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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	Licensure credentials and examination requirements
Document preparation date	8/24/06

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The substantive change being proposed is to require that applicants who sat for the United States Medical Licensing Examination (USMLE) must pass Steps 1, 2, and 3 within a ten-year period, unless the applicant is Board-certified in a specialty approved by the American Board of Medical Specialties or the Bureau of Osteopathic Specialists of the American Osteopathic Association. The current requirement is passage within a seven-year period except for "good cause shown."

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. ...*

Provisions in the Medical Practice Act relating to requirements for examination include:

§ 54.1-2930. Requirements for admission to examination.

The Board may admit to examination for licensure to practice medicine, osteopathy, chiropractic and podiatry any candidate who has submitted satisfactory evidence verified by affidavits that he:

- 1. Is eighteen years of age or more;*
- 2. Is of good moral character;*
- 3. Has successfully completed all or such part as may be prescribed by the Board, of an educational course of study of that branch of the healing arts in which he desires a license to practice, which course of study and the educational institution providing that course of study are acceptable to the Board; and*
- 4. Has completed one year of satisfactory postgraduate training in a hospital approved by an accrediting agency recognized by the Board for internships or residency training. At the discretion of the Board, the postgraduate training may be waived if an applicant for licensure in podiatry has been in active practice for four continuous years while serving in the military and is a diplomate of the American Board of Podiatric Surgery. Applicants for licensure in chiropractic need not fulfill this requirement.*

In determining whether such course of study and institution are acceptable to it, the Board may consider the reputation of the institution and whether it is approved or accredited by regional or national educational or professional associations including, but not limited to, such organizations as the Accreditation Council of Graduate Medical Education or other official accrediting body recognized by the American Medical Association, by the Committee for the

Accreditation of Canadian Medical Schools or their appropriate subsidiary agencies, by any appropriate agency of the United States government, or by any other organization approved by the Board. Supervised clinical training which is received in the United States as part of the curriculum of a foreign medical school shall be obtained in an approved hospital, institution or school of medicine offering an approved residency program in the specialty area for the relevant clinical training. The Board may also consider any other factors that reflect whether that institution and its course of instruction provide training sufficient to prepare practitioners to practice their branch of the healing arts with competency and safety in the Commonwealth.

§ 54.1-2931. *Examinations; passing grade.*

A. The examination of candidates for licensure to practice medicine and osteopathy shall be the Federation Licensing Examination, the joint Licensure Examination Sequence prepared by the National Board of Medical Examiners and the Federation of State Medical Boards, or such other examinations as determined by the Board. The minimum passing score shall be determined by the Board prior to administration of the examination.

B. The examination of candidates for licensure to practice chiropractic shall include the National Board of Chiropractic Examiners Examinations and such other examinations as determined by the Board. The minimum passing score shall be determined by the Board prior to administration of the examination.

C. The examination of candidates for licensure to practice podiatry shall be the National Board of Podiatry Examiners Examinations and such other examinations as determined by the Board. The minimum passing score shall be determined by the Board prior to administration of the examination.

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 and the problems the proposal is intended to solve.

The Board's purpose is to address a regulatory issue that has been raised by the Credentials Committee in the process of considering applications for licensure. Current regulations require that all three steps of the United States Medical Licensing Examination (USMLE) be taken within seven years, with an exception to the rule "for good cause shown." The Board has received several such requests, and the Credentials Committee has had no standard by which to interpret the rule. Without clear criteria for "good cause," the Board has some concern that the rule could be applied inconsistently. Therefore, it has proposed a more definitive regulation for passage of the examinations, but will allow board certification in a specialty to substitute for the ten-year limitation if necessary. A clear ten-year standard for passage of USMLE will encourage qualified applicants who may need more than seven years to complete advanced training to seek licensure in Virginia. Elimination of the waiver option for "good cause shown" may also provide greater protection for patients since Virginia will be less likely to attract applicants who would not qualify in other states.

Substance

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

While USMLE still believes that it is best for the three examinations to be taken within seven years, passage of Step 3 may be a sufficient measure of an applicant’s competency and ability to retain medical knowledge over a longer period of time. Therefore, the Board believes extension of the seven-year rule to ten years is appropriate without compromising its responsibility to ensure minimum competency to practice with skill and safety. Primarily, the ten-year time limit is needed for MD/PhD candidates, but there may be other legitimate reasons why someone needs a longer period of time for completion. If Step 3 cannot be completed within ten years, the applicant would have to demonstrate competency by another standard, namely board certification in a specialty.

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 primary advantage to the public is a clearer standard for the licensure examination to assure that the applicants for licensure in medicine or osteopathic medicine are qualified and competent. Since most states do not allow licensure if an applicant did not complete USMLE in 7 or 10 years, Virginia is one of the only options available for persons who have had to repeat Step 3 multiple times. If the rule is clearly set at a maximum of 10 years or board certification, there may be a few individuals who will not qualify, but the Board does not believe the proposed standard will disqualify any competent individual who should have a license to practice in Virginia. There are no disadvantages to the public.
- 2) There are no advantages or disadvantages to the agency or the Commonwealth.
- 3) There are no other matters of interest.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a</p>	<p>a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and</p>
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<p>delineation of one-time versus on-going expenditures</p>	<p>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 are no on-going costs to the agency.</p>
<p>Projected cost of the regulation on localities</p>	<p>None</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the regulation</p>	<p>The entities that are likely to be affected by this amendment would be those who have taken longer than 7 years to pass USMLE Step 3.</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Please include an 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.</p>	<p>Currently, there are approximately 15 - 20 persons who appeal to the Credentials Committee for licensure, based on possible waiver of the 7-year rule for the “good cause shown.” Since most states make no exceptions and do not allow licensure if an applicant did not complete USMLE in 7 or 10 years, Virginia is one of only a few options available for licensure. There are no small businesses affected.</p>
<p>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</p>	<p>There are no costs to the affected entities.</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.

Seven-year limitation for completion of USMLE examination:

In 1998, following the recommendation of the Federation of State Medical Boards, the Board adopted a rule requiring all three steps of the USMLE examination to be taken within seven years. Several applicants presented situations which, in the opinion of the Board, justified a delay in completing the Step 3 examination within seven years. To address those concerns, the Board amended the regulation in 2001 to allow for exceptions to the seven-year rule “for good cause shown.” Counsel advised the Board to not implement the requirement until August 1, 2005. As of that date, any application received by an applicant who took longer than seven years to complete all three steps, no matter when they initially passed Step 1 (even if it were prior to 1998), would be subject to the requirement.

The only alternative to amending section 140 to eliminate the requirement that the first three steps of the USMLE examination be taken within seven years is to continue holding an informal conference before the Credentials Committee at which the applicant presents his case for the “good cause” exception. The lack of specificity in the exception provides little guidance for the Board in granting or denying the exception for the seven-year rule or for the applicant who has to bear the expense of appearing before the committee to plead their cause. Board counsel has advised that a denial of an applicant’s request for a “good cause” exception would have to be based on evidence that the applicant is not competent to practice. USMLE still believes that it is best for the three examinations to be taken within seven years, and 42 states presently have a seven-year rule, but many allow 10 years for certain exceptions.

The Board considered various alternatives found in other states, such as: 1) elimination on any time frame for passage (3 other states); 2) extending the time limit to 10 years (3 other states); or 3) allowance of another three years for persons who are MD/PhD candidates (10 other states). Eight other states allow an extension with board approval for illness or MD/PhD candidacy, and one state requires completion within five years. The Executive Director of the Board recommended an additional alternative in which everyone would be given 10 years (to cover the vast majority of extenuating circumstances that might extend the time beyond 7 years). If a person has obtained board certification in a specialty field, such evidence of competency would supplant the 10-year limitation on passage of USMLE, if applicable.

Requirement for supervised clinical training in medical school

The NOIRA for this action identified an issue with a requirement for supervised clinical training for graduates of non-accredited (foreign) medical schools. When off-shore medical schools began to be organized, the Board became concerned that the students were being sent to the U. S. to do their clinical rotations in non-approved hospitals without residency programs in the specialty area, so a requirement for those training sites to have an approved residency program was added. The Credentials Committee pointed out that there is inconsistency and inequity in the rule because it only applies to training that was received in the U. S. If the clinical training was received in a foreign country, there is no oversight or regulatory requirement that the hospital, school or institution have an approved residency program. Therefore, it was recommended that the Board look for other language that will eliminate the inconsistency and will be reasonable and enforceable.

However, the requirement in regulation is consistent with §54.1-2930, which states: “Supervised clinical training which is received in the United States as part of the curriculum of a foreign medical school shall be obtained in an approved hospital, institution or school of medicine offering an approved residency program in the specialty area for the relevant clinical training.” Therefore, deletion of the same requirement in section 122 of the regulation would have no impact and might cause confusion, so no amendment was proposed.

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

The Notice of Intended Regulatory Action was published in the Register on June 26, 2006 and sent to the Public Participation Guidelines list with comment requested until July 26, 2006. There was no public comment received.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact 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. Detail all new provisions and/or all changes to existing sections.

Current section number	Current requirement	Proposed change and rationale
140 E 2	Applicants who sat for the United States Medical Licensing Examination (USMLE) shall provide evidence of passing Steps 1, 2, and 3 within a seven-year period except for good cause shown.	<p>Applicants who sat for the United States Medical Licensing Examination (USMLE) shall provide evidence of passing Steps 1, 2, and 3 within a <u>ten-year period unless the applicant is Board-certified in a specialty approved by the American Board of Medical Specialties or the Bureau of Osteopathic Specialists of the American Osteopathic Association.</u></p> <p><i>Ten years to complete USMLE is sufficient time to cover almost every reasonable circumstance – such as time for PhD/MD candidates, maternity leave, short-time illness, etc. Beyond 10 years, there is concern that too much knowledge from medical school has been lost, and the candidate has had difficulty in demonstrating competency. The one exception to that rule would be for a doctor who has gone on to Board certification in a specialty. Such evidence of competency could replace the 10-year limitation, applicable and necessary.</i></p>