

TRANSMITTAL SHEET FOR  
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners

Rule No. 540-X-4-.02

Rule Title: Limitation on Zohydro ER

New  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? NO

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

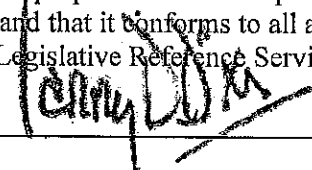
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Does the proposed rule have an economic impact? NO

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 Section 41-22-23, Code of Alabama 1975.

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Certification of Authorized Official

I certify that the attached proposed rule has been proposed 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 

Date: May 22, 2014

**ALABAMA STATE BOARD  
OF MEDICAL EXAMINERS**

**NOTICE OF INTENDED ACTION**

**AGENCY NAME:** Alabama State Board of Medical Examiners

**RULE NO. & TITLE:** 540-X-4-.02, Limitation on Zohydro ER

**INTENDED ACTION:** To propose a new rule

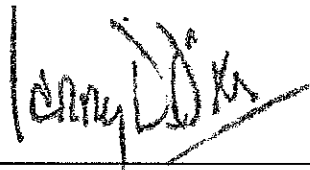
**SUBSTANCE OF PROPOSED ACTION:** To propose a new rule (and renumber remaining sections) providing that specific requirements be met before Zohydro ER can be ordered, administered, dispensed or prescribed in the state of Alabama by a licensed physician.

**TIME, PLACE, MANNER OF PRESENTING VIEWS:** All interested persons may submit data, views, or arguments, orally or in writing, concerning the proposed new rules. For written submissions, submit to: Patricia E. Shaner, Office of General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, 848 Washington Avenue (36104), Montgomery, Alabama 36101-0946, by mail or in person between the hours of 8:30 a.m. and 4:30 p.m., Monday through Friday, until and including Friday, August 5, 2014.

**For oral submissions, a public hearing to receive oral comments concerning the proposed rules is scheduled on Thursday, July 17, 2014, at 2:00 p.m., CDT, at the offices of the Board of Medical Examiners, 848 Washington Avenue, Montgomery AL 36104.** Persons wishing to obtain copies of the text of this rule should contact Patricia E. Shaner, Office of General Counsel, (334-242-4116), PO Box 946, 848 Washington Avenue (36104), Montgomery, Alabama 36101-0946, email [ckruger@albme.org](mailto:ckruger@albme.org), or obtain it from the Board's web site, [www.albme.org/rules](http://www.albme.org/rules).

**FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:** August 5, 2014

**CONTACT PERSON AT AGENCY:** Patricia E. Shaner, Esq.



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Larry D. Dixon, Executive Director

NEW

540-X-4-.02 Limitation on Zohydro ER.

(1) Before Zohydro ER can be ordered, administered, dispensed or prescribed in the state of Alabama by a licensed physician, the following requirements shall be met:

(a) The physician shall hold a valid and current Alabama Controlled Substances Certificate which authorizes the prescribing, ordering, administering or dispensing of Schedule II controlled substances.

(b) The physician shall have taken and completed a Risk Evaluation and Mitigation Strategy (REMS) course specific to Zohydro ER offered by the Alabama Board of Medical Examiners.

(c) The physician and patient shall have entered into a pain management treatment agreement which includes, but is not limited to, the requirement of drug screening and monitoring of the number of pills prescribed.

(d) For each office visit when a prescription for Zohydro ER is issued to a patient, the physician shall access the Alabama Department of Public Health Prescription Drug Monitoring Data Bank.

(e) Zohydro ER may not be purchased, obtained, maintained or ordered as stock supply or inventory and may not be dispensed as that term is used in Board of Medical Examiners Administrative Rules, Chapter 540-X-19, Standards for Pain Management Services.

**Author:** Alabama Board of Medical Examiners

**Statutory Authority:** Code of Alabama 1975, §§ 20-2-50, 20-2-51, 20-2-52, 20-2-54.1.

**History:** Adopted/Approved for Publication: May 22, 2014.