



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
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September 15, 2014

Andrew S. Levine, Esq.
Donahue, Barrett & Singal
One Beacon Street, Suite 1320
Boston, MA 02180-3106

RE: EasCare, LLC, Special Project Waiver Request for Out-of-Hospital Paramedic Care, Approval of July 25, 2014 Supplemental Submission

Dear Mr. Levine:

EasCare, LLC 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 "Out-of-Hospital Paramedic Care."

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 entitled: Out of Hospital Paramedic Care, dated February 10, 2014, as modified by the Supplemental Submission dated July 25, 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 EasCare, in collaboration with Community Care Alliance ("CCA"), to provide paramedic care to CCA patients in their residence between the hours of 6:00 PM to 6:00 AM 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: EasCare, a Department-licensed ambulance service; Gregory Davis, EasCare Project Manager; Matthew Goudreau, EasCare Clinical Director and Principal Investigator (PI); Scott Cluett III, EasCare Logistics Director; Daniel Muse, MD, Medical Director, EasCare; John Loughnane, MD, Medical Director, CCA. Boston Medical Center and Signature Healthcare Brockton Hospital (Brockton Hospital) are involved in the Project.

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 EasCare that it has satisfactorily complied with the following terms:
 - a) EasCare 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 15 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) EasCare 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 EasCare 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, Dr. Muse, as EasCare's Affiliate Hospital Medical Director for Brockton Hospital, 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 Department waives the provision of 105 CMR 170.300(E) governing delegation of medical control by the affiliate hospital and specifically authorizes Brockton Hospital to delegate on-line medical direction to CCA primary care physicians as described in the Special Project Request.
6. The Special Project Approval is conditioned on limiting the enrollment to 2,000 CCA patients located in the geographic areas of Boston (Region IV) and South Shore (Region V).
7. EasCare will utilize a maximum of ten (10) community paramedics.
8. EasCare 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.
9. CCA 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.
10. Nothing contained in the Special Project Request shall be modified or altered without prior approval of the Department.
11. The Department reserves the right to revoke the Special Project Approval at any time should it determine that EasCare, 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

12. The Department approves EasCare's request to waive the transport requirement contained in 170 CMR 170.355(A) for emergency responses. For purposes of this Special Project Approval, EasCare and its community paramedics are authorized to provide emergency response services at the CCA patient's residence provided that:
 - a) the CCA-enrolled patient calls CCA between the hours of 6 PM and 6 AM and describes a condition or situation that needs (or the patient perceives the need) for immediate medical attention; and
 - b) the clinician determines that 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.

13. Planned visits to the CCA patient's residence do not constitute an emergency response as set forth in paragraph 12(a) and (b) and shall be specifically excluded from the Special Project Approval.
14. 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.
15. The community paramedics are authorized to perform the following functions when dispatched to provide emergency responses as set forth in paragraph 12(a) and (b):
 - a) Administration of medications within the STP, at home;
 - b) Maintenance of PICC and peripheral lines in accordance with the October 10, 2003 Advisory issued by the State Medical Director. See: <http://www.mass.gov/eohhs/docs/dph/emergency-services/treatment-protocols-advisory-picc.pdf>;
 - c) Assessment and management of wounds and injuries (not including stitching, staples, glue, suturing);
 - d) Assessment of respiratory conditions, chronic heart failure, chronic obstructive pulmonary disease, diabetes, hypertension, cellulitis;
 - e) Management of nausea, vomiting and diarrhea;
 - f) Assessment of non-acute altered mental status;
 - g) Specimen acquisition and point of care testing.
16. 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) Wound/injury care that requires stitching, staples, glue, suturing; (b) Management of do not resuscitate patients; and (c) Insertion and maintenance of Foley catheters.
17. The Department recognizes that the training received by paramedics under the *National EMS Education Standards* covers "Management of do not resuscitate". The Department will reconsider its determination with respect to this intervention after EasCare provides the Department with the protocols that further define the community paramedic's role and function with regard to "do not resuscitate" patients beyond honoring MOLST and CC/DNR forms, as set forth in the STP. 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.
18. The community paramedic providers shall have 24-hour access to the CCA patient's electronic medical record as described in the Special Project Request.

EasCare's Responsibilities

19. During the term of the Special Project Waiver, EasCare shall comply with the following conditions:
- a) EasCare's Principal Investigator (PI) shall be responsible for maintaining the training records of the community paramedics.
 - b) EasCare 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) EasCare 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) EasCare shall notify the Department of any changes in medical oversight or physician involvement within three (3) days of such change.
 - f) EasCare's Clinical Director shall notify the PI and the Department's Clinical Coordinator immediately of all adverse incidents. The PI, the Medical Director for EasCare, 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) EasCare 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) EasCare 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.
20. 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: George Gilpin, President and CEO, EasCare Ambulance
Daniel Muse, MD, Medical Director, EasCare Ambulance
John Loughnane, MD, Commonwealth Care Alliance
Gregory Davis, EasCare Ambulance
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