

APA-1
11/96

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Alabama Department of Public Health

Rule Number 420-7-2-.12

Rule Title Prescription Drug Monitoring Program Reporting to 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? Yes

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 Patricia Sine Date 8/20/2014

**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 Reporting to Database by Dispensers

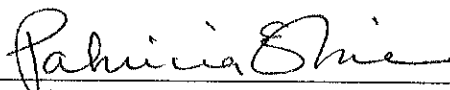
INTENDED ACTION: Amendment to Rule 420-7-2-.12.

SUBSTANCE OF PROPOSED ACTION: This update will reflect changes that clarify who should report to the database, and requirements to update reporting period to a daily basis.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held at 9:00 a.m. on September 12, 2014, at the Alabama Department of Public Health, RSA Tower, Suite 1540, 201 Monroe Street, Montgomery, AL 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 October 05, 2014. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Charlie Thomas, State Pharmacy Director, Department of Public Health, 201 Monroe Street, Suite 1010, Montgomery, Alabama 36104. Telephone number (334) 206-5666.



Patricia E. Ivie, Agency Secretary

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

~~(a) All dispensers will report at~~ At least once weekly ~~daily~~ 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) 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) 4) 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.