Virginia Regulatory Town Hall

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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	Periodic review
Date this document prepared	11/17/09

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.*

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

As a result of a periodic review of regulations governing the practice of medicine, osteopathic medicine, podiatry and chiropractic, the Board of Medicine has proposed amendments to update and clarify terminology, eliminate the requirement for applicant discharged by the military to submit discharge papers, eliminate the limitation on the number of times an intern or resident can renew a license, eliminate the Continued Competency Activity and Assessment Form, and create an exception to the 10-hour definition of immediate use for drugs in fat emulsion that are mixed, diluted or reconstituted.

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.

USP – United States Pharmacopeia

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., the 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.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

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 will update or clarify the regulations for ease of compliance. An amendment to the requirements for mixing, diluting or reconstituting drugs by doctors or persons under their supervision is necessary to comply with standards for sterile compounding in order to ensure that drugs mixed in fat emulsions that are highly susceptible to microbial growth are free from contaminates and safe for administration.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

The Legislative Committee of the Board of Medicine served as the workgroup to conduct the periodic review. The following recommendations were adopted by the board:

Section 22. Fees
The board did not recommend an increase in any fees charged to applicants or regulants but restated the reinstatement fee to clarify that the total fee includes the application and late fees.

Section 120. The requirement for applicants discharged from the military to submit discharge papers is eliminated.

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 changed the word "indicate" to "attest to" completion of at least 60 hours of continuing learning activities within the past two years. The board has also eliminated the requirement for completion of the Continued Competency Activity and Assessment Form.

Section 400. The board considered inclusion of revised USP Chapter 797 standards but chose to leave the definition of immediate use at administration within 10 hours with an exception for fat emulsion drugs.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

1) The only issue that generated discussion and had a potential impact on medical practice was the proposed change in immediate use for compounding sterile drug products. Since the draft proposal of a 4-hour limitation on immediate use was not adopted by the board, the issue was resolved satisfactorily. A one-hour limitation on fat emulsion drugs will provide greater protection for vulnerable patients from infections resulting from intravenous administration. There are no disadvantages to the public, who continue to be reasonably protected by the rules for mixing, diluting or reconstituting sterile drug products.
2) There are no quantitative advantages or disadvantages to the Commonwealth or the agency. Clarification of some requirements may result in fewer requests for interpretation or resubmission of required information.
3) There are no other pertinent issues.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal, which are 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 by the proposed regulation.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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 via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or **elaine.yeatts@dhp.virginia.gov** or by fax to (804) 527-4434**.** Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and the Commonwealth Calendar. Both oral and written comments may be submitted at that time.

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.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.	a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There will no additional on-going expenditures relating these amendments.
Projected cost of the *new regulations or changes to existing regulations* on localities.	None
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	The entities that are likely to be affected by these regulations would be: Interns or residents who need to renew their licenses beyond the current limitation of five years; and doctors of medicine or osteopathic medicine who mix, dilute or reconstitute sterile drug products in fat emulsion or who supervise personnel in their practice who mix, dilute or reconstitute such drugs.
Agency's best estimate of the number of such entities that will be affected. Please include an	There are 27,191 doctors of medicine who have active licenses and 1,145 doctors of osteopathic

estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	medicine. It is likely that only a handful of those would be engaged in mixing, diluting or reconstituting drugs in fat emulsion. The board is not aware of any interns or residents who will be able to extend the time of the residency due to a change in regulations.
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and do include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	The costs for compliance with the stricter definition of "immediate use" for small businesses should be minimal since the vast majority of drugs are mixed, diluted or reconstituted are not in fat emulsion or are compounded for administration to a patient at the same time. For those practices that mix, dilute or reconstitute batches of drugs in fat emulsion for subsequent administration, the task would have be performed within one hour of administration. An example of such a drug would be Liposyn or Intralipid, a fat emulsion nutritional mixture administered intravenously. Mixing of such a drug would almost always be performed by a hospital pharmacy, which is subject to USP standards.
Beneficial impact the regulation is designed to produce.	Costs for reporting continuing education hours may be reduced with the elimination of the Continuing Competency Activity Form which currently must be submitted along with documentation of hours. Maintaining the Form is an additional task for licensees who must also maintain documentation of completion of continuing competency hours.

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.

On September 19, 2008, the Legislative Committee of the Board of Medicine conducted its periodic review of 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.
There were two issues addressed in the Notice of Intended Regulatory Action that the board considered in the adoption of proposed regulations.

1) 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 they are allowed to perform surgery on a member of one's family and whether there are rules or guidelines for such a decision. The board discussed those factors that may be considered when deciding whether to perform surgery on a member of one's family and concluded that the definition of surgery was so broad and the circumstances so varied that regulatory language could be burdensome and could make the issue more problematic. Therefore, the board chose not to address surgery on family members in regulation but leave it to the professional judgment of practitioners and the hospitals in which they practice.

2) Section 400. Requirements for immediate-use sterile mixing, diluting or reconstituting. At the time Chapter 20 was under periodic review, the USP came out with revised standards for sterile compounding, including a definition of "immediate use" of administration to begin within one hour of compounding the drug product. Since there was disparity between the USP definition of "immediate use" in sterile compounding and the Board of Medicine regulations for mixing, diluting or reconstituting sterile drug products, the issue was considered during the review. At the request of the board, Dr. David Newton (Professor of Pharmacy at Shenandoah University and Chair of the USP Sterile Compounding Committee) prepared a scientific review of bacterial and fungal growth rates and their implications for immediate-use compounded sterile drugs. Based on the information presented, the Legislative Committee recommended a four-hour limitation on immediate use of such drug products. Given objections from the medical community and the lack of specific complaints about patient harm resulting from drugs compounded in physician practices, the full board did not adopt the committee recommendation but did adopt an one-hour exception for fat emulsion drugs that have the greatest risk for microbial growth.

Regulatory flexibility analysis

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.

With the exception of eliminating the Continuing Competency Activity and Assessment Form, which is used for reporting on compliance with continuing competency requirements, there are no other alternative regulatory methods that would achieve the purpose of public safety in licensing doctors.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

There were no comments following publication of the NOIRA. However, after the development of proposed regulations by the Legislative Committee on September 18, 2009, there was public comment in opposition to the draft amendment to change the time limitation for immediate use in mixing, diluting, or reconstituting sterile drugs from 10 hours to 4 hours. The Medical Society of Virginia, the Virginia Society of Ophthalmology and several oncology groups communicated by written comment or in person at the board meeting on October 29, 2009, that such a change would create a hardship on medical practices and their patients. The board reviewed the scientific data about microbial growth and took into consideration the impact of regulation on medical practices and determined that the current 10-hour limitation on immediate use should remain in place with the exception of drugs in fat emulsion that have the greatest risk for microbial growth.

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 of the proposed regulatory action on the institution of the family and family stability.

Detail of changes

Please detail 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 if implemented in each section. Please detail the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

Current section number	Current requirement	Proposed change, rationale, and consequences
22	Establishes fees for licensees and applicants	Clarifies that the total amount of reinstatement of an expired license includes the reinstatement application fee **and** the late fee. The total amount is the same as the current fees for reinstatement.
120	Sets out the prerequisites for licensure	Clarifies that the chronological record of professional activities required for the application package should

		show activity since graduation from professional school. Eliminates the requirement for discharge papers from military services if the applicant was discharged within the past five years. *Eliminates a burden on military applicants that is unnecessary.*
121	Sets out the educational requirements for graduates of approved institutions	Updates the name of the podiatric accrediting body.
131	Sets out requirements for a doctor who practices acupuncture	Eliminates an outdated and unnecessary effective date for the regulation.
140	Establishes the examinations required for various types of licensure	In subsection B, the correct title for the FLEX examination is used. In subsection C, the reference to an examination equivalent to the Board of Medicine examination is amended since there is no longer a board examination.
220	Sets out the requirements for temporary licenses issued to interns and residents	Eliminates the limitation of five renewals for the intern or resident license. *Since the license can only be renewed upon recommendation of the chief or director of graduate medical education, the limitation is unnecessary. If, for some reason, the director approved an internship and residency of longer than five years, the board would find that acceptable.*
235	Establishes the requirements for continued competency for renewal	Eliminates the requirement for completion of the Continued Competency Activity and Assessment Form. *On renewal, a licensee must attest to completion of 60 hours of learning activities within the past two years. If audited, the practitioner must provide all supporting documentation, but would not be required to complete or submit the Form.* Also eliminates the percentage of licensees to be audited. *Currently, the number of licensees to be audited is calculated to produce a random sampling.*
290	States the requirements for reporting of medical malpractice judgments and settlements	The trigger for reporting is stated in the Code as "more than $10,000" so the regulation is amended accordingly.
400	Establishes the requirements for immediate use mixing, diluting and reconstituting sterile drugs	Subsection A establishes the criteria for immediate use as administration is to begin within 10 hours of completion of the preparation. The amendment creates an exception for drugs in fat emulsion of one hour. *Testimony to the board from doctors involved in mixing, diluting and reconstituting opposed a change from the 10-hour standard but acknowledged that drugs in fat emulsions were much more likely to develop microbial growth that could lead to infection. Therefore, the board adopted a one-hour standard for immediate use for those drugs, but did not adopt the USP standard of one-hour for all drugs that are mixed, diluted or reconstituted.*