MARYLAND ADVISORY BOARD ON PRESCRIPTION DRUG MONITORING

OCTOBER 17, 2011
10:30 AM TO 12:30 PM
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
ALCOHOL AND DRUG ABUSE ADMINISTRATION
55 WADE AVENUE, CATONSVILLE MD 21228

MINUTES

Attendees

Advisory Board: Nancy Adams, MBA, RN, President, Board of Nursing; Hoover Adger, Jr., MD, MPH, MBA, Appointee; Cpt. Daniel Alioto, Appointee; Janet M. Beebe, CRNP, Appointee; ; Linda Bethman, JD, MA, Designee of the President, Maryland Board of Pharmacy; Paul T. Elder, MD, Chair, Maryland Board of Physicians; J. Ramsay Farah, MD, MPH, Appointee; Vinu Ganti, MD, Appointee; Janet Getzey Hart, Appointee; Laura Herrera, MD, MPH, Designee of the Secretary of DHMH & Advisory Board Chair; Gail Amalia B. Katz, MPH, Appointee; Sharon Krumm, PhD, RN, Designee of the Chair of MHCC; Orlee Panitch, MD, Appointee; Faryal Qureshi, PharmD, Appointee; Howard R. Schiff, Appointee; Thelma B. Wright, MD, Appointee.

Observers: Erin Artigiani, CESAR; Hoai-An Truong, UMD School of Pharmacy; Dixit Shah, UMD School of Pharmacy

PDMP Staff: Michael Baier, ADAA

I. **Welcome & PDMP Overview:** Dr. Herrera welcomed the Board on behalf of Secretary Sharfstein, provided a personal introduction, gave a brief overview of prescription monitoring, the core mandates of the PDMP authorizing legislation and the meeting materials, and reviewed the meeting agenda.

II. **Introductions:** PDMP staff, Board members and observers gave brief personal introductions, including a description of any PDMP-related activities.

III. **PDMP Legislation Review:** Michael Baier, PDMP Coordinator, led a review of SB 883, 2011, the PDMP authorizing legislation. Notable points include:
   A. Mandate to implement a balanced approach to prescription monitoring that reduces prescription drug abuse and diversion while preserving legitimate professional practice and patient access to pharmaceutical-assisted care.
   B. Definitions of important terms
      1. Exemptions to the term "dispenser" that will not be required to report Rx data, including hospital pharmacies dispensing only to inpatients, opioid maintenance programs,

veterinarians, dispensing to residents of health and long term care facilities, and dispensing to hospice inpatients.
2. Rx drugs for which reporting is required: CDS Schedules II-V
3. "Prescriber" includes only current, valid DEA registrants

C. General legislative provisions
1. PDMP shall be implemented subject to availability of funds
2. PDMP will be housed in ADAA
3. DHMH is authorized to contract with an IT vendor to create electronic monitoring system
4. DHMH must consult with MHCC on the IT approach
5. DHMH must educate dispensers, prescribers and consumers on purposes and use of the PDMP
6. PDMP data may not be used as the basis for imposing clinical practice standards
7. DHMH employees are not liable for inaccuracy of data submitted to program or unlawful use or disclosure by persons who received data from the program lawfully
8. 5 year sunset provision; law must be reauthorized

D. Areas that regulations must address
1. The specific Rx monitoring data to be reported must include, at a minimum, identifying information for patient, prescriber, dispenser and drug dispensed
2. Means of data submission
3. PDMP must not unduly increase workload or impose fees on dispensers or prescribers and should integrate with existing business practices to greatest extent possible
4. PDMP must provide IT to dispensers necessary to report data
5. Prescribers and dispensers not required to use PDMP and are not subject to liability solely from acting on or failing to act on information provided by the program
6. Procedures for disclosure to Technical Advisory Committee
7. Allowable re-disclosure from authorized recipients
8. Protections for confidentiality of data

E. Overview of PDMP Advisory Board
1. Composition, appointment process, terms and reimbursement for travel expenses
2. Board must meet no fewer than 3 times annually, though more frequent meetings (probably monthly) will be required initially
3. Responsibilities:
   a. Make recommendations to Secretary related to design and implementation of PDMP, regulations, and funding, including Harold Rogers and other federal, state and private grants
   b. 6 month (April, 2012) and annual reports to General Assembly & governor to report on patient access and impact on Rx abuse and diversion and make recommendations related to modification and continuation of PDMP
   c. Design ongoing evaluation component

D. Disclosure of Rx monitoring data from PDMP
1. Disclosure from PDMP other than those authorized in law are prohibited
2. Prescribers and dispensers may delegate access to a "licensed health care practitioner"
   a. Regulations must define which practitioners can be delegated access
   b. How will delegate access be setup? Options include sub-accounts based on DEA number w/ suffix, separate access authorization with credentials tied to delegating prescriber/dispenser, etc.
   c. What liability do prescribers and dispensers have for unlawful use of PDMP by delegated practitioners?

3. Law enforcement access will require a subpoena pursuant to an existing individual investigation.
    a. Subpoena require means that PDMP will have to process law enforcement requests manually; it is unlikely that electronic request system is viable.
    b. Law enforcement agencies currently share information gained through subpoena with each other to support joint and continuing investigations. Since regulations will have to address allowable re-disclosure of PDMP data, there is an open question as to whether such sharing will be permissible.
4. Licensing Board access will require submission of an administrative subpoena voted on by a quorum of the Board. Regarding re-disclosure from the Boards, Dr. Elder noted that the Board of Physicians is authorized to share information with other enforcement agencies.
5. A rehabilitation program under a licensing board is required by the law to have an administrative subpoena to access PDMP data. The logic behind giving these programs access was so that they could monitor the compliance of their impaired professional clients without knowledge of or oversight by the licensing board.
    a. There are open questions about the procedures each Board employs in relation to its authorized rehabilitation program, specifically whether, given the subpoena requirement, a rehab program could access PDMP data without the licensing board being informed.
    b. Ms. Adams noted that the Executive Director of the Board of Nursing has the authority to issue administrative subpoenas.
6. Patients must be allowed to request a report on their own Rx history. Regulations must address how patient access is handled. The PDMP must also develop a means for a patient or their prescriber to have data that they believe is incorrect to be corrected.
7. Certain units of DHMH, including Medicaid, Inspector General, Office of Health Care Quality and Chief Medical Examiner, may request data on authorization of the Secretary pursuant to an existing investigation
8. Research and education requests: data must be stripped of information that could identify any person. Prior IRB approval may be necessary.
9. Other states' PDMPs
    a. Data requests from other states may be honored, provided that they comport with the requirements of MD's legislation
    b. PDMP may pursue interoperability with other states' programs (may require MOU or other agreements)
    c. DOJ and NABP have developed interoperability platforms that a few states are currently using to process inter-state data requests

E. Technical Advisory Committee: 5 member group of medical and pharmacy professionals
1. Must review disclosure requests from law enforcement, boards, rehab programs, other states' PDMPs and units of DHMH before release of info
2. Provide advice to Secretary on how to respond to request and clinical guidance and interpretation of data to data recipient should the request be honored
3. How long will TAC have to reply to requests?
4. How will communication between the TAC, the PDMP and the data requestors be handled? By email, phone, etc?

F. Penalties
1. Civil penalty for dispenser failure to report data: $500 per incident

2. Criminal penalty for unlawful use or disclosure of data: misdemeanor offense subject to imprisonment not to exceed 1 year and up to a $10,000 fine
3. Administrative sanctions against a practitioner by licensing board are possible

IV. PDMP Implementation Update

A. Timeframe for promulgating regulations: Dr. Herrera noted that the entire process for promulgating regulations will need to be completed by early February, 2012, in order to avoid having to wait until after the 2012 legislative session. This includes a 30 day public comment period to be followed by time to answer all comments.

B. Implementation to date: Board members are encouraged to review implementation timeline included in meeting materials

C. Funding: Mr. Baier reviewed funding currently available to the PDMP, including
1. $500,000 Byrne Justice Assistance Grant (BJAG) (initial 1.5 year grant period, to be extended as needed) from the Governor's Office of Crime Control & Prevention
2. $400,000 Harold Rogers PDMP Grant (2-year grant period) from the federal DOJ's Bureau of Justice Assistance (grant is to GOCCP but delivered as a pass-through to ADAA)
3. The BJAG grant funded July 1- Sept 30, 2011, but funds were de-obligated upon notice of award of the Rogers grant, which has now picked up all PDMP costs starting Oct 1, 2011. Once Rogers funds are expended, the remainder of the BJAG will be available.
4. Both applications were based on a prior (2010) DHMH Rogers application to DOJ that was not funded. Costs include personnel, computers, travel and contractual (vendor) fees.

D. Personnel: Mr. Baier reviewed the current status of PDMP personnel and positions. Three PINs have been approved for the PDMP, including an Administrator IV (PDMP Coordinator, currently staffed by Mr. Baier), IT Functional Analyst II and Administrative Secretary III.

E. Webpage: Mr. Baier noted that a webpage has been created for the PDMP on ADAA's website to provide basic information about the program and its implementation.

F. Information Technology: Mr. Baier gave an overview of discussions on integration between PDMP and the statewide Health Information Exchange. ADAA, DHMH, and MHCC have held discussions with Chesapeake Regional Information System for our Patients (CRISP), the entity designated by MHCC to develop the statewide HIE, about areas for potential collaboration with the PDMP and adoption of certain PDMP functions by the HIE. Initial discussions indicate that these approaches could possibly be implemented in a timeframe similar to a typical process for vendor implementation of a traditional PDMP system (which includes an RFP).
1. Data reporting: There is a possibility that Rx dispensing data could be collected by tapping into existing data networks in the pharmacy industry, specifically the "switching" services that electronically process third-party payer billing for pharmacy claims adjudication. These transactions include a great amount of data that could be useable by the PDMP, take place in real time at the point of dispensing and are already part of regular pharmacy business practice. Tapping into these networks could greatly reduce or eliminate the need for pharmacies to submit periodic uploads of batch datasets to the PDMP, increase the timeliness of data available within the PDMP database and decrease the burden on PDMP staff to ensure reporting compliance among dispensers. Obstacles to this process include the fact that data on cash-only payments are typically not sent through the switches (but the technical capability, and in some cases the actual practice, currently exists) and the current business model for switching services (pharmacies are charged per transaction, so a requirement that pharmacies report cash-only dispensing in this manner

could not have as a consequence increased costs to pharmacies). CRISP could configure the HIE to connect with the switches to receive Rx data, perform any data standards translation necessary, run the data through the HIE's Master Patient Index to help identify unique patients and direct store the data in its own data warehouse.

2. Data request: CRISP is already developing user authentication and credentialing processes for provider access to the HIE. Access to PDMP data could be included in a user's credentials, and PDMP data could therefore be made available to providers through the same web interface through which they currently access all other patient-specific health information available through the HIE. As CRISP works to integrate the HIE with EHR applications, PDMP data could be made directly available within EHRs rather than having providers go to a separate portal for PDMP data only. This could better integrate PDMP data access into existing provider workflows and increase PDMP utilization. Existing state PDMPs are currently looking at these options or implementing pilots

V. Administrative Discussion: Dr. Herrera closed with a discussion about administrative issues for the Board, including:

A. Future meetings. The next meeting will be scheduled for the end of November or the first week of December. Teleconferencing and webconferencing options were suggested by multiple members; future meetings will have the capabilities and will also be scheduled in the early morning or late afternoon to facilitate attendance.

B. Subcommittees. Likely topics could include regulations, IT, education and evaluation. Requests for subcommittee topics and assignments will be sent out before the next meeting.