Form: TH- 03

Virginia Regulatory Town Hall

Final Regulation
Agency Background Document

Agency Name:	Board of Medicine, Department of Health Professions
VAC Chapter Number:	18 VAC 85-10-10 et seq.
Regulation Title:	Regulations Governing Public Participation Guidelines
Action Title:	Periodic review
Date:	6/7/01

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form,Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

Regulations are promulgated to provide guidelines for public participation in the regulatory process of the board. The amendments are intended to further enable electronic communication, notification and comment in the development of regulations.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

No changes to proposed regulations have been made in the adoption of final amendments.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On June 7, 2001, the Board of Medicine adopted final amendments to 18 VAC 85-10-10 et seq., Regulations Governing Public Participation Guidelines.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law

The statutory authority for this regulation is the Administrative Process Act. § 9-6.14:7.1 specifically mandates the adoption of public participation guidelines pursuant to the provisions of the Act. Regulations so adopted do not exceed the mandate of the Act but do provide additional clarity to the public for their participation in the regulatory process.

§ 9-6.14:7.1. Public participation; informational proceedings; effect of noncompliance.

A. Any person may petition an agency to request the agency to develop a new regulation or amend an existing regulation. The agency receiving the petition shall consider and respond to the petition within 180 days. Agency decisions to initiate or not initiate rulemaking in response to petitions are not subject to judicial review.

B. In the case of all regulations, except those regulations exempted by § 9-6.14:4.1, an agency shall provide the Registrar of Regulations with a Notice of Intended Regulatory Action which describes the subject matter and intent of the planned regulation. At least thirty days shall be provided for public comment after publication of the Notice of Intended Regulatory Action. An

agency shall not file proposed regulations with the Registrar until the public comment period on the Notice of Intended Regulatory Action has closed.

C. Agencies shall state in the Notice of Intended Regulatory Action whether they plan to hold a public hearing on the proposed regulation after it is published. Agencies shall hold such public hearings if required by basic law. If the agency states an intent to hold a public hearing on the proposed regulation in the Notice of Intended Regulatory Action, then it shall hold the public hearing. If the agency states in its Notice of Intended Regulatory Action that it does not plan to hold a hearing on the proposed regulation, then no public hearing is required unless, prior to completion of the comment period specified in the Notice of Intended Regulatory Action: (i) the Governor directs that the agency shall hold a public hearing or (ii) the agency receives requests for a public hearing from twenty-five persons or more.

D. Public participation guidelines for soliciting the input of interested parties in the formation and development of its regulations shall be developed, adopted and utilized by each agency pursuant to the provisions of this chapter. The guidelines shall set out any methods for the identification and notification of interested parties, and any specific means of seeking input from interested persons or groups which the agency intends to use in addition to the Notice of Intended Regulatory Action. The guidelines shall set out a general policy for the use of standing or ad hoc advisory panels and consultation with groups and individuals registering interest in working with the agency. Such policy shall address the circumstances in which the agency considers such panels or consultation appropriate and intends to make use of such panels or consultation.

E. In formulating any regulation, including but not limited to those in public assistance programs, the agency pursuant to its public participation guidelines shall afford interested persons an opportunity to submit data, views, and arguments, either orally or in writing, to the agency or its specially designated subordinate. However, the agency may, at its discretion, begin drafting the proposed regulation prior to or during any opportunities it provides to the public to submit input.

F. In the case of all regulations, except those regulations exempted by § 9-6.14:4.1, the proposed regulation and general notice of opportunity for oral or written submittals as to that regulation shall be published in the Virginia Register of Regulations in accordance with the provisions of subsection B of § 9-6.14:22. In addition, the agency may, in its discretion, (i) publish the notice in any newspaper and (ii) publicize the notice through press releases and such other media as will best serve the purpose and subject involved. The Register and any newspaper publication shall be made at least sixty days in advance of the last date prescribed in the notice for such submittals. All notices, written submittals, and transcripts, summaries or notations of oral presentations, as well as any agency action thereon, shall be matters of public record in the custody of the agency.

G. Before delivering any proposed regulation under consideration to the Registrar as required in subsection H below, the agency shall deliver a copy of that regulation to the Department of Planning and Budget. In addition to determining the public benefit, the Department of Planning and Budget in coordination with the agency, shall, within forty-five days, prepare an economic impact analysis of the proposed regulation. The economic impact analysis shall include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply; the identity of any localities and types of businesses or other entities particularly affected by the regulation; the projected number of persons and employment positions to be affected; the impact of the regulation on the use and value of private property;

and the projected costs to affected businesses, localities or entities to implement or comply with such regulations, including the estimated fiscal impact on such localities and sources of potential funds to implement and comply with such regulation. Agencies shall provide the Department with such estimated fiscal impacts on localities and sources of potential funds. The Department may request the assistance of any other agency in preparing the analysis. The Department shall deliver a copy of the analysis to the agency drafting the regulation, which shall comment thereon as provided in subsection H, and a copy to the Registrar for publication with the proposed regulation. No regulation shall be promulgated for consideration pursuant to subsection H until such impact analysis has been received by the Registrar. For purposes of this section, the term "locality, business, or entity particularly affected" means any locality, business, or entity which bears any identified disproportionate material impact which would not be experienced by other localities, businesses, or entities. The analysis shall represent the Department's best estimate for the purposes of public review and comment on the proposed regulation. The accuracy of the estimate shall in no way affect the validity of the regulation, nor shall any failure to comply with or otherwise follow the procedures set forth in this subsection create any cause of action or provide standing for any person under Article 4 (§ 9-6.14:15 et seq.) of this chapter or otherwise to challenge the actions of the Department hereunder or the action of the agency in adopting the proposed regulation.

H. Before promulgating any regulation under consideration, the agency shall deliver a copy of that regulation to the Registrar together with a summary of the regulation and a separate and concise statement of (i) the basis of the regulation, defined as the statutory authority for promulgating the regulation, including an identification of the section number and a brief statement relating the content of the statutory authority to the specific regulation proposed; (ii) the purpose of the regulation, defined as the rationale or justification for the new provisions of the regulation, from the standpoint of the public's health, safety or welfare; (iii) the substance of the regulation, defined as the identification and explanation of the key provisions of the regulation that make changes to the current status of the law; (iv) the issues of the regulation, defined as the primary advantages and disadvantages for the public, and as applicable for the agency or the state, of implementing the new regulatory provisions; and (v) the agency's response to the economic impact analysis submitted by the Department of Planning and Budget pursuant to subsection G. Any economic impact estimate included in the agency's response shall represent the agency's best estimate for the purposes of public review and comment, but the accuracy of the estimate shall in no way affect the validity of the regulation. Staff as designated by the Code Commission shall review proposed regulation submission packages to ensure the requirements of this subsection are met prior to publication of the proposed regulation in the Register. The summary; the statement of the basis, purpose, substance, and issues; the economic impact analysis; and the agency's response shall be published in the Virginia Register of Regulations, together with the notice of opportunity for oral or written submittals on the proposed regulation.

I. When an agency formulating regulations in public assistance programs cannot comply with the public comment requirements of subsection F of this section due to time limitations imposed by state or federal laws or regulations for the adoption of such regulation, the Secretary of Health and Human Resources may shorten the time requirements of subsection F. If, in the Secretary's sole discretion, such time limitations reasonably preclude any advance published notice, he may waive the requirements of subsection F. However, the agency shall, as soon as practicable after the adoption of the regulation in a manner consistent with the requirements of

subsection F, publish notice of the promulgation of the regulation and afford an opportunity for public comment. The precise factual basis for the Secretary's determination shall be stated in the published notice.

J. For the purpose of this article, public assistance programs shall consist of those specified in § 63.1-87.

K. If one or more changes with substantial impact are made to a proposed regulation from the time that it is published as a proposed regulation to the time it is published as a final regulation, any person may petition the agency within thirty days from the publication of the final regulation to request an opportunity for oral and written submittals on the changes to the regulation. If the agency receives requests from at least twenty-five persons for an opportunity to submit oral and written comments on the changes to the regulation, the agency shall (i) suspend the regulatory process for thirty days to solicit additional public comment and (ii) file notice of the additional thirty-day public comment period with the Registrar of Regulations, unless the agency determines that the changes made are minor or inconsequential in their impact. The comment period, if any, shall begin on the date of publication of the notice in the Register. Agency denial of petitions for a comment period on changes to the regulation shall be subject to judicial review.

L. In no event shall the failure to comply with the requirements of subsection F of this section be deemed mere harmless error for the purposes of § 9-6.14:17.

M. This section shall not apply to the issuance by the State Air Pollution Control Board of variances to its regulations.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

Since the effective date of the current public participation guidelines in 1994, the Board has followed the regulations by sending notices to the public for any meeting at which a regulatory action is to be considered, for an intended regulatory action, for comment on a proposed regulation, and for adoption of a final regulation. Opportunities for written and oral comment have been provided at each stage of the regulatory process, including holding a public hearing on any regulatory amendments affecting the licensure of the professions the Board regulates. With the availability of e-mail and fax, comments may now be received electronically. In addition, the Board has provided information on the Regulatory Townhall to all persons on the public participation guidelines mailing list with instruction on how to access regulatory submissions and request to join the mailing list.

Following a review of every regulation, the Board has determined that the current public participation guidelines are reasonable, clearly stated and adequate to protect the public interest in the development and promulgation of regulations. Amendments are necessary for additional clarity and updating of the requirements in order to provide for electronic submissions by the agency and the affected parties. These regulations are intended to ensure participation in the

process of developing and promulgating regulations for the health professions which are essential for public health, safety and welfare.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

The Board has adopted amendments to its Public Participation Guidelines regulations in order to improve the clarity of the rule, to incorporate forms of notification through the Virginia Regulatory Townhall and the Commonwealth Calendar, and to improve the procedures for public involvement in the process.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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 include a sentence to that effect.

For the most part, regulations providing public participation guidelines are requirements on the Board in compliance with the Administrative Process Act. The primary issue identified during the review of these regulations was the need to incorporate electronic forms of regulatory submission, notification and communication that are currently available or may become available in the near future. Therefore, amendments that would permit notification and comment by facsimile, email or other electronic means were incorporated in the amendments. Amendments will also ensure that an electronic mailing list may be maintained on a state website in addition to the traditional list for mailings by the Board.

While requirements for public participation in the regulatory process should be electronically inclusive, the Board continues to be obligated to notify by regular mail if an entity chooses that form of notification. The regulation must continue to provide for notification and comment in that fashion.

Advantages and Disadvantages

There are no disadvantages of the amended regulations to members of the public, who may chose to remain on the regular mailing list, be notified of regulatory actions electronically or both. Public comment on Notices of Intended Regulatory Action or proposed regulations is currently permitted and being received by facsimile or email, but amended regulations will ensure that type of transmission.

There are no disadvantages to the Board which is currently posting meeting notices affecting regulations and all regulatory submissions on the Townhall. If electronic notification and comment become more prevalent, there may be a modest reduction in the Board's cost of mailings.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

A public hearing was held before the Board of Medicine at the Department of Health Professions in Richmond on April 6, 2001. No comment was presented at that time nor was any written or electronically submitted comment received.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

Amendments to regulations are recommended in the following sections:

Purpose.

- An amendment would clarify that the purpose includes expanded participation in the rule-making process by electronic exchanges.

Definitions.

- A new definition for "notification lists" is proposed to facilitate an understanding of that term as used in the amended regulation.

Composition of mailing lists.

- Amendments are proposed to expand the concept of a mailing list to more than one list, which may include a listing of persons who have chosen to be notified electronically
- The word "entity" is deleted since "person" is defined as including any legal entity.
- Subsection D is amended to clarify that the Board should remove persons from the mailing list if they fail to indicate an interest in continuing to receive notifications from the Board and that persons who chose to be notified electronically may continue to also receive notices sent by regular mail.

Documents to be sent to person on the mailing list.

- Amendments will provide for electronically-transmitted notices, will identify the notices to be sent, and will require that the notices include instructions on how to obtain a copy of the

regulation and any supporting documentation, either from the Board office or from the Virginia Regulatory Townhall.

Notice of Intended Regulatory Action.

- Subsection C is amended to provide greater clarity in the requirement for a public hearing to be held on a proposed regulation if requested by at least 25 persons during the 30-day comment period on the NOIRA.

Notice of Comment Period.

- An amendment clarifies that the public may provide any comment on proposed regulations, including comments received electronically, including facsimile or internet. The regulation will also clarify that oral comment, outside of a scheduled public hearing, will not be accepted.

Notice of Meeting.

- The notice of meeting described in this section may take a different form than the one provided by the Registrar, so the capitalized name has been changed to lower case and the requirement for electronic posting has been added.

Periodic review of regulations.

- An amendment is adopted to recognize that Executive Orders may direct a schedule of regulatory review which is different from a review each biennium, but the review is to occur at least every two years.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which 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.

In its analysis of the proposed regulatory action, the agency has determined that there is no potential impact on the institution of the family and family stability, economic self-sufficiency, or the marital commitment. The amendments will not increase or decrease disposable family income.

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