

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

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

To ensure that ~~proposed modifications in EMS patient care align with community proposals promote~~ the foundational principles of patient ~~and clinician safety~~, patient-centered ~~approach~~ care, evidence-based ~~practice, patient safety, practices~~, clinical efficacy, health equity, ~~robust comprehensive~~ data collection, and continuous quality improvement.

Commented [A1]: Clarified language

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.*

## III. DEFINITIONS

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

Commented [A2]: Added LEMSAs definition

### Foundational Principles:

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

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**Community Partner Proposal:** A project aimed to evaluate improvements in 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 and clinical outcomes. Project.

**Commented [A3]:** Added additional detail to clarify what types of projects may qualify as a Community Partner Proposal

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
- 2-3. Quality improvement
- 3-4. Local Optional Scope of Practice (LOSOP) practice
4. Enhanced Care Access Programs
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.

**Commented [A4]:** Added definition for what types of medical practitioners may be included in a Special Project

#### IV. POLICY

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

**Commented [A5]:** Re-drafted policy statement for clarity

##### A. LEMSA Community Partner Proposal Requirements

Community partner proposals shall include:

**Commented [A6]:** Refined Special Project Proposal elements to be inclusive of the many program, clinical, and operational variations

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1. ~~Scope~~Description of scope and purpose, including:
  - a. ~~A statement demonstrating an evidence~~Evidence-based and patient-centered need for the program
  - b. ~~Includes definition~~Definition of the proposed changes ~~into~~ current practice or policy
  - c. ~~Identifies measurable~~Measurable program goals, ~~outputs,~~ and outcomes
    - i. ~~Addresses the foundational principles~~
  - d. ~~A description~~Adherence to Foundational Principles
2. Details and descriptions of the proposed program's geographic:
  - ~~d.a.~~ Geographic area of coverage
  - ~~e.b.~~ A description of the program'sIntended operation (e.g., as needed, during surge events, as a regular system, or ~~on-call~~ as needed a special resource)
  - ~~f.c.~~ A description andImplementation timeline of how the program will be implemented
  - ~~g.d.~~ A description of how the program will interfaceProcess for integration with the organized EMS system and receiving facilities
  - ~~h.~~ A detailed list of staff classifications or employees participating in the proposed program. CoSD EMS must be notified in writing within 10 calendar days if staffing patterns or other changes occur
  - ~~e.~~ Proposed program policiesCredential 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.
- ~~2.3.~~ Policies and procedures for modifications to:
  - ~~a.~~ A description of any deviations from the CoSD EMSCoSD EMS policy or practice, including the response to, clinical management of, and disposition of EMS patients
  - ~~b.~~ A description of any innovativeCurrent patient care pathways ~~not currently in place,~~ including alterations to current CoSD EMSCoSD EMS policy and practice
  - ~~c.~~ A description of any modification from the CoSD EMS formulary or inventory, how equipment and drugs will be stored and/or transported, and a program for equipment maintenance
  - ~~d.~~ CoSD EMS inventory, including types of and par levels of medications and equipment
- ~~3.4.~~ Education and training materials
  - a. A description of ~~the associated~~ education and training program(s), including ~~draft~~ educational materials, knowledge assessments, ~~skills stations,~~ and any clinical observation that may be required, ~~depending on the proposed program's scope and goals~~

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- ~~4-5.~~ Processes to ensure patient safety and health equity, including reporting frameworks, longitudinal monitoring, and other strategies to demonstrate efficacy/adherence to the Foundational Principles
- ~~5-6.~~ Quality ~~assurance and management plan that integrates with the CoSD EMS quality improvement/management plan, including goals and metrics:~~
- ~~a.~~ A ~~process/priori~~ criteria to determine pilot period duration
  - ~~a-b.~~ A procedure for reporting policy, protocol, pilot program discrepancies, or deviations and adverse events to the in policies, protocols, or pilot program agency or hospital provider and CoSD EMS programs to the CoSD EMS
  - ~~b.~~ A quality improvement plan (e.g., a standalone plan or an amendment to an existing EMS organization Quality Improvement Plan)
  - ~~c.~~ The QA/QI plan should describe the specialty program's A procedure for sharing quality management data with program participants
  - ~~c-d.~~ The data collection, monitoring, case review, trend analysis, and anticipated quality improvement process
  - ~~e.~~ The QA/QI plan must comply Defined quality measures (e.g., outcome, process, balancing measures tracked throughout implementation)
  - ~~d-f.~~ Complies with all CoSD EMS/CoSD EMS Quality Improvement/Management Plan provisions and include provisions for 100% review of all patient care reports in which the special program was attempted or utilized
  - ~~e-g.~~ CoSD EMS/The CoSD EMS may require the collection and submission of additional data and patient care report rates
- ~~6-7.~~ Anticipated ~~utilization/use~~ rates of the proposed program
- ~~7-8.~~ Data submission and reporting to ~~CoSD EMS/the CoSD EMS~~
- ~~a.~~ Reporting frequency shall be at least monthly during ~~the~~ initial program implementation
  - ~~b.~~ Data/Program data submission ~~must meet or exceed/shall comply with the~~ requirements of California Health and Safety Code Section 1797.227 ~~prior to implementation~~
- ~~8.~~ Proposed milestones and program review with CoSD EMS
9. Written statement of support to include an analysis of current scientific evidence supporting implementation of the proposal from the proposing agency's/organization's medical advisor.

**~~B.~~ Proposals meeting State EMS Authority (EMSA) Requirements**

~~The LEMSA Medical Director shall submit proposals determined to meet LOSOP or trial study or Local Optional Scope of Practice (LOSOP) criteria to EMSA for approval.~~

- ~~4-10.~~ Program requests, shall include all ~~items included in IV. A. criteria above~~ and:

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- ~~a. Clearly defined proposed treatment, procedure, or intervention~~
- ~~b. Description of the medical condition(s) the intervention would treat~~
- ~~e.a. Current treatment alternatives~~ 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.
- ~~d.b. Estimated frequency of use of the proposed treatment, procedure, or intervention~~
- ~~e.c. Supporting data for the proposed treatment, procedure, or intervention, including relevant studies and medical literature~~
- ~~f. Proposed policies, procedures, or treatment indications for the proposed treatment, procedure, or intervention~~
- ~~g.d. Commitment of the proposing organization to travel to various~~ attend advisory bodies/committee meetings, including at the state-level committees, when the proposal is being evaluated

~~2.11. Requests for CoSD EMS support of~~ Proposals meeting trial studies requiring EMSA approval, shall include all items in IV. A. & ~~C-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, as when indicated
- d. Additional supporting documentation demonstrating compliance with California Health and Safety Code section 1797.221

**Commented [A7]:** Included a proposal's potential need for independent consent or ethics review

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

- 1. Local EMS System participants, ~~hospital-based programs, and academic researchers may request CoSD EMS requesting CoSD EMS support for EMS-based or field research. These requests projects~~ shall ~~include~~ 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~~ CoSD EMS staff time commitment ~~for research conduct~~
  - f. Ethics review status
  - g. Process for participant consent, if necessary as relevant

**Commented [A8]:** Clarified elements for research projects

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2. Research support requests must align with:

- a. the Foundational Principles
- b. CoSD EMS performance improvement goals, and
- c. the CoSD EMS's statutory and regulatory requirements

2.3. For research that may disclose the identity of the ~~care provider (i.e., individual or organization or individual)~~, data access authorization is required. This authorization shall include written permission from the organization's executive officer for ~~CoSD EMS~~ the CoSD EMS to release ~~agency/organization~~-identifiable data for research use. This written authorization shall be provided to ~~CoSD EMS~~ the CoSD EMS before any data ~~may be~~ are released. ~~CoSD EMS reserves the right to~~ The CoSD EMS will validate any such authorization.

4. CoSD EMS For data requests beyond the purview of ~~the CoSD EMS~~, the community partner will be referred to the relevant entities who own or maintain the data.

~~D.C. The CoSD EMS~~ may assess ~~established~~ fee(s) for Special ~~Program~~ Project reviews, research, analysis, or data project authorization.

D. CoSD EMS ~~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 ~~the CoSD~~ CoSD EMS; and ongoing, regular reporting.

E. The 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).

~~E.F. The CoSD EMS~~ may rescind authorization for any Special ~~Program~~ Project at the ~~CoSD EMS~~ CoSD EMS Medical Director's discretion. Special ~~Program~~ Project Authorization may be ended early if supported by established metrics for patient safety, equity, or efficacy ~~indicate such action is appropriate~~ data.

**Commented [A9]:** Provided process for Special Project transitions

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~~CoSD EMS will rescind authorization for Special Programs that fail to maintain the requirements outlined within this policy (e.g., data submission, reporting, and other QAVQI metrics).~~

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