

 <b>COUNTY OF SAN DIEGO</b> EMERGENCY MEDICAL SERVICES	SYSTEMS		<b>S-070</b>
	<b>SPECIAL PROJECT PROPOSALS</b>		
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## I. PURPOSE

To establish a procedure for submission and evaluation of community proposals for authorization to pilot prehospital treatments, policies, standards, equipment, practices, education, or other medical interventions not currently authorized by local policies and protocols.

To ensure that community proposals promote the foundational principles of patient and clinician safety, patient-centered care, evidence-based practices, clinical efficacy, health equity, comprehensive data collection, and continuous quality improvement.

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**II. AUTHORITY:** California Health and Safety Code Section 1797.200, 1797.204, 1797.206, 1797.208, 1797.214, 1797.220, 1797.221, 1797.223, 1797.227, 1798 *et seq.*

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## III. DEFINITIONS

**San Diego County EMS Office (CoSD EMS):** The designated Local EMS Agency (LEMSA) for the County of San Diego. LEMSAs function, as authorized in California Health and Safety Code, Division 2.5, Sections 1797 & 1798 *et seq.*, include providing medical oversight and assuring medical accountability through the planning, implementation, and evaluation of the prehospital health care system within the LEMSAs' geographic boundaries.

### **Foundational Principles:**

1. Safety
2. Patient-centered
3. Evidence-based
4. Clinical efficacy
5. Health equity
6. Comprehensive data collection
7. Continuous quality improvement

**Community Partner Proposal:** A project aimed to evaluate safety and efficacy of any change in prehospital patient management. Proposals may include evaluation of safety and efficacy of medications or equipment, expanded scopes of practice, research projects, and any other proposal

that alters patient management. This includes proposed changes performed by any EMS clinician or public safety professional at all levels of the EMS system from dispatch to definitive care.

Proposal categories include, but are not limited to:

1. Modifications to local protocols or policies, including the use of new medical equipment or clinical interventions
2. Research
3. Quality improvement
4. Scope of practice
5. Patient care access or existing patient outreach programs

**EMS Clinician:** Prehospital care personnel credentialed as Emergency Medical Technicians (EMTs), Advanced EMTs (AEMTs), Paramedics, or CoSD EMS-authorized Registered Nurses operating within the organized EMS delivery system and within established local and state scopes of practice.



#### **IV. POLICY**

The CoSD EMS Medical Director has statutory authority for establishing all prehospital medical policies, protocols, and procedures, including credentialing, training, treatment, and performance standards. Not all proposals will be deemed to require CoSD EMS authorization, tracking, or review.

A community partner may submit a proposal to CoSD EMS for consideration. CoSD EMS staff may consult with the requestor for proposal clarifications. CoSD EMS may refer proposals to relevant advisory bodies for additional evaluation. The CoSD EMS Medical Director has final decision-making authority.

##### **A. Community Partner Proposal Requirements**

1. Description of scope and purpose, including:
  - a. Evidence-based and patient-centered need for the program
  - b. Definition of the proposed changes to current practice or policy
  - c. Measurable program goals and outcomes
  - d. Adherence to Foundational Principles
2. Details and descriptions of the proposed program's:
  - a. Geographic area of coverage

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- b. Intended operation (e.g., as needed, during surge events, as a regular system, or a special resource)
- c. Implementation timeline
- d. Process for integration with the organized EMS system and receiving facilities
- e. Credential levels for intended EMS clinician participants
  - i. The proposal should include the identification of any additional credentialed medical professionals who interact with EMS clinicians or are integrated into the EMS delivery system.
- 3. Policies and procedures for modifications to:
  - a. CoSD EMS policy or practice, including the response to, clinical management of, and disposition of EMS patients
  - b. Current patient care pathways, including alterations to current CoSD EMS policy and practice
  - c. CoSD EMS inventory, including types of and par levels of medications and equipment
- 4. Education and training materials
  - a. A description of education and training program(s), including educational materials, knowledge assessments, and any clinical observation that may be required
- 5. Processes to ensure patient safety and health equity, including reporting frameworks, longitudinal monitoring, and other strategies to demonstrate adherence to the Foundational Principles
- 6. Quality management plan that integrates with the CoSD EMS quality management plan, including:
  - a. *A priori* criteria to determine pilot period duration
  - b. A procedure for reporting deviations and adverse events in policies, protocols, or pilot programs to CoSD EMS
  - c. A procedure for sharing quality management data with program participants
  - d. The data collection, monitoring, case review, trend analysis, and anticipated quality improvement process
  - e. Defined quality measures (e.g., outcome, process, balancing measures tracked throughout implementation)
  - f. Complies with all CoSD EMS Quality Management Plan provisions
  - g. CoSD EMS may require the collection and submission of additional data and patient care report rates
- 7. Anticipated use rates of the proposed program
- 8. Data submission and reporting to CoSD EMS
  - a. Reporting frequency shall be at least monthly during initial program implementation
  - b. Program data submission shall comply with the requirements of California Health and Safety Code Section 1797.227

9. Written statement of support to include an analysis of current scientific evidence supporting implementation of the proposal from the proposing organization's medical advisor.
10. Proposals meeting State EMS Authority (EMSA) trial study or Local Optional Scope of Practice (LOSOP) criteria, shall include all criteria above and:
  - a. Alternatives to the proposed treatment, procedure, or intervention. This should include any advantages and disadvantages of the proposed treatment, procedure, or intervention when compared to the current treatment alternatives.
  - b. Estimated frequency of use of the proposed treatment, procedure, or intervention
  - c. Supporting data for the proposed treatment, procedure, or intervention, including relevant studies and medical literature
  - d. Commitment to attend advisory committee meetings, including at the state-level, when the proposal is being evaluated
11. Proposals meeting trial studies requiring EMSA approval, shall include all items in IV. A. 1-10 and:
  - a. Research protocols
  - b. Ethics review status (i.e., Institutional Review Board presentations and approvals)
  - c. Process for participant consent, including meeting *Exception From Informed Consent* (EFIC) requirements when indicated
  - d. Additional supporting documentation demonstrating compliance with California Health and Safety Code section 1797.221

**B. EMS Research and Academic Data Request Requirements**

1. Local EMS System participants requesting CoSD EMS support for research projects shall submit and specify the following:
  - a. Requested data sources
    - i. Limited data set information and definitions
    - ii. Confidentiality standards
  - b. Data acquisition methods
  - c. Research protocols
  - d. Estimated research timeframe
  - e. Estimated CoSD EMS staff time commitment
  - f. Ethics review status
  - g. Process for participant consent, as relevant
2. Research support requests must align with:
  - a. the Foundational Principles
  - b. CoSD EMS performance improvement goals, and
  - c. CoSD EMS's statutory and regulatory requirements

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3. For research that may disclose the identity of the individual or organization, data access authorization is required. This authorization shall include written permission from the organization's executive officer for CoSD EMS to release organization-identifiable data for research use. This written authorization shall be provided to CoSD EMS before any data are released. CoSD EMS will validate any such authorization.
  4. For data requests beyond the purview of CoSD EMS, the community partner will be referred to the relevant entities who own or maintain the data.
- C.** CoSD EMS may assess fee(s) for Special Project reviews, research, analysis, or data project authorization.
- D.** The CoSD EMS Medical Director may transition Special Projects from trial or pilot status to established programs after metrics demonstrate operational safety, efficacy, and equity, in alignment with the Foundational Principles.
1. Pilot programs may convert to:
    - a. Adoption as a system policy or protocol; or
    - b. Refinement and reassessment after additional data collection; or
    - c. Discontinuation.
  2. Transition from special/pilot authorization to standard policy, protocol, or procedure may require EMSA and/or State of California authorization; a written agreement with CoSD EMS; and ongoing, regular reporting.
- E.** CoSD EMS may rescind authorization for a Special Project for policy non-compliance (e.g., failure to meet requirements for data submission, reporting, or other quality metrics).
- F.** CoSD EMS may rescind authorization for any Special Project at the CoSD EMS Medical Director's discretion. Special Project Authorization may be ended early if supported by established metrics for patient safety, equity, or efficacy data.