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Regulatory
Town Hall

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Fast Track Proposed Regulation Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC85-20-10 et seq.
Regulation title	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic
Action title	Pharmacotherapy for weight loss
Date this document prepared	6/24/14

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.

In response to a petition for rulemaking, the Board has amended section 90 on pharmacotherapy for weight loss by adding a provision allowing physician assistants and nurse practitioners who have practice agreements with a supervising or collaborating physician to perform the functions and prescribe the controlled substances in accordance with the specified standard of care for weight loss drugs, provided such treatment is authorized in the practice agreement.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

PA = physician assistant

NP = nurse practitioner

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On June 19, 2014, the Board of Medicine amended section 90 of 18VAC85-20-10 et seq., Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the amended regulation is appropriate access to treatment for persons suffering from obesity and its accompanying health risks. A physician assistant under the supervision of a physician or a nurse practitioner who has a collaborative arrangement with a patient care team physician should be able to perform the physical examination, order the tests and follow a patient for whom weight loss drugs are being prescribed. Currently, regulations specify those functions

may only be performed by the physician. The goal of the amended regulation is to clarify that the protocol or standard of care set forth in section 90 is essential for appropriate treatment with weight loss drugs, but that an NP or PA may be authorized by a practice agreement with a collaborating or supervising physician to treat such a patient. Section 90 was originally adopted in response to serious complications from the over-prescribing of weight loss drugs and the failure of some physician practices to properly screen and follow patients. While the Board believes care of those patients, including prescribing, is within the scope of practice of nurse practitioners and physician assistants, the protocol or standard of care must be applied to their practice as well as the physicians with whom they have a practice agreement to protect the health and safety of patients.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Since this action does not expand the scope of practice of nurse practitioners or physician assistants, it will not be controversial. The amended action clarifies the standard of care for all types of practitioners who are treating and prescribing for weight loss.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

The amended provision is the addition of subsection C of section 90: "If specifically authorized in his practice agreement with a supervising or collaborating physician, a physician assistant or nurse practitioner may perform the physical examination, review tests, and prescribe Schedules III through VI controlled substances for treatment of obesity, as specified in subsection B of this section."

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*
3) *other pertinent matters of interest to the regulated community, government officials, and the public.*
If there are no disadvantages to the public or the Commonwealth, please indicate.

1) The primary advantage to the public is expanded access to weight loss treatment that includes prescribing of controlled substances by PA's and NP's. By tying such practice to the standard of care set forth in regulations for the physician with whom the PA practices or with whom the NP

has a collaborative agreement, patients are protected against some of the potentially serious risks associated with such drugs. There are no disadvantages.

- 2) There are no advantages or disadvantages to the agency or the Commonwealth.
- 3) There is no other pertinent information.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Regulatory flexibility analysis

Pursuant to §2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There are no alternative regulatory methods; the standard of care for such practice is clearly set out in regulation in section 90 which must be amended to clearly permit prescribing for obesity by PA's and NP's.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

<p>Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board</p>	<p>The individuals affected would be nurse practitioners or physician assistants who may be authorized to prescribe weight loss medications in accordance with the protocol set forth in regulation and with their practice agreement.</p>
<p>Agency’s best estimate of the number of (1) entities that will be affected, including (2) small businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than \$6 million.</p>	<p>There is no estimate of the number of entities affected because the Board does not license doctors by specialty.</p>
<p>Benefits expected as a result of this regulatory proposal.</p>	<p>The benefit will be increased access to treatment for persons suffering from obesity.</p>
<p>Projected cost to the <u>state</u> to implement and enforce this regulatory proposal.</p>	<p>There are no costs to the state.</p>
<p>Projected cost to <u>localities</u> to implement and enforce this regulatory proposal.</p>	<p>There are no costs to localities.</p>
<p>All projected costs of this regulatory proposal for <u>affected individuals, businesses, or other entities</u>. Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.</p>	<p>There are no costs to affected individuals or entities. The regulation is permissive and will expand access to care.</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The regulatory action is in response to a petition for rulemaking from an NP who has a practice in Southwest Virginia. As she pointed out, treating patients with obesity and prescribing Schedule III or IV drugs for weight loss is within the scope of practice of a nurse practitioner. However, regulations of the Board of Medicine specify that the patient must be seen by a physician before such prescribing can occur. While 18VAC85-20-10 et seq. are regulations for doctors and not nurse practitioners, the standard of care set forth in section 90 precludes a physician who has a practice agreement with a nurse practitioner (or a PA) from authorizing treatment of obese patients in conflict with his or her regulations governing a physician’s practice. Therefore, the Board determined that section 90 needed to be amended to clarify that physician could authorize a PA or NP to examine, treat and prescribe for obese patients, but that the protocol for such patients must be followed as the standard of care.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the family.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre-emergency** regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
90	Sets out the requirements or standard of care for prescribing controlled substances for weight loss.	<p>Subsection C is added:</p> <p>If specifically authorized in his practice agreement with a supervising or collaborating physician, a physician assistant or nurse practitioner may perform the physical examination, review tests, and prescribe Schedules III through VI controlled substances for treatment of obesity, as specified in subsection B of this section.</p> <p><i>The change will clearly allow physicians to authorize treatment of obesity with controlled substances in practice agreements with NP's and PA's. The impact will be greater access to care, especially in areas where NP's are likely to be primary care providers.</i></p>