

APA-1
6/93

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Department or Agency Alabama Department of Public Health

Rule Number 420-7-2-.12

Rule Title Prescription Drug Monitoring Program Reporting to the Database By Dispensers

 New XXX Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety? No

Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? N/A

Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public? Yes

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of Certifying Officer P. B. Helo Date 6/13/16



FORM APA2
11/96

STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-7-2-.12, Prescription Drug Monitoring Program Reporting to Database By Dispensers

INTENDED ACTION: Amendment to Rule 420-7-2-.12

SUBSTANCE OF PROPOSED ACTION: To amend current rule to remove veterinaries from reporting to the Prescription Drug Monitoring Database as specified in Code of Alabama, 1975 §20-2-213 (3).

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held on July 29, 2016, at 9:00 a.m., 201 Monroe Street, Suite 1540, Montgomery, Alabama 36104.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on August 4, 2016. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Nancy Bishop, R.Ph., Pharmacy Director, Department of Public Health, 201 Monroe Street, Suite 1010, Montgomery, Alabama 36104. Telephone number (334) 206-3014.



P. Brian Hale, Agency Secretary

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, and 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.~~

~~(e)~~(b) 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: Nancy Bishop, 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.