



**St. Louis County  
Prescription Drug Monitoring Program  
Rules and Regulations**

Chapter 602 of the St. Louis County Revised Ordinances (“SLCRO”) and the following Rules and Regulations shall implement the Prescription Drug Monitoring Program. St. Louis County (“County”) reserves the right to review, update, and/or change this document at any time.

**I. General Provisions**

a. Authority

- i. The Director of Public Health (“Director”) has promulgated rules and regulations pursuant to Section 602.802 SLCRO.

b. Title

- i. The complete title of this document is the St. Louis County Prescription Drug Monitoring Program Rules and Regulations (“Rules and Regulations”).

c. Definitions

- i. The following terms shall have the meanings ascribed to them, thus:
  1. “Authorized User” means persons authorized to be provided dispensation information per Section 602.806 SLCRO.
  2. “Controlled substance” means a drug, substance or immediate precursor in Schedules I through V as set out in Chapter 195 R.S.Mo.
  3. “Department” means the St. Louis County Department of Public Health (“DPH”).
  4. “Director” means the Director of DPH, or the person or persons duly designated by the Director to carry out the duties of the Director specified in Section 602.800-602.808 SLCRO.
  5. “Dispensers” have two roles in the PDMP: Data Submitters and Authorized Users.
    - a. Dispenser as Authorized User (“Dispenser”) means a person who delivers a Schedule II, III, or IV controlled substance to a Patient. Dispenser is a person, whether in or out of the State of Missouri, who is 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
    - b. “Dispenser as Data Submitter” means the party responsible for submitting dispensation information for the Dispenser by which they are employed.
    - c. However, the term Dispenser does not include:
      - i. 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;
      - ii. a practitioner or other authorized person who administers such a substance; or

- iii. a wholesale distributor of a Schedule II, III, or IV controlled substance.
  - 6. "Patient" means a person who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed, not including a hospice patient enrolled in a Medicare-certified hospice program who has controlled substances dispensed to him or her by such hospice program.
  - 7. "PDMP" means the St. Louis County Prescription Drug Monitoring Program. The platform or web-based solution is hosted by Vendor and known as the PDMP.
  - 8. "Prescriber" means a person, whether in or out of the State of Missouri, who is 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.
  - 9. "Schedule II, III, or IV controlled substance" means 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.
  - 10. "Subscribing County" means a county or jurisdiction that has enacted appropriate legislation authorizing participation in the St. Louis County PDMP and executed a User Agreement with St. Louis County.
  - 11. "Vendor" means the provider of the software platform that hosts the PDMP.
- d. Conflict of Terms; Priority
- i. The terms contained in Chapter 602 SLCRO shall prevail over the terms of these Rules and Regulations to the extent that such terms conflict.

## **II. Subscribing Counties**

- a. DPH may allow other jurisdictions (counties or municipalities) to participate in or subscribe to the PDMP; those jurisdictions are considered "Subscribing Counties."
- b. To subscribe to the PDMP, Subscribing Counties must enact legislation authorizing participation in the PDMP and execute a User Agreement with St. Louis County. Legislation enacted by Subscribing Counties must align with St. Louis County Ordinance No. 26352.
- c. Subscribing Counties are responsible for enforcement of violations as well as continued community engagement and outreach as outlined in the User Agreement.

## **III. Data Privacy and Security**

- a. DPH will follow all applicable provisions of the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH).
- b. DPH requires the PDMP Vendor to be HIPAA-compliant and comply with all other applicable federal, state, and local laws.
- c. All Authorized Users of the PDMP must follow all applicable provisions of HIPAA and HITECH.
- d. All Dispensers of Schedule II, III, and IV controlled substance prescriptions are required to collect and report dispensation information. Such reporting without individual authorization by the Patient is allowed under HIPAA, 45 CFR § 164.512, paragraphs (a) and (d).

- e. If DPH receives notification that an Authorized User violates HIPAA, DPH shall deactivate such Authorized User's PDMP account and may, if the violation is knowing, take additional action including, but not limited to, notification of Law Enforcement, Professional Licensing, Certification, or Regulatory Agencies.

#### **IV. Data Submission**

- a. Dispensers as Data Submitters are required to electronically report dispensation information on all Schedule II, III, and IV controlled substances dispensed in Subscribing Counties. Dispensers as Data Submitters are requested to only submit data from Subscribing Counties.
- b. Dispensers as Data Submitters are encouraged to submit dispensation information to the PDMP daily. Dispensers as Data Submitters are in violation and non-compliant when data submission has not occurred within seven business days of dispensation.
- c. If a Dispenser as Data Submitter fails to submit dispensation information to the PDMP as required by authorizing legislation or submits incorrect dispensation information, DPH will contact the Dispenser as Data Submitter and may take additional action including, but not limited to, notification of the Missouri Board of Pharmacy.
- d. Dispensers as Data Submitters must submit dispensation information from the effective date for each Subscribing County's legislation.
  - i. Dispensers unable to submit dispensation information from the effective date of appropriate legislation may request a waiver.

#### **V. Suspension of Reporting Requirement**

- a. The Director may suspend the requirement of reporting for a particular category of information required to be submitted to the PDMP if the Director determines that reporting will conflict with collection of other reported information by the collection management system of the PDMP.

#### **VI. Authorized User Registration**

- a. Section 602.806 SLCRO details persons authorized to be provided dispensation information and other data. The type of Authorized User determines the level of access to the PDMP and to PDMP data. Authorized Users are divided into three categories with varying levels of access to the PDMP and to PDMP data. The three types of access and examples of Authorized Users are below. For all Authorized Users, DPH will validate the appropriate credentials prior to providing access to the PDMP.
  - i. **Authorized Users with direct, full access to the PDMP for the purpose of providing medical or pharmaceutical care.** Prescribers and Dispensers have direct, full access to the PDMP. Prescribers and Dispensers may also supervise and delegate access to the PDMP but maintain all liability.
  - ii. **Authorized Users with ability to request PDMP data but do not directly access the PDMP.** Persons may request their own dispensation information in accordance with law.
  - iii. **Authorized Users with restricted or limited access to the PDMP.** These Authorized Users will register in the PDMP and can submit search requests, but these requests require DPH approval and verification of additional ordinance requirements before Authorized Users are provided with any PDMP data. Authorized Users with restricted PDMP access include state regulatory boards,

law enforcement or prosecutorial officials, MO HealthNet, and judges or judicial officers.

**VII. Interstate Data Sharing**

- a. DPH may elect to participate in an interstate exchange of PDMP data. Participation in an interstate exchange will be in compliance with St. Louis County Ordinance 26352.

**VIII. Reporting Exemptions and Electronic Transmission Waiver**

a. Reporting Exemptions

- i. If a Dispenser meets the conditions outlined in Section 602.801 SLCRO, the Dispenser is exempt from submitting data to the PDMP. Those Dispensers exempt from reporting per Section 602.801 SLCRO are:
  - 1. 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 or discharge from such facility;
  - 2. a practitioner or other authorized person who administers such a substance; or
  - 3. a wholesale distributor of a Schedule II, III, or IV controlled substance.
- ii. Persons licensed to dispense Schedule II, III, or IV controlled substances not meeting the exemption criteria above may request an exemption on grounds of not dispensing controlled substances.
  - 1. The Director shall make a decision concerning an application for an exemption within ten business days of receipt thereof. An applicant for an exemption who has been aggrieved by a decision of the Director may appeal the decision according to law within three business days of the Director's decision.
  - 2. If the person responsible requests a hearing in a timely manner, the Director shall schedule a hearing to be held at the earliest practical time. Decisions of the Director are subject to judicial review pursuant to Chapter 536 R.S.Mo.
  - 3. Upon approval, DPH will grant a reporting exemption valid for one year from date of issuance.
  - 4. If DPH determines a violation has occurred and the Dispenser is or has dispensed Schedule II, III, or IV controlled substances, DPH will notify the Missouri Board of Pharmacy.

b. Electronic Transmission Waiver

- i. Per Section 602.802 SLCRO, the Director is authorized to issue a waiver of the electronic transmission requirement to a Dispenser demonstrably unable to comply with the requirement.
  - 1. The Director shall make a decision concerning an application for a waiver or extension within three business days of receipt thereof. An applicant for a waiver or extension who has been aggrieved by a decision of the Director may appeal the decision according to law within three business days of the Director's decision.
  - 2. If the person responsible requests a hearing in a timely manner, the Director shall schedule a hearing to be held at the earliest practical time. Decisions of the Director are subject to judicial review pursuant to Chapter 536 R.S.Mo.

3. A Dispenser who has not received a waiver of the electronic submission requirement but who, due to unforeseen circumstances, is temporarily unable to transmit dispensation information electronically, may upon application to the Director receive an extension of up to ten business days in which to submit the required dispensation information by electronic transmission, which extension may be renewed upon subsequent showing of need by the requesting Dispenser.

**IX. Violations and Fines**

- a. No person, absent lawful authority, shall knowingly access or disclose prescription or dispensation information maintained by DPH pursuant to Section 602.800-602.808 SLCRO or knowingly violate any other provision of Section 602.800-602.808 SLCRO.
- b. Any person convicted of violating Section 602.800-602.808 SLCRO shall be punished by a fine of up to \$1,000.00 or up to one year in jail, or both.