

Regulatory Analysis Form

REC'D
2003 DEC 16 PM 12:07
REVIEW COMMISSION

This space for use by IRRC

(1) Agency

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

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

16A-5312

IRRC Number: #2376

(3) Short Title

Osteopathic Physician Delegation of Medical Services

(4) PA Code Cite

49 Pa. Code §§25.21 and 25.217

(5) Agency Contacts & Telephone Numbers

Primary Contact: Amy L. Nelson, Counsel
State Board of Osteopathic Medicine
(717)783-7200
Secondary Contact: Joyce McKeever, Deputy Chief Counsel, Department of State
(717)78 3-7200

(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 under which an osteopathic physician may delegate the performance of medical services. These regulations mirror the regulations currently proposed by the State Board of Medicine. The State Boards of Medicine and Osteopathic Medicine anticipate coordinating the promulgation of the regulations.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.
Section 3 of the Osteopathic Medical Practice Act, (63 P.S. §271.3) permits osteopathic physicians to delegate the performance of medical services. Section 3 provides in relevant part as follows: Nothing in this act shall be construed to prohibit services and acts rendered by a qualified physician assistant, technician or other allied medical person if such services and acts are rendered under the supervision, direction or control of a licensed physician.”
Section 16 of the Osteopathic Medical Practice Act , 63 P.S. §271.16, authorizes the Board to promulgate such regulations as are necessary to carry out the purposes of the Act.

Regulatory Analysis Form

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

No.

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

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

(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 osteopathic physicians in ascertaining whether delegation is appropriate.

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.)

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.)

The approximately 6500 osteopathic physicians licensed in the Commonwealth 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.

Under Executive Order 1996-1 public comment was solicited by persons who have identified themselves to the Board as interested in Board activity. In addition, the State Board of Medicine had previously solicited comments on the initial draft of their delegation regulation. They amended their regulation pursuant to the comments. The Osteopathic Medical Board's proposed language is identical to the State Board of Medicine's amended language. Only the Pennsylvania Society of Physician Assistants commented on the Osteopathic Board's proposal. They indicated their support of the proposed regulation.

(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.

Regulatory Analysis Form

(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.

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. N/A

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	N/A	N/A	N/A	N/A	N/A	N/A
Regulated						
Local Government						
State Government						
Total Savings						
COSTS:	N/A	N/A	N/A	N/A	N/A	N/A
Regulated						
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:	N/A	N/A	N/A	N/A	N/A	N/A
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 99 - 00	FY -2 00 - 01	FY -1 01 - 02	Current FY 02 - 03
State Board of Osteopathic Medicine	405,527.84	457,338.63	503,718.72	1,172,000.00

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

There is no cost associated with this regulation. It is anticipated that patient safety will be increased when medical services are performed by qualified personnel. This regulation will assist Osteopathic physicians in ascertaining whether delegation is appropriate.

(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 procedure, 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 osteopathic physicians 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 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. However, the Board discusses its proposed regulations at monthly public meetings. A schedule of Board meeting dates is available on the Department of State's website at <http://www.dos.state.pa.us/bpoa>.

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.

(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.

N/A

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The regulation will become effective on publication as a final-form regulation.

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

The Board continuously monitors the effectiveness of its regulations.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED
2003 DEC 16 PM 12:07
REVIEW COMMISSION

#2376

DO NOT WRITE IN THIS SPACE

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

Arny M. Ethrath
BY: _____
(DEPUTY ATTORNEY GENERAL)

DEC 08 2003

DATE OF APPROVAL

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

State Board of Osteopathic Medicine
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-5312

DATE OF ADOPTION: _____

BY: *Thomas R. Czarnicki*

Thomas R. Czarnicki, D.O.

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

BY: _____
Tanya C. Gable
11/12/03
DATE OF APPROVAL

Asst.
(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 PROPOSED RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF OSTEOPATHIC MEDICINE
49 PA. CODE, CHAPTER 25
DELEGATION OF MEDICAL SERVICES

The State Board of Osteopathic Medicine (Board) proposes to amend §25.1 (relating to definitions) by adding a definition for “Emergency medical services personnel” and to amend Subchapter D – Minimum Standards of Practice by adding a new section 25.217 pertaining to osteopathic physician delegation of medical services, to read as set forth in Annex A.

A. Effective Date

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

B. Statutory Authority

Section 16 of the Osteopathic Medical Practice Act (the Act) (63 P.S. §271.16) authorizes the Board to promulgate such regulations as are necessary to carry out the purposes of the Act. Section 3 of the Act permits osteopathic physicians to delegate medical services and acts to physician assistants, technicians or other allied medical personnel if such services and acts are rendered under the supervision, direction or control of a licensed physician.

C. Background and Purpose

The Board routinely receives inquiries about whether a particular delegation of medical services is appropriate. In an effort to be responsive to the regulated community, and to provide a framework that places patient safety and welfare at the forefront of the osteopathic physician’s decision making process, the Board determined to codify basic criteria under which an osteopathic physician may delegate the performance of medical services to non-physicians.

D. Description of Proposed Regulation

Section 3 of the Osteopathic Medical Practice Act (63 P.S. §271.3) permits osteopathic physicians to delegate the performance of medical services. Section 3 provides in relevant part as follows:

“Nothing in this act shall be construed to prohibit services and acts rendered by a qualified physician assistant, technician or other allied medical person if such services and acts are rendered under the supervision, direction or control of a licensed physician.”

The proposal would add §25.217 (relating to delegation). This section would establish general criteria under which an osteopathic physician may exercise professional judgment in making the decision to delegate medical services.

Section 25.217(a) would establish the criteria under which delegation could occur.

Specifically, §25.217 (a)(1) would require 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 25.217 (a)(2) would prohibit an osteopathic physician 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 those services by the other health care practitioner. Section 25.217 (a)(3) would require the osteopathic physician to assure that the individual practitioner or technician to whom the delegation is being made has sufficient education, training, and competency so that the delegatee knows how to perform the service safely. Accordingly, the osteopathic physician 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 25.217 (a)(4) would prohibit delegations when the particular patient presents with unusual complications, family history or condition so that the performance of the medical service poses a special risk to that particular patient. Unlike the other provisions, this provision directs the osteopathic physician's attention to the needs of the particular patient. A determination shall 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 25.217 (a)(5) would recognize that patients are autonomous and that consideration of patient autonomy and dignity is a responsibility of the osteopathic physician. Thus, it is the osteopathic physician's responsibility to assure that the patient is advised as to the nature of the medical service and the reason for the delegation, so that the patient might exercise his or her right to request the service be performed by the osteopathic physician. 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 25.217(a)(6) would direct the osteopathic physician 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 osteopathic physician is ultimately responsible for the patient's well-being and requires the physician to maintain the level of involvement in the treatment process as required by Section 3 of the Osteopathic Medical Practice Act (63 P.S. §271.3).

Section 25.217 (b) would prohibit the delegation of a medical service when the service is sufficiently complicated, difficult or dangerous that it would require a degree of education and training possessed by osteopathic physicians, but not commonly possessed by non-physicians. Additionally, this section would prohibit delegation of medical services in situations when potential adverse reactions may not be readily apparent to an individual without physician training. These criteria are intended to prohibit the delegation of medical services when the delegation poses undue risk to patients generally.

Section 25.217 (c) would require the osteopathic physician to be sufficiently knowledgeable about the medical service so that the osteopathic physician 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 the knowledge, ability and competency pertaining to the performance of those services.

Section 25.217 (d) reminds osteopathic physicians that they retain responsibility for the performance of the service whether they perform it themselves or direct another to do so.

Section 25.217 (e) would recognize the reality that emergencies arise when available health care personnel must immediately attend to patients, even though under nonemergency circumstances, the osteopathic physician would be the most appropriate person to care directly for the patient.

Section 25.217 (f) would recognize that licensed or certified health care practitioners have a 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 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. Only the Pennsylvania Society of Physician Assistants provided comments to the Board. The Society indicated its support of the regulation.

F. Fiscal Impact and Paperwork Requirements

There is no adverse fiscal impact or paperwork requirement imposed on the Commonwealth, political subdivisions, or the private sector. Citizens of this Commonwealth will benefit in that this regulation promotes 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

Under Section 5(a) of the Regulatory Review Act (71 P.S. §745.5(a)), the Board submitted a copy of this proposed regulation on December 16, 2003, to the Independent Regulatory Review

Commission (IRRC), the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. In addition to submitting the proposed rulemaking, 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.

Under section 5(g) of the Regulatory Review Act (71 P.S. § 745.5(a)), if IRRC has comments, recommendations or objections regarding any portion of the proposed rulemaking, it will notify the Board approximately 30 days from the close of the public comment period. The notification will specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review of comments, recommendations and objections by the Board, the General Assembly, and the Governor prior to publication of the regulations.

I. Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulation to Amy L. Nelson, Board Counsel, P.O. Box 2649, Harrisburg, Pennsylvania 17105-2649 **within 30 days following publication of the proposed regulation in the Pennsylvania Bulletin**. Please cite to “delegation of medical services” when submitting comments.

Thomas R. Czarnecki, D.O.
Chairperson
State Board of Osteopathic Medicine

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

SUBPART A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 25. STATE BOARD OF OSTEOPATHIC MEDICINE

SUBCHAPTER A. GENERAL PROVISIONS

§ 25.1 Definitions.

* * * * *

Emergency medical services personnel – Individuals who deliver emergency medical services and who are regulated by the Department of Health under the Emergency Medical Services Act, Act of July 3, 1985, P.L. 164, as amended, 35 P.S. §§ 6921-6938.

* * * * *

SUBCHAPTER D. MINIMUM STANDARDS OF PRACTICE

* * * * *

§25.217. Delegation.

(a) An osteopathic physician may delegate to a health care practitioner or technician the performance of a medical service if the following conditions are met:

(1) The delegation is consistent with the standards of acceptable medical practice embraced by the osteopathic physician community in this Commonwealth. Standards of acceptable medical practice may be discerned from current peer reviewed medical literature and texts, teaching facility practices and instruction, the practice of expert practitioners in the field and the commonly accepted practice of practitioners in the field.

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

(3) The osteopathic physician has knowledge that the delegatee has education, training, experience and continued competency to safely perform the medical service being delegated.

(4) The osteopathic physician has determined that the delegation to a health care practitioner or technician does not create an undue risk to the particular patient being treated.

(5) 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. Unless otherwise required by law the explanation may be oral and may be given by someone other than the osteopathic physician.

(6) The osteopathic physician assumes the responsibility for the delegated medical service, including the performance of the service, and is available to the delegatee as appropriate to the difficulty of the procedure, the skill of the delegatee and risk to the particular patient.

(b) An osteopathic physician may not delegate the performance of a medical service if performance of the medical service or if recognition of the complications or risks associated with the delegated medical service requires knowledge and skill not ordinarily possessed by non-physicians.

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

(d) An osteopathic physician shall be responsible for the medical services delegated to the health care practitioner or technician.

(e) An osteopathic physician may approve a standing protocol delegating medical acts to another health care practitioner who encounters a medical emergency that requires medical services for stabilization until the osteopathic physician or emergency medical services personnel are available to attend to the patient.

(f) This section does not prohibit a health care practitioner 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, nurse midwives, 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 OSTEOPATHIC MEDICINE
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-4858

December 16, 2003

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 Osteopathic Medicine
16A-5312: Delegation of Medical Services

Dear Chairman McGinley:

Enclosed is a copy of a proposed rulemaking package of the State Board of Osteopathic Medicine pertaining to 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,

Thomas R. Czarnecki, D.O., Chairperson
State Board of Osteopathic Medicine

TRC/ALN:lm

Enclosure

c: Andrew Sislo, Chief Counsel
Department of State
Scott J. Messing, Deputy Commissioner
Bureau of Professional and Occupational Affairs
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
Amy L. Nelson, Counsel
State Board of Osteopathic Medicine
State Board of Osteopathic Medicine

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT



RECEIVED

I.D. NUMBER: 16A-5312
SUBJECT: Delegation of Medical Services
AGENCY: DEPARTMENT OF STATE

2003 DEC 16 PM 12:07

INDEPENDENT REGULATORY
REVIEW COMMISSION

TYPE OF REGULATION

- X Proposed Regulation
- Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
- a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
12/10/03	<i>Sandra J. Harper</i>	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
12/10/03	<i>Mary Walmer</i>	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
12/10/03	<i>D. Belmont</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
12/10/03	<i>C. Lee Bern</i>	LEGISLATIVE REFERENCE BUREAU (for Proposed only)

December 10, 2003