

Original: 2003

W. Anthony Gerard, MD
5456 Ridge Rd.
Elizabethtown, Pa. 17022
717-361-8321

Dear IRRC Members,

I am writing to ask you to postpone the final approval of the EMS rules and regulations (2003), or change several areas that present both political and legal problems for the EMS system. I raised these concerns during the public comment period, and met with members of the EMS staff. I appreciate their efforts to resolve the difficult issue of physician certification, but feel that several concepts in the final form regulations will present problems for the state.

I have been actively involved in EMS as a medical command physician for 15 years and more recently as an ALS director. I have also been involved in the development of national and state policy regarding the certification of emergency physicians. This is a controversial issue within the specialty, and the EMS regulations need to be unbiased and criteria based. Unfortunately, the proposed final draft does not achieve this.

The regulations need to include the American Association of Physician Specialists (AAPS) in the definition of board certification or delete the definition of board certification entirely (1001.2, pg.5). The present definition implies recognition of two of the three certifying bodies (ABEM and AOBEM), and not the third (BCEM).

The final form regulations also need to substitute "board certification in emergency medicine" for the references to "residency training in emergency medicine (1003.2), or they will conflict with most policies on certification.

Although I realize that the Department of Health was trying to respond to the conflicting comments and interests on a controversial issue, the final form regulations present several untenable problems:

1) They conflict with national policy and accepted standards on certification and residency training in emergency medicine. ACEP and ABEM emphasize the importance of residency training, but require board certification as the final step in ensuring quality for new physicians.

2) Work force issues also need to be considered since the majority of emergency physicians who are ABEM boarded are not residency trained in emergency medicine but grand fathered into the specialty. As proposed, the regulations would deter recruitment of many experienced emergency physicians to Pennsylvania since they could not qualify as ALS directors unless they were residency trained.

3) The rules and regs exclude the BCEM and AAPS process by implication, and reveal a bias that is without merit or criteria. This presents potential legal problems for the state if the BCEM challenges this (as they have in other state), and a political problem since there are more BCEM diplomates than there are AOBEM diplomates.

I would suggest that the IRRC direct the Department to rewrite the sections of the rules and regulations so that state policy reflects an inclusive or at least more neutral approach to board certification, and clarifies that residency training does not supersede board certification.

I appreciate your time on this issue. I have dedicated many hours of time in ACEP on these issues, and would like to see the state adopt Rules and Regulations that are equitable and consistent with national standards.

Sincerely,

Tony Gerard

cc- Dr. Jim Holliman, Dr. Doug Kupas, David Blunk

RECEIVED
2000 SEP 12 AM 8:38
REGULATORY
REVIEW COMMISSION

Original: 2003

RECEIVED EMBARGOED MATERIAL

2000 SEP -6 AM 8:19

INDEPENDENT REGULATORY
REVIEW COMMISSION

Robert E. Nyce
Executive Director
Independent Regulatory Review
333 Market St.
14th Floor
Harrisburg, PA 17101

August 30, 2000

Dear Mr. Nyce:

I recently received the final-form regulations governing Emergency Medical Services for the State of Pennsylvania and wanted to share my comments on these regulations with you concerning the issue of board certification and the minimum qualifications of medical command physicians.

On April 15, 1999, the Independent Regulatory Review Commission recommended to the Pennsylvania Department of Health (PDOH) Emergency Medical Services Office that *"the Department should justify the need and reasonableness of limiting 'board certification' to ABMS or AOA certification" in hiring criteria.*

In recently received regulations, the PDOH stated, *"The Department has decided to limit the definition, as proposed, to include only those certifications issued by boards recognized by the ABMS or AOA. However, it has removed board certification in emergency medicine as a criterion for qualifying as a regional EMS council director, a medical command facility medical director, and a medical command physician."*

"The proposed regulations did not include the certification in emergency medicine issued by the Board of Certification in Emergency Medicine (BCEM). This board is recognized by the American Association of Physician Specialists (AAPS). The primary reason the Department had proposed to exclude the BCEM certification is that emergency medicine boards recognized by the other two organizations, the American Board of Emergency Medicine (ABEM) and the American Osteopathic Board of Emergency Medicine (AOBEM), required, at the time, completion of a three-year residency in emergency medicine for the certifications they issue, and the BCEM did not". However, over one-third of all ABEM and AOA certified physicians were certified through a practice track that was equivalent to the one used by the AAPS.

The operative phrase in this response is "at the time". Perhaps the PDOH is unaware that the ABEM and the AOBEM previously offered practice tracks and did not require a three-year emergency medicine residency for eligibility for their board certification. These boards "grandfathered in" physicians who did not have this medical residency requirement for certification under "practice tracks" greatly similar to that of the BCEM.

2.

Therefore, today many ABEM and AOBEM-certified emergency medicine physicians would not qualify under the new three-year residency criterion for regional EMS council medical director, medical command facility medical director or medical command physician. Does this mean that the postgraduate qualifications of each and every physician will be examined to determine if that individual completed a three-year emergency medicine residency or meets one of the other criteria? Or, will the PDOH waive this requirement if a physician is ABEM or AOBEM certified?

In addition, the PDOH very loosely uses the term "recognition" when it refers to the ABMS, AOA and AAPS boards. No outside authority has been conferred to AAPS to recognize boards of certification nor does this authority reside in its by-laws. AAPS is the administrative agent for its affiliated boards of certification; it does not "recognize" them. We would be very interested to learn by what authority ABMS or AOA boards "recognize" boards of certification. Does some outside accrediting body grant this right to them or is it an assumed authority?

The PDOH rejected a recommendation to revise the definition of "board certification" to include the American Association of Physician Specialists, Inc. stating that *"the Department is not sufficiently familiar with the qualifying criteria for other boards functioning under the umbrella of AAPS to conclude that the certification issued by these boards are equivalent to those issued by boards recognized by the ABMS and the AOA"*.

The AAPS, on several occasions, has provided information on the eligibility requirements for its affiliated boards of certification to the Pennsylvania Department of Health's Emergency Medical Services Offices. To date, we have received no inquiries, either verbal or written, requesting clarification of this material or for additional data. I would think it is the responsibility of the PDOH to the people of Pennsylvania to expend the maximum effort to become "sufficiently familiar" with all information necessary for a decision-making process that greatly impacts the health of its citizens.

Indeed, the AAPS would be most happy to assist the PDOH in becoming "sufficiently familiar" with the qualifying criteria for its affiliated boards of certification so that the citizens of Pennsylvania will have the best emergency medical care.

Lastly, the Department states that the issue of "board certification" is *"moot since the final regulations do not retain board certification in emergency medicine as a qualifying criterion for any position for which the Department prescribes qualifications"*. If this statement is true, why then does the definition of "board certification" remain in Section 1001.2 of the final-form regulations? This definition includes the American Boards of Medical Specialties and the American Osteopathic Association but excludes the American Association of Physician Specialists, Inc.

3.

AAPS feels that the PDOH is attempting to obfuscate the issue of board certification as a hiring qualification by deleting board certification as a criterion but still favoring certain boards of certification as having de facto recognition by the State of Pennsylvania in the definition section. We request that the Emergency Medical Services Office thoroughly review the eligibility requirements and other information previously provided by AAPS and include its affiliated boards of certification in the definition of "board certification" in Section 1001.2 or remove this definition from the regulations entirely.

Respectfully,



James W. Freeman, MD

To: Robert E. Nyce
Executive Director
Independent Regulatory Review
333 Market St.
14th Floor
Harrisburg Pa 17101

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2000 SEP -6 AM 8:19

INDEPENDENT REGULATORY
REVIEW COMMISSION

(1)

RE: Regulations governing Emergency Medical Services
for the State of Pennsylvania

EMBARGOED MATERIAL

INDEPENDENT REGULATORY REVIEW COMMISSION

To: Kenneth E. Brody, Regulatory Coordinator
Agency: Department of Health
Phone: 3-2500
Fax: 5-6042, 3-3794 or 2-6959

From: Kristine M. Shomper
Deputy Director for Administration
Company: Independent Regulatory Review
Commission
Phone: 3-5419 or 3-5417
Fax: 3-2664

Date: September 6, 2000
of Pages: 9

Comments: Embargoed Mail. Thank you.

*sent
9/6/00
8:45 am*



P.O. Box 927
Mechanicsburg, PA 17055-0927
Phone: 717-691-8995, 888-AMB-9121
Fax: 717-691-8993
www.aa-pa.org

August 29, 2000

Margaret E. Trimble, Director
Pennsylvania Department of Health
Emergency Medical Services Office
P.O. Box 90
Harrisburg, PA 17108

Original: 2003

Dear Ms. Trimble:

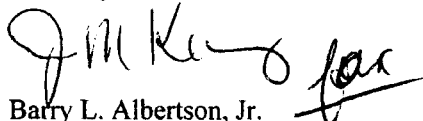
As you are aware, the Ambulance Association of PA (AAP) has actively participated in the preparation of comments to the draft Act 45 Rules and Regulations during the last few years. We were contacted by the IRRC yesterday to determine whether we had any issues with the final form regulations. We have two remaining issues.

We continue to have concerns about the definition of "responsible person." Since our last meeting with you and Mr. Brody, our legal counsel has reviewed the final form regulations and indicates, arguments could be made that the application of the term as it is found in the final form regulations may be beyond its original statutory intent. Of course, this would put the content of the regulations which addresses the implementation of human resource policies and procedures and the requirement for a list of the responsibilities of individuals managing and staffing air and ground ambulance services in question. Although we appreciated your comprehensive explanations regarding the addition of this term to the ambulance licensure chapter, we remain uncomfortable with its possible ramifications to EMS organizations should a need for legal interpretation occur.

Our second issue is based on a previous jury trial case in Dauphin County involving Millersburg Ambulance. We are deeply distressed that the skill of bag-valve-mask ventilation with an endotracheal tube or other advanced airway adjunct is not included in the scope of practice for ambulance attendant, first responder and EMT. BLS providers throughout the Commonwealth perform this skill daily. Unfortunately, this skill is not clearly identified in national curricula, which is the basis for our training programs and therefore may not be included in the "publication of approved skills."

We wanted to take this opportunity to share these issues with you prior to the September 7, 2000, IRRC hearing. If we can be of any further assistance to you or your staff, please feel free to contact our office.

Sincerely,


Barry L. Albertson, Jr.
President

pc: Kenneth Brody, Esq.
Eloise Frazier, Esq.
Don DeReamus, Chair
IRRC

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2000 SEP - 1 AM 8:33
EMERGENCY MEDICAL SERVICES
REVIEW COMMISSION



Original: 2003

RECEIVED

2000 AUG 18 AM 8: 23

INDEPENDENT REGULATORY
REVIEW COMMISSION

August 14, 2000

Ms. Mary Lou Harris
Independent Regulatory Review Commission
State of Pennsylvania
14th Floor, 333 Market Street
Harrisburg, PA 17101

Dear Ms. Harris:

I recently received the final-form regulations governing Emergency Medical Services for the State of Pennsylvania and wanted to share my comments on these regulations with you concerning the issue of board certification and the minimum qualifications of medical command physicians.

On April 15, 1999, the Independent Regulatory Review Commission recommended to the Pennsylvania Department of Health (PDOH) Emergency Medical Services Office that *"the Department should justify the need and reasonableness of limiting 'board certification' to ABMS or AOA certification"* in hiring criteria.

In the recently received regulations, the PDOH stated, *"The Department has decided to limit the definition, as proposed, to include only those certifications issued by boards **recognized** by the ABMS or AOA. However, it has removed board certification in emergency medicine as a criterion for qualifying as a regional EMS council director, a medical command facility medical director, and a medical command physician."*

*"The proposed regulations did not include the certification in emergency medicine issued by the Board of Certification in Emergency Medicine (BCEM). This board is **recognized** by the American Association of Physician Specialists (AAPS). The primary reason the Department had proposed to exclude BCEM certification is that emergency medicine boards **recognized** by the other two organizations, the American Board of Emergency Medicine (ABEM) and the American Osteopathic Board of Emergency Medicine (AOBEM), required, **at that time**, completion of a three-year residency in emergency medicine for the certifications they issue, and the BCEM did not" (emphasis added).*

The operative phrase in this response is **"at the time"**. Perhaps the PDOH is unaware that the ABEM and the AOBEM previously offered practice tracks and did not require a three-year emergency medicine residency for eligibility for their board certification. These boards "grandfathered in" physicians who did not have this medical residency requirement for certification under "practice tracks" greatly similar to that of the BCEM.

EXECUTIVE OFFICES

2296 HENDERSON MILL ROAD, SUITE 206, ATLANTA, GEORGIA 30345 • TELEPHONE 770-939-8555 • FAX 770-939-8559 • TOLL FREE 800-447-9397

Ms. Mary Lou Harris,
August 14, 2000
Page 2

Therefore, today many ABEM and AOBEM-certified emergency medicine physicians would not qualify under the new three-year residency criterion for regional EMS council medical director, medical command facility medical director or medical command physician. Does this mean that the postgraduate qualifications of each and every physician will be examined to determine if that individual completed a three-year emergency medicine residency or meets one of the other criteria? Or, will the PDOH waive this requirement if a physician is ABEM or AOBEM certified?

In addition, the PDOH very loosely uses the term "recognition" when it refers to the ABMS, AOA and AAPS boards. No outside authority has been conferred to AAPS to recognize boards of certification nor does this authority reside in its by-laws. AAPS is the administrative agent for its affiliated boards of certification; it does not "recognize" them. We would be very interested to learn by what authority ABMS or AOA boards "recognize" boards of certification. Does some outside accrediting body grant this right to them or is it an assumed authority?

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The AAPS, on several occasions, has provided information on the eligibility requirements for its affiliated boards of certification to the Pennsylvania Department of Health's Emergency Medical Services Offices. To date, we have received no inquiries, either verbal or written, requesting clarification of this material or for additional data. I would think it is the responsibility of the PDOH to the people of Pennsylvania to expend the maximum effort to become "sufficiently familiar" with all information necessary for a decision-making process that greatly impacts the health of its citizens.

Indeed, the AAPS would be most happy to assist the PDOH in becoming "sufficiently familiar" with the qualifying criteria for its affiliated boards of certification so that the citizens of Pennsylvania will have the best possible emergency medical care.

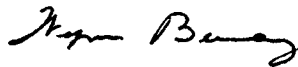
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Ms. Mary Lou Harris
August 14, 2000
Page 3

AAPS feels that the PDOH is attempting to obfuscate the issue of board certification as a hiring qualification by deleting board certification as a criterion but still favoring certain boards of certification as having de facto recognition by the State of Pennsylvania in the definition section. We request that the Emergency Medical Services Office thoroughly review the eligibility requirements and other information previously provided by AAPS and include its affiliated boards of certification in the definition of "board certification" in Section 1001.2 or remove this definition from the regulations entirely.

I would appreciate your thoughts on these issues.

Sincerely,

A handwritten signature in cursive script, appearing to read "Wynn E. Busby".

Wynn E. Busby
Director of Governmental Affairs

WEB:lh

Original: 2003



RECEIVED
2000 AUG 21 AM 9:43
INDEPENDENT REGULATORY
REVIEW COMMISSION
10

August 15, 2000

Mr. Robert E. Nyce, Director
Pennsylvania Independent Regulatory Review Commission
14th Floor, Harristown 2
333 Market Street
Harrisburg, PA 17101

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Mr. Robert E. Nyce
August 15, 2000
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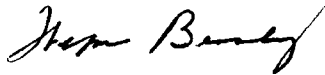
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Mr. Robert E. Nyce
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Wynn E. Busby
Director of Governmental Affairs

WEB:lh

Original: 2003

RECEIVED

2000 SEP -5 AM 8: 35

INDEPENDENT REGULATORY
REVIEW COMMISSION

W. Anthony Gerard, MD
5456 Ridge Rd.
Elizabethtown, Pa. 17022
717-361-8321

FAX to IRRC
c/o Mr. Robert
Nyce

717-783-2664

Dear IRRC Members,

I am writing to ask you to postpone the final approval of the EMS rules and regulations (2003), or change several areas that present both political and legal problems for the EMS system. I raised these concerns during the public comment period, and met with members of the EMS staff. I appreciate their efforts to resolve the difficult issue of physician certification, but feel that several concepts in the final form regulations will present problems for the state.

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Although I realize that the Department of Health was trying to respond to the conflicting comments and interests on a controversial issue, the final form regulations present several untenable problems:

- 1) They conflict with national policy and accepted standards on certification and residency training in emergency medicine. ACEP and ABEM emphasize the importance of residency training, but require board certification as the final step in ensuring quality for new physicians.
- 2) Work force issues also need to be considered since the majority of emergency physicians who are ABEM boarded are not residency trained in emergency medicine but grand fathered into the specialty. As proposed, the regulations would deter recruitment of many experienced emergency physicians to Pennsylvania since they could not qualify as ALS directors unless they were residency trained.
- 3) The rules and regs exclude the BCEM and AAPS process by implication, and reveal a bias that is without merit or criteria. This presents potential legal problems for the state if the BCEM challenges this (as they have in other state), and a political problem since there are more BCEM diplomates than there are AOBEM diplomates.

I would suggest that the IRRC direct the Department to rewrite the sections of the rules and regulations so that state policy reflects an inclusive or at least more neutral approach to board certification, and clarifies that residency training does not supersede board certification.

I appreciate your time on this issue. I have dedicated many hours of time in ACEP on these issues, and would like to see the state adopt Rules and Regulations that are equitable and consistent with national standards.

cc- Dr. Jim Holliman, Dr. Doug Kupas, David Blunk

Tony Gerard

Sincerely,

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Department of Health, Emergency Medical Services Office
Comments for EMS Regulation IRRC Hearing
September 7, 2000

RECEIVED
2000 SEP - 7 AM 10: 27
REGULATORY
REVIEW COMMISSION

Introduction and Background

For the past four years the DOH, the state EMS advisory council and a myriad of stakeholders have been working on a comprehensive update of the regulations governing the delivery of emergency medical services to this Commonwealth. The original regulations promulgated in 1989 supported the system well until the EMS Act was amended in 1994. Interim regulations helped to further guide the system until this comprehensive update could be accomplished.

After town meetings, informal hearings, distribution of thousands of copies of proposed language, including posting on the advisory council web site and dialogue with hundreds of invested parties, we have produced what we believe are regulations that have seriously and equitably considered and balanced the public safety needs with the interests of stakeholders.

Why are they important now?

New regulations are particularly important to our EMS system now. Some examples of why may help communicate the compelling need for their approval:

1. They will support the new national curricula for training prehospital personnel so that our system can keep pace with expanding knowledges and skills.
2. They will allow for a less burdensome process for approving the use of improved technologies for patient care more quickly: devices such as automated external defibrillators, new drugs for the treatment of stroke and transport of patients who are at home with sophisticated life support equipment.
3. Because of the improvements in computerized information management systems, the ambulance licensure and other accreditation processes can be streamlined into a single state process rather than the presently operating multiple regional licenses and accreditations.

We need the regulatory authority to implement these important system improvements.

Notable Comments Received by the DOH

Over the course of developing the regulations, a concerned group of physicians (those with BCEM board certification) expressed to us that the definition of "board certification" and the exclusion of the BCEM certification from that definition, and consequently exclusion of BCEM certification as a criterion for qualifying as a medical command physician or medical command facility medical director, would adversely affect their continued employment in the EMS system. We reviewed the many letters, met with representatives of this group and discussed the issue with the IRRC staff, the State Advisory Council and other stakeholders.

As a result of this process, no medical command physician or medical command facility medical director is now required to be board certified by these final-form regulations. All physicians may qualify for either position by meeting ONE of the following criteria: 1) completion of three years training in an emergency medicine residency program, or 2) having already served as a medical command physician in Pennsylvania. By virtue of the second route, a grandfather provision, no physician currently in the system will be removed from the system or need to requalify.

Additionally, a physician may qualify to be a medical command physician by going through a third route, completion of certain courses on a one-time basis and the ACLS course every two years. Finally, the regulations provide that if a physician does not qualify through any of these routes, the physician may apply for an exception and will be given the opportunity to convince DOH that he or she meets equivalent standards.

Also, a physician who does not qualify to be a medical command facility medical director through the emergency residency program route or the grandfather provision, is afforded a third route comprised of the third route for a medical command physician plus one of five board certifications--internal medicine, family medicine, surgery, anesthesiology and pediatrics. At issue here is that the definition of "board certification" does not include the AAPS affiliated boards in these medical specialties. But, just as the final-form regulations offer physicians interested in serving as a medical command physician a fourth route, the opportunity to apply for an exception based upon equivalent qualifications, the same route is offered by the final-form regulations for a physician interested in qualifying as a medical command facility medical director.

This means that no one who has the emergency medicine residency training, is already a command physician or whose experience and credentials demonstrate their capabilities to function in these roles will be excluded from the system.

What we do believe has clouded and confused the issues that we addressed most intensively: that is, assuring that an adequate supply of qualified medical command physicians and medical command facility medical directors are available in the EMS system and that no practitioner was inadvertently adversely affected, is the language that is in the present regulations, and continued in the final-form regulations as the third alternative route for a physician to qualify as a medical command facility director.

AAPS, the organization that has lobbied for recognizing its affiliated boards in these regulations, has stated through representatives that the omission of those boards adversely affects the operation of their members in the EMS system in Pennsylvania. We cannot control the hiring practices of hospitals, but our regulations do afford physicians certified by AAPS affiliated boards multiple avenues to qualify as medical command physicians or medical command facility medical directors. To illustrate this, several of the letter writers ARE medical command physicians or medical command facility medical directors and others could qualify under both the current and the final-form regulations. If a BCEM certified physician does not qualify through any of these routes, the exception route is still available. The same option exists for ABEM and AOBEM physicians who do not qualify through any of the express routes.

The route for future inclusion of the AAPS affiliated boards is possible through a process already in place: that is, the organization may submit to the DOH a request for consideration of its affiliated boards of anesthesia, internal medicine, pediatrics, surgery and family practice for the purpose of exception to the primary avenues of recognition as a medical command facility director. The DOH would request the review of the state advisory council and the Commonwealth Emergency Medical Director and a decision would then be made after considering their input.

I want to assure you that we have taken the concerns expressed to us very seriously. At the same time, I must emphasize that the department's primary concern in issuing these regulations is meeting the needs of 1.3 million patients treated annually by the over 52,000 EMS personnel around the Commonwealth. We can continue to move forward in our system improvement and also work with AAPS to address its concerns, and we have communicated to AAPS our willingness to do so.

Original: 2003

RECEIVED

EMBARGOED MATERIAL

Robert E. Nyce
Executive Director
Independent Regulatory Review
333 Market St.
14th Floor
Harrisburg, PA 17101

2000 SEP -5 PM 2: 28

INDEPENDENT REGULATORY
REVIEW COMMISSION

August 30, 2000

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Indeed, the AAPS would be most happy to assist the PDOH in becoming "sufficiently familiar" with the qualifying criteria for its affiliated boards of certification so that the citizens of Pennsylvania will have the best emergency medical care.

Lastly, the Department states that the issue of "board certification" is *"moot since the final regulations do not retain board certification in emergency medicine as a qualifying criterion for any position for which the Department prescribes qualifications"*. If this statement is true, why then does the definition of "board certification" remain in Section 1001.2 of the final-form regulations? This definition includes the American Boards of Medical Specialties and the American Osteopathic Association but excludes the American Association of Physician Specialists, Inc.

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AAPS feels that the PDOH is attempting to obfuscate the issue of board certification as a hiring qualification by deleting board certification as a criterion but still favoring certain boards of certification as having de facto recognition by the State of Pennsylvania in the definition section. We request that the Emergency Medical Services Office thoroughly review the eligibility requirements and other information previously provided by AAPS and include its affiliated boards of certification in the definition of "board certification" in Section 1001.2 or remove this definition from the regulations entirely.

Respectfully


James N. Rintoul, MD

EMBARGOED MATERIAL

To: Robert E. Nyce
Executive Director
Independent Regulatory Review
333 Market St.
14th Floor
Harrisburg Pa 17101

RECEIVED
2000 SEP -5 PM 2:28
INDEPENDENT REGULATORY
REVIEW COMMISSION

RE: Regulations governing Emergency Medical Services
for the State of Pennsylvania

INDEPENDENT REGULATORY REVIEW COMMISSION

To: Kenneth E. Brody, Regulatory Coordinator
Agency: Department of Health
Phone: 3-2500
Fax: 5-6042, 3-3794 or 2-6959

From: Kristine M. Shomper
Deputy Director for Administration
Company: Independent Regulatory Review
Commission
Phone: 3-5419 or 3-5417
Fax: 3-2664

Date: September 5, 2000
of Pages: 5

Comments: Embargoed comments Thank you.

*-Faxed
9/5/00
2:45 pm*

Original: #2005

EMBARGLED MATERIAL

**DEPARTMENT OF
HEALTH**

...in pursuit of good health

717-787-8740

RECEIVED

2000 SEP -7 AM 10: 22

DEPARTMENT REGULATORY
REVIEW COMMISSION

47

August 31, 2000

Mr. Barry Albertson
Byrd Avenue
Allentown, PA 18103

Dear Mr. Albertson,

I reviewed the letter from the Association dated August 29, 2000 and we have subsequently talked by phone. I appreciate the Association's concerns and believe that the further explanation that I will provide to you in this response will help the Association to understand the thinking which led to the language in the regulations.

In response to the first matter you raise in the letter, I want to clarify that the Department's responsibility to determine whether an ambulance service is staffed by responsible persons is a statutory licensure mandate, not a matter of regulatory discretion. As the final-form regulations explain, in determining whether that standard is met, the Department will consider the criminal and disciplinary history of only the management team and EMS personnel of the ambulance service. However, the Department will consider each case involving a criminal or disciplinary history on an individual basis. Mitigating and militating factors, not limited to matters such as type of conviction, number of convictions, and the time that has passed since a conviction, will be considered.

The final-form regulations require ambulance services to solicit and consider disciplinary and criminal conviction information, but the regulations do not mandate ambulance service action based on that information and do not penalize an ambulance service if it solicits the information and a staff person falsifies the information he or she provides.

With respect to the meaning of the statutory language "staffed by responsible persons," the EMS Office agrees with you that it would be helpful to define that language in regulation. The EMS Office intends to pursue that. Unfortunately, it is hampered in its ability to do that at this time, as there is a disciplinary proceeding in process in which the meaning of that statutory language is at issue. When a final decision is made in the disciplinary proceeding, the Department will issue an adjudication that addresses the meaning of "staffed by responsible persons." The EMS Office plans to use that adjudication's handling of the issue to then pursue additional regulatory amendments to define the language. The Ambulance Service of Pennsylvania will certainly be a welcomed participant in that process.

In response to the second matter for which the Association expressed concern (that a particular skill, bag-valve-mask ventilation with an endotracheal tube or other advanced airway

adjunct, was not specifically listed in the regulatory language as a skill for First Responder, EMT and ambulance attendant), the reasoning is this: We want to assure that the new regulations do not impede implementing new skills or adjuncts for any level of EMS caregiver. In the past regulations, practitioners complained that the "floor was the ceiling." When specific limits on scope of practice were written into the regulations, such as listing the specified skills allowable, the mechanism to change the scope of practice required a rewrite of the regulation. By drafting the language in such a way that the skills could be listed in the PA Bulletin by level of practitioner, the EMS system can expand interventions that benefit patients without delay. Barb Seifert, of our staff, has almost completed the list for publication in the Bulletin and I can assure you that this skill is included for the practitioners about which you have concern. The skill is permissible if listed in the Bulletin as I described, the practitioner has successfully completed training to perform the skill and has been evaluated as competent to perform the skill. I believe that this will clarify the interpretation and allowable skills for future legal inquiries as referenced in your letter.

Should you have questions or need further clarification, please do call me at 717-787-8740.

Sincerely,



Margaret E. Trimble
Director, EMS Office
PA Department of Health

MET:drp

cc: Kenneth Brody, Esq.
Eloise Frazier, Esq.
Don DeReamus, Chair
IRRC



EMERGENCY HEALTH SERVICES FEDERATION, INC.
722 Limekiln Road • New Cumberland, PA 17070-2354
717-774-7911 • 1-800-833-7777 • 717-774-6163 fax
web page • www.ehsf.org

2000 SEP -5 AM 9:48

INDEPENDENT REGULATORY
REVIEW COMMISSION

Original: 2003

30 August 2000

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

Dear Mr. McGinley:

We have become aware of the meeting of the Independent Regulatory Review Commission to review the proposed regulations to the EMS Act. The meeting is scheduled for 7 September and unfortunately; we are unable to attend due to prior commitments.

However, we are extremely interested in the activities relating to these proposed regulations. The current regulations to the EMS Act have been in place since 1989 with only minor revisions as a result of an amendment to the EMS Act. There have been significant changes in the EMS System since that time. The outdated regulations have hampered improvements to patient care, implementation of new technologies and overall quality management of our EMS System.

We support the adoption of these proposed regulations to the EMS Act as written. There has been an exhaustive review of them over the past several years by many parties associated with the EMS System. It is time we get the proposed regulations adopted so we can continue to improve our EMS System and provide the citizens of Pennsylvania with the latest and most appropriate care.

We appreciate the opportunity to express our support of the proposed regulations to the EMS Act. We look forward to the approval by Independent Regulatory Review Commission in order that these regulations can be implemented in an expeditious manner.

Again, thank you for the ability to provide this information to you.

Sincerely,

Cynthia S. Ehlers
President

cc: Ms. Trimble

EMBARGOED MATERIAL

Original: 2003

RECEIVED

Robert E. Nyce
Executive Director
Independent Regulatory Review
333 Market St.
14th Floor
Harrisburg, PA 17101

2000 SEP -6 AM 8:19

INDEPENDENT REGULATORY
REVIEW COMMISSION

August 30, 2000

Dear Mr. Nyce:

I recently received the final-form regulations governing Emergency Medical Services for the State of Pennsylvania and wanted to share my comments on these regulations with you concerning the issue of board certification and the minimum qualifications of medical command physicians.

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Richard F. Luley M.D.

Richard F. Luley, MD

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REVIEW COMMISSION

To: Robert E. Nyce
Executive Director
Independent Regulatory Review
333 Market St.
14th Floor
Harrisburg Pa 17101

RE: Regulations governing Emergency Medical Services
for the State of Pennsylvania

EMBARGOED MATERIAL

For health care close to home.

Original: 2003

Robert E. Nyce
Executive Director
Independent Regulatory Review
333 Market St.
14th Floor
Harrisburg, PA 17101

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2000 SEP -5 PM 3:43

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REVIEW COMMISSION

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Albert K. Iguchi MD

Albert K. Iguchi, MD . -

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To: Robert E. Nyce
Executive Director
Independent Regulatory Review
333 Market St.
14th Floor
Harrisburg Pa 17101

RE: Regulations governing Emergency Medical Services
for the State of Pennsylvania

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REVIEW COMMISSION

INDEPENDENT REGULATORY REVIEW COMMISSION

To: Kenneth E. Brody, Regulatory Coordinator
Agency: Department of Health
Phone: 3-2500
Fax: 5-6042, 3-3794 or 2-6959

From: Kristine M. Shomper
Deputy Director for Administration
Company: Independent Regulatory Review
Commission
Phone: 3-5419 or 3-5417
Fax: 3-2664

Date: September 5, 2000
of Pages: 5

Comments: Embargoed Mail. Thank you.

*Just
9/5/00
3:50 pm*