Mississippi Secretary of State
125 South Congress St., P. O. Box 136, Jackson, MS 39205-0136

ADMINISTRATIVE PROCEDURES NOTICE FILING

AGENCY NAME		CONTACT PERSON	TELEPHONE NUMBER	
Mississippi State Board of Medical Licensure		Jonathan Dalton	601-987-3079	
ADDRESS		CITY	STATE	ZIP
1867 Crane Ridge Drive, Suite 200-B		Jackson	MS	39216
EMAIL	SUBMIT DATE	Name or number of rule(s):		
mboard@msbml.ms.gov	4/7/2023	30 Miss. Admin. Code, Pt. 2640 R. 1.5 *Use of Diet Medication*		

Short explanation of rule/amendment/repeal and reason(s) for proposing rule/amendment/repeal: Proposed revision of the regulations regarding the use of diet medications. The change allows the Board to waive FDA requirements for good cause.

Specific legal authority authorizing the promulgation of rule: Miss. Code Ann., §73-43-11

List all rules repealed, amended, or suspended by the proposed rule: Rule 1.5

ORAL PROCEEDING:

☐ An oral proceeding is scheduled for this rule on Date: _____ Time: _____ Place: _____

☒ Presently, an oral proceeding is not scheduled on this rule.

If an oral proceeding is not scheduled, an oral proceeding must be held if a written request for an oral proceeding is submitted by a political subdivision, an agency or ten (10) or more persons. The written request should be submitted to the agency contact person at the above address within twenty (20) days after the filing of this notice of proposed rule adoption and should include the name, address, email address, and telephone number of the person(s) making the request; and, if you are an agent or attorney, the name, address, email address, and telephone number of the party or parties you represent. At any time within the twenty-five (25) day public comment period, written submissions including arguments, data, and views on the proposed rule/amendment/repeal may be submitted to the filing agency.

ECONOMIC IMPACT STATEMENT:

☒ Economic impact statement not required for this rule. ☐ Concise summary of economic impact statement attached.

TEMPORARY RULES	PROPOSED ACTION ON RULES	FINAL ACTION ON RULES
_____ Original filing	**Action proposed:**	**Date Proposed Rule Filed:** _____
_____ Renewal of effectiveness	_____ New rule(s)	**Action taken:**
To be in effect in _____ days	__X__ Amendment to existing rule(s)	_____ Adopted with no changes in text
Effective date:	_____ Repeal of existing rule(s)	_____ Adopted with changes
_____ Immediately upon filing	_____ Adoption by reference	_____ Adopted by reference
_____ Other (specify): _____	**Proposed final effective date:**	_____ Withdrawn
	__X__ 30 days after filing	_____ Repeal adopted as proposed
	_____ Other (specify): _____	**Effective date:**
		_____ 30 days after filing
		_____ Other (specify): _____

Printed name and Title of person authorized to file rules: Jonathan Dalton, Director of Investigations

Signature of person authorized to file rules: Jonathan Dalton

OFFICIAL FILING STAMP	DO NOT WRITE BELOW THIS LINE OFFICIAL FILING STAMP	OFFICIAL FILING STAMP
	FILED APR 07 2023 MISSISSIPPI SECRETARY OF STATE	
Accepted for filing by	**Accepted for filing by** 26848	**Accepted for filing by**

The entire text of the Proposed Rule including the text of any rule being amended or changed is attached.

Rule 1.5 Use of Diet Medication.

Pursuant to Mississippi Code, Section 41-29-139(e), it is unlawful for any licensee to prescribe, dispense or administer any medication classified as Schedule II, pursuant to Section 41-29-115, for the exclusive treatment of obesity, weight control, or weight loss.

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 must be in compliance with applicable state and federal laws.

The licensee providing comprehensive treatment of obesity must be present at the facility when he or she prescribes or dispenses[1] controlled substances for the purpose of weight reduction or the treatment of obesity. A licensee may administer, order, dispense or prescribe controlled substances for the purpose of weight loss or the treatment of obesity only as an adjunct to a clearly documented comprehensive program of behavior modification, comprehensive nutritional education, and exercise or physical therapy intervention. The licensee must comply with all of the following conditions:

A. An initial comprehensive evaluation is to be conducted by and thoroughly recorded by the prescribing licensee prior to the prescribing, ordering, dispensing or administering of any drug. Such evaluation should include a thorough history and thorough physical exam of the patient to include at a minimum:
    1. Past medical history, past surgical history, social history, family history, weight history, dietary history, gynecological history, review of systems, allergies and medications.
    2. A physical exam to include height; weight; blood pressure; pulse; % body fat or waist circumference/weight hip ratio; lungs; heart; abdomen; and extremities.
    3. Appropriate testing related to medical weight loss (CBC, comprehensive metabolic profile, lipid panel, thyroid panel, EKG, if prior or present history of cardiac disease, hypertension, diabetes, dyslipidemia, or strong family history of cardiac disease age >60
    4. The licensee must determine and record the patient's Body Mass Index ("BMI"). No patient should receive anorexic medications unless the patient has (i) a BMI of ≥ 30.0 in a normal otherwise healthy patient, or (ii) a BMI ≥ 27.0 in an individual with at least one associated co-morbidity, or (iii) current body weight ≥ 120 percent of a well-documented, long standing healthy weight that the patient maintained after the age of 18, or (iv) body fat $\geq 30\%$ in females, or body fat $\geq 25\%$ in males, or (v)-waist-hip circumference such that the individual is known to be at increased cardiovascular and/or co-morbidity risk because of abdominal visceral fat, or presence of a co-morbidity condition or conditions aggravated by the patients excessive adiposity. The indication for anorexic therapy must be documented in the record and re-evaluated at each visit or with each prescription refill.
    5. Absolute contraindications of Schedule III or IV anorectic drugs for purposes of weight loss management are pregnancy, breast feeding, or severe allergic reactions to these medications. Relative contraindications of Schedule III and IV anorectics for the purpose of weight loss management are uncontrolled bipolar, uncontrolled epilepsy,

[1] Part 2640, Rule 1.9, controls in all cases. Physician assistants are not permitted to dispense medication.

uncontrolled hypertension, episodic tachyarrhythmia, excessive stimulation, history of substance abuse, severe anticholinergic effects, such as, extreme dryness of mouth or unmanageable constipation should be addressed with licensee prior to starting weight loss medications. Schedule III and IV anorectics can be used in conjunction with any other medications deemed safe by the licensee.

B. The licensee must not utilize any Schedules III, IV or V controlled substance when he or she knows or has reason to believe an absolute contraindication exists or relative contraindication exists that would be harmful to the patient.
C. A licensee is not permitted to prescribe, order, or dispense controlled substances for the purpose of weight reduction or treatment of obesity greater than a 30-day supply. Exempted from this requirement are those licensees defined in Rule 1.2(M) and those licensees treating patients resulting from a referral to those licensees defined in Rule 1.2(M).
D. A patient continued on a controlled substance for the purpose of weight reduction or the treatment of obesity must undergo an in-person re-evaluation once every 30 days; however, those licensees defined in Rule 1.2(M) may re-evaluate patients once every 90 days. A recording of weight, BMI, blood pressure, pulse, and/or any other test which may be necessary for monitoring potential adverse effects of drug therapy should be completed at each visit. Once medically established goals have been met for an individual patient, the need for ongoing medication should be re-evaluated and documented in the record.
E. Continuation of the prescribing, ordering, dispensing, or administering of controlled substances 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.
F. A licensee must not utilize a schedule III, IV or V controlled substance or legend drug for purposes of weight loss unless it has an FDA approved indication for this purpose and then only in accordance with all of the above enumerated conditions. The purpose of this rule is to prohibit the use of such drugs as diuretics and thyroid medications for the sole purpose of weight loss.

   Off-label use of any medication that does not have Food and Drug Administration approval for use in the treatment of weight loss is prohibited if administered solely for the purpose of weight loss. Thyroid hormone, diuretics, vitamin B12, B1, B2, B6, methionine, choline, inositol, chromium picolate, and human chorionic gonadotropin are examples of medications that may not be used in this manner. This prohibition does not apply to FDA categories of nutritional supplements sold without prescription.

   Licensees may request the Board waive the FDA requirements set forth in Rule 1.5(F) on a per-medication or class of medications basis, for good cause. Temporary waiver may be approved by the Executive Director until the request can be heard before the Board.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

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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 must be in compliance with applicable state and federal laws.

The licensee providing comprehensive treatment of obesity must be present at the facility when he or she prescribes or dispenses[2] controlled substances for the purpose of weight reduction or the treatment of obesity. A licensee may administer, order, dispense or prescribe controlled substances for the purpose of weight loss or the treatment of obesity only as an adjunct to a clearly documented comprehensive program of behavior modification, comprehensive nutritional education, and exercise or physical therapy intervention. The licensee must comply with all of the following conditions:

A. An initial comprehensive evaluation is to be conducted by and thoroughly recorded by the prescribing licensee prior to the prescribing, ordering, dispensing or administering of any drug. Such evaluation should include a thorough history and thorough physical exam of the patient to include at a minimum:
    1. Past medical history, past surgical history, social history, family history, weight history, dietary history, gynecological history, review of systems, allergies and medications.
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    3. Appropriate testing related to medical weight loss (CBC, comprehensive metabolic profile, lipid panel, thyroid panel, EKG, if prior or present history of cardiac disease, hypertension, diabetes, dyslipidemia, or strong family history of cardiac disease age >60
    4. The licensee must determine and record the patient's Body Mass Index ("BMI"). No patient should receive anorexic medications unless the patient has (i) a BMI of ≥ 30.0 in a normal otherwise healthy patient, or (ii) a BMI ≥ 27.0 in an individual with at least one associated co-morbidity, or (iii) current body weight ≥ 120 percent of a well-documented, long standing healthy weight that the patient maintained after the age of 18, or (iv) body fat $\geq 30\%$ in females, or body fat $\geq 25\%$ in males, or (v)-waist-hip circumference such that the individual is known to be at increased cardiovascular and/or co-morbidity risk because of abdominal visceral fat, or presence of a co-morbidity condition or conditions aggravated by the patients excessive adiposity. The indication for anorexic therapy must be documented in the record and re-evaluated at each visit or with each prescription refill.
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