

**OFFICE OF EMERGENCY MEDICAL SERVICES**Administrative Requirements Manual

EFFECTIVE: September 7, 2010      AUTHORIZATION: AR      PAGE: 1 of 3

A/R TITLE: WAIVERS FOR SPECIAL PROJECTS: APPLICATION PROCESS AND  
PROCEDURE FOR REVIEW AND APPROVAL

SUPERSEDES: 4/1/03

**PURPOSE:**

To define the requirements for obtaining waivers for special projects, pursuant to 105 CMR 170.405.

**DEFINITION:**

105 CMR 170.405 provides that “at the discretion of the Department, regulations established in 105 CMR 170.000 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.” The Department interprets experimental to mean innovative, and would include in this category projects that would require institutional review board (IRB) review.

**APPLICATIONS:**

All applications for waivers for special projects must be submitted in writing to the Department’s Office of Emergency Medical Services (OEMS).

**A. Each application must include the following:**

1.
  - a. Name and address of the Applicant
  - b. Licensed Ambulance Service(s) involved
  - c. Regional affiliation(s)
  - d. Hospital(s) involved in project
  - e. Contact person for special project, including address, phone number, fax number and e-mail address.
2. A detailed description of the proposed special project, indicating why a waiver is required, including, but not limited to:
  - a. Level of EMT(s) involved in the special project
  - b. The number of EMTs involved in the special project
  - c. Name of Licensee
  - d. Name of Medical Director(s) for the service, project and affiliate hospital, if relevant
  - e. Regulation(s) requiring a waiver
  - f. Purpose for/goals of special project
  - g. Proposed time frame for special project
  - h. Nature of the project
  - i. Description of the population to be served by the special project
  - j. A letter of review and evaluation from the relevant regional Medical Director and Executive Director

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3. Analysis of available literature that supports the safety and efficacy of the proposed waiver and a description of why the public health and safety will not be compromised by the proposed special project.
4. Documentation of EMS programs in other states with the same or comparable projects, if available, including a description of the duration of the program and a summary of the results.
5. Plan for QA/QI and on-going review of the special project with specific time frames, guidelines and evaluation tools. Include the name of the individual responsible for quality review and the organizational structure for quality review. This section should include a description of factors that would mandate that the special project waiver designation be withdrawn, if specific conditions are not met.

**B. Review and Approval of Applications for Special Projects**

Applications may be submitted at any time. The Department's OEMS shall review all applications for special projects upon receipt to determine whether the application is complete. No application will be considered if incomplete.

1. The Medical Services subcommittee of EMCAB will review all applications. The Department will set the time schedule for review of such applications. The subcommittee, upon review, will make a recommendation on relevant clinical aspects of special project proposals.
2. The State EMS Medical Director will review with the Department any Medical Services subcommittee recommendations.
3. EMCAB committee review shall include clinical review by the Medical Services subcommittee described above and may include Executive Committee, full EMCAB and other Standing Committee review, at the Department's discretion.
4. The Department shall review all recommendations from EMCAB subcommittees and is the only entity with authority to approve special project waivers. Approval is not final until it is signed by the Director of the Department's OEMS.

**C. Conduct of Special Projects**

1. No special project shall commence until the applicant receives written authorization from the Department. The Department shall have the right to deny consideration of approval for any applicant who commences the special project prior to receiving explicit written approval from the Department.

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2. The Department may attach conditions to the approval of special projects, which must be met in order to conduct the special project with Department approval.
3. Special projects will be required to submit data results quarterly. Failure to submit data timely may constitute a basis for revocation of the approval and disqualify the project from consideration for renewal.
4. Special projects may be approved for one or two years, and may be renewed for comparable periods, if the extension is justified to fulfill the stated goals of the project.
5. Once approved and under way, special projects may be amended only with the explicit approval of the Department.
6. The Department may deny, suspend or revoke any special project approval, under the following circumstances:
  - a. The continuation of the project is a threat to the public health and safety;
  - b. Conduct of the project fails to adhere to all the terms and conditions of the special project designation;
  - c. Designated representatives of the project fails to submit required data, or
  - d. Designated representatives of the project fail to cooperate with the Department.
7. Approval of a special project waiver is subject to the Department's discretion. Denial of a special project waiver is not subject to administrative appeal.