

MONTANA BOARD OF PHARMACY

May 8, 2014

Senator David Wanzenried – Chair Children, Families, Health and Human Services Interim Committee Senator Bruce Tutvedt – Chair Economic Affairs Interim Committee 63rd Montana Legislature P.O. Box 201706 Helena, MT 59620-1706

RE: Montana Prescription Drug Registry (MPDR) 2014 Interim Report

Dear Chair Wanzenried, Chair Tutvedt, and Members of the Legislative Interim Committees,

The Montana Board of Pharmacy (Board) submits the following report regarding the Montana Prescription Drug Registry (MPDR, or Registry) to the legislative interim committees on Children, Families, Health and Human Services and Economic Affairs. Pursuant to 37-7-1514, MCA, this report constitutes the Board's update on the status of the MPDR program.

Additionally, the Children, Families, Health and Human Services Interim Committee has requested recommendations from the Board on ways to improve the MPDR as the Committee responds to Senate Joint Resolution (SJR) 20 study and considers tools in addressing prescription drug abuse in Montana. To this end, the Board offers the following report and possible areas of interest for the interim committees to consider. Sections discussed in this report include: background, areas of interest, recognition, and next steps.

BACKGROUND

The MPDR program allows authorized health care providers to review a patient's prescription history for controlled substances and use that information as a tool to improve patient safety and enhance the quality of patient care when making health care decisions. MPDR information may also indicate potential prescription drug misuse, abuse, and/or diversion issues.

MPDR Access

Access to the Registry is authorized pursuant to 37-7-1506(1), MCA. Prescribers and dispensers have direct online access (www.mpdr.mt.gov) to the Registry after completing education and an online registration process. The type of prescribers and dispensers who currently have access include: physicians, naturopathic physicians, dentists, optometrists, podiatrists, physician assistants, advanced practice registered nurses with prescriptive authority, pharmacists, and Board of Pharmacy authorized staff for administrative purposes.

Other authorized users of the Registry, such as professional licensing boards and law enforcement, are not authorized for direct online access and must either submit a Board investigational request or provide a subpoena. In addition, individuals may request a copy of their own prescription history as it appears in the MPDR.

The MPDR program began receiving reports into the registry database in March 2012 and maintains a 3 year history of prescriptions for controlled substances. The program requires licensed pharmacies to report controlled substance prescription data to the MPDR on a weekly basis but some pharmacies do report on a near daily basis. Reported data with no errors is automatically uploaded into the Registry and generally searchable that day. The MPDR program became fully functional in November 2012 when registered users began searching the online Registry.

Use of Registry Information

The Registry information is being used to generate information related to the following:

- Data regarding a patient's history of controlled substance prescriptions is routinely provided to registered MPDR users as search results for that specific patient.
 Information is provided as reported from the pharmacy.
- Data regarding a prescriber's own controlled substance prescribing history is routinely provided as a search result back to that individual prescriber.
- MPDR staff routinely responds to subpoenas from law enforcement or requests from licensing board investigators by providing either a patient's history of controlled substance prescriptions or a provider's prescribing history of controlled substance prescriptions.
- MPDR staff has received one request from a patient for a copy of their own controlled substance prescription data stored in the MPDR.
- MPDR staff provides monthly statistics that include the number of prescriptions in the database, the number of patients in the database, the number of pharmacies reporting to the MPDR, the number of pharmacy reports submitted, the number of registered users (prescribers and pharmacists) authorized to search the Registry, and the number of patient history searches conducted.

MPDR staff typically responds to requests from law enforcement, board investigators and individuals within 2 business days. In some instances, the online program features available to MPDR staff do not yet meet requirements of the request. In such events, MPDR staff submits the request to its software vendor Montana Interactive, LLC (MI) so the MI team can manually retrieve the requested information. MI response to requests is often directed by timelines in subpoena or board investigator requests which may be up to 30 days. In addition, MPDR and MI staff field daily customer service calls and emails from users of the program.

MPDR Statistics

As of April 30, 2014, MPDR statistical reports indicate:

- Over 4.8 million prescriptions are in its database (March 2012 to present);
- Over 620,000 patients are represented in the database (recognizing that some records are duplicates);
- 2,296 users are registered to search the Registry, which represents 24.4% of all eligible health care providers licensed in Montana (located in-state and out-of-state);
- 36.3% of eligible licensees located in Montana are registered users;
- Over 9,600 patient history searches were conducted in April 2014 (121,880 searches since November 2012);
- Over 21,800 patient history searches were conducted in the first quarter of 2014;
- Staff responded to 15 law enforcement subpoenas in April 2014 (239 since November 2012); and
- Staff responded to 5 requests from licensing board investigators (17 since November 2012).

Some government entities who dispense controlled substances to patients in Montana but do not hold Montana licensure as a pharmacy report controlled substance dispensing information to the MPDR through a memorandum of understanding (MOU) with the Board. Examples include but are not limited to: Indian Health Services (IHS), Tribal Health, and the U.S. Department of Veterans Affairs (VA).

MPDR Funding

To date, the MPDR has received a total of \$887,250 in federal funds for planning, implementation, operating, maintenance, and enhancement funding as follows:

- 2007 = \$50,000
- 2009 = \$50,000
- 2011 = \$397.521
- 2013 = \$389,729 (Funds became available April 2014)

A general outline of the MPDR's 12-months budget is provided in **Table A**.

Table A

MPDR 2014 Budget and Expenses as Outlined in Grant Funding	12-Month Total
Montana Interactive Enhancements	\$127,525
General Operating Costs*	\$67,321
Montana Interactive Hosting & Support	\$58,350
Printing & Postage	\$24,537
Purchase National Drug Code (NDC) File	\$9,641
Travel	\$8,384
Contracted Trainer	\$5,000
Total Expenses Before Fee Offset**	\$300,758

^{*} Includes salaries, benefits, legal, dues, temporary staff, supplies/materials, file storage, etc.

The federal funds stem from grants awarded to the MPDR through the Montana Board of Crime Control, which receives its federal grant funding from the Harold Rogers Prescription Drug Monitoring Program/Bureau of Justice Assistance (within the U.S. Department of Justice). These grants generally operate on an 18 month cycle. The 2011 grant was extended for 6 months, while 2013 grant funds became available April 1, 2014 with a focus of building MPDR system enhancements in addition to covering operating costs.

Based on the current budget numbers from the 2013 grant, the general MPDR operating budget and system enhancement expenses are \$300,758 per year. The MPDR's annual operating and system enhancement budget requirements will remain the same for the foreseeable future.

In addition to grant funding, the Board began collecting the MPDR fee from certain Montana licensees in 2013, pursuant to 37-7-1511, MCA. Those prescribers or dispensers who hold Montana licensure and actively prescribe or dispense controlled substances were each charged \$15. As of December 2013, the Board received \$85,035 in MPDR fee payments from licensees.

^{**} Collection of fees in 2014 will offset operating costs. See **Table C** for additional information.

Fees were collected from the following Department of Labor and Industry (Department) licensure types: physicians (includes resident and telemedicine), naturopathic physicians, dentists, optometrists, podiatrists, physician assistants, advanced practice registered nurses with prescriptive authority, and pharmacists.

The Board anticipates sending invoices to licensees in late May to collect the \$15 MPDR fee for 2014. Using 2013 fee collection as a model, the Board expects to receive 2014 fee payments of approximately \$94,000 depending on the number of licensees and whether or not the licensees actively prescribe or dispense controlled substances. In the event the MPDR fee is extended in statute beyond July 1, 2015, the Board anticipates collecting MPDR fees from licensees at the time of license renewal or upon application instead of at a separate time.

Table B indicates fees collected in 2013 and **Table C** indicates projected fees to be collected in 2014. The gap in funding for a \$300,758 yearly budget is covered by the Harold Rogers grant funding.

Table B

MPDR 2013 Fee Collection	\$15 Fee
FY13 Fees Collected	\$85,035
FY13 Surplus or (Deficit)	(\$215,723)
Grant	\$215,723
Balance	\$0

Table C

MPDR 2014 Fee Collection	\$15 Fee
FY14 Fees Collected – Projected as	\$75,000
Indicated in 2013 Grant	
Additional Fees Projected to Collect	\$18,976
Based on Comparison to 2013	
Total Projected Fee Collection	\$93,976
FY14 Surplus or (Deficit)	(\$206,782)
Grant	\$250,758
Projected Balance	\$43,976

^{*} Fees and projected balance funds will be used to offset operating expenses as outlined in the grant budget.

Phase 1 MPDR Implementation

As part of Phase 1 MPDR implementation in 2011 and 2012, efforts focused on the design, programming and launch of the following online services: pharmacy registration to submit data, pharmacy data collection and data storage, provider registration to search the database, patient history search features for registered providers, and basic Board management functions such as compliance auditing of pharmacy data submissions. MI is actively working on the design and building of the pharmacy compliance audit data warehouse and report which will complete Phase 1 tasks. This will better allow MPDR staff to identify pharmacy compliance in reporting data to the MPDR database.

The primary purpose of Phase 1 implementation was to get the core functionality of the MPDR program up and running; as of November 2012 registered users could conduct an online search for a patient's controlled substance prescription history. Members of the MPDR advisory group provided input into the proposed functionality of the core system, and eligible members also participated in a pilot group of users when the online search features were launched.

Phase 2 MPDR Implementation and Enhancements

As of April 2014, the MPDR program is now in Phase 2 of implementation focused on the design, programming and launch of enhancements to the MPDR's core system while continuing to address maintenance and user issues. These enhancements will increase efficiencies in MPDR administration and management, while improving the user's experience. The 2013 grant funding accommodates general operating costs and education/outreach in addition to having dedicated funds to support planning, analysis and programming of program enhancements. Implementation activities also include gathering feedback from the MPDR advisory group.

Staff members from MPDR, MI and the Department's licensing database and information technology (IT) team are currently holding weekly work group meetings to plan and analyze each of the MPDR's system enhancement requests as part of Phase 2 implementation. The work group is also gathering feedback from the MPDR advisory group and other stakeholders as part of the planning process. These weekly analysis meetings will continue until the details of all outstanding enhancement projects have been thoroughly reviewed and agreed upon. By the end of each project analysis, MI will be able to provide the Board with a cost estimate and a proposed estimated timeline for each project. Once the project analysis is completed for the multiple projects, subsequent meetings will be held on an asneeded basis.

Importantly, additional staff resources have been designated as part of Phase 2 implementation. Specifically, MI has assigned a project analyst to the work group, and

further assistance and project management is being provided by the Department's IT staff involved in the project.

Also, several administrative and user issues have recently been addressed, including modification of: online search parameters; MPDR home page information and links; and law enforcement reports to improve the process and information to respond to subpoenas or board investigator requests. In addition, MI has and continues to conduct on-site visits at St. Peter's Hospital (in Helena, MT) to further understand and resolve ongoing user search issues and address user concerns.

Summary examples of Phase 2 pending and in-progress enhancements projects include:

- Delegate Access creates an online registration for delegate user accounts which
 will allow registered prescribers and pharmacists (as supervisors) to delegate MPDR
 access privileges to approved members of their health care team. The project
 includes building relationship functionality and tracking between a supervising
 provider and a delegate, creating management capabilities for supervising providers
 and MPDR staff, and modifying the online search service while continuing to comply
 with required privacy and security measures.
- Interstate Data Sharing will facilitate the sharing of MPDR data with prescription monitoring programs in other states. This project will require the development of an interface program, and will require modifications to the online search service that will enable a requesting MPDR user to identify the participating states whose data they want to see in a search result. We intend to use the National Association of Boards of Pharmacy's (NABP) PMP InterConnect (PMPI) service and platform. PMPI features include a robust user-defined management console that will allow us to enforce the MPDR's access requirements and limitations while exchanging data with other states. Currently, the PMPI has 24 participating states.
- Statistical Reporting includes the development of additional statistical reporting
 and data analysis capabilities. It will also allow for the creation of a report or series
 of reports that meet one or more aspects of the MPDR's overall reporting
 requirements. Such functionality will allow MPDR staff to generate reports and
 statistical information more efficiently on demand rather than submitting a request to
 MI for such data. Once completed, this project will enable the MPDR program to
 meet all quarterly reporting requirements set forth for recipients of Harold Rogers
 grants, and provide statistical information for educational, research and/or public
 information purposes.
- **Unsolicited Reporting** capability will allow the Board staff to notify registered prescribers and pharmacists of possible misuse or diversion of controlled

substances based on information in the registry. Threshold guidelines have been suggested in administrative rule, ARM 24.174.1706. The report functionality will also assist in meeting certain reporting requirements indicated in Harold Rogers grants.

MPDR AREAS OF INTEREST

The Board is actively engaged in discussions with stakeholders and potential payers of the MPDR fee who are not presently paying, including representatives of professional associations and the MPDR advisory group, regarding possible changes and clarification to 37-7-1511, MCA, the statute that authorizes fee collection and funding of the Registry. These discussions are ongoing and no decision has been made regarding possible proposed amendments to the statutes. The Board understands the importance of addressing the MPDR funding issue in the 2015 Legislative Session and will continue to update the interim committees as discussions with stakeholders continue.

MPDR Funding

The Board continues to gather feedback on key issues and is considering options and identifying potential solutions related to funding of the MPDR program. The key focus areas that the Board is considering potential legislative revisions include:

- Authority to collect fees (current sunset provision is July 1, 2015);
- Fee collection from "person" as an individual versus "person" as individuals and facilities including pharmacies and/or wholesalers;
- Fee collection from licensees who prescribe and dispense controlled substances versus all licensees authorized to prescribe, dispense, and distribute prescription drugs; and,
- Fee amount set in statute versus fee amount commensurate with cost through administrative rule.

For reference, the current MPDR funding statute (37-7-1511, MCA) is included below:

- **37-7-1511.** Prescription drug registry -- funding. (1) Each person licensed under Title 37 who prescribes, dispenses, or distributes controlled substances shall pay to the board a nonrefundable fee that is set by rule and that may not exceed \$15.
- (2) The board may apply for any available grants and may accept gifts, grants, or donations to assist in establishing and maintaining the registry.
- (3) Funds collected pursuant to this part must be deposited into a state special revenue account to the credit of the department. The money must be used to defray the expenses of the board in establishing and maintaining the registry and in discharging its administrative and regulatory duties under this part. (Subsection (1) terminates July 1, 2015--sec. 20, Ch. 241, L. 2011.)

History: En. Sec. 12, Ch. 241, L. 2011

Confidentiality

The Department's staff has received several questions from licensed health care providers and attorneys about the confidentiality and use of MPDR information. In particular, prescribers and pharmacists want to know who they can lawfully share MPDR information to (whether disclosure is required or on a discretionary basis).

To this end, 37-7-1505, MCA states that MPDR information is protected, and 37-7-1506(1), MCA explains that MPDR information is health care information (as defined in 50-16-504, MCA) and confidential. The Board believes that any efforts to clarify the lawful disclosure of any and all health information by health care providers would encompass MPDR information, and no specific amendments may be necessary to the MPDR statutes.

RECOGNITION

The Board is pleased to inform the interim committees that the MPDR program received two distinguished awards, including:

- 2013 Digital Government Achievement Award for Excellence in Government to Citizen Services – Honorable Mention for cutting-edge web development from the Center for Digital Government; and
- 2013 State of Montana Information Technology Project Excellence Award in recognition of State IT projects that demonstrate innovation, are well managed, and use IT to meet business needs in an effective and efficient manner.

NEXT STEPS

As the 2015 Legislative Session approaches, the Board will continue communication with the legislative interim committees and other stakeholders and engage the MPDR advisory group regarding issues of potential system enhancements and funding. The Board will also continue to review information on the operation of prescription drug programs in other states as our program evolves and system enhancements are implemented.

In addition, the Board aims to:

- Continue and increase outreach and educational efforts through print, electronic, online and presentation vehicles;
- Pursue new collaboration with the Montana Department of Public Health and Human Services on awareness and improved statistical reporting;
- Assess existing program functions for continuous quality improvement; and
- Continue to engage in national efforts to better integrate registry information into provider workflows, electronic health records, and pharmacy operating systems.

Finally, the Board will continue to promote the values of the MPDR as a patient safety tool for health care providers to utilize that also provides information that may be helpful in addressing or identifying potential prescription drug abuse, misuse and/or diversion issues.

The MPDR program's Web site is: www.mpdr.mt.gov.

For additional information, please contact:

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Thank you for your time and the opportunity to provide information related to the MPDR. Please contact the Board if we can be of further assistance.

Sincerely,

MONTANA BOARD OF PHARMACY

Mike Bertagnolli, RPh, MBA, President