MARYLAND ADVISORY BOARD ON PRESCRIPTION DRUG MONITORING

NOVEMBER 30, 2011
4:00 PM TO 6:00 PM
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
201 WEST PRESTON STREET
BALTIMORE, MD 21201

MINUTES

Attendees

Advisory Board: Cpt. Daniel Alioto, Appointee; Janet M. Beebe, CRNP, Appointee; Howard Blumenfeld, Appointee; 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 President, Maryland Health Care Commission; Orlee Panitch, MD, Appointee; Faryal Qureshi, PharmD, Appointee; Howard R. Schiff, Appointee; Michael Souranis, President, Maryland Board of Pharmacy; Thelma B. Wright, MD, Appointee.

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

Presenters: Michele Phinney, Director, Regulations and Policy Coordination, DHMH

PDMP Staff: Michael Baier, PDMP Coordinator, ADAA

I. Introductions, Agenda Review and Approval of Minutes

II. Overview of DHMH Regulations Promulgation Process – Michele Phinney, Director, Regulations and Policy Coordination, DHMH

A. Important requirements for regulations
   1. Secretary must have authority within law to promulgate regulations
   2. Can take form guideline, rule, standard, statement of interpretation or policy
   3. Cannot govern only internal management of unit and must affect the public

B. Promulgation Process
   1. Can take 4-6 months total
   2. ADAA should solicit comments from affected groups prior to publication
   3. Internal DHMH review follows sign-off by ADAA leadership & Deputy Sec.
   4. Governor's Office, DHMH Office of Governmental Affairs and Budget Office review
   5. AG sign-off for legal sufficiency and approval by Secretary
   6. Submission to AELR Committee prior to publication in Maryland Registry; AELR has 15 days to comment

7. 30 public comment period- must respond to every comment at end of period
8. Non-substantive changes are allowed- AG must determine if changes are substantive
9. Substantive changes require resubmission to AELR and new 30 day comment period
10. Final sign-off through DHMH required after comment period and Secretary must wait 15 days to sign off
11. AELR can hold regs for any reason during 45 day comment and DHMH sign-off period
12. AELR can hold hearings and request comments & responses
13. Secretary can issue letter of intent to adopt regs within 30 days if AELR action not forthcoming; forces AELR to vote on regs
14. Can appeal to Governor for final resolution if no resolution with AELR
15. Any substantive change at this stage will still require resubmission for public comment

III. Review of Draft PDMP Regulations –Michael Baier, PDMP Coordinator, ADAA

A. Draft was developed by ADAA/DHMH working group during autumn based on review of code and regulations in other states with similar legal framework
B. Approach taken in regs was dictated by the requirements of the law in most areas, but some interpretation was necessary on a few issues
C. Definition for "licensed health care practitioner" was added in order to specify precisely who could be delegated authority to request PDMP data on behalf of a prescriber or dispenser
    1. Evidence from other states indicates PDMP access is better incorporated into provider business practices when delegated access is available
    2. Limiting delegation to licensed, certified or registered practitioners allows for ability to sanction for misuse of PDMP access
    3. Discussion of whether residents and fellows in an academic center could be delegated access. Under current definition, they would need to be at least registered by a licensing entity.
    4. HIE currently has user credentialing process that can assign different levels of access to subordinate users; access to PDMP data could be delegated in a similar way.
D. Dispensing from VA will not be reported to PDMP
    1. VA is waiting for states to integrate programs
    2. VA representative could brief Board on future plans for cooperation with PDMP
E. Discussion about the included exemption for "starter doses"
    1. Janet Hart and Dr. Elder suggested that exemption could be exploited by physicians who repeatedly prescribe starter doses
    2. Reporting exemption for starter doses will be removed from draft since starter doses are not specifically exempted in law
    3. Board could suggest inclusion of exemption for starter doses in its legislative report
F. Definition of patient was added (does not appear in law) to distinguish from drug recipient
G. Definition for prescriber includes references to MD code granting prescriptive authority and Criminal Law Article section relevant to state CDS permit. Second part will be changed to reference federal code/regs for DEA registration per Janet Hart's recommendation.
H. Review of data elements to be reported to PDMP- came from other states' law /regs
    1. Inclusion of Patient ID is attempt to get one more piece of identifying information, not to impose ID requirement for dispensing
    2. "Employer ID number" will be changed to "Employer-issued ID number"
    3. Social Security number will be removed as option
    4. Janet Hart suggested green card number should be included
    5. Discussion about possibility of including NPI number

a. IT approach may allow for capture of NPI in addition to DEA
b. Suggestion that NPI is necessary for billing claims purposes

I. Janet Hart suggested that necessity for dispensers to resubmit data in 1 day based on notice of original submission of incomplete/inaccurate data is unrealistic

J. Prescribers and dispensers who wish to request data from the PDMP must register with the program and receive access credentials. Users must notify PDMP is credentials are compromised.

K. Prescribers and dispensers have responsibility to monitor access by their delegates
1. PDMP will have ability to audit user access
2. Dr. Farah suggested that prescriber/dispenser ability to manage delegation authority directly may increase ability to monitor and ensure compliance
3. Current language requires prescriber/dispenser to notify PDMP immediately if access authority should be changed, and only PDMP will have the ability to change it
4. IT capability may determine at what level delegation can be monitored

L. Technical security precautions that protect against unauthorized access must be balanced against need to facilitate system access and use by practitioners

M. Disclosure of PDMP data to prescribers and dispensers
1. Both disclosure requirements include language intended to limited access to data on patients with whom practitioner has a bona fide medical relationship
2. Janet Hart suggested that under current language a pharmacist that denies dispensing to a patient based on review of PDMP data will not have any evidence that a patient interaction actually occurred if questions are raised about the legitimacy of the data request.

N. Law enforcement request will require a subpoena that includes a case number or other identifier, references a unique person, specifies the precise time frame for the report, and bear the name, title and signature of the person under whose authority the subpoena is issued. Captain Alioto indicates this information is typically included in subpoenas and should not be a problem, though subpoenas often also include prohibition against disclosure of existence of subpoena by subpoena recipient.

O. Discussion of licensing board access
1. There was an issue discussed as to whether disclosure of a case number in an administrative subpoena from the Board of Physicians would conflict with current investigative processes.
2. Dr. Farah noted the danger to physicians reputation of errant investigations
3. Board should follow up through the regulations subcommittee on this issue

P. Discussion of disclosure to a practitioner rehabilitation program operating under the authority of a licensing board
1. Linda Bethman indicates that rehab program under pharmacy board does not have ability to issue subpoenas, and executive director does not have ability to issue subpoenas on their behalf.
2. This section of law was likely written with nursing board operations specifically in mind.

Q. The Board should review sections not covered this meeting (including patient access, request from other states' PDMPs, research requests, the review process by the Technical Advisory Committee, notice requirements, confidentiality and security, etc.) and provide feedback to the regulations subcommittee.

IV. Administrative Discussion – Laura Herrera, MD

A. Subcommittees
1. Board member interest in subcommittee assignments was solicited prior to meeting.

2. Four subcommittees were established (regulations, IT, evaluation and educational initiatives) and members were assigned.
3. Conference call for regulations subcommittee will be scheduled to review Board suggestions. Board will have 2 weeks to submit comments to subcommittee

B. Next meeting will be scheduled for early February, 2012

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