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INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

April 15, 1999

Honorable Gary Gurian, Acting Secretary
Department of Health
802 Health and Welfare Building
Harrisburg, PA 17108

Re: IRRC Regulation #10-143 (#2003)
Department of Health
Emergency Medical Services

Dear Acting Secretary Gurian:

Enclosed are our Comments on the subject regulation. They are also available on our website at http://www.irrc.state.pa.us.

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

If you would like to discuss these Comments, please contact Mary Lou Harris at 772-1284, James M. Smith at 783-5439 or John Jewett at 783-5475.

Sincerely,

Robert E. Nyce
Executive Director

REN:wbg
Enclosure
cc: Kimberly Sokoloski
Margaret Trimble
Office of General Counsel
Office of Attorney General
Pete Tartline

COMMENTS OF THE INDEPENDENT REGULATORY REVIEW COMMISSION

ON

DEPARTMENT OF HEALTH REGULATION NO. 10-143

EMERGENCY MEDICAL SERVICES

APRIL 15, 1999

We have reviewed this proposed regulation from the Department of Health (Department) and submit for your consideration the following objections and recommendations. Subsections 5.1(h) and 5.1(i) of the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) specify the criteria the Commission must employ to determine whether a regulation is in the public interest. In applying these criteria, our Comments address issues that relate to economic impact, feasibility, need, reasonableness and clarity. We recommend that these Comments be carefully considered as you prepare the final-form regulation.

1. Section 1001.2. Definitions. - Reasonableness and Clarity

"Ambulance call report"

"Ambulance call report" is defined as a summary of ambulance responses and transports that "shall contain information specified in a format provided by the Department." The last sentence of the definition is a substantive requirement. Substantive requirements in definitions are not enforceable. Therefore, this sentence would be more appropriately placed in Section 1001.41 (Data and information requirements for ambulance services).

"Board certification"

This definition limits "board certification" to physicians certified by the American Board of Medical Specialties (ABMS) and American Osteopathic Association (AOA). Several commentators, including Representative Leo J. Trich and the Pennsylvania Academy of Family Physicians, expressed the concern that this definition may unduly limit the number of physicians who can qualify as medical command physicians. In addition, some commentators indicated that physicians who do not have ABMS or AOA certification, but currently hold medical command positions, may no longer be qualified for these positions when the proposed regulation is adopted. The Department should justify the need and reasonableness of limiting "board certification" to ABMS or AOA certification.

"Medical Command Base Station Course"

This definition refers to a course that "provides an overview of the medical command system and base station direction." Although there is a definition for the term "medical command," there is no definition for the term "base station." Because the term "base station" is used in the regulation, the Department should define the term.

"Medical coordination"

In Subparagraph (iv), the term "medical" was deleted in front of the word "treatment" in the *Pennsylvania Bulletin.* The Department's draft reads: "Transfer and [M]medical treatment protocols." Because the term "medical treatment protocols" is included as a separate definition, the word "medical" should be retained.

"Prehospital personnel"

The definition lists the two terms "prehospital registered nurses" and "health professional physicians" separately. They are combined into one term by the definition of "health professional" in the Emergency Medical Services Act (Act) and this regulation. Rather than include both terms, the definition of "prehospital personnel" should simply list the term "health professional."

"Receiving facility"

Commentators questioned the need for including the term "cardiac" and suggested that the term "medical" was all that was necessary. Others suggested the terms "medical and psychiatric" be added to the list of terms describing the types of emergencies that a physician is trained to manage at a receiving facility. At a minimum, the term "medical" should be included. The Department should carefully review the commentators' concerns and revise the definition to insure that it accurately describes a "receiving facility."

"Service area"

The definition states a "service area" is an "area in which an ambulance service routinely provides services." In the Preamble, the Department explains the definition is added to clarify which political subdivisions an ambulance service must notify when it is going out of business. Any political subdivision that relies on the ambulance service would need notice, regardless of how "routinely" services were provided. Accordingly, the Department should delete the word "routinely" from the definition.

2. Section 1001.4. Exceptions. - Reasonableness and Clarity

In the Preamble, the Department refers to this section and uses the phrase "standards equal to or greater than those employed by the private certifying bodies." However, the phrase "standards equal to or greater than" does not appear in this section of the regulation. The Department should explain what standards and procedures will be used for granting exceptions to certification requirements. Since the phrase, "standards equal to or greater than," is not in Section 1001.4, it is unclear how this criterion will be used. The Department should describe this process and clarify this section.

The regulation adds a new Subsection 1001.4(f), which states that the Department may grant an exception if "the substantive requirements of Subsection (a) are satisfied." The Department should identify the "substantive requirements" referred to in Subsection (a) and explain the process for determining whether they are satisfied. Additionally, the Department should either explain what is a "justifiable reason" or delete the phrase "for justifiable reason" from the first sentence in Subsection (a).

3. Section 1001.5. Investigations. - Reasonableness, Need for Rule and Clarity

This section is being revised to read: "The Department may investigate any person, entity or activity for compliance with the provisions of the act or this part." In contrast, Section 5(b)(13) of the Act (35 P.S. § 6925(b)(13)) states that the Department shall have the authority to: "Investigate complaints related to the delivery of services by trauma centers and forward the results of the investigation to the accrediting entity with a recommendation for action." The Department should explain its intent for this section and should identify its authority and power to investigate matters related to the Act.

4. Section 1001.24. Application for contract. - Clarity

Subsections 1001.24(2) and (3) both require applicants for funding to include information about their "organizational structure." Since the term is used in Subsection (2), Subsection (3) may be redundant and unnecessary. Either the term "organizational structure" should be deleted from Subsection (2) or Subsection (3) should be deleted.

5. Section 1001.25. Technical assistance. - Clarity.

The purpose of the last sentence in Subsection (a) is unclear. It reads: "Special consideration shall be given to contractors in rural areas." The Department should revise the sentence to clarify its purpose, or delete it.

6. Section 1001.41. Data and information requirements for ambulance services. - Reasonableness, Feasibility and Clarity.

The proposed regulation deletes a list of specific items to be included in the "ambulance call report." The preamble and the definition of this term states that the required information will be in a format provided by the Department. However, the regulation does not indicate how ambulance services will obtain this format. The regulation should specify where ambulance services may obtain copies of the required contents and format for the ambulance call report.

Several ambulance services questioned the need for ambulance staff to complete and submit a full ambulance call report within 24 hours of concluding service. This new requirement is set forth in Subsection 1001.41(d). The Department should explain the need for the 24-hour requirement and whether there may be exceptions to the rule.

Commentators questioned the process for submitting the ambulance call report. Some questioned the cost of submitting it by e-mail. Others asked if it was acceptable to fax the completed call report. We note that the submittal or delivery process must also be compatible with the specific receiving facility. Therefore, the regulation should identify all of the acceptable methods for submitting and transmitting the data.

7. Section 1001.65. Cooperation. - Clarity

This section is one long sentence. It should be separated into at least two sentences. The first sentence could end after the words: "quality improvement programs." The next sentence would state that EMS personnel and entities "will provide data, reports and access to records as requested...."

8. Section 1001.123. Responsibilities. - Clarity

This section lists the responsibilities of regional EMS councils. Subsection 100.123(20) reads: "Performing other duties deemed appropriate by the Department." This subsection should end with the phrase: "regarding the responsibilities of regional EMS councils."

9. Section 1001.161. Research. - Reasonableness and Feasibility

This section is being revised to give the Department the sole authority to control both the flow of clinic investigation proposals as well as their final approval. The Department should explain why it needs to review proposals for merit before it refers proposals to the Board of Directors of the Pennsylvania Emergency Health Services Council and regional EMS councils.

10. Section 1003.1. Commonwealth Emergency Medical Director. - Clarity

Paragraph (a)(5) lacks clarity due to its length and the subjects covered. Existing Paragraph (a)(5) covers only the responsibility for medical protocols. The language added to Paragraph (a)(5) expands the responsibilities to include transfer protocols and additional medical criteria. The regulation would be clearer if medical responsibilities and transfer responsibilities were in separate paragraphs.

11. Section 1003.2. Regional EMS medical director. - Clarity

Paragraphs (a)(1), (3), (4), (5), and (6) state the regional EMS medical director's duty is to "assist" the regional EMS council. The word "assist" does not designate a specific duty or function to the EMS medical director. For example, in Paragraph (a)(1) it is not clear how the EMS medical director would fulfill the duty to assist the regional EMS council to approve or reject an application. The duty to assist could range from simply being available to answer questions to making an actual recommendation on each application for the EMS council to consider. Paragraphs (a)(1), (3), (4), (5), and (6) should be clearer regarding the duty of the EMS medical director.

12. Section 1003.3. Medical command facility medical director. - Clarity

The amendment to Section 1003.3(b)(1)(ii) substantially duplicates Section 1003.4(b)(2). Existing Section 1003.3(b)(1)(i) requires a medical command facility medical director to be a

medical command physician. The minimum qualifications for a medical command physician are found in Section 1003.4(b). Section 1003.3(b)(1)(ii) should be amended to only specify qualifications in addition to the minimum qualifications for a medical command physician.

13. Section 1003.4. Medical command physician. - Need and Clarity

Subsection (b) Minimum qualifications.

The regulation is not clear regarding the process and standards the Department will use to qualify medical command physicians who do not have board certification in emergency medicine. The Department explained that physicians without board certification, as defined in Section 1001.2, may qualify as medical command physicians through Section 1003.4(b)(2). We note that Section 1001.4 *Exceptions* does not appear to be the process by which the Department grants exceptions to board certification for medical command physicians.

Paragraph (b)(2) concludes with the phrase "or other programs determined by the Department to meet or exceed the standards of those programs." It is not clear what other "programs" would meet or exceed the standards of board certification in emergency medicine. For example, would the Department consider physicians qualified based on their experience in emergency medicine rather than board certification? Would the Department grandfather currently approved medical command physicians who do not have board certification? The Department should explain the following:

a) The process whereby a physician may qualify without board certification.

b) What other programs or experience the Department anticipates will meet or exceed the standards of board certification in emergency medicine.

c) The effect of the regulation on existing medical command physicians and those who require medical command physician status for their positions who are not board certified.

d) The effect on EMS systems that currently employ medical command physicians who are not board certified.

Finally, Paragraph (b)(2) is not clear in two regards. First, it is not clear which specific programs may be met or exceeded. The alternative in Paragraph (b)(2) could be interpreted to apply only to individual course requirements, only to board certification in emergency medicine, or both. Second, the regulation is also not clear concerning which courses only need to be taken once rather than every two years. The Department should amend Paragraph (b)(2) to clarify its intent.

Subsection (c) Approval of medical command physician.

Paragraphs (2) and (3) provide parameters for the regional EMS council to use in evaluating the approval of medical command physicians. It is not clear why the regional EMS council's parameters are included in the provisions for medical command physicians. The Department should move Paragraphs (2) and (3) to the provisions for regional EMS councils in Subchapters F and G.

Paragraph (2) requires the physician to meet the qualifications in Subsection (b), or to complete "voluntary medical command certification program administered by the Department." The regulation is not clear concerning how this voluntary certification is a substitute for the six specific qualifications listed in Subsection (b). The Department should explain which qualifications in Subsection (b) could be acquired through the "voluntary medical command certification program administered by the Department."

Paragraph (3) requires the physician to "establish" that he is working under the auspices of a medical command facility. It is not clear how a physician would satisfy this requirement. The Department should amend the regulation to state how it would be determined whether the physician is in compliance.

Subsection (c)(3)(i) provides a waiver from Department recognition. The waiver is determined by the regional EMS council. The Department should explain why it is appropriate for the regional EMS council to make determinations on equivalencies for Department recognition.

Subsection (d) Notice requirements.

Paragraphs (1) and (2) set forth requirements for medical command facilities and regional EMS councils, not the medical command physician. The Department should move paragraphs (1) and (2) to the appropriate provisions under Section 1009.1, or Subchapter F or G.

14. Section 1003.5. ALS service medical director. - Clarity

The phrase "Providing guidance to the ALS ambulance with respect to" in Section 1003.5(a)(1)(ii) is not needed. It duplicates the introduction of the list in Paragraph (a)(1). The phrase also lacks clarity because it uses the designation of "ALS ambulance" rather than the defined term "ALS ambulance service." Accordingly, the Department should delete this phrase from Section 1003.5(a)(1)(ii).

15. Section 1003.21. Ambulance attendant. - Clarity

Section 1003.21 references advanced first aid sponsored by the American Red Cross. One commentator stated that the American Red Cross does not offer an advanced first aid course. The Department should review Section 1003.21 to assure its requirements are consistent with the courses that are available.

16. Section 1003.22. First responder. - Clarity

The specific intent of Subsection (e)(4) is not clear. It appears to state that some courses are offered which may not be counted as continuing education credits or may not be used to expand the scope of the first responder's duties. The Department should amend Subsection (e)(4) to clarify its intent.

17. Section 1003.23. EMT. - Clarity

Subsection (e)(2) only allows an EMT to transport a patient with an intravenous catheter without medication running. One commentator stated that Subsection (e)(2) may be overly restrictive. Many outpatients are using patient controlled devices, or are using devices monitored by visiting nurses in the home. The commentator suggests adding an exception to allow transport when the medication is part of the patient's normal outpatient treatment plan. The Department should explain how outpatient medication will be administered in this situation.

The specific intent of Subsection (e)(3) is not clear. It appears to state that some courses are offered which may not be counted as continuing education credits or may not be used to expand the scope of the EMT's duties. The Department should amend Subsection (e)(3) to clarify its intent.

18. Section 1003.24. EMT-paramedic. - Clarity

Annex A and the preamble of the proposed regulation both indicate that Subsection (c) *Transition of EMT-paramedic I and EMT-paramedic II certification to EMT-paramedic* is to be deleted. However, a bracket to indicate the deletion of Subsection (c) was omitted in the regulation. The Department should ensure the proper placement of brackets for the deletion of Subsection (c) in the final-form rulemaking.

The specific intent of Subsection (d)(19) is not clear. It appears to state that some courses are offered which may not be counted as continuing education credits or may not be used to expand the scope of the EMT-paramedic's duties. The Department should amend Subsection (d)(19) to clarify its intent.

19. Section 1003.25b. Prehospital registered nurse. - Clarity

Subsection (c) *Scope of practice*, as amended, will include "...other ALS services authorized by Professional Nursing Law...." We were unable to locate any reference to Advanced Life Support (ALS) services in the Professional Nursing Law. The existing regulation allows any service authorized by the Professional Nurses Law. It is not clear what services would be authorized under the amended language of "other ALS services authorized by Professional Nursing Law." The Department should delete the acronym ALS from Subsection (c), or explain how it applies.

20. Section 1003.28. Medical command personnel. - Clarity

The first two sentences of Subsection (b)(3) and the last sentence of Subsection (c)(2) lack clarity due to their length. These subsections would be clearer if they were broken into shorter sentences, or where appropriate, a list of requirements. The Department should amend Subsections (b)(3) and (c)(2) to clarify its intent.

21. Section 1003.29. Continuing education requirements. - Clarity

Subsections (a)(1) and (b)(1) require that during the first full certification period, half of the continuing education credits must be in medical and trauma education. It is not clear whether this requirement only applies to the first certification period, or whether this is a requirement for all recertifications. The Department should clarify the intent of the language in Subsections (a)(1) and (b)(1).

22. Section 1003.31. Credit for continuing education. - Clarity

The term "prehospital practitioner" is used throughout Section 1003.31. The term "prehospital practitioner" lacks clarity because it is not defined in Section 1001.2. However, Section 1001.2 does have a definition of "prehospital personnel." The Department should delete the term "prehospital practitioner" from Section 1003.31 and replace it with the defined term "prehospital personnel."

23. Section 1005.1. General Provisions. - Clarity

The first word "No" in the second sentence of Subsection 1005.1(a) is bracketed for deletion in the *Pennsylvania Bulletin*. This deletion is problematic because nothing is proposed to replace the first word. This error needs to be corrected by replacing "No" with the word "A." A similar change is needed for consistency in Subsection 1007.1(a) relating to general provisions for licensing of air ambulance services.

In addition, the word "exempted" in the last phrase of Subsection 1005.1(a) is also deleted in the *Pennsylvania Bulletin*. In the Department's draft, the word is retained in the phrase: "or is exempted from these prohibitions under the act." This phrasing is also consistent with the last words in Subsection 1007.1(a). The word "exempted" needs to be restored or the end of the subsection will be unclear.

24. Section 1005.6. Out-of-State providers. - Reasonableness and Clarity

This section states that "ambulance services located or headquartered outside of this Commonwealth that regularly engages in the business of providing emergency medical care and transportation of patients from within this Commonwealth..." are required to be inspected and licensed by the Department. First, the word "engages" should be "engage" to agree with the plural noun. Second, the term "regularly" is vague. The Department should explain whether all out-of-state providers who provide service in Pennsylvania are required to be inspected and licensed by the Department.

25. Section 1005.10(d). Personnel requirements. - Economic Impact, Reasonableness and Clarity

Subsection 1005.10(d)(1)(iii) requires staff to commit to being available at specified times. Volunteer services may not be able to meet a "duty roster" that requires staff to "commit"

to being available at specific times. Commentators suggest that the Department use an outcome-based or performance standard. If adequate service is being provided, the Department should explain why volunteers should be required to make specific commitments.

26. Section 1005.10(i). Accident, injury and fatality reporting. - Reasonableness and Clarity

Section 1005.10(i) requires reporting of an "injury...that results in medical treatment at a facility." It is not clear what degree of injury would require reporting. These facilities may treat the individuals for very minor injuries. The Department should revise Section 1005.10(i) to state what degree of injury must be reported.

27. Section 1009.1. Operational criteria. - Clarity

Subsection (12) requires the medical command facility to maintain communication records and tapes. However, one commentator questioned how long the records and tapes must be kept. The Department should provide guidance for the length of time records are to be maintained under Subsection (12).

28. Section 1009.2. Recognition process. - Need and Clarity

There appears to be a typographical error in Subsection (a). The word "medical" appears twice in succession.

29. Chapter 1011. Accreditation of training institutes. - Clarity

Section 1001.2 deletes the definition of "BLS training institute" and adds the definition of "EMS training institute." However, the language in Chapter 1011 repeatedly uses the phrase ALS and BLS training institute, but does not use the new phrase "EMS training institute." The term, "EMS training institute" should be used consistently.

30. Section 1011.1. BLS and ALS training institutes. - Clarity

The subparagraph designations under Paragraph (b)(1) have a typographical error. The second subparagraph should be (ii), not (iii).

In Subsection (f)(4) the regulation references a "Prehospital Practitioner Manual." Section 1001.2 defines a "Prehospital Personnel Training Manual." The Department should revise the reference in Subsection (f)(4) to "Prehospital Personnel Training Manual," or explain if another manual is referenced.

Subsections (g) and (h) provide for clinical and field preceptors at ALS training institutes. One commentator suggested using clinical and field preceptors at BLS training institutes. Is

there a specific reason the Department did not include the use of clinical and field preceptors at BLS training institutes?

31. Section 1013.3. Special event EMS personnel and capability requirements. - Need and Clarity

One commentator expressed a need to coordinate Chapter 1013 *Special Event EMS* with other Commonwealth of Pennsylvania documents including the "Commonwealth Emergency Operations Plan," the "Special Event Emergency Action Plan Guide" and the "Planning Guidance for Mass Fatalities Incidents." The Department should explain how it intends to coordinate the requirements in this regulation with other Commonwealth of Pennsylvania documents. Where the Department's requirements vary from other Commonwealth of Pennsylvania documents, the Department should explain the need to vary.

32. Section 1013.8. Special event report. - Need

Section 1013.8 requires the person or organization who filed a special event EMS plan to also file a special event report. The Department should explain the need for this report. The Department should also consider requiring a report only if EMS services were needed at the event.