

Regulatory Analysis Form

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REVIEW COMMISSION

(1) Agency

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

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

16A-5313

IRRC Number: 2382

(3) Short Title

Continuing Medical Education

(4) PA Code Cite

49 Pa. Code §§ 25.1, 25.271

(5) Agency Contacts & Telephone Numbers

Primary Contact: Amy L. Nelson (717) 783-7200
Counsel, State Board of Osteopathic 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. Although the Osteopathic Medical Board already required 100 credit hours of continuing medical education credits, Act 13 imposed a requirement that the Board establish a minimum of hours in the areas of patient safety and risk management. Retired physicians, physicians on inactive status, and physicians holding a temporary training permit continue to be exempt from the continuing education requirements, while those licensed for the first time are exempt for the biennial renewal period following initial licensure.

(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. §§ 1301.101-1303.910).

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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.

Regulatory Analysis Form

(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 6,000 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 Osteopathic Medical Association.

(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.

Osteopathic physicians are already required to obtain 100 hours of CME each renewal period, so there should not be any increased cost to this community.

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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 Osteopathic Medical license fee regulations, 16A-5311.

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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

Regulatory Analysis Form

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

Program	FY-3 99 - 00	FY-2 00 - 01	FY-1 01 - 02	Current FY 02 - 03
State Board of Osteopathic Medicine	405,527.84	457,338.63	503,718.72	1,172,000.00

(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.

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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 make minor changes to the Board's existing continuing medical education regulations. They are also consistent, to the extent possible, with the proposed continuing medical education requirements of the Pennsylvania 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 second Wednesday 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.

Currently, licensees verify their completion of the CME requirement on their renewal form. It is anticipated that minor changes may be made to this verification.

(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 November 1, 2002 licensure renewal period. That is, as a condition of renewal on November 1, 2004, 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

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REVIEW COMMISSION

(Pursuant to Commonwealth Documents Law)

2382

DO NOT WRITE IN THIS SPACE

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

BY: _____
(DEPUTY ATTORNEY GENERAL)

DEC 30 2003

DATE OF APPROVAL

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

State Board of Osteopathic Medicine
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-5313

DATE OF ADOPTION: _____

BY: Thomas R. Czarneski, D.O.
Thomas R. Czarneski, D.O.

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

BY: Tamara C. ...

DATE OF APPROVAL

7/31/03

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

- Check if applicable
Copy not approved.
Objections attached.
- Check if applicable. No Attorney
General approval or
objection within 30 day
after submission.

NOTICE OF PROPOSED RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF OSTEOPATHIC MEDICINE
49 PA. CODE, CHAPTER 25
CONTINUING MEDICAL EDUCATION

The State Board of Osteopathic Medicine ("Board") proposes to amend §25.1 (relating to definitions) and §25.271 (relating to licensure renewal and continuing 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 of 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, Act of March 20, 2002, P.L. ___, No. 13, 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 licensure renewal of physician licenses by the State Board of Medicine and the State Board of Osteopathic Medicine. Although the Osteopathic Medical Board already required 100 credit hours of continuing medical education each biennium, Act 13 imposed a requirement that the Board establish a minimum number of hours in the areas of patient safety and risk management.

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 Osteopathic Association (AOA) category 1 credits and that at least 10 credit hours must be in the area of patient safety and risk management. 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 regulations further designate the Accreditation Council on Continuing Medical Education (ACCME) and the AOA as the accrediting bodies 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

Input was sought and obtained from the Pennsylvania Osteopathic Medical Association.

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 January 20, 2004 to the Independent Regulatory Review Commission (IRRC), the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC), and the House Professional Licensure Committee (HPLC). 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 that 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 Osteopathic Medicine, P.O. Box 2649, Harrisburg, PA 17105-2649, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

Thomas R. Czarnecki, D.O.
Chairperson
State Board of Osteopathic Medicine

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

SUBPART A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 25. STATE BOARD OF OSTEOPATHIC MEDICINE

Subchapter A. GENERAL PROVISIONS

§25.1 Definitions.

* * * *

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

* * * *

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

* * * *

Subchapter G. LICENSING, EDUCATION AND GRADUATE TRAINING

* * * *

LICENSURE RENEWAL AND CONTINUING EDUCATION

* * * *

§25.271 Requirements for renewal.

(c) Beginning with [1994 renewals] the licensure renewal period commencing November 1, 2004, proof of completion of 100 credit hours of continuing medical education in the preceding biennial period will be required for licensure renewal for Osteopathic physicians.

(1) At least 20 credit hours shall be completed in AOA category 1 [AOA] 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 [remainder] remaining 75 credit hours shall be completed in any [courses approved by the AOA or ACCME] approved courses. Credit will not be granted for courses in office management or practice building.

(2) [A licensee] 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 15(a)(6) of the Osteopathic Medical Practice Act (63 P.S. § 271.15(a)(6)).

(3) [A retired or inactive licensee is not required to comply with this requirement, if the licensee offers no service requiring a medical license and files an Affidavit of Non-Practice with the renewal form.]

The following exemptions apply for certain physicians:

i. 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.

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 licensee who has been on inactive status shall have completed 100 credit hours of continuing medical education in the 2-year period immediately prior to reactivation. For the renewal cycle immediately subsequent to reactivation, the licensee shall complete 12.5 credit hours for each full calendar quarter in which his license is active.] A physician suspended for disciplinary reasons is not exempt from the requirements of this section.

(5) [The Board may grant a hardship waiver only under extraordinary circumstances when it finds that good cause has been shown and that the public's safety and welfare will not be jeopardized by the granting of the waiver.]

Waiver of the 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.

[(6) A licensee suspended for disciplinary reasons is not exempt from the requirements of this section.

(7) A licensee graduating from an approved osteopathic medical college is exempt from the requirements in this section for the renewal cycle immediately subsequent to the receipt of an original license.

(8) A licensee holding a current temporary training license is exempt from the requirements of this section.

(9) For the renewal cycle immediately subsequent to licensure, a licensee licensed by reciprocal endorsement shall complete 12.5 credit hours for each full calendar quarter in which the licensee has been licensed.]



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF OSTEOPATHIC MEDICINE
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-4858

January 20, 2004

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 Osteopathic Medicine
16A-5313: Continuing Medical Education

Dear Chairman McGinley:

Enclosed is a copy of a proposed rulemaking package of the State Board of Osteopathic 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,

A handwritten signature in black ink that reads "Thomas R. Czarnecki".

Thomas R. Czarnecki, D.O., Chairperson
State Board of Osteopathic Medicine

TRC/ALN:lm

Enclosure

c: Andrew Sislo, Chief Counsel
Department of State
Basil L. Merenda, Acting 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 Osteopathic Medicine
State Board of Osteopathic Medicine

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

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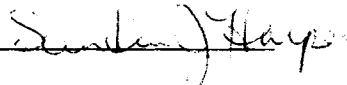
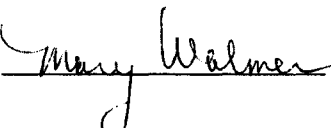
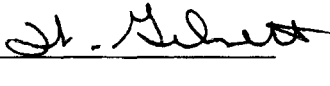
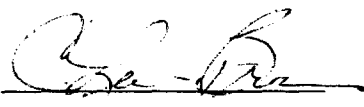
REGULATORY REVIEW COMMISSION

I.D. NUMBER: 16A-5313
SUBJECT: Continuing Medical Education
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
1/20/04		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
1/20/04		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
1/20/04		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
1/20/04		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

January 6, 2004