

Comments of the Independent Regulatory Review Commission



Department of Health Regulation #10-190 (IRRC #2917)

Emergency Medical Services System

December 28, 2011

We submit for your consideration the following comments on the proposed rulemaking published in the October 29, 2011 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the Department of Health (Department) to respond to all comments received from us or any other source.

1. Whether the regulation is consistent with the intent of the General Assembly.

This proposed rulemaking is intended to facilitate the implementation of the Emergency Medical Services System Act of 2009 (Act) (35 Pa.C.S. §§ 8101 – 8157). Both the Act and the proposed rulemaking are comprehensive documents. We appreciate the time and effort put forth by the Department in developing this regulatory package.

When reviewing a regulation, and as required by the Regulatory Review Act (71 P.S. §§ 745.1 – 745.14), this Commission must first and foremost determine whether the agency has the statutory authority to promulgate the regulation and whether the regulation conforms to the intention of the General Assembly. (71 P.S. § 745.5b.) In the Regulatory Analysis Form (RAF) submitted with the rulemaking, the Department has identified sections of the Act that provide the Department with both general and specific statutory authority. However, the identified sections of the Act are not cross-referenced to specific sections of the regulation. In order to assist this Commission in determining if the regulation is consistent with the intent of the General Assembly, we request that the Department identify specific sections of the Act that correlate to specific sections of the regulation.

2. Publications in the *Pennsylvania Bulletin*. – Consistency with statute; Implementation procedures; Reasonableness; Clarity.

The Emergency Medical Services System Act provides for the Department to publish changes in the *Pennsylvania Bulletin* relating to Emergency Medical Services (EMS) patient reports (35 Pa.C.S.A. §8106(f)), skills within the scope of practice of each type of EMS provider (35 Pa.C.S.A. §8113(g)) and vehicle construction and equipment and supply requirements for EMS agencies (35 Pa.C.S.A. §8129(j)). In several of the provisions, the regulation provides for

changes to requirements through publication in the *Pennsylvania Bulletin*. Provisions in the regulation that provide for Department publications in the *Pennsylvania Bulletin* include:

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| • § 1021.24(b) | • § 1023.26(d)(1) | • § 1023.31(g)(1) |
| • § 1021.24(e) | • § 1023.26(d)(2) | • § 1023.31(h)(1) |
| • § 1021.25(10) | • § 1023.26(d)(3) | • § 1023.34(b) |
| • § 1021.41(a) | • § 1023.27(d)(1) | • § 1027.1(b)(6) |
| • § 1021.41(c) | • § 1023.27(d)(2) | • § 1027.3(c) |
| • § 1021.43(c) | • § 1023.27(d)(3) | • § 1027.4(b) |
| • § 1023.24(d)(1) | • § 1023.31(a) | • § 1027.6(c) |
| • § 1023.24(d)(2) | • § 1023.31(b)(1) | • § 1027.36(d) |
| • § 1023.24(d)(3) | • § 1023.31(c)(1) | • § 1027.37(f) |
| • § 1023.25(d)(1) | • § 1023.31(d)(1) | • § 1027.38(b)(1) |
| • § 1023.25(d)(2) | • § 1023.31(e)(1) | • § 1027.38(b)(2)(i) |
| • § 1023.25(d)(3) | • § 1023.31(f)(1) | • § 1029.21(b) |

The above provisions relate to scope of practice, continuing education, reporting, equipment, licensure, funding, medications and facilities.

We have three concerns relating to the use of publications in the *Pennsylvania Bulletin*. First, we ask the Department to explain how each of the regulation's use of publications in the *Pennsylvania Bulletin* is consistent with the Act.

Second, Governor's Executive Order 1996-1 at 1.f., states, "Compliance shall be the goal of all regulations." As a practical matter, portions of this regulation will not present the information needed to comply. Instead, the reader will have to search the *Pennsylvania Bulletin* to see if the Department published any changes and if so, what the changes are. This would be further complicated in the future, if the Department has the need to publish more than one change to a provision. While these publications in the *Pennsylvania Bulletin* may provide flexibility for the Department, the Department should explain how the regulated community can reasonably comply because the regulated community will need to know whether the requirements in the regulation have been amended and how to find those specific publications in the *Pennsylvania Bulletin*.

Finally, related to the above concerns, the Department should explain how it will implement provisions that can be altered by publication in the *Pennsylvania Bulletin*. Has the Department considered, for example, placing on its website a compendium of changes published in the *Pennsylvania Bulletin* after the effective date of this regulation?

3. Economic impact of the regulation.

In the responses to questions 17 to 20 of the RAF, the Department describes several costs. For example, in Response 17, the Department recognizes additional costs for the regulated community to operate on a full-time basis and for a medical director. However, the Department concludes it is impossible to estimate the costs and shows zero dollars in the cost estimate in response to Question 20. In fact, the only cost shown in response to Question 20 is \$84,000 to \$95,000 in state government costs. We ask the Department to review its responses to questions 17 to 20 and, to the best of its ability, provide dollar estimates of the costs and/or savings associated with implementation of the regulation.

4. Section 1012.2. Definitions. – Whether the regulation is consistent with the intent of the General Assembly; Implementation procedures; Clarity.

Ambulance – The regulatory definition of this term differs from the statutory definition. It does not include a “water vehicle.” We ask the Department to explain the reason for this difference and how this deviation is consistent with the legislative intent of the General Assembly.

Medical command – This term is not defined in this section. However, it is used throughout the regulation. We believe a definition for this term would improve the clarity of the regulation and assist the regulated community with compliance.

PSAP – Public safety answering point – Paragraph (ii) of this definition states that “A PSAP is operated 24 hours a day.” This provision is substantive (i.e., regulatory). Substantive provisions are not appropriate for definitions. We recommend that the provision be moved to the body of the regulation. See § 1.7(c) of the Pennsylvania Code and Bulletin Style Manual.

Specialty receiving facility – This definition states that a “special receiving facility” will be “identified” by the Department. What process will the Department use to make this designation and is the process set forth in regulation? Would a facility have to request this designation from the Department? How would the regulated community know if a facility has been identified as a “special receiving facility”?

5. Section 1021.24. Use of EMSOF funding by a regional EMS council. – Clarity.

Subsection (a)(1)(i) includes the term “911 system” and Subsection (a)(1)(ii) includes the term “specialty services.” We believe definitions for these terms would improve the clarity of the regulation and assist the regulated community with compliance.

6. Section 1021.62. Regional quality improvement programs. – Reasonableness; Clarity.

We have three concerns with this section. First, a commentator believes that the regulation should specifically list the parties that will be asked to provide input on regional EMS quality improvement programs. We believe it would be reasonable to include such a provision and ask the Department to consider it as it prepares the final-form regulation.

Second, under Paragraph (1), regional EMS councils are required to conduct quality improvement audits of regional EMS systems. The final-form regulation should specify how often quality improvement audits must be conducted.

Third, Paragraph (5) requires regional EMS councils to “Submit to the Department reports as prescribed by the Department.” This requirement is vague. It does not establish a binding norm and would be difficult to comply with. We recommend that it be deleted or enhanced to specify the type of information that would be required in the reports.

7. Section 1021.83. Complaints. – Economic impact; Need.

A commentator notes the potential for duplicative investigations by the Department and the Division of Acute and Ambulatory Care, which is also under the Department. The Department should explain how these investigations will be conducted and whether there is any duplication. If there is any duplication, the Department should explain why the duplication is needed and how the cost of the duplication is justifiable.

8. Section 1021.103. Governing body. – Economic impact; Reasonableness.

Subsection (d) requires the governing body to make the annual report available to the public. Would placing this annual report on the council’s or governing body’s website satisfy this requirement? If so, we suggest adding this to the regulation.

9. Chapter 1023. Personnel, Subchapter A. Administrative and Supervisory EMS Personnel. – Protection of the public health, safety and welfare.

This subchapter establishes the roles and responsibilities and the minimum qualifications for the EMS agency medical directors, medical command physicians, medical command facility medical directors, regional EMS medical directors and Commonwealth EMS Medical Directors. Some of these positions require the completion of an application for the position and triennial renewal, but other positions do not. What are the reasons for these differences? Is the public health, safety and welfare of the citizens of the Commonwealth adequately protected without the requirement for the submittal of applications and triennial renewal for all positions?

10. Section 1023.21. General rights and responsibilities. – Protection of the public health, safety and welfare.

Paragraph (b)(1) states, in part, that “An applicant for an EMSVO [Emergency Medical Services Vehicle Operator] certification shall also report to the Department any other conviction of an offense involving reckless driving or driving under the influence of alcohol or drugs.” We note that EMSVO is defined in Section 1021.1 of the regulation and the Act as “an individual who is certified by the Department to operate a ground EMS vehicle.” A commentator questions why the reporting requirements only apply to ambulances and therefore, paramedics and Emergency Medical Technicians. The commentator believes the requirements should also be applicable to Quick Response Service, rescue squad, fire truck, motorcycle and police vehicles.

Regarding emergency vehicle operators under the Department's jurisdiction, we ask the Department to review this provision of the regulation and explain whether the reporting requirements in Paragraph (b)(1) apply to all vehicle operators under its jurisdiction. If not, the Department should explain why this reporting is not necessary for all vehicle operators.

11. Section 1023.31. Continuing education requirements. – Clarity.

Subsection (a) pertains to continuing education requirements for EMS vehicle operators. The subsection requires continuing education, but fails to specify the subject areas that would be appropriate. This differs from continuing education requirements for other personnel listed under this section. For example, Subsection (b) requires EMR continuing education instruction in subjects related to an EMR's scope of practice. We recommend that Subsection (a) be amended to include the type of instruction that would be appropriate for EMS vehicle operator continuing education.

12. Section 1023.51. Certified EMS instructors. – Consistency with statute; Clarity.

Under Subsection (a), an individual seeking certification as an EMS instructor must meet seven qualifications. One of the qualifications is to successfully complete an EMS instructor course approved by the Department or possess, "at a minimum, a bachelor's degree in education or a teacher's certification in education." A commentator has noted that this provision differs from the corresponding provision found in the Act, which includes a reference to a "doctorate or master's degree." 35 Pa.C.S. § 8124. What is the reason for this deviation from the Act? Would an individual with a doctorate or a master's degree satisfy this requirement?

13. Section 1025.22. Responsibilities of continuing education sponsors. – Clarity.

Subsection (f) requires continuing education sponsors to retain records for "at least 4 years from the presentation of the course." This requirement is vague and should be amended to include a specific time frame such as "4 years from the presentation of the course."

14. Section 1027.3. Licensure and general operating standards. – Statutory authority; Implementation procedures; Fiscal impact; Clarity.

Subsection (h) pertains to dispatching. We have two concerns. First, Subsection (h)(3) states that certain costs of PEMA and local governments associated with training and certification/recertification of an EMS agency dispatch center's calltakers and dispatchers is the responsibility of the EMS agency. What is the Department's statutory authority for this provision? How would it be implemented? What is the anticipated cost to the entire EMS agency community for this provision?

Second, Subsection (h)(5) states, "References in 4 Pa. Code §§ 120d.104 and 120d.105 to the Pennsylvania Emergency Management Agency, 911 communications centers and remote dispatch points are replaced with the Department and EMS agency dispatch centers for the purpose of this regulation." We believe the clarity would be improved and the regulated

community better served if the requirements of 4 Pa. Code §§ 120d.104 and 120d.105 were set forth in directly in this regulation.

15. Section 1029.21. Receiving facilities. – Consistency with statute; Economic impact; Reasonableness.

Subsection (b) would allow the Department to publish a list of special receiving facilities through notice in the *Pennsylvania Bulletin* and to update the list as appropriate. A commentator states that this is problematic because it would give the Department great authority to determine where EMS providers transport patients with certain conditions, but there is no criteria identifying how the Department's decisions would be made. The commentator recommends a public comment period.

We agree that changes to the list will have significant implications to receiving facilities. What is the Department's specific statutory authority to establish, maintain and update a list of special receiving facilities via publication in the *Pennsylvania Bulletin*? In addition, the Department should consider adding provisions to the regulation explaining the process that will be used to update the list and how the affected parties will have the opportunity to comment on any contemplated changes.

16. Chapter 1031. Complaints, disciplinary actions, adjudications and appeals. – Statutory authority; Consistency with intent of the General Assembly.

This chapter sets forth the grounds for discipline and the types of authorized discipline for the various professions and agencies that are subject to this regulation. The grounds for discipline and the types of authorized discipline for EMS providers, EMS vehicle operators and EMS agencies closely follow similar provisions in the Act. However, this chapter applies to other professions and agencies beyond those listed above. What is the statutory basis for imposing discipline on the other professions and agencies? In addition, what is the Department's statutory authority for Section 1031.6, relating to emergency suspension for EMS provider and EMS vehicle operator certifications, and Section 1031.9, relating to automatic suspension for incapacity?

17. Section 1031.1. Administrative and appellate procedure. – Implementation procedures; Clarity.

This section of the rulemaking adds a reference to 1 Pa. Code Part II (relating to general rules of administrative practice and procedure or GRAPP). Subsection (b) also adds rules supplementing GRAPP. In order to assist the regulated community with compliance, we recommend that a cross-reference be included to show which GRAPP provisions are being supplemented. For example, the Department should consider including a new subsection that reads, "(6) Subsection (b) supplements 1 Pa. Code § _____ (relating to _____)."

18. Chapter 1033. Special event EMS. – Implementation procedures.

A “special event” is defined in Section 1021.2 as “a planned and organized activity or contest, which places participants or attendees, or both, in a defined geographical area in which the potential need for EMS exceeds local EMS capabilities or where access by emergency vehicles might be delayed due to crowd or traffic congestion at or near the event.” Section 1027.38, relating to special operations EMS service, includes Subsection (e), relating to mass-gathering EMS services. In the Preamble to the final-form regulation, we ask the Board to explain how Chapter 1033 will be administered in conjunction with Section 1027.38(e).