

Regulatory Analysis Form

This space for use by IRRC

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REVIEW SUBMISSION

(1) Agency

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

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

16A-4912

IRRC Number: *2212

(3) Short Title

Physician Delegation of Medical Services

(4) PA Code Cite

49 Pa. Code §18.401

(5) Agency Contacts & Telephone Numbers

Primary Contact: Gerald S. Smith, Counsel
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
 Final, Proposed Omitted

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

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

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

The proposed regulation would establish criteria pursuant to which a medical doctor may delegate the performance of medical services.

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

Section 17(b) of the Medical Practice Act of 1985, 63 P.S. §42217(b).

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(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No.

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

The regulation provides much sought after direction pertaining to the appropriate delegation of medical services by medical doctors.

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

Inappropriate delegation of medical services increases the risk of harm to 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.)

Patient safety is increased when medical services are performed by qualified personnel. This regulation would assist medical doctors in ascertaining whether delegation is appropriate.

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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.)

This proposed regulation would not adversely affect anyone.

(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.)

45,000 medical doctors licensed in the Commonwealth.

(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.

Pursuant to Executive Order 1996-1 public comment was solicited by persons who have identified themselves to the Board as interested in Board activity. The Board amended the draft as a result of 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 costs or savings are generated by this regulation.

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(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

No costs or savings are generated by this regulation.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting or consulting procedures which may be required.

No costs or savings are generated by this 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. N/A

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:						
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:						
Regulated						
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:						
Regulated						
Local Government						
State Government						
Total Revenue Losses						

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

N/A

Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation. N/A					
Program	FY -3	FY -2		FY -1	Current FY
(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs. N/A					
(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal. The nonregulatory alternative of publishing the guidelines informally led to requests from the regulated community for more formal guidance.					
(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal. Alternative regulation would establish procedure by procedures specialty by specialty requirements which would be overly restrictive, impossible to monitor, and cost prohibitive.					

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.

No.

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

The regulation establishes general criteria medical doctors should consider in making delegation decisions. The regulation is not restrictive and will not place Pennsylvania at a competitive disadvantage. To the contrary, the regulated community is receptive to the proposal.

Four of our bordering sister states responded to inquiries pertaining to their regulatory scheme regarding physician delegation of medical services.

Ohio indicated that they do not have specific regulations addressing the issue but rather provided guidance through policy directives which were under review and not currently available.

New York indicated that regulations were not currently in place but rather statutory provisions contained in the New York Public Health law permitted physicians to delegate.

Delaware provided a copy of the Delaware Board of Medicine Rule, Section 21, which authorizes physicians to delegate to non-physicians. Substantively, the Delaware regulation appeared similar to this proposal with some additional detail vis-a-vis patient re-evaluation, and levels of supervision.

Maryland provided a copy of a notice of proposed action (rulemaking) published December 30, 1999. The Maryland proposal, though more extensive, is not inconsistent with this proposal. However, the scope of Maryland's proposal is different from this proposed regulation. The Maryland proposal seeks to address specific medical acts which may be delegated and under what circumstances. The Pennsylvania Board has long held the position that specific procedure by procedure regulations are generally overly restrictive and impede safe and effective delivery of health care.

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

No.

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

No public hearings are scheduled.

Regulatory Analysis Form	
<p>(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.</p> <p style="padding-left: 40px;">No.</p>	
<p>(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.</p> <p style="padding-left: 40px;">N/A</p>	
<p>(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?</p> <p style="padding-left: 40px;">The regulation will become effective on final publication of form.</p>	
<p>(31) Provide the schedule for continual review of the regulation.</p> <p style="padding-left: 40px;">The Board continuously monitors the effectiveness of its regulations.</p>	

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU
(Pursuant to Commonwealth Documents Law)

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REVIEW COMMISSION

DO NOT WRITE IN THIS SPACE

#2212

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

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

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

Paul J. Doherty
BY: _____
(DEPUTY ATTORNEY GENERAL)

STATE BOARD OF MEDICINE
(AGENCY)

John V. Curran
BY: _____
(Executive or Independent Agency)

MAR 22 2001

DATE OF APPROVAL

DOCUMENT/FISCAL NOTE NO. 16A-4912

DATE OF ADOPTION: _____

2/2/01
DATE OF APPROVAL

BY: *Daniel B. Kimbrell Jr.*

DANIEL B. KIMBRELL, JR., MD

Charles D. Hummer Jr.
TITLE: CHAIRMAN
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

Charles D. Hummer, Jr., MD

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

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

ORDER OF PROPOSED RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
49 PA. CODE, CHAPTER 18
PHYSICIAN DELEGATION OF MEDICAL SERVICES

The State Board of Medicine (Board) proposes to adopt new regulations pertaining to medical doctor delegation of medical services. These new regulations will be contained at 49 Pa. Code, Chapter 18 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

Section 17(b) of the Medical Practice Act of 1985 (63 P.S. §422.17(b)) authorizes the Board to promulgate criteria pursuant to which a medical doctor may delegate the performance of medical services, preclude a medical doctor from delegating the performance of certain types of medical services, or otherwise limit the ability of a medical doctor to delegate medical services.

C. Background and Purpose

The Board routinely receives inquiries about whether particular delegations are appropriate. In order to assist medical doctors in exercising professional judgment regarding delegation, the Board published in its Summer 1997 newsletter an article which provided an analytical framework for making delegation decisions. The concepts discussed in that article were well received by the medical doctor community. However, the Board continued to receive numerous requests for regulatory guidelines pertaining to delegation. In an effort to be responsive to the regulated community, and in order to provide a framework that placed patient safety and welfare at the forefront of the medical doctor's decision making process, the Board determined to codify basic criteria pursuant to which a medical doctor may delegate the performance of medical services.

D. Description of Amendments

Section 17 of the Medical Practice Act of 1985 (63 P.S. §422.17) authorizes medical doctors to delegate the performance of medical services. Section 17 provides as follows:

(a) General rule - A medical doctor may delegate to a health care practitioner or technician the performance of a medical service if:

(1) The delegation is consistent with the standards of acceptable medical practice embraced by the medical doctor community in this Commonwealth.

(2) The delegation is not prohibited by regulations promulgated by the board.

(3) The delegation is not prohibited by statutes or regulations relating to other licensed health care practitioners.

(b) Regulations - The board may promulgate regulations which establish criteria pursuant to which a medical doctor may delegate the performance of medical services, preclude a medical doctor from delegating the performance of certain types of medical services or otherwise limit the ability of a medical doctor to delegate medical services.

(c) Responsibility - A medical doctor shall be responsible for the medical services delegated to the health care practitioner or technician in accordance with subsections (a) and (b). A medical doctor's responsibility for the medical service delegated to the health care practitioner or technician is not limited by any provisions of this section.

Against this statutory backdrop the Board proposes this rulemaking.

The proposal would add a new section to the Board's regulations at 49 Pa. Code §18.401. This section would establish general criteria pursuant to which a medical doctor may exercise professional judgment in making the decision to delegate medical services.

Section 18.401(a) would establish criteria pursuant to which delegation could occur:

Section 18.401(a)(1) would reiterate the statutory requirement found at Section 17(a)(1) of the Medical Practice Act (63 P.S. §422.17(a)(1)) that delegation be consistent with standards of acceptable medical practice. Standards of acceptable medical practice may be discerned from current medical literature and texts, medical teaching facilities publications and faculty, expert practitioners in the field and the commonly accepted practice of practitioners experienced in the field.

Section 18.401(a)(2) would reiterate Section 17(a)(3) of the Medical Practice Act (63 P.S. §422.17(a)(3)). This section would prohibit a medical doctor from expanding the scope of practice of other health care practitioners where the general assembly or the licensing board responsible for regulating the other health care practitioner has prohibited the performance of such services by the other health care practitioner. Section 18.401(a)(3) and (a)(4) would require the medical doctor to assure that the individual practitioner or technician to whom the delegation is being given has sufficient education, training, and competency such that they know how to perform the service safely. Accordingly, the medical doctor would be obligated to determine whether the delegatee is competent to perform the procedure. This may be accomplished by determining whether the delegatee is licensed, certified, or possesses documented education and training related to the service. The physician may choose to monitor the delegatee in order to become satisfied as to the delegatee's competence.

Section 18.401(a)(5) would prohibit delegations where the particular patient presents with unusual complications, family history or condition such that the performance of the medical service poses a special risk to that particular patient. Unlike the other provisions, this provision directs the medical doctor's attention to the needs of the particular patient. A determination must be made that the service may be rendered to the particular patient without undue risk. It is the physician's responsibility to make that assessment.

Section 18.401(a)(6) would recognize that patients are autonomous and that consideration of patient autonomy and dignity is a responsibility of the medical doctor. Thus, it is the medical doctor's responsibility to assure that the patient is advised as to the nature of the medical service and the reason for the delegation, such that the patient might exercise their right to request the service be performed by the medical doctor. The primary relationship in the delivery of medical services is between the patient and the physician. The person in charge of this relationship is the patient. Communication with the patient and education of the patient is essential to the proper delivery of medical services, and a primary obligation of physicians.

Section 18.401(a)(7) would direct the medical doctor to provide the level of supervision and direction appropriate to the circumstance surrounding the delivery of the medical service. It underscores the fact that the medical doctor is ultimately responsible for the patient's well being and requires the doctor to maintain the level of involvement in the treatment process as required by Section 21 of the Medical Practice Act (63 P.S. §422.21).

Section 18.401(b) would prohibit the delegation of a medical service where such service is sufficiently complicated, difficult or dangerous such that it would require a degree of education and training possessed by medical doctors, but not commonly possessed by non-medical doctors. Additionally, this section would prohibit delegation of medical services in situations where potential adverse reactions may not be readily apparent to an individual without medical doctor training. These criteria are intended to prohibit the delegation of medical services where the delegation poses undue risk to patients generally.

Section 18.401(c) would require the medical doctor to be sufficiently knowledgeable about the medical service so that the medical doctor is not merely a straw man. It should be axiomatic that the individual who has responsibility and authority for directing others in delivering medical services, has knowledge ability and competency pertaining to the performance of such services.

Section 18.401(d) would reiterate the statutory requirement contained at

Section 18.401(d) would reiterate the statutory requirement contained at Section 17(c) of the Medical Practice Act (63 P.S. §422.17(c)). It reminds the medical doctor that they retain responsibility for the performance of the service whether they perform it themselves or direct another to do so.

Section 18.401(e) would recognize the reality that emergencies arise where available health care personnel must immediately attend to patients, even though under non-emergency circumstances, the medical doctor would be the most appropriate person to care directly for the patient.

Section 18.401(f) would recognize that licensed or certified health care practitioners have scope of practice defined by statute and regulations. This proposed regulation is not intended to restrict or limit the performance of medical services that fall within the parameters established by law. Specific examples have been provided because of concerns that were expressed to the Board pertaining to those practitioners. They are provided as examples and are not intended to be all inclusive.

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. Citizens of the Commonwealth will benefit in that these regulations promote patient safety and welfare as a consideration in making medical service delegation decisions.

G. Sunset Date

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

H. Regulatory Review

Pursuant to Section 5(a) of the Regulatory Review Act, the Act of June 30, 1989 (P.L. 73, No. 19), as amended, 71 P.S. §745.5(a), the Board submitted a copy of this proposed regulation on August 24, 2001, 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 in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of the material is available to the public upon request.

If IRRC has any objections to any portion of the proposed regulation, it will notify the Board within ten days after the expiration of the Committee review period. Such notification shall specify the regulatory review criteria which have not been met by that portion. The Act specifies detailed procedures for review, prior to final publication of the regulation, by the agency, the General Assembly and the Governor of objections raised.

I. Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulation to Cindy Warner, 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 Pennsylvania Bulletin. Please cite to delegation of medical services when submitting comments.

Subchapter G. Medical Doctor Delegation of Medical Services

§18.401 Delegation

(a) A medical doctor may delegate to a health care practitioner or technician the performance of a medical service if all of the following conditions are met:

(1) The delegation must be consistent with the standards of acceptable medical practice embraced by the medical doctor community in this Commonwealth.

(2) The delegation is not prohibited by the statutes or regulations regulating the other health care practitioner.

(3) The delegatee has documented education and training to perform the medical service being delegated.

(4) The medical doctor has determined that the delegatee is competent to perform the medical service.

(5) The medical doctor has determined that the delegation to a health care practitioner or technician does not create an undue risk to that patient.

(6) The nature of the service and the delegation of the service has been explained to the patient and the patient does not object to the performance by the health care practitioner or technician.

(7) The medical doctor assumes the responsibility for evaluating and monitoring the performance of the service and is available as appropriate to the difficulty of the procedure, the skill of the delegatee and risk level to the particular patient.

(b) A medical doctor may not delegate the performance of a medical service if performance of the medical service requires medical doctor education and training or if recognition of the complications or risks associated with the delegated medical service requires medical doctor education and training.

(c) A medical doctor may not delegate a medical service which the medical doctor is not trained, qualified and competent to perform.

(d) A medical doctor shall be responsible for the medical services delegated to the health care practitioner or technician.

(e) A medical doctor may approve a standing protocol delegating medical acts to another health care provider who encounters a medical emergency that requires medical services for stabilization until

the medical doctor is able to attend to the patient.

(f) This section does not prohibit a health care provider who is licensed or certified by a Commonwealth agency from practicing within the scope of that license or certificate or as otherwise authorized by law. For example, this section is not intended to restrict the practice of certified registered nurse anesthetists, certified registered nurse practitioners, physician assistants, or other individuals practicing under the authority of specific statutes or regulations.



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 24, 2001

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

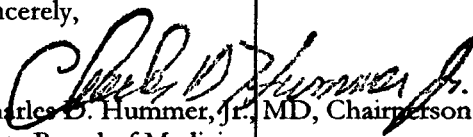
Re: Proposed Regulation
State Board of Medicine
16A-4912: Physician Delegation of Medical Services

Dear Chairman McGinley:

Enclosed is a copy of a proposed rulemaking package of the State Board of Medicine pertaining to physician delegation of medical services.

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., MD, Chairman
State Board of Medicine

CDH/GSS:kp

Enclosure

c: John T. Henderson, Jr., Chief Counsel
Department of State
Albert H. Masland, Commissioner
Bureau of Professional and Occupational Affairs
Joyce McKeever, Deputy Chief Counsel
Department of State
Christal Pike-Nase, Regulatory Counsel
Bureau of Professional and Occupational Affairs
Gerald S. Smith, Senior Counsel in Charge
Bureau of Professional and Occupational Affairs
Amy L. Nelson, Counsel
State Board of Medicine
State Board of Medicine

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

I.D. NUMBER: 16A-4912
 SUBJECT: State Board of Medicine - Physician Delegation of Medical Services
 AGENCY: DEPARTMENT OF STATE

TYPE OF REGULATION	
<input checked="" type="checkbox"/>	Proposed Regulation
<input type="checkbox"/>	Final Regulation
<input type="checkbox"/>	Final Regulation with Notice of Proposed Rulemaking Omitted
<input type="checkbox"/>	120-day Emergency Certification of the Attorney General
<input type="checkbox"/>	120-day Emergency Certification of the Governor
<input type="checkbox"/>	Delivery of Tolled Regulation
a. <input type="checkbox"/>	With Revisions
b. <input type="checkbox"/>	Without Revisions

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 INDEPENDENT REGULATORY
 REVIEW COMMISSION

FILING OF REGULATION		
DATE	SIGNATURE	DESIGNATION
8/24/01	<i>Lori A. Clark</i>	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
8/24/01	<i>Lanny Weaver</i>	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
8/24/01	<i>Elena Pagan</i>	INDEPENDENT REGULATORY REVIEW COMMISSION ATTORNEY GENERAL
8/24/01	<i>John C. ...</i>	LEGISLATIVE REFERENCE BUREAU

March 26, 2001