

# Regulatory Analysis Form

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REGULATORY  
REVIEW COMMISSION

(1) Agency

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

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

16A-4912

IRRC Number: 2212

(3) Short Title

Physician Delegation of Medical Services

(4) PA Code Cite

49 Pa. Code §§18.401 – 18.402

(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 regulation establishes criteria under 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. §422.17(b)).

### 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 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.**

(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 regulation would not adversely affect anyone.**

### **Regulatory Analysis Form**

(15) List the persons, groups, entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

**36,000 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.

**Under 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 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.**

(18) Provide a specific estimate of the costs and/or savings to local governments 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.**

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulations, 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
<b>SAVINGS:</b>	N/A	N/A	N/A	N/A	N/A	N/A
Regulated Community						
Local Government						
State Government						
Total Savings						
<b>COSTS:</b>	N/A	N/A	N/A	N/A	N/A	N/A
Regulated Community						
Local Government						
State Government						
Total Costs						
<b>REVENUE LOSSES:</b>	N/A	N/A	N/A	N/A	N/A	N/A
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

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

N/A

### Regulatory Analysis Form

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

Program	FY -3 1999-2000	FY -2 2000-2001	FY -1 2001-2002	Current FY 2002-2003
State Board of Medicine	\$2,562,885.01	\$2,595,622.41	\$2,884,504.70	\$6,747,000.00

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

**There should be no adverse effects and costs associated with compliance with the regulation. The benefits of the regulation are described in paragraphs 11 & 13 above.**

(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's regulation, 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.**

## Regulatory Analysis Form

(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.**

(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**

## Regulatory Analysis Form

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

**The regulation will become effective on publication of the order of final rulemaking.**

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

**The Board continuously monitors the effectiveness of its regulations.**



(3) \* \* \*

[(4)] (3) \* \* \*

(b) Incumbent local exchange telecommunications utilities with annual intraState gross revenues in excess of \$10 million shall file a financial report for the 12-month period ending each June 30 and December 31.

(c) The following public utilities shall file a financial report for the 12-month period ending each December 31:

\* \* \* \* \*

(2) [Local] Incumbent local exchange telecommunications utilities with annual intraState gross revenues in excess of \$1 million but which do not exceed \$10 million.

\* \* \* \* \*

[(c)] (d) \* \* \*

[(d)] (e) \* \* \*

[Pa.B. Doc. No. 01-1644. Filed for public inspection September 7, 2001, 9:00 a.m.]

# STATE BOARD OF MEDICINE

[49 PA. CODE CH. 18]

## Physician Delegation of Medical Services

The State Board of Medicine (Board) proposes to adopt Chapter 18, Subchapter G (relating to medical doctor delegation of medical services) to read as set forth in Annex A.

### A. Effective Date

The regulation will be effective upon publication as a final-form regulation in the *Pennsylvania Bulletin*.

### B. Statutory Authority

Section 17(b) of the Medical Practice Act of 1985 (act) (63 P.S. § 422.17(b)) authorizes the Board to promulgate criteria under 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. 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 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 under which a medical doctor may delegate the performance of medical services.

### D. Description of the Amendment

Section 17 of the act (63 P.S. § 422.17) authorizes medical doctors to delegate the performance of medical services. Section 17 of the act 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 under 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 § 18.401 (relating to delegation). This section would establish general criteria under which a medical doctor may exercise professional judgment in making the decision to delegate medical services.

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

Section 18.401(a)(1) would reiterate the statutory requirement found in section 17(a)(1) of the act that the 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 act. This section would prohibit a medical doctor from expanding the scope of practice of other health care practitioners when 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 18.401(a)(3) and (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 so 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 to become satisfied as to the delegatee's competence.

Section 18.401(a)(5) 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 medical doctor'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 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, so that the patient might exercise the 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 act (63 P. S. § 422.21).

Section 18.401(b) would prohibit the delegation of a medical service when the service is sufficiently complicated, difficult or dangerous so that it would require a degree of education and training possessed by medical doctors, but not commonly possessed by nonmedical doctors. Additionally, this section would prohibit delegation of medical services in situations when 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 when 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 the knowledge, ability and competency pertaining to the performance of those services.

Section 18.401(d) would reiterate the statutory requirement contained in section 17(c) of the act. It reminds the medical doctor that the medical director retains responsibility for the performance of the service whether the doctor performs it or directs another to do so.

Section 18.401(e) would recognize the reality that emergencies arise when available health care personnel must immediately attend to patients, even though under nonemergency 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 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.

#### 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)), on August 24, 2001, the Board submitted a copy of this proposed regulation 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 10 days after the expiration of the Committees' review period. The notification shall specify the regulatory review criteria which 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 Board, 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, PA 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.

CHARLES D. HUMMER, Jr.,  
Chairperson

Fiscal Note: 16A-4912. No fiscal impact; (8) recommends adoption.

## Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL  
STANDARDSCHAPTER 18. STATE BOARD OF  
MEDICINE—PRACTITIONERS OTHER THAN  
MEDICAL DOCTORSSubchapter G. MEDICAL DOCTOR DELEGATION  
OF MEDICAL SERVICES

Sec.

18.401. Delegation.

## § 18.401. Delegation.

(a) A medical doctor 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 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.

[Pa.B. Doc. No. 01-1645. Filed for public inspection September 7, 2001, 9:00 a.m.]

NOV-08-2001 THU 10:59 AM

FAX NO.

P. 02

*cc: Smith  
To: Gerald Smith*

JOHN R. MCGINLEY, JR., ESQ., CHAIRMAN  
ALVIN C. BUSH, VICE CHAIRMAN  
ARTHUR COCCODRILLI  
ROBERT J. HARRISON, III  
JOHN F. MITZNER, ESQ.  
ROBERT E. NYCE, EXECUTIVE DIRECTOR  
MARY S. WYATTE, CHIEF COUNSEL



PHONE (717) 783-5417  
FAX (717) 783-2664  
irrc@irrc.state.pa.us  
http://www.irrc.state.pa.us

**INDEPENDENT REGULATORY REVIEW COMMISSION**  
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

November 8, 2001

Charles D. Hummer, Jr., M.D., Chairman  
State Board of Medicine  
116 Pine Street  
Harrisburg, PA 17105

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DOS LEGAL COUNSEL



Re: Regulation #16A-4912 (IRRC #2212)  
State Board of Medicine  
Physician Delegation of Medical Services

Dear Chairman Hummer:

Enclosed are our Comments. They will soon be available on our website at [www.irrc.state.pa.us](http://www.irrc.state.pa.us).

Our Comments list objections and suggestions for consideration when you prepare the final version of this regulation. We have also specified the regulatory criteria which have not been met. These Comments are not a formal approval or disapproval of the proposed version of this regulation.

If you would like to discuss these Comments, please contact my office at 783-5417.

Sincerely,

Robert E. Nyce  
Executive Director  
wbg  
Enclosure

- cc: Honorable Mario J. Civera, Jr., Majority Chairman, House Professional Licensure Committee
- Honorable William W. Rieger, Democratic Chairman, House Professional Licensure Committee
- Honorable Clarence D. Bell, Chairman, Senate Consumer Protection & Professional Licensure Committee
- Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection & Professional Licensure Committee
- Honorable Kim Pizzingrilli, Secretary, Department of State

## Comments of the Independent Regulatory Review Commission

on

### State Board of Medicine Regulation No. 16A-4912

#### Physician Delegation of Medical Services

November 8, 2001

We submit for your consideration the following objections and recommendations regarding this regulation. Each objection or recommendation includes a reference to the criteria in the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) which have not been met. The State Board of Medicine must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered by October 9, 2003, the regulation will be deemed withdrawn.

#### 1. General. - Need.

This regulation is designed to implement Section 422.17(a) of The Medical Practice Act (Act) (63 P.S. §422.17(a)) which provides: "A medical doctor may delegate to a health care practitioner or technician the performance of a medical service" if certain conditions are met. Further, Section 422.17(b) of the Act provides: "The board may promulgate regulations which establish criteria pursuant to which a medical doctor may delegate the performance of medical services...." (Emphasis added).

However, the regulation essentially incorporates the statutory language without adding specific criteria to guide the delegation. The Board states in the Preamble that this regulation is necessary because it has received inquiries concerning delegation. We question how a regulation that reiterates a statutory provision can be responsive to any concerns or inquiries.

However, if the Board submits the final-form regulation, it should explain the need for this regulation and respond to the following concerns.

#### 2. Definitions. - Clarity.

The regulation does not define the terms "medical service," "health care practitioner" or "technician." We recommend that the Board add a new "Definitions" section to Chapter 18. This section should reference the definitions of the terms contained in the Act.

#### 3. Section 18.401. Delegation. - Clarity.

##### *Subsection (a)(1)*

This subsection states delegation must be consistent "with the standards of acceptable medical practice...." This phrase is unclear. In the Preamble, the Board explains "[S]tandards 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." This language clarifies the requirement in Subsection (a)(1). The Board should consider including the explanatory language from the Preamble in Subsection (a)(1).

*Subsection (a)(4)*

Subsection (a)(4) allows the medical doctor to delegate medical services once he has "determined that the delegatee is competent to perform the medical service." Does the Board have a set criteria to assist medical doctors in making such determinations? The Board should explain.

*Subsection (a)(5)*

This subsection allows the medical doctor to determine that the delegation "does not create an undue risk to that patient." Should the regulation require that the medical doctor's determination be documented in the patient's records?

*Subsection (a)(6)*

Subsection (a)(6) allows "[T]he nature of the service and the delegation of the service has been explained to the patient and the patient does not object...." Will it be explained to the patient that the patient has the right to object? The Board should explain what constitutes an explanation of the nature and delegation of the service sufficient to enable a patient to object in the Preamble to the final-form regulation.

*Subsection (a)(7)*

This subsection allows the medical doctor to be "available as appropriate to the difficulty of the procedure, the skill of the delegatee and risk level to the particular patient." We have two concerns with this subsection. First, it is not clear what the phrase "available as appropriate to the difficulty" means. Second, Section 422.17(c) of the Act establishes that the "medical doctor shall be responsible for the medical services delegated to the health care practitioner or technician...." We agree with the House Professional Licensure Committee's comments that Subsection (a)(7) should be amended so that it is consistent with Section 422.17(c) of the Act.

*Subsection (b)*

Subsection (b) provides that a medical doctor may not delegate a medical service if recognition of the complications or risks that may result from the service "requires medical doctor education and training." This provision would seem to unduly restrict a doctor's ability to delegate, since all medical functions carry a certain degree of risk. The phrase "technical knowledge and skill not ordinarily possessed by non-physicians" has been suggested to the Board as a replacement for the phrase "medical doctor education and training." We recommend that the new language be considered.

*Subsections (e) and (f)*

The Board refers to "health care provider" in these subsections rather than the term "health care practitioner." To be consistent throughout the regulation and with the language in the Act, the Board should change the references from "health care provider" to "health care practitioner."

MARIO J. CIVERA, JR., MEMBER  
HOUSE POST OFFICE BOX 202020  
MAIN CAPITOL BUILDING  
HARRISBURG, PENNSYLVANIA 17120-2020  
PHONE: (717) 787-3850  
FAX: (717) 705-1851

232 LONG LANE  
UPPER DARBY, PENNSYLVANIA 19082  
PHONE: (610) 352-7800  
FAX: (610) 352-3389



*House of Representatives*  
COMMONWEALTH OF PENNSYLVANIA  
HARRISBURG

COMMITTEES

PROFESSIONAL LICENSURE,  
MAJORITY CHAIRMAN  
LIQUOR CONTROL  
FIREFIGHTERS' CAUCUS,  
COCHAIRMAN EMERITUS

October 24, 2001

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OCT 29 2001

DOS LEGAL COUNSEL

John R. McGinley, Jr., Chairman  
Independent Regulatory Review Commission  
14th Floor, Harrisstown 2  
333 Market Street  
Harrisburg, PA 17101

Dear Chairman McGinley:

I am writing to inform you that the House Professional Licensure Committee held a meeting on October 23, 2001, and voted to approve Regulation 16A-644, State Board of Auctioneer Examiners; Regulation 16A-674, State Board of Occupational Therapy Education and Licensure; and Regulation 16A-5711, State Board of Veterinary Medicine.

The Committee voted to take no formal action on Regulation 16A-639, State Board of Psychology, until a final form regulation is submitted.

In addition, the Committee voted to take no formal action on Regulation 16A-4912, State Board of Medicine, until final form regulations are promulgated. However, the Committee submits the following comments:

1. The Committee requests clarification as to which non-physician health care providers the proposed regulations are directed. In explaining the provisions of proposed sections 18.401(a)(3) and (4), the Board states that a medical doctor can determine if a delegee is competent to perform a delegated procedure by determining whether or not the delegee is licensed or certified. If a health care provider is licensed or certified to perform a procedure, why would a delegation by a physician to perform the procedure be necessary?
2. The Committee requests clarification of proposed Sec. 18.401(a)(6). Who is responsible for explaining a delegation of services to a patient? Should the patient's consent or objection to the delegation be written?

John R. McGinley, Jr., Chairman  
Independent Regulatory Review Commission  
Page 2  
October 24, 2001

3. The Committee requests clarification of proposed Sec. 18.401(b). Specifically, what kinds of medical services do not require medical education and training as opposed to those that do require medical education and training?
4. The Committee questions the necessity of including Sec. 18.401(f) in the proposed regulations. Under what circumstances would regulations of the Board prohibit another licensed or certified health care provider from practicing within the scope of that license or certificate?
5. Pursuant to Sec. 17c of the Act, a medical doctor is responsible for all medical services delegated to a health care practitioner or technician. Accordingly, the Committee recommends that proposed Sec. 18.401(a)(7) be amended to read: "The medical doctor assumes the responsibility for the delegated medical services, including performance of the service, and is available to the delegatee as is appropriate based upon the difficulty of the procedure, the skill of the delegatee and risk level to the particular patient."

If you have any questions, please feel free to contact me.

Sincerely,



Mario J. Civera, Chairman  
House Professional Licensure Committee

MJC/sms  
Enclosures

cc: ✓ Charles D. Hummer, Jr., MD, Chairperson  
State Board of Medicine  
Brian V. Harpster, V.M.D., Chairperson  
State Board of Veterinary Medicine  
Alex M. Siegel, J.D., Ph.D., Chairman  
State Board of Psychology  
Ralph M. Stewart, Chairperson  
State Board of Auctioneer Examiners  
Melanie A. Wennick, Chairperson  
State Board of Occupational Therapy  
Education and Licensure  
Honorable Kim H. Pizzigrilli, Secretary of the Commonwealth  
Department of State



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Basilio J. Kalogredis  
Frederic B. Sansweet<sup>1,2</sup>  
David R. Dearden<sup>2</sup>  
Michael R. Burke<sup>1</sup>

987 Old Eagle School Road, Suite 704  
Wayne, PA 19087-1708  
(610) 687-8314  
(800) 688-8314  
Fax (610) 687-8402

Laurie Lawton-Smith, Paralegal  
Susan M Harmon<sup>1</sup>, Of Counsel

Also Member NJ Bar  
Also Member MA Bar  
LL.M. in Taxation

September 27, 2001

Cindy Warner  
Health Licensing Division  
Bureau of Professional and Occupational Affairs  
P.O. Box 2649  
Harrisburg, PA 17105-2649

Re: Delegation of Medical Services

Re: Request for Board Newsletter

Dear Ms. Warner:

I reviewed the State Board of Medicine's proposed addition to Title 49 in the September 8, 2001 Pennsylvania Bulletin, Volume 31, No. 36.

Our office has been involved in health care for many years and we represent many physicians and other professionals in the Commonwealth of Pennsylvania. Therefore, we deem ourselves to be interested persons and we have enclosed our suggestions concerning the proposed regulation.

Section 18.401(a)(1) – Even though this regulation mirrors 63 P.S. §422.17(a)(1) it suffers from the same defect. This provision is simply vague and does not give the practitioner a clear idea of what is required when delegating duties. Therefore, this regulation adds nothing to Pennsylvania law as written.

It might be helpful if the language from the explanatory comments are part of the proposed regulation. It would be helpful for practitioners to understand that the "standards of acceptable medical practice" are derived from current medical literature and texts, medical teaching facilities publications and faculty, expert practitioners in the field and commonly accepted practice of practitioners experienced in the field.

A practitioner would have greater confidence that the proposed delegation would match Pennsylvania law if the practitioner was reminded to have an expert opinion supporting the act of delegation.

Section 18.401(a)(6) - The proposed regulation seems to be inconsistent with the explanatory comments. In the explanatory comments it is suggested that both the nature and reason for the delegation need to be provided to the patient. Furthermore, the explanatory comments indicate that the patient should be able to exercise the right to request that the proposed delegated service be performed by the medical doctor. The proposed regulation only indicates that after having the nature of the service and the delegation of the service explained, the practitioner may proceed with the delegation if the patient does not object. What is not clear is whether or not the patient is to be advised by the physician that the patient has the right to object to the delegation. If the Board will require that this particular information be provided so that the patient can be fully advised of his or her rights to object to the delegation, and this is not part of the regulation, this could lead to the disciplining of physicians without fair notice to the physician of what exactly is required.

Therefore, I believe that this proposed regulation needs to be reconsidered.

As I reviewed the explanatory section of the proposed regulation I noticed that reference was made to a newsletter published by the Board in the Summer of 1997. I would like to receive a copy of that newsletter and would ask that I be added to the newsletter mailing list.

Thank you for your cooperation.

Very truly yours,

A handwritten signature in cursive script, appearing to read "David R. Dearden".

David R. Dearden

DRD/kom



# Pennsylvania MEDICAL SOCIETY®

RECEIVED

MAR 18 2002

DOS LEGAL COUNSEL

March 13, 2002

HOWARD A. RICHTER, MD  
President

EDWARD H. DENCH JR., MD  
President Elect

JITENDRA M. DESAI, MD  
Vice President

MICHAEL J. PRENDERGAST, MD  
Chair

GEORGE F. BUERGER, JR., MD  
Secretary

ROGER F. MECUM  
Executive Vice President

Richard E. Wright, MD  
Chairman  
Committee on Minimal Standards of Medical Practice  
Pennsylvania State Board of Medicine  
P.O. Box 2649  
Harrisburg, PA 17105-2649

Dear Dr. Wright:

The Pennsylvania Medical Society would like to present a few minor suggestions for the draft regulations on Medical Doctor Delegation of Medical Services as reviewed by the Medical Board during its February 26 meeting. Please understand that these suggestions are for the purpose of improving these regulations but we do not wish in any way to delay promulgation of the regulations.

In what is now (a) (5) of the draft, we appreciate the clarification that the explanation to the patient can be oral and need not be performed by the physician. We suggest that in your draft language, you substitute "...the physician or his or her designee." for "...someone other than the medical doctor." This clearly maintains the direct tie back to the physician delegating the task and does not allow anyone who is not the direct agent of the physician to participate.

We also suggest that in the preamble to these regulations, you place a statement to the effect that physicians or their designees need only indicate to the patient what procedure is being performed and who is performing it. If the patient does not object to that person's performance, the requirement has been met. The preamble could also state that if a physician were to post information or otherwise communicate to the patient indicating that he or she may delegate some medical services to other staff members, that would also meet the requirement of the regulation. One should also add a statement clarifying that this requirement only applies to medical services and not administrative services such as delegating a staff person to call the local pharmacy with a prescription.

Finally, in (c), one could add "currently" to the section so that it reads "...qualified and currently competent to perform." This would prohibit a physician from delegating a task he or she performed once or twice many years ago in residency.

Thank you very much for considering our suggestions. We hope they prove useful as the Medical Board moves forward with these regulations.

Sincerely,

Howard A. Richter, MD  
President

777 East Park Drive

P.O. Box 8820

Harrisburg, PA 17105-8820

Tel: 717-558-7750

Fax: 717-558-7840

E-Mail: stat@pamedsoc.org

www.pamedsoc.org

**Cc: Charles Hummer, Jr., MD  
Gerald Smith , Esq.  
Albert Masland  
Robert Muscalus, DO**



Pennsylvania Academy of  
FAMILY PHYSICIANS

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John S. Jordan, CAE

October 9, 2001

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

Re: Delegation of Medical Services Draft Regulations

Dear Ms. Warner:

On behalf of the over 4,800 members of the Pennsylvania Academy of Family Physicians, I write to offer several suggested modifications to the draft regulations on Physician Delegation of Medical Services as published in the Pennsylvania Bulletin. The Academy supports the need for these regulations and hopes that its suggestions will strengthen their intended purpose.

**Clarification of "Explanation"**

At the end of §(a)(6), the Academy recommends the Board add the phrase "Nothing in this section shall require the physician to obtain the patient's written informed consent as a condition to providing treatment or delegating services." This phrase would clarify any potential interpretive ambiguity, which might suggest that full informed consent must be given at the time of treatment. It is the Academy's position that the Board might exceed its constitutional authority should informed consent be the interpretation of the proposed draft regulation.

**Clarification of Education and Training**

In §(b), the Academy recommends that the Board clarify the terms "education and training." Reasonable minds offer different interpretations. For example, it is reasonable to interpret this provision to allow nothing to be delegated because everything a physician does is based on education and training. Alternatively, it could be interpreted to allow every service to be delegated that any other limited licensed practitioner may perform. Without clarification, a physician might find it difficult to appropriately delegate where areas of scopes of practice overlap.

**Deletion or Clarification of §(c)**

The Academy recommends that the Board delete or clarify specific terms in §(c). The Academy believes the terms "trained and qualified and competent" are vague and ripe for misinterpretation. Unless the Board can define these terms clearly and have some mechanism to measure compliance independently, the clause is extremely, if not unconstitutionally vague. It is a further concern of the Academy that physicians not be subject to discipline based on vague and unclear standards that cannot be objectively measured.

Thank you for the opportunity to submit these comments on behalf of the Academy. Should you have any questions or would like to discuss them further, please do not hesitate to contact me.

Sincerely,



Mark Burd, MD  
President

cc: The Honorable Clarence D. Bell – Chair, Senate Consumer Protection and Professional Licensure Committee  
The Honorable Lisa M. Boscola, Minority Chair, Senate Consumer Protection and Professional Licensure Committee  
The Honorable Mario J. Civera, Jr. – Chair, House Professional Licensure Committee  
The Honorable William W. Rieger – Minority Chair, House Professional Licensure Committee  
Wanda Filer, MD – Academy Chair, Public Policy Commission  
John S. Jordan, CAE – Academy Executive Vice-President  
Charles I. Artz, Esq. – Academy General Counsel  
Andrew J. Sandusky – Academy Director of Governmental Affairs

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HEALTH LICENSING DIVISION

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American College  
of Physicians

American Society  
of Internal Medicine

PENNSYLVANIA CHAPTER

PENNSYLVANIA COLLEGE OF INTERNAL MEDICINE

VICTORIA BUSINESS CENTER  
SUITE 230  
489 BALTIMORE PIKE  
SPRINGFIELD, PA 19064

PHONE: (800) 846-7746 • (610) 543-6880  
FAX: (610) 543-6806  
EMAIL: pcim.hq@verizon.net

October 5, 2001

Ms. Wendy Warner  
Health Licensing Division  
FAX (717)-787-7769  
Bureau of Professional and Occupational Affairs  
P O Box 2649  
Harrisburg, PA 17105-2649

Dear Ms. Warner:

RE: Proposed Rulemaking 31 Pa.B.5113,  
PHYSICIAN DELEGATION OF MEDICAL SERVICES

Dear Ms. Warner:

I am writing on behalf of the Pennsylvania College of Internal Medicine and its 5,700 member physicians. PCIM members are internists, all of whom specialize in adult medical care, and include the many subspecialties of internal medicine: allergists, cardiologists, pulmonary specialists, hematologists, endocrinologists, gastroenterologists, infection disease specialists, nephrologists, oncologists, rheumatologists and neurologists.

We welcome the opportunity to respond to Proposed Rulemaking 31 Pa.B.5113, PHYSICIAN DELEGATION OF MEDICAL SERVICES. Our members see tens of thousands of Pennsylvanians daily and fundamental changes to the practice of medicine should be carefully reviewed and evaluated before implementation.

PCIM strongly urges the Board of Medicine to clarify the language proposed in Chapter 18.401, Item (6), Annex A. We see potential for confusion with the language that states "delegation of the service has been explained..." to the patient. Such clarification should include responsibility for explanation, documentation of the

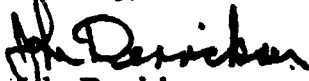
PCIM

Page 2/2

explanation, and potential review of that delegation. Our members are greatly concerned about the difficulty of understanding the full impact or value of this proposal to our patients and to appropriate health care professionals.

Again, on behalf of PCIM, thank you for the opportunity to comment on these proposed regulations.

Sincerely,



John Derrickson  
Executive Director  
PCIM

cc: Mr. John R. McGinley, Jr., Chairman, Independent Regulatory Review  
Commission

Charles D. Hummer, Jr., MD, Chairman, Board of Medicine

Ralph Schmeltz, MD, President, PCIM





THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

October 5, 2001

Cindy Warner  
Health Licensing Division  
Bureau of Professional and Occupational Affairs  
P.O. Box 2649  
Harrisburg, PA 17105-2649

**Re: Delegation of Medical Services**

Dear Ms. Warner:

On behalf of The Hospital & Healthsystem Association of Pennsylvania (HAP), which represents approximately 250 member institutions, including 125 stand-alone hospitals and another 120 hospitals that comprise 32 health systems across the state, we appreciate the opportunity to comment on the State Board of Medicine's proposed rule on delegation of medical services.

HAP's concerns reside more with implementation and interpretation of the regulation than the language as proposed. From discussions that have occurred at the State Board of Medicine meetings during the open "sunshine" portions of the meeting, it is evident that some of the board members see the delegation regulations as a step toward additional oversight requirements for certified registered nurse anesthetists (CRNA). HAP does not believe that these regulations do, or should, provide the regulatory authority for an increased oversight requirement for CRNAs or any licensed health care professional.

Specifically, the regulations address medical doctor *delegation of medical services*. Obviously, services that are within the scope of practice of a licensed health care professional do not need to be *delegated* to them since they are already *authorized* to perform the services under their practice act and regulations. Including licensed professionals in these delegation regulations makes little sense: a physician can't delegate anything to a licensed professional that is not within their scope of practice and doesn't need to delegate something licensed professionals are already authorized to do under their practice acts. Subsequently, the only persons to whom a physician could delegate a medical service are those who are by definition dependent practitioners (for example, physician assistants) or unlicensed. Therefore, HAP would recommend that modifications be made to the proposed regulations to better reflect the fact that delegation can only occur with dependent practitioners or unlicensed personnel—not those already licensed and authorized by statute and regulation to practice within the scope of their respective licenses.

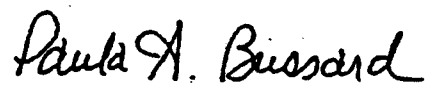


HAP

Cindy Warner  
October 5, 2001  
Page 2

Thank you for the opportunity to comment.

Sincerely,



PAULA A. BUSSARD  
Senior Vice President  
Policy and Regulatory Services

PAB/dd



## PENNSYLVANIA ASSOCIATION OF NURSE ANESTHETISTS

908 NORTH SECOND STREET • HARRISBURG, PA 17102  
(300) 495-7262 • (717) 441-6046 • FAX (717) 236-2046 • www.pana.org

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

RE: Delegation of medical services regulation

Dear Ms. Warner:

I am writing as President of the Pennsylvania Association of Nurse Anesthetists (PANA), representing 2300 Nurse Anesthetists in Pennsylvania. PANA opposes the State Board of Medicine proposed regulation entitled, "Physician Delegation of Medical Services", which was published in the Pennsylvania Bulletin September 8, 2001. Adoption of the regulation is unnecessary, unsupported by legitimate evidence, and would exceed the Board's regulatory jurisdiction. There is no public compelling interest. We request the Board withdraw the proposed regulation. However, should the Board decide to continue with the regulation, we recommend the following changes.

This proposed regulation at 49 PA code 18.401 is based on the authority granted to the State Board of Medicine by section 17(b) of the Medical Practice Act of 1985, 63 P. S. 422.17(b). **Section 17 was not intended to authorize the medical profession to roll back another health care practitioner's scope of practice under the guise of controlling what a medical doctor may delegate.** In fact, Section 20 of the Medical Practice Act, 63 P. S. 422.20, expressly provides that "*nothing in this act (including nothing in Section 17) shall be construed to prohibit a health care professional from Practicing that profession within the scope of the health care practitioner*" license or certificate or otherwise authorized by law." Significantly, Section 17 and Section 20 were enacted simultaneously. The Pennsylvania legislature grants each regulatory board the authority to establish, within the statutory definition, the rules and regulations governing a specific profession to regulate itself.

The proposed regulation deals with the parameters within which a medical doctor may "delegate" a "medical service". Treating a service performed by a health care practitioner other than a medical doctor as a "medical service" would, at least in some cases, be inconsistent with the state and regulations governing the other profession. In our example, "administration of anesthesia" is a "medical service" when performed by a medical doctor, it is a "nursing service" when it is performed by a CRNA in accordance with the Nursing Board's regulation at 49 PA Code 21:17. Section 18:401(f) implicitly recognizes the distinction by proving that the proposed regulation does not prohibit a

licensed or certified health care provider from practicing within that provider's scope of practice.


Accordingly 18.401 should be amended to make it expressly inapplicable to any "nursing service" performed within the particular nurse's scope of practice. Similarly section 18.401(a)(3) requires the delegatee to document the education and training needed to determine that the delegatee is competent to perform the medical service. **Nowhere is it spelled out what education and training or other competence the medical doctor is to deem acceptable.** This action by the State Board of Medicine will not only impose an unnecessary burden on the physicians who "delegate" but will set up a legal precedent for liability to the delegating physician simply by the process of delegation. The consumer will ultimately bear the cost, without any foreseeable benefit.

It is also possible that a lack of access could result for the most vulnerable long term patients who depend upon nurses to provide care. For instance, consider homebound diabetics, who rely on the nurse to go to their homes to monitor blood sugar and report to the patients' physician. The physician would then first have to document the education and training of another practitioner who has already passed boards, been credentialed by the institution employing the nurse, and suddenly the nurse is declared unable to function in the home setting as the State Board of Medicine works out delegation. Nursing in Pennsylvania already supports continuing competence in professional practice. This continuing competence is already assessed by the professional association, employers, insurers, credentialing bodies, providers, or continuing education and the regulatory body of the State board of Nursing. Determining the competence of a nurse, or any other non-physician health care provider, cannot be reasonably expected to be a function of a physician.

Finally, we believe that this regulation could have the intended consequence of allowing a physician to use 18.401 (a)(6) to restrict or control a delegatee's scope of practice. The language of section (f) is not exhaustive, so it leaves to the interpretation of individuals whether a practitioner who is not specifically mentioned is to be included under the category of "other individuals practicing under the authority of specific statutes or regulations." Therefore, we suggest that, in addition to, or in lieu of, the disclaimer in section (f), there be a definition of "delegation" that describes in detail exactly what delegation is, and what it IS NOT. In other words, make it clear that when a non-physician is providing a service that is within his or her scope of practice, that is not a delegation, but rather a referral, an instance of comanagement, or simply a supervised act, depending on the circumstances.

We thank you for your consideration of our comments.

Sincerely,



Joan Joyce Cahill, CRNA, MS  
President



*Leadership and Advocacy for Today's Nurses*

2578 Interstate Drive, Suite 101 ■ Harrisburg, PA 17110  
717-657-1222 ■ 1-888-707-7762 ■ Fax: 717-657-3796  
E-mail: [psna@psna.org](mailto:psna@psna.org) ■ [www.psna.org](http://www.psna.org)

October 9, 2001

Charles D. Hummer, Jr.  
Chairperson  
Pennsylvania State Board of Medicine  
PO Box 2649  
Harrisburg, PA 17105-2649

Dear Dr. Hummer:

Please consider the attached a formal statement of the Pennsylvania State Nurses Association's (PSNA) opposition to the proposed regulation concerning the Physician Delegation of Medical Services published in the *Pennsylvania Bulletin*, Volume 31, Number 36, dated September 8, 2001.

Thank you in advance for your consideration of our comments.

Sincerely,

Michele P. Campbell, MSN, RNC  
Executive Administrator

cc: Pennsylvania State Board of Nursing  
Mario J. Civera, Jr.  
Chair, Professional Licensure Committee  
Clarence D. Bell  
Chair, Consumer Protection and Professional Licensure Committee

## DELEGATION OF MEDICAL SERVICES

### COMMENTS OF THE PENNSYLVANIA STATE NURSES ASSOCIATION TO THE PROPOSED RULEMAKING OF THE STATE BOARD OF MEDICINE CONCERNING THE DELEGATION OF MEDICAL SERVICES Regulation 16A-4912

The Pennsylvania State Nurses Association submits the following comments to the Proposed Rulemaking of the State Board of Medicine concerning the Physician Delegation of Medical Services. This proposed regulation was published in the Pennsylvania Bulletin on September 8, 2001, requesting comments in thirty days, October 9, 2001.

As presently drafted the proposed regulation has the potential to inappropriately expand the scope of practice of unlicensed personnel that may be working for a medical doctor in an office or other setting, has the potential to create inconsistencies with statutes and regulations governing the practices of other health care practitioners, and has the potential to establish yet another difference between the practices of medical doctors and osteopathic physicians. All of these potential outcomes of the regulation can pose significant risks to the public. For these reasons the Pennsylvania State Nurses Association must oppose these regulations as currently drafted.

#### STATUTORY AUTHORITY

The proposed regulation states that it is based on the authority granted to the State Board of Medicine by Section 17(b) of the Medical Practice Act of 1985 (63 P.S. § 422.17(b)). However the authority of Section 17(b) must be construed consistent with Section 20 of the Act, which was enacted simultaneously with Section 17(b). Section 20 of the Medical Practice Act of 1985 (63 P.S. § 422.20) expressly provides that "[n]othing in this act shall be construed to prohibit a health care practitioner from practicing that profession within the scope of the health care practitioner's license or certificate or as otherwise authorized by the law. Thus, Section 17 was not intended to authorize the medical physician profession to limit another health care practitioner's scope of practice under the guise of controlling what a medical doctor may delegate.

The proposed regulation deals with the parameters within which a medical doctor may delegate a "medical service". Treating a service performed by a health care practitioner other than a medical doctor as a "medical service" would, at least in some instances, be inconsistent with the statutes, regulations and practices governing that other profession. For example, the administration of injections, anesthesia, chemotherapeutic agents, and the access of intravascular devices would probably be considered a "medical service" when performed by a medical doctor. However, these are "nursing services" when performed by a licensed or certificated nurse under the governance of the State Board of Nursing.

While Section 18.401 (f) of the proposed regulation could be construed to implicitly recognize the distinction by providing that the regulation does not prohibit a licensed or certified health care provider from practicing within that provider's scope of

practice, it should be made clear and explicit. For example, the proposed regulation should be amended to make it expressly inapplicable to any "nursing service" performed within the particular nurse's scope of practice.

## EDUCATION AND TRAINING

Section 18.401(a)(3) requires the delegatee to document the education and training needed to perform the medical service being delegated. Section 18.401(a)(4) requires the medical doctor to determine the competence of the delegatee to perform the medical service. Unfortunately, neither of these sections indicates the education, training, or other evidence of competence, which is to be used as the standard by which the medical doctor can make his or her determination. This lack of any standards creates several problems.

1. Since there is no definition of health care practitioner or technician and no standards for the medical doctor to determine education, training or competency, the proposed regulation appears to allow unlicensed personnel that may be working for a medical doctor in an office or other setting to provide services that are licensed activities. For example, the administration of an immunization is a very complex activity and requires knowledge regarding the location of nerves, blood vessels, anatomic landmarks, age appropriate information and considerable manual dexterity in order to do so safely. In order for a registered nurse to administer chemotherapy, he or she must have specific education related to chemotherapy administration, supervised practice and documentation of continuing competency. PSNA is concerned that the broad language of the proposed regulation would permit unlicensed professionals or even licensed professionals without the appropriate qualifications and background to access Port-a-caths or other intravenous devices to administer chemotherapeutic agents including vesicants, or other medications.
2. PSNA believes that training for unlicensed personnel in highly regulated settings, such as hospitals, is extremely variable as there are no state training requirements. It follows that the education and training of unlicensed personnel in an individual medical doctor's practice is even more subjective. If an unlicensed individual is trained to perform a specific task, this could result in medical services being performed by individuals without the broad depth of knowledge that comes with professional education and licensure and is required in order for that skill to be performed safely and to identify and treat unforeseen complications in a timely manner. It would be unrealistic to expect that the State Board of Medicine would have the capability of monitoring education and training in a great variety of settings and to be able to assure the public that medical services are being provided in a safe and competent manner.
3. If these regulations are interpreted to permit every medical doctor to inquire beyond whether a delegatee is appropriately licensed or certified,

the result could be the de facto imposition of restrictions on the delegatee's scope of practice in contradiction of Section 20 of the Medical Practice Act.

PSNA believes that a delegatee should be deemed to have "documented education and training" and is "competent" if the delegatee has a valid license or certificate issued by the delegatee's licensing state board or by a licensed health care facility.

## EXPLANATION OF DELEGATION

Section 18.401(a)(6) requires the medical doctor to explain the nature of the service to be delegated and have the patient consent to the delegation. This provision could have several unintended consequences.

1. Since the term medicine and surgery is broadly defined in Section 2 of the Medical Practice Act and since the term "medical services" is not defined at all in the proposed regulation, virtually any function performed by another health care professional could be construed as "medical service". Thus, the medical doctor could be required to explain to the patient every delegation of any service not being performed by the medical doctor and receive the patient's informed consent. It is unclear how such a requirement will increase patient safety or permit expeditious treatment to the patient.
2. A medical doctor would have the economic incentive under this provision to restrict the scope of practice of another health care professional by suggesting to the patient that the delegation could increase the risk of the procedure.

PSNA believes this provision does not further patient safety and is cumbersome at best. If the health care professional is appropriately licensed or certified, there is no apparent need for the patient's consent to the delegation. If the health care professional is not appropriately licensed or certified, a medical doctor should not be delegating the service with or without the patient's consent.

## TERMINOLOGY

PSNA believes that the references to "health care practitioners" and to "health care providers" is confusing. Are they intended to be the same? The proposed regulation should be clarified to provide consistent use of terminology.

PSNA requests, for all of the foregoing reasons, that the proposed regulations be clarified to more accurately reflect the competencies and education of other health care professionals in the interest of improving patient safety



PHENSA, Inc.

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DOS LEGAL COUNSEL

Pennsylvania Higher Education Nursing Schools Association, Inc.

3969 Green Street, Harrisburg, Pennsylvania 17110

November 15, 2001

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

Re: Delegation of Medical Services

Dear Ms. Werner:

The Pennsylvania Higher Education Nursing Schools Association (PHENSA) is the organization representing the Deans and Directors of Pennsylvania's baccalaureate and higher degree nursing education programs. PHENSA submits these comments to the State Board of Medicine in opposition to the Board's proposed regulations to permit a medical doctor to delegate a medical service.

PHENSA interprets this proposal as effectively permitting a medical doctor to delegate any act that he/she determines to be within the practice of a physician, and to delegate in such a way as to supercede practice acts of other licensed professionals. We believe that the proposal will enable medical doctors to assign unlicensed individual duties that are within the legal scope of other licensed practitioners.

Consumer health safety and welfare is at stake when unlicensed individuals undertake delegated acts for which they may not be trained nor competent to perform. The purpose of licensure is to assure that citizens receive care from individuals who have met licensure standards and are subject to formal disciplinary procedures as licensees. This proposal will place the medical doctor in a position to authorize unlicensed individuals to perform "licensed activities" and therefore compromise the delivery of safe health care.

Sincerely,

*Laurie Murray*  
Laurie Murray, DSN, RN  
President

The Insurance Federation of Pennsylvania, Inc.

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JAN 23 2002

DOS LEGAL COUNSEL

1600 Market Street  
Suite 1520  
Philadelphia, PA 19103  
Tel: (215) 665-0500 Fax: (215) 665-0540  
E-mail: mailbox@ifpenn.org

John R. Doubman  
Secretary & Counsel

January 17, 2002

Gerald S. Smith, Esq., Counsel  
State Board of Medicine  
116 Pine Street  
Harrisburg, PA 17105

Re: Delegation of Medical Services  
Regulation 16A-4912

Dear Mr. Smith:

Thank you for discussing the background of this regulation with me on January 8 and for considering these late filed comments. You indicated that you are working toward developing a final form regulation for submission to the Independent Regulatory Review Commission which must, of course, be accomplished before October 9, 2003.

The Insurance Federation on behalf of its member companies recommends that the State Board of Medicine delay filing the final form regulation until the Pennsylvania Supreme Court decides Kleinberg v. SEPTA. With the crucial issue of physical therapy services delegation in front of the Commonwealth's highest appellate tribunal, it would be unwise to go forward with a regulation without the guidance on the various practice acts which will necessarily be part of that decision.

You may be correct that the Board's proposed regulation does not favor either position on the issue involved in Kleinberg, namely, the permissibility of the delegation of physical therapy services by physicians to unlicensed personnel. However, the Board has gone since 1997 without

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Page two

the need to promulgate its informal interpretation as a regulation. Moreover, many insurers see the promulgation of this regulation now as an effort to dissuade the Court from confirming the Commonwealth Court's reading of the Physical Therapy Practice Act in Kleinberg.

The Insurance Federation has always taken the position that physical therapy services covered under an auto policy must be performed by licensed physical therapists. We think this serves the public interest in that the Motor Vehicle Financial Responsibility Law intends to ensure both quality medical services and affordable auto insurance. That statute refers to affording "licensed physical therapy" as a first party benefit and we see no reason in policy or statutory warrant why it should be interpreted as also allowing for unlicensed treatment. In general, then, when it comes to delegation, it is the Federation's view that when the General Assembly has legislated specific licensing criteria for a given discipline, the general practice laws should be interpreted to honor this intention.

Specifically as to this proposed regulation, however, the following points support the course recommended by the Federation:

#### 1. Clarity and Utility

The Independent Regulatory Review Commission in its November 8, 2001 comments views the proposed regulation as of questionable necessity and clarity. Even crediting your assertion that the regulation is neutral on physical therapy delegation, IRRC's comments are a good indication that the regulation is not a particularly useful guide. In light of the controversy surrounding the delegation issue, the promulgation of a regulation which really just restates the Act and offers no specific guidance is probably counterproductive.

At this time, it makes more sense to allow the Supreme Court the time to clarify whether the legislature in passing subspecialty licensing requirements intends to occupy the field for those rendering certain types of

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Page three

services, or, whether the way to harmonize the various practice acts is to regard those licensing requirements as effective only as to those regulated services being rendered outside the scope of traditional medical and chiropractic practices.

The usefulness of the regulation, not to mention its clarity, will be immensely improved if it can be promulgated with the Supreme Court's rationalization of these practice acts in hand.

## 2. Statutory Consistency

There is another problem which arises, other than that of necessity, when the Board drafts the regulation so close to the statutory language without adding any additional guidance. That problem is that the slightest differences in nuance are seen as crucial by those affected by the regulation, especially at a time when the issue of delegation is before the Court.

For example, although you have mirrored the language of 63 P.S. Section 422.17(a)(1) in proposed Section 18.401(a)(1), the regulation is being promulgated over ten years since when the law was passed. Consequently, the practice standards which have been embraced by the medical community have conceivably changed, particularly on this issue of delegation. The regulation will be a point of contention and less than fully useful as long as it is subject to this type of interpretation, no matter what the Board's intent.

Similarly, in Section 18.401(a)(2) the Board has varied from Section 422.17(a)(3) by referring to statutes and regulations "regulating" as opposed to "relating to" the other practitioners and omitting the qualifier "licensed" with respect to the practitioners. While Kleinberg remains undecided, those subtle differences can be interpreted as undercutting the limits on delegation which the industry supports in that case.

In summary, it appears to be a sounder approach to achieving your goal of providing meaningful guidance to

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Page four

medical providers and others to await the Court's analysis of the practice acts. At that time, if the Court upholds the Commonwealth Court in requiring that physical therapy services be performed only by licensed practitioners, the Board will want to clarify its regulation. On the other hand, if the Court reverses the Commonwealth Court, insurers will likely have no grounds for continuing to object to a regulation which sanctions the delegation of physical therapy services by physicians to unlicensed assistants as part of their medical practices.

Thank you for considering our views. Please feel free to contact us with any comments or questions.

Sincerely,



John R. Doubman

c: Charles C. Hummer, State Board of Medicine  
Kimberly T. deBien, IRRRC  
Honorable Mario J. Civera, Jr.  
Honorable William W. Rieger  
Honorable Clarence D. Bell  
Honorable Lisa M. Boscola

# Wolf, Block, Schorr and Solis-Cohen LLP

212 Locust Street  
Suite 300  
Harrisburg, PA 17101

T: 717 237 7160  
F: 717 237 7161  
www.wolfblock.com

Christine S. Dutton  
Direct Dial: 717-237-7163  
Direct Fax: 717-237-2743  
E-Mail: cdutton@WolfBlock.Com

October 8, 2001

## VIA E-Mail and HAND DELIVERY

Cindy Warner  
Health Licensing Division  
Bureau of Professional and Occupational Affairs  
P.O. Box 2649  
Harrisburg, PA 17105-2649

RE: Delegation of Medical Services

Dear Ms. Warner:

The State Board of Medicine's proposed regulations regarding physician delegation of medical services were reviewed by board members of the Pennsylvania Society of Anesthesiologists (PSA). The following comments are submitted on behalf of PSA.

PSA supports the Medical Board's efforts to provide definition and guidance in this important area of practice, which has a significant impact on patient safety and the quality of medical services provided. At the same time, they are supportive of the appropriate role of physician extenders and the benefit which they provide to patients and physicians who work with them.

PSA had previously commented upon draft delegation regulations which were circulated by the Board pursuant to Executive Order 1996-1, Section 3. PSA had also reviewed comments submitted by other interested parties at that time. PSA believes that the regulations as proposed in the September 8, 2001 Pennsylvania Bulletin do an excellent job of responding to and incorporating those comments where appropriate. Thus, PSA continues to strongly support the concepts as well as the current wording of the proposed delegation regulations.

The regulations embody provisions, particularly subsections (a)(7), (c) and (d), which are important to maintain patient safety and the high standard of medical practice in Pennsylvania. Even though some of these principles may seem obvious to many of physicians practicing

DS11:29130.1

Cindy Warner  
October 8, 2001  
Page 2

medicine on a daily basis, they apparently are not clear to some. Therefore, the Board must clearly state its position that, in order to adequately discharge his or her responsibility, a physician must be qualified to perform, and must assume responsibility for, the service delegated to a health care practitioner or technician.

One issue that did come up during PSA's review involved the issue of whether redelegation of the medical service is permitted by the proposed regulations. PSA believes that the Board may want to clarify that redelegation by the delegatee is not permissible without the medical doctor's involvement. A simple correction is suggested. In section (a)(4), change the language as follows: "The medical doctor has determined that the delegatee who performs the medical service is competent to perform the medical service."

Thank you for the opportunity to comment upon these important regulations.

Very truly yours,



Christine S. Dutton  
For WOLF, BLOCK, SCHORR and SOLIS-COHEN LLP

cc: Stephen Strelec, M.D.  
Sean Kennedy, M.D.  
Don McCoy



## **PENNSYLVANIA SOCIETY OF ANESTHESIOLOGISTS**

August 14, 1999

Daniel B. Kimball, Jr. M.D.  
Chairman  
Pennsylvania State Board of Medicine  
P. O. Box 2649  
Harrisburg, Pennsylvania 17105-2649

RE: Proposed Regulations - Physician Delegation of Medical Services

Dear Dr. Kimball:

The Pennsylvania Society of Anesthesiologists has previously commented on the details of the proposed regulations regarding Physician Delegation of Medical Services. At this time, we are pleased to be able to strongly support the concepts included in the most recent draft of these regulations that we received, dated June 24, 1999. The regulations embody provisions, particularly (a)(9), (b), and (c), which are important to maintain patient safety and the high standards of medical practice in Pennsylvania. Even though these principles may seem obvious to many of us practicing medicine on a daily basis, they are apparently still not being followed by some. Therefore, the Board must clearly state its position that, in order to adequately discharge his or her responsibility, a physician must be qualified to perform, and must assume responsibility for, any service delegated to a health care practitioner or technician.

Sincerely,

Donald E. Martin, M.D.  
Secretary/Treasurer



*Louis J. Dell' Aquila*

*Attorney at Law*

*220 Camp Meeting Road*

*Sewickley, Pa 15143*

*(412) 741-1164 • Fax: (412) 741-2561*

*E-mail: aquila@nauticom.net*

October 5, 2001

RECEIVED

OCT 15 2001

DOS LEGAL COUNSEL

Ms. Cindy Warner  
Health Licensing Division  
Bureau of Professional and Occupational Affairs  
Post Office Box 2649  
Harrisburg, PA 17105-2649

Re: Proposed Rulemaking  
State Board of Medicine  
Physician Delegation of Medical Services  
31 Pa.B. 5113  
Pa.B. Doc. No. 01-1645. Filed September 7, 2001

Dear Ms. Warner:

The proposed change in physician delegation of medical services would be a *complete disaster* for physicians, dentists, podiatrists, hospitals, ambulatory care facilities, clinics and all Pennsylvanians who utilized said professionals and/or facilities.

The proposed change would create a new legal venue and an additional basis for negligence and/or malpractice litigation simply based upon the failure or inability of a physician, dentist, podiatrist or medical facility to comply with the proposed change. It will be "open season" for attorneys to initiate legal action in many situations *where it did not previously exist*.

This proposed change in physician delegation is presented as a framework for better patient safety, welfare and to codify basic criteria. This is a gross subterfuge! This proposed change would not create new or safer facilities or procedures in the health care industry. The only effect of this proposal will be to create a new basis of additional revenue for physician-specialists, e.g. anesthesiologists (board certified or not board certified). It will increase medical costs and insurance costs which are already more than the consuming public of Pennsylvania can bear, particularly our senior citizens and those on medicare or medicad. This proposed change is another example of the many attempts of the anesthesiologists to create new turf (income) and is not based upon the improvement of health care. The proposed change has no demonstrable redeeming value!

In addition to the above, this proposed rulemaking change is in fact an attempt to create new law, which is beyond the scope of authority of the State Board of Medicine. The Board is attempting to legislate!

October 5, 2001

Equally important is the fact that this proposal utilizes the subterfuge of re-affirming the basic rule of not limiting the scope of practice of any health care practitioner. In reality, this proposed change in the regulations would create the opposite result and limit the practice of all health care practitioners. This proposal is *specifically designed by physician-specialists, e.g. anesthesiologists, to ambush, delude and deceive all healthcare practitioners and healthcare facilities* and to create new standards that will remove all existing legal safe-harbors that presently exist, solely for the purpose of creating new "turf" (money).

This regulation must not go into effect. It is illegal, unauthorized and will not improve health care in Pennsylvania. It will *only* add to insurance costs, consumer costs and increase the revenue of certain physician-specialist, e.g. anesthesiologists.

Sincerely,



Louis J. Dell'Aquila  
Legal Counsel  
Pennsylvania Association of Nurse Anesthetists

CC: Governor  
Lieutenant Governor  
Members of the State Legislature  
Department of Health  
Hospital & Healthsystem Association of Pennsylvania  
Pennsylvania Dental Association  
Pennsylvania Podiatric Medical Association  
Pennsylvania Chiropractic Association

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

RECEIVED  
2003 OCT -8 AM 10:34  
LEGISLATIVE REFERENCE BUREAU  
REVIEW COMMISSION

# 2212

DO NOT WRITE IN THIS SPACE

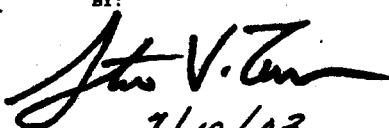
Copy below is hereby approved as to form and legality. Attorney General

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

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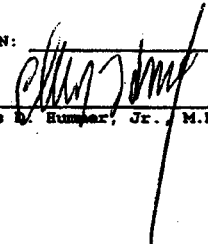
BY: \_\_\_\_\_  
(DEPUTY ATTORNEY GENERAL)

State Board of Medicine  
\_\_\_\_\_  
(AGENCY)

BY:   
7/10/03  
DATE OF APPROVAL

DOCUMENT/FISCAL NOTE NO. 16A-4912

DATE OF ADOPTION: \_\_\_\_\_

BY:   
Charles B. Humber, Jr. M.D.

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

FINAL REGULATION  
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) adopts new regulations pertaining to medical doctor delegation of medical services. These new regulations are found at 49 Pa. Code, §§18.401- 18.402 as set forth in Annex A.

**A. Effective Date**

The amendments are effective upon publication as final-form regulations in the Pennsylvania Bulletin.

**B. Statutory Authority**

Section 17(b) of the Medical Practice Act of 1985 (Act) (63 P.S. §422.17(b)) authorizes the Board to promulgate criteria under 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. 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 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 under which a medical doctor may delegate the performance of medical services.

**D. Description of Amendments**

Section 17 of the Act 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.

The amendments add §18.402 (relating to delegation). This section establishes general criteria under which a medical doctor may exercise professional judgment in making the decision to delegate medical services. In response to comments received, the Board added § 18.401 (regarding definitions). This section adds the statutory definition of Emergency Medical Services Personnel which is later referenced in § 18.402(e).

Section 18.402(a) establishes criteria under which delegation could occur as follows:

Section 18.402(a)(1) reiterates the statutory requirement found in section 17(a)(1) of the Act that the delegation be consistent with standards of acceptable medical practice. The regulation identifies examples of sources of standards of acceptable medical practice such as 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 18.402(a)(2) reiterates Section 17(a)(3) of the Act. This section prohibits a medical doctor from expanding the scope of practice of other health care practitioners when 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 18.402(a)(3) requires the medical doctor to assure that the individual practitioner or technician to whom the delegation is being given has sufficient education, training, experience and competency so that they know how to perform the service safely. Accordingly, the medical doctor is 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 to become satisfied as to the delegatee's competence.

Section 18.401(a)(4) as proposed was deleted; the requirement that the physician determine that the delegatee is competent to perform the delegated task was incorporated into section 18.402(a)(3). Renumbered 18.402(a)(4) (formerly subsection (5)) prohibits 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 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 18.402(a)(5) (formerly § 18.401(a)(6) as proposed ) recognizes 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, so that the patient might exercise the 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 18.402(a)(6) (formerly § 18.401(a)(7) in the proposed regulation) directs 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 Act.

Section 18.402(b) prohibits the delegation of a medical service when the service is sufficiently complicated, difficult or dangerous so that it would require a degree of knowledge and skill possessed by medical doctors, but not commonly possessed by non-physicians. Additionally, this section prohibits delegation of medical services in situations when 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 when the delegation poses undue risk to patients generally.

Section 18.402(c) requires 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 the knowledge, ability, and competency pertaining to the performance of those services.

Section 18.402(d) reiterates the statutory requirement contained at Section 17(c) of the Act. It reminds medical doctors that they retain responsibility for the performance of the service whether they perform it themselves or direct another to do so.

Section 18.402(e) recognizes the reality that emergencies arise when available health care personnel must immediately attend to patients, even though under nonemergency circumstances, the medical doctor would be the most appropriate person to care directly for the patient.

Section 18.402(f) recognizes that licensed or certified health care practitioners have scope of practice defined by statute and regulations. This 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 and Public Comment.**

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. Proposed rulemaking was published on September 8, 2001 at 31 Pa. B. 5113. The Board entertained public comment for a period of 30 days during which time the Board received eleven comments from individuals and organizations. 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 following is a summary of the comments and the Board's response.

IRRC submitted several comments and suggestions. IRRC expressed concern that the regulation merely restated the statutory delegation provisions and did not provide guidance beyond those. The Board disagrees with that assessment. The regulation provides a framework for practitioners to determine if delegation is appropriate. IRRC also suggested that the Board define the terms "medical service", "health care practitioner" and "technician". Because those terms are defined in the Medical Practice Act, the Board declined to restate the definitions in the regulations. IRRC also recommended that the Board clarify in subsection (a)(1) what constitutes standards of acceptable medical practice. The law firm of Kalogredis, Sansweet, Dearden and Burke also recommended that an explanation of that term be added to subsection (a)(1). The Board agreed that an explanation would be helpful, and therefore it amended the regulation to include the explanation set forth in the Preamble.

IRRC also expressed concern that subsection (a)(4) of the proposed regulation did not indicate how a doctor was to determine that a delegatee was competent to perform the delegated service. The Board agreed, and amended the regulation by deleting subsection (a)(4) and amending (a)(3) to require the doctor to have actual knowledge that the delegatee has the necessary education, training, experience and competency to safely perform the delegated task. The Board declined IRRC's suggestion that former subsection (a)(5) (now subsection (a)(4)) be amended to require the doctor to document in the patient's chart that the delegation does not present an undue risk to the patient. Many of the delegated tasks are routine medical procedures such as taking blood pressure or giving a shot. It would be burdensome to require that each delegated task be separately documented. The Board did amend former subsection (a)(6) (now subsection (a)(5)) to further clarify the manner in which the nature of the service and delegation are explained to the patient. IRRC also recommended amending former subsection (a)(7) (now subsection (a)(6)) to clarify that the physician must retain responsibility for the delegated service. The Board agreed with this suggested and amended the regulation.

The Board also accepted IRRC's recommendation that it replace the language "medical doctor education and training" in section (b) with the phrase "knowledge and skill not ordinarily possessed by non-physicians". The Board also accepted IRRC's suggestion that it use the term "health care practitioner" rather than "health care provider" in sections (e) and (f).

The HPLC questioned why delegation is necessary if a non-physician health care provider is licensed or certified to perform the delegated service. Section 17 of the Act specifically permits a doctor to delegate the performance of a medical service to a health care practitioner. A health care practitioner is defined in § 2 of the Act (63 P.S. §422.2) as an individual, other than a physician assistant, who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Commonwealth licensing agency or board. A medical service is defined in § 2 of the Act as an activity which lies within the scope of the practice of medicine and surgery. In the Board's view the legislation signifies an intent that delegation of a medical service to a licensed or certified individual is appropriate, and that the individual's license or certificate does not authorize the individual to perform medical services absent delegated authority from the physician.

The HPLC shared IRRC's concerns about the manner in which the nature of the service and delegation are explained to the patient in former subsection (a)(6) (now subsection (a)(5)). The Board added language to further clarify that subsection. The Board also amended former subsection (a)(7) (now subsection (a)(6)) to include the language suggested by the HPLC.

The HPLC asked "what kind of medical services do not require medical education and training as opposed to those that do require medical education and training." 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 services requires medical doctor education and training knowledge and skill not ordinarily possessed by non-physicians. That subsection was included to prohibit a physician from delegating those medical services which are so complicated, difficult or dangerous that they would normally require a degree of education and training possessed by physicians, but not normally possessed by non-physicians. Subsection (f) was added in response to concerns expressed by groups representing various non-physician licensed or certified health care practitioners that the proposed regulation may prohibit these licensees from performing medical services that fall within the parameters established by their licensing acts.

The Pennsylvania Medical Society wrote in favor of the regulations, but suggested that former subsection (a)(5) (now subsection (a)(4)) be amended to indicate that the individual explaining the nature and delegation of the service be the physician or the physician's designee, so that only the physician or a direct agent of the physician is responsible for this task. The Board agreed that this change clarified the lines of responsibility. The Medical Society also suggested that subsection (c) be amended to read that the physician must be trained, qualified and currently competent to perform the delegated service. The Board determined that adding the word "currently" would be superfluous, since a doctor who was not currently competent would not be considered qualified to perform the delegated service.

The Pennsylvania Academy of Family Physicians (PAFP) and the Pennsylvania College of Internal Medicine wrote to request clarification of former subsection (a)(6) (now subsection (a)(5)) regarding the manner in which the explanation of the medical service and delegation is given, as well as who will have responsibility for giving the explanation. The Board amended that language accordingly. PAFP also requested clarification of the terms "education and training" in subsection (b) of the regulation. As noted above, the Board replaced this language with the phrase "knowledge and skill not ordinarily possessed by non-physicians". PAFP also objected to the language "trained and qualified and competent" in subsection (c) of the regulation, claiming that it was too vague. The Board disagrees and believes that this subsection is consistent with existing § 16.61 (a)(3) (relating to unprofessional conduct) of the Board's regulations and provides sufficient guidance to physicians that they may not delegate medical services which they do not have sufficient knowledge, ability and competency to perform themselves.

The (Hospital and Healthsystem Association of Pennsylvania), the Pennsylvania Association of Nurse Anesthetists, the Pennsylvania State Nurses Association, and the Pennsylvania Higher Education Nursing Schools Association all expressed concern that the proposed regulations would restrict the practice of other licensed health care practitioners. The Hospital and Healthsystem Association of Pennsylvania also expressed concern that this regulation could enable doctors to delegate things to unlicensed individuals that should be done by other licensed health care practitioners. Under the Medical Practice Act, such delegation may currently occur. These regulations will give further guidance to physicians in delegating medical services to both licensed health care practitioners as well as unlicensed technicians. A private attorney, Louis J. Dell'Aquila,

wrote to oppose the regulation claiming that the regulation would create an additional basis for negligence or malpractice litigation. Obviously, there are some individuals and attorneys who will use these regulations and any others published by the Board for their own gain. However, the Board believes that these regulations will be helpful and will provide guidance to most physicians. Section (f) of the regulation specifically states that the regulation does not prohibit or restrict other licensed or certified health care practitioners from practicing within the scope of their license or certification. The Insurance Federation of Pennsylvania asked the Board to delay implementation of the regulation until the Pennsylvania Supreme Court decided Kleinberg v. SEPTA. The Board has long been of the opinion that these regulations do not favor either party's position in the Kleinberg case. Moreover, that case was decided by the Supreme Court on November 13, 2002.

The Pennsylvania Society of Anesthesiologists wrote in 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 copies of the notice of proposed rulemaking, published at 31 Pa.B. 5113, on September 8, 2001, to the IRRC, the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) and the HPLC for review and comment.

In compliance with section 5(c) of the Regulatory Review Act (71 P.S. § 745.5(c)), the Board also provided IRRC, SCP/PLC, and HPLC with copies of comments received as well as other documents. In preparing the final-form regulation, the Board has considered the comments received from IRRC, SCP/PLC, HPLC, and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), this final-form regulation was (deemed) approved by the HPLC on \_\_\_\_\_, and (deemed) approved by SCP/PLC on \_\_\_\_\_. Under section 5.1(e) of the Regulatory Review Act (71 P.S. § 745.5a(e)), IRRC met on \_\_\_\_\_, 2003, and (deemed) the final-form regulation approved.

**I. 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 gerasmith@state.pa.us.

**J. Findings**

The State Board of Medicine finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the Commonwealth Documents Law (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 amendment does not enlarge the purpose of proposed rulemaking published at 31 Pa.B. 5113.

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

**K. Order**

The State Board of Medicine, acting under its authorizing statutes, orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 18, are amended by adding §§18.401 and 18.402 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 18. STATE BOARD OF MEDICINE – PRACTITIONERS OTHER THAN  
MEDICAL DOCTORS**

**Subchapter G. Medical Doctor Delegation of Medical Services**

**§18.401. DEFINITIONS.**

THE FOLLOWING WORDS AND TERMS, WHEN USED IN THIS SUBCHAPTER, HAVE  
THE FOLLOWING MEANINGS, UNLESS THE CONTEXT CLEARLY INDICATES  
OTHERWISE:

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, 35 P.S. §§ 6921-6938.

§18.402. DELEGATION.

(a) A medical doctor 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 medical doctor 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 regulating RELATING TO the other health care practitioners.

(3) The MEDICAL DOCTOR HAS KNOWLEDGE THAT THE delegatee has documented education, and training, EXPERIENCE AND CONTINUED COMPETENCY to SAFELY

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~~ THE PARTICULAR patient BEING TREATED.

~~(6)~~ (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 THE PHYSICIAN OR THE PHYSICIAN'S DESIGNEE.

~~(7)~~ (6) The medical doctor assumes the responsibility for evaluating and monitoring 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 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  
KNOWLEDGE AND SKILL NOT ORDINARILY POSSESSED BY NON-PHYSICIANS.

(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 PRACTITIONER who encounters a medical emergency that requires medical services for stabilization until the medical doctor OR EMERGENCY MEDICAL SERVICES PERSONNEL ARE AVAILABLE is able to attend to the patient.

(f) This section does not prohibit a health care provider 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 MEDICINE**  
Post Office Box 2649  
Harrisburg, Pennsylvania 17105-2649  
(717) 783-1400

October 8, 2003

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

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

Dear Chairman McGinley:

Enclosed is a copy of a final 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,

A handwritten signature in black ink, appearing to read "Charles D. Hummer, Jr.".

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

CDH/GSS:kp

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, 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: Physician Delegation of Medical Services  
 AGENCY: DEPARTMENT OF STATE

**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  
 2003 OCT - 8 AM 10:34  
 INDEPENDENT REGULATORY  
 REVIEW COMMISSION

**FILING OF REGULATION**

DATE	SIGNATURE	DESIGNATION
10/3/03	<i>Sandra J. Harper</i>	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
10/5/03	<i>May Walmer</i>	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
10/8/03	<i>Elena Payne</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
_____	_____	ATTORNEY GENERAL (for Final Omitted only)
_____	_____	LEGISLATIVE REFERENCE BUREAU (for Proposed only)