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September 13, 2001

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Secretary

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Executive Vice President

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

Dear Ms. Warner:

We read with interest the recently published "delegation of medical services" (Title 49, Chapter 18, Subchapter G, Section 18.401) rulemaking from the State Board of Medicine. On July 30, 1999, we wrote a letter of support for an earlier version of these regulations. I am reiterating our very strong support in this letter.

The Society is very pleased to note that this version keeps intact (c) clarifying that one cannot delegate what one is not trained, qualified and competent to perform. We believe that this is a critical element within these regulations and strongly encourage the Medical Board to keep it intact in the final version.

Sincerely,

Carol E. Rose, MD
President

777 East Park Drive

P.O. Box 8820

Harrisburg, PA 17105-8820

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Fax: 717-558-7840

E-Mail: stat@pamedsoc.org

www.pamedsoc.org

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Pennsylvania MEDICAL SOCIETY®

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REVIEW DIVISION

September 13, 2001

CAROL E. ROSE, MD
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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-1400

October 16, 2001

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

Re: Public Comment: Proposed Rulemaking (16A-4912)
State Board of Medicine
Delegation of Medical Services

Dear Chairman McGinley:

Pursuant to Section 5(b.1) of the Regulatory Review Act (71 P.S. §845/5(b.1)), enclosed is a copy of written comments received by the State Board of Medicine regarding Regulation 16A-4912.

Sincerely,

A handwritten signature in cursive script that reads "Charles D. Hummer, Jr.".

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

CDH/ALN/lam

Enclosure

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

Louis J. Dell' Aquila

Attorney at Law

220 Camp Meeting Road

Sewickley, PA 15143

(412) 741-1164 • Fax: (412) 741-2561

E-mail: aquila@naulicom.net

October 5, 2001

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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!

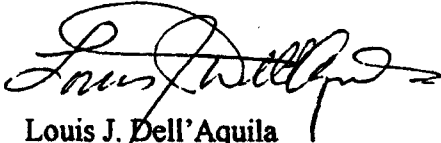
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Equally important is the fact that this proposal utilizes the subterfuge of re-affirming the basic rule of not limiting the scope of practice of any health care practitioner. In reality, this proposed change in the regulations would create the opposite 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 & Heathsystem Association of Pennsylvania
Pennsylvania Dental Association
Pennsylvania Podiatric Medical Association
Pennsylvania Chiropractic Association

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The Insurance Federation of Pennsylvania, Inc.

**1600 Market Street
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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, IRRC
Honorable Mario J. Civera, Jr.
Honorable William W. Rieger
Honorable Clarence D. Bell
Honorable Lisa M. Boscola



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FAX

Cindy Warner

TO: *c/o Joanne Troutman*
787-7769

FROM: *Michelle P. Campbell*
Executive Administrator

PAGES: 5, including cover sheet

RE: Comments of PSNA

Comments: *Formal statement - proposed regulation re: the*
Physician Delegation of Medical Services

Please confirm receipt of this fax.

Thank you,

Fraz Manning
ext 205

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PENNSYLVANIA STATE NURSES ASSOCIATION
REVIEW COMMISSION

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



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THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

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REGULATORY REVIEW COMMISSION

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.

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Cindy Warner
October 5, 2001
Page 2

Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in black ink that reads 'Paula A. Bussard'.

PAULA A. BUSSARD
Senior Vice President
Policy and Regulatory Services

PAB/dd



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PENNSYLVANIA ASSOCIATION OF NURSE ANESTHETISTS

908 NORTH SECOND STREET • HARRISBURG, PA 17102
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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

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

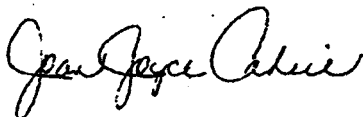
Accordingly 18.401 should be amended to make it expressly inapplicable to any "nursing service" performed within the particular nurse's scope of practice. Similarly section 18.401(a)(3) requires the delegatee to document the education and training needed to determine that the delegatee is competent to 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,

A handwritten signature in cursive script that reads "Joan Joyce Cahill".

Joan Joyce Cahill, CRNA, MS
President

Original: 2212

Louis J. Dell' Aquila

Attorney at Law
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October 8, 2001

Ms. Cindy Warner
Health Licensing Division
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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

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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 medicaid. 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!

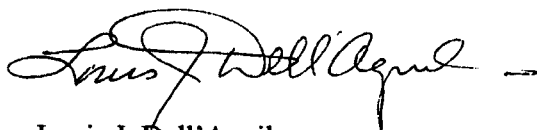
In addition to the above, this proposed rulemaking change is in fact an attempt to create new law, which is beyond the scope of authority of the State Board of Medicine. The Board is attempting to legislate!

October 9, 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
Independent Regulatory Review Commission
Hospital & Heathsystem Association of Pennsylvania
Pennsylvania Dental Association
Pennsylvania Podiatric Medical Association
Pennsylvania Chiropractic Association



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Pennsylvania Academy of
FAMILY PHYSICIANS

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PROFESSIONAL REGULATORY
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October 9, 2001

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Harrisburg, PA 17105-2649

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Philadelphia

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Erie

Re: Delegation of Medical Services Draft Regulations

Executive Vice President

John S. Jordan, CAE

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.

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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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THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

Original: 2212

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.

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P.O. Box 8600
Harrisburg, PA 17105-8600
717.564.9200 Phone
717.561.5334 Fax
haponline.org



Cindy Warner
October 5, 2001
Page 2

Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in black ink that reads "Paula A. Bussard". The signature is written in a cursive style.

PAULA A. BUSSARD
Senior Vice President
Policy and Regulatory Services

PAB/dd



THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

4750 Lindle Road
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F A X T R A N S M I S S I O N

3 page(s), including cover sheet

TO: *Kim deBiem, 9me*

FAX: *783-2664*

FROM: *Retsy Taylor*

DATE: *10-8-01*

SUBJECT:

MESSAGE:



Original: 2212

Wolf, Block, Schorr and Solis-Cohen LLP

212 Locust Street
Suite 300
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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

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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



American College
of Physicians

American Society
of Internal Medicine

Original: 2212

PENNSYLVANIA CHAPTER

PENNSYLVANIA COLLEGE OF INTERNAL MEDICINE

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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

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HARRISBURG, PA

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.

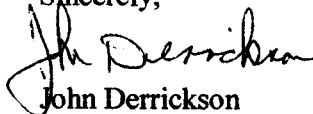
PCIM strongly urges the Board of Medicine to clarify the language proposed in Chapter 18.401, Item (6), Annex A. We see potential for confusion with the language that states "delegation of the service has been explained..." to the patient. Such clarification should include responsibility for explanation,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



American College
of Physicians

Original: 2212

American Society
of Internal Medicine

PENNSYLVANIA CHAPTER

PENNSYLVANIA COLLEGE OF INTERNAL MEDICINE

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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:

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HEALTH LICENSING DIVISION

PCIM
Page 2/2

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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

Original: 2212

KALOGREDIS, SANSWEET, DEARDEN AND BURKE, LTD.

Vasilios J. Kalogredis
Jeffrey B. Sansweet^{1,3}
David R. Dearden²
Michael R. Burke¹

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

Laurie Lawton-Smith, Paralegal
Susan M Harmon¹, Of Counsel

1 Also Member NJ Bar
2 Also Member MA Bar
3 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.

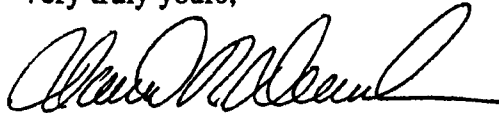
Section 18.401(a)(6) - The proposed regulation seems to be inconsistent with the explanatory comments. In the explanatory comments it is suggested that both the nature and reason for the delegation need to be provided to the patient. Furthermore, the explanatory comments indicate that the patient should 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

Original: 2212



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 2, 2001

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

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

Dear Chairman McGinley:

Pursuant to Section 5(b.1) of the Regulatory Review Act (71 P.S. §845/5(b.1)), enclosed is a copy of a written comment received by the State Board of Medicine regarding Regulation 16A-4912.

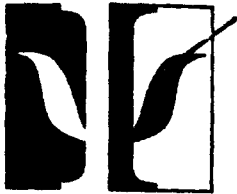
Sincerely,
Handwritten signature of Charles D. Hummer, Jr. in cursive script.

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

CDH/GSS/kp
Enclosure

c: Christal Pike-Nase, Regulatory Counsel
Department of State

Joanne Trounman, Board Administrator
State Board of Medicine



*An affiliate of the
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Association*

PENNSYLVANIA PSYCHOLOGICAL ASSOCIATION

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September 18, 2001

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Samuel J. Knapp, Ed.D.

Government Relations Consultant

Susan M. Shanaman, J.D.

Website

www.PaPsy.org

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

RE: Delegation of Medical Services

Dear Ms. Warner:

On behalf of the Pennsylvania Psychological Association, I am responding to the proposed regulation published in the Pennsylvania Bulletin on September 8, 2001.

We believe that the regulation should be modified so it is explicit that the proposed regulation does not contradict Section 2152, 8 (c) of Act 68 of 1998 which reads "Utilization review that results in a denial of payment for a health care service shall be made by a licensed physician, except as provided in subsection (d)."

Sincerely,

Samuel Knapp, Ed.D.

Director of Professional Affairs

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