



MEMORANDUM

To: Board of Maine Emergency Medical Services
From: Maine EMS Rules Sub-Committee
Date: September 19, 2023
Subject: Pilot Project Rule

Introduction:

Pilot Programs/Projects are being utilized more as our system looks to explore and understand the way prehospital medical care is provided in our State. They have expanded from the incorporation of a particular emergency medical treatment technique or piece of equipment to exploring alternative methods and structures of delivery of services (Maine Operational Physician Pilot Project, Jackman Pilot Project, Portland Mobile Medical Outreach). It is appropriate to review our current rules and to consider formulating a separate pilot program/project chapter to address this expansion. Clearly defined expectations and processes are necessary to protect the health, welfare, and safety of the residents and visitors to the State of Maine. There may be additional value in defining the involvement and expectations of the MDPB in the review and authorization of these pilot programs/projects.

Background:

Currently, Maine EMS's rules address Pilot Projects in three areas:

- Ch. 3 § 10 - "For the purpose of evaluating the workability and appropriateness of incorporating a particular emergency medical treatment technique or a type of equipment into any licensure level, the Board may elect to exempt a service from the requirements of the relevant licensure level so as to permit the service to utilize the designated techniques or equipment on an experimental basis. Such authorizations may be continued at the discretion of the Board. Such authorizations should not be construed as levels of licensure."
- Ch. 4 §12 - "For the purpose of evaluating the workability and appropriateness of incorporating a particular emergency medical treatment technique or a type of equipment into any licensure level, the Board may elect to exempt a service from the requirements of the relevant licensure level so as to permit the service to utilize the designated techniques or equipment on an experimental basis. Such authorizations may be continued



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- Ch. 18 §2(1) – “The Maine EMS Quality Assurance and Improvement Committee is authorized by the Board to perform EMS system quality assurance and improvement, including, but not limited to...G. Reviewing quality assurance and improvement management of Board-approved pilot projects when requested by the Board, the Medical Direction and Practices Board or the pilot project participant(s)...”

The language currently found in our rules addresses an emergency medical treatment technique or equipment, but not a structure for alternative delivery of services or service structure. The current language does not address with clarity any processes for applying to the Board for authorization, changes in programs/projects while authorized, and expectations of Board/MDPB/committee involvement.

Furthermore, it does not appear the Maine EMS QA/QI Committee participates with any frequency in the review of pilot projects.

Suggested Action:

That the Rule Subcommittee approaches the Board to consider creating a chapter of rule addressing pilot programs/projects, with topic areas that may include:

- Application Standards:
 - A project/program timeline
 - A project/program outline
 - Metric(s) (What is being measured, how is it significant)
 - Goal(s)/Outcome(s)
 - Impacted population(s)
 - What notice or communication to the affected population, if any, should occur?
 - Disclosure of conflicts of interest
 - Project/program funding (if applicable)
 - Overall project/program responsibility
- Reporting requirement(s):
 - Frequency/schedule of reporting/updates
 - Is there any desire to set a standard for a graduated reporting process (i.e. first-year monthly, 2nd every two months, 3rd year quarterly, etc.)?
 - Establishing a process for determining the appropriateness of report recipients (i.e. MDPB, Board, QA/QI Committee, etc.)
- Authorization of Changes to the Pilot Program/Project after initial approval:
 - Who can modify the Program/Project (Board, MDPB, combination)?



- What is the expectation of when/how changes are communicated to impacted populations?
- Term of authorization and process for re-authorization:
 - What is the maximum amount of time a project should be authorized
 - How does a project receive an extended authorization/renewal of authorization
 - What is the pathway through which a project/program moves from pilot to standing (i.e. exit ramp)
- Accountability:
 - Process and expectations for evaluating deviations from the authorized program/project (i.e. personnel/service issues to investigations, project/case review to MDPB or QA/QI committee, revocation of authorization by the Board, etc

Conclusion:

As the use of pilot programs/projects expands and more entities seek approval from the Board for these efforts, it is necessary to review our current rules and adjust, where and as needed, the rules to support these programs and projects while maintaining guardrails necessary for the health, safety, and welfare of the public. It is also necessary to ensure that there are clearly communicated and defined expectations of pilot program/project participants, the Board, its sub-committees, the MDPB, the Office of Maine EMS, and other advisory committees.