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**INDEPENDENT REGULATOR
REVIEW COMMISSION**

Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on
IRRC's website)

(1) Agency:

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

(2) Agency Number: 16A

Identification Number: 16A-4925

IRRC Number: 2956

(3) PA Code Cite: 49 Pa. Code §§ 16.1, 16.18, 16.31 - 16.35, 17.4, 17.6 and 17.7

(4) Short Title: **Mcare**

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: **Teresa Lazo, Counsel, State Board of Medicine, Department of State, 2601 North
Third Street, Harrisburg, PA 17105; Phone Number: (717) 783-7200; Fax Number: (717) 787-
0251; E-mail address: tlazo@pa.gov**

Secondary Contact: **Cynthia Montgomery, Regulatory Counsel, Department of State, P.O. Box
2649, Harrisburg, PA 17105-2649 (phone 717-783-7200) (fax 787-0251) cymontgome@pa.gov**

(6) Type of Rulemaking (check applicable box):

Proposed Regulation

Final Regulation

☒ Final Omitted Regulation

☐ Emergency Certification Regulation;

☐ Certification by the Governor

☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

Throughout the Board's regulations are references to the Health Care Services Malpractice Act (40 P.S. § 1301.101-1301.1006) which was repealed by the act of March 20, 2002 (P.L. 154, No. 13) (Act 13 of 2002). Act 13 of 2002 also enacted the Medical Care Availability and Reduction of Error (Mcare) Act (40 P.S. § 1303.101-1303.910). Because of the repeal of the Health Care Services Malpractice Act and enactment of the Mcare Act, the Board's regulations must be amended to reference the current act in order to avoid confusion within the regulated community and to provide appropriate references to current law.

(8) State the statutory authority for the regulation. Include specific statutory citation.

This rulemaking is authorized by section 8 of the Medical Practice Act of 1985 (act) (63 P.S. § 422.8).

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

Yes, the amendments are mandated by state law in that the state law currently referenced in the Board's regulations has been repealed and replaced.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The rulemaking is required to conform the Board's regulations to current state statutes.

(11) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

This rulemaking is not based upon any scientific data, studies, or references.

(12) Describe who and how many people will be adversely affected by the regulation. How are they affected?

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

(13) 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.

Physicians licensed by the Board who are subject to the Mcare Act will be required to comply with the provisions of the regulations.

(14) 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. Explain how the dollar estimates were derived.

The amendments do not impose any costs or savings on the regulated community. The amendments merely conform the Board's regulations to reference current statutes.

(15) 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. Explain how the dollar estimates were derived.

There are no costs or savings to local governments associated with the rulemaking.

(16) 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. Explain how the dollar estimates were derived.

There are no costs or savings to state government associated with the rulemaking.

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

(17a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
State Board of Medicine	\$5,836,998.79	\$5,800,654.85	\$4,834,369.34	\$6,349,000.00

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

There are no costs to the regulation. The benefit of the regulation is that it will avoid confusion to have the Board's regulations reference a statute that is currently in effect rather than one that has been repealed.

(19) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

The Board discussed this final rulemaking at its December 27, 2011, meeting. The rulemaking had been previously discussed in 2003 after enactment of the Mcare Act. All of these discussions are held in public session before stakeholders and interested parties.

(20) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory schemes were considered.

(21) 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 regulations.

This rulemaking would not be more stringent and would not overlap or conflict with any federal requirements.

(22) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete with other states?

Comparisons with other states are not instructive, as this rulemaking merely conforms references in the Board's regulations to the current, effective statute.

This rulemaking would not put Pennsylvania at a competitive disadvantage.

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

This rulemaking would not affect other regulations of the Board or other state agencies.

(24) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

There are no legal, accounting or consulting procedures or additional reporting or paperwork required for implementation of the regulation.

(25) 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 Board has determined that there are no special needs of any subset of its applicants or licensees for whom special accommodations should be made.

(26) Include a schedule for review of the regulation including:

- A. The date by which the agency must have received public comments: **Not applicable.**
- B. The date or dates on which public meetings or hearings were held: **12/27/2011**
- C. The expected date of promulgation of the proposed regulation as a final-form regulation: **Summer 2012**
- D. The expected effective date of the final-form regulation: **Upon publication.**
- E. The date by which compliance with the final-form regulation will be required: **Upon publication.**
- F. The date by which required permits, licenses or other approvals must be obtained: **Not applicable.**

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

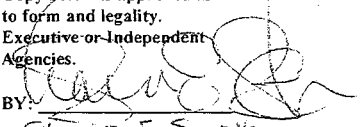
The Board continuously reviews its regulations at its scheduled meetings. The Board meets monthly on the fourth Tuesday of each month.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

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(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

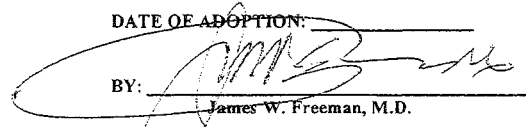
Copy below is hereby approved as to
form and legality. Attorney GeneralCopy below is hereby certified to be a true and correct
copy of a document issued, prescribed or promulgated by:Copy below is approved as
to form and legality.
Executive or Independent
Agencies.BY: _____
(DEPUTY ATTORNEY GENERAL)State Board of Medicine
(AGENCY)BY: 
Shawn E. SmithDOCUMENT/FISCAL NOTE NO. 16A-4925

JUN 15 2012

DATE OF APPROVAL

DATE OF APPROVAL

DATE OF ADOPTION: _____

BY: 
James W. Freeman, M.D.(Executive Deputy General Counsel
Strike inapplicable title)TITLE: Chair
(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.

FINAL RULEMAKING
(WITH NOTICE OF PROPOSED RULEMAKING OMITTED)
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
49 PA. CODE §§ 16.1, 16.18, 16.31 – 16.35, 17.4 AND 17.7
MCARE REVISIONS

The State Board of Medicine (Board) hereby amends §§ 16.1, 16.18, 16.31 - 16.35, 17.4, 17.6 and 17.7 to read as set forth in Annex A.

Effective Date

The amendments will be effective upon publication in the Pennsylvania Bulletin.

Statutory Authority

Section 8 of the Medical Practice Act (63 P.S. § 422.8) authorizes the Board to adopt regulations that are reasonably necessary to carry out the purposes of the act.

Omission of Proposed Rulemaking

Under section 204 of the Act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. § 1204), known as the Commonwealth Documents Law (CDL), the Board is authorized to omit the procedures for proposed rulemaking in sections 201 and 202 of the CDL (45 P.S. §§1201 and 1202) if the Board finds that the criteria of section 204 are met.

Throughout the Board's regulations are references to the Health Care Services Malpractice Act (40 P.S. §§ 1301.101-1301.1006), which was repealed by the act of March 20, 2002 (P.L. 154, No. 13) (Act 13 of 2002). Act 13 of 2002 also enacted the Medical Care Availability and Reduction of Error Act (40 P.S. §§ 1303.101-1303.910) (Mcare Act). Under authority of section 204(3) of the CDL (45 P.S. § 1204(3)), proposed rulemaking has been omitted as unnecessary because the amendments are required to delete references to the repealed Health Care Services Malpractice Act, and to replace them, as applicable, by references to the Mcare Act.

Background and Need for Amendment

Due to the repeal of the Health Care Services Malpractice Act and enactment of the Mcare Act, the Board's regulations must be amended to reference the current applicable law. In addition, because the Mcare act applies to both physicians and nurse-midwives, the Board must amend its references to the requirements of the Mcare Act to include both physicians and nurse-midwives.

Description of Amendments

The Board is amending §§ 16.1, 16.18, 16.31 - 16.35, 17.4, 17.6 and 17.7 to delete references and citations to the Health Care Services Malpractice Act and replace these references and citations to the applicable sections of the Mcare Act.

The Board is also amending the references to “physicians and surgeons” in these sections by replacing them with references to “physicians and nurse-midwives” because (1) the Board no longer uses the term “physicians and surgeons” to refer to its physician licensees and (2) because the Mcare Act applies to both physicians and nurse-midwives.

Fiscal Impact

The amendments will have no fiscal impact on the Board, its licensees, the private sector, the general public or political subdivisions.

Paperwork Requirements

The regulation will not create additional paperwork for the Board, its licensees, the private sector, the general public or political subdivisions.

Sunset Date

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

Regulatory Review

Under section 5.1(c) of the Regulatory Review Act (RRA) (71 P.S. §745.5a(c)), on June 26, 2012, the Board submitted copies of the final rulemaking, with proposed rulemaking omitted, to the Independent Regulatory Review Commission (IRRC), and the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) and the House Professional Licensure Committee (HPLC). On the same date, the Commission submitted a copy of the regulation to the Office of Attorney General under the Commonwealth Attorneys Act (71 P.S. §§ 732-101-732-506).

Under section 5.1(j.2) of the RRA (71 P.S. §745.5(j.2)), the final rulemaking was approved by the HPLC on _____, and deemed approved by the SCP/PLC on _____. Under section 5.1(e) of the RRA (71 P.S. § 745.5a(e)), IRRC met on _____, and approved the final rulemaking.

Additional Information

For additional information about the final rulemaking, submit inquiries to Teresa Lazo, Counsel, State Board of Osteopathic Medicine, P.O. Box 2649, Harrisburg, PA 17105-2649, (717) 783-7200.

Findings

The Board finds that:

- (1) Public notice of the Board's intention to amend its regulations under the procedures in sections 201 and 202 of the CDL (45 P.S. §§ 1201 and 1202) has been omitted under the authority of section 204 of the CDL (45 P.S. § 1204), because public comment is unnecessary in that this rulemaking merely deletes references to a repealed statute and replaces them with references to the current statute.
- (2) The amendment of the Board's regulations in the manner provided in this order is necessary and appropriate for the administration of the act.

Order

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

- (a) The regulations of the Board, 49 Pa. Code, Chapters 16 and 17, at §§ 16.1, 16.18, 16.31 - 16.35, 17.4, 17.6 and 17.7 are amended to read as set forth in Annex A.
- (b) The Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as to form and legality as required by law.
- (c) The Board shall certify this order and Annex and deposit them with the Legislative Reference Bureau as required by law.
- (d) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

James W. Freeman, M.D.
Chairperson

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

Subchapter A. BASIC DEFINITIONS AND INFORMATION

§ 16.1. Definitions.

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

* * * * *

Mcare Act — The Medical Care Availability and Reduction of Error Act (40 P.S. §§ 1303.101-1303.910).

* * * * *

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

* * * * *

§ 16.18. Volunteer license.

* * * * *

(e) *Renewal of license.* A volunteer license [shall] must be renewed biennially on forms provided by the Board. The applicant [shall be] is exempt from payment of the biennial renewal fee of § 16.13 (relating to licensure, certification, examination and registration fees), and [shall

be] is exempt from the requirements with regard to the maintenance of liability insurance coverage under [section 701 of the Health Care Services Malpractice Act (40 P.S. § 1301.701) and § 16.31 (relating to notification)] section 711 of the Mcare Act (40 P.S. §§ 1303.711), as provided in section 9 of the Volunteer Health Services Act (35 P.S. § 449.49).

* * * * *

Subchapter D. HEALTH CARE [MALPRACTICE] PROFESSIONAL LIABILITY

§ 16.31. Notification.

(a) *Applicants for original licensure.* A physician [or surgeon] who has successfully [passed the medical examination or who has been approved for licensure by endorsement] met the qualifications for licensure will be notified by letter that he may enter upon the practice of medicine in this Commonwealth only after [:

(1) Registering with the Department of State under section 25 of the act (63 P.S. § 422.25).

(2) Complying] complying with section [701 of the Health Care Services Malpractices Act (40 P.S. § 1301.701)] 711 of the Mcare Act (40 P.S. § 1303.711), by making prompt application for [malpractice] medical liability insurance.

(b) *Licensees applying for biennial renewal.* A licensee applying for biennial renewal will be notified with the renewal application that if he practices in this Commonwealth he is required to furnish satisfactory proof [to the Office of the Medical Professional Liability Catastrophe Loss Fund that he is in compliance with the Health Care Services Malpractices Act (40 P.S. §§ 1301.101-1301.1006)] of compliance with the medical professional liability insurance and Medical Care Availability and Reduction of Error Fund provisions under sections 711 and 712 of the Mcare Act (40 P.S. §§ 1303.711 and 1303.712) as a condition of practice.

§ 16.32. Requirements of the [Health Care Services Malpractice] Mcare Act.

[An applicant for licensure or a licensee applying for biennial review as required by the Health Care Services Malpractice Act (40 P.S. §§ 1301.101—1301.1006), and the regulations pertaining thereto, shall maintain the required amount of professional liability insurance or an approved self-insurance plan and shall have paid the required fee and surcharges as set forth therein.]

(a) Except as provided in subsections (b) and (c), a physician or nurse-midwife shall maintain the required amount of professional liability insurance, or have an approved self-insurance plan, and pay the required Medical Care Availability and Reduction of Error (Mcare) Fund assessment as a condition of practice under sections 711 and 712 of the Mcare Act (40 P.S. §§ 1303.711 and 1303.712). Failure to comply with this section subjects the physician or nurse-midwife to disciplinary action by the Board.

[(1)] (b) A [licensee] physician or nurse-midwife practicing solely as a Federal [employee] employee is not required to participate in the professional liability insurance program, nor is the [licensee] physician or nurse-midwife required to comply with the [Health Care Services Malpractice] Mcare Act.

[(2)] (c) A [licensee] physician or nurse-midwife who provides no medical service in this Commonwealth is not required to pay the [arbitration fees] Mcare Fund assessment or comply with the insurance requirements of the [Health Care Services Malpractice] Mcare Act. Proof of nonpractice [shall] must be furnished by notarized statement.

§ 16.33. Certification of noncompliers; noncompliance letters.

The Director of the [Medical Professional Liability Catastrophe Loss] Medical Care Availability and Reduction of Error (Mcare) Fund will furnish the Board office with a

certification of the names of those licensed physicians and [surgeons] nurse-midwives who are not in compliance with the [Health Care Services Malpractice Act (40 P.S. §§ 1301.101-1301.1006)] Mcare Act (40 P.S. §§ 1303.101-1303.910) or have not demonstrated compliance. Upon receipt of the certification, the Board will forward a letter to the physician or nurse-midwife requiring [him] the physician or nurse-midwife to either furnish sufficient evidence of compliance to the Office of the [Medical Professional Liability Catastrophe Loss] Mcare Fund or to request a hearing.

§ 16.34. Formal hearings for noncompliance.

A physician or [surgeon] nurse-midwife who has requested a hearing or who has failed to demonstrate compliance with the [Health Care Services Malpractice Act (40 P.S. §§ 1301.101-1301.1006)] Mcare Act (40 P.S. §§ 1303.101-1303.910), will be issued a citation and notice of hearing. The formal hearings will be conducted under Subchapter E (relating to medical disciplinary process and procedures).

§ 16.35. Penalty.

Failure to comply with the [Health Care Services Malpractice Act (40 P.S. §§ 1301.101-1301.1006)] Mcare Act (40 P.S. §§ 1303.101-1303.910), the regulations issued thereunder, and this subchapter [will] may result in [the suspension or revocation] discipline of a license after a formal hearing.

CHAPTER 17. STATE BOARD OF MEDICINE—MEDICAL DOCTORS

Subchapter A. LICENSURE OF MEDICAL DOCTORS

* * * * *

§ 17.4. Extraterritorial license.

* * * * *

(b) An extraterritorial license will be issued under the following circumstances:

(1) The applicant shall satisfy the following:

* * * * *

(iii) Submit evidence with the application that the applicant is in compliance with professional liability insurance responsibilities imposed by the [Health Care Services Malpractice Act (40 P.S. §§ 1301.101—1301.1006)] Mcare Act (40 P.S. §§ 1303.101 – 1303.910).

* * * * *

§ 17.6. Temporary license.

* * * * *

(h) Temporary licensees are considered health care providers who conduct 50% or less of their health care business or practice within this Commonwealth for purposes of the [Health Care Services Malpractice Act (40 P.S. §§ 1301.101-1301.1006)] Mcare Act (40 P.S. §§ 1303.101-1303.910).

§ 17.7. Interim limited license.

* * * * *

(c) To qualify for an interim limited license, an applicant shall satisfy the following:

* * * * *

(7) Present evidence of having made arrangements for professional liability insurance coverage in accordance with the [Health Care Services Malpractice Act (40 P.S. §§ 1301.101-1301.1006)] Mcare Act (40 P.S. §§ 1303.101-1303.910).

* * * * *



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

June 26, 2012

The Honorable Silvan B. Lutkewitte, III, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Final Omitted Regulation
State Board of Medicine
16A-4925: Mcare

Dear Chairman Lutkewitte:

Enclosed is a copy of a final omitted rulemaking package of the State Board of Medicine pertaining to Mcare.

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, appearing to read "James W. Freeman MD".

James W. Freeman, Chair
State Board of Medicine

CKM/TL:jsg

Enclosure

cc: Katie True, Commissioner
Bureau of Professional and Occupational Affairs
Rebecca Oyler, Director of Policy, Department of State
Steven V. Turner, Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Teresa Lazo, Counsel
State Board of Medicine
State Board of Medicine

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

I.D. NUMBER: 16A-4925
SUBJECT: MCARE REVISIONS
AGENCY: DEPARTMENT OF STATE (STATE BOARD OF MEDICINE)
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

TYPE OF REGULATION

Proposed Regulation
Final Regulation
XX 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

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FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
6/26/12	<i>Angie Kelly</i>	MAJORITY CHAIR <u>Julie Harhart</u>
6/26/12	<i>Mary Walmer</i>	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
		MAJORITY CHAIR <u>Robert M. Tomlinson</u>
6/26/12	<i>K Cooper</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
6-26-12	<i>Julie Harst</i>	ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

June 15, 2012