

Monterey County EMS System Policy



Policy Number: 6170
Effective Date: 7/1/2023
Review Date: 6/30/2026

PILOT PROGRAMS

I. PURPOSE

- A. To define the process by which the Monterey County EMS Agency plans, develops, implements, and monitors Pilot Programs.

II. POLICY

- A. The EMS Agency Director and Medical Director must review and approve all Pilot Programs prior to implementation.
- B. Pilot Program studies are typically small scale and short term for the purpose of evaluating quality indicators and/or operational improvements for local EMS policies and/or protocols.
- C. Projects involving any of the following will be considered as research and require approval according to the Monterey County EMS System Policy #6160 (Research Policy):
 1. Changes in the State EMS Authority EMT-P Scope of Practice or untested intervention.
 2. The goal of the project is to test a hypothesis.
 3. The investigators intend to submit the results for publication in a professional journal.
 4. When questions arise as whether a project is quality improvement versus research, the investigator will consult with the Institutional Review Board.
- D. The Pilot Program Investigator(s) shall submit a Pilot Program Proposal to the EMS Agency at least three (3) months prior to the planned implementation date in order to allow time for the Pilot Program Review Process.
 1. The EMS Agency shall review the Pilot Program Proposal and solicit EMS Stakeholder input through the most appropriate EMS advisory subcommittee, either the Medical Advisory Subcommittee (MAC) or Operations Subcommittee (OPS), or both. Recommendations from the EMS Agency and the EMS advisory subcommittee shall be presented to the Emergency Medical Care Committee (EMCC) for review, discussion, and recommendations.
 2. The Pilot Program Proposal shall include the following:

- a) Background/Significance: Describe the rationale for the Pilot Program, citing relevant research. Identify what questions remain and how the proposed Pilot Program will address these questions. Specify how the Pilot Program may improve the quality of care in the EMS System.
- b) Objectives: List the objectives upon which the outcome of the Pilot Program will be based. Identify the predictor and outcome variables and the expected outcome of the Pilot Program.
- c) Design/Methods: Identify the type of study, the outcome variables to be measured, and how each outcome variable is an indicator of quality of care. Describe the methods used to collect the data and avoid bias.
- d) Evaluation: Describe the data management and statistical methods that will be used to evaluate the data. Include methods used to minimize bias and standards or benchmarks proposed to accept the conclusions.
- e) Conflicts of Interest: Identify and describe any proprietary, personal, familial, social, professional, or financial (*e.g.*, salary, consultant payments, honoraria, royalty payments, dividends, loans, or any other payments or remunerations) conflicts of interest.
- f) References: Provide copies of references cited in the protocol.

III. PILOT PROGRAM REVIEW PROCESS

- A. The EMS Agency Director and Medical Director shall review the Pilot Program Proposal and will present the Pilot Program to the most appropriate subcommittee(s) (MAC and/or OPS) for review and discussion.
- B. Feedback from the reviewing subcommittee will be incorporated into the EMS Agency's presentation of the Pilot Program to EMCC, which shall review the protocol, provide feedback, and vote to recommend approval, modifications, or disapproval of the proposed Pilot Program. Recommendations from EMCC and the reviewing subcommittee shall be considered by the EMS Agency Medical Director, who will make the final determination on whether to approve or deny the implementation of the Pilot Program.
- C. If approved, the data collection period is one (1) year or as determined by the EMS Medical Director.

IV. REPORTING PROCESS

- A. Monthly Reports: The Pilot Program Investigator(s) shall submit monthly reports to the EMS Agency on the 15th day of each month. These reports must summarize the progress of the program and evaluate available outcome data from the previous month. The need for quarterly reports in addition to or instead of monthly reports will be determined by the EMS Agency Medical Director.
- B. Final Report: At the end of the data-collection period, the Investigator must submit a final report to the EMS Agency Medical Director. The final report must include a summary of the Pilot Program including the objectives, methods, data analysis of the outcome

variables, limitations of the study, and conclusions. The final report is due no later than the 15th day of the 3rd month following completion of the data-collection period.

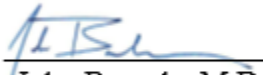
V. EARLY DISCONTINUATION

- A. If, under the judgment of the EMS Medical Director, patient safety concerns or preliminary data demonstrate compelling evidence warranting suspension or early discontinuation of the Pilot Program, the EMS Agency Medical Director may suspend or discontinue the Pilot Program at any time.

VI. COMPLETION OF THE PILOT PROGRAM

- A. The EMS Agency will present the results of the Pilot Program to EMCC and the most appropriate subcommittee(s) (MAC and/or OPS). Members may offer recommendations pertaining to continuation, modification, or discontinuation of the program.
- B. The EMS Medical Director will assign one of the following designations to the Pilot Program:
 - 1. Approved – The Pilot Program demonstrates improved quality of care or benefits the EMS System and its patients, as determined by the EMS Medical Director. The program may be modified or continued under a Local Optional Scope of Practice or revision to EMS policies and/or treatment protocols, pursuant to Monterey County EMS System Policy #1000 (Policy and Procedure Development Process).
 - 2. Extended (up to one year) – There is insufficient data to evaluate the impact of the Pilot Program on quality of care or the EMS System. The data-collection period shall be extended for a defined period of time not to exceed an additional one year from completion of the initial data-collection period.
 - 3. Discontinued – The Pilot Program does not demonstrate improved quality of care or benefit the EMS System and its patients, as determined by the EMS Medical Director. The Pilot Program will be discontinued.

END OF POLICY


John Beuerle, M.D.
EMS Medical Director


Teresa Rios
EMS Bureau Chief