



Fast Track Regulation Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18 VAC 85-20
Regulation title	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic
Action title	Documenting claims in advertisements
Document preparation date	10/30/06

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

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

The proposed action would place the responsibility on the practitioner to have and maintain documentation in support of claims made in advertisements.

Statement of agency final 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 October 19, 2006, the Board of Medicine took action to amend 18 VAC 85-20-10 et seq., Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and

Chiropractic through the fast-track regulatory process to amend section 30, requiring a practitioner who makes claims in an advertisement to the public to maintain documentation in support of those claims.

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of 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 (6) 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. ...*

In the Medical Practice Act, there is a prohibition on advertising claims of superiority or performing any act likely to deceive or defraud the public.

§ 54.1-2915. Unprofessional conduct; grounds for refusal or disciplinary action.

A. The Board may refuse to admit a candidate to any examination; refuse to issue a certificate or license to any applicant; reprimand any person; place any person on probation for such time as it may designate; suspend any license for a stated period of time or indefinitely; or revoke any license for any of the following acts of unprofessional conduct:

- 15. Publishing in any manner an advertisement relating to his professional practice that contains a claim of superiority or violates Board regulations governing advertising;*
- 16. Performing any act likely to deceive, defraud, or harm the public;*

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.

Current regulations prohibit advertising that is false, misleading or deceptive. If a group of practitioners places an advertisement, regulations require the name of the practitioner who is accountable for the validity and truthfulness of the ad to be maintained by the practice for at least two years. What is missing in regulation is a requirement that the practitioner also be able to substantiate any claim made in an advertisement with scientific or other evidence in support of its validity and truthfulness. Without such documentation, the Board often has great difficulty in proving that the ad is false, misleading or deceptive. Further clarification of the practitioner's responsibility should result in fewer advertisements that are intended to falsely promote a service or mislead the public into selecting a health care practitioner based on unsubstantiated claims.

Rationale for using fast track process

Please explain why the fast track process is being used to promulgate this regulation.

Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from (1) 10 or more persons, (2) any member of the applicable standing committee of either house of the General Assembly or (3) any member of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The fast-track process is being used to promulgate the amendment because it is strongly recommended that regulations be clarified to ensure that the practitioner is aware of his responsibility for documenting that a claim made in an advertisement is not false or likely to deceive or defraud the public. The action should not be controversial, as it is reflective of the current standard for ethical practice and is in the interest of public safety and protection.

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.)

The proposed fast-track action clarifies the practitioner has the responsibility for maintaining documentation to support claims made in an advertisement for at least two years.

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.

There are no disadvantages to the public of this amendment. If an advertisement claims certain services or pricing packages are available or that certain outcomes can be guaranteed with a practitioner or a procedure, the practitioner has an obligation to be able to substantiate the truthfulness of such a claim. The public has a definite advantage with a requirement for maintaining such documentation, because it will help to ensure that there is some validity for such a claim.

There are no disadvantages to the agency or the Commonwealth; the proposal will facilitate the investigation of a complaint made regarding the validity or truthfulness of an advertisement.

There are no other pertinent matters of interest.

Economic impact

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</p>	<p>The agency will incur some one-time costs (less than \$1,000) for mailings and conducting a public hearing. Every effort will be made to incorporate those into anticipated mailings or distribute notices by email. There are no ongoing expenditures related to this amendment. 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.</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 individuals who may be affected would be licensees of the Board.</p>														
<p>Agency’s best estimate of the number of such entities that will be affected</p>	<p>The practitioners who could be affected would include:</p> <table style="width: 100%; border: none;"> <tr> <td style="padding-left: 20px;">Athletic trainers</td> <td style="text-align: right;">857</td> </tr> <tr> <td style="padding-left: 20px;">Chiropractors</td> <td style="text-align: right;">1577</td> </tr> <tr> <td style="padding-left: 20px;">Licensed acupuncturists</td> <td style="text-align: right;">347</td> </tr> <tr> <td style="padding-left: 20px;">Licensed midwives</td> <td style="text-align: right;">20</td> </tr> <tr> <td style="padding-left: 20px;">Medical doctors</td> <td style="text-align: right;">29,635</td> </tr> <tr> <td style="padding-left: 20px;">Occupational therapists</td> <td style="text-align: right;">2378</td> </tr> <tr> <td style="padding-left: 20px;">Osteopathic doctors</td> <td style="text-align: right;">1269</td> </tr> </table>	Athletic trainers	857	Chiropractors	1577	Licensed acupuncturists	347	Licensed midwives	20	Medical doctors	29,635	Occupational therapists	2378	Osteopathic doctors	1269
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	Podiatrists 463 Respiratory care practitioners 3319
Projected cost of the regulation for affected individuals, businesses, or other entities	There would be no additional costs to the affected entities. Any claim made in an advertisement should not be speculative, unsubstantiated, or false. Evidence to support the claim should already be in the hands of the practitioner. Regulations already require maintenance of the name of the practitioner responsible for the advertisement for at least two years, so this requirement should not add to cost for maintenance of information relating to the ad.

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.

There are no alternatives to the proposal if the Board intends for its regulation to be clear and enforceable. With the current regulation, the Board is faced with having to provide evidence to disprove the claim made by the practitioner in an investigation or disciplinary proceeding.

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.

Current section number	Current requirement	Proposed change and rationale
30	Advertising ethics. A. Any statement specifying a fee, whether standard, discounted or free, for professional services which does not include the cost of all related procedures, services and products which, to a substantial likelihood, will be necessary for the completion of the advertised service as it would be understood by an ordinarily	Adds subsection F to require that documentation, scientific and otherwise, supporting claims made in an advertisement must be maintained and available for the board’s review for at least two years. <i>The Board proposes to add such a requirement because it is often impossible to “disprove” a claim made in an advertisement, even if it is not</i>

<p>prudent person shall be deemed to be deceptive or misleading, or both. Where reasonable disclosure of all relevant variables and considerations is made, a statement of a range of prices for specifically described services shall not be deemed to be deceptive or misleading.</p> <p>B. Advertising a discounted or free service, examination, or treatment and charging for any additional service, examination, or treatment which is performed as a result of and within 72 hours of the initial office visit in response to such advertisement is unprofessional conduct unless such professional services rendered are as a result of a bona fide emergency. This provision may not be waived by agreement of the patient and the practitioner.</p> <p>C. Advertisements of discounts shall disclose the full fee that has been discounted. The practitioner shall maintain documented evidence to substantiate the discounted fees and shall make such information available to a consumer upon request.</p> <p>D. A licensee shall disclose the complete name of the specialty board which conferred the certification when using or authorizing the use of the term “board certified” or any similar words or phrase calculated to convey the same meaning in any advertising for his practice.</p> <p>E. A licensee of the board shall not advertise information which is false, misleading, or deceptive. For an advertisement for a single practitioner, it shall be presumed that the practitioner is responsible and accountable for the validity and truthfulness of its content. For an advertisement for a practice in which there is more than one practitioner, the name of the practitioner or practitioners responsible and accountable for the content of the advertisement shall be documented and maintained by the practice for at least two years.</p>	<p><i>substantiated or has no validity in scientific evidence. The change will place the onus on the practitioner to maintain any evidence of the validity or truthfulness of the claim. If, for example, the advertisement claimed that a particular chiropractor can eliminate back pain in 30% of his patients, there should be some evidence to support that claim. Any advertisement of an outcome should be substantiated by scientific evidence. If, for example, an advertisement claimed Dr. X was voted the safest orthopedic surgeon for knee replacement, there should be an independent poll substantiating such a claim.</i></p>
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