Prescription Drug Monitoring Program (PDMP) FAQs

Definitions

- **Controlled substance**: a drug, substance, or immediate precursor in Schedules I through V as set out in Chapter 195 R.S.Mo.
  - **Schedule II, III, or IV controlled substance**: a controlled substance listed in Schedules II, III, or IV as set out in Chapter 195 R.S.Mo. or the Controlled Substances Act, 21 U.S.C. Section 812. St. Louis County Ordinance No. 26352 applies to schedule II-IV controlled substances.
- **DPH**: Saint Louis County Department of Public Health.
- **Director**: Director of DPH, or the person or persons duly designated by the Director to carry out the duties of the Director.
- **Dispenser**: a person who delivers a Schedule II, III, or IV controlled substance to a patient. However, the term does not include:
  - A hospital as defined in Section 197.020 R.S.Mo. that distributes such substances for the purpose of inpatient care or dispenses prescriptions for controlled substances at the time of discharge from such facility;
  - A practitioner or other authorized person who administers such a substance; or
  - A wholesale distributor of a Schedule II, III, or IV controlled substance.
- **Subscribing county**: county or jurisdiction that has enacted appropriate legislation authorizing participation in the St. Louis County PDMP and engaged in a User Agreement with St. Louis County.
- **Provider**: medical provider with access to the St. Louis County PDMP.
- **Registered user (user)**: person authorized to access the St. Louis County PDMP. See Table 2 for details.

Program Overview

1. **What is the purpose of the PDMP?**
The St. Louis County Prescription Drug Monitoring Program (PDMP) monitors the prescribing and dispensing of schedule II-IV controlled substances to assist in the identification and prevention of prescription drug misuse and abuse.

2. **What are the goals of the PDMP?**
The program’s goals are to 1) improve controlled substance prescribing by providing critical information regarding a patient’s controlled substance prescription history, 2) inform clinical practice by identifying patients at high-risk who would benefit from early interventions, and 3) reduce the number of people who misuse, abuse, or overdose while making sure patients have access to safe, effective treatment.

Legal

3. **Where can I find the St. Louis County PDMP ordinance?**
4. What might be an example of an entity that needs a waiver (Section 602.802, Article 6)?
Dispensers are the only entities eligible for a waiver as they are the only ones mandated to submit data to the PDMP. The DPH Director is authorized to issue a waiver when the dispenser demonstrates it is unable to comply with the requirements.

5. Is St. Louis County requiring prescribers to check the PDMP before prescribing a Schedule II, III, or IV controlled substance? Should other counties/jurisdictions do that?
St. Louis County Ordinance No. 26352 does not mandate prescribers check the PDMP before writing a prescription. Prescribers are, however, encouraged to use the PDMP.

PDMP Timeline

6. What is the timeline for the PDMP to be implemented or available for use?
The PDMP is anticipated to be live in the early second quarter of 2017. More information, including the Data Submission Guide, dispenser communications, user communications, and registration and user guides are available on the DPH PDMP website, www.stlouisco.com/HealthandWellness/PDMP.

Subscribing Counties/Jurisdictions

7. What jurisdictions are currently subscribing to the PDMP?
The DPH PDMP website, www.stlouisco.com/HealthandWellness/PDMP, contains a list and links to all available ordinances for subscribing counties.

8. What is the process for a jurisdiction to subscribe to the PDMP?
To subscribe to the PDMP, counties/jurisdictions must enact legislation authorizing participation in the PDMP and sign a User Agreement with St. Louis County. Legislation enacted by subscribing jurisdictions must align with St. Louis County Ordinance No. 26352. Subscribers will be onboarded on a quarterly basis after legislation and the User Agreement are in place. Jurisdictions that have enacted legislation and signed the User Agreement by March 1, 2017 are eligible to participate in the initial PDMP implementation. Table 1 contains the onboarding timeline for all jurisdictions joining after the initial implementation phase. Onboarding consists of data submitters (dispensers) registering with Appriss then moving from testing to production (successfully submitting data). Data for each jurisdiction will be visible to users by the first business day of the quarter following onboarding.

Table 1. Onboarding Timeline.

<table>
<thead>
<tr>
<th>Quarter A</th>
<th>Quarter B</th>
<th>Quarter C</th>
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</thead>
<tbody>
<tr>
<td>Jurisdiction Legislation &amp; User Agreement signed</td>
<td>Data Submitter Registration</td>
<td>Clearinghouse Testing → Production</td>
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<td></td>
<td></td>
<td>PDMP (PMP AWARxE) live on 1st business day</td>
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Data Submission

9. Who is the vendor St. Louis County will be using for the PDMP?
St. Louis County selected Appriss as the PDMP vendor through a Request for Proposals (RFP) process. Appriss is the vendor of choice by the majority of states and has the necessary functionality for an effective PDMP. Appriss has created a PDMP platform called PMP AWARxE that the PDMP will use. More information about Appriss can be found at http://www.appriss.com/pmpaware.html.

10. What are the data transmission standards referenced in the St. Louis County ordinance?
The American Society for Automation in Pharmacy (ASAP) has developed national standards for transmission of pharmacy data. The PDMP will use the most current version of these standards, ASAP4.2. More information about ASAP standards can be found at http://www.asapnet.org/.
11. What is the data entry process? Who submits data to the PDMP? Can data be submitted for non-subscribing counties?

**Data Submission:** Dispensers submit data to Appriss through PMP Clearinghouse. Dispensers can submit data individually by store or collectively by chain or through their Pharmacy Benefit Management system (PBM). Providers do not enter anything into the PDMP (though they can request a correction). To submit data, dispensers will first register with PMP Clearinghouse and then can submit data in multiple ways: secure file transfer protocols (sFTP), automatic interfaces to transfer in real time, manual entry, and web-based file uploads. Data submission will follow the national standard developed by the American Society for Automation in Pharmacy (ASAP, http://www.asapnet.org/). The Data Submission Guide outlines the required fields and data submission process for dispensers and will be posted on the DPH PDMP website (www.stlouisco.com/HealthandWellness/PDMP).

**Data Cleaning/Processing:** Appriss validates, cleans, and processes the data before publishing it to the PDMP platform (PMP AWARxE). To the best of their abilities, data submitters will need to filter data to only submit prescriptions dispensed in subscribing counties. DPH has expanded Appriss’ data validation process to include county-level blocking where any data submitted for non-subscribing counties is rejected. DPH will provide quarterly updates to the subscribing county list to Appriss.

**Technical Assistance:** Assistance will be available on multiple sites: PMP Clearinghouse where dispensers submit data, PMP AWARxE where users access the PDMP, and the DPH PDMP website.

12. How are mail order prescriptions to be reported to the PDMP?

All prescriptions **dispensed** within a jurisdiction with PDMP legislation must be reported to the St. Louis County PDMP. For example, if a mail order prescription is dispensed in a subscribing county, that prescription must still be reported to the PDMP.

13. Is there a cost to dispensers to submit data?

There is no data submission cost charged to dispensers by St. Louis County or Appriss. Additional information on data submission will be available in the Data Submission Guide on the DPH PDMP website, www.stlouisco.com/HealthandWellness/PDMP.

14. Who can access the data? What restrictions are in place to ensure data security and privacy?

As outlined in St. Louis County Ordinance No. 26352, Table 2 details the authorized recipients, the requirements each must meet to receive or access information, the level of information provided, and the access that recipient will receive. DPH requires the PDMP vendor to be HIPAA-compliant and comply with all other applicable federal, state, and local laws. Privacy and security policies and procedures will be finalized prior to data collection. The PDMP Coordinator at DPH will operate on a password protected computer, work from an office with a door that can be locked, be HIPAA trained, participate in discussions observing HIPAA guidelines, print to a non-networked (i.e., private) printer, and destroy HIPAA-protected information in a secure shredder.
<table>
<thead>
<tr>
<th>Authorized Recipients</th>
<th>Requirements</th>
<th>Information Provided</th>
<th>Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Public Health Agency (LPHA)</td>
<td>Enact appropriate legislation and sign User Agreement with St. Louis County. Will receive routine, quarterly reports from DPH. Can request additional reports from DPH that will be provided as resources are available.</td>
<td>County-specific reports on prescribing practices. Reports will contain aggregate &amp; de-identified data.</td>
<td>Routine reports from DPH. Ad hoc reports upon request.</td>
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<tr>
<td>Prescribers</td>
<td>Persons, or their duly designated delegates, whether in or out of the State of Missouri, who are authorized to prescribe controlled substances, if the requesting person demonstrates that the request is made for the purpose of providing medical care for a patient.</td>
<td>Patient prescription &amp; delegate user information.</td>
<td>Registered users and have full access to the PDMP.</td>
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<tr>
<td>Dispensers</td>
<td>Persons, or their duly designated delegates, whether in or out of the State of Missouri, who are authorized to dispense controlled substances, if the requesting person demonstrates that the request is made for the purpose of providing pharmaceutical care for a patient.</td>
<td>Patient prescription &amp; delegate user information.</td>
<td>Registered users and have full access to the PDMP.</td>
</tr>
<tr>
<td>Self</td>
<td>Request own dispensation information.</td>
<td>Personal prescription history.</td>
<td>Report upon completed request form.</td>
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<tr>
<td>Board of Pharmacy</td>
<td>Regulate a professional authorized to prescribe or dispense controlled substances and which has requested the information or data in the course of a current and open investigation into the acts of a professional under the jurisdiction of the state board. Only information related to the subject professional shall be provided by the DPH Director.</td>
<td>Information necessary to regulate industry as per their authority.</td>
<td>Routine reports from DPH. Ad hoc reports upon request.</td>
</tr>
<tr>
<td>State Regulatory Boards</td>
<td>Regulate a professional authorized to prescribe or dispense controlled substances and which has requested the information or data in the course of a current and open investigation into the acts of a professional under the jurisdiction of the state board. Only information related to the subject professional shall be provided by the DPH Director.</td>
<td>Information necessary to regulate industry as per their authority.</td>
<td>Routine reports from DPH. Ad hoc reports upon request.</td>
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<tr>
<td>Law Enforcement</td>
<td>Local, state, and federal law enforcement or prosecutorial officials, both in or outside Missouri, who are engaged in the administration, investigation, or enforcement of laws governing prescription drugs based on a specific case and under a subpoena issued pursuant to court order.</td>
<td>All prescriber, dispenser, &amp; patient information as specified in subpoena.</td>
<td>Report upon completed request form with accompanying subpoena.</td>
</tr>
<tr>
<td>MO HealthNet</td>
<td>Regarding MO HealthNet program recipients.</td>
<td>Eligible or enrolled patient Rx information.</td>
<td>Routine reports from DPH. Ad hoc reports upon request.</td>
</tr>
<tr>
<td>Judge/Judicial Officer</td>
<td>Under subpoena issued pursuant to court order.</td>
<td>All prescriber, dispenser, &amp; patient information as specified in subpoena.</td>
<td>Report upon completed request form with accompanying subpoena.</td>
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15. How do users register to use the PDMP? When does registration begin, and what does the registration process entail?
Registration information, including dates and guides, will be available on the DPH PDMP website, www.stlouisco.com/HealthandWellness/PDMP.

16. Once PDMP is live, how is DPH planning to report back to providers? Are there sample reports? What is the report frequency?
All Reports: There are multiple report options, and DPH will run a combination of standard and ad hoc reports. The user guide will have more detailed information on reports and will be available on the DPH PDMP website, www.stlouisco.com/HealthandWellness/PDMP.

Reports to Providers: When providers log on, they will see alerts that apply to patients who have crossed certain threshold criteria (DPH will establish thresholds with input from the Technical Advisory Committee). Providers can also pull a prescription history on their patients. DPH will receive a list of providers with patients that go over the thresholds. DPH can send the provider an unsolicited report directing them back to the PDMP to review their patient(s); unsolicited reports will direct users back to the PDMP and contain no protected health information.

Reports to Subscribers: At a minimum, subscribing counties will receive quarterly reports with utilization and public health indicators. Subscriber reports will be developed in partnership with subscribing counties and the Technical Advisory Committee.

17. Are there alerts/triggers in place that will generate an action?
During the implementation process, DPH will set thresholds that generate automatic system alerts. DPH has formed a Technical Advisory Committee to assist in the development of thresholds, procedures, and policies based on best practices.

18. What is the role of the pharmacy board with this?
The pharmacy board has been largely supportive. The National Association of Boards of Pharmacy is the primary provider of the interstate exchange that allows PDMPs to connect information across state lines and actively supports PDMPs across the nation. Additional information on the Missouri Board of Pharmacy’s role related to the PDMP can be found in Table 2.

19. Will the PDMP participate in interstate sharing? What is the process for that?
The National Association of Boards of Pharmacy (NABP) operates a national PDMP interchange called PMP InterConnect which “facilitates the transfer of prescription monitoring program (PMP) data across state lines. It allows participating state PMPs across the United States to be linked, providing a more effective means of combating drug diversion and drug abuse nationwide.” DPH intends to participate in PMP InterConnect once the PDMP is live for users. For more information on PMP InterConnect, including a map and list of participating states, visit https://nabp.pharmacy/initiatives/pmp-interconnect/.

Provider Outreach

20. Do we anticipate having providers that will not participate? What education plan exists to encourage provider participation?
There will certainly be some providers who do not participate as they are not required to participate. It is mandatory for dispensers to submit data, and DPH can run reports to check the frequency and compliance of each dispenser. To encourage provider use, there will be mass marketing campaigns, grand rounds, informational letters, PDMP website, and any other educational best practices utilized to
increase participation. As the local public health agency, subscribers can best assist in increasing PDMP utilization by disseminating materials and promoting provider use in their jurisdictions.

Additional Information

21. What happens if the State of Missouri enacts a state-level PDMP?
   As part of the contract between St. Louis County and Appriss, Appriss will develop a transition plan if the PDMP is to be superseded by a state PDMP. If a state-level PDMP is enacted, the PDMP will continue to operate until the state-level system is functional and proves it meets the needs of St. Louis County.

22. Where can we get more information? Who can we contact about joining the PDMP?
   For more information, contact the DPH PDMP Coordinator at PDMP.DPH@stlouisco.com or visit www.stlouisco.com/HealthandWellness/PDMP.