Minnesota Board of Pharmacy

Report to the Legislature: Recommendations on Required Use and Other Uses of the MN Prescription Monitoring Program Database

Prepared By: Barbara A. Carter, MN PMP Manager
December 1, 2014
Approved at the December 10, 2014 Board Meeting

COST OF REPORT

MN Stats. §3.197 states that a "report to the legislature must contain, at the beginning of the report, the cost of preparing the reporting, including any costs incurred by another agency or another level of government". The estimated cost of preparing this report was $14,400.

Introduction

The abuse and diversion of controlled prescription drugs is a significant and persistent problem in the United States. Data from the Substance Abuse and Mental Health Services Administration (SAMHSA) 2013 National Drug Survey on Drug Use and Health reveals that approximately 6.5 million individuals aged 12 or older are nonmedical users of controlled prescription drugs (opioid pain relievers, tranquilizers, sedatives, or stimulants)[1]. While the number of non-medical users has remained relatively stable over the past 5 years, the number of treatment admissions and deaths from overdose of controlled substance prescription drugs has increased significantly.

To begin addressing prescription drug abuse in the State, on May 25, 2007, the Governor signed into law MN Stats. §152.126, which required the MN Board of Pharmacy to establish an electronic system for the reporting of controlled substance prescriptions that are dispensed to residents of the state. The Board subsequently implemented the MN Prescription Monitoring Program (PMP). Collection of data from dispensers of controlled substances began on January 4, 2010 with authorized access to the data commencing on April 15, 2010.

During the first year of operation more than 6.1 million prescriptions for controlled substances were reported by dispensers to the PMP. Dispensers are currently defined by MN Stats. §152.126, Subd.1 (d) as a person authorized by law to dispense a controlled substance, pursuant to a valid prescription. A dispenser does not include a licensed hospital pharmacy that distributes controlled substances for inpatient hospital care or a veterinarian who is dispensing prescriptions under section 156.18.

As of October 2014, more than 15,000 prescribers and pharmacists had applied for and been granted direct access to this timely prescription history data. Those authorized users conducted almost 600,000 queries, of the roughly 7.2 million records currently stored in the secure database, during the first 3 quarters of 2014. These queries have helped to determine appropriate medical treatment and interventions, or in some cases have detected "doctor shopping" behaviors. In addition, the data helps to identify patients who could benefit from referral to a pain-management specialist or those who are at risk for addiction and may be in need of substance abuse treatment.

Medical Examiners and Coroners, in an effort to determine an individual's cause of death, have requested more than 1,350 reports on decedents from the PMP since its implementation in 2010.

Through the PMP, personnel from the MN Department of Human Services, Restricted Recipient Program, have performed approximately 15,500 queries of the database to identify recipients whose usage of controlled substances warrants restrictions to a single primary care provider, a single outpatient pharmacy, and a single hospital.

Additionally, the PMP has been used to identify persons engaged in potentially unlawful possession and/or diversion of controlled substances. Law enforcement officials have served more than 1,100 search warrants on the PMP, requesting an individual's controlled substance prescription history, a prescriber's prescribing history or a dispenser's dispensing history to support an investigation.

[1] Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings see http://www.samhsa.gov/data/NSDUH/2013SummNatFindDetTables/NationalFindings/NSDUHresults2013.htm last accessed October 14, 2014.

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Continued outreach efforts by PMP staff and word of mouth promotion by PMP champions have resulted in a steady growth in the number of authorized system users and likewise in the volume of queries performed on the PMP data.

MN PMP Statistics

Table 1. Number of Active PMP System User Accounts vs. Actual Users & Number of Queries 2013-2014.

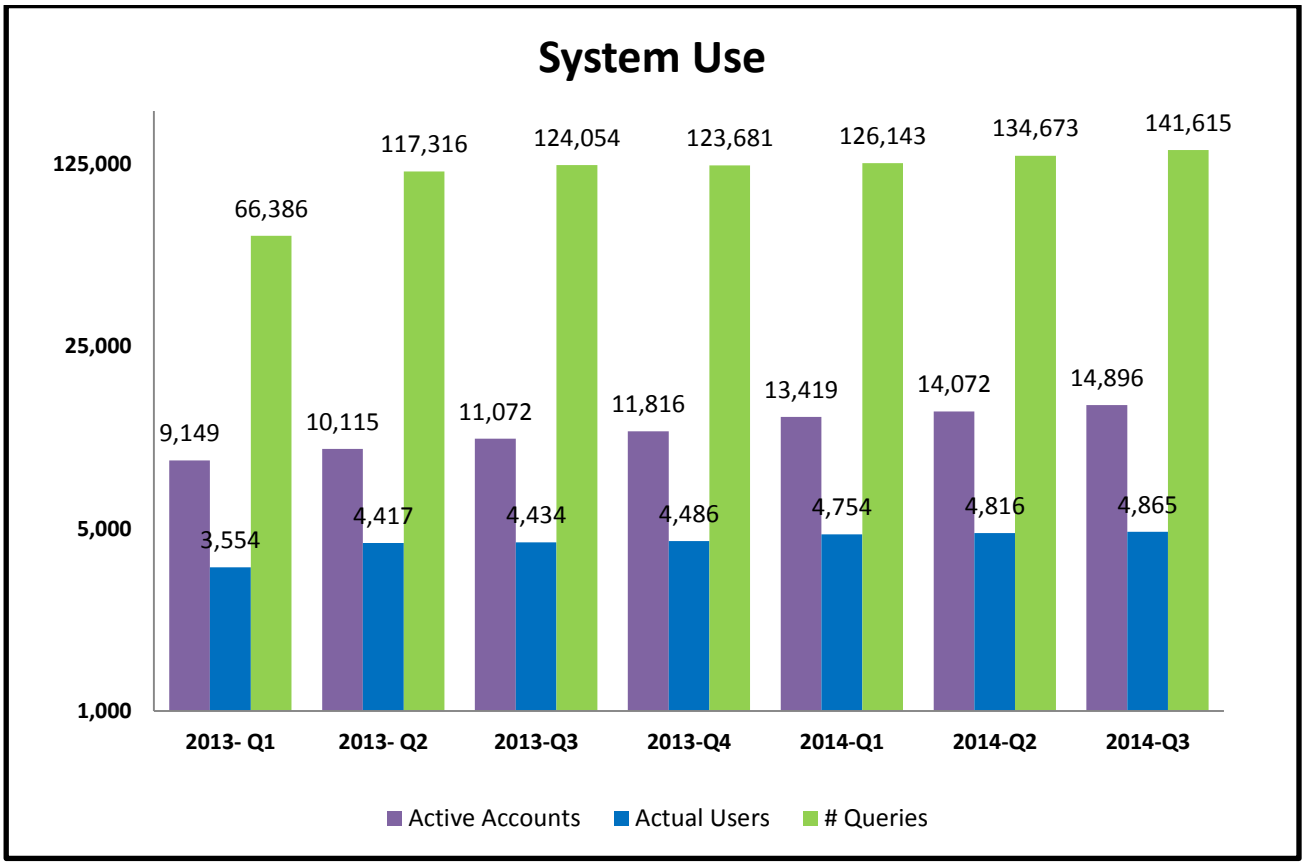


Table 2. Number of Queries by User Type by Quarter 2013-2014

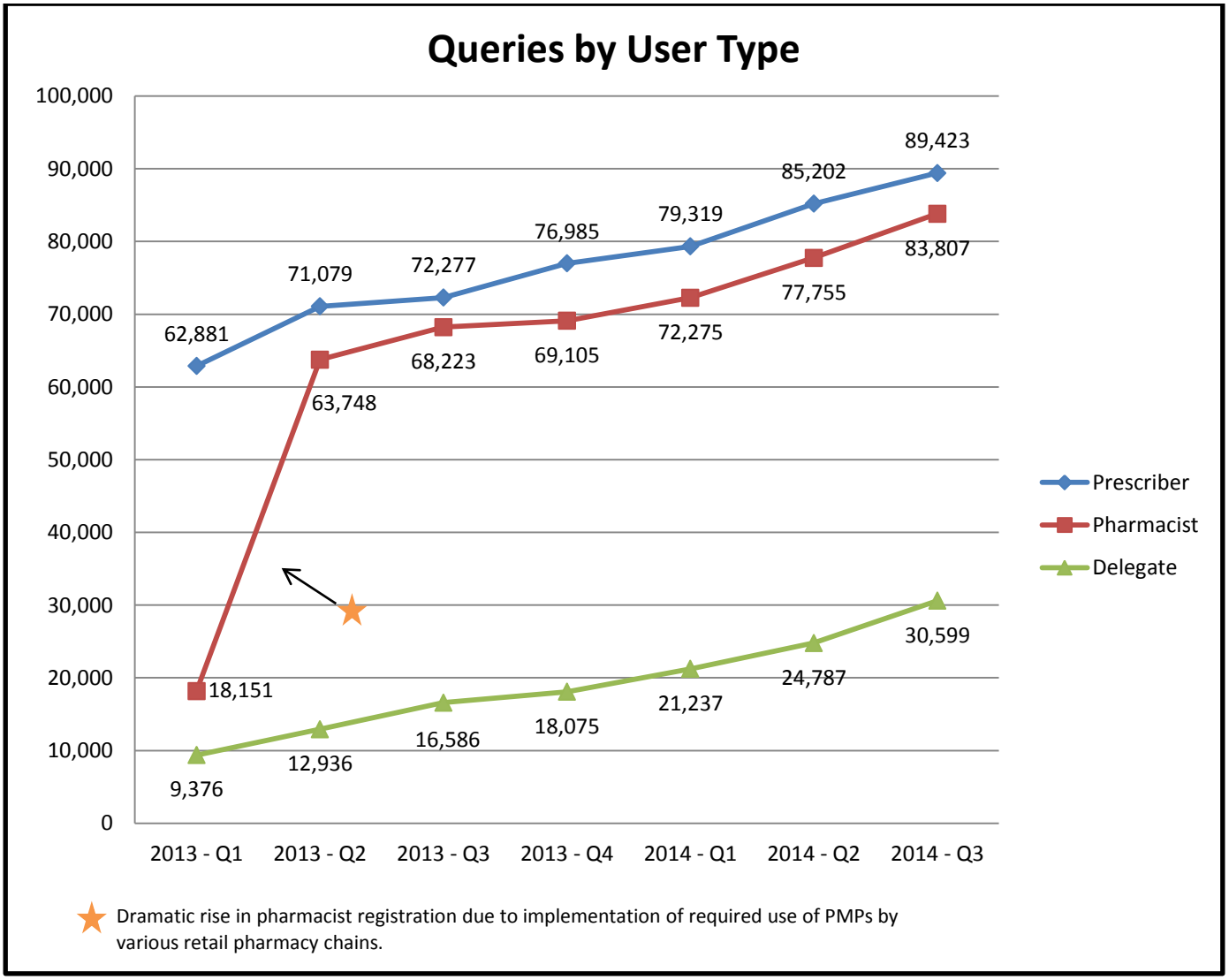
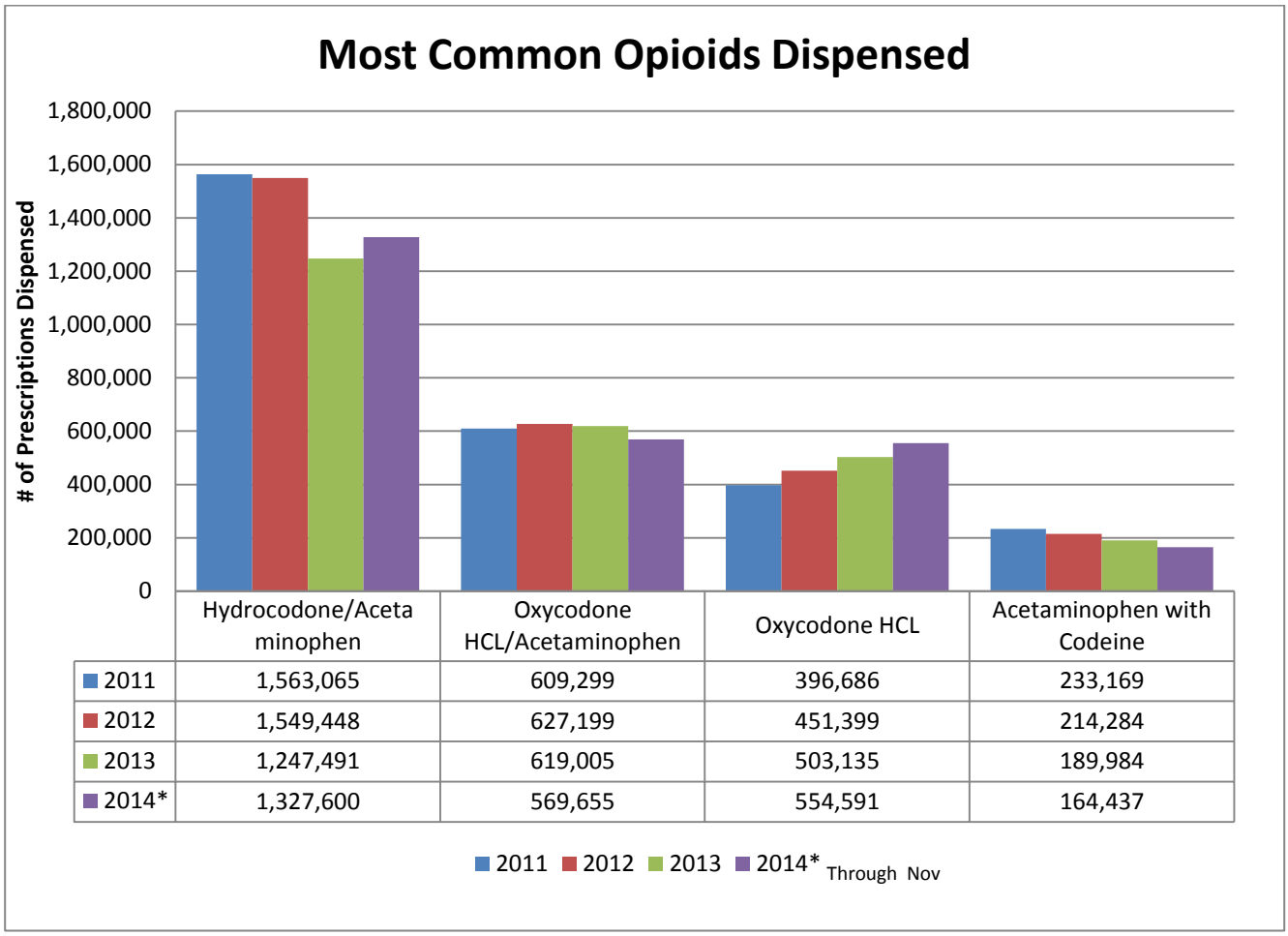
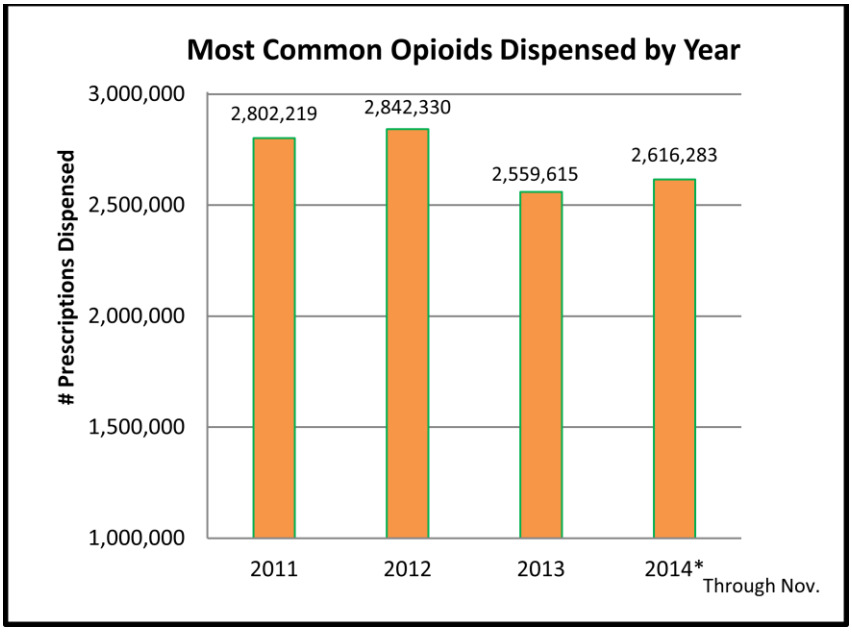


Table 3. Most Common Opioid Prescriptions Reported 2011 - 2014



	Hydrocodone/Acetaminophen	Oxycodone HCL/Acetaminophen	Oxycodone HCL	Acetaminophen with Codeine
2011	1,563,065	609,299	396,686	233,169
2012	1,549,448	627,199	451,399	214,284
2013	1,247,491	619,005	503,135	189,984
2014*	1,327,600	569,655	554,591	164,437



Objective

As a result of the discussions that occurred during the 2014 Legislative session, the Board of Pharmacy (Board), in collaboration with the PMP Advisory Task Force was directed to study the following:

(1) Requiring the use of the PMP database by prescribers when prescribing or considering prescribing, and pharmacists when dispensing or considering dispensing, a controlled substance as defined in MN Stats. §152.126, subdivision 1, paragraph (c);

(2) Allowing for use of the PMP database to identify potentially inappropriate prescribing of controlled substances; and

(3) Encouraging access to appropriate treatment for prescription drug abuse through the PMP.

The purpose of this report is to provide recommendations on required use and other uses of the MN PMP database.

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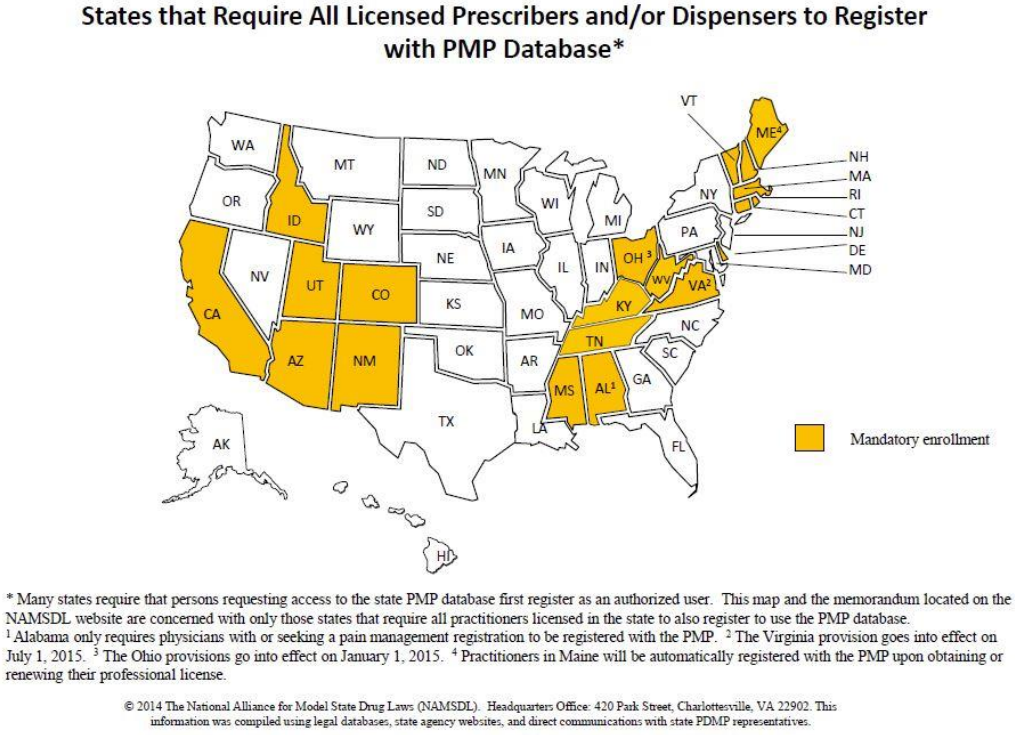
1. Requiring Use of the PMP database by prescribers and pharmacists

Data

A growing number of states are requiring certain practitioners and/or dispensers to access PMP databases in certain circumstances, typically before prescribing a Schedule II or III controlled substance however, those circumstances vary from state to state. All states require authorized users to register for a PMP account prior to allowing direct access to the PMP database. Several states require registration by prescribers and/or pharmacists regardless of whether or not they access the PMP database.

The following map[2] identifies states that currently require registration for access to the PMP regardless of whether or not they access the PMP database.



* Many states require that persons requesting access to the state PMP database first register as an authorized user. This map and the memorandum located on the NAMSDL website are concerned with only those states that require all practitioners licensed in the state to also register to use the PMP database.
[1] Alabama only requires physicians with or seeking a pain management registration to be registered with the PMP. [2] The Virginia provision goes into effect on July 1, 2015. [3] The Ohio provisions go into effect on January 1, 2015. [4] Practitioners in Maine will be automatically registered with the PMP upon obtaining or renewing their professional license.

20 states require registration

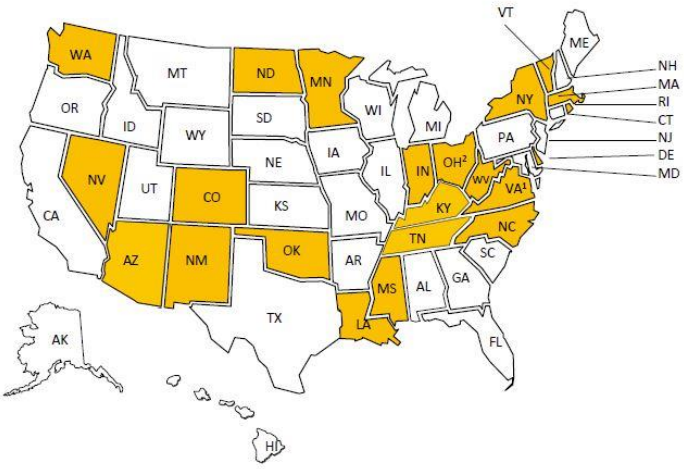
- 8 states requires only prescribers register
- 5 states exempt Veterinarians from registering.
- 1 state initially encouraged practitioners to register with the PMP with the condition that by a certain date a percentage would have to be registered, otherwise mandatory registration would be implemented. At this time mandatory registration is required.

Although registration for access to the PMP is required in these 20 states there are varying mechanisms

[2] The National Alliance for Model State Drug Laws (NAMSDL),States that Require All Licensed Prescribers and/or Dispensers to Register with the PMP, Map (June 2014) see http://www.namsdl.org/library/44749A4C-1372-636C-DDC422A628F7B404 last accessed online on November 7, 2014. This project was supported by Grant No. G1399ONDCP03A, awarded by the Office of National Drug Control Policy.

in place to enable registration, as well as penalties for failure to register.
As previously noted, required use of the PMP is becoming more and more common amongst States. The following map[3] reflects all states that have some form of required use at this time.

States that Require Prescribers and/or Dispensers to Access PMP Information in Certain Circumstances*



* Please see the accompanying memorandum for specifics as to the circumstances under which a prescriber and/or dispenser is obligated to access the PMP database in each state.
[1] The Virginia provision goes into effect on July 1, 2015. [2] A number of the Ohio provisions go into effect on April 1, 2015.

22 states have some form of required use of the PMP

- 1 state requires use for every controlled substance prescription, with some exceptions
- 9 states requires use in specific general practice situations
- 8 states require use only by Opioid Treatment Programs (MN is one of those states)
- 1 state requires use only for worker's compensation clients
- 1 state requires use by Opioid Treatment Programs and Worker's Compensation clients
- 1 state requires use only by pain clinics
- 1 state requires use when the prescriber or pharmacist believes the person is seeking drugs for other than medical use

In a briefing published by the Prescription Drug Monitoring Program, Center of Excellence at Brandeis University[4] it is reported that recent legislative mandates, such as those adopted by KY, TN and NY, tend to have wider and more obligatory conditions of application than those adopted earlier. In 2009, Nevada passed legislation that required a prescriber to check the PMP when the practitioner has

[3] The National Alliance for Model State Drug Laws (NAMSDL), States that Require Prescribers and/or Pharmacists to Access PMP Data in Certain Circumstances, Map (June 2014) see http://www.namsdl.org/library/4477511F-1372-636C-DDB1895D055F9D30 last accessed online on November 7, 2014. This project was supported by Grant No. G1399ONDCP03A, awarded by the Office of National Drug Control Policy.

[4] Prescription Drug Monitoring Program Center of Excellence at Brandeis, Mandating PDMP participation by medical providers: current status and experience in selected states (Revision 2, October 2014) see http://www.pdmpexcellence.org/sites/all/pdfs/COE_briefing_mandates_2nd_rev.pdf last accessed online on November 10, 2014. This project was supported by Grant No. 2011-PM-BX-K002 awarded by the Bureau of Justice Assistance.

reasonable belief that the patient may be seeking the controlled substance for other than medical use. In contrast KY prescribers must query the PMP when initially prescribing a patient a Schedule II drug, must check the PMP every three months for that patient, and review the information before prescribing refills or an additional Schedule II drug for that patient. However, there are some exceptions such as following surgery or during emergency situations. In TN, prescribers must check the PMP when first prescribing opioids and benzodiazepines for more than 7 days and at least annually thereafter if prescribing continues. In NY, practitioners must consult the PMP when prescribing or dispensing controlled substances for Schedules II-IV, with limited exceptions.

Impact of Required Use in Selected States:
The State of NY, in addition to mandating use of the PMP, also enacted other legislative changes such as pain management facility oversight, limiting prescriber dispensing, and requiring continuing medical education in addiction and pain management. They have reported a 75% drop in the number of patients who were seeing multiple prescribers to obtain the same drugs, which would put them at higher risk for overdose. Similarly, TN has seen 36% decrease in "doctor shopping" since the enactment of 2012 legislation requiring use of the PMP under certain circumstances.

Preliminary analysis of data from a study being conducted in the state of KY[5] regarding the impact of House Bill 1 (a bill containing several provisions similar to the NY's legislation) indicates an 8.29% decrease in the number of controlled substance prescriptions dispensed during the first year of enactment. Additionally, it shows an increase in the dispensing of buprenorphine, a drug used to treat opioid addiction and a decrease in the number of overdose deaths related to opioids.

Input From the PMP Advisory Task Force:
A workgroup of Task Force members was formed to make initial recommendations to the full Task Force (Appendix 1) regarding required use of the PMP. Active members of the work group were Carol Falkowski, Kevin Evenson, David Thorson, Jeff Lindoo and Betty Johnson.

Varying opinions as to the level of required use, or even if use of the PMP should be required, were voiced. Although not all members of the workgroup agreed, the workgroup presented several consensus recommendations to the full Task Force.

The workgroup's recommendations were presented to the Task Force at their October 28, 2014 meeting for further consideration. Some of the recommendations, such as requiring all prescribers and pharmacists to register for an account with the PMP, were supported by those members in attendance at the meeting. Other recommendations from the workgroup, such as a universal mandate for use of the PMP when prescribing controlled substances, did not receive consensus support from the full Task Force, although some of the members did support this recommendation during workgroup meetings.

Additional recommendations include

- Encourage and support the integration of access to the PMP data within electronic medical records and other health IT systems;
- No mandate requiring use of the PMP by prescribers and pharmacists; and
- Convene a multi-disciplinary group to discuss and develop guidelines for required use of the PMP by prescribers and pharmacist. In addition, include quality measures to show how the

[5] Presentation: HB1 Impact Evaluation, NASCSA Annual Meeting, October 23, 2014 see http://www.nascsa.org/Conference2014/Presentations/freeman.pdf last accessed online November 12, 2014

guidelines are being used and how effective they are in the fight against prescription drug abuse.

Board Recommendations

At this time there is no solid evidence that mandated use of the PMP database has an impact on prescription drug abuse. Reducing prescription drug abuse requires a multifaceted approach. This is noted in the Office of National Drug Control Policy's 2011 Prescription Drug Abuse Prevention plan, which expands upon the Obama Administration's National Drug Control Strategy and includes action in four major areas - education, monitoring, proper medication disposal and enforcement. Taking into consideration the recommendations of the PMP Task Force, information from various studies and reports published by reliable sources in the PMP community and further research into required use of the PMP, the Board recommends the following:

a) To encourage and increase utilization of the PMP, all MN licensed prescribers holding a DEA registration, which authorizes them to prescribe controlled substances to humans, should be required to register for access to the MN PMP and be required to keep their registration active and up to date. Failure to do so would result in notification from the PMP to the appropriate health licensing board for further action.
b) To encourage and increase utilization of the PMP all MN licensed pharmacists should be required to register for access to the MN PMP and be required to keep their registration active and up to date. Failure to do so would result in notification from the PMP to the Board of Pharmacy for further consideration.
c) Effective July 2014, the Board is now permitted to review the data submitted to the PMP on at least a quarterly basis and, based on established criteria for referring information about a patient to the prescribers and pharmacists who prescribed or dispensed a prescription in question, notify them when the criteria are met. It is recommended that the Board study the effects of implementing this "unsolicited reporting" as a mean to reduce "doctor shopping" and increase voluntary use of the PMP database before the Legislature makes a decision on required use of the PMP.
d) Addressing the issue of prescription drug abuse requires a multi-faceted approach. To avoid unintended consequences such as reducing prescribing when it is appropriate or causing a chilling effect on prescribing, it is recommended that the Board continue to work with other state agencies involved in the State's Substance Abuse Strategy, and organizations that represent health care professionals who prescribe and/or dispense controlled substances, to establish guidelines for suggested use of the PMP by prescribers and pharmacists.

2. Allowing for use of the PMP database to identify inappropriate prescribing of controlled substances

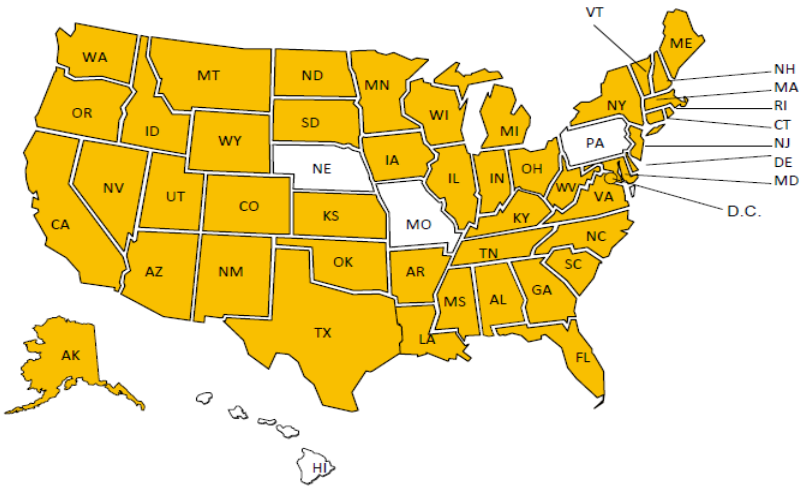
Data

A 2014 news release[6] by the FDA quoted Commissioner Margaret A. Hamburg as saying that illegal diversion, misuse, and abuse of prescription opioids are often fueled by inappropriate prescribing, improper disposal of unused medications, and the illegal activity of a small number of health care providers. Commissioner Hamburg goes on to say that prescribers and patients can play an important role in addressing the Prescription Drug Abuse epidemic.

The information contained in the PMP database can be a valuable tool in identifying potential inappropriate prescribing. PMP data can be used by the boards that license prescribers to assist them in expediting actions that will protect the public's health and educate prescribers in appropriate prescribing of controlled substances. To assist in identifying prescribers who may display certain prescribing patterns, several states have permitted licensing and regulatory boards to receive data from the PMP.

The following map[7] identifies states that currently authorize the PMP to release data to licensing and regulatory boards.

Types of Authorized Recipients - Licensing/Regulatory Boards



[6] FDA Commissioner Margaret A. Hamburg Statement on Prescription Opioid Abuse see http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm391590.htm last accessed online November 13, 2014.

[7] The National Alliance for Model State Drug Laws (NAMSDL), Types of Authorized Recipients – Licensing/Regulatory Boards see http://www.namsdl.org/library/40DEE560-65BE-F4BB-AA3653280055B0F2 last accessed online November 13, 2014. This project was supported by Grant No. G1399ONDCP03A awarded by the Office of National Drug Control Policy.

A review of information published by the National Alliance for Model State Drug Laws[8], which outlines each State's statutes and regulations regarding access by regulatory and licensing boards, reveals the following:

- 44 states allow the PMP to provide data to various regulatory and licensing boards
    - 4 states require the request be in writing and based on a bona fide investigation
    - 33 states allow the PMP to provide data to the boards for a variety of reasons, usually based on an investigation
    - 1 state (MN) allows only the Board of Pharmacy to access data related to its licensees.
    - 1 state allows the boards direct access to the PMP
    - 4 states require a court order or subpoena

Input From the PMP Advisory Task Force:
A workgroup of Task Force members was formed to make initial recommendations to the full Task Force regarding use of the PMP database to identify inappropriate prescribing of controlled substances. Active members of the workgroup were Neal Benjamin, Julia Wilson, Alfred Anderson, Connie Jacobs and Julie Sabo.

The workgroup formulated a list of initial recommendations that, after being reviewed by the full Task Force, were agreed upon by the majority of the members. One member objected to the recommendation due to concern for data privacy and their stand on garnering consent before accessing PMP information. The following are the recommendations of the PMP Advisory Task Force:

- It is recommended that access to the PMP data be granted to health licensing boards that license prescribers, when investigating a bona fide complaint alleging the inappropriate prescribing of controlled substances.
- It is recommended that each board that licenses prescribers of controlled substances develop a set of conditions, which when met, would trigger the request for PMP data, prior to requesting data from the PMP.
- It is recommended that the PMP database will not be accessed directly by each board; instead a report will be requested through staff of the PMP.

The workgroup also recommends that access to the PMP data be granted to health licensing boards, and the Emergency Medical Services Regulatory Board, when investigating a bona fide complaint alleging that a licensee or registrant is chemically dependent or abusing controlled substances. Access to the PMP data would be via a written request presented to the PMP staff and no direct access to the PMP database by the other board's representative would be permitted.

Board Recommendations:
The Board recognizes the value of the data in the PMP database in identifying individuals who may be misusing, abusing or diverting controlled substance medications and continues to support the efforts of the health-licensing boards that license prescribers to ensure safe and responsible prescribing of controlled substances. The Board also recognizes the efforts put forth by the PMP Advisory Task Force

[8] The National Alliance for Model State Drug Laws (NAMSDL), Types of Authorized Recipients – Professional Licensing or Regulatory Boards see http://www.namsdl.org/library/40DE10F9-65BE-F4BB-A7567C38B466CE77 last accessed online November 13, 2014. This project was supported by Grant No. G1399ONDCP03A awarded by the Office of National Drug Control Policy.

in developing recommendations for access to the PMP data by other health licensing boards and acknowledges that some members of the Task Force did not agree with those recommendations.

The Board supports, in full, the recommendations made by the Task Force and therefore recommends that:

- Access to the PMP data be granted to health licensing boards that license prescribers, when investigating a bona fide complaint alleging the inappropriate prescribing of controlled substances.
- Each board that licenses prescribers of controlled substances develop a set of conditions, which when met, would trigger the request for PMP data, prior to requesting data from the PMP.
- Access to the PMP data be granted to health licensing boards, and the Emergency Medical Services Regulatory Board, when investigating a bona fide complaint alleging that a licensee or registrant is chemically dependent or abusing controlled substances.
- The PMP database will not be accessed directly by each board; instead a report will be requested through staff of the PMP.

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3. Encouraging access to appropriate treatment through the PMP

Data

In 2013 the MN Medical Association organized several forums regarding prescription opioid abuse across the state to gather opinions and insights from their members. MN PMP staff were present at these meetings to offer the opportunity to register for access to the MN PMP to those in attendance. During these forums it became clear that prescribers are using the MN PMP database and other clinical tools which assist in identifying individuals that may need referral to treatment, buts are not always sure where to turn for treatment resources. While the MN PMP database itself was not designed to provide a *direct* connection to available treatment options, the MN PMP public website does have drug information and drug abuse resources to assist prescribers.

Input From the PMP Advisory Task Force:

A workgroup of Task Force members was formed to make initial recommendations to the full Task Force regarding ways to encourage access to appropriate treatment through the PMP. Active members of the work group were Kevin Evenson and Betty Johnson.

The workgroup formulated a list of initial recommendations that, after being reviewed and fine-tuned by the full Task Force, were agreed upon by a majority of the members. The following are the recommendations of the PMP Advisory Task Force:

- It is recommended that the MN PMP public website be redesigned to include information for healthcare providers such as mental health and substance abuse resources, clinical tools, opioid and pain management guidelines, toolkits and crisis resources.
- It is recommended that the MN PMP public website be redesigned to include information for the patient such as treatment locators, drug abuse prevention information, and other resources that may benefit the patient.
- It is recommended that the State of Minnesota investigate the possibility of a coordinated referral system through a central navigation system, with the possibility of regional walk in assessment centers that could coordinate with central navigation as needed. It would be a "one-stop" public dashboard for practitioners and patients. This concept was adopted from a presentation[9] made by Commissioner Cheryl Bartlett, RN, MA Department of Public Health at the 2014 Harold Rogers Prescription Drug Monitoring Programs National meeting held in Washington, DC.

Board Recommendations:

The Board supports, in full, the recommendations made by the Task Force to assist in encouraging access to treatment through the PMP, by means of its public website. Additionally, the Board supports the recommendation that the MN Department of Human Services, Chemical and Mental Health Division investigate the possibility of creation of a "one stop shop" for referral to substance abuse treatment resources.

[9] Prescription Drug Monitoring Program Training and Technical Assistance Center, Annual Harold Rogers Prescription Drug Monitoring Program see http://www.pdmpassist.org/pdf/PPTs/National2014/1-01_Bartlett.pdf last accessed online November 19, 2014.

Conclusions

There is growing evidence that PMPs are effective in improving medical care, reducing misuse, abuse, and diversion of controlled substances, identifying inappropriate prescribing, and assisting in drug investigations amongst other efforts to curtail prescription drug abuse. The effectiveness of PMPs is likely to increase as states adopt and expand on evidence-based best practices. Should the legislature adopt the Board's recommendations, MN will continue to be an active stakeholder in the fight against prescription drug abuse. Requiring licensed prescribers and pharmacists to register for an account with the PMP is expected to result in increased use of the PMP. Unsolicited reporting may reduce doctor shopping and increase voluntary use of the PMP. Studying the impact of these two initiatives will provide evidence that can be used in determining the necessity of mandating the use of the PMP. Meanwhile, the Board will continue to work with other state agencies and organizations that represent health care professionals who prescribe and/or dispense controlled substances to establish guidelines for suggested use of the PMP.

Just as other states have permitted licensing and regulatory boards to receive data from the PMP, the Board is recommending that other boards be granted access to a prescriber's prescribing history or the individual prescription history of a licensee or registrant as a means of ensuring public health and safety.

In regards to the availability of substance abuse resources through the PMP, the Board fully supports the recommendations made by the Task Force. If a prescriber is unaware of available resources, the PMP website will include guidelines and tools to encourage substance abuse treatment. Likewise, should a patient be unsure where to turn for treatment or need additional information on prescription drug abuse, the PMP website will serve as a resource for this purpose. It is recommended that the MN Department of Human Services investigate the possibility of creating a "one stop shop" for substance abuse resources for both practitioners and the public.

In summary, requiring registration for access to PMP data, studying the effectiveness of unsolicited reporting, and providing further resources for substance abuse treatment through the PMP website will aid in the State's fight against prescription drug abuse. Through the recommendations listed in this report, the State of Minnesota can enhance patient care, promote safe prescribing and dispensing, and have a positive impact on reducing prescription drug abuse.

Appendix 1

MN Prescription Monitoring Program Advisory Task Force

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