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S-070

SPECIAL PROGRAM AUTHORIZATIONS

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I. PURPOSE

To establish the requirements for applying for special program authorization.

To build and lead an adaptable and innovative EMS system by providing a framework to demonstrate Special Program efficacy, equity, and patient safety to meet the evolving needs of the population.

To establish guiding principles for the development, implementation, evaluation, and review of special programs in the EMS delivery system.

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. DEFINITION(S)

Special Program Guiding Principles: Special Program design must serve the needs of the patients, families, clinicians, and communities using six guiding principles:

- 1. Inherently safe and effective,
- 2. integrated and seamless,
- 3. reliable and prepared,
- 4. socially equitable,
- 5. sustainable and efficient, and
- 6. adaptable and innovative.

Special Program: A research or pilot project to evaluate for improvements or an alternative approach to existing CoSD EMS policies and procedures to enhance the EMS delivery system, such as special field response methods, adoption of optional scopes of practice, emergency intake strategies, or alterations to medical call-taking and dispatch.

Commented [BC1]: Numbered list instead of dotpoints.

Commented [BC2]: Added clarification to better describe projects related to background research as compared to operational or clinical pilots.

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IV. POLICY

A Special Program may be requested by field provider agencies, hospital or specialty care providers, training providers, and other organizations within the EMS delivery system. All EMS providers interested in implementing pilot programs related to the triaging of emergency medical requests for service, patient care management, or other elements within the CoSD EMS Medical Director's purview shall submit a written request and pilot proposal for review and consultation. CoSD EMS staff will review proposals in the order received. Staff consultation and plan refinement with the pilot program requestor are likely. Program proposals may require additional comments from CoSD EMS advisory bodies for a well-rounded review.

A. Local EMS Agency Reviews and Authorization Standards

Requests for CoSD EMS approval shall include:

- 1. Special program scope and purpose
 - A statement demonstrating an evidence-based and patient-centered need for the program
 - 1) Includes definition of proposed alterations compared to current practice or policy
 - 2) Identifies measurable program goals, outputs, and outcomes
 - 3) Addresses the Special Program's six guiding principles
 - b. A description of the program's geographic area
 - A description of the program's operation (e.g., as needed, during surge events, as a regular system or on-call resource)
 - d. A description and timeline of how the program will be implemented
 - e. A description of how the program will interface with the organized EMS system
 - f. A detailed list of staff classifications or employees participating in the proposed program. CoSD EMS must be notified in writing within 10 days if staffing patterns or other changes occur
- 2. Proposed program policies and procedures
 - a. A description of any deviations from the CoSD EMS policy or practice, including the response to, clinical management of, and disposition of EMS patient contacts
 - b. A description of any innovative patient care pathways not currently in place, including deviations from current CoSD EMS policy and practice
 - c. A description of any deviations from the CoSD EMS formulary or inventory, how equipment and drugs will be stored and/or transported, and a program for equipment maintenance
- 3. Education and training materials
 - a. A description of the associated training program(s), including draft educational materials, knowledge assessments, manipulative stations, and any clinical observation that may be required, depending on the proposed program's scope and goals

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- 4. Processes to ensure patient safety and health equity, including reporting frameworks, longitudinal monitoring, and other strategies to demonstrate efficacy
- 5. Quality assurance and quality improvement plan, including goals and metrics
 - a. A process for reporting policy, protocol, pilot program deviations, or adverse events to the pilot program EMS or hospital provider and CoSD EMS.
 - b. A quality improvement plan (e.g., a standalone plan or an amendment to an existing EMS provider Quality Improvement Plan)
 - The QA/QI plan should describe the specialty program's data collection, monitoring, case review, trend analysis, and anticipated quality improvement process
 - The QA/QI plan must comply with all CoSD EMS Quality Improvement Plan provisions and include provisions for 100% review of all patient care reports in which the special program was attempted or utilized
 - 3) CoSD EMS may require the collection and submission of additional data as necessary
- 6. Anticipated utilization rates of the proposed program
- 7. Data submission and reporting to CoSD EMS
 - a. Reporting frequency shall be at least monthly during the initial program implementation
 - Data submission must meet or exceed California Health and Safety Code 1797.227 prior to implementation
- 8. Proposed milestones and program review with CoSD EMS
- 9. Written statement of support from the proposing agency medical director
- **B.** A special program proposal should include early consultation with CoSD EMS, prior to endorsement by a local government body. This advanced communication allows for the most efficient and successful approach to authorization and implementation.
- C. State EMS Authority and Local EMS Agency Reviews and Authorization Standards

Some programs may require additional authorizations, including California EMS Authority review and approval.

- 1. Program requests that may include Local Optional Scope of Practice application to the California EMS Authority shall include all items included in IV. A. and:
 - a. Clearly defined proposed treatment, procedure, or intervention
 - b. Description of the medical condition(s) the intervention would treat
 - c. Current treatment 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. Estimated frequency of use of the proposed treatment, procedure, or intervention
 - Supporting data for the proposed treatment, procedure, or intervention, including relevant studies and medical literature

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- f. Proposed policies, procedures, or treatment indications for the proposed treatment, procedure, or intervention
- g. Willingness of the proposing organization to travel to various advisory bodies, including state level committees.
- 2. Requests for CoSD EMS support of trial studies requiring California EMS Authority approval shall include all items in IV. A. & C. and:
 - a. Research protocols
 - b. Ethics review status (i.e., Institutional Review Board presentations and approvals)
 - c. Process for participant consent
 - d. Any other supporting documentation demonstrating compliance with California Health and Safety Code section 1797.221

D. Local EMS Agency Research and Academic Data Requests Review and Authorization Standards

Local EMS System participants, hospital-based programs, and academic researchers may request CoSD EMS support for EMS-based or field research. These requests shall include:

- 1. Requested data sources
 - a. Limited data set information and definitions
 - b. Confidentiality standards
- 2. Data acquisition methods
- 3. Research protocols
- 4. Estimated research timeframe
- 5. Estimated CoSD EMS commitment for research conduct
- 6. Ethics review status
- 7. Process for participant consent, if necessary
- 8. For research that may disclose the identity of the care provider (i.e., organization or individual), data access authorization is required. This authorization shall include written permission from the organization's executive officer for CoSD EMS to release agency-identifiable data for research use. This written authorization shall be provided to CoSD EMS before any data may be released. CoSD EMS reserves the right to validate any such authorization.

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- E. CoSD EMS may assess established fee(s) for Special Program reviews, research, analysis, or data project authorization.
- F. CoSD EMS may rescind authorization for any Special Program at the EMS Medical Director's discretion. Special Program Authorization may be ended early if established metrics for patient safety, equity, or efficacy indicate such action is appropriate.
- G. 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 QA/QI metrics).