

APA3  
10/96

CERTIFICATION OF ADMINISTRATIVE RULES  
FILED WITH THE LEGISLATIVE REFERENCE SERVICE  
JERRY L. BASSETT, DIRECTOR

(Pursuant to Code of Alabama, 1975, §41-22-6, as amended.)

I certify that the attached is/are correct copies of rule/s as promulgated and adopted on the 15th of October 2014, and filed with the agency secretary on the 20th day of October 2014.

AGENCY NAME: Alabama Department of Public Health

xxx Amendment      \_\_\_\_\_ New      \_\_\_\_\_ Repeal

Rule No.: 420-7-2-.12

Rule Title: Prescription Drug Monitoring Program Reporting to Database by Dispensers

ACTION TAKEN: Rule was adopted with changes from proposal.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME **XXXII**, ISSUE NO. 11,  
DATED **AUGUST 29, 2014**.

STATUTORY RULE MAKING AUTHORITY: Code of Alabama, 1975, §22-20-5.



Certifying Officer  
Pat Ivie

NOTE: In accordance with Code of Alabama, 1975, §41-22-6(b), as amended, a proposed rule is required to be certified within 90 days after completion of notice.

REC'D & FILED  
OCT 20 2014  
LEGISLATIVE REFERENCE SERVICE

420-7-2-.12 Prescription Drug Monitoring Program Reporting to Database by Dispensers

(1) Entities and practitioners that dispense controlled substances, Class II-V, shall report controlled substances prescription information to the Prescription Drug Monitoring Program database. These entities and practitioners include but are not limited to:

(a) Licensed pharmacies;

(b) Mail order pharmacies or pharmacy benefit programs filling prescriptions for or dispensing controlled substances to residents of Alabama; and

(c) Licensed physicians, dentists, podiatrists, optometrists, and veterinarians who dispense controlled substances.

(2) The reporting requirement in this rule does not apply to a controlled substance dispensed:

(a) By a pharmacy of a hospital, nursing home, or other inpatient health care facility if administered and used by a patient on the facility's premises;

(b) By a practitioner if administered during the course of a patient's treatment by injection, topical application, suppository administration, or oral administration; or

(c) By a practitioner as an appropriately labeled sample medication.

(3) Entities and practitioners shall submit reports as follows:

(a) Entities and nonveterinary practitioners shall submit reports at least once daily by 11:59 p.m.

1. If an entity or practitioner does not dispense a controlled substance on a specific day, the entity or practitioner shall report that zero controlled substances were dispensed.

2. The daily reporting requirement does not apply on days that the entity or practitioner's business is closed and no controlled substances are dispensed.

(b) Veterinary practitioners shall submit reports at least once monthly by 11:59 p.m. on the last business day of the month. If a veterinary practitioner does not dispense a controlled substance in a specific month, the veterinary practitioner shall report that zero controlled substances were dispensed.

(c) Reports must be in electronic format according to American Society for Automation in Pharmacy Standards using the U.S. Postal Service's Postal Addressing Standards.

1. If electronic transmission is not feasible, an entity or practitioner may request a waiver.

2. An entity or practitioner who receives a waiver may submit prescription information in an alternate format approved by the Prescription Drug Monitoring Program.

3. Entities and practitioners shall submit waiver requests and reports formatted pursuant to a valid waiver to:

Alabama Department of Public Health  
Prescription Drug Monitoring Program  
The RSA Tower, Suite 1010  
P.O. Box 303017  
Montgomery, AL 36130-3017  
Fax: (334) 206-5663

4. Penalties for noncompliance/non-reporting:

(a) On a monthly basis or as designated by the Prescription Drug Monitoring Program, licensing boards shall supply an electronic listing to the Prescription Drug Monitoring Program of entities and practitioners required to report controlled substances.

(b) The Prescription Drug Monitoring Program will monitor the list of entities and practitioners provided by the licensing boards for compliance in reporting to the database.

(c) The Department will notify the appropriate licensing board of an entity or practitioner's failure to report. Upon notification of a non-reporting entity or practitioner, the relevant licensing board shall investigate and report to the Department the outcome.

**Author:** Charles C. Thomas, R. Ph., State Pharmacy Director

**Statutory Authority:** Code of Ala. 1975, §22-21-20, et. seq.

**History: New Rule:** Filed October 20, 2005; effective November 24, 2005. **Amended:** Filed February 17, 2006; effective March 24, 2006. **Amended:** Filed October 20, 2014; effective November 24, 2014.

420-7-2-.12 Prescription Drug Monitoring Program Reporting to Database by Dispensers

(1) ~~All entities~~ Entities and practitioners that dispense controlled substances, Class II-V, are required to shall report controlled substances prescription information to the Prescription Drug Monitoring Program database. These entities and practitioners include but are not limited to:

(a) ~~Licensed community, ambulatory, hospital outpatient, and medicinal oxygen~~ pharmacies;

(b) Mail order pharmacies or pharmacy benefit programs filling prescriptions for or dispensing controlled substances to residents of Alabama; and

(c) Licensed physicians, dentists, podiatrists, optometrists, ~~or~~ and veterinarians who dispense controlled substances ~~other than samples directly to patients.~~

(2) The reporting requirement in this rule does not apply to a controlled substance dispensed:

(a) By a pharmacy of a hospital, nursing home, or other inpatient health care facility if administered and used by a patient on the facility's premises;

(b) By a practitioner if administered during the course of a patient's treatment by injection, topical application, suppository administration, or oral administration; or

(c) By a practitioner as an appropriately labeled sample medication.

~~(2 3) Submission shall be made~~ Entities and practitioners shall submit reports as follows: in the following manner:

~~(a) All dispensers will report at~~ Entities and nonveterinary practitioners shall submit reports at least once weekly daily by 11:59 p.m. by the Board of Pharmacy

1. If an entity or practitioner does not dispense a controlled substance on a specific day, the entity or practitioner shall report that zero controlled substances were dispensed.

2. The daily reporting requirement does not apply on days that the entity or practitioner's business is closed and no controlled substances are dispensed. Data elements will be submitted in a format to be specified by the Prescription Drug Monitoring Program. Dispensers will be notified by the Prescription Drug Monitoring Program of the proper procedures for data submission.

(b) Veterinary practitioners shall submit reports at least once monthly by 11:59 p.m. on the last business day of the month. If a veterinary practitioner does not dispense a controlled substance in a specific month, the veterinary practitioner shall report that zero controlled substances were dispensed.

~~(c) Dispensers must electronically report~~ Reports must be in electronic format according to American Society for Automation in Pharmacy (ASAP) Standards using the US U.S. Postal Service's Postal Addressing Standards.

~~(e) 1. In the event that the~~ If electronic transmission of the information is not feasible, the dispenser must request an entity or practitioner may request a waiver, in advance to

2. An entity or practitioner who receives a waiver may submit prescription information in an alternate format approved by the Prescription Drug Monitoring Program.

3. Waiver Entities and practitioners shall submit waiver requests and reports formatted pursuant to a valid waiver alternate formats must be submitted to:

Alabama Department of Public Health  
Prescription Drug Monitoring Program  
The RSA Tower, Suite 1010  
P.O. Box 303017  
Montgomery, AL 36130-3017  
Phone: (334)206-5226  
Fax: (334) 206-5663

~~(3) The following entities are not required to report dispensing of a controlled substance, so long as the controlled substance is administered and used by a patient on the premises of the facility:~~

~~(a) General and specialized hospitals;~~

~~(b) Nursing homes;~~

~~(c) Other health care facilities that provide inpatient care.~~

~~(4) The following drugs are not required to be reported:~~

~~(a) Sample medications;~~

~~(b) Controlled substances administered to patients by injection, topical application, suppository administration, or oral administration during the course of treatment on the premises.~~

~~(5) Penalties for noncompliance/non-reporting:~~

(a) Licensing On a monthly basis or as designated by the Prescription Drug Monitoring Program, licensing boards shall supply an electronic listing to the Prescription Drug Monitoring Program of dispensers entities and practitioners required to report controlled substances on a monthly basis or as designated by the Prescription Drug Monitoring Program.

(b) The Prescription Drug Database Monitoring Program will monitor the list of ~~dispensers~~ entities and practitioners provided by the licensing boards for compliance in reporting to the database.

(c) ~~The Alabama Department of Public Health will~~ The Department will notify each the appropriate licensing board ~~in writing twice yearly on January 30 and July 30 of the~~ of an entity or practitioner's failure to report to the Database. Upon notification of a non-reporting ~~dispensers~~ entity or practitioner, each the relevant licensing board ~~will~~ shall investigate and report to the ~~Alabama Department of Public Health~~ the outcome.