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Sent Via Electronic Mail
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Paul Vazquez, Executive Director
Florida Board of Medicine
4052 Bald Cypress Way, Bin #C03
Tallahassee, Florida 32399-3253

Re: Comments on Rule Development Workshop Rule 64B8-9.012 (telemedicine and prescriptions for obesity drugs)

Dear Mr. Vazquez:

These comments are respectfully submitted in connection with the Board's forthcoming August 5, 2021 rule development workshop on telemedicine and obesity drugs.

Foley & Lardner's Telemedicine & Digital Health Industry Team has been at the forefront of providing strategic legal and regulatory advice to providers on the appropriate deployment and use of telemedicine across a variety of specialties and health care settings throughout Florida and across the United States. There is growing enthusiasm and demand for telemedicine services in our State, and the current environment presents a valuable opportunity to drive expanded access to quality health care for all Floridians.

We are therefore encouraged by the Board's revision of Rule 64B8-9.012, F.A.C., so it can accommodate telemedicine-based care consistent with the requirements of Section 456.47, F.S. A few minor changes to the language of the current rule can accomplish this. To that end, we recommend the following minimal revisions:

- Deleted text has a ~~**strikethrough**~~.
- New text has an **underline**.

64B8-9.012 Standards for the Prescription of Obesity Drugs.

The prescription of medication for the purpose of enhancing weight loss should only be performed by physicians qualified by training and experience to treat obesity. All licensees are expected to abide by the following guidelines and standards in the utilization of any drug, any synthetic compound, any

nutritional supplement, or herbal treatment, for the purpose of providing medically assisted weight loss.

(1) To justify the use of weight loss enhancers as set forth above, the patient must have a Body Mass Index (BMI) of 30 or above, or a BMI of greater than 27 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 total body weight for women. The prescription of such weight loss enhancers is not generally appropriate for children. Any time such prescriptions are made for children, the prescribing physician must obtain a written informed consent from the parent or legal guardian of the minor patient in addition to complying with the other guidelines and standards set forth in this rule. BMI is calculated by use of the formula BMI = kg/m_2.

(2) Physicians in Florida are prohibited from prescribing, ordering, dispensing, or administering any weight loss enhancer that is both a serotonergic and anorexic agent unless the drug has been approved by the Food and Drug Administration (FDA) specifically for use in weight loss management. Selective serotonin re-uptake inhibitors (SSRIs) that have not been approved by the FDA for weight loss may not be prescribed, ordered, dispensed, or administered for such purposes.

(3) An initial evaluation of the patient shall be conducted prior to the prescribing, ordering, dispensing, or administering of any drug, synthetic compound, nutritional supplement or herbal treatment and such evaluation shall include an appropriate physical and complete history; appropriate tests related to medical treatment for weight loss; and appropriate medical referrals as indicated by the physical, history, and testing; all in accordance with general medical standards of care.

(a) The initial evaluation may be delegated to an appropriately educated and trained physician's assistant licensed pursuant to Chapter 458, F.S., or an appropriately educated and trained advanced registered nurse practitioner licensed pursuant to Chapter 464, F.S.

(b) If the initial evaluation required above is delegated to a physician's assistant or to an advanced registered nurse practitioner, then the delegating physician must personally review the resulting medical records prior to the issuance of an initial prescription, order, or dosage.

(4) Prescriptions or orders for any drug, synthetic compound, nutritional supplement or herbal treatment for the purpose of providing medically assisted weight loss must be in writing and signed by the prescribing physician. **Electronic prescribing is allowed.** ~~**Initial prescriptions or orders of this type shall not be called into a pharmacy by the physician or by an agent of the physician.**~~ Even if the physician is registered as a dispensing physician, a **physical or electronic** ~~**hard**~~ copy of the written prescription must be maintained in the patient's medical records for each time such weight loss enhancers are prescribed, ordered, dispensed, or administered.

(5) At the time of delivering the initial prescription or providing the initial supply of such drugs to a patient, the prescribing physician must consult with the patient and obtain an appropriate written informed consent from the patient. Such consent must state that there is a lack of scientific data regarding the potential danger of long term use of combination weight loss treatments, and shall discuss potential benefits versus potential risks of weight loss treatments. The written consent must also clearly state the need for dietary intervention and physical exercise as a part of any weight loss regimen. A physical or electronic copy of the signed informed consent shall be included in the patient's permanent medical record.

(6) Each physician who is prescribing, ordering, or providing weight loss enhancers to patients must assure that such patients undergo a~~n in person~~ re-evaluation within 2 to 4 weeks of receiving a prescription, order, or dosage. The re-evaluation shall include the elements of the initial evaluation and an assessment of the medical effects of the treatment being provided. Any patient that continues on a drug, synthetic compound, nutritional supplement or herbal treatment assisted weight loss program shall be re-evaluated at least once every 3 months.

(7) Each physician who prescribes, orders, dispenses, or administers any drug, synthetic compound, nutritional supplement or herbal treatment for the purpose of assisting a patient in weight loss shall maintain medical records in compliance with Rule 64B8-9.003, F.A.C., and must also reflect compliance with all requirements of this rule.

(8) Each physician who prescribes, orders, dispenses, or administers weight loss enhancers for the purpose of providing medically assisted weight loss shall provide to each patient a legible physical or electronic copy of the Weight-Loss Consumer Bill of Rights as set forth in Sections 501.0575(1)(a) through (e)3., F.S. The physician shall also conspicuously post said document in those rooms or the physician's website wherein patients are evaluated for weight loss treatment.

(9) Any physician who advertises practice relating to weight loss or whose services are advertised by another person or entity shall be responsible for assuring that such advertising meets the requirements of Rule 64B8-11.001, F.A.C. In addition advertising of weight loss treatment shall be considered false, deceptive, or misleading if it contains representations that:

(a) Promise specific results;
(b) Raise unreasonable expectations;
(c) Claim rapid, dramatic, incredible, or safe weight loss;
(d) State or suggest that diets or exercise are not required, or
(e) Suggest that weight loss is effortless or magical.

(10) A physician may use telehealth, as defined in Section 456.47, F.S., to fulfill the requirements of this Rule, and to conduct initial or subsequent patient evaluations, assessments, or consults.

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We appreciate the Board's efforts in this important area of public policy and look forward to continuing the conversation as the rule development process continues. Thank you for your consideration of our comments.

Sincerely,

Nathaniel M. Lacktman, Esq.

Chair, Telemedicine & Digital Health Industry Team
Foley & Lardner, LLP