Regulatory Analysis Form

This space for use by IRRC

RECEIVED

2017 AUG 15 PM 12: 21

INDEPENDENT REGULATORY REVIEW COMMISSION

(1) Agency

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

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

16A-4923

IRRC Number: 2630

(3) Short Title

Expert Witnesses

(4) PA Code Cite

49 Pa. Code § 16.52

(5) Agency Contacts & Telephone Numbers

Primary Contact: **Gerald S. Smith, Senior Counsel in Charge, State Board of Medicine (717) 783-7200**

Secondary Contact: **Joyce McKeever, Deputy Chief Counsel, Department of State (717) 783-7200**

(6) Type of Rulemaking (check one)

X Proposed Rulemaking
___Final Order Adopting Regulation
___Policy Statement

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

X No
__ Yes: By the Attorney General
__ Yes: By the Governor

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

In order to enhance the quality of testimony given in proceedings before the Board and its hearing examiners, the Board is proposing to adopt the criteria for qualification as an expert established by section 512 of the Mcare Act, 40 P.S. § 1303.512. The Board has found that expert testimony offered by witnesses who do not possess the same specialty qualifications as the Respondent whose conduct is under review has led to assertion of expert opinions that lack the thoroughness and accuracy that the nature of the proceedings before the Board demand. The Board is of the opinion that a physician is not competent to offer an expert medical opinion in a disciplinary action before the Board unless that physician possesses sufficient education, training, knowledge and experience to provide credible, competent testimony and fulfills the qualifications set forth in the proposed rulemaking.

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

Sections 8 and 9 of the Medical Practice Act of 1985 (act)(63 P.S. §§ 422.8 and 422.9) authorize the Board to promulgate regulations addressing procedures to be followed in proceedings before it consistent with the requirements of section 9 of the act.

Regulatory Analysis Form

(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.

No.

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

The Board has found that expert testimony offered by witnesses who do not possess the same specialty qualifications as the Respondent whose conduct is under review has led to assertion of expert opinions that lack the thoroughness and accuracy that the nature of the proceedings before the Board demand.

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

Poor quality expert testimony may lead to erroneous decisions impacting the rights of physicians and/or the health, safety and welfare of patients.

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

Improved testimony benefits all parties to proceedings before the Board, as well as the general public.

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.)

No adverse impact is anticipated.

(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.)

Expert witnesses appearing in formal proceedings before the Board and its hearing examiners.

(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.

The Board has solicited comment under Executive Order 1996-1. The Board received comments from the Hospital and Healthsystem Association of Pennsylvania (HAP), the Pennsylvania Medical Society (PMS) and the Pennsylvania Academy of Family Physicians (PAFP). All comments were considered.

Regulatory Analysis Form

(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.

No anticipated costs or identifiable savings.

(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.

Local governments will not be affected by the 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 Board will not incur an increase in administrative costs by implementing the regulation.

Regulatory Analysis Form

(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 06-07	FY +1 Year 07-08	FY +2 Year 08-09	FY +3 Year 09-10	FY +4 Year 10-11	FY +5 Year 11-12
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.

The proposed amendments will not generate costs or savings.

Regulatory Analysis Form

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

Program	FY – 03-04	FY – 04-05	FY – 05-06	CURRENT FY 06-07
State Board of Medicine	**$4,426,129.18**	**$5,621,389.18**	**$8,794,000.00**	**$9,348,000.00**

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

There are no identifiable costs associated with the regulation; therefore, the benefits of the proposed amendments to the quality of testimony before the Board in disciplinary proceedings outweigh any perceived adverse effects.

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

No nonregulatory alternatives were considered because existing regulations need to be amended through the regulatory process.

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

No alternative regulatory schemes were considered because the proposal established standards that are regulatory in nature.

Regulatory Analysis Form

(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.

This question is not applicable to this rulemaking.

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

This regulation is particular to proceedings before the Board. Other states' standards have no relevance to this rulemaking. The rulemaking will not 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.

The regulation will have no effect on other regulations of the Board or other state agencies.

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

The Board reviews regulatory proposals at regularly scheduled monthly public meetings. A schedule of board meetings can be found on the Department of State's website at www.dos.state.pa.us/bpoa. The Board provided a draft of the proposed regulations to those persons and organizations who have identified themselves as interested in the regulatory proposals of the Board. All public comments will be considered in drafting the final rulemaking.

Regulatory Analysis Form

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

The rulemaking has no impact on existing reporting, record keeping or other paperwork requirements.

(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 Board has perceived no special needs of any subset of applicants or licensees for whom special accommodations should be made.

(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 become effective on publication of the final-form rulemaking in the *Pennsylvania Bulletin*.

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

The Board reviews its regulations continually.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED
2007 AUG 15 PM 12:21
INDEPENDENT REGULATORY
REVIEW COMMISSION
DO NOT WRITE IN THIS SPACE

1 2630

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

BY: _____
(DEPUTY ATTORNEY GENERAL)

JUN 20 2007
DATE OF APPROVAL

Counsel

Agency
inapplicable

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

State Board of Medicine
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-4923

DATE OF ADOPTION: _____

BY: _____
Charles D. Hummer, Jr., M.D.

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

BY: _____
Andrew C. Clark

MAY 25 2007
DATE OF APPROVAL

(~~Executive~~ Deputy General
(~~Chief~~ Counsel,
~~Independent~~
~~Strike~~
~~title~~)

[ ] Check if applicable
Copy not approved.
Objections attached.

[ ] Check if applicable. No Attorney General approval or objection within 30 day after submission.

PROPOSED RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
49 PA. CODE, CHAPTER 16
EXPERT WITNESSES

The State Board of Medicine (Board) proposes to amend §16.52 (relating to creation of lists of medical consultants), to read as set forth in Annex A.

A. Effective Date

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

B. Statutory Authority

Sections 8 and 9 of the Medical Practice Act of 1985 (act) (63 P.S. §§422.8 and 422.9) authorize the Board to promulgate regulations addressing procedures to be followed in proceedings before it consistent with the requirements of section 9 of the act.

C. Background and Purpose

In order to enhance the quality of testimony given in disciplinary proceedings before the Board and the hearing examiners who hear matters on behalf of the Board, the Board is proposing to adopt the criteria for qualification as an expert witness established by section 512 of the Medical Care Availability and Reduction of Error Act (Mcare Act) (40 P.S. § 1303.512). The Board has found that expert testimony offered by witnesses who do not possess the same specialty qualifications as the Respondent whose conduct is under review has led to the assertion of expert opinions that lack the thoroughness and accuracy that the nature of the proceedings before the Board demands. The Board is of the opinion that a physician is not competent to offer an expert medical opinion in a disciplinary action before the Board alleging medical professional negligence, incompetence or violation of the standard of care unless that physician possesses sufficient education, training, knowledge and experience to provide credible, competent testimony and fulfills the qualifications as set forth in this proposed rulemaking.

D. Description of Amendments

Existing §16.52 would be amended to delete references to the maintenance of lists of expert medical consultants who might serve as expert witnesses and would instead establish qualifications consistent with section 512 of the Mcare Act (40 P.S. § 1303.512) for experts testifying in proceedings before the Board.

Section 16.52(a) would establish the general rule that no person shall be competent to offer an expert medical opinion in a disciplinary action before the Board unless that person possesses sufficient education, training, knowledge and experience to provide credible, competent testimony and fulfills the additional qualifications set forth in this section as applicable.

Section 16.52(b) would establish qualifications for an expert to testify on a medical matter, including the standard of care, risks and alternatives, causation and the nature and extent of the injury. Those qualifications would include: (1) possessing an

unrestricted physician's license to practice medicine in any state or the District of Columbia; and (2) being engaged in, or having retired within the previous 5 years from, the active clinical practice or teaching of medicine. The Board may waive these requirements for an expert on a matter other than the standard of care if the Board determines that the expert is otherwise competent to testify about medical or scientific issues by virtue of education, training or experience.

Section 16.52(c) would establish additional requirements for experts relating to standard of care issues. The expert would need to: (1) be substantially familiar with the applicable standard of care for the specific care at issue as of the time of the alleged breach of the standard of care; (2) practice in the same specialty and subspecialty as the Respondent physician or in a subspecialty that has a substantially similar standard of care for the specific care at issue; and (3) in the event a Board-recognized certifying board certifies the Respondent physician, the expert shall also be board certified by the same or a similar approved board.

Under § 16.52(d) the Board may waive the same subspecialty requirement for an expert testifying on the standard of care for the diagnosis or treatment of a condition if the Board determines that: (1) the expert is trained in the diagnosis or treatment of the condition, as applicable; and (2) the Respondent physician provided care for that condition and such care was not within the Respondent physician's specialty.

Under § 16.52(e), the Board may waive the same specialty, subspecialty, and board certification requirements for an expert testifying as to a standard of care if the Board determines that the expert possesses sufficient training, experience and knowledge to provide the testimony as a result of active involvement in or full-time teaching of medicine in the applicable subspecialty or a related field of medicine within the previous 5-year time period.

Finally, under § 16.52(f), the Board reserves its authority to apply its own expertise in determining the applicable standard of care in disciplinary matters before the Board.

E. Compliance with Executive Order 1996-1

In accordance with the requirements of Executive Order 1996-1 (February 6, 1996), in drafting and promulgating the regulation, the Board solicited input and suggestions from the regulated community and other parties who have identified themselves as interested in the Board's regulatory agenda. The Board received comments from the Hospital and Healthsystem Association of Pennsylvania (HAP), the Pennsylvania Medical Society (PMS), and the Pennsylvania Academy of Family Physicians (PAFP). Comments from HAP and PMS were supportive of the proposal. PAFP suggested the standards should only apply to experts testifying against the Respondent physician and not those testifying on behalf of the Respondent physician. The Board disagrees. Improvement in the quality of expert testimony on all sides can only serve to benefit the quality of the entire proceeding. PAFP also believes only

Pennsylvania licensed physicians should be qualified to testify. The Board believes that PAFP's position is not supported by the Mcare Act (40 P.S. § 1303.101 et seq.), the Medical Practice Act of 1985 (63 P.S. § 422.1 et seq.), or the Pennsylvania Rules of Evidence.

F. Fiscal Impact and Paperwork Requirements

There is no adverse fiscal impact or paperwork requirement imposed on the Commonwealth, political subdivision, or the private sector.

G. Sunset Date

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

H. Regulatory Review

Under Section 5(a) of the Regulatory Review Act (71 P.S. §745.5(a)), on August 15, 2007, 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 the chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and 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 that 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 and objections raised.

I. Public Comment

Interested persons are invited to submit written comments, recommendations, or objections regarding the proposed regulation to Gerald S. Smith, Senior Counsel in Charge, Department of State, P.O. Box 2649, Harrisburg, Pennsylvania 17105-2649 within 30 days following publication for the proposed regulation in the Pennsylvania Bulletin. Please refer to 16A-4923: Expert Witnesses when submitting comments.

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

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE – GENERAL PROVISIONS

Subchapter E. MEDICAL DISCIPLINARY PROCESS AND PROCEDURES

HEARING EXAMINERS AND MEDICAL CONSULTANTS

* * * * *

§ 16.52. [Creation of lists of medical consultants] Expert witnesses.

[The Board, through the cooperation of various State and local professional societies, has created lists of licensed physicians and surgeons of varied expertise, specialty and training from which medical consultants can be selected to serve on a part-time basis as resource personnel, with medical expertise required for the individual case.]

In order to enhance the quality of expert testimony given in disciplinary proceedings before the Board and its hearing examiners, the Board adopts the criteria for qualification as an expert established by section 512 of the Medical Care Availability and Reduction of Error Act (Mcare Act) (40 P.S. § 1303.512), as follows:

(a) *General rule.* No person shall be competent to offer an expert medical opinion in a disciplinary action before the Board unless that person possesses sufficient education, training, knowledge and experience to provide credible, competent testimony and fulfills the additional qualifications set forth in this section as applicable.

(b) *Medical testimony.*

(1) An expert testifying on a medical matter, including the standard of care, risks and alternatives, causation and the nature and extent of the injury, shall:

(i) Possess an unrestricted physician's license to practice medicine in any state or the District of Columbia.

(ii) Be engaged in, or retired within the previous 5 years from, active clinical practice or teaching of medicine.

(2) The Board may waive the requirements of this subsection for an expert on a matter other than the standard of care if the Board determines that the expert is otherwise competent to testify about medical or scientific issues by virtue of education, training or experience.

(c) *Standard of care.* In addition to the requirements set forth in subsections (a) and (b), an expert testifying as to a physician's standard of care shall:

(1) Be substantially familiar with the applicable standard of care for the specific care at issue as of the time of the alleged breach of the standard of care.

(2) Practice in the same specialty and subspecialty as the Respondent physician or in a subspecialty that has a substantially similar standard of care for the specific care at issue, except as provided in subsection (d) or (e).

(3) In the event a Board-recognized certifying board certifies the Respondent physician, the expert shall also be board certified by the same or a similar approved board, except as provided in subsection (e).

(d) *Care outside specialty.* The Board may waive the same subspecialty requirement for an expert testifying on the standard of care for the diagnosis or treatment of a condition if the Board determines that:

(1) The expert is trained in the diagnosis or treatment of the condition, as applicable.

(2) The Respondent physician provided care for that condition and such care was not within the Respondent physician's specialty.

(e) *Otherwise adequate training, experience and knowledge.* The Board may waive the same specialty, subspecialty, and board certification requirements for an expert testifying as to a standard of care if the Board determines that the expert possesses sufficient training, experience and knowledge to provide the testimony as a result of active involvement in or full-time teaching of medicine in the applicable subspecialty or a related field of medicine within the previous 5-year time period.

(f) *Application of Board's own expertise.* Nothing in this subsection shall be construed to preclude the Board from applying its own expertise in determining the applicable standard of care in disciplinary matters before the Board.

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

August 15, 2007

The Honorable Arthur Coccodrilli, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation
State Board of Medicine
16A-4923: Expert Witnesses

Dear Chairman Coccodrilli:

Enclosed is a copy of a proposed rulemaking package of the State Board of Medicine pertaining to expert witnesses.

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

Sincerely,

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

CDH/GSS:kmh
Enclosure
cc: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Albert H. Masland, Chief Counsel
Department of State
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Cynthia K. Montgomery, Senior Counsel in Charge
Department of State
Gerald S. Smith, Senior Counsel in Charge
State Board of Medicine
State Board of Medicine

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-4923
SUBJECT:	EXPERT WITNESSES
AGENCY:	DEPARTMENT OF STATE STATE BOARD OF MEDICINE

TYPE OF REGULATION

X Proposed Regulation

Final Regulation

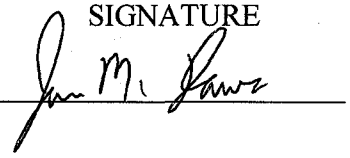
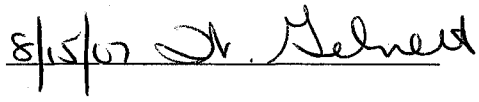
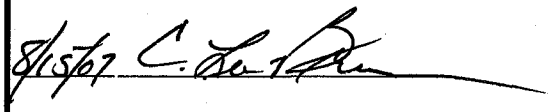
Final Regulation with Notice of Proposed Rulemaking Omitted

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
8/15/07		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
8-15-07		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
8/15/07		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
8/15/07		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

June 22, 2007