This space for use by IRRC Regulatory Analysis Form 7561 MAR 99 - AH 11: 35 (1) Agency REV. 1. 1 (4) \$12. 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 (5) Agency Contacts & Telephone Numbers Primary Contact: Gerald S. Smith, Senior Counsel in Charge, State Board of Medicine (717) 783-7200 49 Pa. Code, §§ 16.51, 16.55, 16.56, Secondary Contact: Joyce McKeever, Deputy Chief 16.57, 16.58 Counsel, Department of State (717) 783-7200 (6) Type of Rulemaking (check one) (7) Is a 120-Day Emergency Certification Attached? X Proposed Rulemaking Final Order Adopting Regulation X No Yes: By the Attorney General **Policy Statement** Yes: By the Governor (8) Briefly explain the regulation in clear and nontechnical language. The proposed regulations will codify the process and procedures that are currently followed in

The proposed regulations will codify the process and procedures that are currently 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 Section 5104 of the Mcare Act repealed these provisions of the Health Care Services Malpractice Act.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.

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(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).

(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.

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.)
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.
(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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	specific estimate ading any legal, ac					iated with
Local governi	nents will not be	affected by the	e regulation.			
(19) Provide a spimplementation or required.	pecific estimate of the regulation, in	f the costs and cluding any leg	l/or savings to s gal, accounting, o	tate governme	nt associated	with the
	ll not incur an inc	crease in admi	nistrative costs	by implement	ing the regu	lation.
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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 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 proposed amendments will not generate costs or savings.

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
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(22) Describe the nonregular Provide the reasons for their No nonregulatory alternative reasons.	atory alternatives considered at the second	onsidered and the codered.	osts associated wi	th those alternativ

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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. No public comments were received.

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.
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.

State Board of Medicine Proposed Rulemaking 16a-4918 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.

FACE SHEET FOR FILING DOCUMENTS WITH THE LEGISLATIVE REFERENCE BUREAU

2001/MAR 20 ADM: 35

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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 General

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

2399

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

(E)

(DEPUTY ATTORNEY GENERAL)

-State Board of Medicine
(AGENCY)

Executive or Independent Agencies.

OCT 3 0 2003

DOCUMENT/FISCAL NOTE NO. 16A-4918

9/30/03

DATE OF APPROVAL

DATE OF ADOPTION:

: Charles D. Hummer, Jr., No.

(Deputy General Counsel (Chief Counsel

Independent Agency Strike inapplicable title)

TITLE: Chairman (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

Objections attached.

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

PROPOSED REGULATION

COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF STATE

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

STATE BOARD OF MEDICINE

49 PA. CODE, CHAPTER ¹⁶

DISCIPLINARY PROCESS AND PROCEDURE

The State Board of Medicine (Board) proposes to amend its regulations pertaining to its disciplinary process and procedures. These amended regulations will be contained at 49 Pa. Code, Chapter 16, §§16.51, 16.55,16.56, 16.57, and 16.58 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 proposed regulations 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), Act 13 of 2002 (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.

D. Description of Amendments

Existing §16.51 (relating to hearing examiners) would be 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 would also provide 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.

Existing $\S\S16.52 - 16.54$ would not be amended by this rulemaking.

Section 16.55 would be added to provide a description of the complaint process. Subsection 16.55(a) would provide that a written complaint may be submitted to the complaints office. Subsections 16.55(b)-(d) would describe the internal processing of complaints. Specifically, in keeping with the decision in <u>Lyness v. State Board of Medicine</u>, 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), subsection 16.55(c) would reiterate 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) would provide for the Board prosecutor to enter negotiations to settle the case by Consent Agreement.

Section 16.56 would provide for formal hearings to be open to the public.

Section 16.57 would provide 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) would provide 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 would provide for review of the Board's decision under 2 Pa.C.S. § 702 (relating to appeals).

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.

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, the Act of June 30, 1989 (P.L. 73, No. 19), (71 P.S. §745.5(a)), the Board submitted a copy of this proposed regulation on March 30, 2004, 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. In addition to submitting the regulation, the Board has provided IRRC and the committees with a copy of a detailed regulatory analysis form prepared by the Board. A copy of the material is available to the

public upon request.

If IRRC has any comments, recommendations, or objections to any portion of the proposed regulation, it will notify the Board within thirty days after the expiration of the public comment period. The notification will specify the regulatory review criteria that have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the regulation, by the agency, 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 Joanne Troutman, Health Licensing Division, Bureau of Professional and Occupational Affairs, P.O. Box 2649, Harrisburg, Pennsylvania 17105-2649 within thirty (30) days following publication for the proposed regulation in the <u>Pennsylvania Bulletin</u>. Please refer to <u>disciplinary procedures</u> 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

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. All 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. No person who has investigated or has access to or custody of documents, materials or information which are confidential and privileged under this subsection shall 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. All Consent Agreements must be approved as to form and legality by the Office of General Counsel and adopted by the Board. Until such time as the Board approves a Consent Agreement, the terms of the agreement are confidential. 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. Similarly, any 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. 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. Upon application for review by any party or upon the Board's own

notice, the Board shall review the hearing examiner's decision. 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. Additional testimony

will be taken as soon as practicable. 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 shall 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).

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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

March 30, 2004

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

Re:

Proposed Regulation

State Board of Medicine

16A-4918: Disciplinary Process and Procedure

Dear Chairman McGinley:

Enclosed is a copy of a proposed 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

Charles D. Hummer, Jr., 40.D., Chairperson

State Board of Medicine

CDH/GSS:lm

Enclosure cc: Ba

Basil L. Merenda, Commissioner

Bureau of Professional and Occupational Affairs

Linda C. Barrett, 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	R: 16A-4918											
SUBJECT:	Disciplinary Process and Procedure											
AGENCY:	DEPARTMENT OF STATE # 2399											
Х	TYPE OF REGULATION Proposed Regulation											
	Final Regulation	r-3 c0 c0										
	Final Regulation with Notice of Proposed Rulemaking Omitted	3										
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	Delivery of Tolled Regulation a. With Revisions b. Without Revisions	လ တ										
	FILING OF REGULATION											
DATE	SIGNATURE DESIGNATION											
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