Form: TH- 02

Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Board of Medicine, Department of Health Professions
VAC Chapter Number:	18 VAC 85-110-10 et seq.
Regulation Title:	Regulations Governing the Practice of Licensed Acupuncturists
Action Title:	Written documentation for diagnostic examination
Date:	2/13/00

This information is required pursuant 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*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Amendments to regulation are required in order to conform to an enactment clause in Chapter 814 of the 2000 Acts of the Assembly requiring the Board to promulgate regulations for the requirement of a standard form recommending a diagnostic examination for provision by the licensed acupuncturist to the patient. Emergency regulations were authorized by the bill and are replaced by the Board in the promulgation of this proposed amendment.

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 must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals.

§ 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.*

4. *To establish schedules for renewals of registration, certification and licensure.*

5. *To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.*

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 and Chapter 25 of this title.*

7. *To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.*

8. *To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.*

9. *To take appropriate disciplinary action for violations of applicable law and regulations.*

10. *To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final thirty days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the thirty-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.*

11. *To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.*

12. *To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.*

The legal authority to promulgate regulations is in second enactment clause of Chapter 814 of the 2000 Acts of the Assembly, which states: "That the Board of Medicine, in consultation with the Advisory Board on Acupuncture, shall promulgate regulations, including education and training requirements for doctors of medicine, osteopathy, chiropractic and podiatry who utilize acupuncture, and including the requirement for a standard form recommending a diagnostic examination for provision to the patient by the acupuncturist, to implement the provisions of this act within 280 days of enactment."

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed 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.

The law requires the licensed acupuncturist to either get written documentation that the patient has received a diagnostic examination by a licensed practitioner of medicine, osteopathy, chiropractic or podiatry or to provide a written recommendation for such an examination to the patient. The enactment clause requires the board to promulgate regulations for this requirement, including a standard form to be signed by the patient.

While the Code of Virginia no longer requires that a person get a medical examination and referral prior to receiving acupuncture, concerns remain that a medical problem will go undiagnosed and untreated during the course of acupuncture treatment. Therefore, the requirement for a written recommendation for an examination by a physician will provide a measure of protection for a patient's safety and health.

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 providing detail of the regulatory action's changes.

Regulations for licensed acupuncturists are amended to specify a form which must be provided by a licensed acupuncturist to a patient who has not received a diagnostic examination from a physician within the past six months.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 include a sentence to that effect.

There have been no issues related to the written recommendation form; the Code of Virginia requires that such a form be given to acupuncture patients. Many licensed acupuncturists already utilize such a form for their own protection and their concerns about their patients. Discussion by the Acupuncture Advisory Committee related to the composition of the form; the most important information and signature lines have been placed at the top of the form with the information intended for the acupuncturist at the bottom. Since licensed acupuncturists are not required to be fluent in English and the patient may not understand English, the instructions provide that the licensee has an obligation to either provide the form in the language of the patient or ensure that it has been translated for their understanding.

There are no disadvantages to the public; the public is better protected by the requirement for a disclosure form that will ensure the patient is aware of the need for a diagnostic examination by a doctor.

There are no disadvantages to the agency, since there are no additional tasks or responsibilities involved in compliance with these regulations.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

Projected cost to the state to implement and enforce:

(i) Fund source: 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.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: 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 copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled.

Projected cost on localities:

There are no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be licensed acupuncturists.

Estimate of number of entities to be affected:

Currently, there are approximately 108 acupuncturists who are licensed by the Board of Medicine to practice acupuncture.

Projected costs to the affected entities:

There should be very minimal cost for compliance consisting of costs for copying the required form and maintaining a copy in the patient's file.

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 cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

18 VAC 85-110-100. General requirements.

The amended regulation requires that the written recommendation for a diagnostic examination be provided on a form specified by the Board and signed by the patient. A copy of the form must be maintained in the patient's chart.

Alternatives

Please describe the specific 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.

Since there was a legal mandate for a written recommendation for an examination, the Advisory Committee on Acupuncture and the Board of Medicine did not consider an alternative to the requirement. It did consider alternatives to the wording of the standard form to implement the requirement and reviewed those currently in use by licensed acupuncturist and required by other states. The form adopted requires that the patient will receive a copy, that a copy be maintained in the patient's file, and that the licensed acupuncturist has a responsibility to ensure that the recommendation has been translated for the non-English patient. The content of the form was unanimously approved by both the Advisory Committee and the Board.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

An announcement of the board's intent to amend its regulations was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the PPG mailing list for the board. Public comment was received until January 17, 2001. During the 30-day comment period, no comments were received from members of the public, but the Acupuncture Advisory Committee discussed the content and composition of the patient form and suggested several changes.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The Advisory Committee on Acupuncture, comprised of licensed acupuncturists, physician acupuncturists and members of the Board met to work on draft regulations, made suggestions to clarify certain portions of the patient form. While the content was not changed from the form adopted as a part of the emergency regulation, it was rearranged for improved consumer understanding. The emergency regulations were reviewed and recommended by the Department of Planning & Budget, the Secretary of Health and Human Resources and the Office of the Governor. The Assistant Attorney General who provides counsel to the Board has been involved during the development and adoption of proposed regulations to ensure clarity and compliance with law and regulation. Since the regulations were drafted and approved in conjunction with those working on the Regulatory Townhall, the Board is satisfied that the regulation is clearly written and will be easily understandable by the individuals affected.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

Public participation guidelines require the Board to review regulations each biennium or as required by Executive Order. Regulations will be reviewed again during the 2003-04 fiscal year.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential 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 preliminary 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.