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Proposed Regulation Agency Background Document

Agency Name:	Board of Medicine
VAC Chapter Number:	18 VAC 85-40-10 et seq.
Regulation Title:	Regulations Governing the Practice of Respiratory Care Practitioners
Action Title:	Periodic review; continuing education
Date:	6/24/02

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summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed.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.

The board is recommending amendments to its regulations for the licensure of respiratory care practitioners in order to address concerns about the continued competency of practitioners who are renewing their licenses. Proposed regulations establish requirements for 20 hours of continuing education per biennium from an approved sponsor or organization, provide for exemptions or extensions of time for compliance, maintenance and provision of documentation upon request, and evidence of continuing education for reinstatement or reactivation of a license. Other amendments are recommended for greater clarity for the regulated entities or for adaptability to computerized testing.

Basis

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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.

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- 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.

In addition to general provisions in § 54.1-2400, the Board of Medicine is guided by provisions in the Medical Practice Act related to the licensure and regulation of respiratory care practitioners as follows:

§ 54.1-2954. Respiratory care practitioner; definition.

"Respiratory care practitioner" means a person who has passed the examination for the entry level practice of respiratory care administered by the National Board for Respiratory Care, Inc., or other examination approved by the Board, who has complied with the regulations pertaining to licensure prescribed by the Board, and who has been issued a license by the Board.

§ 54.1-2954.1. Powers of Board concerning respiratory care.

The Board shall take such actions as may be necessary to ensure the competence and integrity of any person who claims to be a respiratory care practitioner or who holds himself out to the public as a respiratory care practitioner or who engages in the practice of respiratory care and to that end the Board shall license persons as respiratory care practitioners. The provisions hereof shall not prevent or prohibit other persons licensed pursuant to this chapter from continuing to practice respiratory care when such practice is in accordance with regulations promulgated by the Board.

The Board shall establish requirements for the supervised, structured education of respiratory care practitioners, including preclinical, didactic and laboratory, and clinical activities, and an examination to evaluate competency. All such training programs shall be approved by the Board.

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§ 54.1-2955. Restriction of titles.

It shall be unlawful for any person not holding a current and valid license from the State Board of Medicine to practice as a respiratory care practitioner or to assume the title, "Respiratory Care Practitioner" or to use, in conjunction with his name, the letters "RCP."

§ 54.1-2956. Advisory Board on Respiratory Care; appointment; terms; duties; etc.

A. The Advisory Board on Respiratory Care shall assist the Board in carrying out the provisions of this chapter regarding the qualifications, examination, and regulation of licensed respiratory care practitioners.

The Advisory Board shall consist of five members appointed by the Governor for four-year terms. Three members shall be at the time of appointment respiratory care practitioners who have practiced for not less than three years, one member shall be a physician licensed to practice medicine in the Commonwealth, and one member shall be appointed by the Governor from the Commonwealth at large. Vacancies occurring other than by expiration of term shall be filled for the unexpired term. No person shall be eligible to serve on the Advisory Board for more than two consecutive terms.

B. The Advisory Board shall, under the authority of the Board, recommend to the Board for its enactment into regulation the criteria for licensure as a respiratory care practitioner and the standards of professional conduct for holders of licenses.

The Advisory Board shall also assist in such other matters dealing with respiratory care as the Board may in its discretion direct.

§ 54.1-2956.01. Exceptions to respiratory care practitioner's licensure.

The licensure requirements for respiratory care practitioners provided herein shall not prohibit the practice of respiratory care as an integral part of a program of study by students enrolled in an accredited respiratory care education program approved by the Board. Any student enrolled in accredited respiratory care education programs shall be identified as "Student RCP" and shall only deliver respiratory care under the direct supervision of an appropriate clinical instructor recognized by the education program.

The Board of Medicine has a <u>specific statutory mandate</u> to promulgate regulations to ensure practitioner competence with requirements such as continuing education.

§ 54.1-2912.1. Continued competency requirements.

A. The Board shall prescribe by regulation such requirements as may be necessary to ensure continued practitioner competence which may include continuing education, testing, and/or any other requirement. B. In promulgating such regulations, the Board shall consider (i) the need to promote ethical practice, (ii) an appropriate standard of care, (iii) patient safety, (iv) application of new medical technology, (v) appropriate communication with patients, and (vi) knowledge of the changing health care system. C. The Board may approve persons who provide or accredit such programs in order to accomplish the purposes of this section.

In addition, the Board is also authorized by § 54.1-103 to specify additional training for licensees seeking renewal of licenses.

§ 54.1-103. Additional training of regulated persons; reciprocity; endorsement.

A. The regulatory boards within the Department of Professional and Occupational Regulation and the Department of Health Professions may promulgate regulations specifying additional training or conditions for individuals seeking certification or licensure, or for the renewal of certificates or licenses.

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The Office of the Attorney General has certified by letter that the Board has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

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.

Through a periodic review of regulations, the Advisory Board on Respiratory Care identified several rules that needed to be clarified or updated. It particularly noted the need for a specific requirement for continuing education as an indication that the practitioner has updated his knowledge base and ability to practice. While regulations currently require 160 hours of practice in a biennium to renew an active license, comments during regulatory review strongly favored some requirement for continuing education to ensure that respiratory care practitioners have maintained their skills and competencies in order to protect the public health, safety and welfare. As with other fields in medicine, respiratory care is continuously changing with new technology and treatments; continuing education is essential if the Board is going to ensure minimal competency of its licensees. Documentation of continuing competency activities will ensure that the person resuming active practice or licensure in Virginia has maintained current knowledge and skills to appropriately manage and treat patients.

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.

Amended regulations will require 20 hours of continuing education each biennium as approved and documented by a sponsor or provider recognized by the national professional body, the American Association for Respiratory Care. Licensees are granted an exemption from the requirement in the first renewal following initial licensure and are also allowed to petition the Board for an extension of time if unable to fulfill their hours. Documentation from the AARC must be retained for four years following renewal and provided to the Board within 30 days in the event the licensee is audited. In addition, the amendments establish a continuing education requirement for reactivation or reinstatement of an inactive license.

Other amendments are "housekeeping" to clarify certain sections or to allow the Board flexibility in approval of examination or the receipt of examination results.

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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.

Advantages or disadvantages to the public:

There are definite advantages of the proposed amended regulations to the public, which will have greater assurance that the licensees for the Board are engaged in activities to maintain and improve their knowledge and skills in providing care to their patients. The public is also better served by a continuing competency requirement for licensees who have allowed their license to lapse or have been inactive.

Advantages to the licensees:

The continuing competency requirements are intended to provide some assurance to the public that licensees of the Board are maintaining current knowledge and skills, while providing the some flexibility to licensees. The Board believes that the majority of respiratory care practitioners already obtain sufficient hours of continuing competency activities or courses in a biennium. Licensees who work for organizations are often required to take in-service training or continuing education for employment. The resources for earning the hours and engaging in the required learning are numerous and readily available in all parts of Virginia.

Disadvantages to the licensees:

For a small minority of practitioners who do not currently engage in any continuing learning in their profession, these requirements will represent an additional burden. However, it was determined by enactment of the statute and by the Board's concurrence that those practitioners and their patients would greatly benefit from continuing learning requirements, and that the public is better protected if there is some assurance of that effort.

Advantages or disadvantages to governmental agencies:

Government agencies that employ respiratory care practitioners may incur some additional costs if they elect to hire individuals to present workshops or seminars to their staff or to pay for continuing education. The Board will incur additional costs to monitor compliance of licensees, and to hold additional disciplinary hearings for individuals who do not comply with the requirement.

Fiscal Impact

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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 ongoing 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 \$2,000) 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, so there is no additional cost for board member per diem or travel.

There may also be some ongoing expenditures related to compliance enforcement. The Board expects to conduct an audit of approximately 2% of its licensees at the conclusion of each biennium. For respiratory care practitioners, that would involve auditing CE for approximately 60 licensees. Each practitioner selected for the audit will be required to submit the required documentation of continuing education activities. There will be some staff time involved in review of the documentation and in communicating with licensee about their deficiencies.

It is also expected that a small percentage of licensees selected for audit will result in a disciplinary case being opened. From the experience of boards within the agency that currently have continuing competency requirements for renewal, the majority of those cases (estimated to be 5 or 6 per biennium) will probably be settled with a pre-hearing consent order. In those cases, the only costs would be for charges back to the Board from the Administrative Proceedings Division (APD) of the Department. Costs for cases that do result in an informal conference committee proceeding (estimated to be one or two per biennium) would include travel expenses and per diem for board members as well as costs for the services of APD. Informal conference committees typically hear several cases in a day, so the costs per case for board member and APD time would be minimized.

Biennial cost estimates for disciplinary cases related to the failure to comply with continuing competency regulations range from \$100 to cases resulting in pre-hearing consent orders (total of \$500 to \$600) to \$500 per case for those that result in an informal conference committee (\$500 to

\$1,000). All expenses relating to enforcement of these regulations can be absorbed in the existing budget of the Board of Medicine.

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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 respiratory care practitioners.

Estimate of number of entities to be affected:

Currently, there are approximately 3,000 persons licensed to practice respiratory care.

Projected costs to the affected entities:

Regulations adopted by the Board require a licensee to have 20 hours of approved continuing education each biennium. The cost for compliance will vary depending on the practitioner and the method chosen for acquiring the required hours.

Many organizations, hospitals and large practices offer in-service training for their therapy staff at no cost to the practitioners. For example, a manager of a small community hospital in Virginia commented that she was confident that it would not be an issue nor would it be cost prohibitive for respiratory therapists to obtain the required continuing education. Another commented that maintaining 20 hours would not be difficult due to the numerous routes for obtaining hours, both live lecture and nontraditional routes. According to respiratory care practitioners, there are numerous opportunities to obtain CE credits through conferences, journals, district meetings, and in-service with hospitals and home health care agencies. The Advisory Board has estimated that the cost would be \$0 to \$20 per hour. Courses offered by sponsors recognized by the AARC are always open to members and non-members; sometimes but not always, the cost per course is slightly higher for non-members. Membership in the AARC costs \$90 a year. It would appear from licensee comments and discussions by the Advisory Board that there is an sufficient amount of continuing education offered in all regions of the state at a minimal cost.

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 85-40-10. Definitions.

A definition for the acronym "AARC" is added as the term is used in new requirements for continuing education.

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18 VAC 85-40-35. Fees.

A new section is added to include the fee provisions under General Provisions in Part I. The section replaces section 80, which is being repealed. There are no proposed changes to fees.

18 VAC 85-40-40. Application requirements.

The Board recommends an amendment to the requirement for "documentation" of passage of the national examination. Evidence of passage may be delivered on-line in the future.

18 VAC 85-40-45. Educational requirements.

It is recommended that an amendment be added to give the Board authority to accept equivalent education to that required for credentialing by the National Board on Respiratory Care (NBRC) if another equivalent, national credential became available.

18 VAC 85-40-50. Examination requirements.

An amendment would delete the requirement for "written evidence, verified by affidavit" to permit the Board to receive national examination scores on-line.

18 VAC 85-40-60. Renewal of license.

The Board recommends an amendment to clarify that the license must attest on the renewal form that he has engaged in active practice as defined in section 10 and that he has met the continuing education requirements set forth in section 66.

18 VAC 85-40-61. Inactive license.

An amendment is proposed for reactivation of an inactive license to require 10 hours of continuing education for each year in which the license has been inactive, not to exceed three years.

18 VAC 85-40-65. Inactive license.

An amendment is proposed for reactivation of an inactive license to require 10 hours of continuing education for each year in which the license has been inactive, not to exceed three years.

18 VAC 85-40-66. Continuing education requirements.

New regulations for continuing education will require an active licensee to complete 20 hours each biennium of continuing education in respiratory care offered by a sponsor or provider recognized by the AARC. The regulations provide for an exemption in the first renewal following initial licensure and empower the Board to grant exemptions for all or part of the requirement for circumstances beyond the control of the licensee. Licensees are also allowed to submit a written request for an extension of time for up to one year. Licensees must retain CE documentation for four years following renewal and are required to provide such documentation within 30 days of receiving notification of a CE audit. Failure to comply with CE requirements may subject the licensee to disciplinary action.

18 VAC 85-40-80. Fees.

Amendments are recommended to place the fees under Part I, General Provisions for consistently with other regulations under the Board of Medicine and to state the current policy of the board, which is that all fees are nonrefundable unless otherwise specified.

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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.

Issues that were addressed in the development of these regulations and the alternatives selected were:

1) Continuing competency hours

The Advisory Board considered the options for continuing competency and recommended that 20 hours of continuing education each biennium, combined with the current requirement for 160 hours of active practice, would provide the assurance that a respiratory care practitioner was maintaining his current knowledge and skills and being exposed to new ideas, techniques and technologies. Such a requirement is less burdensome that the current requirement for doctors of medicine, osteopathy, podiatry or chiropractic (60 hours each biennium) and similar to other professions regulated by the Board of Medicine. The hours are consistent with or less than other similar professions such as occupational therapists who are required to obtain 20 hours per biennium, radiological technologists who are required to obtain 24 hours per biennium, and physical therapists who must have 30 hours per biennium.

Out of the 43 states that regulate respiratory care, 37 states have continuing education requirements with the average number of hours required to be approximately 19 per biennium. In the neighboring states, the hour-requirement is also similar to the proposed regulation in Virginia. For two years or a biennium, the requirements are as follows: North Carolina – 20; South Carolina – 30; Tennessee – 20; West Virginia – 20; Kentucky – 24; and Maryland – 16.

2) Selection of approved providers or sponsors of continuing education.

Rather than grant approval on a case-by-case basis, the Board followed the example of other boards with the Department by setting out in regulation that the organizations or sponsors that were considered "approved" providers of continuing education would be those recognized by the American Association for Respiratory Care. In reviewing the alternatives for approving continuing education courses or hours, the Board found that AARC recognition is standard in the profession of respiratory care. Community college courses, programs offered by the Virginia Society for Respiratory Care (an affiliate of AARC), and in-service training are typically approved by AARC. There was no support for Board-recognition of other accrediting bodies or for board approval of individual sponsors.

3) Requirements for reactivation of an inactive or lapsed license.

Along with requirements for continuing competency for renewal of licenses, the Board is proposing new requirements for reactivation of an inactive license or reinstatement of a lapsed license as necessary to ensure that practitioners are competent to resume practice. The Board determined that it was necessary for a practitioner whose license has been inactive or lapsed for at least two years to provide evidence of continuing competency hours equal to the amount of time the license has not been active, not to exceed three years. This requirement is also consistent with other health care practitioners who are required to demonstrate continued competency.

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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 November 7, 2001. During the 30-day comment period, there were 2 comments received by letter, 10 comments on the Regulatory Townhall, and by 2 comments by email to the agency.

Summary of comment:

- All commenters supported the enactment of continuing education requirements for active respiratory care practitioners with a minimum of 15 to 20 hours each biennium. Several noted that there are many opportunities for CE through professional organizations and institutions and that meeting such a requirement would not be burdensome. The Virginia Society for Respiratory Care supported a requirement of 20 hours on continuing education biennially, consistent with the average amount required in other states. One commenter expressed some concern about the availability of CE in some parts of the state for licensees who are independently employed in non-hospital settings.
- Two commenters raised questions about the definition of supervision of and practice by students in respiratory care prior to licensure.
- Several commented in opposition to requiring retesting for someone who has taken inactive status and wants to return to active practice, and one person raised questions about the meaning of inactive status.

The Advisory Board on Respiratory Care held several public meeting to conduct a review of regulations and discuss issues related to evidence of continued competency. Based on the concerns expressed by licensees about continued practitioner competence and support for 20 hours of continuing education, the Advisory Board voted to recommend the proposed amendments to regulations.

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.

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The Advisory Board on Respiratory Therapy, comprised of licensed respiratory care practitioners, a physician and a public member met to work on draft regulations. The regulations were also reviewed and approved by the Legislative Committee of the Board prior to adoption on June 6, 2002. 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.

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 2004-05 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.

The amendments will have no impact on the authority and rights of parents in the education, nurturing or supervision of their children. They may encourage self-pride for licensees who obtain additional training that they may not have otherwise pursued. The amendments should have no impact on the marital commitment. Disposable income of practitioners who are required to obtain the training will decrease slightly depending on the type of continuing competency activities selected.