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TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners

Rule No. 540-X-17

Rule Title: Guidelines and Standards for the Utilization of Controlled Substances for Weight Reduction

X 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

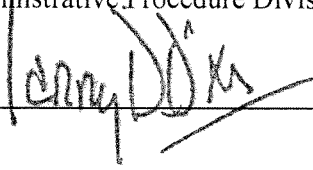
Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

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.

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: October 20, 2011

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**ALABAMA STATE BOARD
OF MEDICAL EXAMINERS**

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State Board of Medical Examiners

RULE NO. & TITLE: 540-X-17, Guidelines and Standards for the Utilization of
Controlled Substances for Weight Reduction

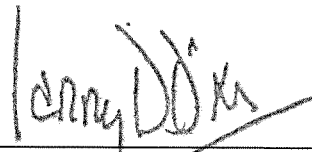
INTENDED ACTION: To add a new Chapter

SUBSTANCE OF PROPOSED ACTION: To add a new Chapter of Rules providing guidelines
and standards for the utilization of controlled substances for weight reduction

TIME, PLACE, MANNER OF PRESENTING VIEWS: A public hearing will be held on
Thursday, December 1, 2011, at 2:00 p.m., CST, at the offices of
the Board of Medical Examiners, 848 Washington Avenue,
Montgomery, AL 36104

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: Written or oral comments
will be received until the close of the record at 5:00 p.m.,
December 5, 2011. All comments and requests for copies of the
proposed rules should be addressed to the contact person listed
below

CONTACT PERSON AT AGENCY: Patricia E. Shaner, Office of General Counsel,
334-242-4116; PO Box 946, Montgomery, AL 36101-0946; 848
Washington Avenue, Montgomery, AL 36104



Larry D. Dixon, Executive Director

RULES OF THE
ALABAMA BOARD OF MEDICAL EXAMINERS

GUIDELINES AND STANDARDS FOR THE UTILIZATION OF
CONTROLLED SUBSTANCES FOR WEIGHT REDUCTION

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540-X-17-.01 Preamble.

(1) The purpose of these rules is to provide guidelines, and in some instances standards, for licensed medical doctors (M. D.s) and doctors of osteopathy (D. O.s) who determine that the use of a controlled substance as an adjunct for a weight reduction regimen is medically appropriate for a patient.

(2) The Board of Medical Examiners is obligated under the laws of the state of Alabama to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including those used for the purpose of weight reduction, may lead to drug diversion and abuse by individuals who seek drugs for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(3) Prescribing or dispensing a controlled substance for weight reduction or the treatment of obesity should be based on accepted scientific knowledge and sound

clinical grounds. All such prescribing and dispensing should be in compliance with applicable state and federal law.

(4) Each case of prescribing or dispensing a controlled substance for weight reduction or the treatment of obesity will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines and standards, if good cause is shown for such deviation. Whether the drug used is medically and/or pharmacologically recognized to be appropriate for the patient's individual needs will be considered by the Board in evaluating individual cases. The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 20-2-54, 34-24-53, 34-24-360

History: Approved for publication: October 19, 2011.

540-X-17-.02 Schedule II Controlled Substances. A physician shall not order, prescribe, dispense, supply, administer or otherwise distribute any Schedule II amphetamine or Schedule II amphetamine-like anorectic drug, or Schedule II sympathomimetic amine drug or compound thereof or any salt, compound, isomer, derivative or preparation of the foregoing which is chemically equivalent thereto or other non-narcotic Schedule II stimulant drug, which drugs or compounds are classified under Schedule II of the Alabama Uniform Controlled Substances Act, to any person for the purpose of weight control, weight loss, weight reduction or treatment of obesity.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §§ 20-2-54, 34-24-53, 34-24-360

History: Approved for publication: October 19, 2011.

540-X-17-.03 Schedule III, IV and V Controlled Substances.

(1) Only a doctor of medicine or doctor of osteopathy licensed by the Medical Licensure Commission of Alabama may order, prescribe, dispense, supply, administer or otherwise distribute a controlled substance in Schedule III, IV or V to a person for the purpose of weight control, weight loss, weight reduction or treatment of obesity.

(2) A written prescription or a written order for any controlled substance for a patient for the purpose of weight reduction or treatment of obesity shall be signed by the prescribing physician on the date the medication is to be dispensed or the prescription is provided to the patient. If an electronic prescription is issued for any controlled substance for a patient for the purpose of weight reduction or treatment of obesity, the prescribing physician must sign and authorize the transmission of the electronic controlled substance prescription in accordance with federal law and must comply with all applicable requirements for Electronic Prescriptions for Controlled Substances (See 21 CFR Parts 1300, 1304, 1306 and 1311, as amended effective June 1, 2010). Such prescriptions or orders shall not be called in to a pharmacy by the physician or an agent of the physician.

(3) The prescribing/ordering physician shall be present at the facility when he or she prescribes, orders or dispenses a controlled substance for a patient for the purpose of weight reduction or treatment of obesity.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 34-24-53

History: Approved for publication: October 19, 2011.

540-X-17-.04 Initial Requirements.

(1) Before initiating treatment for weight reduction or obesity utilizing any Schedule III, IV or V controlled substance, a physician should comply with the following:

(a) An initial evaluation of the patient should be conducted by and recorded by the prescribing physician prior to the prescribing, ordering, dispensing or administering of any drug. Such evaluation should include an appropriate physical and complete history; appropriate tests related to medical treatment for weight reduction; and appropriate medical referrals as indicated by the physical, history, and testing; all in accordance with general medical standards of care. Relative contraindications to the use of anorectic drugs should be addressed prior to prescribing or dispensing these medications.

(b) The patient should have a Body Mass Index (BMI) of 30 or above, or a BMI of greater than 25 with at least one comorbidity factor, or a measurable body fat content equal to or greater than 25% of total body weight for male patients or 30% of body weight for female patients, or an abdominal girth of at least 40 inches for male patients or an abdominal girth of at least 35 inches for women. BMI is calculated by use of the formula $BMI = \text{kg}/\text{m}^2$.

(c) The prescribing physician should assess and document the patient's freedom from signs of drug or alcohol abuse and the presence or absence of contraindications and adverse side effects.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 34-24-53

History: Approved for publication: October 19, 2011.

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.

Authors: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 34-24-53

History: Approved for publication: October 19, 2011.

540-X-17-.06 Medical Records.

(1) Every physician who prescribes, orders, dispenses or administers a controlled substance to a patient for the purpose of weight reduction or treatment of obesity should maintain medical records in compliance with the provisions of this Chapter and Medical Licensure Commission Rule 545-X-4-.09, Minimum Standards for Medical Records.

(2) The treatment of obesity should be based on evidence based medicine.¹ Adequate medical documentation should be kept so that progress as well as the success or failure of any modality is easily ascertained.

(3) At a minimum, every thirty-five (35) days when a controlled substance is being provided to a patient for the purpose of weight reduction or treatment of obesity, the physician or PA or CRNP should record in the patient record, information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of

¹An example of evidence based medicine would include the Bariatric Practice Guidelines as established by the American Society of Bariatric Physicians and which can be found on the website www.ASBP.org.

contraindications, adverse effects and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 34-24-53

History: Approved for publication: October 19, 2011.

540-X-17-.07 Conditions Warranting Discontinuance of a Controlled Substance.

(1) A physician should not initiate or should discontinue utilizing a controlled substance for the purpose of weight reduction or treatment of obesity of a patient immediately upon ascertaining or having reason to believe:

(a) That the patient has failed to progress toward medically established goals while under treatment with the controlled substance over a period of seventy (70) days, which determination should be made by assessing the patient with regard to previously established goals at least every thirty-five (35) days.

(b) That the patient has developed tolerance to the anorectic effects of the controlled substance being utilized.

(c) That the patient has a history of or shows a propensity for alcohol or drug abuse or has made any false or misleading statement to the physician or PA or CRNP relating to the patient's use of drugs or alcohol.

(d) That the patient has consumed or disposed of a controlled substance other than in compliance with the treating physician's directions.

(e) That the patient has repeatedly failed to comply with the physician's treatment recommendations.

(f) That the patient is pregnant.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 34-24-53

History: Approved for publication: October 19, 2011.