

Regulatory Analysis Form

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IRRC REVIEW COMMISSION

(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: Amy L. Nelson (717) 783-7200
Counsel, State Board of Medicine

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 10 must be in the area of patient safety and risk management. The regulation provides definitions for the AMA, the AMA PRA, the ACCME, and the terms "approved course" and "immediate family member". It also sets forth those groups of licensees who are exempt from the requirements, and describes the procedure for seeking a waiver.

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

The Medical Care Availability and Reduction of Error (McCare) 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 18, 2002, P.L. ___, No. 13. Section 910(h) of the Mcare Act requires that regulations be promulgated within six (6) months of the effective date, which is November 18, 2002.

(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, causing some physicians to cease practice or leave the Commonwealth. The legislature has employed a multi-pronged approach to address both of these issues. One of those "prongs" is mandatory continuing medical education for physicians. It is hoped that physicians who obtain continuing medical education will be safer practitioners, leading to reduced medical errors and commensurately reduced malpractice insurance premiums.

(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 and obtained from the Pennsylvania Medical Society.

(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.

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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.

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

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

N/A

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(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.

No other regulatory schemes were considered. These regulations mirror, to the extent possible, those already in existence for the Osteopathic Medical Board. Other provisions were dictated by Act 13.

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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 similar to the requirements of the American Medical Association's Physician Recognition Award, which is given to physicians who obtain at least 50 category 1 continuing medical education credits annually. They are also consistent to the extent possible with the continuing medical education requirements of the Pennsylvania Osteopathic Medical Board.

(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 116-124 Pine 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. Comments from the public are always welcome.

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(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 submit evidence of compliance with the regulations biennially when they renew their licenses. A reporting form has not yet been developed, but will likely mirror the one used by the Osteopathic Medical Board.

(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 complied with beginning with the January 1, 2003, licensure renewal period. That is, as a condition of renewal on January 1, 2005, physicians must demonstrate compliance with these regulations during the 2003 – 2004 biennium.**

(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.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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REVIEW COMMISSION

#2375

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

Copy below is approved as to form and legality. Executive or Independent Agencies.

BY: Amey M. Elliott
(DEPUTY ATTORNEY GENERAL)

State Board of Medicine
(AGENCY)

John V. Turner

SEP 25 2003

DOCUMENT/FISCAL NOTE NO. 16A-4914

7/10/03
DATE OF APPROVAL

DATE OF APPROVAL

DATE OF ADOPTION:

BY: Charles D. Sumner, 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.
- Check if applicable. No Attorney General approval or objection within 30 day after submission.

PROPOSED 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) proposes to amend § 16.1 (relating to definitions) and to adopt § 16.19 (relating to continuing medical education) to read as set forth in Annex A.

Effective Date

The regulation will be effective upon publication as an Order of Final Rulemaking in the Pennsylvania Bulletin. The Legislature has required that the Board promulgate regulations within six (6) months of the effective date of section 910, the Medical Care Availability and Reduction of Error (Mcare) Act, Act of March 20, 2002, P.L. ____, No. 13 (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 two-year licensure period.

Background and Purpose

The proposed regulation will implement section 910 of the Mcare Act (40 P.S. §1303.910) which requires completion of 100 credit hours of continuing education as a condition of biennial license renewal of physician licenses by the State Boards of Medicine and Osteopathic Medicine.

Description of Proposed Amendments

The proposed regulation requires proof of completion of 100 credit hours of continuing medical education as a condition of license renewal, and sets forth a requirement that at least 20 of the 100 hours be American Medical Association Physician Recognition Award (AMA PRA) 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 such topics as improving medical records and record-keeping, reducing medical errors, professional conduct and ethics, improving communications, preventative medicine, and healthcare quality improvement. The regulations further designate the Accreditation Council on Continuing Medical Education (ACCME) as the accrediting body for purposes of approving continuing medical education providers.

Fiscal Impact and Paperwork Requirements

The proposed regulation 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.

Compliance with Executive Order 1996-1, Regulatory Review and Promulgation

Due to the legislative requirement that these regulations be promulgated within six months of the effective date of section 910 of the Mcare Act, the Board did not request pre-draft comment from the usual list of interested parties, however, the Pennsylvania Medical Society did submit comments to the Board for consideration.

Regulatory Review

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

Under section 5(g) of the Regulatory Review Act (71 P.S. § 745.5(g)), if IRRC has comments, recommendations or objections regarding any portion of the proposed rulemaking, it will notify the Board approximately 30 days from the close of the public comment period. The notification will specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review of comments, recommendations and objections by the Board, the General Assembly, and the Governor prior to publication of the regulations.

Public Comment

Interested persons are invited to submit written comments, recommendations, or objections regarding this 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
State Board of Medicine

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.

* * * *

ACCME – The Accreditation Council for Continuing Medical Education.

* * * *

AMA – American Medical Association.

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

Approved course – Continuing Medical Education course offered by a provider
accredited by the ACCME.

* * * *

Immediate family member - A parent, a spouse, a child or an 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.

- (a) 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 such topics 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 any approved courses. Credit will not be granted for courses in office management or practice building.

(b) 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, pursuant to 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)).

(c) The following exemptions apply for certain physicians:

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

2. A physician holding a current temporary training license shall be exempt from the continuing medical education requirement.
3. A retired physician who provides care only to immediate family members shall be exempt from the continuing medical education requirement.
4. 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.

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

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

1. 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.

2. 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.
3. 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

December 16, 2003

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

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

Dear Chairman McGinley:

Enclosed is a copy of a proposed 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/ALN:lm

Enclosure

c: Andrew Sislo, Chief Counsel
Department of State
Scott J. Messing, Deputy Commissioner
Bureau of Professional and Occupational Affairs
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
Amy L. Nelson, Counsel
State Board of Medicine
State Board of Medicine

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT



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REGULATORY REVIEW COMMISSION

I.D. NUMBER: 16A-4914

SUBJECT: Continuing Medical Education (State Board of Medicine)

AGENCY: DEPARTMENT OF STATE

TYPE OF REGULATION

- X 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
12/16/03	<i>Brenda J. Harper</i>	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
12/16/03	<i>Mary Walmer</i>	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
12/16/03	<i>J. Belmont</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
12/16/03	<i>LeBaron</i>	LEGISLATIVE REFERENCE BUREAU

December 16, 2003