

# Regulatory Analysis Form

This space for use by IRRCC

(1) Agency

Department of State, Bureau of Professional and Occupational Affairs, State Board of Medicine

(2) I.D. Number (Governor's Office Use)

16A-4914

IRRC Number: 2375

(3) Short Title

**Continuing Medical Education**

(4) PA Code Cite

49 Pa. Code § § 16.1, 16.19

(5) Agency Contacts & Telephone Numbers

Primary Contact: Gerald S. Smith (717) 783-7200  
Senior Counsel in Charge, Department of State  
Secondary Contact: Joyce McKeever (717) 783-7200

(6) Type of Rulemaking (check one)

- Proposed Rulemaking  
 Final Order Adopting Regulation  
 Final Order, Proposed Rulemaking Omitted

(7) Is a 120-Day Emergency Certification Attached?

- No  
 Yes: By the Attorney General  
 Yes: By the Governor

(8) Briefly explain the regulation in clear and nontechnical language.

This regulation implements the continuing medical education mandate of Act 13 of 2002. It requires medical doctors to obtain 100 hours of continuing medical education as a condition of license renewal. Of the 100 hours, 20 must be AMA PRA Category 1 credits, and 12 must be in the area of patient safety and risk management. The regulation also establishes record keeping requirements and provides for exemptions and waivers. Because of the limited time remaining before renewal the Board has provided a limited implementation for January 1, 2005, and has delayed full implementation until January 1, 2007.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The Medical Care Availability and Reduction of Error (Mcare) Act,  
Act 13 of 2002, Act of March 18, 2002, P.L. \_\_\_, No. 13 (40 P.S. §1303.101-1303.910).

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(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

**Yes. Act 13 of 2002, Act of March 20, 2002, P.L. 154, No. 13. Section 910(h) of the Mcare Act requires that regulations be promulgated.**

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

**Recent studies have demonstrated that medical errors are occurring at a significant rate both within the Commonwealth and across the nation. At the same time, medical malpractice insurance rates have skyrocketed. The legislature has established mandatory continuing medical education to aid in alleviating this problem.**

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

**Mandatory continuing medical education will help practitioners stay current on developing trends in medicine, which will, in turn, make them better and safer practitioners.**

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

**Consumers, as well as the profession as a whole, will benefit from continuing medical education.**

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(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

**There are no perceived people or groups of people who would be adversely affected by this regulation.**

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

**All physicians, except those exempted by the regulation (first time applicants, those holding temporary training licenses, retired and inactive licensees), are required to comply with the regulation. Currently there are approximately 46,000 physician licensees of the Board.**

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

**Input was sought from physician groups, the Pennsylvania Medical Society, the Hospital and Healthsystems Association of Pennsylvania, hospitals, and the general public.**

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures, which may be required.

**It is difficult to estimate the cost to the regulated community. Much will depend upon where the licensees choose to obtain their continuing medical education. There are many programs that are offered at little or no cost through hospitals, local medical societies, etc. Many, if not most, licensees already obtain the required continuing medical education credits in order to maintain national board certification. Physicians will be required to maintain records of compliance.**

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(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures, which may be required.

N/A

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures, which may be required.

**The costs associated with implementing these regulations is hard to quantify. There will be costs incurred for auditing, verifying and prosecuting cases relating to completion of continuing medical education credits. However, the overhead cost involved in these activities was considered and included in the Medical license fee regulations, 16A-4913.**

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(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	<b>Current</b>	<b>FY +1</b>	<b>FY +2</b>	<b>FY +3</b>	<b>FY +4</b>	<b>FY +5</b>
<b>SAVINGS:</b>	\$N/A	\$ N/A	\$ N/A	\$ N/A	\$ N/A	\$ N/A
<b>Regulated Community</b>						
<b>Local Government</b>						
<b>State Government</b>						
<b>Total Savings</b>						
<b>COSTS:</b>	\$ N/A	\$ N/A	\$ N/A	\$ N/A	\$ N/A	\$ N/A
<b>Regulated Community</b>	Unable	to	Determine			
<b>Local Government</b>						
<b>State Government</b>						
<b>Total Costs</b>						
<b>REVENUE LOSSES:</b>	\$	\$	\$	\$	\$	\$
<b>Regulated Community</b>						
<b>Local Government</b>						
<b>State Government</b>						
<b>Total Revenue Losses</b>						

(20a) Explain how the cost estimates listed above were derived.

**Costs associated with physician compliance will vary based upon charges assessed by Continuing Medical Education providers. There are numerous activities available at no cost.**

### Regulatory Analysis Form

(20b) Provide the past three-year expenditure history for programs affected by the regulation.

Program	FY-3 1999-2000	FY-2 2000-2001	FY-1 2001-2002	Current FY 2002-2003
State Board of Medicine	\$2,562,885.01	\$2,595,622.41	\$2,884,504.70	\$6,747,000.00

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

**There should be no adverse effects and costs associated with compliance with the regulation. The benefits of the regulation are described in paragraphs 11 & 13 above.**

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

**Because these regulations were required by statute, no nonregulatory alternatives were considered.**

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

**Because these regulations were required by statute, no other regulatory schemes were considered.**

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(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

**There are no applicable federal standards. However, these regulations, which require 100 continuing medical education credits biennially, are consistent with the nationally recognized standard established by the American Medical Association's Physician Recognition Award, which requires at least 50 continuing medical education credits annually.**

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

**A poll of neighboring states has revealed the following:**

**New York – No CME requirement**

**Delaware – CME requirement: 40 hours Category 1 for biennial renewal**

**Ohio – CME requirement: 40 hours Category 1, 60 hours Category 2 biennially**

**Maryland – CME requirement: 50 hours Category 1 biennially**

**West Virginia – CME requirement: 50 hours Category 1 biennially**

**Since most states require CME, it is not anticipated that these regulations will put Pennsylvania at a competitive disadvantage.**

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

**No.**

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

**The Board meets in public session on the fourth Tuesday of every month at which time information relative to all rulemaking is discussed. Meetings are held at the Board's offices at 2601 N. Third Street, Harrisburg, PA. A schedule of Board meeting dates is available on the Department of State's website at [www.dos.state.pa.us/bpoa](http://www.dos.state.pa.us/bpoa). Comments from the public are always welcome.**

**Regulatory Analysis Form**

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports, which will be required as a result of implementation, if available.

**Yes. Physician licensees will be required to maintain evidence of compliance with the regulations.**

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

**The regulation provides an exemption for retired or inactive licensees, as well as for those holding a temporary training license.**

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

**The regulation will be effective on publication as final rulemaking.**

**The continuing education requirements must be met as a condition of renewal on January 1, 2005.**

(31) Provide the schedule for continual review of the regulation.

The Board continuously reviews its regulations, periodically communicates with licensees through newsletters and obtains information and feedback from its licensees on a frequent basis.



proper fees and permit the Board to charge the fees for continuing education approval which it has continuing authority to charge. The proposed rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions. The proposed rulemaking will impose no additional paperwork requirements upon the Commonwealth, its political subdivisions or the private sector.

**E. Sunset Date**

The Board monitors its regulations on a continuing basis. Therefore, no sunset date has been assigned.

**F. Regulatory Review**

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on December 16, 2003, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

**G. Public Comment**

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Christina Stuckey, Board Administrator, State Board of Examiners of Nursing Home Administrators, P. O. Box 2649, Harrisburg, PA 17105-2649, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference No. 16A-628 (Deletion of Examination Fees) when submitting comments.

ROBERT H. MORROW, NHA,  
*Chairperson*

**Fiscal Note:** 16A-628. No fiscal impact; (8) recommends adoption.

**Annex A**

**TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS**  
**PART I. DEPARTMENT OF STATE**  
**Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS**  
**CHAPTER 39. STATE BOARD OF EXAMINERS OF NURSING HOME ADMINISTRATORS**  
**RENEWAL**

**§ 39.72. Fees.**

The following is a schedule of fees charged by the Board:

	* * * * *	
[N.A.B. examination fee .....		\$235
State rules and regulations examination .....		\$87

<b>Complete nursing home administration examination .....</b>	<b>\$322 ]</b>
* * * * *	

Continuing education program application fee per clock hour .....	[ \$10 ] \$15
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<b>Continuing education individual program application fee .....</b>	<b>\$20</b>
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[Pa.B. Doc. No. 04-15. Filed for public inspection January 2, 2004, 9:00 a.m.]

**STATE BOARD OF MEDICINE**

[49 PA. CODE CH. 16]

**Continuing Medical Education**

The State Board of Medicine (Board) proposes to amend § 16.1 (relating to definitions) and add § 16.19 (relating to continuing medical education) to read as set forth in Annex A.

*Effective Date*

The proposed rulemaking will be effective upon final publication in the *Pennsylvania Bulletin*. The Legislature has required that the Board promulgate regulations within 6 months of the effective date of section 910 of the Medical Care Availability and Reduction of Error (MCARE) Act (act) (40 P. S. § 1303.910).

*Statutory Authority*

Under section 910 of the act, the Board is required to establish requirements for continuing medical education for physicians as a condition for renewal of their licenses. Physicians are required to complete 100 credit hours of mandatory continuing medical education during each 2-year licensure period.

*Background and Purpose*

The proposed rulemaking will implement section 910 of the act, which requires completion of 100 credit hours of continuing education as a condition of biennial license renewal of physician licenses by the Board and the State Board of Osteopathic Medicine.

*Description of Proposed Rulemaking*

The proposed rulemaking requires proof of completion of 100 credit hours of continuing medical education as a condition of license renewal and requires that at least 20 of the 100 hours be American Medical Association Physician Recognition Award category 1 credits and that at least 10 credit hours must be in the areas of patient safety and risk management. Courses in the areas of patient safety and risk management may include topics such as improving medical records and recordkeeping, reducing medical errors, professional conduct and ethics, improving communications, preventative medicine and healthcare quality improvement. The proposed rulemaking further designates the Accreditation Council on Continuing Medical Education as the accrediting body for purposes of approving continuing medical education providers.

*Fiscal Impact and Paperwork Requirements*

The proposed rulemaking will require the Board to alter its license renewal forms to include data regarding

the physician's compliance with the continuing education requirements and will also require physicians to maintain their own records of continuing education credits, but otherwise, should have no adverse fiscal impact on the Commonwealth or its political subdivisions.

*Sunset Date*

The Board continuously monitors the cost effectiveness of its regulations. Therefore, no sunset date has been assigned.

*Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on December 16, 2003, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

*Public Comment*

Interested persons are invited to submit written comments, recommendations or objections regarding the proposed rulemaking to Amy L. Nelson, Counsel, State Board of Medicine, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

CHARLES D. HUMMER, Jr., M.D.,  
*Chairperson*

**Fiscal Note:** 16A-4914. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

Subchapter A. BASIC DEFINITIONS AND INFORMATION

§ 16.1 Definitions.

The following words and terms, when used in this chapter and Chapters 17 and 18 (relating to State Board of Medicine—medical doctors; and State Board of Medicine—practitioners other than medical doctors), have the following meanings, unless the context clearly indicates otherwise:

**ACCME**—The Accreditation Council for Continuing Medical Education.

**AMA**—American Medical Association.

**AMA PRA**—American Medical Association Physician's Recognition Award.

\* \* \* \* \*

**Approved course**—A continuing medical education course offered by a provider accredited by the ACCME.

\* \* \* \* \*

**Immediate family member**—A parent, spouse, child or adult sibling residing in the same household.

\* \* \* \* \*

Subchapter B. GENERAL LICENSE, CERTIFICATION AND REGISTRATION PROVISIONS

§ 16.19. Continuing medical education.

Beginning with the licensure renewal period commencing January 1, 2005, proof of completion of 100 credit hours of continuing medical education in the preceding biennial period will be required for licensure renewal for medical doctors.

(1) At least 20 credit hours shall be completed in AMA PRA category 1 approved courses. At least 10 credit hours shall be completed in approved courses in the area of patient safety and risk management. Approved courses in the area of patient safety and risk management may include topics such as improving medical records and recordkeeping, reducing medical errors, professional conduct and ethics, improving communications, preventative medicine and healthcare quality improvement. The remaining 70 credit hours shall be completed in any approved courses. Credit will not be granted for courses in office management or practice building.

(2) Physicians shall retain official documentation of attendance for 2 years after renewal, and shall certify completed courses on a form provided by the Board for that purpose, to be filed with the biennial renewal form. Official documentation proving attendance shall be produced, upon Board demand, under random audits of reported credit hours. Electronic submission of documentation is permissible to prove compliance with this subsection. Noncompliance may result in disciplinary proceedings under section 41(6) of the Medical Practice Act of 1985 (63 P. S. § 422.41(6)).

(3) The following exemptions apply for certain physicians:

(i) A physician applying for licensure in this Commonwealth for the first time shall be exempt from the continuing medical education requirement for the biennial renewal period following initial licensure.

(ii) A physician holding a current temporary training license shall be exempt from the continuing medical education requirement.

(iii) A retired physician who provides care only to immediate family members shall be exempt from the continuing medical education requirement.

(iv) A physician who is on inactive status shall be exempt from the continuing medical education requirement, except that a physician who is seeking to reinstate an inactive or lapsed license shall show proof of compliance with the continuing education requirement for the preceding biennium.

(4) A physician suspended for disciplinary reasons is not exempt from the requirements of this section.

(5) Waiver of the CME requirements may be permitted, as follows:

(i) The Board may grant a hardship waiver of all or a part of the continuing medical education requirement in cases of serious illness, military service or other good cause provided that the public's safety and welfare will not be jeopardized by the granting of the waiver.

(ii) Requests for waiver shall be made in writing, with appropriate documentation, and shall include a description of circumstances sufficient to show why compliance is impossible.

(iii) Waiver requests will be evaluated by the Board on a case-by-case basis. The Board will send written notification of its approval or denial of a waiver request.

[Pa.B. Doc. No. 04-16. Filed for public inspection January 2, 2004, 9:00 a.m.]

## STATE BOARD OF OSTEOPATHIC MEDICINE

[49 PA. CODE CH. 25]

### Delegation of Medical Services

The State Board of Osteopathic Medicine (Board) proposes to amend § 25.1 (relating to definitions) by adding a definition for "emergency medical services personnel" and to add § 25.217 (relating to delegation) to read as set forth in Annex A.

#### A. Effective Date

The proposed rulemaking will be effective upon publication as a final-form rulemaking in the *Pennsylvania Bulletin*.

#### B. Statutory Authority

Section 16 of the Osteopathic Medical Practice Act (act) (63 P. S. § 271.16) authorizes the Board to promulgate regulations necessary to carry out the purposes of the act. Section 3 of the act (63 P. S. § 271.3) permits osteopathic physicians to delegate medical services and acts to physician assistants, technicians or other allied medical personnel if services and acts are rendered under the supervision, direction or control of a licensed physician.

#### C. Background and Purpose

The Board routinely receives inquiries about whether a particular delegation of medical services is appropriate. In an effort to be responsive to the regulated community and to provide a framework that places patient safety and welfare at the forefront of the osteopathic physician's decision making process, the Board determined to codify basic criteria under which an osteopathic physician may delegate the performance of medical services to nonphysicians.

#### D. Description of Proposed Rulemaking

Section 3 of the act permits osteopathic physicians to delegate the performance of medical services. Section 3 of the act provides in relevant part as follows:

"Nothing in this act shall be construed to prohibit services and acts rendered by a qualified physician assistant, technician or other allied medical person if such services and acts are rendered under the supervision, direction or control of a licensed physician."

The proposed rulemaking adds § 25.217. This section establishes general criteria under which an osteopathic physician may exercise professional judgment in making the decision to delegate medical services.

Section 25.217(a) establishes the criteria under which delegation could occur. Specifically, § 25.217(a)(1) requires that delegation be consistent with standards of acceptable medical practice. Standards of acceptable medical practice may be discerned from current medical literature and texts, medical teaching facilities publications and faculty, expert practitioners in the field and the commonly accepted practice of practitioners experienced in the field.

Section 25.217(a)(2) prohibits an osteopathic physician from expanding the scope of practice of other health care practitioners where the General Assembly or the licensing board responsible for regulating the other health care practitioner has prohibited the performance of those services by the other health care practitioner. Section 25.217(a)(3) requires the osteopathic physician to assure that the individual practitioner or technician to whom the delegation is being made has sufficient education, training and competency so that the delegatee knows how to perform the service safely. Accordingly, the osteopathic physician would be obligated to determine whether the delegatee is competent to perform the procedure. This may be accomplished by determining whether the delegatee is licensed, certified or possesses documented education and training related to the service. The physician may choose to monitor the delegatee to become satisfied as to the delegatee's competence.

Section 25.217(a)(4) prohibits delegation when the particular patient presents with unusual complications, family history or condition so that the performance of the medical service poses a special risk to that particular patient. Unlike the other provisions, this section directs the osteopathic physician's attention to the needs of the particular patient. A determination shall be made that the service may be rendered to the particular patient without undue risk. It is the physician's responsibility to make that assessment.

Section 25.217(a)(5) recognizes that patients are autonomous and that consideration of patient autonomy and dignity is a responsibility of the osteopathic physician. Thus, it is the osteopathic physician's responsibility to assure that the patient is advised as to the nature of the medical service and the reason for the delegation, so that the patient might exercise his right to request the service be performed by the osteopathic physician. The primary relationship in the delivery of medical services is between the patient and the physician. The person in charge of this relationship is the patient. Communication with the patient and education of the patient is essential to the proper delivery of medical services, and a primary obligation of physicians.

Section 25.217(a)(6) directs the osteopathic physician to provide the level of supervision and direction appropriate to the circumstance surrounding the delivery of the medical service. It underscores the fact that the osteopathic physician is ultimately responsible for the patient's well-being and requires the physician to maintain the level of involvement in the treatment process as required by section 3 of the act.

Section 25.217(b) prohibits the delegation of a medical service when the service is sufficiently complicated, difficult or dangerous that it would require a degree of education and training possessed by osteopathic physi-

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(DEPUTY ATTORNEY GENERAL)

State Board of Medicine

(AGENCY)

BY: *Tanya C. Gable*

DOCUMENT/FISCAL NOTE NO. 16A-4914

*6/16/84*

DATE OF APPROVAL

DATE OF ADOPTION: \_\_\_\_\_

BY: \_\_\_\_\_  
Charles D. Hummer, Jr., M.D.

(Deputy General Counsel  
~~Chief Counsel,~~  
~~Independent Agency~~  
Strike inapplicable  
title)

TITLE: Chairman  
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

- Check if applicable  
Copy not approved.  
Objections attached.
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General approval or  
objection within 30 day  
after submission.

FINAL RULEMAKING  
COMMONWEALTH OF PENNSYLVANIA  
DEPARTMENT OF STATE  
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS  
STATE BOARD OF MEDICINE  
49 PA. CODE, CHAPTER 16  
CONTINUING MEDICAL EDUCATION

The State Board of Medicine (Board) hereby amends §16.1 (relating to definitions) and adds §16.19 (relating to continuing medical education) to read as set forth in Annex A.

**A. Effective Date**

The amendments are effective upon publication as final-form regulations in the Pennsylvania Bulletin.

**B. Statutory Authority**

Under Section 910 of the Medical Care Availability and Reduction of Error (Mcare) Act. (40 P.S. §1303.910), the Board is required to establish requirements for continuing medical education for physicians as a condition for renewal of their licenses.

**C. Background and Purpose**

The proposed regulation will implement section 910 of the Mcare Act, which requires completion of continuing medical education as a condition of biennial license renewal of physician licenses by the State Board of Medicine.

**D. Description of Amendments**

Section 16.1 (relating to definitions) is amended to include new definitions that relate to the continuing medical education requirement. Acronyms for the Accreditation Council for Continuing Medical Education (ACCME), the American Medical Association (AMA) and the American Medical Association Physician's Recognition Award (AMA PRA) have been included. The ACCME is the national oversight body for continuing medical education. The AMA PRA is the nationally recognized standard for continuing medical education. Continuing medical education activities that adhere to the published standards of the AMA PRA are eligible for continuing medical education credit.

Because continuing medical education activities are much broader than typical didactic course work and may include such activities as rounds, research, independent study, teaching, and the like, the final regulation changes the definition of approved course to approved activity. This definition also has been amended to more accurately reflect that in the field of continuing medical education activities are accepted for credit in a decentralized process by organizations designated by the ACCME. Definitions have also been added to identify that continuing medical education activities are delineated under the AMA PRA standard into Category 1 activities and Category 2 activities. Category 1 and Category 2 are terms of art in the continuing medical education field and are well understood by the physician and continuing medical education

communities, accordingly, further defining these terms is unnecessary and likely to generate confusion rather than clarity.

Section 16.19 has been amended in final rulemaking in several respects. Because of the short time period remaining between publication of this regulation in final form and the January 1, 2005, deadline for renewal of license, the Board has determined to significantly reduce the continuing education requirement for this renewal period. However, the Board has determined that it is important to implement at least a minimum continuing education requirement. Accordingly, §16.19 has been amended in final rulemaking such that for the licensure renewal period commencing January 1, 2005, proof of completion of 25 credit hours of continuing medical education in the preceding biennial period running January 1, 2003 through December 31, 2004, will be required. The 25 credit hours for the January 1, 2005 license renewal period may be completed in either AMA PRA Category 1 or AMA PRA Category 2, and must include 3 hours of patient safety and risk management.

Full implementation of the continuing education requirement has been delayed until the licensure renewal period commencing January 1, 2007. At that time proof of completion of 100 credit hours of continuing medical education in the preceding biennial period running January 1, 2005 through December 31, 2006 will be required for licensure renewal for medical doctors.

Under §16.19(a), once full implementation occurs, at least 20 credit hours of the 100 will be required to be completed in AMA PRA Category 1 approved activities. Further, at least 12 credit hours of the 100 will be required to be completed in AMA PRA Category 1 or Category 2 activities related to the area of patient safety and risk management. Approved activities in the area of patient safety and risk management may include such topics as improving medical records and record-keeping, reducing medical errors, professional conduct and ethics, improving communications, preventative medicine, and healthcare quality improvement. Credit will not be granted for courses in office management or practice building.

Under §16.19(b), physicians are required to retain documentation of participation for 2 years after renewal and shall certify they completed continuing medical education activities on a form provided by the Board for that purpose. Documentation proving completion of continuing medical education must be produced, upon Board demand, pursuant to random audits of reported credit hours. Electronic submission of documentation is permissible to prove compliance. Noncompliance may result in disciplinary proceedings under section 41(6) of the Medical Practice Act of 1985 (63 P.S. 422.41(6)). Section 16.19(b)(2) and (3) identifies acceptable forms of documentation evidencing completion of continuing medical activities.

Section 16.19(c) provides for exemption from the continuing medical education requirement for a physician who is applying for licensure in the Commonwealth for the first time; holds a current training license; is a retired physician providing care only to immediate family members or is on inactive status, except that a physician seeking to reinstate an inactive

or lapsed license shall show proof of compliance with the continuing education requirement for the preceding biennium. Section 16.19(d) provides that a physician suspended for disciplinary reasons is not exempt from the requirements of this section.

Section 16.19(e) authorizes the Board to grant discretionary waivers of the continuing medical education requirements in cases of serious illness, military service or other good cause provided that the granting of the waiver will not jeopardize the public's safety and welfare.

**E. Compliance with Executive Order 1996-1 and Public Comment.**

In accordance with the requirements of Executive Order 1996-1 (February 6, 1996), in drafting and promulgating the regulation, the Board solicited input and suggestions from the regulated community and other parties who have identified themselves as interested in the Board's regulatory agenda. Proposed rulemaking was published at 34 Pa. B. 56 on January 3, 2004.

The Board entertained public comment for a period of 30 days during which time the Board received comments from individuals and organizations including the Hospital and Healthsystem Association of Pennsylvania (HAP), several hospitals and the Pennsylvania Medical Society (PMS). Following the close of the public comment period, the Board received comments from the Independent Regulatory Review Commission (IRRC) and the House Professional Licensure Committee (HPLC). The Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) did not comment. The following is a summary of the comments and the Board's responses.

The comments were in the main supportive of the proposed regulation but expressed concern regarding the amount of time remaining in the renewal period and whether it would be practicable to fully implement the continuing medical education requirement for the January 1, 2005, renewal. The HPLC and IRRC echoed this concern. The Board agrees that full implementation is not practicable at this point in time and has amended the regulation in final form to delay full implementation until January 1, 2007. However, the Board has provided for a minimum continuing medical education requirement for the upcoming renewal.

HAP also requested that the regulations clarify that the existing nationally recognized AMA PRA Category 1 and Category 2 system of accepting continuing medical education would continue. The Board agrees that the proposed rulemaking was not clear in this intent and has made the suggested amendments to the final regulation.

The HPLC and the IRRC pointed out that the proposed rulemaking appeared in error in regard to the counting of patient safety and risk management activities in relation to the full 100-hour requirement. The Board corrected the final regulation to clarify that patient safety and risk management was part of the over 100 hours of required continuing medical education. The

Board increased the number of required hours in patient safety and risk management from 10 to 12 in keeping with the Governor's Plan For Medical Malpractice Liability Reform of June 9, 2003.

**F. Fiscal Impact and Paperwork Requirements**

There is no adverse fiscal impact or paperwork requirement imposed on the Commonwealth, political subdivisions, or the private sector. Citizens of this Commonwealth will benefit in that this regulation promotes patient safety and welfare as a consequence of maintaining physician participation in continuing medical education activities.

**G. Sunset Date**

The board continuously monitors its regulations. Therefore, no sunset date has been assigned.

**H. Regulatory Review**

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on January 3, 2004, the Board submitted a copy of the notice of proposed rulemaking, published at 34 Pa.B. 56, to IRRC and the Chairpersons of the House Professional Licensure Committee (HPLC) and the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on \_\_\_\_\_ this final-form rulemaking was approved by the HPLC, On \_\_\_\_\_, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on \_\_\_\_\_, and approved the final-form rulemaking.

**I. Contact Person**

Further information may be obtained by contacting Gerald S. Smith, Counsel, State Board of Medicine, and P.O. Box 2649, Harrisburg, PA 17105-2649 or by e-mail at [gerasmith@state.pa.us](mailto:gerasmith@state.pa.us).



**J. Findings**

The State Board of Medicine finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) This final-form rulemaking does not enlarge the purpose of proposed rulemaking published at 34 Pa.B. 56.

(4) This final-form rulemaking is necessary and appropriate for administering and enforcing the authorizing acts identified in Part B of this Preamble.

**K. Order**

The Board, acting under its authorizing statutes, orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 16, are amended to read as set forth in Annex A.

(b) The Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General as required by law.

(c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect on publication in the *Pennsylvania Bulletin*.

Charles D. Hummer, Jr. M.D.  
Chairperson

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

SUBPART A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE

SUBCHAPTER A. BASIC DEFINITIONS AND INFORMATION

**§16.1 Definitions.**

The following words and terms, when used in this chapter and chapters 17 and 18 (relating to State Board of Medicine – medical doctors; and State Board of Medicine – practitioners other than medical doctors), have the following meanings, unless the context clearly indicates otherwise:

\* \* \* \*

ACCME – The Accreditation Council for Continuing Medical Education.

\* \* \* \*

AMA – American Medical Association.

AMA PRA – American Medical Association Physician’s Recognition Award.

Approved ACTIVITY course – A continuing Medical Education ACTIVITY course  
ACCEPTED FOR AMA PRA CREDIT offered by a provider accredited by the ACCME.

\* \* \* \*

*CATEGORY 1 ACTIVITIES –*

CONTINUING MEDICAL EDUCATION ACTIVITIES APPROVED FOR  
AMA PRA CATEGORY 1 CREDIT.

*CATEGORY 2 ACTIVITIES –*

CONTINUING MEDICAL EDUCATION ACTIVITIES APPROVED FOR  
AMA PRA CATEGORY 2 CREDIT.

\* \* \* \*

Immediate family member – A parent, spouse, child or adult sibling residing in the same  
household.

\* \* \* \*

**Subchapter B. GENERAL LICENSE, CERTIFICATION AND REGISTRATION  
PROVISIONS**

\* \* \* \*

**§16.19 Continuing Medical Education.**

(a) Beginning with the licensure renewal period commencing January 1, 2005, proof of completion of ~~100~~ 25 credit hours of continuing medical education in the preceding biennial period will be required for licensure renewal for medical doctors. THE 25 CREDIT HOURS FOR THE JANUARY 1, 2005 LICENSE RENEWAL PERIOD MAY BE COMPLETED IN EITHER AMA PRA CATEGORY 1 OR AMA PRA CATEGORY 2 ACTIVITIES, AND MUST INCLUDE 3 HOURS IN PATIENT SAFETY AND RISK MANAGEMENT.

(b) BEGINNING WITH THE LICENSURE RENEWAL PERIOD COMMENCING JANUARY 1, 2007, PROOF OF COMPLETION OF 100 CREDIT HOURS OF CONTINUING MEDICAL EDUCATION IN THE PRECEDING BIENNIAL PERIOD WILL BE REQUIRED FOR LICENSURE RENEWAL FOR MEDICAL DOCTORS.

- (1) At least 20 credit hours shall be completed in AMA PRA category 1 approved ~~courses~~ ACTIVITIES. At least ~~10~~ 12 credit hours shall be completed in AMA PRA CATEGORY 1 OR AMA PRA CATEGORY 2 approved ~~courses~~ ACTIVITIES in the area of patient safety and risk management. Approved ~~courses~~ ACTIVITIES in the area of patient safety and risk management may include topics such as improving medical records and record keeping, reducing medical errors, professional conduct and ethics, improving communications, preventative medicine and healthcare quality improvement. The

remaining 70 credit hours shall be completed in AMA PRA CATEGORY 1 OR AMA PRA CATEGORY 2 ~~any approved courses~~ ACTIVITIES. Credit will not be granted for courses in office management or practice building.

- (2) Physicians shall retain official documentation of attendance for 2 years after renewal, and shall certify completed ~~courses~~ ACTIVITIES on a form provided by the Board for that purpose, to be filed with the biennial renewal form. Official documentation proving ~~attendance~~ COMPLETION OF CONTINUING MEDICAL EDUCATION ACTIVITIES shall be produced, upon Board demand, under random audits of reported credit hours. Electronic submission of documentation is permissible to prove compliance with this subsection. Noncompliance may result in disciplinary proceedings under section 41(6) of the Medical Practice Act of 1985 (63 P.S. 422.41(6)).

(i) ACCEPTABLE DOCUMENTATION FOR CATEGORY 1 ACTIVITIES

ARE:

- (A) AMA PRA CERTIFICATES.
- (B) CERTIFICATE OF COMPLETION OF A CATEGORY 1 ACTIVITY SPONSORED BY AN ORGANIZATION ACCREDITED BY ACCME OR DESIGNEE OF THE ACCME.

- (C) CERTIFICATES FROM A MEDICAL PROFESSIONAL SOCIETY OR SPECIALTY CERTIFICATION BY A MEMBER ORGANIZATION OF THE AMERICAN BOARD OF MEDICAL SPECIALTIES.
- (D) HEALTHCARE SYSTEM CREDENTIAL CERTIFICATION.
- (E) THIRD PARTY PAYOR CREDENTIALING CERTIFICATION.
- (F) CERTIFICATION BY A CME ORGANIZATION WHOSE STANDARDS MEET OR EXCEED THOSE ESTABLISHED BY AMA PRA.

(ii) ACCEPTABLE DOCUMENTATION FOR CATEGORY 2 ACTIVITIES ARE:

- (A) DOCUMENTATION FROM SOURCES ACCEPTABLE FOR CATEGORY 1 ACTIVITIES.
- (B) DOCUMENTATION MAINTAINED BY THE PHYSICIAN CONTEMPORANEOUS TO THE CME ACTIVITY SUCH AS PERSONAL LOG BOOKS, DIARIES, JOURNAL NOTES, OR APPLICATIONS FOR CREDENTIALING OR CERTIFICATION BY AN ORGANIZATION RECOGNIZED BY THE ACCME OR DESIGNEE OF THE ACCME. THE

DOCUMENTATION SHALL IDENTIFY THE  
ACTIVITY AND THE AMOUNT OF TIME SPENT IN  
THE ACTIVITY.

(3) The following exemptions apply for certain physicians:

(i) A physician applying for licensure in this Commonwealth for the first time shall be exempt from the continuing medical education requirement for the biennial renewal period following initial licensure.

(ii) A physician holding a current temporary training license shall be exempt from the continuing medical education requirement.

(iii) A retired physician who provides care only to immediate family members shall be exempt from the continuing medical education requirement.

(iv) A physician who is on inactive status shall be exempt from the continuing medical education requirement, except that a physician who is seeking to reinstate an inactive or lapsed license shall show proof of compliance with the continuing education requirement for the preceding biennium.

(4) A physician suspended for disciplinary reasons is not exempt from the requirements of this section.

(5) Waiver of the CME requirements may be permitted, as follows:

(i) The Board may grant a hardship waiver of all or a part of the continuing medical education requirement in cases of serious illness, military service or other good cause provided that the public's safety and welfare will not be jeopardized by the granting of the waiver.

(ii) All requests for waiver shall be made in writing, with appropriate documentation, and shall include a description of circumstances sufficient to show why compliance is impossible.

(iii) Waiver requests will be evaluated by the Board on a case-by-case basis. The Board will send written notification of its approval or denial of a waiver request.





COMMONWEALTH OF PENNSYLVANIA  
DEPARTMENT OF STATE  
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS  
STATE BOARD OF MEDICINE  
Post Office Box 2649  
Harrisburg, Pennsylvania 17105-2649  
(717) 783-1400

June 22, 2004

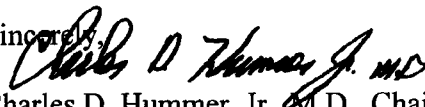
The Honorable John R. McGinley, Jr., Chairman  
INDEPENDENT REGULATORY REVIEW COMMISSION  
14th Floor, Harrisstown 2, 333 Market Street  
Harrisburg, Pennsylvania 17101

Re: Final Regulation  
State Board of Medicine  
16A-4914: Continuing Medical Education

Dear Chairman McGinley:

Enclosed is a copy of a final rulemaking package of the State Board of Medicine pertaining to Continuing Medical Education.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,  
  
Charles D. Hummer, Jr., M.D., Chairperson  
State Board of Medicine

CDH/GSS:lm  
Enclosure

- c: Basil L. Merenda, Commissioner  
Bureau of Professional and Occupational Affairs
- Linda C. Barrett, Chief Counsel  
Department of State
- Joyce McKeever, Deputy Chief Counsel  
Department of State
- Cynthia Montgomery, Regulatory Counsel  
Department of State
- Gerald S. Smith, Senior Counsel in Charge  
Department of State
- Sabine I. Howell, Counsel  
State Board of Medicine
- State Board of Medicine

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE  
REGULATORY REVIEW ACT**

I.D. NUMBER: 16A-4914  
SUBJECT: Continuing Medical Education  
AGENCY: DEPARTMENT OF STATE

# 2375

**TYPE OF REGULATION**

- Proposed Regulation
- Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
  - a. With Revisions
  - b. Without Revisions

**FILING OF REGULATION**

DATE	SIGNATURE	DESIGNATION
6/22/04	<i>Sandra J. Harper</i>	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
6/22/04	<i>Mary Walmer</i>	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
6/22/04	<i>Steph J. Hoffman</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)