APA-1
6/93

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-17-.05
Rule Title: Continued Use of a Controlled Substance for the Purpose of Weight Reduction or Treatment of Obesity
____ New _X_ 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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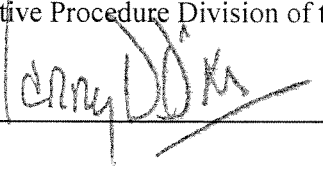
Certification of Authorized Official

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: January 18, 2013

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6/93

ALABAMA STATE BOARD
OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State Board of Medical Examiners

RULE NO. & TITLE: 540-X-17-.05, Continued Use of a Controlled Substance for the Purpose of Weight Reduction or Treatment of Obesity

INTENDED ACTION: To amend the rule

SUBSTANCE OF PROPOSED ACTION: To amend the rule to provide for refills of the weight loss drug Qsymia™

TIME, PLACE, MANNER OF PRESENTING VIEWS: All interested persons may submit data, views, or arguments concerning the proposed new rule(s) and regulation(s) in writing to: Patricia E. Shaner, General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, 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 Thursday, March 7, 2013. Persons wishing to obtain copies of the text of this rule and submit data, views, or comments or arguments orally should contact Patricia E. Shaner, by telephone (334-242-4116) during said period in order to set up an appointment for a hearing respecting such oral data, views, or arguments. The rule amendment will also be available at the Board's web site, www.albme.org.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: March 7, 2013

CONTACT PERSON AT AGENCY: Patricia E. Shaner

Larry D. Dixon, Executive Director

540-X-17-.05 Continued Use of a Controlled Substance for the Purpose of Weight Reduction or Treatment of Obesity.

(1) A physician should not prescribe, order or dispense a controlled substance for the purpose of weight reduction or treatment of obesity in an amount greater than a thirty-five (35) day supply.

(2) Within the first thirty-five (35) days following initiation of a controlled substance for the purpose of weight reduction or treatment of obesity, the patient should be seen by the prescribing physician, a physician assistant supervised by the prescribing physician, or a certified registered nurse practitioner collaborating with the prescribing physician, and a recording should be made of weight, blood pressure, pulse, and any other tests which may be necessary for monitoring potential adverse effects of drug therapy.

(3) Continuation of the prescribing, ordering, dispensing or administering of a controlled substance to a patient for the purpose of weight reduction or treatment of obesity should occur only if the patient has continued progress toward achieving or maintaining medically established goals and has no significant adverse effects from the medication.

(4) A patient continued on a controlled substance for the purpose of weight reduction or treatment of obesity should undergo an in-person re-evaluation at least once every thirty-five (35) days. Once medically established goals have been met for an individual patient, it is strongly recommended that reduced dosing and drug holidays be implemented for those patients who need maintenance medication.

(5) If the re-evaluation is delegated to a physician assistant or certified

registered nurse practitioner, then the prescribing physician should personally review the resulting medical records prior to the continuance of the patient on a controlled substance for the purpose of weight reduction or treatment of obesity.

(6) For the prescribing of only the drug, Qsymia(TM), the following applies:

(a) Refills of Qsymia(TM) are allowed after an initial Qsymia(TM) prescription and one follow up visit for an in-person re-evaluation.

(b) Continued prescribing/refills of Qsymia(TM) must be in accordance with the Risk Evaluation and Mitigation Strategy (REMS) required by the Federal Food and Drug Administration (FDA) for Qsymia(TM).

(c) Refills allowed pursuant to this rule are specific for the brand name drug Qsymia(TM), and refills are not allowed for generic substitutes or for individual prescriptions of phentermine or for individual prescriptions of topiramate.

Authors: Alabama Board of Medical Examiners
Statutory Authority: Code of Alabama § 34-24-53
History: Approved for publication: October 19, 2011. Effective Date: January 20, 2012. Amended/approved for publication: January 16, 2013.