

Regulatory Analysis Form

This space for use by IRRC

(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: Beth Sender Michlovitz (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 requires 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.

(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.

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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 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 will 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.

No costs or savings are generated by this regulation.

(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

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(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 is 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 2601 North 3rd 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, 2006 licensure renewal period. That is, as a condition of renewal on November 1, 2006, physicians must demonstrate compliance with these regulations during the 2004 – 2006 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.

(b) *Deadlines.* The payment of the producer charges shall be postmarked and mailed, or actually delivered to the Program, by the first day of February immediately following the previous marketing season.

(c) *Form of payment.* Payments of producer charges shall be by check or money order made payable to the "PA Wine Marketing Program."

(d) *Address.* Payments of producer charges shall be mailed or delivered to:

Department of Agriculture,
Bureau of Market Development
Attn: Pennsylvania Wine Marketing Program
2301 North Cameron Street
Harrisburg, Pennsylvania 17110-9408.

(e) *Penalty for failure to account or pay.* Producers who fail to mail or deliver the required producer charges owed the Program within 30 days of the due date, as described in subsection (b), shall be required to pay a penalty of at least \$100 but not more than \$5,000, and as nearly equivalent to 100% of the amount of the delinquent producer charges as is practicable. An action seeking the imposition of a penalty, plus payment of producer charges due the Program, may be brought in the appropriate magisterial district. A penalty imposed shall be in addition to the delinquent producer charges owed the Program.

[Pa.B. Doc. No. 04-176. Filed for public inspection January 30, 2004, 9:00 a.m.]

STATE BOARD OF OSTEOPATHIC MEDICINE

[49 PA. CODE CH. 25]

Continuing Medical Education

The State Board of Osteopathic Medicine (Board) proposes to amend §§ 25.1 and 25.271 (relating to definitions; and requirements for renewal) to read as set forth in Annex A.

Effective Date

The proposed rulemaking will be effective upon final-form 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 implements section 910 of the act, 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 Board. Although the Board already required 100 credit hours of continuing medical education each biennium, the act imposed a requirement that the

Board establish a minimum number of hours in the areas of patient safety and risk management.

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 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 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 and the AOA as the accrediting bodies for purposes of approving continuing medical education providers.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking requires the Board to alter its license renewal forms to include data regarding the physician's compliance with the continuing education requirements, and also requires 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 January 20, 2004, 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 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

Fiscal Note: 16A-5313. 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 25. STATE BOARD OF OSTEOPATHIC MEDICINE

Subchapter A. GENERAL PROVISIONS

§ 25.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings unless the context clearly indicates otherwise:

* * * * *

Approved course—A 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 topics such as improving medical records and recordkeeping, 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 either 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 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 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 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) 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 in 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 in this section.

Comments of the Independent Regulatory Review Commission

on

State Board of Osteopathic Medicine Regulation No. 16A-5313

Continuing Medical Education

March 31, 2004

We submit for your consideration the following comments that include references to the criteria in the Regulatory Review Act (71 P.S. § 745.5b) which have not been met. The State Board of Osteopathic Medicine (Board) must respond to these comments when it submits the final-form regulation. The public comment period for this regulation closed on March 1, 2004. If the final-form regulation is not delivered within two years of the close of the public comment period, the regulation will be deemed withdrawn.

1. Section 25.1. Definitions. - Reasonableness; Clarity

Approved course

There are two concerns pertaining to this definition. First, it limits “approved courses” to those accredited by the Accreditation Council on Continuing Medical Education (ACCME) or the American Osteopathic Association (AOA). Will the Board accept courses accredited by other organizations such as state medical associations or the American Medical Association?

Second, the definition of “approved course” should include credits that are not formally accredited by the ACCME and AOA. Alternatively, the Board could amend the language of Section 25.271 to allow other credits for the remaining credit hours.

2. Section 25.271. Requirements for renewal. - Implementation procedures; Feasibility; Reasonableness; Clarity.

Sufficient notice

The House Professional Licensure Committee questions whether licensees have received sufficient notice to complete continuing education by the deadline for license renewal. The Board should explain:

- The specific date a licensee will be required to certify completion of ten continuing education credits in the area of patient safety and risk management to renew a license.
- What notice the Board has given to licensees of this continuing education obligation.
- How licensees can reasonably comply with this requirement by the Board’s deadline.

Approved courses in the area of patient safety and risk management

Related to our comment on the definition of “approved course,” are the 10 credit hours in patient safety and risk management required to be Category I or Category II courses?

Remaining credit hours

Subsection (c)(1) has a typographical error. It should state, “...the remaining 70 credit hours...”

Regulation 16A-5313

State Board of Osteopathic Medicine

PROPOSAL: Regulation 16A-5313 amends 49 PA Code, Chapter 25, regulations of the State Board of Osteopathic Medicine. The amendment will implement Sec. 910 of the Medical Care Availability and Reduction of Error (Mcare) Act which requires physicians to complete 100 credit hours of continuing education as a condition of biennial license renewal.

The proposed Rulemaking was published in the Pennsylvania Bulletin on January 31, 2004.

ANALYSIS: Section 16.19 would be added to the Board's regulations to implement the continuing education requirement of Sec. 910 of the Mcare Act (40 P.S. Sec. 1303.910). Beginning with the biennial renewal period commencing November 1, 2004, osteopathic physicians will be required to show proof of completion of 100 credit hours of continuing education in order to renew their licenses. At least 20 of the 100 hours must be completed in American Osteopathic Association (AOA) courses. At least 10 credit hours must be completed in approved courses in the area of patient safety and risk management. The remaining 70 hours can be completed in any approved courses. "Approved course" is defined as a continuing medical education course offered by a provider accredited by the Accreditation Council for Continuing Medical Education (ACCME) or the AOA. No credit will be granted for courses in office management or practice building.

Physicians must retain official documentation of CE attendance for 2 years after renewal. Physicians applying for licensure for the first time will be exempt from the CE requirement for the renewal period following initial licensure. Also exempted are holders of temporary training licenses and retired physicians who provide care only to immediate family members. Physicians on inactive status are exempt but must show proof of compliance with the CE requirement for the preceding biennium when seeking reinstatement. Physicians suspended for disciplinary reasons are not exempt from CE requirements.

The Board is authorized to grant waivers of the CE requirement in cases of serious illness, military service or other good cause. Requests for waivers must be in writing with appropriate documentation. Waiver requests will be evaluated on a case-by-case basis with written notification to the licensee of approval or denial.

RECOMMENDATIONS: It is recommended that the Professional Licensure Committee take no formal action until final form regulations are promulgated. However, the Committee submits the following comments:

1. Proposed Sec. 25.271(c) provides that the continuing medical education requirement will begin with the licensure renewal period commencing November 1, 2004, so that physicians will be required to complete CE during the current biennium. The Committee

questions whether licensees have received sufficient notice of the implementation of CE
in order to provide them with enough time to complete the requirement.

2. In Sec. 25.271(c)(1), the Committee notes that the reference to “remaining 75 credit hours” appears to be a typo and should actually read “remaining 70 credit hours.”

House of Representatives
Professional Licensure Committee
February 2, 2004

Commonwealth of Pennsylvania
Department of State

DATE:

SUBJECT: Final Rulemaking
State Board of Osteopathic Medicine
16A-5313: Continuing Medical Education

TO: David J. DeVries, Executive Deputy General Counsel
Office of General Counsel

FROM: Beth Sender Michlovitz, Counsel
State Board of Osteopathic Medicine

BSM

There are no significant legal and policy issues presented by this regulation which amends the Board regulation at 49 Pa. Code § 25.271.

I certify that I have reviewed this regulation for form and legality, that I have discussed any legal and policy issues with the administrative officers responsible for the program, and that all information contained in the Preamble and Annex is correct and accurate.

BSM:lw

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

#2382

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

BY: _____
(DEPUTY ATTORNEY GENERAL)

State Board of Osteopathic Medicine
(AGENCY)

Thomas Czarniecki

DOCUMENT/FISCAL NOTE NO. 16A-5313

8.31.04

DATE OF APPROVAL

DATE OF ADOPTION: _____

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

Asst.
(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.

NOTICE OF FINAL 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) adopts amendments to §§25.1 and 25.271 (relating to definitions; and requirements for renewal) to read as set forth in Annex A.

Effective Date

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

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.

Background and Purpose

The regulation will implement section 910 of the Mcare Act 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.

Summary of Comments and Responses on Proposed Rulemaking

Notice of the proposed rulemaking was published at 34 Pa.B. 563 (January 31, 2004). The Board received comments from the Independent Regulatory Review Commission (IRRC), the House Professional Licensure Committee (HPLC) and the Pennsylvania Medical Society (PMS).

IRRC questioned whether the definition of “approved course” at § 25.1 would allow the Board to accept courses accredited by other organizations such as state medical associations or the American Medical Association. The Board has determined that such courses would be acceptable. IRRC also suggested that the definition include credits not formally accredited by the Accreditation Council for Continuing Medical Education (ACCME) and American Osteopathic Association (AOA) or that the Board amend the language of § 25.271 to allow other credits for the remaining credit hours. PMS also noted that ACCME and AOA do not accredit sponsors of Category 2 continuing medical education and that much Category 2 continuing medical education is self-directed and has no sponsor. PMS suggested removing the word “approval” and substituting “medical educational activities” to correct the problem. The Board agreed with PMS and has changed the term “approved course” to “approved activity.” The Board has also defined “approved activity” to mean continuing medical education activity accepted for American Medical Association Physician’s Recognition Award (AMA PRA) or AOA credit.

IRRC and HPLC questioned whether licensees would have received sufficient notice to complete continuing education by the deadline for license renewal. The Board has revised § 25.217(c) to require proof of completion of the continuing education credits for the 2006 renewal period. Because the Board currently requires 100 hours of continuing education credits for renewal of licenses, the 2006 biennial renewal date will apply to the 10 hours of continuing education in the area of patient safety and risk management. IRRC also asked whether the 10 credit hours in patient safety and risk management is required to be Category 1 or Category 2 courses. The Board has revised § 25.271(c)(1) to clarify that the 10 hours may be in Category 1 or Category 2 approved activities.

IRRC, HPLC and PMS asked whether the reference to “remaining 75 credit hours” in Section 25.271(c)(1) is a typographical error and should, instead, read as the “remaining 70 credit hours.” The Board agrees that the number “75” is incorrect and has substituted “the remaining credit hours” in its place because the patient safety hours may be either Category 1 (and go toward the 20 required Category 1 credits) or Category 2. Therefore, it is not clear exactly how many credit hours will be remaining.

Compliance with Executive Order 1996-1

The Board reviewed this final-form rulemaking and considered its purpose and likely impact on the public and regulated population under the directives of Executive Order 1996-1.

Fiscal Impact and Paperwork Requirements

The 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, will 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 January 31, 2004 the Board submitted a copy of the notice of proposed rulemaking, published at 34 Pa.B. 563, 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 _____, the final-form rulemaking was approved by the HPLC. On _____, 2004, the final-form rulemaking was deemed approved by SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____ and approved the final-form rulemaking.

Contact Person

Interested persons may obtain information regarding the final-form rulemaking by writing to Beth Sender Michlovitz, Board Counsel, State Board of Osteopathic Medicine, P.O. Box 2649, Harrisburg, PA 17105-2649 or bmichlovit@state.pa.us.

Findings

The Board 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 at 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) The final-form rulemaking is necessary and appropriate for administration and enforcement of the authorizing act identified in Part B of this preamble.
- (4) The amendments to the final-form rulemaking are necessary and appropriate for administration and enforcement of the authorizing act identified in Part B of this preamble and do not enlarge the purpose of the proposed rulemaking published at 34 Pa.B. 563.

Order

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

- (a) The regulations of the Board, 49 Pa. Code Chapter 25, are amended by amending §§ 25.1 and 25.271 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 to 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.

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.

The following words and terms, when used in this chapter, have the following meanings unless the context clearly indicates otherwise:

* * * *

AMA PRA – AMERICAN MEDICAL ASSOCIATION PHYSICIAN'S RECOGNITION AWARD.

* * * *

Approved ACTIVITY course – A continuing medical education course offered by a provider accredited by the ACCME or the AOA ACTIVITY ACCEPTED FOR AMA PRA OR AOA CREDIT.

* * * *

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, 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, 2004-2006, 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) BEGINNING WITH THE LICENSURE RENEWAL PERIOD COMMENCING NOVEMBER 1, 2006, At least 20 credit hours shall be

completed in AOA category 1 [AOA] approved ~~courses~~ ACTIVITIES. At least 10 credit hours shall be completed in CATEGORY 1 OR 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 recordkeeping, 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] CATEGORY 1 OR CATEGORY 2 approved courses ACTIVITIES. 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 ACTIVITIES 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 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 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 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) 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
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October 1, 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 Osteopathic Medicine
Continuing Medical Education: 16A-5313

Dear Chairman McGinley:

Enclosed is a copy of a final rulemaking package of the State Board of Osteopathic Medicine pertaining to Continuing Medical Education (16A-5313).

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

Sincerely,


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

TRC:BSM:lw

Enclosure

c: Linda C. Barrett, Chief Counsel
Department of State
Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia K. Montgomery, Regulatory Counsel
Department of State
Herbert Abramson, Senior Counsel in Charge
Department of State
Beth Sender Michlovitz, Counsel
State Board of Osteopathic Medicine
State Board of Osteopathic Medicine

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

I.D. NUMBER: 16A-5313
SUBJECT: State Board of Osteopathic Medicine - Continuing Medical Education
AGENCY: DEPARTMENT OF STATE

TYPE OF REGULATION

Proposed Regulation

X 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

RECEIVED
REGULATORY REVIEW ACT
AUG 31 2004

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
10/1/04	<i>Dwight J. Harper</i>	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
10/1/04	<i>Mary Walmer</i>	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
10/1/04	<i>Step J. Hoff</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

August 31, 2004