Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA) 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	Periodic review
Date this document prepared	10/22/08

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The goal of this action is to update regulations consistent with current practices of the professions and policies of the Board. While Chapter 20 of Board of Medicine regulations has not had a periodic review since 2004, it has been amended 19 times in the interim. Therefore, the Board does not intend to adopt substantive changes to the regulations but will respond to issues raised by comments on the Notice of Intended Regulatory Action.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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:*
>
> *1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*
>
> *2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*
>
> *3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*
>
> *…*
> *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. …*

Specific regulatory authority for the Board of Medicine is found in Chapter 29 of Title 54.1.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

On September 19, 2008, the Legislative Committee of the Board of Medicine reviewed 18VAC85-20-10 et seq. to determine whether regulations are necessary to interpret the law or to protect the public health, safety or welfare of the public. The Committee determined that continuation of Chapter 20 is essential in order to set criteria for licensure and renewal of licensure for doctors of medicine, osteopathic medicine, podiatry and chiropractic as required by law. Additionally, regulations governing office-based anesthesia, mixing, diluting and reconstituting of drugs, and other standards of practice are both responsive to statutory provisions and necessary to protect the public health and safety.

Amendments to be considered will update or clarify the regulations for ease of compliance. Amendments to the requirements for mixing, diluting or reconstituting drugs by doctors or persons under their supervision may be necessary to comply with standards for sterile compounding in order to ensure that such drugs are free from contaminates and safe for administration.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

The Legislative Committee of the Board served as the workgroup to conduct the periodic review and has made the following recommendations:

Section 22. Fees
The Board will consider the actual cost of an activity for which a fee has been established. For example, the fee for a duplicate wall certificate is set at $15 but the actual cost to the Board is higher. As much as possible, fees should be set to cover the costs incurred for a product or a service. The application fee for a limited professorial license is set at $55, but processing such an application and issuing the license is more expensive. There is a fee for verification of licensure to another jurisdiction, but no fee for verification to another entity. Since it is possible for anyone to verify licensure online, a request for written verification should cover the cost of staff time, processing and postage and should be charged to all recipients.

Section 25. Treating and prescribing for self or family.
Currently there is regulatory guidance on prescribing for family members but the Board often gets questions from practitioners wanting to know whether it is allowed to perform surgery on a member of one's family and whether there are rules or guidelines for such a decision. Therefore, the Board intends to discuss those factors that may be considered when deciding whether to perform surgery on a member of one's family. There is no intent to prohibit such a practice, but members would like to receive comment on whether there should be regulatory guidance for such surgery.

Section 120. Prerequisites for licensure.
Currently regulations require submission of credentials with the executive director "by a date established by the board." That provision is no longer applicable and should be deleted.

Section 220. Temporary licenses to interns and residents.
Subsection C limits the renewal of an intern or resident license to five annual renewals. Since the license can only be renewed upon recommendation of the chief or director of graduate medical education of the program, the limitation is unnecessary.

Section 235. Continued competency requirements for renewal of an active license.
The Board will consider changing the word "indicate" to "attest to" completion of at least 60 hours of continuing learning activities within the past two years. The Board will also consider modifications to the requirement for completion of the Continued Competency Activity and Assessment Form.

Part IX. Mixing, Diluting or Reconstituting of Drugs for Administration.

The Board will include consideration of revised USP Chapter 797 standards and review them in conjunction with current regulations for mixing, diluting and reconstituting.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

On September 19, 2008, the Legislative Committee of the Board of Medicine reviewed 18VAC85-20-10 et seq. to determine whether regulations are necessary to interpret the law or to protect the public health, safety or welfare of the public. The Committee determined that continuation of Chapter 20 is essential in order to set criteria for licensure and renewal of licensure for doctors of medicine, osteopathic medicine, podiatry and chiropractic as required by law. Additionally, regulations governing office-based anesthesia, mixing, diluting and reconstituting of drugs, and other standards of practice are both responsive to statutory provisions and necessary to protect the public health and safety. Therefore, there were no alternatives possible to achieve the intent of these regulations.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, (804) 527-4434 (fax) or **Elaine.yeatts@dhp.virginia.gov** or comment may be posted on the Regulatory Townhall at **www.townhall.virginia.gov** Written comments must include the name and address of the

commenter. In order to be considered comments must be received by the last day of the public comment period.

In addition, the agency is seeking information on (1) the continued need for the regulation; (2) the complexity of the regulation; (3) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

A public hearing will be held after the Board has adopted proposed regulations. Notice of the hearing may be found on the Virginia Regulatory Town Hall website **www.townhall.virginia.gov** and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

Family impact

Assess the potential 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.

Periodic review – Public comment

If this NOIRA is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 36, e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

The Board Medicine noticed interested parties that it was conducting a periodic review of its current regulations governing doctors of medicine, osteopathic medicine, podiatry and chiropractic and was requesting comment on the following current regulations. Comments were requested from July 21, 2008 to August 20, 2008. There were no comments received during that period, however the Board did review and consider two letters received prior to the review announcement.

Commenter	Comment	Agency response
American Chiropractic Association	Requested a requirement that all chiropractors be required to have continuing education in documentation and recordkeeping as a condition of renewal because of unacceptable high claims error	The Board declined to include the request in the notice for amending regulations.

	rates within Medicare as determined by CMS. They are concerned that CMS may stop paying chiropractic claims and believe such a requirement would help "eliminate this major threat to achieving our rightful place in the federal Medicare program."	
Medical Society of Virginia	Requested that the Board consider possible amendments to the regulations for mixing, diluting and reconstituting as standards under USP Chapter 797 have recently been revised. Specifically, physicians are concerned with the standard for low-risk compounding that requires "routine disinfection and air quality testing to maintain an ISO 5 environment.	The Board will include consideration of revised USP Chapter 797 standards and review them in conjunction with current regulations for mixing, diluting and reconstituting. It will consult with the Chair of the USP Chapter 797 committee, who is a pharmacy professor in Virginia.

Periodic review - Discussion

If this NOIRA is the result of a periodic review or if the periodic review is to be performed in combination with the NOIRA, please include a discussion of the agency's consideration of: (1) the continued need for the rule; (2) the complexity of the regulation; (3) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, include a discussion of the agency's determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

1) There is a continued need for the regulation because it is mandated by statute (Chapter 29 of Title 54.1), which requires the promulgation of regulations for the licensure and practice of doctors of medicine, osteopathic medicine, podiatry and chiropractic.
2) The regulation has been amended repeatedly as necessary for consistency with changes in law and practice for the professions. Through the periodic review of regulations, amendments have been identified that are needed for clarity or to delete out-dated language or requirements.
3) The regulation does not overlap with federal law or regulation; licensure of doctors is a power exercised by individual states. In its review, the Board did not identify any regulation that overlaps with the Code; in several sections of law, the Board is expressly required to adopt a regulation, such as requirements for continuing competency and mixing, diluting or reconstituting of drugs.
4) A periodic review was last completed for Chapter 20 in 2004, but 19 regulatory actions have been completed on the chapter since that time. Amendments have been adopted as needed or mandated by changes in the Code of Virginia.
The regulation should be amended to eliminate unnecessary provisions, but there will likely be no substantive amendments proposed.