

ARKANSAS REGISTER

Transmittal Sheet

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For Office
Use Only:

Effective Date _____ Code Number _____

Name of Agency Arkansas State Medical Board

Department _____

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Statutory Authority for Promulgating Rules ACA §17-95-303(2)

Rule Title: An Amendment to Regulation 21 Governing Anorexiant Drug Guidelines

Intended Effective Date
(Check One)

- Emergency (ACA 25-15-204)
- 10 Days After Filing (ACA 25-15-204)
- Other _____
(Must be more than 10 days after filing date.)

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Electronic Copy of Rule e-mailed from: (Required under ACA 25-15-218)

Kevin M. O'Dwyer kodwyer@htolaw.com 12/2/15
Contact Person E-mail Address Date

CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted
In Compliance with the Arkansas Administrative Act. (ACA 25-15-201 et. seq.)

Signature

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Phone Number E-mail Address

Executive Secretary, Arkansas State Medical Board
Title

12-2-15
Date

AMENDED REGULATION

REGULATION NO. 21: ANOREXIANT DRUG GUIDELINES

Short term treatment of obesity with Schedule III and IV drugs.

A physician will be considered as exhibiting gross negligence or ignorant malpractice if he prescribes Schedule III and IV scheduled drugs under the Uniform Controlled Substance Act for obesity, except in conformity with the requirements as set below:

1. Anorexiant drugs listed on Schedule III and IV under the Uniform Controlled Substances Act shall not be dispensed or prescribed for the treatment of obesity, except in conformity with the following minimal requirements. Schedule II drugs may not be used in the treatment of obesity (see Regulation 7 of the Arkansas State Medical Board.)
2. The physician should be knowledgeable in the pathophysiology and treatment of obesity. An established physician/patient relationship should exist. The patient should be age 18 or older, or have written consent from parent or guardian. The medication should only be an adjunct to a comprehensive weight loss program focused on appropriate nutrition education, a change in lifestyle, counseling, and an individualized exercise program. The physician should determine whether or not the patient has made a substantial good faith effort to lose weight through diet and alteration of lifestyle prior to beginning drug therapy. The treating physician shall take a complete history of the patient and shall give a complete physical examination. The physical examination shall include checking the blood pressure and pulse, examining the heart and lungs, recording weight and height, and administering any other appropriate diagnostic tests. The history and examination shall be sufficient to determine if the patient has previously been drug dependent, to determine if there is a metabolic cause of the obesity which would make anorexiant drugs inappropriate (e.g. hypothyroidism) and to determine if other contraindications to use of the drugs exist. The treating physician shall enter each of those findings in the patient's records.
3. The physician should discuss with the patient different approaches to the treatment of obesity, and the risks and benefits associated with each approach. Risks should include potential side effects (e.g. cardiovascular and pulmonary complications, as outlined in the package insert), as well as the potential for lack of success with weight loss. The physician should be aware of potential drug interactions between anorexiants, and other centrally acting drugs. The treating physician shall prescribe a diet for weight loss and appropriate counseling regarding lifestyle change, and record these changes on the patient record. Consideration on the use of anorexiant medications should take into account the degree of overweight, and concomitant medical conditions. The body mass index (BMI) should be used as a guide to determine the degree of overweight. The BMI is defined as the weight (kg) divided by the height (meters squared). A chart to determine BMI is enclosed. In general, anorexiant medication should only be used if the BMI is more than 27. In the case of concomitant obesity-related medical conditions, anorexiant medications may be considered with a BMI above 25. Obesity related medical conditions include diabetes, hypertension, dyslipidemia, cardiovascular disease, sleep apnea, psychological conditions, disc disease and severe arthritis of the lower extremities.
4. The treating physician shall prescribe a daily dosage that does not exceed the dosage recommended in the manufacturer's prescribing information for the drug prescribed or dispensed, unless peer reviewed medical literature exists in support of this cause.

5. The treating physician shall not dispense or prescribe more than a 30-day supply for a patient on the first visit. The patient shall be weighed at each visit prior to dispensing or prescribing an additional supply of the drug and the weight shall be entered in the patient's record.
6. At the time of each return patient visit, the treating physician shall monitor progress of the patient. The patient's weight, blood pressure, pulse, heart and lungs shall be checked. The findings shall be entered in the patient's record. In addition to any side effects of the medications, the physician should perform appropriate exams and tests to monitor the safety of any weight loss. This may include a more detailed dietary questionnaire, serum electrolytes, blood glucose, and other tests deemed appropriate. The Rule and Regulation for patients who are no longer obese for such period of time as to allow the patient to adapt to a lifestyle change for no more than an additional sixty (60) days.
7. Except as otherwise provided by this regulation, Schedule III or IV anorexiants are only recommended for short-term use (e.g. 90 days). However, the treating physician may extend therapy beyond 90 days under the following conditions:
 - a. When the anorexiants are indicated for treatment of diseases other than obesity; and
 - b. When, in the physician's professional judgment, the treating physician is observing and recording significant progress or benefit from the drugs and no adverse effects occur that are related to the treatment. These observations shall be documented in the patient's record.
 - c. When the drug involved has been FDA approved for longer use or maintenance.
8. Specialty clinics which market themselves to the public as centers for the treatment of obesity will be required to prescribe a comprehensive behavior modification program and dietary counseling directed by a professional during the course of treatment.
9. The board encourages any physician who prescribes medications pursuant to Regulation 21 to make themselves fully aware of the guidelines set forth by the American Heart Association for the management of obesity.