosis, caregiver, name picking up, etc., there is going to be no current way to provide this data. To add this specific data would be very costly to pharmacies.

Kentucky and Virginia provisions for information sharing with other states:

KRS §218A.245. Reciprocal agreements with other states to share prescription drug monitoring information.

(1) The secretary of the Cabinet for Health and Family Services may enter into reciprocal agreements with any other state or states of the United States to share prescription drug monitoring information if the other state's prescription drug monitoring program is compatible with the program in Kentucky. If the secretary elects to evaluate the prescription drug monitoring program of another state as authorized by this section, priority shall be given to a state that is contiguous with the borders of the Commonwealth.

(2) In determining compatibility, the secretary shall consider:

- (a) The essential purposes of the program and the success of the program in fulfilling those purposes;
- (b) The safeguards for privacy of patient records and its success in protecting patient privacy;
- (c) The persons authorized to view the data collected by the program;
- (d) The schedules of controlled substances monitored;
- (e) The data required to be submitted on each prescription;
- (f) Any implementation criteria deemed essential for a thorough comparison; and
- (g) The costs and benefits to the Commonwealth in mutually sharing particular information available in the Commonwealth's data base with the program under consideration.

(3) The secretary shall review any agreement on an annual basis to determine its continued compatibility with the Kentucky prescription drug monitoring program.

(4) The secretary shall prepare an annual report to the Governor and the Legislative Research Commission that summarizes any agreement under this section and that analyzes the effectiveness of that agreement in monitoring the dispensing of controlled substances in the Commonwealth.

(5) Any agreement between the cabinet and another state shall prohibit the sharing of information about a Kentucky resident, practitioner, pharmacist, or other prescriber for any purpose not otherwise authorized by this section or KRS 218A.202.

Va Stat. Ann. § 54.1-2523. Confidentiality of data; disclosure of information; discretionary authority of Director

D. The Director may enter into agreements for mutual exchange of information among prescription monitoring programs in other jurisdictions, which shall use the information only for purposes allowed by this chapter.

Recommendation No. 5 : How submission of data information is to be made

The Advisory Council recommends that data required to be submitted should be electronically submitted in a form as determined by the Secretary upon advice and recommendation from the Advisory Board on Prescription drug Monitoring be Established within the Department of Health and Mental Hygiene. For good cause the Secretary may authorize a dispenser to submit data by an alternative form of submission or omit one or more elements of prescription monitoring data.³⁶ It is the recommendation of the Advisory Council that the system used for submitting data should not be a stand-alone system. Rather, it is recommended that the data base for collection of information be developed in connection with the Maryland Health Care Commission (MHCC) Health Information Exchange (HIE).³⁷

Commentary

The Advisory Council considered three separate possibilities with regard to this all important part of the PDMP to be developed:

1. Wait for the implementation of the Health Information Exchange now being developed for the capture of health care records through the Maryland Health Care Commission,
2. Establish a stand-alone system through funding obtained by the Harold Rogers Program and other sources, or
3. The possible use of software from another established state program to be adapted to the requirements of a Maryland system

³⁶ P 6 of the October 1, 2009 report on Statewide Health Information Exchange through the Maryland Health Care Commission notes that the statewide HIE intends to benefit all Marylanders and to recognize the challenges of uninsured and underserved populations. There are going to be a few dispensers who are not technologically sufficiently proficient that will have to be allowed a time to submit data in a form other than electronically.

³⁷ The vote by the Advisory Council was 13 in favor of this recommendation with 3 members in favor of a stand alone system.

The stand-alone program and funding:

Dr. J. Ramsay Farah, a Member of the Advisory Council was a lead proponent for the establishment of a stand-alone system, which has been utilized by so many other states that have PDMPS. He expressed concerns about the possibility that this PDMP effort be sidelined by relying on the schedule of implementation of the MHCC efforts of a comprehensive approach to Maryland's Data processing. That project is three years away from being tapped into for any component. Dr. Farah suggested that we indeed do not have to wait for this, and actually it makes more sense to start ASAP on a PDMP program. The legislators will hardly be willing to invest \$900,000 on a yet to be proven program. The proposal for a stand-alone system will be a "Win-Win" for all parties concerned.

The highlights of the stand-alone system as outlined by Dr. Farah are stated below. It is noted in this recommendation that the Advisory Council was successful in submitting an application for a grant to the Harold Rogers appropriations committee for a study of the program to be established for which we received the sum of \$50,000. There are implementation funds available in the amount of \$400,000 upon approval of an application. Lastly, there are subsequent funds for improvement of an existing systems which may be applied for in an amount up to \$200,000. Dr. Farah suggests:

1. Apply for the \$400,000 grant from the Harold Rogers appropriations, Bureau of Justice. (We are favored if we pass legislation this upcoming cycle. The grant request would go in by end of January 2010. With Legislators and the governor deciding by the end of April of the system to be employed, the application for a grant would be contingent on passing legislation favoring this approach. The Harold Rogers grantor decides if we would be awarded the funds in July 2010 with distribution of the funds to start in October 2010.
2. Apply for the \$200,000 grant from NASPER. (We are favored as it would be the accepted precedent step of year two. The grant is designed to improve and enhance year two of initiated programs.
3. Initiate the program as stand-alone from the data perspective with the proviso that the technical team work with MHCC IT and the software vendor for the first three years of the program with the goal of a transition in the future.
4. The funds of \$600,000 now available, may not necessarily be there in three years. We can use a number of income venues to self sustain this program in future years. Having the seed money is extremely valuable in the formative years, until we position ourselves to be independent fiscally. Revenues from user fees, CDS licensure, or through appropriations from criminal seizures and/or fines have been floated as ideas for consideration and study.
5. Time and diligent work is needed for a successful start. Once we iron out the bugs of this new initiative, it would make it easier for all parties to make the decision as to the merits of a PDMP in Maryland worthy of long term funding.
6. This recommendation is made because we need a viable program now that addresses concerns of: (a) patient safety, (b) a practice tool enhancer that empowers providers in optimal prescribing and decreases the potential of diversion, and (3) an ipso-facto (by its mere presence) deterrent for patients abusing the system. Granted that stand-alone systems cannot be forever robust with today's advancing technology, but that is why with proper proactive planning and proper use of

today's available seed money, we can launch the starting elements of a great service for the citizens of Maryland.

Dr. Peter Cohen, the Medical Director of the Alcohol and Drug Abuse Administration (ADAA) was a regular attendee at meetings of the Advisory Council. Dr. Cohen supports Dr. Farah's recommendation for strategic, logistical and financial reasons. He notes that PDMPs now in place in other states have a history of growing ease in "talking" to one another which is important because of the drug abuse and diversion across State lines. Finally, he questions why data submission through a stand-alone system established now cannot be utilized in connection with the HIE in the future.

As to Dr. Cohen's comments regarding the ability of one system to talk to another, the Advisory Council received this information advertisement from a third party vendor:

"Optimum Technology is happy to announce the public availability of Optimum's Prescription Monitoring Information Exchange Module or PMIX Module. The PMIX Module allows any State PMP to easily, effectively and securely share data with the PMIX Hub and other States. The PMIX Module is easily integrated into any existing modern PDMP system independent of technology platform or vendor it may have been built upon or purchased from.

Once again, it works with any modern PDMP system regardless of what vendor you bought it from or who built it!

Install takes less than 30-days and allows States with a current PDMP to securely request and submit data to the PMIX Hub. As many States already know the ability to share PDMP data allows greater visibility into potential doctor shopping and controlled substance use patterns. Federal grants may be available for States wishing to upgrade their PDMP system to take advantage of the PMIX Hub and data sharing.

Call or e-mail now to schedule a brief discussion on how PMIX can help your State and your State's PDMP.

Gregory J. Davda, Sr.
Optimum Technology, Inc.
100 E. Campus View Blvd., Suite 380
Columbus, Ohio 43235

email: greg.davda@otech.com
tel: 614-547-0015
fax: 614-547-0068

The Maryland Health Care Commission position:

The MHCC Technology to Support a DMP in Maryland, October 1, 2009 Report informs us that PDMPs that use A File Transfer Protocol (FTP) to transfer data are often faced with a number of critical challenges in managing the program: the cost to obtain and pay for disk space on a FTP server, the availability of automatic backup, the unreliability of some FTP connections, the corruption of files that sometimes occurs, the necessity to

encrypt data before it is transferred, and the fact that FTP servers do not normally use data mirroring.³⁸ Therefore, the Advisory Council is of the opinion that the Secretary should be relied upon to make the final decision as to how the data is to be submitted.³⁹

Most other state PDMPs have like provisions relying on an experienced body to make the final decisions regarding transmission of data.⁴⁰

³⁸ P. 11 of the Report citing Perkins, Donovan, *Considerations in Secure Data and Information Exchange Protocols between Banks and Corporations*. Available online at: www.acuprint.com/articles/transporterconsiderations.

³⁹ The 2006Bill/HB1286 provided:

(B) EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS SECTION, A DISPENSER SHALL SUBMIT PRESCRIPTION MONITORING DATA TO THE PROGRAM BY ELECTRONIC SUBMISSION.

(C) THE PROGRAM, FOR GOOD CAUSE SHOWN, MAY AUTHORIZE A DISPENSER TO:

- (1) SUBMIT PRESCRIPTION MONITORING DATA BY AN ALTERNATIVE FORM OF SUBMISSION; OR**
- (2) OMIT ONE OR MORE ELEMENTS OF PRESCRIPTION MONITORING DATA.**

⁴⁰ **Oklahoma:** 63 Okl. St. §2-309C.

B. The information required by this section shall be transmitted:

1. On an electronic device which is compatible with the receiving device of the central repository or by computer diskette, magnetic tape, CD-ROM or in a format or other media designated acceptable by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control; and

2. Within thirty (30) days of the time that the substance is dispensed.

* * *

D. The Director of the Bureau shall have the authority to allow paper submissions on the universal claim form, if the dispenser has an appropriate hardship.

Florida: Fla. Stat. §893.055

(3) The pharmacy dispensing the controlled substance and each prescriber who directly dispenses a controlled substance shall submit to the electronic system, by a procedure and in a format established by the department and consistent with an ASAP-approved format, the following information for inclusion in the data base: . . .

(4) Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but not more than 15 days after the date the controlled substance is dispensed unless an extension is approved by the department for cause as determined by rule. A dispenser must meet the reporting requirements of this section by providing the required information concerning each controlled substance that it dispensed in a department-approved, secure methodology and format. Such approved formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail.

Virginia: Va Code. Ann §54.1-2521

C. The reports required herein shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.

How Information is to be Submitted—through the Statewide Health Information Exchange (as stated by David Sharp, Ph.D.)

The statewide HIE consists of a hybrid technology model where electronic health information is kept with the originating provider, and uses the HIE as the conduit for information sharing. The statewide HIE serves as a secure and trusted conduit, rather than a centralized repository, that provides a roadmap for properly routing information to the appropriate location. A hybrid model is generally less threatening to providers and consumers because it is less disruptive to existing, trusted relationships between consumers and their health care providers, and raises fewer regulatory issues in today's privacy and security focused regulatory environment. The architecture is capable of connecting with the existing 47 acute care hospitals, 7,914 physician practices, and 1,628 pharmacies throughout Maryland.⁴¹

The statewide HIE provides the ability for one system to communicate with another and eliminates the need to manually collect data from pharmacies and prescribers. A flexible infrastructure enables the statewide HIE to deploy technology designed to carve out pharmacy transaction data at different points for insured and wholesale transactions. The impact of the PDMP through the statewide HIE on pharmacies would be minimal; today, insured data is routinely sent electronically to payers and pharmacy benefit managers. The statewide HIE can coalesce and securely store the data in an independent data base where only appropriately authenticated individuals would have access to the data. It is conceivable that a statewide HIE can have data available for analysis within minutes from when a transaction is processed by the pharmacy.

As currently designed, the infrastructure incorporates standards consistent with that of emerging national technology. The statewide HIE will only implement technology that meets federally endorsed standards and integration protocols that bridge proprietary boundaries. This ensures that the statewide HIE is not vulnerable to vendor selection issues or risks, and is also compatible with HIEs developed in other states and the federal initiative, critical to an effective PDMP.

How Information is Submitted

The statewide HIE is currently under development and well suited to support a PDMP. The technology will enable electronic patient information to reside with the provider and information to be shared securely across the Internet. Using the statewide HIE as the infrastructure to maintain a PDMP, among other things, allows the data to be accessed in real-time. Today, prescription data is routinely transmitted via the pharmacy information system to pharmacy benefit managers and third party payers during the prescription fill

⁴¹ Information on hospitals obtained from the Health Services Cost Review Commission, physician data from the Maryland Board of Physicians, pharmacy data provided by the Maryland Board of Pharmacy.

process. The statewide HIE would gather select data elements as it flows through the exchange.

Private pay transactions could be made available to the statewide HIE with minimal effort on the part of pharmacies. The simplest way to gather private pay transaction is to require pharmacies to treat cash transactions as they do today with third party payers and electronically transmit them to the statewide HIE. This approach allows PDMP data to be available for analysis almost immediately after the transaction is processed. PDMP data can either be securely stored within the HIE or elsewhere, or the data can be made available on an as needed basis to appropriate authorized users through queries. Integrating a PDMP into the HIE is achievable over the next three to five years.⁴² This is the same amount of time required to fully implement a standalone client-server model.

The statewide HIE will enable providers to take advantage of an existing data sharing infrastructure for reporting prescription drugs. Stringent requirements around access, authentication, audit, and authorization will ensure the appropriate use of the system; how usage of the system is governed; how users are accurately and appropriately identified; and how records of that usage are captured, stored, and utilized for various audit purposes. Access to the statewide HIE is based on defined roles for each participating entity. Users of the system will have access to a limited data set. States that have a PDMP currently limit the amount of data that is reported and available for access. A limited data set for a Maryland PDMP is consistent with the minimum access requirements under the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) Administrative Simplification provisions.

The statewide HIE will support nationally endorsed standards and integration protocols. Implementing a data sharing infrastructure that uses existing standards minimizes interoperability challenges as providers connect to the statewide HIE. This also ensures that the technology is not vulnerable to vendor selection issues or risks, and is compatible with HIEs developed in other states. The architecture of the statewide HIE is capable of connecting with the existing 47 acute care hospitals, 7,914 physician practices, and 1,628 pharmacies throughout Maryland.⁴³

Dr. Robert L. Lyles, Jr., a Member of the Advisory Council supports the HIE solution as the best alternative. He feels this alternative is consistent with the rapidly progressing national efforts for the establishment of a uniform, interoperable health system that the PDMP would use to provide its data network. In his opinion, the timeline for the HIE will be similar to the implementation of a free standing system which would be technologically obsolete and very expensive to maintain and administer even if it is an

⁴² Use Cases are services in a system developed through analysis of the requirements into a set of possible sequences of interactions between systems and users in a particular environment and related to a particular goal.

⁴³ Information on hospitals obtained from the Health Services Cost Review Commission, physician data from the Maryland Board of Physicians, pharmacy data provided by the Maryland Board of Pharmacy.

open source code system. The transition will be difficult from a free standing data silo approach primarily because during the three years of development of the silo, not only will the State be dealing with an obsolete technology but also with a proprietary established administrative “function” that will attempt to assume a “life of its own” via contracts, personnel.

Also, Dr. Lyles states, that EMR usage is also going to continue to develop. For those who presently have an EMR system, the industry wide SureScripts data network which has been developed by pharmacy, carriers, PDMP’s, etc., and supported by Medicare with a minor reimbursement for eprescribing has been available and providing pharmacy history for several years. As for self pay prescriptions reporting, there would be no difference between any of the systems. Self pay prescriptions would be required to be reported via the data base network. From a technological data base point of view, the use of a SureScripts type of data network as an interim solution would provide for an easy transition to the use of a fully implemented HIE system. We will see the increased implementation of EMR’s since the Fed Govt via Medicare has “earmarked” funds of \$44,000.00 per provider for EMR purchase. The real impetus is that without an EMR system providers will not be able to participate in with Medicare in the future. Many of the EMR vendors are sure enough of the funding that they are willing to provide the system to the providers and forgive the cost if the FED does not provide the funding. Overall, the HIE solution is the best solution for the State of Maryland both during the interim period and for the long haul.

Finally, Dr. Lyles notes that the data base shall be considered a health record as defined in the State of Maryland and shall comply with the State of Maryland regulations and statutes for health IT including those regulations promulgated through HB 706 (2008 session) compliance.

Another possible approach:

From: Dr. Robert L. Lyles, Jr.:

An additional option for consideration is to require electronic health networks and other intermediaries to submit a limited data set from the electronic prescription to a specific data base. Electronic health networks and intermediaries have evolved as we have progressed through the advancements in data base technology since the 2006 legislation for the PDMP effort is the interim usage of the pharmaceutical industry (PBMs, carriers, chain pharmacies, etc). Hub data base networks applications that are presently available and being used for eprescribing with Electronic Medical Records can contain patient specific prior medication history. Examples of these applications include SureScripts, eRx Network, Express Scripts, Allscripts, Emdeon, DrFirst RCopia which are used within the Electronic Medical Records solutions in physician’s offices.

This alternative would rely on using the available Electronic Medical Record (EMR) systems *eprescribing software* applications which are increasingly operational and functional in many medical practices in Maryland. This approach to the PDMP solution uses the existing pharmaceutical industry data base networks that presently provide a connection between prescribers, pharmacists-pharmacies, carriers, and PBM/payers to compose a composite electronic pharmaceutical record data base. This connected data base give the prescriber (example: physician, NP, PA, etc) the ability to securely access and aggregate the patient's prescription history from community pharmacies, patient medication history from payers, and pharmacy benefit managers. The use of the eprescribing software in physician's offices would be for an interim solution and allow time and resources to be used for the development of State regulations concerning PDMP and medical data access and usage, as well as, progress to the State wide HIE in the near future.

Providers

No additional costs for software if the provider has an EMR with eprescribing application. This eprescribing application is functionally integrated into Electronic Medical Record software packages providing prescription benefits, prescription history, and the ability to electronically transmit prescriptions with exceptions secondary to the DEA regulations. It should be noted that depending on entry into the data bases, the prescriber can observe the history of all medications including class II through IV medications, but cannot eprescribe class II medications per DEA. Moreover, there is access to free eprescribing software for the providers who are still considering a full EMR system. Additional advantages for the provider include:

- Enables prescribers to meet Medicare requirements of eprescribing with eligibility for additional 2% reimbursement—this requirement for eprescribing will be mandatory on January 1, 2012 for Medicare patients.
- Providers are eligible for a Medicare payment of up to \$44,000.00 per provider to purchase an EMR system — these incentive payments are scheduled to be available in January, 2011.
- Operationally, the prescriber can work within the EMR system and does not have to exit the EMR to separately access the PDMP system files in accordance with regulations—this may increase compliance and usage of the PDMP.
- The prescriber will have access to all of the patient's medication history – not just schedule II through IV pharmacy history.
- Costs of operations of the EMR to the prescriber would be included in the EMR costs -- these costs may also be covered via regulations developed through HB 706 which will require carrier to reimburse providers for EMR costs.

Dispensers

The data base network was developed by the pharmacy industry. It presently exists and is fully functional covering the majority of the approximately 61,000 pharmacies in the US including mail order pharmacies and is very well represented in the Maryland and Mid - Atlantic region. Pharmacies already submit the pharmacy information for the carrier/pharmaceutical industry for eligibility, level of benefits, and formulary coverage to determine carrier responsibility, etc. This data base is presently collected by the pharmacies and is entered into the industry data base network. An important consideration is that the self pay patient data may not be complete. This data set could be accommodated through special designation and collected for the State of Maryland through regulation. An important requirement would be that since self pay prescriptions may not presently be entered into the industry data network, the self pay prescriptions may require additional effort on the part of the dispenser - this self pay prescription data may not be captured without a special requirement and is estimated to be 1 to 3 % of prescriptions. Self pay prescription records are presently maintained on a local and composite pharmacy basis as required by State and Federal laws.

With the exception of efforts associated with data entry for the self pay prescription requirement, the requirements for the dispenser should essentially not change.

State of Maryland

The State of Maryland and the Federal Agencies, Departments, etc., would have access through regulation. Examples are as follows:

- Access to the data base network through an agency which DHMH should have through its pharmacy or other divisions and the Medicaid Pharmacy program by regulation and pharmacy benefit management;
- Development of regulations and administration for access to the portion of the data base used as with all approaches to PDMP -- regulations for usage;
- All levels of law enforcement will have access via the State of Maryland regulations for PDMP usage; and
- Start-up schedule would depend on the development of the necessary regulations for access and usage for “those” who wish access prescription data other than providers and pharmacists which are already using this and the other pharmacy based systems presently.

The cost of the programs and the money available or not available:

With the purpose of the Advisory Council being to make responsible recommendations to the legislature in the report, there is a question of the worth of a PDMP system which should be considered. Many states have not seen any significant change in the societal

effects of diversion after implementation. Additional economic burdens should not be placed on practitioners and dispensers without some program effectiveness.

Ms. Gail Amalia B. Katz, a Member of the Advisory Council has been in touch with individuals regarding the workings of the McKesson System which has been advertised to her:

“The system is configured to accommodate multiple user types. We typically leave it up to the individual state to determine what report types are available to user type. For example, prescribers and pharmacists typically only see prescriptions by patient. State administrators can see all report types, including audit reports. The system can be modified to fit state specific requirements. In most cases, we can configure without making code changes, however, we would need to understand the scope of any state specific requirements first.

The McKesson PDMP is fairly self supporting. Typically, states allocate either 1 - 1 ½ FTE’s to run the system. We provide our customer help desk for data collection efforts. We also provide a customer help desk for system users (prescribers and pharmacists, etc.). Most calls will come from external system users.⁴⁴

Ms. Katz attended the San Diego Conference of the National Alliance Convention. She reports that there was virtual agreement at the conference that there is no available data, studies, information, etc., on which to rely that would demonstrate whether these PDMPs are effective.

Recommendation No. 6: Who may have access to data base? Confidentiality

The Advisory Council recommends that access to the data base should be available to the following individuals and entities. The parameters of this access shall be determined by regulations to be adopted by the Secretary upon consultation with the Advisory Board on Prescription Drug Monitoring to be established within the Department of Health and Mental Hygiene:

1. A prescribing practitioner in connection with the medical care of a patient;
2. A dispenser in connection with the dispensing of a monitored prescription drug;
3. To Federal, State, and local law enforcement, upon issuance of a subpoena for the purpose of furthering an existing bona fide individual investigation;

⁴⁴ Ms. Katz was contracted by Brad Bauer whom I met at the San Diego conference. Apparently, McKesson, which is a prescription management company and mail-order pharmacy, already has a data base that is in use covering almost 90% of all scripts (his numbers). They have a ‘turnkey’ data base for PDMs which he thought we might want to consider.

4. To certain health care regulatory boards (Physicians, Pharmacy, Nursing, Dental, Podiatric), upon the issuance of a subpoena;
5. To the Secretary for calculating performance measures and fulfilling his/her responsibility to report to the Governor, the President of the Senate and the Leader of the House; and for information for the purpose of bona fide research, analysis, and public reporting or education by qualified personnel approved by the Secretary; and
6. To individual patients whose data has been submitted to the data base

For security and privacy, information from the Data Base to be used for reports to the Governor and the Legislature and to evaluate performance of the program, as well for bona fide research, analysis, and public reporting or education, shall not contain any information that could identify a patient, prescriber or dispenser. Information within the data base shall not be discoverable, subject to a subpoena, or admissible in a civil, criminal, or administrative action except as is specifically authorized by the legislation to be enacted establishing a Prescription Drug Monitoring Program.

Further, it is recommended that there be established a Multidisciplinary Consultation Team to assist federal, State or local law enforcement or a Health Care Licensing Board in the interpretation of data and considering whether the data, in the context of the nature of a prescriber's or a dispenser's practice, a patient's medical condition, or any other relevant facts, suggests the need for further investigation or a practice not in conformity with the existing standard of care and responsibility of the practitioner in dispensing CDS.

Commentary

Within this commentary are the following subject headings:

1. Some Maryland statutes protecting against the disclosure of patient health care records;
2. Extracted provisions from selected statutes;
3. Practitioners and Dispensers;
4. Law Enforcement;
5. Health Care Boards;
6. A Multidisciplinary Team
7. Statutory excerpts in more detail
8. The Maryland Health Care Commission and the Health Information Exchange
9. Concern from some in the Medical Community

1. Some Maryland statutes protecting against the disclosure of patient health care records:

Maryland has statutory provisions protecting against the disclosure of patient medical records, not the least of which is the Maryland Confidentiality of Medical Records Act. HG, Title 4. Statistics and Records, Subtitle 3, Confidentiality of Medical Records.

HG § 4-305. Disclosures without authorization of person in interest - In general.

HG § 4-306. Disclosures without authorization of person in interest - Investigations.

HG § 4-302. Confidentiality and disclosure generally.

(a) *In general.*- A health care provider shall:

- (1) Keep the medical record of a patient or recipient confidential; and
- (2) Disclose the medical record only:
 - (i) As provided by this subtitle; or
 - (ii) As otherwise provided by law.

* * *

(c) *Directory information.*- A health care provider may disclose directory information about a patient without the authorization of a person in interest, except if the patient has instructed the health care provider in writing not to disclose directory information.

(d) *Redisclosure.*- A person to whom a medical record is disclosed may not redisclose the medical record to any other person unless the redisclosure is:

- (1) Authorized by the person in interest;
- (2) Otherwise permitted by this subtitle;
- (3) Permitted under 1-202(b) or (c) of the Human Services Article; or
- (4) Directory information.

* * *

Mental Health Records disclosure is further limited by **HG § 4-307. Disclosure of mental health records.**

HO § 8-320. Confidentiality of Board records. (Nursing Board)

(a) *Records generally not discoverable or admissible.*- Except by the express stipulation and consent of all parties to a proceeding before the Board or any of its investigatory bodies, in a civil action, the proceedings, records, and files of the Board or any of its investigatory bodies are not discoverable and are not admissible in evidence.

(b) *Applicability of section.*- This section does not apply to a civil action brought by a party to a proceeding before the Board who claims to be aggrieved by the decision of the Board.

(c) *Later production not prohibited.*- If any medical or hospital record or any other exhibit is subpoenaed and otherwise is admissible in evidence, the use of the record or exhibit in a proceeding before the Board or any of its investigatory bodies does not prevent its production in any other proceeding.

2. Extracted provisions from selected statutes:

EXHIBIT E contains the legislation pertaining to a number of PDMPs which are currently active. Virginia, our sister state to the South, has had a PDMP working well for years. Oklahoma and Vermont are two of the newer statutory schemes enacted with the benefit of

avoiding a number of mistakes from other State systems enacted some years ago. Kentucky has one of the most recognized PDMPs and is often held up for the advances made in that state over many years in the area of Prescription Drug Monitoring.

Important statutory extracts from these statutory schemes are:

- A. Information in the data base for the electronic prescription drug monitoring system is not discoverable or admissible in any civil or administrative action, except in an investigation and disciplinary proceeding by the department or the appropriate regulatory board.
- B. Disclosure to any other person or entity, including disclosure in the context of a civil action where the disclosure is sought either for the purpose of discovery or for evidence, is prohibited unless specifically authorized by this section.
- C. The advisory reports issued by the department are not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of the report; and a person who participates in preparing, reviewing, issuing, or any other activity related to an advisory report may not be permitted or required to testify in any such civil action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with preparing, reviewing, or issuing such a report.
- D. Confidential information that has been received, maintained or developed by any board or disclosed by the board...shall not, under any circumstances, be available for discovery or court subpoena or introduced into evidence in any medical malpractice suit or other action for damages arising out of the provision of or failure to provide services. However, this subsection shall not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2.

3. The Practitioners and Dispensers:

Dispensers and practitioners should have immediate access to the data base for medical care and dispenser inquiry information pertaining to a patient. Regulations enacted will develop the terms of that access starting with a recognition and agreement that access will be through code identifying the one entering the system. Both the dispenser and practitioner making application for access to the data base, by that access, will certify that a legitimate practitioner-patient relationship exists or that there is a legitimate inquiry by a pharmacist regarding a prescription presented to him/her to be filled for a customer. Experience from other states involved with the application process will form the basis of the provisions of regulations to be enacted to cover the access required security process.

While the Advisory Council is of the opinion that the language of the recommendation above is sufficient, the Legislature may opt for more inclusive language that has appeared in other statutory schemes:

➤ **HB1287-2006**

In connection with the Medical Care of a patient

In connection with the dispensing of a monitored prescription drug

➤ **Fla. Stat.**

A pharmacy, prescriber, or dispenser shall have access to information in the prescription drug monitoring program's data base which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history.

➤ **Va. Code Ann.**

Information on a specific recipient to a prescriber, as defined in this chapter, for the purpose of establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the prescriber is initiating treatment of such recipient.

Information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription in accord with § 54.1-3303 when the recipient is seeking a covered substance from the dispenser or the facility in which the dispenser practices.

➤ **Vermont**

A health care provider or dispenser who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient.

➤ **Kentucky**

A practitioner or pharmacist who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient.

4. Law enforcement:

Law enforcement on both the federal and state side have said they are satisfied with obtaining information through the issuance of a subpoena pursuant to a lawful investigation. That subpoena process is in place to aid the workings of law enforcement at the present time.⁴⁵

⁴⁵ Dr. Marcia D. Wolf, a Member of the Advisory Council is very concerned over the chilling effect that over-zealous prosecution may well have on the responsibility of practitioners to properly provide pain medication to their patients and to the ability of those patients suffering from pain to receive proper and competent treatment. She points to the input from Member of the Advisory Council, John J. Mooney of the Maryland State Police, that the State Police does not have the budget, manpower or will to create a Virginia like system where a group of officers is specifically designated to handle PDMP data information. Dr. Wolf's concern results in her questioning whether

Should the Legislature feel that something other than the wording of our recommendation regarding law enforcement and the subpoena process is desirable, there are the following is available:

➤ **HB1287-2006**

For the purpose of furthering an existing bona fide individual investigation.

➤ **Kentucky**

A Kentucky peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full time peace officer of another state, or federal peace officer whose duty is to enforce the laws of this Commonwealth, of another state, or of the United States relating to drugs and who is engaged in a bona fide specific investigation involving a designated person

Statutory and Rule provisions give examples as to how this subpoena process plays out in the clinical situation that is a legitimate investigation:

Maryland Rules of Criminal Procedure - Rule 4-264. Subpoena for tangible evidence before trial in circuit court.

On motion of a party, the circuit court may order the issuance of a subpoena commanding a person to produce for inspection and copying at a specified time and place before trial designated documents, recordings, photographs, or other tangible things, not privileged, which may constitute or contain evidence relevant to the action. Any response to the motion shall be filed within five days.

[Amended Dec. 4, 2007, effective Jan. 1, 2008.]

CR § 15-108. Subpoena power in criminal investigation. (State's Attorney)

(a) *Limited purpose; service.-*

(1) For the limited purpose of furthering an ongoing criminal investigation, a State's Attorney or a deputy State's Attorney designated in writing by the State's Attorney may issue in the county served by the State's Attorney a subpoena to a person to produce telephone, business, governmental, or corporate records or documents.

(2) The subpoena may be served in the same manner as one issued by a circuit court.

(b) *Right to attorney.-*

there should not be a single individual designated by law enforcement when it is felt necessary that inquiry be made to obtain information from the PDMP data base. It would be helpful if that individual designated had a health care degree. Dr. Wolf wonders whether the State MedEvac or crime lab personnel would not be in a better position to have a degree in nursing, pharmacy, or pharmacology that would be helpful to law enforcement when information is sought from the data base.

Dr. Wolf proposes that if a special officer is to be designated that this individual be a part of a working professional technical committed to be established. That dual representation individual would then be both the source point and able to communicate medical appropriateness to investigating police as well as keep the committee abreast of the time law enforcement concerns. This, Dr. Wolf feels, would be a benefit.

(1) A person may have an attorney present during any contact made under subsection (a) of this section with a State's Attorney or an agent of the State's Attorney.

(2) The State's Attorney shall advise a person of the right to counsel when the subpoena is served.

(c) *Reporting failure to obey subpoena; right to hearing.*-

(1) (i) The State's Attorney immediately may report the failure of a person to obey a lawfully served subpoena under subsection (a) of this section to the circuit court of the county served by the State's Attorney.

(ii) The State's Attorney shall provide a copy of the subpoena and proof of service to the circuit court.

(2) After conducting a hearing at which the person who allegedly failed to comply with a subpoena issued under subsection (a) of this section has an opportunity to be heard and represented by counsel, the court may grant appropriate relief.

(d) *Effect of section.*- This section does not allow the contravention, denial, or abrogation of a privilege or right recognized by law.

[An. Code 1957, art. 10, 39A(a)-(c), (e), (f); 2008, ch. 15, 2.]

Financial Institutions Article [FI] 1-304. Permitted disclosures - Subpoena.

(a) *"Subpoena" defined.*- In this section, "subpoena" means a subpoena, summons, warrant, or court order that appears on its face to have been issued on lawful authority.

(b) *Disclosure or production permitted.*- A fiduciary institution may disclose or produce financial records or information derived from financial records in compliance with a subpoena served on the fiduciary institution, if:

(1) The subpoena contains a certification that a copy of the subpoena has been served on the person whose records are sought by the party seeking the disclosure or production of the records; or

(2) Contains a certification that service has been waived by the court for good cause.

5. Health Care Boards:

Maryland Health Care Boards have subpoena authority for investigation purposes. Provision is made through various statutes that the subpoena can only be issued over the authority of the President, Chair or Executive Director of a Board. That properly limits the authority to make inquiry for a legitimate investigation. Provisions from other statutory schemes regarding access by Health Care Boards are as follows:

HB1287-2006

(3) FOR THE PURPOSE OF FURTHERING AN EXISTING BONA FIDE INDIVIDUAL INVESTIGATION.

Oklahoma

The executive director or chief investigator, as designated by each board, of the following state Boards: Board of Pharmacy; State Board of Medical Licensure and Supervision

Virginia

In accordance with the Department's regulations and applicable federal law and regulations the Director may, in his discretion, disclose:

Information relevant to an investigation or regulatory proceeding of a specific dispenser or prescriber to other regulatory authorities concerned with granting, limiting or denying licenses, certificates or registrations to practice a health provision when such regulatory authority licenses such dispenser or prescriber or such dispenser or prescriber is seeking licensure by such regulatory authority.

Subpoena authority exists with the Boards – Examps: Board of Physicians and Board of Pharmacy.

HO §14-401. Investigations.

(i) *Subpoenas; oaths.*- The Board may issue subpoenas and administer oaths in connection with any investigation under this section and any hearing or proceeding before it.

HO §12-315. Hearings.

(e) *Subpoenas and oaths.*- Over the signature of an officer or the executive director of the Board, the Board may issue subpoenas and administer oaths in connection with any investigation under this title and any hearings or proceedings before it.

The Advisory Council discussed and this should be noted that the type of subpoena required of law enforcement when conducting an investigation is not equivalent to what is required by the Maryland and Federal Constitutions for the issuance of a warrant. Both the Health Care Boards and Law Enforcement are emphatic that a probable cause requirement should not be required for the issuance of a subpoena pursuant to an investigation. The Advisory Board agrees. No search of an individual's home or seizure of his/her property is involved. Reference is made to Section No. 9 below with concern expressed against the position the Advisory Board has taken on this subpoena issue.

Through the years, the subpoena authority of both Law Enforcement and the Health Care Regulatory Boards has not resulted in any significant allegation of abuse. The system of the requirement of a subpoena pursuant to a lawful investigation has worked well and should be continued to access to the records collected in the data base. It is not recommended that the information from the data base would be able to be introduced into evidence. It may serve as the road map for the collection of evidence from other sources.

MARYLAND CONSTITUTION

[AMENDMENT IV.]

[Security from Unwarrantable Search and Seizure]

The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

6. A Multidisciplinary Team

The Recommendation by the Advisory Council for the creation of a Multidisciplinary Consultation Team for consultation by law enforcement and the licensing boards is a very strong one. Significant in the legislative directive to this Advisory Council is the concern of the Legislature that the practitioner's ability to properly treat patients be maintained throughout the process. Physicians and others who deal with the patient experiencing pain are more familiar with acceptable prescribing practices. What may appear to a licensing board or law enforcement as excess may very well be desirable and necessary to treat the pain experienced by an individual patient. Having a Multidisciplinary team available for consultation and advice is needed. Much concern is experience by those in pain that over-zealous activities of law enforcement and licensing boards has a chilling effect on the ability of these patients to be properly treated for the pain they experience.

Included in HB1287-2006 was the following:

➤ **HB1287-2006
21-2A-04.**

(A) THE SECRETARY SHALL APPOINT A MULTIDISCIPLINARY CONSULTATION TEAM ~~WITHIN THE PROGRAM.~~

(B) THE MULTIDISCIPLINARY CONSULTATION TEAM SHALL REFLECT THE DIVERSITY AND BALANCE OF PERSPECTIVES REPRESENTED ON THE BOARD.

~~(B)~~ (C) THE MULTIDISCIPLINARY CONSULTATION TEAM SHALL CONSIST OF:

(1) PROGRAM STAFF;

(2) MEMBERS OF THE BOARD; AND

(3) ANY CONSULTANTS THAT THE SECRETARY DETERMINES ~~WILL PROVIDE BROAD EXPERIENCE IN PAIN MANAGEMENT, SUBSTANCE ABUSE, AND PRESCRIPTION DRUG DIVERSION~~ HELP ACHIEVE THE DIVERSITY AND BALANCE OF PERSPECTIVES REPRESENTED ON THE BOARD.

~~(C)~~ (D) IN ACCORDANCE WITH REGULATION, THE MULTIDISCIPLINARY CONSULTATION TEAM SHALL ASSIST A FEDERAL LAW ENFORCEMENT AGENCY, A STATE OR LOCAL LAW ENFORCEMENT AGENCY, OR A LICENSING ENTITY THAT HAS RECEIVED PRESCRIPTION MONITORING DATA FROM THE PROGRAM IN INTERPRETING THE DATA AND CONSIDERING WHETHER THE DATA, IN THE CONTEXT OF THE NATURE OF A PRESCRIBER'S OR A DISPENSER'S PRACTICE, A PATIENT'S MEDICAL CONDITION, OR ANY OTHER RELEVANT FACTS, SUGGEST THE NEED FOR FURTHER INVESTIGATION.

21-2A-02.

(A) THE DEPARTMENT SHALL ESTABLISH AND MAINTAIN, IN CONSULTATION WITH THE BOARD, A PRESCRIPTION DRUG MONITORING PROGRAM THAT ELECTRONICALLY COLLECTS AND STORES DATA CONCERNING MONITORED PRESCRIPTION DRUGS.

(B) THE SECRETARY MAY:

(D) THE REGULATIONS ADOPTED BY THE SECRETARY SHALL:

(4) (5) IDENTIFY THE CIRCUMSTANCES UNDER WHICH A FEDERAL LAW ENFORCEMENT AGENCY, A STATE OR LOCAL LAW ENFORCEMENT AGENCY, OR A LICENSING ENTITY THAT HAS RECEIVED PRESCRIPTION MONITORING DATA SHALL CONSULT WITH THE MULTIDISCIPLINARY CONSULTATION TEAM ESTABLISHED UNDER § 21-2A-04 OF THIS SUBTITLE ABOUT THE INTERPRETATION OF THE PRESCRIPTION MONITORING

The Advisory Council recommendations have strengthened the wording of HB1276-2006 for inclusion.

7. Statutory excerpts:

Except for participating practitioners and dispensers in the performance of their professional functions, access to the PDMP data base should be limited.⁴⁶ Regulations may e adopted in consultation with law enforcement and health regulatory board personnel to limit access to the data base to designated individuals within disciplinary boards and law enforcement.

The importance of this issue of access has caused the Advisory Council to set forth statutory and other authority authorizing access from some other states:

<p>HB1276-2006</p>	<p>21-2A-06.</p> <p>(B) THE PROGRAM MAY, IN ACCORDANCE WITH REGULATION, DISCLOSE PRESCRIPTION MONITORING DATA TO AN AUTHORIZED RECIPIENT;</p> <p>(1) <u>IN CONNECTION WITH THE MEDICAL CARE OF A PATIENT;</u></p> <p>(2) <u>IN CONNECTION WITH THE DISPENSING OF A MONITORED PRESCRIPTION DRUG; OR</u></p> <p>(3) <u>FOR THE PURPOSE OF FURTHERING AN EXISTING BONA FIDE INDIVIDUAL INVESTIGATION.</u></p> <p>(C) EXCEPT AS PROVIDED BY REGULATION, AN AUTHORIZED RECIPIENT WHO RECEIVES PRESCRIPTION MONITORING DATA FROM THE PROGRAM MAY NOT DISCLOSE THE DATA.</p> <p>(D) THE PROGRAM MAY DISCLOSE PRESCRIPTION MONITORING DATA AFTER REDACTION OF ALL INFORMATION THAT COULD IDENTIFY A PATIENT, PRESCRIBER, DISPENSER, OR OTHER INDIVIDUAL.</p>
<p>Oklahoma</p> <p>63 Okl. St.</p>	<p>§ 2-309D. Central repository information--Confidentiality--Access--Disclosure--Penalties--Liability</p> <p>A. The information collected at the central repository pursuant to the Anti-Drug Diversion Act shall be confidential and shall not be open to the public. Access to the information shall be limited to:</p>

⁴⁶ Regulations may be adopted in consultation with law enforcement and health regulatory board personnel to limit access to the data base to designated individuals within disciplinary boards and law enforcement.

1. Peace officers certified pursuant to Section 3311 of Title 70 of the Oklahoma Statutes who are employed as investigative agents of the Oklahoma Bureau of Narcotics and Dangerous Drugs Control;
2. The United States Drug Enforcement Administration Diversion Group Supervisor;
3. The executive director or chief investigator, as designated by each board, of the following state boards:
 - a. Board of Podiatric Medical Examiners,
 - b. Board of Dentistry,
 - c. Board of Pharmacy,
 - d. State Board of Medical Licensure and Supervision,
 - e. State Board of Osteopathic Examiners, and
 - f. State Board of Veterinary Medical Examiners;

provided, however, that the executive director or chief investigator of each of these boards shall be limited to access to information relevant to licensees of the employing board of such executive director or chief investigator; and

4. A multicounty grand jury properly convened pursuant to the Multicounty Grand Jury Act, Sections 350 through 363 of Title 22 of the Oklahoma Statutes.

B. This section shall not prevent the disclosure, at the discretion of the Director of the Oklahoma Bureau of Narcotics and Dangerous Drugs Control, of investigative information to peace officers and investigative agents of federal, state, county or municipal law enforcement agencies, district attorneys and the Attorney General in furtherance of criminal investigations or prosecutions within their respective jurisdictions, and to registrants in furtherance of efforts to guard against the diversion of controlled dangerous substances.

C. Any unauthorized disclosure of any information collected at the central repository provided by the Anti-Drug Diversion Act shall be a misdemeanor. Violation of the provisions of this section shall be deemed willful neglect of duty and shall be grounds for removal from office.

D. Notwithstanding the provisions of subsection B, registrants shall have no requirement or obligation to access or check the information in the central repository prior to dispensing or administering medications or as part of their professional practices. Registrants shall not be liable to any person for any claim of damages as a result of accessing or failing to access the information in the central repository and no lawsuit may be predicated thereon. Nothing herein shall be construed to relieve a registrant from any duty to monitor and report the sales of certain products pursuant to subsection E of Section 2-309C of this title.

§ 2-309E. Central repository information--Control of access

All access to information in the central repository shall be controlled by and made through the Oklahoma Bureau of Narcotics and Dangerous Drugs Control.

Florida

§ 893.055. Prescription drug monitoring program.

(7)

(b) A pharmacy, prescriber, or dispenser shall have access to information in the

Fla. Stat
§893.055

prescription drug monitoring program's data base which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. Other access to the program's data base shall be limited to the program's manager and to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's data base and its system in support of the requirements of this section and in furtherance of the prescription drug monitoring program. Confidential and exempt information in the data base shall be released only as provided in paragraph (c) and s. 893.0551.

(c) The following entities shall not be allowed direct access to information in the prescription drug monitoring program data base but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that is confidential and exempt under s. 893.0551. Prior to release, the request shall be verified as authentic and authorized with the requesting organization by the program manager, the program manager's program and support staff, or as determined in rules by the department as being authentic and as having been authorized by the requesting entity:

1. The department or its relevant health care regulatory boards responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances and who are involved in a specific controlled substance investigation involving a designated person for one or more prescribed controlled substances.

2. The Attorney General for Medicaid fraud cases involving prescribed controlled substances.

3. A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances.

4. A patient or the legal guardian or designated health care surrogate of an incapacitated patient as described in s. 893.0551 who, for the purpose of verifying the accuracy of the data base information, submits a written and notarized request that includes the patient's full name, address, and date of birth, and includes the same information if the legal guardian or health care surrogate submits the request. The request shall be validated by the department to verify the identity of the patient and the legal guardian or health care surrogate, if the patient's legal guardian or health care surrogate is the requestor. Such verification is also required for any request to change a patient's prescription history or other information related to his or her information in the electronic data base. Information in the data base for the electronic prescription drug monitoring system is not discoverable or admissible in any civil or administrative action, except in an investigation and disciplinary proceeding by the department or the appropriate regulatory board.

(d) The following entities shall not be allowed direct access to information in the prescription drug monitoring program data base but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that contains no identifying information of any patient, physician, health care practitioner, prescriber, or dispenser and that is not confidential and exempt:

1. Department staff for the purpose of calculating performance measures pursuant to subsection (8).

2. The Program Implementation and Oversight Task Force for its reporting to the Governor, the President of the Senate, and the Speaker of the House of Representatives regarding the prescription drug monitoring program. This subparagraph expires July 1, 2012.

(e) All transmissions of data required by this section must comply with relevant state and federal privacy and security laws and regulations. However, any authorized agency or person under s. 893.0551 receiving such information as allowed by s. 893.0551 may maintain the information received for up to 24 months before purging it from his or her records or maintain it for longer than 24 months if the information is pertinent to ongoing health care or an active law enforcement investigation or prosecution.

Virginia

§ 54.1-2523. Confidentiality of data; disclosure of information; discretionary authority of Director.

Va. Code Ann

B. Upon receiving a request for information in accordance with the Department's regulations and in compliance with applicable federal law and regulations, the Director shall disclose the following:

1. Information relevant to a specific investigation of a specific recipient or of a specific dispenser or prescriber to an agent designated by the superintendent of the Department of State Police to conduct drug diversion investigations pursuant to § 54.1-3405.

2. Information relevant to an investigation or inspection of or allegation of misconduct by a specific person licensed, certified, or registered by or an applicant for licensure, certification, or registration by a health regulatory board; information relevant to a disciplinary proceeding before a health regulatory board or in any subsequent trial or appeal of an action or board order to designated employees of the Department of Health Professions; or to designated persons operating the Health Practitioners' Monitoring Program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.) of this title.

3. Information relevant to the proceedings of any investigatory grand jury or special grand jury that has been properly impaneled in accordance with the provisions of Chapter 13 (§ 19.2-191 et seq.) of Title 19.2.

4. Information relevant to a specific investigation of a specific dispenser or specific prescriber to an agent of the United States Drug Enforcement Administration with authority to conduct drug diversion investigations.

C. In accordance with the Department's regulations and applicable federal law and regulations, the Director may, in his discretion, disclose:

1. Information in the possession of the program concerning a recipient who is over the age of 18 to that recipient.

2. Information on a specific recipient to a prescriber, as defined in this chapter, for the purpose of establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the prescriber is initiating treatment of such recipient. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the prescriber from the Prescription Monitoring Program.

3. Information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription in accordance with § 54.1-3303 when the recipient is seeking a covered substance from the dispenser or the facility in which the dispenser practices. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the dispenser from the Prescription Monitoring Program.

4. Information relevant to an investigation or regulatory proceeding of a specific dispenser or prescriber to other regulatory authorities concerned with granting, limiting or denying licenses, certificates or registrations to practice a health profession when such regulatory authority licenses such dispenser or prescriber or such dispenser or prescriber is

seeking licensure by such other regulatory authority.

5. Information relevant to an investigation relating to a specific dispenser or prescriber who is a participating provider in the Virginia Medicaid program or information relevant to an investigation relating to a specific recipient who is currently eligible for and receiving or who has been eligible for and has received medical assistance services to the Medicaid Fraud Control Unit of the Office of the Attorney General or to designated employees of the Department of Medical Assistance Services, as appropriate.

6. Information relevant to determination of the cause of death of a specific recipient to the designated employees of the Office of the Chief Medical Examiner.

7. Information for the purpose of bona fide research or education to qualified personnel; however, data elements that would reasonably identify a specific recipient, prescriber, or dispenser shall be deleted or redacted from such information prior to disclosure. Further, release of the information shall only be made pursuant to a written agreement between such qualified personnel and the Director in order to ensure compliance with this subdivision.

D. The Director may enter into agreements for mutual exchange of information among prescription monitoring programs in other jurisdictions, which shall use the information only for purposes allowed by this chapter.

E. This section shall not be construed to supersede the provisions of § 54.1-3406 concerning the divulging of confidential records relating to investigative information.

F. Confidential information that has been received, maintained or developed by any board or disclosed by the board pursuant to subsection A shall not, under any circumstances, be available for discovery or court subpoena or introduced into evidence in any medical malpractice suit or other action for damages arising out of the provision of or failure to provide services. However, this subsection shall not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2.

§ 54.1-2523.2. Authority to access data base

Any prescriber authorized to access the information in the possession of the Prescription Monitoring Program pursuant to this chapter may, pursuant to regulations promulgated by the Director to implement the provisions of this section, delegate such authority to up to two health care professionals who are (i) licensed, registered, or certified by a health regulatory board under the Department of Health Professions, and (ii) employed at the same facility and under the direct supervision of the prescriber.

Vermont

Chapter 84A: § 4284. Protection and disclosure of information

(a) The data collected pursuant to this chapter shall be confidential, except as provided in this chapter, and shall not be subject to public records law. The department shall maintain procedures to protect patient privacy, ensure the confidentiality of patient information collected, recorded, transmitted, and maintained, and ensure that information is not disclosed to any person except as provided in this section.

(b) The department shall be authorized to provide data to only the following persons:

(1) A patient or that person's health care provider, or both, when VPMS reveals that a patient may be receiving more than a therapeutic amount of one or more regulated substances.

(2) A health care provider or dispenser who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient.

(3) A designated representative of a board responsible for the licensure, regulation, or discipline of health care providers or dispensers pursuant to a bona fide specific investigation.

(4) A patient for whom a prescription is written, insofar as the information relates to that patient.

(5) The relevant occupational licensing or certification authority if the commissioner reasonably suspects fraudulent or illegal activity by a health care provider. The licensing or certification authority may report the data that are the evidence for the suspected fraudulent or illegal activity to a trained law enforcement officer.

(6) The commissioner of public safety, personally, if the commissioner of health personally makes the disclosure, has consulted with at least one of the patient's health care providers, and believes that the disclosure is necessary to avert a serious and imminent threat to a person or the public.

(7) Personnel or contractors, as necessary for establishing and maintaining the VPMS.

(a) A peace officer specified in subsection (6)(b) of this section who is authorized to receive data or a report may share that information with other peace officers specified in subsection (6)(b) of this section authorized to receive data or a report if the peace officers specified in subsection (6)(b) of this section are working on a bona fide specific investigation involving a designated person. Both the person providing and the person receiving the data or report under this paragraph shall document in writing each person to whom the data or report has been given or received and the day, month, and year that the data or report has been given or received. This document shall be maintained in a file by each law enforcement agency engaged in the investigation; and

(b) A representative of the Department for Medicaid Services may share data or reports regarding overutilization by Medicaid recipients with a board designated in subsection (6)(a) of this section, or with a law enforcement officer designated in subsection (6)(b) of this section; and

(c) The Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B.

Kentucky

218A.202. Electronic system for monitoring controlled substances -- Penalty for illegal use of system -- Pilot project -- Continuing education programs.

(6) The Cabinet for Health and Family Services shall only disclose data to persons and entities authorized to receive that data under this section. Disclosure to any other person or entity, including disclosure in the context of a civil action where the disclosure is sought either for the purpose of discovery or for evidence, is prohibited unless specifically authorized by this section. The Cabinet for Health and Family Services shall be authorized to provide data to:

(a) A designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;

(b) A Kentucky peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full-time peace officer of another state, or a federal peace officer whose duty is to enforce the laws of this Commonwealth, of another state, or of the United States relating to drugs and who is engaged in a bona fide specific investigation involving a designated person;

(c) A state-operated Medicaid program;

(d) A properly convened grand jury pursuant to a subpoena properly issued for the

records;

(e) A practitioner or pharmacist who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient;

(f) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Medical Licensure, for any physician who is:

1. Associated in a partnership or other business entity with a physician who is already under investigation by the Board of Medical Licensure for improper prescribing practices;

2. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing may be occurring; or

3. In a designated geographic area for which a report on another physician in that area indicates a substantial likelihood that inappropriate prescribing may be occurring in that area;

(g) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Nursing, for any advanced registered nurse practitioner who is:

1. Associated in a partnership or other business entity with a physician who is already under investigation by the Kentucky Board of Medical Licensure for improper prescribing practices;

2. Associated in a partnership or other business entity with an advanced registered nurse practitioner who is already under investigation by the Board of Nursing for improper prescribing practices;

3. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing may be occurring; or

4. In a designated geographic area for which a report on a physician or another advanced registered nurse practitioner in that area indicates a substantial likelihood that inappropriate prescribing may be occurring in that area; or

(h) A judge or a probation or parole officer administering a diversion or probation program of a criminal defendant arising out of a violation of this chapter or of a criminal defendant who is documented by the court as a substance abuser who is eligible to participate in a court-ordered drug diversion or probation program.

8. The Health Information Exchange and the Maryland Health Care Commission

In commenting on the Health Information Exchange (HIE) through the Maryland Health Commission, the Report of 10/1/2009 states on p. 8 that the system is capable of connecting with approximately 47 Acute Care Hospitals, 7914 Physician practitioners, and 1,628 pharmacies in Maryland with this information having been obtained through the State Cost Review Commission and the Boards of Physicians and Pharmacy.

All access to the HIE through the Maryland Health Care Commission is to be consistent with the federal and state confidentiality of medical records acts so that access may be given in a manner to achieve a balance between complexity, usability and administrative overuse.

Requestors should be required to submit an abstract to the administrative agency outlining the purpose and scope of the intended analysis. Data will be extracted should be provided to requestors as de-identified information unless the data is supporting a bona fide public health emergency.

9. Concern from some in the Medical Community.

Dr. Robert L. Lyles, Jr., a Member of the Advisory Council states that it is important for the Legislature to know that there is concern in the physician community that the Board of Physicians and the Boards must not have unfettered access to the PDMP data base via administrative subpoena. The use of the administrative subpoena for access by the Board of Physicians is easy access for the asking and may lead to abusive use of the PDMP data base. This was the point of major concern in the 2006 legislation that law enforcement and the Boards would have the ability to access the data base at will and without oversight. Once again the data base access and perhaps usage as “fishing” source for any complaint that the Board of Physicians may consider relevant even if the complaint does not involve schedule II through IV medications. As we have discussed in the task force meetings, access to the PDMP data base must be only for an ongoing investigation involving a complaint concerning schedule II through IV medications involved in diversion. The Board of Physicians like all other elements of law enforcement should have access to specific data in the PDMP data base that is specific to an ongoing investigation involving diversion activity. The Board of Physicians must not be able to use the data base to view the prescribing habits of providers since prescribing for legitimate medical purposes can vary widely while being specific for the individual patient (patient have varying degrees of metabolism and require patient specific dosing). The purpose of the previous legislation (2006 and 2008) after amendments was to provide access to prescription data such that the patient can be more effectively treated and law enforcement can work with the medical community to limit and/or prevent diversion of prescription medications in a balanced way. Moreover, the PDMP data base will contain very sensitive data on practically all of the citizens of the State of Maryland along with most providers and dispensers. This data should be treated as a mental health record since the treatment of pain is always the treatment of associated comorbid conditions involving multiple elements of mental health.

Dr. Lyles states that many physicians feel that The Board of Physicians should have access to the PDMP data base only for an ongoing investigation involving schedule II through IV medications via a “court order subpoena” with cause. The use of the PDMP data base should be positive for the provider community and not result in “chilling” the physician community resulting in changes in prescribing habits that has occurred in Virginia. In Virginia, the result of the PDMP with “open access” by law enforcement has been such that prescribing habits of providers have been scrutinized resulting in a change in the treatment of chronic pain patients from medical management using pain medications, to that of more procedural based pain management to eliminate the possibility of criticism of the provider pain specialists concerning opiate dosing.

This “chilling” effect that alters the practice patterns of providers that may also manifest itself in Maryland unless we can effectively manage the usage of the PDMP data base.

Recommendation No. 7: Patient Access to Data Base

It is the recommendation of the Advisory Council that the Legislature provide for patient access to the data base. Many states allow this access and it seems only fair that the patient knows what records there are concerning him/her and what those records say. As to any patient correction of the records, we recommend that the patient be allowed to make comments and to state corrections that should be made but that the record should not be changed. This is consistent with the provisions of the Maryland Confidentiality of Medical Records Act.

Commentary

The Maryland provisions concerning patient access and changes to medical records:

From the Health-General Article, Title 4. Statistics and Records, Subtitle 3. Confidentiality of Medical Records.

HG 4-304. Copies of records; changes in records.

(a) Requests for copies.-

(1) Except as otherwise provided in this subtitle, a health care provider shall comply within a reasonable time after a person in interest requests in writing:

- (i) To receive a copy of a medical record; or
- (ii) To see and copy the medical record.⁴⁷

* * *

(b) Changes in records.-

(1) A health care provider shall establish procedures for a person in interest to request an addition to or correction of a medical record.

(2) A person in interest may not have any information deleted from a medical record.

(3) Within a reasonable time after a person in interest requests a change in a medical record, the health care provider shall:

- (i) Make the requested change; or
- (ii) Provide written notice of a refusal to make the change to the person in interest.

(4) A notice of refusal shall contain:

- (i) Each reason for the refusal; and

⁴⁷ Not included are the remainder or the provisions of this section dealing with psychiatric records.

(ii) The procedures, if any, that the health care provider has established for review of the refusal.

(5) If the final determination of the health care provider is a refusal to change the medical record, the provider:

(i) Shall permit a person in interest to insert in the medical record a concise statement of the reason that the person in interest disagrees with the record; and

(ii) May insert in the medical record a statement of the reasons for the refusal.

(6) A health care provider shall give a notice of a change in a medical record or a copy of a statement of disagreement:

(i) To any individual the person in interest has designated to receive the notice or statement; and

(ii) To whom the health care provider has disclosed an inaccurate, an incomplete, or a disputed medical record within the previous 6 months.

(7) If a health care provider discloses a medical record after an addition, correction, or statement of disagreement has been made, the provider shall include with the medical record a copy of each addition, correction, or statement of disagreement.

(c) *Payment of copying costs.*⁴⁸

* * *

Patient access statutory provisions:

Some states do not provide for patient access to the PDMP data base.⁴⁹ Some states do:

Virginia

Va Code Ann. § 54.1-2523. Confidentiality of data; disclosure of information; discretionary authority of Director

C. In accordance with the Department’s regulations and applicable federal law and regulations, the Director may, in his discretion, disclose:

1. Information in the possession of the program concerning a recipient who is over the age of 18 to that recipient.⁵⁰

⁴⁸ If the Legislature determines to allow access to patients, it may well want to reference the costs provision of the Maryland Confidentiality of Medical Records Act calling for the payment of costs, what costs may be charged, etc.

⁴⁹ It does not appear that either Florida or Oklahoma allow patient access to their system.

⁵⁰ The Virginia Web site makes reference to the ability of a patient over the age of 18 to obtain records information from the data base and provides for the patient to obtain a form on line. On the web site the following appears: “The request must be accompanied by a copy of a valid photo identification issued by a government agency of any jurisdiction in the United States. The identification must verify that the recipient is over the age of eighteen. Additionally, the request must include a notarized signature of the requesting party. A request form may be hand delivered, mailed or faxed to the Prescription Monitoring Program. The mailing address is:

Prescription Monitoring Program
Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico Virginia 23233-1463
Fax number: 804-527-4470.

The Recipient form can be [\[found here.\]](#)

Chapter 84A: VERMONT PRESCRIPTION MONITORING SYSTEM

§ 4284. Protection and disclosure of information

(a) The data collected pursuant to this chapter shall be confidential, except as provided in this chapter...

(b) The department shall be authorized to provide data to only the following persons:

(1) A patient or that person’s health care provider, or both, when VPMS reveals that a patient may be receiving more than a therapeutic amount of one or more regulated substances.

* * *

(4) A patient for whom a prescription is written, insofar as the information relates to that patient.

There are going to be questions concerning the application of federal law (HIPPA) and the Maryland Confidentiality of Medical Records Act. It seems to the Advisory Council that a blanket provision as is included in the Virginia law that states: “In accordance with the Department’s regulations and applicable federal law and regulations [and the Maryland Confidentiality of Medical Records Act]” a PDMP data base record may be disclosed to . . . will take care of any applicable provisions and changes in the federal and state law.

Recommendation No. 8: Confidentiality and Security

How to best insure that information in data base remain confidential?

The Advisory Council recommends a number of provisions toward assuring confidentiality of the data collected by a PDMP in Maryland and against the dissemination of that information by individuals who have access to the data base or, otherwise, obtain the data for a purpose other than allowed by statute and regulation:

(1) The data system utilized must be of the highest quality to restrict access other than allowed by statute;

(2) Unauthorized access should be punishable by disciplinary action against health care professionals; and

(3) Unauthorized access and unauthorized disclosure of data base information should be punishable by criminal penalties (misdemeanor) and a system of civil penalties and attorneys fees that can be obtained by a patient whose confidentiality has been compromised.

Data collected should statutorily be pronounced as confidential, privileged, and not subject to discovery, subpoena, or other means of legal compulsion in civil litigation. It should be

Requests for information may not be accepted over the phone or by email. Results cannot be given over the phone or faxed. The report will be mailed to the address listed on the identification or delivered to the recipient at the Department of Health Professions. In most cases results from requests will be processed the same day.”

specifically noted that access other than provided by the statute creating the PDMP is prohibited. A specific provision should be added that no information collected is subject to disclosure under the Maryland Public Information Act (State Government Article §10-611, *et. seq.*). Injunctive authority should be given to the Office of the Attorney General to carry out the provisions of the law to maintain confidentiality.

Individuals allowed to have access to the system must be credentialed. All data should be encrypted.

Though the systems employed by the PDMPs are difficult to hack into, there was a breach early in 2009 of the Virginia system which caused the system to be shut down for a period of time. The etiology of the breach and the extent of the breach have not been determined but Virginia took immediate steps to notify users of the problem and to assure them and inform them concerning the steps that were taken to seal off the system. It is to be noted that Virginia utilizes a system of gathering and storing of data that is less than the state of the art utilized by the newer systems.

One of the duties of the Advisory Board on Prescription Drug Monitoring recommended to be established within the Department of Health and Mental Hygiene of the State of Maryland should be to keep abreast of the technology in the field with systems available and utilized by other States.

Commentary

EXHIBIT D is a 166 page compilation in PDF format entitled: “Access, Disclosure and Confidentiality Provisions of State Prescription Monitoring Programs.” This exhibit D was compiled by the National Alliance for Model State Drug Laws (NAMSDL) 703-836-7496 and furnished to the Advisory Council by Ms. Sherry Green, the CEO for NAMSDL. sgreen@namsdl.org.

Few considerations are more important with any PDMP than determining how to ensure that the data collected is privileged and confidential other than as access is provided by a statute. Some States have made unlawful access a felony.

Maryland legislative enactments provide for civil and criminal penalties for unlawful conduct or access to confidential records. The Office of the Attorney General and the various States Attorneys throughout the State have the authority to conduct investigations and to request the imposition of both civil and criminal penalties for a violation of the confidentiality provisions of various laws. Individuals, whose right to confidentiality has been compromised should also have the right to bring an action for the imposition of civil penalties and for injury as a result of disclosure or re-disclosure of confidentiality information contained in the data base.

Penalties

Penalties for violation of the Maryland Confidentiality of Medical Records Act:

HG 4-309. Refusal to disclose records; violations of subtitle; penalties.

* * *

(c) *Violations of subtitle.*- A health care provider or any other person is in violation of this subtitle if the health care provider or any other person:

- (1) Requests or obtains a medical record under false pretenses or through deception; or
- (2) Discloses a medical record in violation of this subtitle.

(d) *Criminal penalties.*- Except as otherwise provided in subsection (e) of this section, a health care provider or any other person, including an officer or employee of a governmental unit, **who knowingly and willfully violates any provision of this subtitle is guilty of a misdemeanor and on conviction is subject to a fine not exceeding \$1,000 for the first offense and not exceeding \$5,000 for each subsequent conviction for a violation of any provision of this subtitle.**

(e) *Fraudulent obtaining of records; wrongful disclosure of records.*-

(1) A health care provider or any other person, including an officer or employee of a governmental unit, who knowingly and willfully requests or obtains a medical record under false pretenses or through deception or knowingly and willfully discloses a medical record in violation of this subtitle is guilty of a misdemeanor and on conviction is subject to the following penalties: **(i) A fine not exceeding \$50,000, imprisonment for not more than 1 year, or both;**

(ii) If the offense is committed under false pretenses, a fine not exceeding \$100,000, imprisonment for not more than 5 years, or both; and

(iii) If the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, a fine not exceeding \$250,000, imprisonment for not more than 10 years, or both.

(2) This subsection does not apply to an officer or employee of a governmental unit that is conducting a criminal investigation.

(f) *Civil penalties.*- **A health care provider or any other person who knowingly violates any provision of this subtitle is liable for actual damages.**

Excerpt from maryland wiretapping statute:

CJ 10-410. Civil liability; defense to civil or criminal action.

(a) *Civil liability.*- Any person whose wire, oral, or electronic communication is intercepted, disclosed, or used in violation of this subtitle shall have a civil cause of action against any person who intercepts, discloses, or uses, or procures any other person to intercept, disclose, or use the communications, and be entitled to recover from any person:

(1) Actual damages but not less than liquidated damages computed at the rate of \$100 a day for each day of violation or \$1,000, whichever is higher;

(2) Punitive damages; and

(3) A reasonable attorney's fee and other litigation costs reasonably incurred.

(b) *Defense.*- A good faith reliance on a court order or legislative authorization shall constitute a complete defense to any civil or criminal action brought under this subtitle or under any other law.

[1977, ch. 692, 3; 1988, ch. 607.]

CJ 10-402. Interception of communications generally; divulging contents of communications; violations of subtitle.

(b) *Penalty.*- **Any person who violates subsection (a) of this section is guilty of a felony and is subject to imprisonment for not more than 5 years or a fine of not more than \$10,000, or both.**

(f) *Violations of subtitle.*-

(1) A person who engages in conduct in violation of this subtitle is subject to suit by the federal government or by the State in a court of competent jurisdiction, if the communication is:

(i) A private satellite video communication that is not scrambled or encrypted and the conduct in violation of this subtitle is the private viewing of that communication, and is not for a tortious or illegal purpose, or for purposes of direct or indirect commercial advantage, or private commercial gain; or

(ii) A radio communication that is transmitted on frequencies allocated under Subpart D of Part 74 of the Rules of the Federal Communications Commission that is not scrambled or encrypted and the conduct in violation of this subtitle is not for a tortious or illegal purpose or for purpose of direct or indirect commercial advantage or private commercial gain.

(2) (i) The State is entitled to appropriate injunctive relief in an action under this subsection if the violation is the person's first offense under subsection (e)(1) of this section and the person has not been found liable in a prior civil action under 10-410 of this subtitle.

(ii) In an action under this subsection, if the violation is a second or subsequent offense under subsection (e)(1) of this section or if the person has been found liable in a prior civil action under 10-410 of this subtitle, the person is subject to a mandatory civil fine of not less than \$500.

(3) The court may use any means within its authority to enforce an injunction issued under paragraph (2)(i) of this subsection, and shall impose a civil fine of not less than \$500 for each violation of an injunction issued under paragraph (2)(i) of this subsection.

The Advisory Council discussed at length the fact that some other jurisdictions have made unlawful access to the data base a felony. It is the thought of the Council that this is not necessary. Unlawful access to medical records is punishable as a misdemeanor stating the intent of the Legislature in that regard and the Council feels that is sufficient.

It has been reported to the Advisory Council that there has been disciplinary action taken against physicians by the Maryland Board of Physicians for unauthorized access to a medical record in situations where a bona fide physician-patient relationship has not been established. To date the Maryland Board of Pharmacy reports there has been no report of an unauthorized access and thus no disciplinary action instituted.

Provisions from other states addressing this issue of penalties include:

Oklahoma
63 Okl.St.

§2-309D. Central repository information – Confidentiality – Access – Disclosure – Liability

C. Any unauthorized disclosure of any information collected at the central

	<p>repository provided by the Anti-Drug Diversion Act shall be a misdemeanor. Violation of the provisions of this section shall be deemed willful neglect of duty and shall be grounds for removal from office.</p>
<p>Fla. Stat. § 893.055</p>	<p>§ 893.055. Prescription drug monitoring program.</p> <p>(9) Any person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.</p>
<p>Va. Code Ann.</p>	<p>§ 54.1-2525. Unlawful disclosure of information; disciplinary action authorized; penalties.</p> <p>A. It shall be unlawful for any person having access to the confidential information in the possession of the Program or any data or reports produced by the program to disclose such confidential information except as provided in this chapter. Any person having access to the confidential information in the possession of the program or any data or reports produced by the program who discloses such confidential information in violation of this chapter shall be guilty of a Class 1 misdemeanor upon conviction.</p> <p>B. It shall be unlawful for any person who lawfully receives confidential information from the Prescription Monitoring Program to redisclose or use such confidential information in any way other than the authorized purpose for which the request was made. Any person who lawfully receives information from the Prescription Monitoring Program and discloses such confidential information in violation of this chapter shall be guilty of a Class 1 misdemeanor upon conviction.</p> <p>C. Unauthorized use or disclosure of confidential information received from the Prescription Monitoring Program shall also be grounds for disciplinary action by the relevant health regulatory board.</p>

From the Maryland Health Care Commission (MHCC)

Confidentiality and Security

The use of prescription drugs has increased exponentially over the last two decades. Since 1999, the abuse, misuse, and overdose of prescription drugs have risen. Each year more than 20,000 persons in the U.S. die from drug overdoses.⁵¹ Millions of prescriptions written every year give people access to a wide range of prescription drugs. The risks to privacy and security, and the cost of implementing and operating a PDMP differ from one state to another depending on the policies that are developed to govern the use, collection, and storage of the information; the technology that is utilized to support such a system; and the sufficiency of the budget and manpower available to administer the PDMP program.

⁵¹ Association of State and Territorial Health Officials, *Prescription Drug Overdose: State Health Agencies Respond*, 2008.

Implementing a PDMP via the statewide Health Information Exchange (HIE) is consistent with the expectations for a PDMP system described by the Office of the Attorney General in the 2005 report on the prescription drug abuse in Maryland.⁵² The statewide HIE provides an efficient approach to implementing a secure system that prevents abuse, trafficking, and diversion of controlled substances; and is an invaluable information source for providers and the public of trends in the use and abuse of prescription drugs.

Due to the unique design, the statewide HIE serves as a secure and trusted technology that will properly route information to the appropriate location. A Policy Board established by the MHCC⁵³ will develop policies governing the statewide HIE. The separation of responsibilities assures a strong role for the public in both policy development and operational oversight. Members of the Policy Board have been selected to assure expertise, breadth of stakeholder representation, and a strong consumer voice in establishing the policies essential to building trust. Appointments to the Policy Board are for three years, with one option for reappointment, and were made by the MHCC with stakeholder support.

Policies developed by the Policy Board will enable and foster information sharing within the state and eventually across state borders. The Policy Board could serve as the body that develops policy or it could oversee an independent PDMP Advisory Board appointed by the Secretary of the Department of Health and Mental Hygiene that would consist of a wide-range of stakeholders, which would make recommendations to the HIE Policy Board about the appropriate use of the data to support a PDMP program. Implementing policies through the statewide HIE would allow for a high degree of policy neutrality; provide the level of knowledge and skills necessary for development and operation of a sophisticated, highly efficient, and secure PDMP system; standardize monitoring and reporting on the success of the PDMP program; and allow for the ability to make policy changes more rapidly.

Although the standalone systems currently employed by state PDMPs are generally considered secure, a breach did occur early in 2009 in the Virginia system that caused the system to be shut down for a period of time. This event has received national attention and was recently reported on *60 Minutes*, an investigative television broadcast. The cause of the breach and the impact to the data that was accessed cannot be fully determined. However, Virginia has taken steps to notify consumers listed in the data base of the breach and implement safeguards to protect the data from future unauthorized access. The Virginia data was stored in a data base that did not deploy the latest security protections, which are fundamental to the statewide HIE. What occurred in Virginia serves as an important reminder of the vulnerability of a PDMP that uses a client-server model where security protections are often insufficient to protect the data.

⁵² *PRESCRIPTION FOR DISASTER, The Growing Problem of Prescription Drug Abuse in Maryland*, State of Maryland Office of the Attorney General, September 2005.

⁵³ Requirement for a Policy Board was identified in the Maryland Health Care Commission and Health Services Cost Review Commission Request for Application for *A Consumer-Centric Health Information Exchange for Maryland*, April 15, 2009.

Recommendation No. 9. Housing of Data Base

The Advisory Council recommends that the data base operations for the Prescription Drug Monitoring Program be housed in the Division of Drug Control of the Secretary of Health and Mental Hygiene of Maryland.

Commentary

Currently, there are 40 states with statutes of enabling legislation and 33 of these states have operational prescription drug monitoring programs within the United States.

Based on Council discussions and after several presentations the Council has determined that in Maryland, there are three plausible Agencies/Groups that could effectively manage and control a prescription drug monitoring program (PDMP). Specifically, these are the Board of Pharmacy, Maryland State Police, and the Division of Drug Control within the Department of Health and Mental Hygiene. Realistically, the implementation of a PDMP will likely take approximately 12 to 18 months once the PDMP becomes law.

The goal in finding the proper domicile for the PDMP is to ensure several things including the following:

1. Having secure and appropriate funding for implementation of the program and continued operation of the program⁵⁴
2. Providing accurate education for input and support
3. Ensuring dispensers are reporting and know the requirements for reporting
4. Providing accurate data from the dispensers
5. Finding secure and effective ways to authenticate the users of the system and creating safeguards for logging into the program.

The first plausible domicile is the Board of Pharmacy. The Board of Pharmacy may initially seem like a good fit since they set standards to ensure the provision of safe, quality, medication dispensing for Maryland citizens. Several states do in fact use the Board of Pharmacy to manage their prescription drug monitoring programs since they are an arm of the government and find it easier to guarantee pharmacies comply with the reporting guidelines.

However, the Board of Pharmacy is currently already overburdened with new programs that they have taken over in the last couple years and presumably does not want the additional responsibility of monitoring and maintaining another program such as a PDMP. Additionally, the role of the Board of Pharmacy is to monitor pharmacies by inspecting them for operation,

⁵⁴ According to Fiscal Year Federal Award Amounts compiled by the Bureau of Justice Assistance Prescription Drug Monitoring Program, it appears that on average states have been awarded no more than \$400,000. See attached document. Additionally, the Harold Rogers Prescription Monitoring grant program provides financial assistance to states that want to create, enhance or plan PMP and is a plausible resource.

practice and sanitation and ensuring that the policies that govern the operation of pharmacies are working efficiently and effectively. Furthermore, the Board of Pharmacy does not inspect or maintain the standards of prescribing medications, i.e., controlled dangerous substances (CDS). For all these reasons, it is not recommended that the Board of Pharmacy house the PDMP since they already seemed inundated with their own current programs and systems.

The second possible location for managing and enforcing a PDMP is a law enforcement agency. The Maryland State Police currently does not have a drug diversion unit. Through several of this Councils' discussions and presentations, it has become very clear that this council is leery of having any law enforcement agency in charge of maintaining and monitoring a PDMP. Additionally, the original feeling of the Attorney General's Office under J. Curran was that the program should not be housed in law enforcement since that would exacerbate the uneasiness felt by both prescribers and patients being monitored. Clearly, the goal of PDMP is to ensure that the information being monitored is correct and accurate and to avoid any type of chilling effect that could possibly occur by having a law enforcement agency monitor the program. Therefore, based on all previous discussions and the lack of a system already in place, it is not recommended that the Maryland State Police be the domicile for a Maryland PDMP.

The trend and what this council has been leaning towards is having the PDMP managed and controlled by the Division of Drug Control (DDC or "Division"). This Division is charged with enforcing the Controlled Dangerous Substance (CDS) regulations. The Division possesses diverse backgrounds and expertise in various aspects of pharmacy. Currently, DDC already is inspecting pharmacy practices and compliance with controlled dangerous substance regulations. DDC has the expertise already in place in evaluating the prescribing practices. Specifically, DDC inspects pharmacies and/or dispensing practitioners and is a source of information and expertise concerning controlled dangerous substances. DDC currently works with the Board of Pharmacy and the Drug Enforcement Administration (DEA) and police when necessary to further investigations.

DDC currently has registered approximately 30,000 practitioners and establishments to legally manufacture, distribute, dispense or otherwise handle controlled substances in Maryland. The DDC already maintains a data base of CDS registrants with demographic information including unique identifiers, etc., and is moving toward web-based access for registrants. This current registration process will assist in the implementation of the PDMP since one of the issues in creating the PDMP is ensuring that practitioners as well as establishments will utilize the program.

Since DDC currently has systems in place for inspecting the pharmacies and dispensing practitioners and furthermore, working with the DEA and Board of Pharmacy when needed, it seems only logical that adding another branch of their current program would be both effective and efficient. DDC will need to establish the framework for managing the PDMP program and monitoring its effectiveness. DDC may determine that outsourcing will be the best way to

handle the implementation of this program by administering the database and managing the collection of the data. This information could also be accessed via a secure web portal or secure file transfer.⁵⁵ Such an implementation has a history of taking approximately one (1) year, but should usually be padded with an additional 3 to 6 months to accommodate any unforeseen circumstances. Therefore, DDC is the recommended domicile for Maryland's PDMP.

Dr. Robert L. Lyles, Jr., a member of the Advisory Council feels that the concept of "housing" should be divided into the "physical housing" of the data and the "administrative housing" of the data. The physical housing concept can range from the simple flat database that is only locally accessed and then manually distributed by personnel clearance (not internet connected) to the sophisticated distributed database similar to or identical to that proposed by the Statewide HIE. Dr. Lyles states his belief that the "administrative housing" of the data is the central issue and that his fundamental opposition to the development of the PDMP is that law enforcement will be the guiding force in punitive usage rather than the medical/clinical, i.e., public health usage.

Recommendation No. 10: Funding

The Advisory Council recommends that the Department apply for funds through the Harold Rogers PDMP Grants Program and other federal grants to implement a PDMP with a data base to be developed and is consistent with the Maryland Health Care Commission Health Information Exchange.

Commentary

Based on the Council's research findings from the experience of states that have already established a PDMP, development timelines, implementation, data input and access mechanisms, system users, and other program criteria, can vary greatly based on what type of prescription drug monitoring system is established. The cost of establishing and operating a PDMP varies widely among the states. For example, per capita, it costs 17 times more in Washington State than in Arizona.

The cost of implementing and operating a PDMP differs from state to state because of many variables that exist across geography, types of practice, stakeholder participation (both in number and type), technology available at time of implementation, program requirements, and available funding levels. Typical start-up costs varied from \$450,000 to more than \$1.5M, while annual operating costs, based on data from six operating states, are about \$500,000. State annual operating costs for PDMPs range from \$125,000 (Virginia) to nearly \$1 million (Kentucky). Cost variations are affected by the frequency of data collection (e.g., daily, weekly, bi-weekly, monthly), the use of third party vendors for data collection and analysis, the number of prescriptions written and filled in the state, the number of drug schedules (II-V) and drugs of

⁵⁵ GHS Data Management administers the database and manages the collection of data for the PDMP in Colorado.

interest collected, and the use of official forms or other required collection and submission mechanisms.

Funding is the greatest obstacle for implementation and maintenance of a PDMP. In researching other states' funding, the Council found that state officials have funded PDMPs in various ways. These funding mechanisms have included federal grants, settlement monies received from the states' Attorney General, professional licensing fees, and appropriated state funds from state general funds and revenues from licensing or registration fees paid by authorized PDMP users.

Federal grant funds.

In FY 2002 the U.S. Department of Justice Consolidated Appropriations Act (Public Law 107-77) created a grant program entitled Developing and Enhancing Prescription Drug Monitoring Programs. The grants have become commonly known as the Harold Rogers Grants, in honor of primary sponsor of the act, Congressman Harold (Hal) Rogers from Kentucky's 5th Congressional District. The Bureau of Justice Assistance administers this program with the U.S. Drug Enforcement Administration (DEA), Office of Diversion Control and the Office of National Drug Control Policy (ONDCP).

The primary purpose of this grant program is to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data through a central data base administered by an authorized state agency. The program focuses on providing help for states that want to establish a PDMP and to help states with existing PDMPs to improve the efficiency and effectiveness of the program. States may submit a grant application in one of three categories:

CATEGORY I-PLANNING, with a grant maximum of \$50,000, with a project period of 15 months. States without a PDMP may apply for a planning grant, and need not have legislation or regulations pending or in place.

CATEGORY II: IMPLEMENTATION, with a grant maximum of \$400,000, and a project period of 24 months. States that have in place or pending legislation or regulations that require the submission of dispensing data to a centralized data base and authorize and/or designate a state agency to provide program oversight and implementation may apply for an implementation grant. States developing a voluntary pilot program also may apply for an implementation grant.

CATEGORY III: ENHANCEMENT, with a grant maximum of \$400,000, and a project period of 24 months. States seeking to improve an existing PDMP for diversion efforts are eligible to apply for an enhancement grant.

Eligibility criteria for these grants include that the state government have in place or pending an enabling statute or regulation that requires the submission of controlled substance prescription data to a centralized data base administered by an authorized state agency. The legislation or

regulations must include that data is submitted for prescriptions in Schedules II, III, IV, and V, using data standards established by the American Society for Automation in Pharmacy. Finally, there must be access to collected data by federal, state, and local law enforcement personnel statutorily authorized to access prescription data by traditional, manual methods.

It is important to note that the federal grant funds are both competitive and limited, and therefore are no guarantee for funding. The Department applied for a \$50,000 Harold Rogers Planning Grant in February of 2008 for fiscal year 2009. In October of 2008, the Department received notice that Maryland was not awarded the grant. In February of 2009, the Department reapplied for and received the \$50,000 Planning Grant, which has in part allowed the Council to fulfill its mandate.

If Maryland is successful in obtaining Harold Rogers Implementation and Enhancement Grants (Category II and III), the grants would assist with implementation and enhancement costs of a PDMP program, but these grants can not be relied upon for continued maintenance funding for a PDMP.

State settlement money.

A few PDMPs are funded through settlement money received by their respective states. For example, the Commonwealth of Virginia received PDMP funding through the Purdue Frederick Company, Inc., settlement related to inappropriate marketing of Oxycontin. Connecticut's PDMP recently received \$100,000 from the same Purdue Pharma. The State of Maine's PDMP is funded through State Tobacco Settlement money.

Appropriated State Funds.

Many other states' PDMPs are state funded. Some states provide for the collection of a fee from an individual who holds a license that authorizes him or her to prescribe a controlled substance, if the state appropriations for the direct or indirect costs of the program are insufficient to maintain the program. These fees are collected in conjunction with license renewal fees. The consensus is that legislation for a PDMP should follow HB1287-2006 which prohibited funding a PDMP by charging prescribers, dispensers, or users of the PDMP. Kentucky receives state funding for the administration of its PDMP (known as KASPER). KASPER has received approximately \$5 million over the last two years to continue the program and will receive an estimated \$1.4 million from the Kentucky Legislature next year. Statistically, except for geographical size, Kentucky is similar to Maryland. For example Kentucky's population is ~ 4.5 million (Maryland's is ~ 5 million), has about 1300 reporting pharmacies (Maryland would have ~ 1200 reporting pharmacies).

The Department should apply for the Harold Rogers Grants to assist with implementation and enhancement of a PDMP program, however, grant funding can not be relied upon for continued program administration. It is strongly recommended that State policy makers, including the

General Assembly and the Department begin planning now for continued funding of the PDMP once it is established.

Recommendation No. 11: Immunity

The Advisory Council recommends that there should be a criminal and administrative penalty (disciplinary action) against any Dispenser who willfully fails to report the dispensing of a monitored substance required by the PDMP. However, it is also recommended that notwithstanding the provisions of the law assessing penalties for a “willful” violation of statutory responsibility, that the statute enacted should make it clear that Practitioners and Dispensers shall have no requirement or obligation to access or check the information in the central data base prior to prescribing, dispensing or administering medications as part of a professional practice.

A separate statutory provision should make it clear that a Prescriber and Dispenser shall not be liable to any person for any claim of damages as a result of accessing or failing to access the information in the central data base and that no lawsuit may be predicated thereon.

Also, a Prescriber or Dispenser acting in good faith should be immune from any civil, criminal, or disciplinary liability that might otherwise be incurred or imposed for receiving or using information from the PDMP.

There should also be a provision to the effect that the Secretary, the Advisory Board, and employees of the Secretary are not liable and are immune from any civil damages resulting from the accuracy or inaccuracy of any information reported to and compiled by the Department pursuant to the statute.

Commentary

There are three separate questions associated with the issue of immunity. First, is the question of what penalties should be included in the statute for a dispenser who “knowingly” or “intentionally” fails to comply with the statutory requirements to submit information. Second, is the issue of immunity to be granted to a prescriber or pharmacist who does not utilize system in practice. Third, is the issue of immunity for a prescriber or pharmacist who negligently supplies incorrect information to the data-base. The Advisory Council has addressed all three of these issues in making its recommendations.

Criminal penalties and disciplinary action:

While the Advisory Council recognizes it the prerogative of the Legislature to determine criminal penalties, it does see in the various statutes enacted by states with a PDMP a pattern that might make this provision a viable consideration for the Legislature:

Any dispenser who willfully fails to report the dispensing of a monitored substance as required by this statute is subject to being charged with a misdemeanor punishable, upon conviction, by not more than (1) year imprisonment, or by a fine of not more than One Thousand Dollars (\$1,000.00) or both for each violation⁵⁶; and may be subject to disciplinary action by his or her respective health regulatory board.⁵⁷

Civil liability and good faith for failing to access the data-base:

Perhaps the Legislature may find that the following extracted from statutes enacted in other states with a PDMP may be appropriate.

Notwithstanding the provisions of law, practitioners and dispensers shall have no requirement or obligation to access or check the information in the central data base prior to prescribing, dispensing or administering medications or as part of their professional practices. They shall not be liable to any person for any claim of damages as a result of accessing or failing to access the information in the central data-base and no lawsuit may be predicated thereon when they are acting in good faith.

There is an important consideration to be made here. There should be a statutory provision adequately phrased that states:

Nothing herein shall be construed to relieve a practitioner from any duty to monitor and report the sales of certain drugs that are otherwise required by statute or regulation.

There is omnipresent this concurrent responsibility of the practitioner and the pharmacist relating to the dispensing of CDS that the prescription be issued for a legitimate medical purpose.

COMAR 10.19.03.07 Prescriptions.

C. Purpose of Issue of Prescription (21 CFR § 1306.04).

(1) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the individual practitioner's professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of

⁵⁶ It is to be noted here that the 2006Bill/HB1287 provided only for a civil penalty of \$500.00 for each occurrence. The recommendation for a criminal penalty and incarceration by the Advisory Council is thought to be more in line with what other States have provided as penalties. We recommend that more of a penalty than \$500.00, which supposedly would be enforced by the Office of the Attorney General or a States' Attorney is called for so that the importance of the system working properly may be given emphasis.

⁵⁷ Somewhere in the Bill there should be a reference to the disciplinary health care boards and the fact that a violation of the responsibility of a dispenser is a disciplinary offense. It is also recommended by the Advisory Council that the Legislature also consider adding to the provisions of the respective health disciplinary boards a provision that a violation of the dispenser's responsibility under the Prescription Drug Monitoring Program is disciplinary offense.

professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Maryland Controlled Dangerous Substances Act Criminal Law Article, §§ 5-501--5-505, Annotated Code of Maryland, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled dangerous substances.

Another important consideration and point to emphasize here is the proper language to utilize so as not to interfere with the standard of care responsibility of the individual practitioner and dispenser in accord with his/her job description stating statutorily what constitutes the practice of medicine and the practice of pharmacy. In formulating the recommendation made by the Advisory Council, it should be noted that only a failure to access the central data-base is stated as a point of protection for the practitioner and dispenser. Otherwise, the responsibility under both federal and State law to assure that a CDS Rx is written for a legitimate medical purpose remains intact.

Immunity:

Perhaps the Legislature may find that the following extracted from statutes enacted in other states with a PDMP may be appropriate.

A prescriber or dispenser acting in good faith is immune from any civil, criminal, or disciplinary liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program.

Other states' statutory provisions:

Selected provisions of statutes from some other states contain provisions relating to penalties for a failure of the dispenser to comply with his/her/its statutory responsibility to transmit, for immunity for a failure to utilize the data base and for a qualified immunity from civil liability when acting in good faith regarding the receipt and use of information.

These statutes providing for immunity for dispensers and practitioners from having to utilize the system are considered very important by the States that have enacted prescription drug monitoring programs.

2006Bill/Bill 1287

21-2A-07.

(A) THE DEPARTMENT AND ITS AGENTS AND EMPLOYEES ARE NOT SUBJECT TO LIABILITY ARISING FROM:

(1) THE INACCURACY OF ANY INFORMATION SUBMITTED TO THE PROGRAM IN ACCORDANCE WITH THIS SUBTITLE; AND

(2) THE UNAUTHORIZED USE OR DISCLOSURE OF PRESCRIPTION MONITORING DATA PROVIDED TO AN AUTHORIZED RECIPIENT.

(B) AN AUTHORIZED RECIPIENT, ACTING IN GOOD FAITH, IS NOT SUBJECT TO LIABILITY ARISING SOLELY FROM:

(1) REQUESTING OR RECEIVING, OR FAILING TO REQUEST OR RECEIVE, PRESCRIPTION MONITORING DATA FROM THE PROGRAM; OR

(2) ACTING, OR FAILING TO ACT, ON THE BASIS OF PRESCRIPTION MONITORING DATA PROVIDED BY THE PROGRAM FAILURE TO TAKE ACTION ON THE BASIS OF PRESCRIPTION MONITORING DATA PROVIDED BY THE PROGRAM.

21-2A-09

(A) A DISPENSER WHO KNOWINGLY FAILS TO SUBMIT PRESCRIPTION MONITORING DATA TO THE PROGRAM AS REQUIRED UNDER THIS SUBTITLE SHALL BE SUBJECT TO A CIVIL PENALTY NOT EXCEEDING \$500 FOR EACH FAILURE TO SUBMIT REQUIRED INFORMATION.

Oklahoma

63 Okl. St. § 2-309A (2009)

§ 2-309C...Willful failure to transmit--...

C. Willful failure to transmit information as required by this section shall be a misdemeanor punishable, upon conviction, by not more than one (1) year in the county jail, or by a fine of not more than One Thousand Dollars (\$ 1,000.00), or by both such imprisonment and fine, or administrative action may be taken pursuant to Section 2-304 of this title.

§ 2-309D. Central repository information--Confidentiality--Access--Disclosure--Penalties--Liability

D. Notwithstanding the provisions of subsection B, registrants shall have no requirement or obligation to access or check the information in the central repository prior to dispensing or administering medications or as part of their professional practices. Registrants shall not be liable to any person for any claim of damages as a result of accessing or failing to access the information in the central repository and no lawsuit may be predicated thereon. Nothing herein shall be construed to relieve a registrant from any duty to monitor and report the sales of certain products pursuant to subsection E of Section 2-309C of this title.

Florida

Fla. Stat. § 893.055 (2009)

(9) Any person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(12) A prescriber or dispenser may have access to the information under this section which relates to a patient of that prescriber or dispenser as needed for the purpose of reviewing the patient's controlled drug prescription history. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program. This subsection does not create a private cause of action, and a person may not recover damages against a prescriber or dispenser authorized to access information under this subsection for accessing or failing to access such information.

(14) A pharmacist, pharmacy, or dispensing health care practitioner or his or her agent, before releasing a controlled substance to any person not known to such dispenser, shall require the person purchasing, receiving, or otherwise acquiring the controlled substance to present valid photographic identification or other verification of his or her identity to the dispenser. If the person does not have proper identification, the dispenser may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system will be considered to be proper identification. This subsection does not

	<p>apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted. As used in this subsection, the term “proper identification” means an identification that is issued by a state or the Federal Government containing the person’s photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).</p>
<p>Virginia</p>	<p>Va. Code Ann. § 54.1-2519 (2009)</p> <p>§ 54.1-2524. Immunity from liability</p> <p>A. The Director and the employees of the Department of Health Professions shall not be liable for any civil damages resulting from the accuracy or inaccuracy of any information reported to and compiled and maintained by the Department pursuant to this chapter.</p> <p>Further, the Director and the employees of the Department of Health Professions shall not be liable for any civil damages resulting from the disclosure of or failure to disclose any information in compliance with subsections B and C of § 54.1-2523 and the Department’s regulations.</p> <p>B. In the absence of gross negligence or willful misconduct, prescribers or dispensers complying in good faith with the reporting requirements of this chapter shall not be liable for any civil damages for any act or omission resulting from the submission of such required reports.</p> <p>§ 54.1-2525. Unlawful disclosure of information; disciplinary action authorized; penalties</p> <p>C. Unauthorized use or disclosure of confidential information received from the Prescription Monitoring Program shall also be grounds for disciplinary action by the relevant health regulatory board.</p>
	<p>Chapter 84A: VERMONT PRESCRIPTION MONITORING SYSTEM</p> <p>§ 4283. Creation; implementation</p> <p>(h) A dispenser shall be subject to discipline by the board of pharmacy or by the applicable licensing entity if the dispenser intentionally fails to comply with the requirements of subsection (b), (c), or (d) of this section. (Added 2005, No. 205 (Adj. Sess.), § 1.)</p> <p>§ 4285. Immunity</p> <p>A dispenser or health care provider shall be immune from civil, criminal, or administrative liability as a result of any action made in good faith pursuant to and in accordance with this chapter, but nothing in this section shall be construed to establish immunity for the failure to follow standards of professional conduct or the failure to exercise due care in the provision of services. (Added 2005, No. 205 (Adj. Sess.), § 1.)</p>
<p>Kentucky</p>	<p>218A.202. Electronic system for monitoring controlled substances -- Penalty for illegal use of system -- Pilot project -- Continuing education programs.</p> <p>(11) Intentional failure by a dispenser to transmit data to the cabinet as required by subsection (3), (4), or (5) of this section shall be a Class A misdemeanor for the first offense and a Class D felony for each subsequent offense.</p>

EXHIBIT D contains a List of State Provisions concerning Access, Disclosure and Confidentiality Provisions of State Prescription Monitoring Programs. This exhibit was

compiled by the National Alliance for Model State Drug Laws (NAMSDL) - 703-836-7496 and furnished to the Advisory Council by Ms. Sherry Green, the CEO for NAMSDL. sgreen@namsdl.org. The list is the collection of data through August 2009.

Recommendation No. 12: Technical Review Committee

In accord with what is enacted by the legislature as to who shall have access to the data base, it is recommended by the Advisory Council that a Professional Technical Review Committee be a part of the statutory framework for enactment of a PDMP. Earmarking CDS problems and practice by experts in the field will be important for education, law enforcement, disciplinary boards, and most important, the individual practitioners and dispensers.

The members of this Technical Review Committee will have to be paid a stipend or per diem and be clinicians in active practice.

Regulations should be promulgated to effectuate implementation and operations of this Committee so as to what functions are to be performed by the Committee.

Commentary:

The governing regulations for the technical review committee may include:

1. Providing data along with clinical context, education or advice in response to law enforcement or health care board request;
2. Receiving red flag data of 5X5 patients (5 or more pharmacies and 5 or more prescribers) used by a patient/customer to review for possible unsolicited reporting to prescribers and dispensers and possible forwarding to law enforcement of disciplinary boards when appropriate;
3. Providing data for educational purpose review outlining Practitioner/Dispenser practice generally and for notification to a Practitioner/Dispenser; and
4. To “red flag” and to advise as to whom reports shall be released and under what circumstances.

This Committee may consist of the following individuals:

- Anesthesiologist (Maryland Society of Anesthesia)
- Certified Addiction Medicine Specialist (outpatient) designated or nominated by Maryland Society for Addiction Medicine
- PMR (outpatient) designated by Maryland Society PMR
- Pain specialist (outpatient) designated by Maryland Pain SIG
- Pharmacist (outpatient)
- Oncology/pain nurse practitioner
- Pain treating Psychiatrist designated by Maryland Society of Psychiatry

- Legal Council non-voting
- Caregiver non-voting.

It is very important that all provisions in the PDMP that emphasize immunity and the inability to reach recommendations of this Committee through discovery, etc., be applicable to this Committee.

The members of this Technical Review Committee will have to be paid a stipend or per diem and be clinicians in active practice.

Regulations should be promulgated to effectuate implementation and operations of this Committee so as to what functions are to be performed by the Committee which may include:

1. Providing data along with clinical context, education or advice in response to law enforcement or health care board request;
2. Receiving red flag data of 5X5 patients (5 or more pharmacies and 5 or more prescribers) used by a patient/customer to review for possible unsolicited reporting to prescribers and dispensers and possible forwarding to law enforcement of disciplinary boards when appropriate;
3. Providing data for educational purpose review outlining Practitioner/Dispenser practice generally and for notification to a Practitioner/Dispenser; and
4. To “red flag” and to advise as to whom reports shall be released and under what circumstances.

This Committee may consist of the following individuals:

- Anesthesiologist (Maryland Society of Anesthesia)
- Certified Addiction Medicine Specialist (outpatient) designated or nominated by Maryland Society for Addiction Medicine
- PMR (outpatient) designated by Maryland Society PMR
- Pain specialist (outpatient) designated by Maryland Pain SIG
- Pharmacist (outpatient)
- Oncology/pain nurse practitioner
- Pain treating Psychiatrist designated by Maryland Society of Psychiatry
- Legal Council non-voting
- Caregiver non-voting.

It is very important that all provisions in the PDMP that emphasize immunity and the inability to reach recommendations of this Committee through discovery, etc., be applicable to this Committee.

Recommendation No. 13: Public Policy

It is the recommendation of the Advisory Council that the Legislature state as strongly as it can the Legislative Purpose for the enactment of a PDMP.

The HB1287-2006 took note of the fact that:

- (1) Thousands of Marylanders are suffering from pain and need to have access to pain medication;
- (2) The increasing number of Maryland adults and adolescents engaged in prescription drug abuse and diversion to the detriment of their health and welfare;
- (3) that a monitoring program should be established but should not interfere with the legitimate professional practice and patient care;
- (4) that identification, treatment, prevention of prescription drug abuse and diversion are the purposes for which a PDMP is enacted, and
- (5) that the data collected through the program should be available for research purposes about the effects of the PDMP.

EXHIBIT I “A Prescription for Disaster–The Growing Problem of Prescription Drug Abuse in Maryland” reported on pp. 1-15 on disturbing statistics of the number of individuals suffering from pain; the use of prescription drugs by Americans; the non-medical use of prescription drugs; the rise in narcotic analgesics abuse, the rising abuse of prescription drugs; teen abuse of prescription drugs; and prescription drug abuse and diversion throughout Maryland and the United States of America.

The U. S. Drug Enforcement Administration has requested that its statistics be made a part of the recommendations and exhibits made available to the legislature. Theses are available in **EXHIBIT P**. Examples of the current statistics from this exhibit show that in 2007 the misuse of prescription drugs was second only to marijuana. One in five teens reports abusing prescription medications. Unintentional overdose deaths involving prescription opioids increased 114% from 2001 to 2005, and 6.2 million Americans abuse CDS. The magnitude of the problem can not be over emphasized.

Recommendation No. 14: Education

The Advisory Council recommendation on education is more by way of information to the Legislature and a recommendation to the PDMP once it is established. Information concerning the workings of the program and the need for the program should include:

- (1) A Web site containing easy access to virtually all information concerning the program;
- (2) Initial contact by letter to dispensers and practitioners concerning the program accompanied by forms for registration;
- (3) A manual for software manufacturers setting forth requirements needed to comply with the reporting provisions of the program;
- (4) A personal initiative for visits to hospitals and medical societies throughout the State of Maryland to present information and field questions concerning the PDMP;⁵⁸
- (5) Pamphlets and frequently asked questions (FAQ) to educate the public, dispensers, practitioners, and patients concerning the program;
- (6) Procedural manuals for the program;⁵⁹ and
- (7) Availability of a help desk help to assist individuals in need of assistance regarding all aspects of the program.

Commentary

Vermont explains that the State is small and one of their main education initiatives is to do Grand Rounds at hospitals. Accompanying Meika Zilberberg (mzilber@vdh.state.vt.us) is the Medical Director of the Vermont PDMP, the Attorney for the Vermont Medical Society, and a Detective Specialist involved with Drug Control. They talk about drug abuse and the program and answer questions. Following these visits, they ask those in attendance to fill out a survey as to the helpfulness of the visit and invite individuals to make contact with the program for any questions that may arise.

For the most part, PDMP have good web sites offering extensive information which includes:

- FAQ for providers, dispensers, patients and the public;
- Brochures for the public;
- Applicable statutes, rules and reports;
- Health Care Provider or Dispenser Registration Forms;
- Technical assistance contacts for those submitting information;
- Practitioner access request form;

⁵⁸ Meika Zilberberg, MS, Program Coordinator, Vermont Prescription Monitoring System, Vermont Department of Health {phone} 802-652-4147 {email} mzilber@vdh.state.vt.us <http://healthvermont.gov/adap/VPMS.aspx> emphasized the importance of this initiative. Vermont is a smaller state which probably added to the ability to make this initiative successful. Ms. Zilberberg said the individuals accompanying her on the visits are the Medical Director of the Vermont PDMP, the Attorney for the Vermont Medical Society and a detective Specialist involved with Drug Control. These presenters talk about drug abuse and the program and answer questions. Following these visits, they ask those in attendance to fill out a survey as to the helpfulness of the visit and invite contact with the program for any questions that may arise.

It should be noted that the Vermont program has no connection with law enforcement and allows no access by law enforcement personnel.

⁵⁹ The Advisory Council emphasizes the need for the implementation of a system that is not difficult to use. Manuals vary in the amount of information they contain. For instance, the Optimum Technology manual for the Oklahoma PDMP consists of 240 pages as opposed to Vermont where the manual does not exceed 30 pages.

- Individual request form;
- Pharmacies and related dispenser access forms;
- Procedural manual and users guide;
- HIPAA and Maryland Confidentiality of Medical Records Act applicability – Security of the data base;
- References to federal, national and other state information systems regarding prescription drug abuse, diversion and PDMPs;
- Implementation guide to meet the PDMP data base software requirements;
- For individuals seeking treatment;
- Yearly reports to the Governor and the Legislature; and
- “Contact us” information.

EXHIBIT K is a compilation of information from various web sites for states that have enacted PDMPs.

Recommendation No. 15: Outcome

The Advisory Council recommends that the Legislation to be enacted provide for future analysis of the effectiveness of the PDMP. Recommendation No. 2 recommends that the Advisory Board created be responsible for implementing procedures to evaluate the effectiveness of the PDMP. We consider this evaluation responsibility and the responsibility to keep advised of advancements in the field of prescription drug monitoring essential to the proper working of the program.

Commentary

Other states which have enacted a PDMP emphasize the importance of assessment and evaluation of the program established.

Florida	<p>Fla. Stat. §893.055 Prescription Drug Monitoring Program</p> <p>(2) . . . The department shall establish policies and procedures as appropriate regarding the reporting, <u>accessing the data base, evaluation</u>, management, development, implementation, operation, storage, and security of information within the system. . . .</p>
Virginia	<p>Va. Stat. Ann. § 54.1-2520. Program establishment; Director’s regulatory authority</p> <p>E. The Director shall also establish an advisory committee within the Department to assist in the implementation <u>and evaluation</u> of the Prescription Monitoring Program.</p>

There are analytic tool companies who will offer their services to the Secretary as part of a system that seeks to analyze the effectiveness of the PDMP. **Exhibit M** is information sent to

the Advisory Council from one such company, Affinity Networks, Inc. VisualLinks for Healthcare states⁶⁰:

VisualLinks can be complementary to other techniques, and addresses the requirement of discovering and exposing new types of fraud patterns. No tacit assumptions are programmed in, therefore all results are based upon the actual data analyzed, making it far superior in the identification of new patterns of fraud and abuse.

Recommendation No. 16: Data Mining

As part of the “access to information” section of the report, the Advisory Council recommends that state agencies and academic institutions be allowed to request data extracts from the PDMP governing body for the purpose of data analysis to support public health and public reporting as defined in statute or regulation for the requesting agency.

Requestors should be required to submit an abstract to the administrative agency outlining the purpose and scope of the intended analysis. Data will be extracted should be provided to requestors as de-identified information unless the data is supporting a bona fide public health emergency.

The importance of this tool makes it important for a separate recommendation to the Legislature concerning the use of data mining.

Commentary

Among the appropriate data uses of a PDMP is data mining. This subject has been discussed by the Advisory Council. Because data mining has multiple utilities, it frequently raises concerns from those whose data is being reviewed. Wikipedia probably has the best definition as it carefully describes the positive use of data mining, addresses the potential pitfalls that need constant attention, and addresses the negative perception that immediately comes to some people’s minds when they hear the phrase.

Data mining is the process of extracting patterns from data. As more data are gathered, with the amount of data doubling every three years,[1] data mining is becoming an increasingly important tool to transform these data into information. It is commonly used in a wide range of profiling practices, such as marketing, surveillance, fraud detection and scientific discovery.

⁶⁰ Mr. Arthur R. Henderson is the President of Affinity Networks. His contact information is: 2200 Wilson Blvd. #102-205 Arlington, VA 22201. Office Phone: (703) 528-4616

In his communication with the Advisory Council by e-mail, Mr. Henderson informs us: “We are a local minority owned firm and have worked extensively in healthcare and law enforcement. One of the tools we bring, which was developed by a Veteran owned Maryland firm, is already in use by the State of Maryland in several places including the University of Maryland Mind Lab, which will provide great economies for scale of licensing.”

While data mining can be used to uncover patterns in data samples, it is important to be aware that the use of non-representative samples of data may produce results that are not indicative of the domain. Similarly, data mining will not find patterns that may be present in the domain, if those patterns are not present in the sample being “mined”. There is a tendency for insufficiently knowledgeable “consumers” of the results to attribute “magical abilities” to data mining, treating the technique as a sort of all-seeing crystal ball. Like any other tool, it only functions in conjunction with the appropriate raw material: in this case, indicative and representative data that the user must first collect. Further, the discovery of a particular pattern in a particular set of data does not necessarily mean that pattern is representative of the whole population from which that data was drawn. Hence, an important part of the process is the verification and validation of patterns on other samples of data.

The term data mining has also been used in a related but negative sense, to mean the deliberate searching for apparent but not necessarily representative patterns in large numbers of data. To avoid confusion with the other sense, the terms data dredging and data snooping are often used. Note, however, that dredging and snooping can be (and sometimes are) used as exploratory tools when developing and clarifying hypotheses.

With a data base as large as one supporting a mature PDMP, data mining can be an invaluable tool for public health and public reporting. The current H1N1 crisis is a good example of the potential utility of a PDMP data base and data mining. The Maryland Health Care Commission (Commission) maintains a large data base of de-identified encounter data which it uses to produce a series of reports on utilization and cost trends, etc. In addition the Commission is now gearing up for the collection of race/ethnicity and language information for analysis of health and health care disparities.

There is a second use of the data that often generates intense emotional reaction. That is data mining by designated trained professionals in the administrative agency for the purpose of identifying aberrances worthy of clinical panel review. Substantiated aberrances would then be referred as information only to the attending physician and/or dispenser. This type of information can be of great use to a clinician or dispenser in medical or drug abuse management. There are software programs that some independent and chain pharmacies use to identify adverse drug interactions but they are only effective if the pharmacy is the sole dispenser. Such software could potentially be an integral part of a PDMP to provide real time feedback. Although this form of data mining can have significant medical management and drug abuse value, it brings with it concerns that it will be used to question medical practice or for punitive action by state Boards or law enforcement. This was one of the most contentious utilities when the legislation was proposed in 2006. It would appear however that such fears should be mitigated if legislation clearly precluded dissemination of information gathered through data mining by the

administering agency to state Boards or law enforcement agencies, absent a subpoena authorized by a judge or a court order.⁶¹

⁶¹ Education to the Advisory Council on Prescription Drug Monitoring on the use of data-mining was provided through the experience and expertise of the Maryland Health Care Commission. The Advisory Council is indebted to Mr. Bruce Kozlowski of MHCC, an Advisory Council Member for his work and advice on this issue. Not all Advisor Council members were aware of the extent that this valuable tool can be used in assistance to further the objectives of the PDMP. Though this is an issue covered with our recommendation as to the role of an Advisory Board, its importance dictates that separate mention and emphasis be made with this recommendation.

List of Exhibits. Exhibits are available as part of the Advisory Council records and are available upon request from Council staff, and can be found on the internet at <http://www.dhmh.state.md.us/drugcont/>

- A – HB1287-2006 – Text, Veto Message, Votes, Fiscal Note
- B – National Alliance Materials (part 1 & part 2)
- C – List of States that Statutorily Mandate that the PMP Use/Work With an Advisory Committee or Council, Task Force or Working Group
- D – List of State Provisions concerning Access, Disclosure and Confidentiality Provisions of State Prescription Monitoring Programs
- E – Selected Statutes (Oklahoma, Florida, Virginia, Vermont, Kentucky)
- F – Transcripts of the Meetings of the Advisory Council
 - F-1 Transcript for meeting on 1/9/2009
 - F-2 Transcript for meeting on 2/27/2009
 - F-3 Transcript for meeting on 4/17/2009
 - F-4 Transcript for meeting on 6/5/2009
 - F-5 Transcript for meeting on 9/11/2009
 - F-6 Transcript for meeting on 10/2/2009
 - F-7 Transcript for meeting on 11/6/2009
 - F-8 Transcript for meeting on 12/4/2009
- G – Selected Statutes from other states
- I – Prescription for Disaster – the Growing Problem of Prescription Drug Abuse in Maryland
- J – Virginia PDMP Information
- K – Web Site Information for PDMPs
- L – Florida PDMP Information (two parts)
- M – Visual Links Information
- N – October 1, 2009 Report from MHCC
- O – 2008 Legislative Enactment Creating Advisory Council on Prescription Drug Monitoring
- P – U.S. DEA statistical information