Virginia Regulatory Town Hall

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Final 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	6/23/11

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

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.

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 or board taking the action, and (3) the title of the regulation.

On June 23, 2011, the Board of Medicine adopted final amendments to 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 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.

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 it 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.

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 identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" 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 there are no disadvantages to the public or the Commonwealth, please 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.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

There were no changes made to the text of the proposed regulation.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

There was no public comment received.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current section	Current requirement	Proposed change, rationale, and consequences

number		
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.

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.

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.