



May 21, 2018

NOTICE OF PROPOSED RULEMAKING
“Prescription Drug Monitoring Program”
Revisions to Chapter 511-7-2

The Department of Public Health proposes the attached amendment to DPH Regulation 511-7-2, pursuant to its authority under O.C.G.A. Sections 31-2A-6, and 16-13-57 through -65.

The proposed rulemaking is intended to implement changes to the PDMP statutes resulting from the enactment of Senate Bill 407 in the 2018 session of the General Assembly. In particular, the proposed revisions revised the requirements of delegates who do not hold a professional health care license; expand access to the PDMP to include out-of-state law enforcement officials and prosecutors; expand the methods by which federal law enforcement officials can gain access to the PDMP to include administrative subpoenas and civil investigative demands; and expand access to the PDMP to include similar prescription drug management data bases operated by other government entities, and to public or privately operated electronic medical records systems with security measures comparable to those employed by DPH.

Interested persons may submit comments on these proposed revisions in writing addressed to:

Sheila Pierce, Director
DPH Prescription Drug Management Program
Georgia Department of Public Health
2 Peachtree Street, NW, 15th Floor
Atlanta, GA 30303

Comment may also be presented in person at a public meeting scheduled for 11:00 a.m. on June, 12, 2018, in room 9-260 “Adina’s Room” at 2 Peachtree Street, NW, Atlanta, Georgia 30303.

A handwritten signature in blue ink, appearing to read 'M. Zain Farooqui', written over a horizontal line.

M. Zain Farooqui
Associate General Counsel

RULES OF THE DEPARTMENT OF PUBLIC HEALTH

CHAPTER 511-7-2 Prescription Drug Monitoring Program

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511-7-2-.01 Definitions.

- (1) “Delegate” means an individual designated by a prescriber or dispenser, and meeting all the requirements of DPH Rule 511-7-2-.04, who is authorized to access the PDMP for the purpose of reviewing a patient’s prescription information.
- (2) “Department” means the Georgia Department of Public Health.
- (3) “Dispenser” means a person licensed under the laws of this state, or any other state or territory of the United States, to dispense or deliver a Schedule II, III, IV, or V controlled substance to an ultimate user in this state, but does not include (a) a pharmacy licensed as a hospital pharmacy by the State Board of Pharmacy pursuant to Code Section 26-4-110; (b) an institutional pharmacy that serves only a health care facility, including but not limited to a nursing home, an intermediate care home, a personal care home, or a hospice program, which provides patient care and which pharmacy dispenses such substances to be administered and used by a patient on the premises of the facility; (c) a licensed health care practitioner or other authorized person who administers such a substance; or (d) a pharmacy operated by, or on behalf of, or under contract with the Department of Corrections for the sole and exclusive purpose of providing services in a secure environment to prisoners within a penal institution, penitentiary, prison, detention center, or other secure correctional institution, including correctional institutions operated by private entities in this state which house inmates under authority of the Department of Corrections.

(4) “PDMP” means the Prescription Drug Monitoring Program database authorized by Code Section 16-13-57 and maintained by the department.

(5) “Prescriber” means a physician, dentist, scientific investigator, or other person licensed, registered, or otherwise authorized under the laws of this state, or any other state or territory of the United States, to prescribe a controlled substance in the course of professional practice or research in this state, and who has been assigned a DEA number. “Prescriber” shall not include a veterinarian.

(6) “Prescription information” means all of the following:

- (a) DEA permit number or approved dispenser facility controlled substance identification number;
- (b) Date the prescription was dispensed;
- (c) Prescription serial number;
- (d) If the prescription is new or a refill;
- (e) National Drug Code (NDC) for drug dispensed;
- (f) Quantity and strength dispensed;
- (g) Number of days’ supply of the drug;
- (h) Patient’s name;
- (i) Patient’s address;
- (j) Patient’s date of birth;
- (k) Patient gender;
- (l) Method of payment;
- (m) Approved prescriber identification number or prescriber’s DEA permit number; and
- (n) Date the prescription was issued by the prescriber.

Authority: O.C.G.A. §§ 31-2A-6, 31-5-5, 16-13-57 through 16-13-65.

511-7-2-.02 Internet access to the Prescription Drug Monitoring Program database (PDMP).

(1) Prescribers and dispensers are eligible to request approval for internet access to the PDMP.

(2) Prescribers and dispensers approved for internet access to the PDMP database may delegate their authority to use that access only as permitted in DPH Rule 511-7-2-.04.

(3) Prescribers and dispensers shall use information obtained from the PDMP database solely to make treatment decisions about their patients, to communicate concerns about a patient’s potential usage, misuse, abuse or underutilization of a controlled substance to prescribers or dispensers involved in the patient’s care, or to report potential violations of Title 16, Chapter 13, Article 2 to the Georgia Drugs and Narcotics Agency.

Authority: O.C.G.A. §§ 31-2A-6, 31-5-5, 16-13-57 through 16-13-65.

511-7-2-.03 Obligation of dispensers to transmit prescription information to the PDMP.

A dispenser shall transmit prescription information electronically to the PDMP database for each prescription dispensed in Georgia for a Schedule II, III, IV, or V controlled substance. Prescription information shall be transmitted no more than 24 hours after the prescription is dispensed. If no prescriptions are dispensed within a 24 hour period, then a report shall be made indicating that fact.

Authority: O.C.G.A. §§ 31-2A-6, 31-5-5, 16-13-57 through 16-13-65.

511-7-2-.04 Delegates.

(1) Subject to the requirements of this Rule, a prescriber or dispenser approved for internet access to the PDMP may designate up to two individuals per shift or rotation to access the PDMP on their behalf as delegates, provided that such individuals are:

- (a) Members of the prescriber's or dispenser's staff;
- (b) Employed by the health care facility in which the prescriber practices, and approved by the medical director of such health care facility; or
- (c) Employed by the emergency department of the hospital in which the prescriber practices, and approved by the medical director of such hospital.

(2) To be eligible to serve as a delegate, an individual must be:

- (a) ~~Licensed~~Hold a current license as a dentist, dental hygienist, optometrist, physician, physician's assistant, or podiatrist under Title 43 of the Official Code of Georgia;
- (b) ~~Licensed~~Hold a current license as a pharmacist or pharmacist intern or registered as a pharmacist technician under Title 26 of the Official Code of Georgia; or
- (c) ~~Registered with the Georgia Board of Pharmacy pursuant to Code Section 16-13-35 after meeting all~~ Comply with the requirements of subsection (4) of this Rule.

(3) An individual shall be ineligible to become a delegate if that person has been convicted of a felony, or of any criminal offense involving illegal drug use, possession, trafficking, or sale. "Convicted" as used in this subsection includes a plea of guilty or *nolo contendere*, but does not include a conviction that has been exonerated and discharged pursuant to Title 42, Chapter 8, Article 3 of the Official Code of Georgia or pardoned.

(4) Before an individual may act as a delegate, the delegating person or entity must:

- (a) Ensure that the proposed delegate has taken the department's online training course entitled "The Georgia Prescription Drug Monitoring Database: Understanding Your Responsibilities" and passed the online test with a score of at least 70:

- (b) Instructed in the prescriber or dispenser's security policies pertaining to the PDMP; and
- (c) Obtain a signed Responsibility Statement from the proposed delegate and place it in the delegate's personnel file.

~~Provided, however, that this paragraph (4) shall not apply to a person licensed as a nurse under Title 43 of the Official Code of Georgia.~~

(5) A delegating person or entity shall maintain records documenting the delegate's completion of the online PDMP training, the execution of the Responsibility Statement, the date on which each delegate was granted access to the PDMP, and the date on which the delegate's access was terminated. Those records shall be made available for inspection by the department.

(6) A delegate may access the PDMP only for the purpose of providing medical or pharmaceutical care to a specific patient of the delegating prescriber or dispenser, or to inform the delegating person or entity of a patient's potential use, misuse, abuse, or underutilization of prescribed medication.

Authority: O.C.G.A. §§ 31-2A-6, 31-5-5, 16-13-57 through 16-13-65.

511-7-2-.05 Dispenser claims for hardship waiver.

A dispenser may submit a written request for a hardship waiver from the requirement that it transmit prescription information within 24 hours by electronic means as required by paragraphs (a) and (b) of Code Section 16-13-59. The request must explain in detail the nature of the hardship, and propose an alternative method whereby the dispenser will report all prescription information within 24 hours. No request for a waiver will be approved without sufficient proof that compliance would impose an undue hardship upon the dispenser, meaning that it lacks sufficient financial resources to arrange for electronic transmission on its own or by arrangement with a third party.

511-7-2-.06 Duty of prescribers and dispensers to safeguard information obtained from the PDMP.

(1) All prescribers and dispensers authorized to have internet access to the PDMP shall protect prescription information obtained from the PDMP in accordance with the federal regulations implementing the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH Act) as they may be amended from time to time. Prescription information obtained from the PDMP may be included in the patient's chart.

(2) All prescribers and dispensers authorized to have internet access to the PDMP shall follow written policies governing access to the PDMP, the recording and use of prescription information obtained from the PDMP, and the protection of any written or electronic records in which prescription information is recorded.

(3) All prescribers and dispensers authorized to have internet access to the PDMP shall review DPH Form 7207 “Guide To The Georgia Prescription Drug Monitoring Database” and sign DPH Form 7207-A “Responsibility Statement.”

Authority: O.C.G.A. §§ 31-2A-6, 31-5-5, 16-13-57 through 16-13-65.

511-7-2-.07 Requests for prescription data held in the PDMP.

(1) This regulation is intended to govern all requests for prescription data from the PDMP other than queries for particular patients made by prescribers, dispensers, or their delegates. Except as provided in this Chapter or by law, prescription information held in the PDMP database is confidential and will not be disclosed by the department.

(2) The following persons may request information contained in the PDMP, for the purposes identified below, and in the manner set forth below:

(a) Local or state law enforcement or prosecutorial officials, pursuant to a search warrant issued pursuant to Title 17, Chapter 5, Article 2 of the Official Code of Georgia by an appropriate court or official ~~in the county~~ for the jurisdiction in which the office of such law enforcement or prosecutorial officials ~~are~~ is located;

(b) Federal law enforcement or prosecutorial officials, pursuant to a search warrant issued pursuant to Title 21 of the United States Code, ~~or~~ a grand jury subpoena issued pursuant to Title 18 of the United States Code, an administrative subpoena, or a civil investigative demand;

(c) The Georgia Drugs and Narcotics Agency, for health oversight purposes, or upon presentation of a subpoena issued by or on behalf of that agency, or as part of an investigation into suspected or reported abuses or regarding illegal access to the PDMP database;

(d) The Georgia Composite Medical Board, for health oversight purposes, or upon presentation of a subpoena issued by or on behalf of such board;

(e) The Georgia Board of Pharmacy, for health oversight purposes, or upon presentation of a subpoena issued by or on behalf of such board;

(f) The Georgia Department of Community Health, for oversight of the state Medicaid program, or upon presentation of a subpoena issued by or on behalf of that agency;

(g) The Georgia Board of Nursing, for health oversight purposes, or upon presentation of a subpoena issued by or on behalf of such board;

(h) The federal Centers for Medicare and Medicaid Services, upon presentation of a subpoena issued by or on behalf of that agency;

(i) An individual whose prescription history appears in the PDMP is entitled to a copy of that history, upon written request made by that person or their attorney;

(j) A prescriber is entitled to a copy of prescription information in the PDMP which pertains to prescriptions written by that person, upon written request made by that prescriber or their attorney;

(k) A dispenser is entitled to a copy of prescription information in the PDMP which pertains to prescriptions dispensed by that person, upon written request made by that dispenser or their attorney;

(l) A prescription drug monitoring program operated by a government entity in another state, or an electronic medical records system operated by a prescriber or health care facility, provided that the program or system has been determined by DPH to contain legal, administrative, technical, and physical safeguards that meet or exceed the security measures employed by DPH in the operation of the PDMP.

(m) Persons or entities may request prescription information for purposes of statistics, education, instruction, drug abuse prevention, or scientific research; provided, however, that such data will first be de-identified according to the standards set forth in 45 C.F.R. 164.514 as it may be amended from time to time.

(3) Requests for data made pursuant to subsections (a) through (k) of this Rule shall be submitted to the Director of the DPH Office of Drug Misuse Evaluation in writing or through a dedicated email address set up by the department for that purpose. Requests for data made pursuant to subsection (l) of this Rule shall be made through the department's Public Health Information Portal (PHIP).

Authority: O.C.G.A. §§ 31-2A-6, 31-5-5, 16-13-57 through 16-13-65.

511-7-2-.08 De-identification of prescription information held in the PDMP for more than two years.

Prescription information entered into the PDMP shall be de-identified two years from the date such information was transmitted to the database by the dispenser. De-identification shall be conducted according to the standards set forth in 45 C.F.R. 164.514 as it may be amended from time to time.

Authority: O.C.G.A. §§ 31-2A-6, 31-5-5, 16-13-57 through 16-13-65.