MARYLAND ADVISORY BOARD ON PRESCRIPTION DRUG MONITORING

FEBRUARY 22, 2012
4:00 PM TO 6:00 PM
ALCOHOL AND DRUG ABUSE ADMINISTRATION
55 WADE AVENUE
CATONSVILLE, MD 21228

MINUTES

Attendees

Advisory Board
Hoover Adger, Jr, MD, MPH, MBA, Appointee
Cpt. Daniel Alioto, Appointee
Janet M. Beebe, CRNP, Appointee
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 President, Maryland Health Care Commission
Orlee Panitch, MD, Appointee
Faryal Qureshi, PharmD, Appointee
Howard R. Schiff, Appointee
Thelma B. Wright, MD, Appointee
Karen Wulff, Designee of the Chair of the Maryland Board of Physicians

Board Adjunct: Linda Bethman, JD, MA, Office of the Attorney General, DHMH

PDMP Staff: Michael Baier, PDMP Coordinator, ADAA

I. **Roll Call, Agenda Review and Approval of Minutes:** Dr. Herrera led roll call and reviewed the meeting agenda. The minutes from the November 30, 2011 meeting were approved with the addition of Sharon Krumm to the attendee list. Michael Baier will be posting meeting minutes on the PDMP webpage on ADAA's website.

II. **Review and Approval of Draft Proposed Regulations:** Dr. Herrera reviewed the current status of the draft proposed regulations for the PDMP. Regulations were first reviewed and edited by the Regulations Subcommittee of the Advisory Board and then submitted for review by relevant agencies within DHMH. These edits were submitted for review by the Board. After final approval by the Board, the regulations will be submitted for publication for a 30 day public comment period.

Michael Baier led a review of the latest proposed changes to the regulations. Notable edits include:

- The definition of "patient" was augmented to include "An individual for whom a dispenser has dispensed or is considering dispensing a monitored prescription drug" to remove any ambiguity that a dispenser that refuses to dispense to a patient after querying the PDMP database has accessed the data legitimately, regardless of whether they have a record of the encounter.
- The definition of "prescriber" was changed to remove the requirement that a prescriber have a Maryland CDS permit, which would limit prescriber access to only Maryland prescribers. Dr. Herrera noted that excluding the requirement for having a CDS permit may allow prescribers whose CDS permit was suspended/revoked by the Division of Drug Control, but whose DEA registration was still active, to access the PDMP database. Suspension of the CDS permit is a factor in a current practitioner disciplinary case and may be so in future cases as well. Language will be drafted to apply the CDS permit requirement only to prescribers licensed to practice in Maryland.
- All dispenser reporting deadlines were changed to 3 business days. Howard Schiff commented that requiring pharmacies to report prescriptions that were filled but never picked up would place a significant burden on pharmacy operations. Michael Baier noted that state PDMPs typically require such corrections to accurately track whether prescriptions were in fact dispensed, and that PDMP reporting typically happens at the point of fill, not at the point of sale. The discussion of specifics of program operation was tabled pending Board review of the Department's information technology (IT) design proposal. To clarify, a definition of "business day" as Monday through Friday, 9 AM to 5 PM will be included.
- A process for dispensers to request a waiver from meeting the reporting deadline for a particular incident was included.
- A requirement was added for prescribers/dispensers that delegate access to the PDMP to licensed health care practitioners to notify the delegate's licensing board if they believe the delegate has unlawfully accessed, used or disclosed PDMP data.
- Prescribers were allowed to request a list of all dispensing records attributed to their DEA number.
- The word "judicial" was removed from the section referencing the subpoena requirement for law enforcement requests in order to allow DEA Diversion investigators to use administrative subpoenas per current practice.
- The requirement that DHMH agencies get approval from the DHMH IRB to get de-identified data from the PDMP was removed.
- To clarify the status of reports of the Technical Advisory Committee (TAC), language was included that establishes that the reports, for all intents and purposes, are equivalent to prescription monitoring data. The Board of Physicians had expressed concern that the reports would be admissible as evidence in administrative proceedings and that members of the TAC could subpoenaed to testify on their interpretation. After consultation with the DHMH Office of the Attorney General, the ADAA has taken the position that including a provision barring admissibility of the reporters as evidence in administrative hearings (as

requested by the Board) would go beyond legislative intent, and should therefore not be included.
- The requirement that prescribers and dispensers notify patients that they may request PDMP data was removed; the instructions regarding notice were made discretionary.
- A term of 1 year for TAC members was added. On Dr. Farah's suggestion, it will be changed to 3 years.

Board member questions:

Gail Amalia Katz asked whether PDMP data turned over to law enforcement pursuant to a subpoena would include patient-identifying information. Michael Baier responded that these reports will include identifying information, but the question of query rules will not be determined until the IT infrastructure is identified and implemented.

Howard Schiff asked if, due to the inclusion of a requirement that dispensing practitioners report to the PDMP as well as pharmacies, the reporting deadline should be 7 days. Dr. Herrera stated that, based on other states' experience, less timely data was a contributing factor to low provider utilization of the system. Michael Baier noted that the Department's goal is to implement program IT capable of facilitating real-time reporting of most if not all prescription monitoring data, regardless of what the official deadline is in regulations. If this approach functions correctly, the regulatory deadline will serve only as a backstop for instances when complications in the real-time reporting infrastructure arise.

III. PDMP Information Technology Proposal: Michael Baier delivered a PowerPoint presentation on the Department's proposed PDMP IT infrastructure design. Notable points include:

- The Department seeks to leverage existing IT as much as possible. Other program goals include real-time data collection, integration of reporting into dispenser workflow, integration of data disclosure into prescriber workflow and minimization of manual data processing. All of these components will support a higher level of provider utilization than what is typical with current PDMP models, therefore promoting the primary public health goal of the program.
- Other states typically contract with one of a small group of vendors to handle one or more PDMP program components.
- Most PDMP data requests in other states are from prescribers, but the rates of prescriber enrollment and utilization of the programs (the number of eligible prescribers that actually register with and request reports from the PDMP) is very low, typically no more than 30%. This is likely due to the difficulty in accessing PDMP data in the context of busy prescriber practices and the perception that the data itself is not timely or dependable. Oklahoma's PDMP administrator reports a large increase in provider utilization following their move to real-time data collection.
- Federal policymakers are recommending that PDMPs create links to state health information exchanges (HIE) and industry electronic health networks (EHNs) to improve access to PDMP data.
- Real-time data collection for most CDS dispensing could be possible with currently available technology if "switches" (EHNs that process pharmacy billing claims with third-party payors) can be a viable conduit for dispenser reporting.

- The Department seeks to integrate, to the greatest extent possible, the required IT components of the PDMP with the existing infrastructure of Maryland's statewide HIE, currently under development by Chesapeake Regional Information System for Our Patients (CRISP). CRISP was designated by MHCC as the statewide HIE after a competitive selection process and has the goal of facilitating electronic information exchange among all of Maryland's physician practices, hospitals and other providers.
- The proposed program design includes data collection by a vendor able to facilitate real-time, transactional reporting from dispensers; data processing and analysis by the HIE, using its currently operational Master Patient Index (MPI) to identify unique patients; database hosting by the HIE and the Department (including a mirrored database at ADAA for data queries by program personnel in response to non-clinical data requests); end-user authentication and credentialing for healthcare providers by the HIE; and disclosure of PDMP data to providers through the HIE web portal and (in the future) connected electronic health record (EHR) systems.
- Due to subpoena and existing investigation requirements, data requests from law enforcement, licensing boards, units of DHMH, etc. will need to be submitted directly to the program, which will then run the reports, manage the TAC review process, and provide the report to the requester agency. The specific processes will be determined at a later date.
- Estimated costs are currently unknown. Discussions with MHCC are ongoing. Vendor costs for real-time reporting technology could be significantly more than for vendor systems operating in other states that rely on periodic batch file uploads from dispensers (switches charge pharmacies per transaction, so the state may have to cover costs related to reporting of cash-only dispensing transactions). However, utilization of existing technologies and networks may produce significant costs savings.
- The Department hopes to have the system implemented by 3rd quarter, FY2013. The procurement process could take 4-6 months.

Board member questions:

Dr. Farah noted that the estimated costs of this program design could be significantly more than the off-the-shelf vendor systems that the PDMP Advisory Council had been briefed about in 2009. Dr. Herrera responded that, should the price to develop this system be over $1 million, the PDMP does not currently have access to sufficient funds.

Gail Amalia Katz asked if the HIE has any interest in or ability to handle the data collection component as well so that a vendor would be unnecessary. Dr Herrera responded that, based on current assessment, the difficulty of connecting all existing dispensers to the HIE directly would be cost prohibitive and extremely difficult logistically.

Dr. Herrera noted that a scope of work for the vendor RFP is currently in development.

IV. Administrative Issues: Dr. Herrera noted a number of administrative and other responsibilities that the Board must tackle over the next few months, including:

- The Board's Interim Report to the General Assembly is due in April. The Board decided to have the Department draft the report and submit to the Board for editing and approval. A draft will be sent within 2-3 weeks.
- The Educational Initiatives Subcommittee will need to become active in the near future to develop a plan for the educational component of the PDMP. Initiatives will need to be targeted for diverse audiences, including providers, law enforcement, the general public, etc.
- A program evaluation component also needs to be developed. The Board was asked to consider the assistance of outside researchers, specifically individuals with existing relationships in ADAA and expertise in prescription monitoring. The Board agreed to accept proposals from researchers. Dr. Farah noted that grant funding available through SAMHSA or other sources to study novel programs should be pursued.

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