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IRRC

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From: Fran Manning [fmanning@psna.org]
Sent: Wednesday, November 19, 2003 10:32 AM
To: IRRC
Subject: Formal Statement - Physician Delegation of Medical Services
Importance: High

2003 NOV 19 AM 10:53

INDEPENDENT REGULATORY
REVIEW COMMISSION

For your information attached is a copy of a letter sent to Chairperson Charles Hummer of the PA State Board of Medicine .

Fran Manning
Executive Assistant
1-888-707-7762, Ext. 205
Pennsylvania State Nurses Association
fmanning@psna.org

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INDEPENDENT PROFESSIONAL
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

IRRC #2212
State Board of Medicine #16A-4912
Physician Delegation of Medical Services

(Form A)

NAME	ADDRESS	DATE of CORRESPONDENCE
David J. Caragun	3328 Waltham Ave Pittsburgh, PA 15216	November 12, 2003
Christopher A. Miller, RN,BSN, SRNA	404 Suncrest Drive Cranberry Twp, PA 16066	November 12, 2003
Paul L. (unreadable)	1826 (unreadable) Pittsburgh, PA	November 12, 2003
Kelly Cannon, RN, BSN,SENA	1040 Portland Street Pittsburgh, PA 15206	November 12, 2003
Lynn Macksey	806 Glenshaw Avenue Glenshaw, PA 15116	November 12, 2003
Meghan A. Connelly	379 Hulton Road Oakmont, PA 15139	November 12, 2003
Richard Bauer	248 Marshall Road Pittsburgh, PA 15295	November 12, 2003
Daniel Anlt, RN, BSN	5759 Howe Street Pittsburgh, PA 15232	November 12, 2003
Kelly L. Wil	418 South Atlantic Ave., Apt 4 Pittsburgh, PA 15224	November 12, 2003
Shelby Boyce, RN,BSN,SRNA	111 Hoy Street Rices Landing, PA 15357	November 12, 2003
Melissa Kiberto, RN,BSN,SRNA	6349 Walnut Street #100 Pittsburgh, PA 15206	November 12, 2003
Erica Pools	132 Alberta Ave Jphnstown, PA 15905	November 12, 2003
Tina Bowser	1030 Hillgate Place, Apt 1A Pittsburgh, PA 15220	November 12, 2003
Michael Tests	245 Melwood Ave, #205 Pittsburgh, PA 15213	November 12, 2003
Patti Krulman	1040 Fayette New Wilmington Road New Wilmington, PA 16142	November 12, 2003
Jamie Volkman	8455 Edward Road Pittsburgh, PA 15237	November 12, 2003
Beth White	959 Highview Road Pittsburgh, PA 15234	November 12, 2003

April Hanber	1023 Center Ave Butler, PA 16001	November 12, 2003
Eva Pet(unreadable)	614 Bear Willow Road Duncanville, PA 16675	November 12, 2003
John Clark	160 Bass Run Drive Pittsburgh, PA 15237	November 12, 2003
Frank Watson	1102 Dallas Ave Natrona Heights, PA 15065	November 12, 2003
Deanne Alko	7168 Baplisi Road, Apt 212 Bethel Park, PA 15102	November 12, 2003
Lisa Adams1	5523 Ellsworth, Apt 8C Pittsburgh, PA 15232	November 12, 2003
Scott Pearson	1721 Fern Ave Windber, PA 15963	November 12, 2003
Cara Malcolli	Oak Hill Road Pittsburgh, PA 15213	November 12, 2003
Rita Machi	2229 Rochester Road Pittsburgh, PA 15237	November 12, 2003
Chad Antman	5030 Center Ave, Apt A56 Pittsburgh, PA 15213	November 12, 2003
Pamela Gill	205 Bear Creek Road Prospect, PA 16052	November 12, 2003
Brent Dunworth	2344 Nicholson Rod Sewickley, PA 15143	November 13, 2003
Sandy Sell	3816 Wolf Way – Box 7527 Pittsburgh, PA 15213	November 13, 2003
John O'Donnell	No address	November 13, 2003
Lisa Scott	61 East West Drive Pittsburgh, PA 15237	November 13, 2003

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333 Market St, 14th Floor
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Fax: (717) 783-2664
www.irrc.state.pa.us

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2003 NOV 12 PM 3:20
INDEPENDENT PROFESSIONAL
REVIEW COMMISSION

Honorable Commission Members,

I am a professional nurse and a graduate student studying anesthesia at the University of Pittsburgh and I am opposed to the final form 16A-4912: Physician Delegation of Services.

My concerns include the following points:

- These regulations are unnecessary, do not improve care, lack clarity, promote delegation of expert services to unlicensed practitioners, and lack any rational basis as to feasibility or reasonableness that would urge their implementation.
- Any new regulation should appropriately address a known or stated problem. It is unclear what consumer or citizens group in the Commonwealth of Pennsylvania has requested or is in need of these particular regulations.
- The Board of Medicine has not produced any evidence "explaining the need for the regulation" and I am extremely concerned that this regulation is part of a national political agenda to introduce anesthesia assistants (AAs) into every state. This legislation opens the door to these unlicensed providers in our state because the term 'technician' is used in the regulation. It appears that a technician can be any unlicensed person to whom a physician chooses to delegate- regardless of whether they have appropriate training or certification.
- The regulation is injurious to most health care providers and to consumers who would see increased costs and decreased care quality.

Sincerely,

David J Caragine RN, BSN, SNAHA
3328 Waltham Ave
Pgh, PA 15216

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IRRC
333 Market St, 14th Floor
Harrisburg, PA 17101

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2003 NOV 17 AM 9:33
MEDICAL MALPRACTICE
REVIEW COMMISSION

Honorable Commission Members,

My name is Brent Hughlen Suddeth. I am a professional nurse and a graduate student studying anesthesia at the University of Pittsburgh and I am **opposed** to the final form 16A-4912: Physician Delegation of Services.

My concerns include the following points:

- These regulations are unnecessary, do not improve care, lack clarity, promote delegation of expert services to unlicensed practitioners, and lack any rational basis as to feasibility or reasonableness that would urge their implementation.
- Any new regulation should appropriately address a known or stated problem. It is unclear what consumer or citizens group in the Commonwealth of Pennsylvania has requested or is in need of these particular regulations.
- The Board of Medicine has not produced any evidence “explaining the need for the regulation” and I am extremely concerned that this regulation is part of a national political agenda to introduce anesthesia assistants (AAs) into every state. This legislation opens the door to these unlicensed providers in our state because the term ‘technician’ is used in the regulation. It appears that a technician can be any unlicensed person to whom a physician chooses to delegate—regardless of whether they have appropriate training or certification.
- The regulation is injurious to most health care providers and to consumers who would see increased costs and decreased care quality.

Should you have any questions or if I may be of assistance to you in any way, don't hesitate to contact me at MFSuddeth@aol.com. My address is:

5609 Elmer Street #303
Pittsburgh, PA 15232

Sincerely,

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IRRC
333 Market Street
14th Floor
Harrisburg, Pa. 17101

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2003 NOV 17 AM 9:34

PROFESSIONAL REGULATORY
REVIEW COMMISSION

Mr Dennis P Smith
30 Eastfield Dr
Lebanon PA 17042-8014



To Whom It May Concern:

The Pennsylvania Association of Nurse Anesthetists emphatically opposes the final form of 16A-4912: Physician Delegation of Medical Services.

We believe the intent of global delegation to all nurses remains the same intent as prior attempts to delegate to nurse anesthetists, which was so heavily opposed by all other organizations except the Pennsylvania Society of Anesthesiologists and the Pennsylvania Medical Society. We believe the actual intent of this regulation is to allow certain physicians to unilaterally restrict another licensee's ability to practice. We believe that the motive behind these attempts has always been, and continues to be increased financial rewards for certain physicians. This expanded regulation now has the intent to restrict the practice of many different licensed professionals.

One of our objections to this regulation is that it does not define the specifics of delegation. For example, anesthesia, when provided by certified registered nurse anesthetists (CRNA's), is clearly not delegation, but an appropriate licensed professional activity. And although 18.402.6f cites specifically the example of CRNAs, and states that it does not prohibit a practitioner licensed or certified by this commonwealth from practicing within the scope of that license, the intent of making delegation an issue is to place services not previously delegated come under physician supervision.

Furthermore, it sets the precedent for the next step, which will conceivably be that anesthesia services should only be delegated by anesthesiologists to the exclusion of collaborative arrangements with other licensed practitioners, such as dentists, podiatrists, surgeons, gastroenterologists, and cardiologists.

This delegation rule would place new burdens on the health care system in the Commonwealth by:

placing certain aspects of care under delegation of persons in many cases less qualified by experience and training than the persons to whom they are delegating;

making the system less efficient; rather than care being provided in a timely fashion or even simultaneously by experts, each providing that aspect of care that they are best able to give, care would be funneled through a limited number of delegators; because of the complexity of care being given, there is no way for these few delegators to be expert and available at all times and for all aspects of care; therefore, their delegation is nominal and potentially obstructive;

- a) providing the framework for placing services currently provided by independent licensed practitioners under delegation; it attempts to broaden responsibilities for medical doctors;

- b) assuming that a medical doctor is always the most appropriate or best person to perform all patient interventions (procedures, education, assessment) when there is no basis for this assumption in tradition or current practice;
- c) creating new physician responsibilities, it creates new billable services and consequently higher costs to the citizenry;
- d) in the current legal environment, physicians are already leaving the state because of increased medical malpractice costs; this regulation would create an additional source of potential exposure for malpractice claims through the simple process of delegating or not delegating a specific service; the result will be that many physicians will be asked to meet delegation requirements that they may or may not have been aware of, and may or may not be comfortable implementing; furthermore, the regulatory analysis does not address what percentage of physicians must be certified by their specialty boards nor does it define what level of training and experience would be necessary for delegation in specific circumstances.
- e) creating new physician responsibilities, it creates new billable services and consequently greater costs to the citizens of the Commonwealth.
- f) in the current legal environment physicians are already leaving the state because of increased medical malpractice costs. This regulation would create an additional source of potential exposure for malpractice claims through the simple process of delegating or not delegating a specific service. The result will be that many physicians will be asked to meet delegation requirements that they may or may not have been aware of and may or may not be comfortable implementing. Further, the regulatory analysis does *not* address what percentage of physicians must be certified by their specialty boards nor does it define what level of training and experience would be necessary for delegation in specific circumstances.

It is my belief as a member of the Pennsylvania Association of Nurse Anesthetists that this document is being driven by individuals who have one primary concern: protecting the income of physicians.

In contrast to what has been stated, there will be a significant fiscal impact. These regulations will create billing criteria for the simplest of tasks where now none currently exists. Further, they will generate increased paperwork and leave unanswered the question as to who would delegate to whom and under what specific circumstances. All that is necessary to understand and appreciate the impact of this regulation is to reference the problems with prescriptive authority that Nurse Practitioners continue to face.

Another intent of the proposed delegation rule may be to provide a door through which to bring a new and unqualified anesthesia provider (Anesthesia Assistants, or AAs) to the State of Pennsylvania. As proposed, this regulation would expand the scope of physician delegation of medical services in the Commonwealth to include licensed and unlicensed technicians/healthcare practitioners, even AAs. The American Association of Anesthesiologists (ASA) has publically advocated the use of AAs and this regulation is simply a means to carry out that openly expressed political mission.

In summary, regulations should appropriately address a known or stated problem. It is unclear what consumer or citizen group in this Commonwealth has requested or is in need of these particular regulations, and in what context the request was ever made. These regulations are unnecessary, do not improve health care, lack clarity, promote delegation of expert services to unlicensed practitioners, and lack any rational basis as to feasibility or reasonableness that would demand their implementation. These proposed regulations would have a significant, negative impact on hospitals by bringing unnecessary and overly restrictive delegation practices, during a time when many facilities are struggling to maintain their bottom line.

Sincerely,

A handwritten signature in black ink that reads "Dennis P. Smith CRNA, BSN". The signature is written in a cursive style.

Dennis P. Smith, CRNA, BSN

Good Samaritan Hospital, Lebanon, Pa. 17042

Original: 2212

IRRC
333 Market St, 14th Floor
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INDEPENDENT REGULATORY
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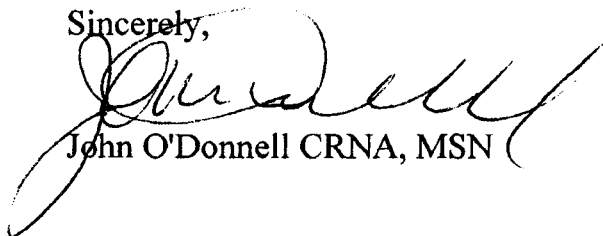
Honorable Commission Members,

I am a professional nurse and a CRNA teaching anesthesia at the University of Pittsburgh and I am **opposed** to the final form 16A-4912: Physician Delegation of Services.

My concerns include the following points:

- These regulations appear to be unnecessary, do not improve care, lack clarity, promote delegation of expert services to unlicensed practitioners, and lack any rational basis as to feasibility or reasonableness that would urge their implementation.
- *Any* new regulation should appropriately address a known or stated problem. It is unclear what consumer or citizens group in the Commonwealth of Pennsylvania has requested or is in need of these particular regulations.
- The Board of Medicine has not produced any evidence “explaining the need for the regulation” and I am extremely concerned that this regulation is part of a national political agenda to introduce anesthesia assistants (AAs) into our state. This legislation opens the door to these unlicensed providers in our state because the term ‘technician’ is used in the regulation. It appears that a technician can be any unlicensed person to whom a physician chooses to delegate—regardless of whether they have appropriate training or certification.
- The regulation is injurious to most health care providers and to consumers who would see increased costs and decreased care quality.

Sincerely,



John O'Donnell CRNA, MSN

Original: 2212

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INDEPENDENT HEALTH CARE
REVIEW COMMISSION

5810 Howe Street
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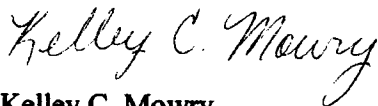
Dear Honorable Commission Members,

I am a professional nurse and a graduate student studying anesthesia at the University of Pittsburgh and I am strongly **opposed** to the final form 16A-4912: Physician Delegation of Services.

My concerns include the following points:

- These regulations are unnecessary, do not improve care, lack clarity, promote delegation of expert services to unlicensed practitioners, and lack any rational basis as to feasibility or reasonableness that would urge their implementation.
- Any new regulation should appropriately address a known or stated problem. It is unclear what consumer or citizens group in the Commonwealth of Pennsylvania has requested or is in need of these particular regulations.
- The Board of Medicine has not produced any evidence "explaining the need for the regulation" and I am extremely concerned that this regulation is part of a national political agenda to introduce anesthesia assistants (AAs) into every state. This legislation opens the door to these unlicensed providers in our state because the term 'technician' is used in the regulation. It appears that a technician can be any unlicensed person to whom a physician chooses to delegate- regardless of whether they have appropriate training or certification.
- The regulation is injurious to most health care providers and to consumers who would see increased costs and decreased care quality.
- Nowhere is the term delegation defined, and the draft also provides the delegating physician would have the knowledge that the delegate has "education, training, experience, and continued competency to perform the delegated service". This is very vague and provides insufficient restriction on unregulated providers.

Sincerely,



Kelley C. Mowry
RN, BSN, SRNA

Original; 2212

November 16, 2003

IRRC
333 Market Street 14th Floor
Harrisburg, PA 17101

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2003 NOV 18 AM 7: 10

INDEPENDENT REGULATORY
REVIEW COMMISSION

Dear Committee Members,

I am writing to urge your opposition to the proposed Regulation #16A-4912, which I feel will jeopardize patient safety, increase medical costs and potentially allow one group of specialists to impose their will on others.

Here are some specific points that have caused me to feel so very strongly that this proposed legislation is a major step in the wrong direction:

- 1) **There is no need for this proposed regulatory scheme.** The law requires a compelling reason why regulations should be adopted. Given the fact that the regulations will alter the status quo and that no legitimate reasons have been offered for the change, it violates IRRC law [71 P.S., Section 745.5 (b)(3)(iii)].
- 2) **The final form regulation substantially "enlarges the scope" beyond the proposed regulation.** Thus, approving the regulation, as now proposed, would violate state law Commonwealth Documents Law, 45 P.S. 1202.
- 3) **The regulation is injurious to most health care providers and to consumers** who would see increased costs and decreased care quality.
- 4) **The regulation DOES NOT define the specifics of delegation.** For example, anesthesia when provided by Certified Registered Nurse Anesthetists is clearly not delegation but an appropriate licensed professional activity. Furthermore, the suggested "delegation" sets the precedent for the next step which will allow anesthesia services to be delegated only by anesthesiologists. This will preclude current collaborative arrangements with practitioners such as dentists, podiatrists, surgeons, gastroenterologists, and cardiologists. It may also open the door to "delegation" to anesthesia providers with less the desirable credentials.
- 5) **The regulation will likely be used by one group of specialists to impose its will on others.** Despite language seemingly protecting the "scope of practice" of these other groups, the regulation can and will allow one group to achieve the control over others that they have failed to achieve by legislation. Essentially, this regulation allows them to achieve a legislative goal by administrative fiat. In this regard, a regulation should not, and may not, "legislate", yet that is precisely what this single regulatory Board is attempting to do, and if permitted to do so, it will upset the carefully planned balance of responsibilities and interrelationships between healthcare practitioners which the General Assembly has already addressed. [IRRC Legislation, 71 P.S. 745.5(b)(a), and 745.5(b)(3) (ii)]
- 6) **The language of the regulation DOES NOT protect nurse anesthetists from encroachment into their profession.** Yes, section 6 (f) of the proposed

regulation contains language that "this section is not intended to restrict the practices of certified registered nurse anesthetists..." Note, however, that this language is considerably different than stating clearly that: "This section shall not in any way restrict the practices of certified registered nurse anesthetists." The language is inadequate and unacceptable.

I strongly urge that you and the other members of the House Professional Licensure Committee oppose this regulation when you meet this coming Monday morning.

Thomas Cholycki
SWYNNECLIFFE Drive
Carnegie Pa 15106

David J Caragani
3328 Waltham Ave
Pgh, PA 15216

Nene A. Mellone
939 Mt. Fern Ave
Pgh. PA 15221

Rick Noderer, Jr.
3155 ANNAPOLIS AVE
Pgh Pa 15216

Sincerely Yours,
Kathleen Mason CRNA
1211 Vivizon Dr.
W. Homestead, Pa 15120

Cacilie McGowan CRNA
1515 Illinois Ave
Pgh PA 15214

Paul D'haag CRNA
179 Roberts Dr
Merhall Pa 15120

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Email: psna@psna.org
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EMBARGOED MATERIAL

November 17, 2003

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 final form regulation concerning the Physician Delegation of Medical Services. These comments will be re-iterating what had been stated back in October 2001 as only the area of confusion related to the terms health care practitioner and health care providers was addressed to our satisfaction.

Thank you in advance for your consideration of our comments.

Sincerely,

Michele P. Campbell, MSN, RNC
Executive Administrator

cc: Pennsylvania State Board of Nursing
Thomas Gaonon
Chair, Professional Licensure Committee
Robert Torilinson
Chair, Consumer Protection and Professional Licensure Committee

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INDEPENDENT PROFESSIONAL
REVIEW COMMISSION

DELEGATION OF MEDICAL SERVICES

COMMENTS OF THE PENNSYLVANIA STATE NURSES ASSOCIATION TO THE FINAL FORM REGULATIONS CONCERNING THE DELEGATION OF MEDICAL SERVICES Regulation 16A-4912

The Pennsylvania State Nurses Association submits the following comments to the Final Form Regulations of the State Board of Medicine concerning the Physician Delegation of Medical Services. The regulations have 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.

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Delegation of Medical Services
Page 2

EDUCATION AND TRAINING

Section 13.402(a)(3) requires the Medical Doctor to have knowledge that the delegate has education experience and continued competency to safely perform the medical service being delegated. Unfortunately, the section does not indicate 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 are no standards for the medical doctor to determine education, training or competency, the 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.

Delegation of Medical Services

Page 3

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 13.401(a)(5) 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.

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.

Original: 2212

RECEIVED

2003 NOV 14 AM 9:36

Teresa L. Salamon CRNA, JD
50 Allyssa Drive
Media, PA 19063
610-566-6694
cmail-tesala@aol.com

RECEIVED
REVIEW COMMISSION

IRRC
333 Market Street
14th Floor
Harrisburg, PA 17101

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

Mr. Gannon: *FRAC*

Please be aware that I am opposed to the adoption of the above proposed regulation for two reasons. First, delegation is unnecessary when the non-physician health care provider is already licensed and or certified to perform the delegated services. Second, the language is vague and ambiguous.

The Regulation is unnecessary.

This was correctly pointed out by the House Professional Licensure Committee in 1996 when the State Board of Medicine submitted its first draft and remains true today despite the Board's attempts to justify the reasoning. The Board offers no compelling reason to adopt this regulation except that Section 17 allows it. This is more likely the Board's attempt to enhance the physician's scope of practice to allow him/her to bring in an unlicensed group of anesthesia assistants and delegate duties already performed by highly qualified CRNAs in an attempt to protect the physicians' economic welfare while decreasing the delivery of quality care.

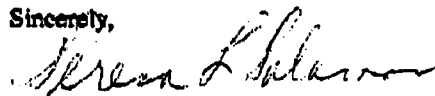
The language is vague and ambiguous.

The language in the regulation, particularly §18.402(a)(6) can be construed to restrict the practice of health care providers, particularly Certified Registered Nurse Anesthetists ("CRNAs") while facilitating an unlicensed group to provide health services under the guise that the physician is exercising his legal right to delegate. By eliminating the phrase "evaluating and monitoring", the provision allows the medical doctor to *assume responsibility for performing the delegated service*. Thus, the regulation could be interpreted to eliminate CRNAs from independent practice in settings where the anesthetist is the sole provider of anesthesia services. CRNAs practice independent from a physician anesthesiologist, under 49 Pa. Code §21.17 when "the registered nurse anesthetist [has] available to her by physical presence or electronic communication an anesthesiologist or consulting physician of her choice. Additionally, the proposed regulation can easily be construed to restrict certain nursing providers and therefore is

in direct conflict with Section 6(f) of the regulation, which states that "it is not intended to restrict" those very same providers. This alone is reason to reject the regulation.

In summary, this proposal submitted by the Board is outside the scope of the Board's regulatory authority and should be rejected. Any changes concerning licensure and practice is a function of the legislature and the Board delegated by them to regulate those health care providers. Any attempt to regulate beyond that can only be viewed as unreasonable and unnecessary encroachment. Thank you for your consideration in this important matter.

Sincerely,



Teresa L. Salamon

Original: 2212

MAYOR ROSS ROHBECK
405 Clinton Avenue Extension
Oakdale, PA 15071
(724) 693-8382

RECEIVED
2003 NOV 18 AM 8:59
INDEPENDENT LABORATORY
REVIEW COMMISSION

November 14, 2003

IRRC
333 Market Street
Harrisburg, PA 17101

Honorable Sir,

I am Ross Rohbeck, Mayor of Oakdale Borough,. I am writing to let you know that I am opposed to the final form of 16A-4912: Physician Delegation of Services.

There has been no known or stated problem published pertaining to the need for this regulation. The Board of Medicine has not produced any evidence explaining the need for this regulation.

This legislation opens the door to unlicensed persons in the state because of the term technician. It would seem that technician can be any unlicensed, certified, or other person in Pennsylvania that a physician chooses to delegate. (The ASA has well documented its campaign to include Anesthesiologist assistants in every state.)

This system would be less efficient, producing more paperwork, confusion, and creating new billable services increasing the escalating cost of health care to the financial gain of a certain few.

These are only a few of the ramifications of this unnecessary legislation. I am hoping that your will support my point of view.

Sincerely,



Mayor Ross Rohbeck

RR/mds



Original: 2212

Pennsylvania Academy of
FAMILY PHYSICIANS

RECEIVED

2003 NOV 17 AM 9:33

INDEPENDENT REGULATORY
REVIEW COMMISSION

President

Wanda D. Filer, MD
York

November 14, 2003

President-Elect

Timothy M. Heilmann, MD
Williamsport

John R. McGinley, Jr., Esq., Chairman
Pennsylvania Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, Pennsylvania 17101

Treasurer

Jane A. Corson, MD
Palmyra

Dear Chairman McGinley:

Immediate Past President

Paul D. Williams, DO
Harrisburg

On behalf of the over 4,800 members of the Pennsylvania Academy of Family Physicians (PAFP), I write in support of final-form regulations submitted by the State Board of Medicine in regards to "Physician Delegation of Medical Services," titled 16A-4912.

Executive Vice President

John S. Jordan, CAE
Harrisburg

Throughout this several year process, the PAFP has participated and commented on the numerous draft forms of these regulations. The PAFP believes that these final-form regulations represent and provide a needed regulatory framework for our members to follow when they are delegating medical services. The PAFP asks for your support and approval.

Should you have questions or concerns regarding this correspondence, please do not hesitate to contact me at (717) 699-2991.

Sincerely,

Wanda D. Filer, MD
President

cc: Chairs, Senate Consumer Protection and Professional Licensure Committee
Chairs, House Professional Licensure Committee

Original: 2212

IRRC

From: Bob Ehle [bobehle@epix.net]
Sent: Friday, November 14, 2003 1:52 PM
To: IRRC
Subject: *OPPOSE* State Board of Medicine Regulation 16A-4912

November 14, 2003

ATTN: IRRC

I am writing to make you aware that I emphatically ***OPPOSE*** **State Board of Medicine Regulation 16A-4912: Physician Delegation of Medical Services**. I see this as nothing more than last year's HB-823, in disguise.

As a licensed and independently practicing Certified Registered Nurse Anesthetist (CRNA) in the Commonwealth since 1986 and employer of 20 CRNAs and Anesthesiologists, it is obvious to me this regulation is simply an attempt by the Pennsylvania Society of Anesthesiologists (PSA) to achieve the type of supervision that they sought legislatively last year. Furthermore, it oversteps the bounds of one health care provider group at the expense of all others – including CRNAs. It also will result in increased health care costs for consumers and provide a back door way to delegate services to under-qualified entities (in the case of anesthesia, these are “Anesthesia Assistants”) – thereby seriously jeopardizing patient safety. There are a myriad of other reasons why it would be a terrible injustice to impose this Regulation, however I will not go into all of those reasons at this time.

Please feel free, however, to contact me at my office for any further discussion at 610.395.4044 x17.

Thank you very much for your attention to this very important matter.

Sincerely,

ROBERT W. EHLE, CRNA
President
Lehigh Anesthesia Associates, PC
5000 Tilghman St., Suite 240
Allentown, PA 18104-9110
610.395.4044 x17 phone
610.395.5693 fax

PROCESSED
2003 NOV 14 PM 2:06
INDEPENDENT BOARD OF
REVIEW COMMISSION

11/14/2003

Original: 2212

RECEIVED
2003 NOV 14 AM 7:05
INDEPENDENT PROFESSIONAL
REVIEW COMMISSION

IRRC
333 Market Street
14th Floor
Harrisburg, PA 17101

11/13/03

Dear IRRC Representative:

I am opposed to 16A-4912: Physician Delegation of Services. As a Registered Nurse practicing in Pennsylvania, I am already appalled by the lack of supervision afforded Medical Assistants working in physician's offices. Unfortunately, I feel that medical tasks being performed by insufficiently trained personnel is already endangering the residents of our Commonwealth, and I feel 16A-4912 will only worsen this scenario. Please oppose this regulation change until further information could be collected and a better understanding of the ramifications on the public would be understood.

Thank you,



Ann K. Savidge, RN
192 Wilcox Drive
New Cumberland, PA 17070

Original: 2212

RECEIVED

2003 NOV 14 AM 7:05

REVIEW COMMISSION

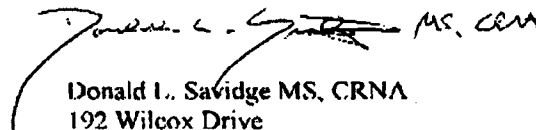
IRRC
333 Market Street
14th Floor
Harrisburg, PA 17101

11/13/03

Dear IRRC Representative:

I am opposed to 16A-4912: Physician Delegation of Services. As a Registered Nurse practicing in Pennsylvania, I am already appalled by the lack of supervision afforded Medical Assistants working in physician's offices. Unfortunately, I feel that medical tasks being performed by insufficiently trained personnel is already endangering the residents of our Commonwealth, and I feel 16A-4912 will only worsen this scenario. Please oppose this regulation change until further information could be collected and a better understanding of the ramifications on the public would be understood.

Thank you,



Donald L. Savidge MS, CRNA
192 Wilcox Drive
New Cumberland, PA 17070

To Whom This May Concern, ^{Nov. 13th}

This letter is written to request your opposition to regulation (16A-4912) as it is another attempt to limit my ability to practice as a nurse anesthetist (CRNA). A very similar type of legislation (HB 823) was defeated last year, this action should be supported by rejection of regulation (16A-4912).

This proposed legislation opposes independent practice by CRNA's requiring supervision by anesthesiologists. Though I currently practice in a setting of teamwork with

anesthetists and anesthesiologists, there are many places where CRNA's practice safely and effectively in conjunction with surgeons, dentists, or podiatrists. Anesthesiologists want this legislation to limit the practice of anesthetists who can function independently so they can allow unlicensed anesthesia assistants (AA's) to practice with them.

They (AA's) are unable to practice anesthesia on their own. CRNA's provided anesthetics before anesthesiologists were even a specialty of medicine. This

legislation would not improve current services making the system more burdensome and costly.

Your consideration would be greatly appreciated in opposing regulation (16A-4912) so that I may continue to provide safe, compassionate, cost-effective anesthesia care to my patients as I have for the last twelve years.

Most Sincerely,
Jewell A. Sargent
Jewell A. Sargent
CRNA

RECEIVED

2003 NOV 18 AM 8:57

PROFESSIONAL REVIEW COMMISSION

J.A.S.
208 Erie St
Johnstown PA
15905

Original: 2212

IRRC

From: Bradley Wheeler [bradw@stargate.net]
Sent: Thursday, November 13, 2003 4:34 PM
To: IRRC
Subject: 16A-4912

RECEIVED
2003 NOV 14 AM 7:32
INDEPENDENT PROFESSIONAL SOCIETY
REVIEW COMMISSION

Dear Sir/Madam,

I am writing to you regarding 16A-4912: Physician Delegation of Medical Services. As a Nurse Anesthetist I am opposed to this regulation. The Board of Medicine has not provided any data supporting the need for these regulations. This would restrict the practice of all advance practice nurses. The rule does not define who the physician can delegate to and uses the vague term technician. It provides the framework for placing services currently provided by independent licensed practitioners under delegation. In the current legal environment physicians are already leaving the state because of increased medical malpractice costs. This regulation would create an additional source of potential exposure for malpractice claims through the simple process of delegating or not delegating a specific service. In summary this regulation provides no service to the healthcare consumers of our state and can only increase costs and decrease accessibility to quality health care in our state.

Thank you
Brad Wheeler CRNA

11/14/2003

Original: #2212

3816 Wolf Way – Box 7527
Pittsburgh, PA 15213
November 12, 2003

IRRC
333 Market St, 14th Floor
Harrisburg, PA 17101
Phone: (717) 783-5417
Fax: (717) 783-2664
www.irrc.state.pa.us

RECEIVED

2003 NOV 17 AM 9:34

INDUSTRY REGULATORY
REVIEW COMMISSION

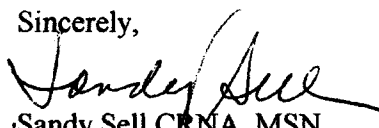
Honorable Commission Members,

I am a professional nurse and a CRNA who teaches anesthesia to nurses enrolled in the Graduate School of Nursing at the University of Pittsburgh. I am writing in **opposition** to the final form 16A-4912: Physician Delegation of Services.

The following issues are my main concerns regarding this legislation:

- These regulations seem to be unnecessary, will not result in improving health care, lack clarity, promote delegation of expert services to unlicensed practitioners, and lack any rational basis as to feasibility or reasonableness that would urge their implementation.
- These regulations do not address a known or stated problem; therefore I ask, who or what interest group in the Commonwealth of Pennsylvania has requested this regulatory change and how will they benefit from it?
- The Board of Medicine has not produced any evidence “explaining the need for the regulation” and I am extremely concerned that this regulation is part of a national political agenda to introduce anesthesia assistants (AAs) into our state. This legislation opens the door to these unlicensed providers in our state because the term ‘technician’ is used in the regulation. It appears that a technician can be any unlicensed person to whom a physician chooses to delegate- regardless of whether they have received appropriate training or certification.
- Finally, this regulation will increase health care costs and decrease quality of care to the members of the Commonwealth, and in addition, will negatively impact most health care providers in the state.

Sincerely,


Sandy Sell CRNA, MSN
sandy.sell@verizon.net

Original: 2212

RECEIVED

2003 NOV 18 AM 8:59

INDIVIDUALS AND PROFESSIONALS
REVIEW COMMISSION

November 13, 2003
245 Spa Lane
Port Matilda, PA.
16870

IRRC
333 Market St
14th Floor
Harrisburg, PA 17101

Dear IRRC:

I am writing to you as a certified registered nurse anesthetist of Pennsylvania residency. Thank you for your support in opposing the final form 16A-4912 Physicians Delegation of Services.

The State Board of Medicine as well as the Pennsylvania Society of Anesthesiologists have historically been trying to control the practice of nurse anesthetists. The actual intent of this regulation 16A-4912 is to allow certain physicians to unilaterally restrict another licensee's ability to practice. The motive for these attempts have always been increased financial rewards for certain physicians. The expanded regulation now has the intent to restrict practice of many different licensed professionals. The intent of making delegation an issue is to place services not previously delegated under physician supervision.

This sets the precedent for the next step which will be that anesthesia services should only be delegated by anesthesiologists to the exclusion of collaborative arrangements with other licensed practitioners such as dentists, podiatrists, surgeons, gastro enterologists and cardiologists. Currently I work in hospitals as a nurse anesthetist as well as giving anesthesia

in an office setting for Mrs. Collins and Hancey, oral surgeons in State College, PA. If this regulation were passed, it would require an anesthesiologist to work with me at this office, creating duplication of services at an increase cost to the patient and for their insurance company. Under my scope of practice, I do not need an anesthesiologist to administer anesthesia in their office. If this regulation passes, it would require duplication of service or more likely the elimination of the CRNA service. This creates new physician responsibilities and creates new-billable services and greater costs to the citizens of Pennsylvania.

Another intent of the proposed delegation rule is to provide a door through which to bring new and unqualified anesthesia providers (Anesthesia Assistants, AA's) to the State of Pennsylvania. As proposed, this regulation would expand the scope of physician delegation of medical services in the Commonwealth to include licensed and unlicensed health care practitioners and even unlicensed technicians such as AA's. The American Society of Anesthesiologists (ASA) has publicly advocated the use of AA's and this regulation is simply a means to carry out their openly expressed political mission.

What consumer or citizen group in Pennsylvania has requested or is in need of these particular regulations? These regulations are unnecessary, do not improve care, lack clarity, promote delegation of expert services to unlicensed practitioners and lack any rational basis as to feasibility or reasonableness that would urge their implementation. There is not a need for this regulation. The Board of Medicine ~~is~~ has not produced any evidence to date supporting the need for regulation. This is being prepared to line the pockets of physicians.

I request your opposition of final form
16 A - 4912 Physician Delegation of Services

Thank-you,
Cheryl Baluk, CRNA
valukwoman@aol.com
814-692-7935

Original: 2212

Frances M. McAuley CRNA
415 Jayson Avenue
Pittsburgh, PA 15228
412-531-3684

November 12, 2003

IRRC
333 Market Street
14th Floor
Harrisburg, Pennsylvania 17101

To Whom It May Concern:

RECEIVED

2003 NOV 18 AM 9:01

INDEPENDENT REGULATORY
REVIEW COMMISSION

The Pennsylvania Association of Nurse Anesthetists emphatically opposes the final form of 16A-4912: Physician Delegation of Medical Services.

We believe the intent of global delegation to all nurses remains the same intent as prior attempts to delegate to nurse anesthetists, which was so heavily opposed by all organizations other than the Pennsylvania Society of Anesthesiologists and the Pennsylvania Medical Society. We believe that the actual intent of this regulation is to allow certain physicians to unilaterally restrict another licensee's ability to practice. We believe that the motive behind these attempts has always been, and continues to be increased financial rewards for certain physicians. The expanded regulation now has the intent to restrict practice of many different licensed professionals.

One objection to this regulation is that it *does not* define the specifics of delegation. For example anesthesia when provided by certified registered nurse anesthetists (CRNA's) is clearly not delegation, but an appropriate licensed professional activity. And, although 18.402.6f cites specifically the example of CRNA's, and states that it does not prohibit a practitioner licensed or certified by this Commonwealth from practicing within the scope of that license, the intent of making delegation an issue is to place services not previously delegated under physician supervision.

Furthermore, it sets the precedent for the next step which will be that anesthesia services should only be delegated by anesthesiologists to the exclusion of collaborative arrangements with other licensed practitioners such as dentists, podiatrists, surgeons, gastroenterologists, and cardiologists.

This delegation rule would place new burdens on the health care system in the Commonwealth by:

- a) Placing certain aspects of care under delegation of persons in many cases less qualified by experience and training, than the persons to whom they are delegating.
- b) Making the system less efficient. Rather than care being provided in a timely fashion or even simultaneously by experts, each providing that aspect of care that they are best able to give, care would be funneled through a limited number of delegators. Because of the complexity of care being given, there is no way for these few delegators to be expert and available at all times and for all aspects of care. Therefore, their delegation is nominal and potentially obstructive.
- c) Providing the framework for placing services currently provided by independent licensed practitioners under delegation. It attempts to broaden responsibilities for medical doctors.
- d) Assuming that a medical doctor is always the most appropriate or best person to perform all patient interventions (procedures, education, assessment) when there is no basis for this assumption in tradition or current practice.
- e) Creating new physician responsibilities, it creates new billable services and consequently greater costs to the citizens of the Commonwealth.
- f) In the current legal environment physicians are already leaving the state because of increased medical malpractice costs. This regulation would create an additional source of potential exposure for malpractice claims through the simple process of delegating or not delegating a specific service. The result will be that many physicians will be asked to meet delegation requirements that they may or may not have been aware of and may or may not be comfortable implementing. Further, the regulatory analysis does not address what percentage of physicians must be certified by their specialty boards nor does it define what level of training and experience would be necessary for delegation in specific circumstances.

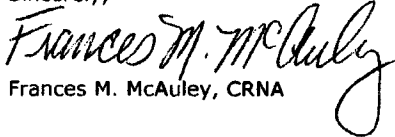
As a representative of the PANA who has *personally* monitored the discussion at the State Board of Medicine, this document is being driven by individuals who have one primary concern: protecting the income of physicians.

In contrast to what has been stated, there will be a significant fiscal impact. These regulations will create billing criteria for the simplest of tasks where none now currently exists. Further they will generate increased paperwork and leave unanswered the question as to who would delegate to whom and under what specific circumstances. All that is necessary to understand and appreciate the impact of this regulation is to reference the problems with prescriptive authority that Nurse Practitioners continue to face.

Another intent of the proposed delegation rule may be to provide a door through which to bring a new and unqualified anesthesia provider (Anesthesia Assistants, or AA's) to the State of Pennsylvania. As proposed, this regulation would expand the scope of physician delegation of medical services in the Commonwealth to include licensed and unlicensed health care practitioners and even unlicensed technicians such as AA's. The American Society of Anesthesiologists (ASA) has publicly advocated the use of AA's and this regulation is simply a means to carry out their openly expressed political mission.

In summary, regulations should appropriately address a known or stated problem. It is unclear what consumer or citizens group in the Commonwealth of Pennsylvania has requested or is in need of these particular regulations, and in what context the request was ever made. These regulations are unnecessary, do not improve care, lack clarity, promote delegation of expert services to unlicensed practitioners, and lack any rational basis as to feasibility or reasonableness that would urge their implementation. These proposed regulations would have a significant negative impact on hospitals by bringing unnecessary and overly restrictive delegation practice during a time when many facilities are struggling to maintain their bottom line.

Sincerely,


Frances M. McAuley, CRNA

Original: 2212

RECEIVED

2003 NOV 18 AM 8: 58

Teresa L. Salamon CRNA, JD
50 Allyssa Drive
Media, PA 19063
610-566-6694
email-tesala@aol.com

INDEPENDENT REGULATORY
REVIEW COMMISSION

IRRC
333 Market Street
14th Floor
Harrisburg, PA 17101

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

Mr. Gannon: *TRIC*

Please be aware that I am opposed to the adoption of the above proposed regulation for two reasons. First, delegation is unnecessary when the non-physician health care provider is already licensed and or certified to perform the delegated services. Second, the language is vague and ambiguous.

The Regulation is unnecessary.

This was correctly pointed out by the House Professional Licensure Committee in 1996 when the State Board of Medicine submitted its first draft and remains true today despite the Board's attempts to justify the reasoning. The Board offers no compelling reason to adopt this regulation except that Section 17 allows it. This is more likely the Board's attempt to enhance the physician's scope of practice to allow him/her to bring in an unlicensed group of anesthesia assistants and delegate duties already performed by highly qualified CRNAs in an attempt to protect the physicians' economic welfare while decreasing the delivery of quality care.

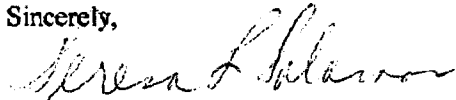
The language is vague and ambiguous.

The language in the regulation, particularly §18.402(a)(6) can be construed to restrict the practice of health care providers, particularly Certified Registered Nurse Anesthetists ("CRNAs") while facilitating an unlicensed group to provide health services under the guise that the physician is exercising his legal right to delegate. By eliminating the phrase "evaluating and monitoring", the provision allows the medical doctor to *assume responsibility for performing the delegated service*. Thus, the regulation could be interpreted to eliminate CRNAs from independent practice in settings where the anesthetist is the sole provider of anesthesia services. CRNAs practice independent from a physician anesthesiologist, under 49 Pa. Code §21.17 when "the registered nurse anesthetist [has] available to her by physical presence or electronic communication an anesthesiologist or consulting physician of her choice. Additionally, the proposed regulation can easily be construed to restrict certain nursing providers and therefore is

in direct conflict with Section 6(f) of the regulation, which states that "it is not intended to restrict" those very same providers. This alone is reason to reject the regulation.

In summary, this proposal submitted by the Board is outside the scope of the Board's regulatory authority and should be rejected. Any changes concerning licensure and practice is a function of the legislature and the Board delegated by them to regulate those health care providers. Any attempt to regulate beyond that can only be viewed as unreasonable and unnecessary encroachment. Thank you for your consideration in this important matter.

Sincerely,



Teresa L. Salamon