AMENDMENT MARK-UP

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 ~~PDR~~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. ~~Thereafter, not more than a 30-day supply shall be dispensed or prescribed at the time of each 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 physician should discontinue the anorexiant medications when the patient reaches his/her weight loss goals. These goals may be defined as a body weight that is no longer "obese" (e.g. BMI of less than or equal to 27), or an improvement in medical conditions (e.g. normalization of blood glucose.)~~ 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 anorexiant drugs are only recommended for short-term use (e.g. 90 days). ~~In addition, anorexiant drugs should not be prescribed to a patient with a BMI of less than 27.~~ However, the treating physician may extend therapy beyond 90 days under the following conditions:

   a. When the anorexiant drugs 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.

History: Adopted March 13, 1998

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE

DEPARTMENT/AGENCY Arkansas State Medical Board

DIVISION

DIVISION DIRECTOR Peggy Pryor Cryer, Executive Secretary

CONTACT PERSON Kevin M. O'Dwyer, Attorney

ADDRESS 211 S. Spring Street, Little Rock, AR 72201

PHONE NO. 501-372-4144 **FAX NO.** 501-372-7480 **E-MAIL** kodwyer@htolaw.com

NAME OF PRESENTER AT COMMITTEE MEETING Kevin M. O'Dwyer

PRESENTER E-MAIL

INSTRUCTIONS

A. Please make copies of this form for future use.
B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.
C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

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1. What is the short title of this rule? Amendment to Regulation 21, Governing Short Term Treatment of Obesity

2. What is the subject of the proposed rule? An amendment to update Regulation due to changes in the prescriptions now available to weight loss

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ☐ No ☒
   If yes, please provide the federal rule, regulation, and/or statute citation.

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes ☐ No ☒
   If yes, what is the effective date of the emergency rule? N/A

   When does the emergency rule expire? N/A

   Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes ☐ No ☒

5. Is this a new rule? Yes ☐ No ☒
If yes, please provide a brief summary explaining the regulation. _____

Does this repeal an existing rule? Yes ☐ No ☒
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. _____

Is this an amendment to an existing rule? Yes ☒ No ☐
If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. §17-95-303 (2)

7. What is the purpose of this proposed rule? Why is it necessary? There have been changes in weight loss prescriptions that are available

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b). www.armedicalboard.org

9. Will a public hearing be held on this proposed rule? Yes ☒ No ☐
If yes, please complete the following:

Date: 6 August 2015

Time: 8:45 a.m.

Place: Offices of the Arkansas State Medical Board, 1401 W. Capitol Ave. Suite 340, Little Rock AR 72201

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
6 August 2015

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
1 September 2015

12. Do you expect this rule to be controversial? Yes ☐ No ☒
If yes, please explain. _____

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.
Arkansas Medical Society; Arkansas Osteopathic Association

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas State Medical Board
DIVISION
PERSON COMPLETING THIS STATEMENT Kevin M. O'Dwyer, Attorney
TELEPHONE NO. 501-372-4144 **FAX NO.** 501-372-7480 **EMAIL:** kodwyer@htolaw.com

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Amendment to Regulation 21, Governing Short Term Treatment of Obesity

1. Does this proposed, amended, or repealed rule have a financial impact? Yes ☐ No ☒

2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule? Yes ☒ No ☐

3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes ☒ No ☐

   If an agency is proposing a more costly rule, please state the following:

   (a) How the additional benefits of the more costly rule justify its additional cost;
   N/A

   (b) The reason for adoption of the more costly rule;
   N/A

   (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;
   N/A

   (d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.
   N/A

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

   (a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	N/A	General Revenue	N/A
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	

Total _____ Total _____

(b) What is the additional cost of the state rule?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	N/A	General Revenue	N/A
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total		Total	

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year	**Next Fiscal Year**
$ _____	$ _____

N/A

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year	**Next Fiscal Year**
$ _____	$ _____

N/A

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars ($100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes ☐ No ☒

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

(1) a statement of the rule's basis and purpose;

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

(3) a description of the factual evidence that:
(a) justifies the agency's need for the proposed rule; and

(b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

(4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

(7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:

(a) the rule is achieving the statutory objectives;
(b) the benefits of the rule continue to justify its costs; and
(c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.