Oregon Prescription Drug Monitoring Program Advisory Commission

May 13, 2011 Meeting Minutes
1:00 PM to 4:00 PM
Portland State Office Building
800 NE Oregon Street, **Room 1C**
Portland, OR 97232

ATTENDEES

Commission Present: Chris Apgar, Diane Cockburn, Teresa Keane, Dennis Smith, Michael Millard, Al Turner, Karen Wheeler

Commission Absent: Gary Cobb, Rick Marinelli, Roger McKimmy, Bill Jordan

OHA Staff: Lisa Millet, Todd Beran, Samantha Greene, Tom Burns

Guests: Noelle LiaBraaten

Decisions		
1. The meeting minutes from March 11, 2011 were approved as amended.		
Action Items		
Item	**Assigned To**	**Status**
1. Review system requirements and submit a list of items to OHA to be reported on	Apgar	Completed
2. At the June 10 meeting present the status of requirements listed in the RFP as designated by Apgar	OHA	Scheduled for 7/8/11 meeting
3. Present a demo of the vendor's uncustomized PMP system	OHA/HID	Scheduled for 7/8/11 meeting
4. Develop language regarding the data upload portion of the system being made available to pharmacies on June 1 – Millard will prepare the initial draft language for OHA's review	Millard/OHA	Completed

Approved as written 7/8/11.

The meeting was called to order by Keane at 1:15 p.m. Attendees introduced themselves.

OLD BUSINESS

Review of 03/11/2011 meeting minutes
The meeting minutes were reviewed and approved as amended. **See Decisions #1**

Report by members regarding communications with healthcare organizations
The members of the Advisory Commission reported on where and to whom they were presenting information about the PDMP.

Millard spoke at the Annual Seminar Pharmacies to an audience of over 200. He spoke to a Kaiser Permanente group with an audience of over 200. He spoke to the Providence Health Plan Pharmacy Network with an audience of over 140. He also spoke with the Office of the National Coordinator – IT policy – and gave presentations to all groups. Michael relayed feedback from the pharmacists he had encounters with. He said the Pharmacists have reservations about notification. The overall tone is positive. The most common questions he was asked referred to implementation and exemptions.

Smith has been in touch with the Optometry Board and the Physicians Association. Smith is scheduled to speak in July and October.

Cockburn spoke with and submitted information to the Oregon Nurses Association and the Oregon Board of Nursing.

Wheeler will speak with the OPERA treatment providers later this month.

Keane has spoken with the Naturopathic Board and Naturopathic Association and practitioners have placed information on website and in newsletters. Keane also agreed to contact the Nurse Practitioners of Oregon to speak at their conference in the fall.

Turner has presented to the Osteopathic Physicians & Surgeons of Oregon and agreed to inquire about speaking with the Board of Medicine and the Oregon Medical Association.

Update on provider pad notice pilot

Keane reported that the provider pad notice pilot was going great. Eight controlled substance providers/prescribers are taking part. She noted that the pilot group does not prescribe a lot and that appointments are an hour long.

NEW BUSINESS

Status Report
Beran gave a progress report on the PDMP IT project. He reported everything was on track. The vendor of the project, Health Information Designs is working efficiently. Beran stated that due to

changes in administrative rules the data upload portion of the system will not be made available to pharmacies until June 1, 2011. At this time pharmacies can begin upload procedures which starts with creating an upload account. There will be no data reported retroactively prior to June 1. Subsequently the OHA is targeting September for when the system will be made available to healthcare providers and pharmacist to apply for accounts to access system data.

Patient Notification
Beran reported that pharmacies will be required to provide individual notification of the PDMP to patients. The Oregon Health Authority sent out a letter to all Oregon CS retail pharmacies with an update on patient notification, and the new administrative rule regarding patient notification. Included in the letter was also suggested language for notification.

Evaluation
Millet discussed different types of evaluation:

- Validity of data in the system
- Customer satisfaction
- Health outcomes

She reported that Acumentra Health in conjunction with OHSU has applied for an NIH grant to evaluate how providers use the system and how useful the system is. Millet has also engaged the services of Program Design & Evaluation Services (PDES) in Public Health to assist with looking at health outcomes related to the system.

OPEN ISSUES
Apgar asked for a report on the system functionality including a status review of requirements listed in the RFP. Beran requested Apgar's assistance in identifying focal items for the status review. Millard requested a demo of the system. **See Action Items #1, #2 and #3.**

PUBLIC COMMENT
Andrea Meyer, representing the ACLU of Oregon, submitted written comment. See the attached.

MEMBER WRAP-UP
Millard requested language regarding the upload portion of the system going online June 1. He will forward the language to pharmacy organizations for posting to help clarify questions posed. **See Action Item #4.**

NEXT MEETING DATE: June 10, 2011:
The next Advisory Commission meeting will be held in Portland at the State Office Building.

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

Approved as written 7/8/11.

Andrea Meyer
ACLU of Oregon
PO Box 40585
Portland, Oregon 97240-0585

May 10, 2011

By electronic transmission
Oregon PDMP Advisory Commission
c/o Oregon Health Authority

Dear Commission Members:

Because I cannot attend the May 13, 2011 Advisory Commission meeting I submit these written comments with the request that they be distributed, and I hope read, prior to the meeting.

Operating the PDMP Database
As far as I know, the plan is to begin collecting and entering patient prescription information on June 1, 19 days from the date of this meeting. Based on the recent release of the final Oregon Administrative Rules (OAR), the requirements to provide actual patient notification, and the remaining issue of the contents of a patient's audit report, we urge that the Commission use whatever authority it has to insist on a delay until all the pieces are put in place.

The legislature recognized that this program raised privacy issues and put a number of restrictions and requirements in place, particularly in regards to patients. The program should honor this part of the law and not move forward with premature implementation at the expense of patients.

While most of you represent a stakeholder tied to various types of providers, as Commission members I know you recognize the additional obligation to act in the interests of the patients, if only to make sure that all parts of the PDMP are considered and running smoothly. Any failure of the system may have significant consequences with the public and legislative trust. It is in the interest of everyone that the system complies with all the requirements in the law before it becomes operational in any form.

Administrative Rules

There is a reason that I have attended almost every Commission meeting and have provided public comment. I do so because the ACLU of Oregon believes that the PDMP law has specific requirements that must be adhered to by those operating and running the program. I have attempted to be diligent and alert the Authority and Commission members to ongoing issues and problems. Unfortunately, since there is no requirement otherwise, the approach has been to simply record but not address my comments.

You now have before you final OARs that contain new language from the draft OAR, specifically: patient notification and the patient audit report. Any difficulty that these new rules provide to either the Authority or any stakeholder was self-inflicted. Certainly, if anyone had asked the right questions that I have raised since the very first Commission meeting on, I believe, January 15, 2010, these issues would have been dealt with in a timely manner. Patients, however, should not be the ones to suffer from these decisions.

1) Patient Notification

As all of you are by now aware, the Attorney General's office has issued a legal opinion determining that ORS 431.962 requires meaningful *individual* notification to patients whose prescriptions are about to be entered into the PDMP system. As the author of that specific language in the PDMP law, I testified before the Commission that this language required meaningful individual notification. Despite my best efforts to bring this to everyone's attention, the program has been developed with the expectation that the law requires only generalized notification. Only now at the 11th hour, with a legal opinion in hand, is there a fundamental shift in the administrative rules to address this legal requirement.

OAR 410-121-4015 purports to address the individualized patient notification. However, by delegating to the Authority the actual language of notification, there is no opportunity for the public to comment on whether or not this new language complies with the law. Nor is it at all clear how pharmacies can *actually* comply.

The OAR provides:
"**Using language provided by the Authority,** a pharmacy shall notify each patient receiving a controlled substance about the Prescription Drug Monitoring Program before or when the controlled substance is dispensed to the patient. The notification shall include that the prescription will be entered into the system."

PROBLEM: What does the actual notice say? Does it inform patients of contact information if they have any problems (such as what to do if a pharmacy refuses to dispense the prescription after review of that patient's PDMP record)? Does it notify patients of their right to obtain a free copy of their report, how to obtain a free copy of their report, how to raise problems with a report, how notification of a breach will be provided, how to contact the Authority at any time if there are

questions or concerns? How to seek legal remedies from possible misuse or breaches?

The Commission should insist that:

1) The notification language be placed in the OAR
2) The notification language be meaningful and complete
3) That all of this is completely and properly done prior to any patient data being entered into the PDMP

(Indeed, *how* can pharmacies legally comply in 19 days with this new (partial) administrative rule on patient notification in light of all their testimony and submission on the draft OAR, stating over and over how it was *impossible and cost prohibitive* for them to provide individual notification.)

2) Content of Patient Report ("Patient Audit Report")

Since the very beginning, at the first Commission meeting, I have made it very clear in my public comments that the patient report is to include the who's, what's, and when's a patient's data has been accessed, otherwise known as a patient audit report. The legislature was *very clear* that this language, added at the behest of the ACLU of Oregon, was intended to be a patient audit report and to act as one of the means of providing privacy safeguards. Only a patient knows whether Doctor X or Pharmacy Y was an actual provider. Only a patient with access to this information can notify the Authority that there has been unauthorized access – be it by negligence or intentionally misuse.

In fact, I recall making this point in public comment at the first Commission meeting in response to one of the Commissioners stating that the patient report will be very useful for patients to have a list of what drugs they are taking. That was not the intention of that language. The reason the ACLU of Oregon added patient access to a free report in the law was always intended to be a tool to address one of our most significant concerns: misuse and improper access of a patient's information.

Despite my diligent effort to bring this matter before the Commission and the Authority, apparently the vendor currently cannot provide this function. That should be completely unacceptable to every member of the Commission.

Indeed, the Authority *acknowledged* six months ago that this would be provided. In an email to Lisa Millet on December 9, 2010, Chris Apgar wrote the following after release of the first draft administrative rules (to which the full Commission was cc'ed):

"Also, I understand that there was an issue regarding whether or not audit logs would be available from the vendor to include in a report to the patient. To me, patient reporting aside, audit logs should be a mandatory security requirement and reflects

DHS/OHA's current Office of Information Security requirements. DHS/OHA cannot police access for misuse without audit logs. If audit logs are available for department auditing, I believe they should be available to include in the patient report. If you have any questions, please let me know."

On the same day, Lisa Millet responded to Chris Apgar's question:

"[a]udit logs are available to staff, audit log information will be included in patient reports, users will be able to look at audit logs and security and QA functions will use audit logs. L" (emphasis added)

Yet, apparently the vendor **cannot currently provide this audit report to a patient** and I am told it will be (at least) 12 months before the system can operate in the way the legislature intended. That delay creates a very real risk that the program will not be operating in full compliance with the law.

It is important to understand what the rules do *and do not say.* The rules purport to "address" this issue with additional language. However, the rules omit the critical piece: namely that the patient report will include this information. Instead, it speaks only to what a patient must do to bring a potential misuse forward but without a patient audit report, a patient can never do this.

OAR 410-121-4020(20)
"A patient may send written notification to the Authority if he or she believes unauthorized access to his or her information has occurred. The notification shall include the patient's name, who is suspected to have gained unauthorized access to the patient's information, what information is suspected to have been accessed by unauthorized use, when the suspected unauthorized access occurred, and why the patient suspects the access was unauthorized. The Authority shall treat such patient notifications as potential unauthorized use of the system."

PROBLEM. Patients should have access to a patient audit report *prior* to the PDMP going live. There is no legal justification for an undetermined delay (or a proposed 12 month delay) to a major part of the law as it relates to the rights of patients. At the same time the system is accessible to pharmacists and providers, it should be available to patients. All three are critical stakeholders and all three must be treated equally. A delay of implementing a patient audit report not only violates the expectation of the law, it puts everyone at risk: if a provider engages in unauthorized use and that goes unchecked for months or years and eventually comes to light only after the patient audit report is available *everyone connected with the operation and the use of this program will be subject to significant criticism as well as liability.* **It is everyone's interest that the patient audit report be available at the time the PDMP begins to operate since it is a critical piece to ensure the system is operating as intended and expected.**

We urge this Commission to insist on meaningful compliance with the law, even if it requires the Authority to delay the program. Notification to patient and patient audit report should be as critical as all the other pieces the Commission has discussed over the past year. To not comply with the law, puts the whole program at risk. As someone who was intimately involved in the law and the author of the amendments that require patient notification and patient audit report *I have done everything in my power to bring these issues to the attention of the Commission and the Authority at every opportunity*. The ACLU of Oregon respectfully urges the Commission to take action to urge the Authority to delay implementation of PDMP until all these issues are fully addressed.

Thank you for your attention and consideration to these issues.

Sincerely,

Andrea Meyer
Legislative Director/Counsel

cc: Lisa Millet
Tom Burns
Rep. Mitch Greenlick
Rep. Tina Kotek