

Regulatory Analysis Form

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IRRC REVIEW COMMISSION

(1) Agency

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

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

16A-4918

IRRC Number: 2399

(3) Short Title

Disciplinary Process and Procedure

(4) PA Code Cite

49 Pa. Code, §§ 16.51, 16.55, 16.56,
16.57, 16.58

(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)

☐ Proposed Rulemaking
☒ Final Order Adopting Regulation
☐ Policy Statement

(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.

The regulations will codify the process and procedures followed in disciplinary matters before the State Board of Medicine. These procedures had previously been indicated in sections 901-905 of the Health Care Services Malpractice Act (formerly 40 P.S. §§1301.901-1301.905). On March 20, 2002, the Governor signed into law the Medical Care Availability and Reduction of Error Act (Mcare Act), Act 13 of 2002. Section 5104 of the Mcare Act repealed these provisions of the Health Care Services Malpractice Act. It is not clear what, if any, impact the repealer provisions have on the procedures followed by the Board. Because the Board's procedures have been effective, the Board has determined that codifying the process will maintain the status quo and avoid unnecessary and unintended confusion.

(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 (63 P.S. §422.9).

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(10) Is the regulations 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?

On March 20, 2002, the Governor signed into law the Medical Care Availability and Reduction of Error Act (Mcare Act), Act 13 of 2002. Section 5104 of the Mcare Act repealed and saved various provisions of the Health Care Services Malpractice Act. It is not clear what, if any, impact the repealer provisions have on the procedures followed by the Board. Because the Board's procedures have been effective and are understood and followed by those attorneys who appear in Board proceedings the Board has determined that codifying the process will maintain the status quo and avoid unnecessary and unintended confusion.

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

Failure to clarify the Board's process in light of the uncertain impact of the Mcare Act on the procedures indicated by the Health Care Services Malpractice Act has the potential of creating unnecessary confusion pertaining to the Board's procedures. This regulation would codify existing practices and thereby avoid such confusion.

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

Individuals appearing before the Board would benefit by having the Board's procedures codified.

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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.)

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.)

All individuals who appear before the Board in a disciplinary proceeding will be required to comply with the regulation.

(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.

In developing and drafting the regulation, the Board sought input from those individuals and groups who have identified themselves to the Board as parties interested in the regulatory proposals of the Board. The Board received no negative public comment pertaining to the proposal. Proposed rulemaking was published on April 10, 2004, at 34 Pa. Bulletin 1963. The preamble fully addresses the comments received.

(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.

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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.

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.

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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 7/1/01	FY +1 Year 7/1/02	FY +2 Year 7/1/03	FY +3 Year 7/1/04	FY +4 Year 7/1/05	FY +5 Year 7/1/06
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:						
Regulated Community						
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

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

The 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 -3 FY 99-00	FY -2 FY 00-01	FY -1 FY 01-02	Current FY FY 02-03
State Board of Medicine	\$ 6,747,000.00	\$ 2,562,885.01	\$2,595,622.41	\$ 2,885,504.70

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

The amendments are cost benefit-neutral because they codify existing practices.

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

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 alternative 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 specific federal standards addressing these procedures. The proposed regulations are consistent with due process requirements of the Constitution of the Commonwealth and the Constitution of the United States.

(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 does not put Pennsylvania licensees at a competitive disadvantage with other states. The Constitution of the Commonwealth of Pennsylvania affords greater due process protections to the citizens of the Commonwealth than other jurisdictions (Lyness v. State Board of Medicine, 605 A.2d 1204 (Pa 1992)) accordingly the procedures utilized by other jurisdictions are not relevant to this rulemaking. Nevertheless, see attachment 1 for a summary of the process followed by our contiguous sister states.

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

This 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 who have identified themselves as interested in the regulatory proposals of the Board. Proposed rulemaking was published April 10, 2004, at 34 Pa. Bulletin 1963.

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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.

No changes to reporting, record keeping, or other paperwork are required by this regulation.

(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 its 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 be effective upon publication as final rulemaking in the *Pennsylvania Bulletin*.

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

The Board reviews its revenues and costs of its programs on a fiscal year and biennial basis.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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REVIEW COMMISSION

2399

DO NOT WRITE IN THIS SPACE

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BY: _____
(DEPUTY ATTORNEY GENERAL)

State Board of Medicine

(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-4918

DATE OF ADOPTION: _____

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

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

BY: _____

1.31.05

DATE OF APPROVAL

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

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

NOTICE OF FINAL RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
49 PA. CODE, CHAPTER 16
MEDICAL DISCIPLINARY PROCESS AND PROCEDURES

The State Board of Medicine (Board) hereby amends §§16.51 (relating to creation of list of hearing examiners) and adds §16.55 - 16.58 to read as set forth in Annex A.

A. Effective Date

The amendments will be effective upon publication as final-form regulations 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 (63 P.S. §422.9).

C. Background and Purpose

The regulations codify the process and procedures that are currently followed in disciplinary matters before the Board. These procedures are derived from sections 901-905 of the Health Care Services Malpractice Act (formerly 40 P.S. §§1301.901-1301.905). On March 20, 2002, the Governor signed into law the Medical Care Availability and Reduction of Error Act (MCARE Act)(40 P.S. §§ 1303.101 – 1303.910). Section 5104 of the MCARE Act repealed sections 901 through 905 of the Health Care Services Malpractice Act. It is not clear what, if any, impact the repealer provisions have on the procedures followed by the Board. Because the Board's procedures have been effective, the Board has determined that codifying the process will maintain the status quo and avoid unnecessary and unintended confusion. The Board has also included language at §16.55(c) (relating to complaint process) specifically provided for by the MCARE Act.

D. Summary of Comments and Responses to Proposed Rulemaking

Proposed rulemaking was published at 34 Pa. B. 1963 on April 10, 2004. The Board entertained public comment for a period of 30 days during which time the Board received comments from the Pennsylvania Academy of Family Physicians. Following the close of the public comment period, the Board received comments from the Independent Regulatory Review Commission (IRRC) and the House Professional Licensure Committee (HPLC). The Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) did not comment. The following is a summary of the comments and the Board's response.

The Pennsylvania Academy of Family Physicians sought the specific statutory authority for the confidentiality provision of §16.55(c). This language is specifically authorized by section 907 of the MCARE Act. The Pennsylvania Academy of Family Physicians also questioned §16.55(d) in regard to the prosecutor's ability, after failed settlement negotiations, to introduce other evidence to prove factual matters disclosed during negotiation. The Academy's position is

that such a practice impairs the settlement and raises due process concerns. Respectfully, the Academy's position is mistaken. While statements made during the negotiation process are not admissible, it is common accepted practice to allow other evidence not disclosed during negotiations to be introduced.

The HPLC and the IRRRC raised similar questions regarding the proposed rulemaking. The HPLC and the IRRRC questioned whether §16.58 (relating to appeals from Board decisions) could be interpreted as limiting a respondent's right of appeal. This was not the intent of the Board and the language creating the confusion has been deleted as suggested. The IRRRC also commented that §16.55 (relating to complaint process) could be clearer by simplifying the language to indicate that any person could file a complaint. The Board has clarified the language as suggested. Because of this change, the HPLC suggestion that a definition of "public officer" be added is moot. The HPLC also suggested that the language regarding the Board's *sua sponte* review of hearing examiner decisions in §16.57 (relating to appeal from the hearing examiner's decision) could be clarified if the Board substituted the word motion for notice. The document the Board issues when it reviews a matter is entitled "Notice of Review." The Board has adopted the suggestion.

E. Description of Amendments

Section 16.51 (relating to hearing examiners) is amended to more accurately reflect that, consistent with the Commonwealth Attorneys Act (71 P.S. §§732-101-732-506), attorneys, including hearing examiners, are assigned to agencies through the Office of General Counsel. The regulation also provides for the Board's current process that, absent an order of the Board otherwise, all matters would be heard by the Board's hearing examiner.

Section 16.55 (relating to complaint process) is added to provide a description of the complaint process. Subsection 16.55(a) provides that any person may submit a written complaint to the complaints office. Subsections 16.55(b)-(d) describe the internal processing of complaints. Specifically, in keeping with the decision in Lyness v. State Board of Medicine, 605 A.2d 1204 (Pa. 1992), the Board prosecutor will cause to be conducted reasonable inquiry and will determine whether to initiate the filing of formal charges. Consistent with section 907 of the MCARE Act (40 P.S. §1303.907), §16.55(c) reiterates that documents, materials or information obtained during the course of an investigation shall be confidential and privileged unless admitted as evidence during the course of a formal disciplinary proceeding. Subsection 16.55(d) provides for the Board prosecutor to enter negotiations to settle the case by consent agreement.

Section 16.56 (relating to formal hearings open to public) provides for formal hearings to be open to the public.

Section 16.57 (relating to appeal from hearing examiner's decision) provides for review of the hearing examiner's decision by the Board on the request of either party or on the Board's own motion. Subsection 16.57(b) provides that, unless otherwise ordered by the Board, neither

the filing of an application for review nor the Board's own notice of intent to review would stay the hearing examiner's decision.

Section 16.58 (relating to appeal from the Board decision) provides for review of the Board's decision under 2 Pa.C.S. § 702 (relating to appeals).

F. Compliance with Executive Order 1996-1

The Board reviewed this rulemaking and considered its purpose and likely impact on the public and the regulated population under the directives of Executive Order 1996-1. This final-form rulemaking addresses a compelling public interest and otherwise complies with Executive Order 1996-1.

G. Fiscal Impact and Paperwork Requirements

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

H. Sunset Date

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

I. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on March 30, 2004, the Board submitted a copy of the notice of proposed rulemaking, published on April 10, 2004, at 34 Pa.B. 1963, 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 _____ this final-form rulemaking was approved by the HPLC, On _____, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____, and approved the final-form rulemaking.

J. Contact Person

Further information may be obtained by contacting Gerald S. Smith, Counsel, State Board of Medicine, P.O. Box 2649, Harrisburg, PA 17105-2649 or by e-mail at gerasmith@state.pa.us.

K. Findings

The State Board of Medicine 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, 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) This final-form rulemaking does not enlarge the purpose of proposed rulemaking published at 34 Pa.B. 1963.

(4) This final-form rulemaking is necessary and appropriate for administering and enforcing the authorizing acts identified in Part B of this Preamble.

L. Order

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

(a) The regulations of the Board, 49 Pa. Code Chapter 16, 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 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*.

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

**SUBCHAPTER E. MEDICAL DISCIPLINARY PROCESS AND
PROCEDURES**

§ 16.51. [Creation of list of h] Hearing examiners.

[As provided under section 902 of the Health Care Services Malpractice Act (40 P.S. § 1302.902), the Board has created a list of individuals with the approval of the Governor from which hearing examiners can be selected to serve on a part-time basis in order to hear formal hearings and render adjudications.] Hearing examiners are appointed by the Governor's Office of General Counsel to hear matters before the Board. Unless otherwise ordered by the Board, all disciplinary matters shall be heard by a hearing examiner.

* * *

§ 16.55 Complaint process.

(a) A person, ~~firm, corporation or public officer~~ may submit a written complaint to the complaints office alleging a violation of the act or this chapter or Chapters 17 or 18 (relating to State Board of Medicine – medical doctors; and State Board of Medicine – practitioners other than medical doctors), specifying the grounds therefore.

(b) The complaints office will assign a complaint to the prosecution and investigatory staff who, together with medical consultants as may be required, will make a determination that the complaint merits consideration. The Board prosecutor will cause to be conducted reasonable inquiry or investigation that is deemed necessary to determine the truth and validity of the allegations in the complaint. The Board prosecutor will provide reports to the Board at its regular meetings on the number, nature, procedure and handling of the complaints received.

(c) Upon review of the complaint, documentation, records and other materials obtained during the course of an investigation, the Board prosecutor will determine whether to initiate the filing of formal charges. The documents, materials or information obtained during the course of an investigation shall be confidential and privileged unless admitted as evidence during the course of a formal disciplinary proceeding. A person who has investigated or has access to or custody of documents, materials or information which are confidential and privileged under this subsection will not be required to testify in any judicial or administrative proceeding without the written consent of the Board.

(d) The Board prosecutor may enter into negotiations at any stage of the complaint.

investigation or hearing process to settle the case by consent agreement.

(1) All consent agreements must be approved as to form and legality by the Office of General Counsel and adopted by the Board.

(2) Until such time as the Board approves a consent agreement, the terms of the agreement are confidential.

(3) Any admissions made by a respondent during the course of negotiations may not be used against the respondent in any formal disciplinary proceeding if a consent agreement cannot be reached.

(4) Admissions made by a respondent in a consent agreement that is ultimately rejected by the Board may not be used against the respondent in any formal disciplinary proceeding.

(5) This subsection does not preclude the Board prosecutor from offering, at a formal disciplinary hearing, other evidence to prove factual matters disclosed during the negotiation process.

§ 16.56 Formal hearings open to public.

Formal disciplinary proceedings are open to the public. Members of the press may request in advance of the hearing permission from the presiding officer for the electronic recording of the proceedings. Upon the consideration of objections by the parties, the hearing examiner may permit the electronic recording of the proceeding by members of the press if the presiding officer determines that the

recording will not interfere with the efficient conduct or impartiality and fairness of the proceedings.

§ 16.57 Appeal from the hearing examiner's decision.

(a) Unless otherwise ordered by the Board, the decision of the hearing examiner shall become final after 20 days of its issuance.

(1) Upon application for review by any party or upon the Board's own notice MOTION, the Board will review the hearing examiner's decision.

(2) The Board will review the entire record and, if it deems it advisable, may hear additional testimony from persons already deposed or from new witnesses as well as arguments of counsel to make a Board decision.

(3) Additional testimony will be taken as soon as practicable.

(4) The Board will issue its final decision, along with its findings of fact and conclusions of law, which will be sent by mail to the parties involved.

(b) Unless otherwise ordered by the Board, neither the filing of an application for review nor the Board's own notice of intent to review will stay the hearing examiner's decision.

§ 16.58 Appeal from the Board decision.

The respondent may, within 30 days from the date of the decision of the Board, appeal to the Commonwealth Court if the appeal is based on allegations of certain errors of law under terms and

conditions as cover appeals and actions involving State agencies under 2 Pa.C.S. § 702 (relating to
appeals).

**State Board of Medicine
Proposed Rulemaking 16A-4918
Disciplinary Process and Procedure
Attachment 1**

Delaware. The Executive Director, or a staff attorney from the Office of the Attorney General shall present evidence in support of the allegations contained in the formal complaint. After the Board accepts a complaint, which has been investigated by the Executive Director, it shall appoint a hearing panel, composed of 3 members of the Board, who shall hear all evidence concerning charges. After the hearing panel has heard all evidence, it shall make a written statement of its findings of fact and conclusions of law. The findings of fact made by the hearing panel shall be binding on the parties appearing before it and shall also be adopted by and binding upon the Board. Should a majority of the members of the Board who consider the matter vote to accept the hearing panel's conclusions of law and recommendation, then no further proceeding shall be held before the Board. If the majority of the members of the Board vote to reject the hearing panel's conclusions of law and recommendation, then a formal hearing shall be held before the Board to enable the Board to make its own conclusions of law and to determine what discipline should be imposed.

Maryland. Designated Board staff shall undertake a preliminary investigation of each complaint. Upon receipt of the report of the Faculty, the Board shall determine whether there is reasonable cause to charge a respondent with failure to meet appropriate standards of care. After reviewing the completed investigatory information and reports, the Board shall make its determination whether to charge the person or dismiss the complaint. After a vote to take formal action, the Board shall refer the matter to the administrative prosecutor for prosecutorial action. The administrative law judge shall consider and decide arguments regarding the sufficiency of the report. The Board shall issue a final order of either dismissal or revocation. After the Board issues its order, a party may file a motion for reconsideration with the Board. There is no automatic right to a hearing before the Board.

New York. An administrative review board for professional medical conduct is created for the purpose of reviewing determinations of committees on professional conduct of the state board for professional medical conduct. The Board, by its committees on professional conduct, shall conduct disciplinary proceedings. The Board for professional medical conduct may investigate on its own any suspected professional misconduct. If the director of the office of professional medical conduct after obtaining the concurrence of a majority of an investigation committee, and after consultation with the executive secretary, determines that a hearing is warranted, the director shall direct counsel to prepare the charges. A committee on professional conduct shall conduct the hearing. The committee shall issue an order based on its determinations. Review is automatic because failure to seek an order of the administrative review board shall not be grounds for dismissal of such a proceeding.

New Jersey. The Board has a power to prosecute. It has two options: 1) hear all the evidence or 2) transfer to the administrative law office. If the case is transferred, ALJ is the initial decision maker. Administrative Law Judge's decision is only a recommendation to the board. The

review by the board is automatic. It may accept or reject the decision. If still unsatisfied, the party may elect to appeal the decision in the superior court.

Ohio. The Board shall investigate evidence that appears to show that a person has violated any provision. It shall designate an attorney at law who has been classified as a hearing examiner to conduct any hearing, which the medical board is empowered to hold. Such hearing examiner shall hear and consider the oral and documented evidence introduced by the parties and issue in writing proposed findings of fact and conclusions of law to the board for their consideration. The board shall upon the favorable vote of three members, allow the parties the opportunity to present oral arguments on the proposed findings of fact and conclusions of law of the hearing examiner prior to the board's final action. The review by the board is not automatic. If the individual requests an adjudicatory hearing by the board, the date set for the hearing shall be within fifteen days after the individual requests the hearing, unless otherwise agreed to by both the board and the individual. If no hearing is requested, the board may order appropriate sanctions.

West Virginia. The Board or its hearing examiner may institute proceedings. Hearings conducted by the Board or by a hearing examiner appointed by the Board, upon a complaint issued by the Board, are a continuance of the investigation designed to enable the Board to properly discharge its administrative functions and authority. The function of a hearing examiner, who is appointed by the president of the board and with the approval of a majority, is to preside at the hearing and to cause to be prepared a record of the hearing so that the Board is able to discharge its functions. Proceedings for review shall be instituted by filing a petition, at the election of the petitioner. Thus, the review is not automatic.



Pennsylvania Academy of
FAMILY PHYSICIANS

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DOS LEGAL COUNSEL

April 26, 2004

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Joanne Troutman
Health Licensing Division
Bureau of Professional and Occupational Affairs
PO Box 2649
Harrisburg, PA 17105-2649

Re: Regulation #16A-4918 - Disciplinary Process and Procedure

Dear Ms. Troutman:

On behalf of the over 4,700 members of the Pennsylvania Academy of Family Physicians (PAFP), I submit these comments on the State Board of Medicine's Proposed Regulation #16A-4918, titled Disciplinary Process and Procedure. Although the stated purpose of the Board's proposed regulations is to codify existing procedures, the PAFP has identified certain substantive provisions contained in the regulations that cause us concern.

Proposed § 16.55(c) includes the following sentence: "A person who has investigated or has access to or custody of documents, materials or information which are confidential and privileged under this subsection will not be required to testify in any judicial or administrative proceeding without the written consent of the Board." The PAFP has been unable to find any applicable statute which authorizes the State Board of Medicine to control who may testify in any judicial or administrative proceeding not under the Board's jurisdiction. Respectfully, the PAFP believes that the sentence provision may exceed the Board's regulatory authority and should be deleted.

Proposed § 16.55(d) concerns confidential negotiations between a prosecuting attorney for the Board and a physician respondent that may or may not lead to a final consent agreement resolving a Board disciplinary matter. Subsection (d)(5) provides: "This subsection does not preclude the Board prosecutor from offering, at a formal disciplinary hearing, other evidence to prove factual matters disclosed during the negotiation process." This provision is contradictory to the relevant rules governing confidentiality of settlement negotiations and also raises constitutional due process concerns. In addition, the provision would likely inhibit the speedy and cost-effective resolution of disciplinary cases. For these reasons, the PAFP believes that this provision also should be deleted.

The PAFP appreciates the Board's consideration of our concerns as you prepare the final regulation. Should you have questions or concerns, please do not hesitate to contact PAFP Director of Governmental Affairs Andrew Sandusky at asandusky@pafp.com or 717-564-5365.

Sincerely,

Wanda D. Filer, MD

Wanda D. Filer, MD
President

WDF/alm

Jo



JOHN R. MCGINLEY, JR., ESQ., CHAIRMAN
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ROBERT E. NYCE, EXECUTIVE DIRECTOR
MARY S. WYATTE, CHIEF COUNSEL

**INDEPENDENT REGULATORY REVIEW COMMISSION
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June 9, 2004

Charles D. Hummer, Jr., M.D., Chairman
State Board of Medicine
2601 North 3rd Street
Harrisburg, PA 17110

Re: Regulation #16A-4918 (IRRC #2399)
State Board of Medicine
Disciplinary Process and Procedure

Dear Chairman Hummer:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulation review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact my office at 783-5417.

Sincerely,

Robert E. Nyce
Executive Director
wbg
Enclosure

cc: Honorable Robert M. Tomlinson, Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable Thomas P. Gannon, Majority Chairman, House Professional Licensure Committee
Honorable William W. Rieger, Democratic Chairman, House Professional Licensure Committee
Honorable Pedro A. Cortes, Secretary, Department of State

Comments of the Independent Regulatory Review Commission

on

State Board of Medicine Regulation No. 16A-4918 (IRRC #2399)

Disciplinary Process and Procedure

June 9, 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 Medicine (Board) must respond to these comments when it submits the final-form regulation. The public comment period for this regulation closed on May 10, 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 16.55. Complaint process. – Clarity.

Subsection (a) begins, “A person, firm, corporation or public officer may submit a written complaint....” To clarify its intent, the Board should delete all the terms except for “person,” which is defined in Section 1991 of the Statutory Construction Act (1 Pa.C.S. § 1991). Section 1991 defines “person” to include all types of organizational entities as well as a natural person.

2. Section 16.58. Appeal from the Board decision. – Reasonableness.

This section allows a respondent to appeal a decision by the Board to the Commonwealth Court if “the appeal is based on allegations of certain errors of law under terms and conditions as cover appeals and actions involving State agencies under 2 Pa.C.S. § 702 (relating to appeals).” The House Professional Licensure Committee (House Committee) in its comments described this language as “too limiting and narrow in its scope.”

The House Committee refers to both statutory and constitutional grounds for its concern. The statute (2 Pa.C.S. § 702) referenced by the Board asserts that any person, who is aggrieved by an adjudication of a Commonwealth agency and has a direct interest in the adjudication, has the right to appeal the decision to the court vested with jurisdiction. The right to an appeal is also included in Article V Section 9 of the Pennsylvania Constitution.

We agree that the right of appeal cannot be limited to “allegations of certain errors of law.” Therefore, language that would constrain the right of appeal should be deleted from this section in the final-form regulation. However, we recommend that the regulation reference the Administrative Agency Law (2 Pa. C.S. §§ 701-704).

Regulation 16A-4918

State Board of Medicine

PROPOSAL: Regulation 16A-4918 amends 49 Pa. Code, Chapter 16, regulations of the State Board of Medicine, relating to the disciplinary process.

Specifically, the proposed regulation seeks to codify the existing method of hearing disciplinary matters. The board was given the authority to conduct investigations and to employ hearing examiners to hear cases, as well as the authority to review those decisions, by the now-defunct Health Care Services Malpractice Act, 40 P.S. 1301.901-1301.905. Since the Health Care Services Malpractice Act was repealed by the General Assembly, the board believes it is wise to codify existing practice in Chapter 16 of Title 49 of the Pennsylvania Code.

Section 8 of the Medical Practice Act of 1985 gives the board the authority to promulgate regulations in order to carry out the act. Section 9 of the Medical Practice Act requires the board to conduct disciplinary proceedings so that the right to notice, appeal, hearing, and adjudication are preserved, in accordance with Title 2 of the Pennsylvania Consolidated Statutes, Administrative Law and Procedure.

The proposed regulation was published in the Pennsylvania Bulletin on April 10, 2004.

Analysis: Below is a section by section analysis of the proposed regulation.

Section 16.51:

This section deals with hearing examiners, specifically the board's ability to select individuals to serve as hearing examiners, with approval of the governor. The proposed regulation deletes the language which refers to the Health Care Services Malpractice Act and states that hearing examiners are appointed by the Governor's Office of General Counsel to hear matters. Further, unless otherwise ordered by the board, all cases are to be heard by a hearing examiner.

The Health Care Services Malpractice Act provided that the board appoint, with approval of the governor, hearing examiners. Those hearing examiners had the power, in accordance with board regulations, to conduct hearings, to issue subpoenas, and to compel the production of documents. 40 P.S. 1301.902.

Section 16.55:

The proposed regulation creates a new section entitled Complaint Process. It provides that a person, firm, corporation or public officer may submit a written complaint to the complaints office. The complaints office will assign the complaint to the prosecution and investigatory staff so that a determination can be made regarding whether the complaint merits consideration. The board prosecutor is given the duty to conduct a reasonable investigation in order to determine the validity of the charges in the complaint. The prosecutor will provide reports to the board at its

regular meetings regarding the number, nature, procedure and handling of the complaints. The board prosecutor will decide whether to bring formal charges.

All documents, materials or other information shall be confidential unless admitted as evidence. No person who has investigated or who has access to records which are privileged shall be required to testify in any judicial or administrative proceeding without written consent of the board.

The section further states that the prosecutor may enter into a Consent Agreement with the respondent at any stage of the proceedings. All consent agreements must be reviewed by Office of General Counsel and adopted by the board. Any admission made by a respondent during the course of negotiations to reach a consent agreement cannot be used in disciplinary proceedings if the consent agreement is not reached. Similarly, if the board rejects a consent agreement, the prosecutor may not use that evidence.

The Health Care Services Malpractice Act empowered the board to employ qualified investigators and attorneys in order to carry out the board's duty to discipline licensees. 40 P. S. 1301.901.

Section 16.56:

The proposed regulation creates a new section 16.56 entitled Formal Hearings Open to Public and states that the public and press may attend.

According to board counsel, this is current practice.

Section 16.57:

The proposed regulation creates a new section 16.57 entitled Appeal From the Hearing Examiner's Decision. It specifies that unless otherwise ordered by the board, the decision of the hearing examiner becomes final after 20 days of its issuance. Upon application for review by any party or upon the board's own motion, the board shall review the hearing examiner's decision. The board must review the entire record and, if it deems advisable, may hear additional testimony, as well as argument. The board will reach a final decision, supported by findings of fact and conclusions of law, which shall be sent to the parties.

The Health Care Services Malpractice Act provided that if an application for review was made to the board within 20 days of the decision of the hearing examiner, the board was commanded to review the evidence and, if deemed advisable by the board, hear argument and additional evidence. As soon as is practicable, the board shall make a decision, as well as findings of fact, and mail it to the parties. 40 P.S. 1301.905.

Section 16.58:

The proposed regulation creates a new section 16.58 entitled Appeal From the Board Decision. This section states that within 30 days from the board's decision, the respondent may appeal to

the Commonwealth Court "if the appeal is based on allegations of certain errors of law under terms and conditions as cover appeals and actions involving State agencies under 2 PaCS 702 (relating to appeals).

RECOMMENDATION: It is recommended the House Professional Licensure Committee take no formal action until final regulations are promulgated. However, the committee submits the following comments:

1. The committee notes that 2 PaCS 702 states that, "Any person aggrieved by an adjudication of a Commonwealth agency who has a direct interest in such adjudication shall have the right to appeal therefrom to the court vested with jurisdiction of such appeals pursuant to Title 42 (relating to judiciary and judicial procedure)," which is an absolute right. The committee notes the right of appeal as set forth in Article V Section 9 of the Pennsylvania Constitution is an absolute right ("There shall be a right of appeal in all cases to a court of record from a court not of record; and there shall also be a right of appeal from a court or record or from an administrative agency to a court of record or to an appellate court, the selection of such as be provided by law..."). Consequently, the committee is concerned that the language found in Section 16.58 of the proposed regulation is too limiting and narrow in its scope. Specifically, the committee recommends that the board place a period after the words "Commonwealth Court" or delete the phrase, "if the appeal is based on allegations of certain errors of law under terms and conditions as cover appeals and actions involving State agencies..."
2. The committee recommends that a definition of "public officer" be provided. The term is found in Section 16.55.
3. The committee recommends that the word "motion" be used in proposed Section 16.57, instead of the word "notice." The word "motion" may be more appropriate in the context of the board reviewing a decision of a hearing examiner sua sponte.

House Professional Licensure Committee
May 11, 2004

LICENSURE OF A FUNERAL DIRECTOR FROM ANOTHER STATE

§ 13.77. Limited license.

(a) A person licensed by a reciprocal state to practice the profession of funeral director who seeks a limited license shall apply to the Board on a form provided by the Board, including:

(i) An original certification from the reciprocal state that the applicant is licensed as a funeral director in that jurisdiction and is in good standing.

(ii) The fee prescribed by § 13.12 (relating to fees).

(b) A limited license shall be subject to biennial renewal.

(c) A limited license shall become inactive upon the revocation, suspension, placement upon inactive status, or other lapse of the holder's license in the reciprocal state. Unless a limited license is otherwise suspended or revoked, the Board may reinstate the limited license to active status upon proof that the holder's license in the reciprocal state is no longer revoked, suspended, placed on inactive status, or otherwise lapsed.

(d) The Board may take disciplinary action against the holder of a limited license for any unprofessional conduct that occurs within this Commonwealth. The Board will report to the reciprocal state any disciplinary action taken against the holder of a limited license.

[Pa.B. Doc. No. 04-608. Filed for public inspection April 9, 2004, 9:00 a.m.]

STATE BOARD OF MEDICINE

[49 PA. CODE CH. 16]

Disciplinary Process and Procedure

The State Board of Medicine (Board) proposes to amend § 16.51 (relating to creation of list of hearing examiners) and add §§ 16.55—16.58 to read as set forth in Annex A.

A. Effective Date

The proposed rulemaking will be effective upon final-form publication 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

The proposed rulemaking will codify the process and procedures that are currently followed in disciplinary matters before the Board. These procedures are derived from sections 901—905 of the Health Care Services Malpractice Act (formerly 40 P. S. §§ 1301.901—1301.905). On March 20, 2002, the Governor signed into law the Medical Care Availability and Reduction of Error Act (MCARE Act) (40 P. S. §§ 1303.101—1303.910). Section 5104 of the MCARE Act (40 P. S. § 1303.) repealed 40 P. S. §§ 1301.901—1301.905. It is not clear what, if any, impact the repealer provisions have on the procedures followed by the Board. Because the Board's proce-

dures have been effective, the Board has determined that codifying the process will maintain the status quo and avoid unnecessary and unintended confusion.

D. Description of the Proposed Rulemaking

Section 16.51 is amended to more accurately reflect that, consistent with the Commonwealth Attorneys Act (71 P. S. §§ 732-101—732-506), attorneys, including hearing examiners, are assigned to agencies through the Office of General Counsel. The proposed rulemaking also provides for the Board's current process that, absent an order of the Board otherwise, all matters would be heard by the Board's hearing examiner.

Section 16.55 (relating to complaint process) is added to provide a description of the complaint process. Section 16.55(a) provides that a written complaint may be submitted to the complaints office. Section 16.55(b)—(d) describes the internal processing of complaints. Specifically, in keeping with the decision in *Lyness v. State Board of Medicine*, 605 A.2d 1204 (Pa. 1992), the Board prosecutor will cause to be conducted reasonable inquiry and will determine whether to initiate the filing of formal charges. Consistent with section 907 of the MCARE Act (40 P. S. § 1303.907), § 16.55(c) reiterates that documents, materials or information obtained during the course of an investigation shall be confidential and privileged unless admitted as evidence during the course of a formal disciplinary proceeding. Section 16.55(d) provides for the Board prosecutor to enter negotiations to settle the case by consent agreement.

Section 16.56 (relating to formal hearings open to public) provides for formal hearings to be open to the public.

Section 16.57 (relating to appeal from the hearing examiner's decision) provides for review of the hearing examiner's decision by the Board on the request of either party or on the Board's own motion. Section 16.57(b) provides that, unless otherwise ordered by the Board, neither the filing of an application for review nor the Board's own notice of intent to review would stay the hearing examiner's decision.

Section 16.58 (relating to appeal from the Board decision) provides for review of the Board's decision under 2 Pa.C.S. § 702 (relating to appeals).

E. Fiscal Impact and Paperwork Requirements

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

F. Sunset Date

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

G. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on March 30, 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 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 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.

H. Public Comment

Interested persons are invited to submit written comments, recommendations or objections regarding the proposed rulemaking to Joanne Troutman, Health Licensing Division, Bureau of Professional and Occupational Affairs, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication in the *Pennsylvania Bulletin*. Refer to "disciplinary procedures" when submitting comments.

CHARLES D. HUMMER, Jr., M.D.,
Chairperson

Fiscal Note: 16A-4918. 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 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

Subchapter E. MEDICAL DISCIPLINARY PROCESS AND PROCEDURES

HEARING EXAMINERS AND MEDICAL CONSULTANTS

§ 16.51. [Creation of list of hearing] Hearing examiners.

[As provided under section 902 of the Health Care Services Malpractice Act (40 P. S. § 1301.902), the Board has created a list of individuals with the approval of the Governor from which hearing examiners can be selected to serve on a part-time basis in order to hear formal hearings and render adjudications.] Hearing examiners are appointed by the Governor's Office of General Counsel to hear matters before the Board. Unless otherwise ordered by the Board, all disciplinary matters shall be heard by a hearing examiner.

§ 16.55. Complaint process.

(a) A person, firm, corporation or public officer may submit a written complaint to the complaints office alleging a violation of the act or this chapter or Chapters 17 or 18 (relating to State Board of Medicine—medical doctors; and State Board of Medicine—practitioners other than medical doctors), specifying the grounds therefore.

(b) The complaints office will assign a complaint to the prosecution and investigatory staff who, together with medical consultants as may be required, will make a determination that the complaint merits consideration. The Board prosecutor will cause to be conducted reasonable inquiry or investigation that is deemed necessary to determine the truth and validity of the allegations in the complaint. The Board prosecutor will provide reports to the Board at its regular meetings on the number, nature, procedure and handling of the complaints received.

(c) Upon review of the complaint, documentation, records and other materials obtained during the course of

an investigation, the Board prosecutor will determine whether to initiate the filing of formal charges. The documents, materials or information obtained during the course of an investigation shall be confidential and privileged unless admitted as evidence during the course of a formal disciplinary proceeding. A person who has investigated or has access to or custody of documents, materials or information which are confidential and privileged under this subsection will not be required to testify in any judicial or administrative proceeding without the written consent of the Board.

(d) The Board prosecutor may enter into negotiations at any stage of the complaint, investigation or hearing process to settle the case by consent agreement.

(1) Consent agreements must be approved as to form and legality by the Office of General Counsel and adopted by the Board.

(2) Until the Board approves a consent agreement, the terms of the agreement are confidential.

(3) Admissions made by a respondent during the course of negotiations may not be used against the respondent in any formal disciplinary proceeding if a consent agreement cannot be reached.

(4) Admissions made by a respondent in a consent agreement that is ultimately rejected by the Board may not be used against the respondent in any formal disciplinary proceeding.

(5) This subsection does not preclude the Board prosecutor from offering, at a formal disciplinary hearing, other evidence to prove factual matters disclosed during the negotiation process.

§ 16.56. Formal hearings open to public.

Formal disciplinary proceedings are open to the public. Members of the press may request in advance of the hearing permission from the presiding officer for the electronic recording of the proceedings. Upon the consideration of objections by the parties, the hearing examiner may permit the electronic recording of the proceeding by members of the press if the presiding officer determines that the recording will not interfere with the efficient conduct or impartiality and fairness of the proceedings.

§ 16.57. Appeal from the hearing examiner's decision.

(a) Unless otherwise ordered by the Board, the decision of the hearing examiner will become final after 20 days of its issuance.

(1) Upon application for review by any party or upon the Board's own notice, the Board will review the hearing examiner's decision.

(2) The Board will review the entire record and, if it deems it advisable, may hear additional testimony from persons already deposed or from new witnesses as well as arguments of counsel to make a Board decision.

(3) Additional testimony will be taken as soon as practicable.

(4) The Board will issue its final decision, along with its findings of fact and conclusions of law, which will be sent by mail to the parties involved.

(b) Unless otherwise ordered by the Board, neither the filing of an application for review nor the Board's own notice of intent to review will stay the hearing examiner's decision.

§ 16.58. Appeal from the Board decision.

The respondent may, within 30 days from the date of the decision of the Board, appeal to the Commonwealth Court if the appeal is based on allegations of certain errors of law under terms and conditions as cover appeals and actions involving State agencies under 2 Pa.C.S. § 702 (relating to appeals).

[Pa.B. Doc. No. 04-608. Filed for public inspection April 9, 2004, 9:00 a.m.]



**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

February 23, 2005

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

Re: Final Regulation
State Board of Medicine
16A-4918: Disciplinary Process and Procedure

Dear Chairman McGinley:

Enclosed is a copy of a final rulemaking package of the State Board of Medicine pertaining to Disciplinary Process and Procedure.

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, reading "Charles D. Hummer, Jr., M.D.".

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

CDH/GSS:lm

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
Gerald S. Smith, Senior Counsel in Charge
Department of State
Sabina I. Howell, Counsel
State Board of Medicine
State Board of Medicine

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

I.D. NUMBER: 16A-4918

SUBJECT: State Board of Medicine - Medical Disciplinary Process and Procedures

AGENCY: DEPARTMENT OF STATE

2399

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
2005 FEB 23 AM 10:12
REGULATORY
REVIEW COMMISSION

FILING OF REGULATION

DATE

SIGNATURE

DESIGNATION

2/23/05 *Walter Baufrogg*

HOUSE COMMITTEE ON PROFESSIONAL LICENSURE

2/23/05 *Mary Walmer*

SENATE COMMITTEE ON CONSUMER PROTECTION &
PROFESSIONAL LICENSURE

2/23/05 *Steph F. Hoff*

INDEPENDENT REGULATORY REVIEW COMMISSION

ATTORNEY GENERAL (for Final Omitted only)

LEGISLATIVE REFERENCE BUREAU (for Proposed only)

February 2, 2005