

Substitute Bill No. 1 for

BILL NO. 36, 2016

ORDINANCE NO. 26,352, 2016

Introduced by Councilmembers Page, O'Mara, Dolan & O'Leary

AN ORDINANCE

AMENDING CHAPTER 602, TITLE VI SLCRO 1974 AS AMENDED, "PUBLIC HEALTH," BY ENACTING AND ADDING NINE NEW SECTIONS PERTAINING TO DEVELOPMENT AND ADMINISTRATION OF A PROGRAM FOR MONITORING THE PRESCRIBING AND DISPENSING OF SCHEDULE II, III AND IV CONTROLLED SUBSTANCES BY PROFESSIONALS LICENSED TO PRESCRIBE OR DISPENSE SUCH SUBSTANCES WITHIN ST. LOUIS COUNTY; ESTABLISHING PENALTIES FOR VIOLATIONS THEREOF; AUTHORIZING THE COUNTY EXECUTIVE TO ACCEPT GRANTS AND DONATIONS IN SUPPORT OF THE MONITORING PROGRAM; AND APPROPRIATING SAME UPON RECEIPT FOR SUPPORT OF THE MONITORING PROGRAM.

BE IT ORDAINED BY THE COUNTY COUNCIL OF ST. LOUIS COUNTY, MISSOURI, AS FOLLOWS:

SECTION 1. Chapter 602, Title VI SLCRO 1974 as amended, is amended by enacting and adding nine new sections, to be known as Sections 602.800 through 602.808, which sections shall read as follows:

Section 602.800 - Title of act; scope; certain persons exempt. - 1. Sections 602.800 through 602.808 shall be known as the "St. Louis County Narcotics Control Act ("NCA")."
2. In order to enhance the public health and prevent the entrance of disease in St. Louis County, the provisions of this chapter shall apply in all unincorporated parts of St. Louis County and in all incorporated areas except any municipality having a population of 75,000 or more people and which maintains an organized health department.
3. The provisions of the NCA shall not apply to persons licensed pursuant to Chapter 340 R.S.Mo.

Section 602.801 - Definitions. - As used in Sections 602.800 through 602.808, the following terms shall have the meanings ascribed to them, thus:

(1) "Controlled substance" means a drug, substance or immediate precursor in Schedules I through V as set out in Chapter 195 R.S.Mo.

(2) "Department" means the St. Louis County Department of Public Health ("DPH").

(3) "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 the NCA.

(4) "Dispenser" means a person who delivers a Schedule II, III or IV controlled substance to a patient. However, the term does not include:

(a) 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;

(b) a practitioner or other authorized person who administers such a substance; or

(c) a wholesale distributor of a Schedule II, III or IV controlled substance.

(5) "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;

(6) "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.

Section 602.802 - Establishment of monitoring program by DPH. - 1. The Director of the Department of Public Health shall establish and maintain a program for monitoring the prescribing and dispensing of all Schedule II, III and IV controlled substances by professionals licensed to prescribe or dispense such substances in St. Louis County, and may implement such departmental rules which in the opinion of the Director are necessary to implement such program. The program established and maintained by the Director shall operate so as to be consistent with federal law concerning regulation of narcotics and with privacy of lawful users of same. The rules may provide for the Director to suspend the requirement of reporting a particular category of information pursuant to subsection 2 of this section, if the Director determines that so reporting will conflict with collection of other reported information by the collection management system of the monitoring program. The rules shall be effective upon approval of the County Council and shall be filed with the Administrative Director.

2. Within seven business days of having dispensed a Schedule II, III or IV controlled substance, the dispenser of same shall

submit to DPH by electronic means information regarding such dispensing. The information submitted for each dispensing shall at minimum include:

- (1) the pharmacy's Drug Enforcement (DEA) number;
- (2) the date of dispensation;
- (3) if dispensed via a prescription, (a) the prescription number or other unique identifier; (b) whether the prescription is new or a re-fill; (c) the prescriber's DEA or National Provider Identifier (NPI) number; (d) the National Drug Code (NDC) of the drug dispensed; (e) the quantity and dosage of the drug dispensed; (f) an identifier for the patient to whom the drug was dispensed, including but not limited to any one of the following: a driver's license number; the patient's government-issued identification number; the patient's insurance cardholder identification number; or the patient's name, address and date of birth.

3. The dispenser's submission of the required information to DPH shall be in accordance with transmission standards established by the American Society for Automation in Pharmacy or any of its successor organizations.

4. The Director is authorized to issue a waiver of the electronic transmission requirement to a dispenser demonstrably unable to comply with the requirement. A waiver shall expire one year from the date of its issuance. Required information submitted under a waiver shall be submitted within the same time frame as is required herein for electronic transmission.

5. 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 applicant dispenser.

6. 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.

602.803 - Dispensation information to be closed pursuant to law. - 1. Except when provided to persons or agencies authorized by this chapter to receive such information, dispensation information submitted to DPH is a closed record and not subject to public disclosure except as provided by law. No person shall provide such information to any person or agency not authorized by this chapter to receive it. A request for dispensation information made under Chapter 610 R.S.Mo. shall be referred to

the County Counselor, who shall take all reasonable and lawful steps to ensure non-disclosure of the information.

2. The Director shall develop and maintain procedures to ensure that the privacy and confidentiality of patients and personal information collected, recorded, transmitted and maintained are not disclosed to persons not authorized by this chapter to receive dispensation information.

602.804 Use of the monitoring system by dispensers not located in St. Louis County. - 1. The Director may permit dispensers located in counties other than St. Louis County to transmit dispensing information to DPH, either on a voluntary basis or pursuant to local or state law. Permission shall be conditional upon the dispenser complying in all respects with the provisions of this chapter.

602.805 Director to notify law enforcement or regulatory agency upon reasonable belief of a law or professional standards violation. - The Director shall review dispensation information transmitted to DPH, and if the Director develops a reasonable belief that a violation of law has occurred, or develops a reasonable belief that a breach of professional standards has occurred, the Director shall notify the appropriate law enforcement agency or the appropriate professional licensing, certification or regulatory agency. The Director may provide any dispensation information requested by such entities when advised that such information is required for conduct of an official investigation.

602.806 Persons authorized to be provided dispensation information. - 1. Dispensation information and other data compiled by DPH in connection with monitoring program established by the Director may be provided to the following persons upon a duly made request:

- (1) Persons, whether in or out of the State of Missouri, who are authorized to prescribe or dispense controlled substances, if the requesting person demonstrates that the request is made for the purpose of providing medical or pharmaceutical care for a patient;
- (2) Persons who request their own dispensation information in accordance with law;
- (3) The State Board of Pharmacy;
- (4) Any state board charged with regulating a professional authorized to prescribe or dispense controlled substances, and which has duly 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 Director.

(5) Local, state and federal law enforcement or prosecutorial officials, both in or outside of Missouri, who are engaged in the administration, investigation of enforcement of laws governing prescription drugs based on a specific case and under a subpoena issued pursuant to court order.

(6) The MO HealthNet division of the Missouri Department of Social Services regarding MO HealthNet program recipients.

(7) A judge or other judicial officer under a subpoena issued pursuant to court order.

2. In addition to the above-specified persons, the Director may provide dispensation information and data to public or private entities for statistical or education purposes; however, the Director shall first delete any information that could reasonably be thought usable to identify individual persons.

602.807 Pharmacists or prescribers not required to obtain information from the Department of Public Health. - This chapter shall not be construed or interpreted to require a pharmacist or prescriber to obtain dispensation information possessed or maintained by the Department of Public Health.

602.808 Obedience to law required. - 1. No person, absent lawful authority, shall knowingly access or disclose prescription or dispensation information maintained by DPH pursuant to the NCA, or knowingly violate any other provision of the NCA.

2. Any person convicted of violating this section shall be punished by a fine of up to \$1000.00 or up to one year in jail, or both.

SECTION 2. The County Executive, on behalf of St. Louis County, is authorized to accept grants or donations from public or private persons or organizations made in support of the prescribing and dispensing monitoring program authorized by this ordinance. The Accounting Officer shall establish an appropriation account into which all such grant or donation funds shall be appropriated upon receipt for the purposes of supporting the expenses related to administering the provisions of the Narcotics Control Act. The Director of Public Health shall report to the County Council all such grants or donations received during the preceding fiscal year.

SECTION 3. Upon the recommendation of the Director of Public Health, if the County Council finds that the provisions of the Narcotics Control Act are substantially similar to a statute of the State of Missouri regulating the same subject, the County Council by order may suspend any or all of the provisions of Sections 602.800 through 602.808 SLCRO 1974 as amended.

ADOPTED: MARCH 1, 2016

MICHAEL E. O'MARA
CHAIRMAN, COUNTY COUNCIL

APPROVED: MARCH 2, 2016

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COUNTY EXECUTIVE

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