

APA-2
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 allow refills for topiramate.

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, April 4, 2016. 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: April 4, 2016

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 drugs, Qsymia(TM) and Belviq®, the following applies:

(a) Refills of Qsymia(TM) and Belviq® are allowed after an initial Qsymia(TM) or Belviq® prescription and one follow up visit for an in-person re-evaluation. For Qsymia(TM) and Belviq®, five (5) refills are allowed. The five (5) refills shall not extend past a period of six (6) months from the date of issue of the original prescription.

(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 drugs Qsymia(TM) and Belviq®, 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. Effective Date: April 25, 2013. Amended/approved for publication: January 15, 2014. Further amended/approved for publication: April 16, 2014. Further amended/approved for publication: May 22, 2014. Effective Date: September 25, 2014. Amended/approved for publication: February 17, 2016