



RECOMMENDATION FOR CONSIDERATION

Board Meeting Date: June 11, 2024

Subject: Development and Use of Agency Level Protocols by Critical Care Ground Ambulances and Special Operations EMS Agencies.

VTR#: 0624-01

Committee/Task Force: (Joint Recommendation from)

1. Medical Advisory
2. Critical Care Transport Task Force
3. Special Operations Task Force

Recommendation:

The Department should authorize the development and use of OPTIONAL agency-level treatment protocols, approved by the Department, by licensed critical care transport ambulance services and special operations EMS agencies.

Background:

Historically, the Department has taken the position that it lacks the regulatory authority to approve agency level protocols not specifically provided for in the EMS regulations. PEHSC believes that previous BEMS leadership may have erred in its interpretation of their authority in this area and can authorize EMS agency level protocols.

Although the EMS regulations establish the Department's authority to establish statewide protocols, there is no prohibition, expressed or implied, preventing the creation of protocols below the statewide level.

When the current rules and regulations were promulgated, language was added to maintain the ability of air ambulance services to continue using agency-level protocols that were developed prior to 2013. Unlike air ambulances, critical care ambulances and special operations EMS services were not defined prior to Act 37 (2009) and the rules and regulations (2013). While possibly an unintentional oversight during regulatory development, there was no intent for agency-level protocols to be the exclusive domain of air ambulance services.

Development of optional agency-level protocols does not preclude the continued development of statewide protocols in these areas of practice if so desired. The use of an approved agency versus statewide protocol will be at the discretion of the agency medical director.

For ground critical care transport ambulance services, not associated with a flight program, and special operations EMS services:

- Their mission and practice environment can be highly variable based on geography, population, event and in the case of ground critical care transport, institutional customer requirements.
- These specialty services tend to have highly engaged medical directors and experienced EMS providers.
- In contrast to the current statewide protocols and those that may be developed in the future, a one-size-fits all approach can adversely affect an agency's ability to function.
- The agency medical director is in the best position to know what type of clinical guidance is needed to serve a particular community.

The scope of this recommendation is limited to licensed:

1. Critical Care Ambulance Services (28 Pa.C. §1027.39)
2. Special Operations EMS Services (28 Pa.C. § 1027.41)
 - a. Tactical
 - b. Wilderness
 - c. Mass Gathering
 - d. Urban Search and Rescue (USAR)

Independent Legal Analysis:

To assist in the development of this recommendation, PEHSC sought the counsel of Kenneth Brody, Esq. from the law firm of Page, Wolfberg and Wirth (PWW). Prior to joining PWW, Mr. Brody was employed by the Commonwealth of Pennsylvania, Department of Health, Office of General Counsel. In this capacity, he provided legal advice to the Bureau of EMS, including being the principal architect of the 2009 PA EMS Systems Act (Act 37) and the Act's rules and regulations, 28 Pa.C. Health and Safety, Part VII. Emergency Medical Services (2013).

On February 9, 2022, Mr. Brody wrote:

"The EMS System Act expressly authorizes only the Department of Health (DOH) pursuant to 35 Pa.C.S. § 8105(c), and regional EMS councils, subject to Department approval, pursuant to 35 Pa.C.S. § 8109(c)(8), to establish protocols governing EMS provider performance when providing EMS. However, DOH has not interpreted these provisions to restrict its authority to authorize other entities to adopt protocols governing EMS provider performance when providing EMS."

"By DOH regulation 28 Pa. Code § 1027.40(e), DOH has authorized an EMS agency that provides air ambulance service to establish for the air ambulance service EMS protocols that address EMS not covered by DOH's EMS protocols, provided the air ambulance protocols are approved by DOH. Pursuant to 28 Pa. Code § 1027.39(b), for a critical care transport (CCT), DOH provides for a health care provider, subject to DOH approval, to

substitute for one of the two EMS providers above an AEMT specified by the regulation to serve as a member of the crew, provided the remaining crew includes one EMS provider above the AEMT level who has successfully completed a CCT educational program approved by DOH. Under this regulation one of the requirement's for DOH approval of the substitute provider is that the EMS agency submit to DOH, for its approval, an EMS agency protocol for its CCT service. Neither of these EMS agency prepared air ambulance or CCT protocols are expressly authorized by the EMS System Act."

"Consequently, consistent with DOH's interpretation of the authority granted to it under the EMS System Act, as reflected in its current regulations, DOH, at least by regulation, may authorize the establishment by EMS agencies of protocols, approved by DOH, to govern the conduct of EMS crews when providing EMS for certain types of ambulance services. Also, because the content of the EMS protocols established by DOH and regional EMS councils is not established by statute, we believe DOH may grant EMS agency specific exceptions to those protocols pursuant to 28 Pa. Code § 1021.4(a) if it is convinced that the policy objectives and intentions of DOH as reflected in the EMS regulations are met by the requested exception, or it is convinced that compliance with the DOH or regional EMS council protocols by the requesting EMS agency would create an unreasonable hardship, but would not impair the health, safety or welfare of the public." #####

"If the project is a research project which would involve an EMS agency violating a Statewide or regional EMS protocol, DOH regulation 28 Pa. Code § 1021.141(g) provides that an EMS agency or other person shall apply for an exception to the protocol under 28 Pa. Code § 1021.4."

Medical Review:

This recommendation has been reviewed and recommended by the medical advisory committee and physician members of the CCT transport and Special Operations task forces.

Fiscal Concerns:

None identified.

Educational Concerns:

The agency medical director, as with all protocols, is responsible to provide education on the use of and compliance with agency level protocols.

Plan of Implementation:

The scope of the agency-level protocols applies to paramedics who have completed additional training in critical care or special operations care as approved by the Department and is credentialed by the agency medical director for an expanded scope of practice or prehospital registered nurses (PHRN). However, this in no way limits the PHRN from practice authority granted by Pennsylvania's nursing practice act.

- Development of optional agency-level protocols does not preclude the continued development, of statewide protocols in these areas of practice and the use of an approved agency versus statewide protocol used in a clinical situation will be at the discretion of the agency medical director.
- The "Approved and Required Medication Lists for Emergency Medical Service Agencies and Emergency Medical Service Providers should be amended to reflect the following:

"Medications not listed previously, but appear in a Department-approved EMS agency-level protocol for use by an expanded scope of practice paramedic, PHRN, PHPE and PHP."

- The approved medications list will also require expansion to capture expanded scope of practice special operations providers.
- Agency level protocols will be subject to Department review and approval consistent with existing regulations for air ambulance agencies, 28 Pa.C Section 1027.40 (e) .
- The "Scope of Practice for Critical Care Transport and Special Operations Emergency Medical Service Providers," should be amended in its preamble, line items or footnotes to authorize procedures for the expanded scope of practice paramedic, PHRN, PHPE or PHP consistent with Department approved agency level protocol.
- The agency medical director is responsible for educating providers on agency level protocols and ensuring compliance when used in patient care.
- The physical presence of agency level protocols during patient care will be consistent with that of statewide protocols for the purpose of agency licensing.

The PEHSC Committee/Task Force offers consultation to the Department in regard to the content of this Vote to Recommend (VTR) and its attached documents. The PEHSC Committee/Task Force specifically offers staff or member support to participate in Department deliberations regarding this recommendation in an effort to convey committee/task force discussions.

Board Meeting Comments/Concerns:

Signed: _____ Date _____
President

For PEHSC Use Only – PA Department of Health Response

Accept: _____ Table: _____ Modify: _____ Reject: _____

Comments:

Date of Department Response: _____