



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
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CHERYL BARTLETT, RN
COMMISSIONER

September 17, 2014

Ronald Quaranto,
Chief Operating Officer
137 Washington Street
Somerville, MA 02143

RE: Cataldo Ambulance Service, Special Project Waiver Request Application,
SmartCare Community Paramedic Program, July 16, 2014 Revised Submission

Dear Mr. Quaranto:

Cataldo Ambulance Service ("Cataldo") submitted the above-referenced Special Project Waiver Application to the Department of Public Health ("Department") and requested that the Department waive certain regulations to allow it to conduct a special project referred to as the "SmartCare Community Paramedic Program."

Legal Authority

The statute governing the Commonwealth's emergency medical system ("EMS"), M.G.L. c. 111C, §22, provides the Commissioner with the authority to approve special project waiver requests related to the delivery of EMS as follows:

The Commissioner may waive any provision of the regulations and guidelines promulgated under this chapter, subject to such terms and conditions as he may impose; provided, however, that no waiver may issue unless the commissioner has determined that such waiver (a) will result in improved quality or accessibility of EMS, (b) is in the public interest and (c) will not endanger public health or safety.

The EMS regulation promulgated under the authority of M.G.L. c. 111C, §22, provides that:

At the discretion of the Department, regulations established in this chapter may be waived for special projects which demonstrate innovative delivery of emergency medical care services. Proposals for special projects must be submitted to the Department in writing and no regulatory standards will be waived without explicit Department approval. Special projects will be considered experimental in nature and will be reviewed and renewed at such time periods as the Department shall establish. 105 CMR 170.405.

The Department's Determination

In making its determination, the Department considered the Special Project Waiver Application ("Application") received on June 27, 2014, as modified by the revisions to the Application received on July 16, 2014 (hereinafter referred to as the "Special Project Request"). After careful review of the materials referenced above and the governing statutory and regulatory provisions, the Department grants approval of the Special Project Request. Specifically, this approval temporarily authorizes Cataldo, in collaboration with the Post-Acute Care Transitions ("PACT") program at Beth Israel Deaconess Medical Center ("BIDMC"), to provide paramedic care to PACT patients in their residence in accordance with the terms and conditions of this letter ("the Special Project Approval"). **Any activity proposed in the Special Project Request that has not been specifically approved by this letter shall be deemed not approved.**

The Special Project Approval is contingent upon the participation of the following entities as set forth in the Special Project Request: Cataldo, a Department-licensed ambulance service; Ronald Quaranto, Chief Operating Officer, Cataldo; Karen Host, Clinical Quality/Regulatory Director and Principal Investigator ("PI"), Cataldo; Jonathan Fisher, MD, Cataldo's Affiliate Hospital Medical Director, Beth Israel Deaconess Medical Center.

Terms and Conditions

General Terms

1. The term of the special project shall be limited to one (1) year from the effective date of the Special Project Approval.
2. The Special Project Approval shall not become effective until the Department notifies Cataldo that it has satisfactorily complied with the following terms:
 - a) Cataldo shall provide the Department, for its approval, with copies of the applicable Statewide Treatment Protocols, Version 12.03 (STP) governing the conditions and functions authorized in paragraph 14 of this letter, noting any deviations of care, other than those relating to transport, that the paramedic (hereinafter referred to as the "community paramedic") will be expected to follow.
 - b) Cataldo shall provide the Department with confirmation that it has notified all primary ambulance services in the geographic areas impacted as set forth in the Special Project Request.
3. This Special Project Approval shall not be construed to authorize Cataldo or any of its community paramedics to act or perform any functions beyond the Massachusetts scope of practice as defined by the STPs, except as specifically authorized by this letter and any Department-approved deviations of the STPs as set forth in paragraph 2(a).
4. Consistent with the provisions of 105 CMR 130.1503(B) governing medical control services, Jonathan Fisher, MD, as Cataldo's Affiliate Hospital Medical Director for BIDMC, shall ensure that all physicians who provide on-line medical direction to the community paramedics provide such direction only as authorized by this letter, the STPs and any Department-approved deviation of the STPs as set forth in paragraph 2(a).

5. The Special Project Approval is conditioned on limiting enrollment to PACT patients with a primary diagnosis or medical history identified as high risk for hospital readmission as set forth in the Special Project Request.
6. Cataldo will utilize a maximum of twenty-five (25) community paramedics as set forth in the Special Project Request.
7. Cataldo shall ensure that its community paramedics are: a) trained and demonstrate competency in the STPs and any Department-approved deviation of the STPs as set forth in paragraph 2(a); and b) receive specific training as described in the Special Project Request.
8. PACT shall provide advanced notification of the Special Project to its enrollees and obtain advanced written consent from the patient as described in the Special Project Request.
9. Nothing contained in the Special Project Request shall be modified or altered without prior approval of the Department.
10. The Department reserves the right to revoke the Special Project Approval at any time should it determine that Cataldo, or any of the individuals/entities identified above, fail to comply with the terms and conditions of the approval or if the Department finds that the Special Project Request endangers the public health and safety.

Limitations on Paramedic Response and Treatment

11. The Department approves Cataldo's request to waive the transport requirement contained in 170 CMR 170.355(A) for emergency responses. For purposes of this Special Project Approval, Cataldo and its community paramedics are authorized to provide emergency response services at the PACT patient's residence provided that:
 - a) the PACT patient contacts a PACT clinician and describes a condition or situation that needs (or the patient perceives the need) for immediate medical attention; and
 - b) the clinician determines that: i) VNA or other health care provider resources are not available; and ii) the patient's clinical needs would be appropriately addressed by a community paramedic response, rather than the 911 transport to the hospital's emergency room.
12. Planned visits to the PACT patient's residence do not constitute an emergency response as set forth in paragraph 11(a) and (b) and shall be specifically excluded from the Special Project Approval.
13. The community paramedics shall activate the 9-1-1 system should they determine that the patient is in need of emergency transport to a hospital as described in the Special Project Request.
14. The community paramedics are authorized to perform the following functions when dispatched to provide emergency responses as set forth in paragraph 11(a) and (b):
 - a) Patient Assessment;
 - b) Glucose Monitoring

- c) Oxygen Monitoring
 - d) ECG Monitoring; 12-lead acquisition and transmission
 - e) Basic Wound Care, not including stitching, staples, glue, suturing
 - f) Bolus Medication Administration only when authorized pursuant to medical control.
15. The following clinical interventions and functions are excluded from the Special Project Approval as these activities are outside the Massachusetts paramedic's scope of practice:
- a) Gait Meter Monitoring
 - b) Loading Medication Administration Device
 - c) Weight Monitoring
 - d) Temperature Monitoring
 - e) ISTAT Device Use
 - f) Wound/injury care that requires stitching, staples, glue, suturing;
 - g) Immunizations
 - h) Home Safety Monitoring
 - i) Fall Prevention.
16. The Department recognizes that the training received by paramedics under the *National EMS Education Standards* covers the clinical interventions of: Gait Monitoring, Loading Medication Administration Device, Temperature Monitoring, and ISTAT Device Use. The Department will reconsider its determination with regard to these interventions or functions after Cataldo provides the Department with the protocols that further define the community paramedic's role and function. Upon receipt, the Department will refer this matter to the EMCAB's Medical Services Committee and request that the Committee review and provide the Department with recommendations at their next regularly scheduled meeting.
17. The community paramedic providers shall have 24-hour access to the PACT patient's electronic medical record as described in the Special Project Request.

Cataldo's Responsibilities

18. During the term of the Special Project Waiver, Cataldo shall comply with the following conditions:
- a) Cataldo's Principal Investigator (PI) shall be responsible for maintaining the training records of the community paramedics.
 - b) Cataldo shall maintain all equipment associated with the Special Project in accordance with the manufacturers' timelines and recommendations. All service records shall be available for Department inspection at any time.
 - c) Cataldo shall ensure that any paramedic vehicle utilized for the Special Project is licensed as an Advanced Life Support Class V ambulance. The Department waives the requirement of Warning Lights and Audible Warning Devices (Administrative Requirement 5-401) for the Class V vehicle utilized in the Special Project.
 - d) The PI shall be responsible for: i) collecting Quality Assurance/Quality Improvement Data (QA/QI); ii) updating the HRSA Evaluation Tool as described in the Special Project

Request; and iii) submitting the QA/QI data and the updated HRSA Evaluation Tool to the Department on the 5th day of every month.

- e) Cataldo shall notify the Department of any changes in medical oversight or physician involvement within three (3) days of such change.
 - f) Cataldo's Clinical Director shall notify the PI and the Department's Clinical Coordinator immediately of all adverse incidents. The PI, the Medical Director for Cataldo, and/or the State Medical Director shall perform an internal review of the adverse incident and develop remediation plans, if deemed necessary. The documentation regarding adverse incidents shall be submitted to the Department.
 - g) Cataldo and all parties identified in the Special Project Request shall make all records and documents available to the Department upon request and shall cooperate with the Department in any evaluation or investigation.
 - h) Cataldo shall comply with all Department regulations, including, but not limited to, affiliation agreements, administrative requirements and advisories. Failure to comply with any requirements may result in the termination of the Special Project Approval.
19. Patricia Reilly, RN, Clinical Coordinator of the Department's Office of Emergency Medical Services will be the Department's primary contact and liaison for the Project. The Clinical Coordinator can be contacted at 617-753-7318 or by email at patricia.reilly@state.ma.us. All documentation required by this approval letter shall be sent to Patricia Reilly at 99 Chauncy Street, 11th Floor, Boston, MA 02111.

Very truly yours,



Deborah Allwes, BS, BSN, MPH
Director, Bureau of Health Care Safety and Quality

cc: Dennis Cataldo, Vice President, Cataldo Ambulance
Karen Host, Clinical Quality/Regulatory Director, Cataldo Ambulance
Jonathan Fisher, MD, Affiliate Hospital Medical Director, BIDMC
Daniel Hoffenberg, Director, Business Development, Cataldo Ambulance
Charles Pozner, MD, EMS Region IV
Derrick Congdon, EMS Director, Region IV
Alec Walker, MD, Medical Director, Region III
Michael Kass, EMS Director, Region III
Jonathan Burstein, MD, OEMS Medical Director
Patricia Reilly, Clinical Coordinator, OEMS
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