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TITLE 22, CALIFORNIA CODE OF REGULATIONS
DIVISION 9. Prehospital Emergency Medical Services, Chapter 6: Critical and Specialty Care

INITIAL STATEMENT OF REASONS

INTRODUCTION

In 1980, the Emergency Medical Services System and Prehospital Emergency Care Personnel Act was signed into law, establishing the Emergency Medical Services Authority (EMSA) and introducing Division 2.5 of the Health and Safety Code (Sections 1797-1799). This act laid the foundation of the California's Emergency Medical Services (EMS) system, providing a comprehensive framework to ensure the coordination and delivery of high-quality emergency medical care statewide. Over the decades the act has been expanded, with additional provisions codified to address the evolving needs of the EMS system.

California's EMS system operates as a two-tiered structure. At the state level, EMSA provides overarching policy, regulatory guidance, and system oversight. Locally, this responsibility is carried out by the 34 Local Emergency Medical Services Authority (LEMSAs), which tailor EMS oversight to meet the specific needs of their regions. While most LEMSAs manage a service within a single county, several oversee multiple counties, reflecting the diverse geography and population distribution of California.

This system ensures a cohesive yet flexible approach to emergency medical care, enabling statewide standards to be implemented effectively while addressing local healthcare priorities and challenges.

PROBLEM STATEMENT

The current regulations in Chapter 6, Critical and Specialty Care Programs, govern trauma, ST-elevation myocardial Infarction (STEMI), stroke and EMS for Children (EMSC) systems, are established under Health and Safety Code Division 2.5. These regulations were previously distributed across multiple chapters and articles but have since been consolidated into Chapter 6 to streamline oversight and improve regulatory clarity for critical and specialty care programs.

These regulations have not been updated in more than seven years, during which time significant advancements in clinical practice, operational and clinical changes and advancements in hospital critical and specialty care,

specialty care center (trauma, STEMI, stroke) designation, and pre-hospital specialty care necessitating an update to existing regulations so that prehospital specialty care in California remains current with existing standard of care.
The proposed revisions were developed in collaboration with the California State technical advisory committees for Trauma, STEMI, Stroke, and EMSC. These committees, which include critical and specialty care physicians, hospital program coordinators, local EMS administrators and medical directors, provided expert input to ensure the updated regulations address the evolving needs of patients, healthcare providers, and the broader EMS system

ANTICIPATED BENEFITS
The proposed updates to the Critical and Specialty Care System regulations aim to align California's EMS with current national standards of care. By modernizing these regulations, the state will ensure that trauma, STEMI, stroke, and EMSC deliver consistent, high-quality care that reflects the latest clinical practices and operational advancements.
A key objective of the proposed changes is to standardize the designation process for specialty care centers, ensuring they meet the national recognized requirements for trauma, STEMI, stroke and EMSC care. This will enhance consistency across the state reducing variability in how specialty care programs are designed and maintained. The updates will introduce clear definitions and protocols for re-triage and inter-facility transfers, ensuring that patients with critical injuries or acute medical conditions receive timely and appropriate care in line with best practices.

Another critical objective is to improve the clarity and specificity of existing regulations. The current language includes vague or outdated provisions that can lead to misinterpretation and inconsistencies in implementation. By refining and expanding regulatory language, the updates will enhance compliance, streamline administrative processes, and reduce confusion for healthcare providers and administrators.

The anticipated benefits of these updates are substantial. They include improved patient outcomes through faster and more accurate care, increased system efficiency by standardizing operations and reducing administrative burdens and enhanced public safety by ensuring that all Californians have access to a consistently high standard of emergency and specialty care. These updates will also provide clearer guidance for LEMSAs and healthcare providers, fostering a more cohesive and effective statewide EMS system.

SPECIFIC PURPOSE OF, AND RATIONALE FOR, EACH PROPOSED CHANGE
The proposed updates to the Critical and Specialty Care System regulations are essential to address operation and clinical gaps, ensuring California's EMS system aligns with national care standards and meets the evolving needs of

healthcare. One primary objective is to align California's critical and specialty care systems with current national standards for trauma, STEMI, stroke, and EMSC. National guidelines from organizations such as the American College of Surgeons (ACS) for trauma care and the American Heart Association (AHA) for STEMI and stroke have evolved significantly. Incorporating these updates ensures California's EMS system remains evidence based and capable of delivering the highest quality care.

The standardization of specialty care program criteria is critical. Currently, the designation processes vary across LEMSAs, leading to inconsistencies in evaluation and recognition. Establishing uniform criteria will promote fairness and reliability, ensuring that specialty care centers across the state meet consistent standards of care. The updates introduce clear protocols for re-triage and inter-facility transfer of patients with critical trauma or acute medical conditions. Defined protocols will address delays in patient care, ensuring timely and appropriate transfers to facilities equipped to provide the necessary level of care, ultimately improving patient outcomes.

The updates aim to clarify vague or ambiguous regulatory language. Certain provisions in the existing regulations are insufficiently detailed or open to interpretation, leading to inconsistent implementation and confusion among LEMSAs and EMS providers. By refining these sections, the proposed updates will enhance compliance and provide clearer guidance for all stakeholders. The regulations incorporate advancements in clinical practices and technology, ensuring that prehospital care and specialty systems benefit from modern innovations in patient care, data collection, and clinical decision-making.

The updates will foster improved coordination and consistency among LEMSAs, specialty care centers, and EMS providers. Strengthening collaboration is essential for maintaining a cohesive and efficient statewide EMS system. Collectively, these changes are critical to ensuring the EMS system remains responsive to advancements in health care, meets national benchmarks, and continues to provide high-quality emergency care to all Californians. Without these updates, the state risks falling behind in care standards, compromising patient safety, and prolonging systemic inefficiencies.

The proposed updates to Chapter 6, now titled "Critical and Specialty Care Programs", modernize and reorganize the regulatory framework to align with current clinical standards and national guidelines. The title change reflects the broader scope of these regulations. Chapter 6.1, previously Trauma Care Systems, has been renamed Critical and Specialty Care Programs Definitions and reorganized to include definitions for all specialty care programs. These definitions are categorized by program-specific articles for clarity and consistency.

CHAPTER 6.1 Critical and Specialty Care Programs Definitions

Outdated/duplicative terms that were deleted:

- "Immediately Available"
- "Promptly Available"
- "Injury Severity Score"
- "On-Call"
- "Senior Resident"
- "Trauma Resuscitation Area"
- "Protocol"
- "Thrombectomy Capable Stroke Center"
- "Comprehensive Stroke Center"
- "Primary Stroke Center"
- "Stroke"

Terms exist elsewhere in EMSA's regulations and have been removed to reduce redundancy:

- "Local Emergency Medical Services Agency"
- "Quality Improvement"
- "Interfacility Transfer"
- "Emergency Medical Services Authority"
- "California Emergency Medical Services Information System (CEMSIS)"
- "National EMS Information System (NEMSIS)"

Terms added to address modern practices:

- (§ 100135.07) "Re-Triage"
- (§ 100135.13) "Trauma Team Activation Criteria"
- (§ 100137.04) "Mobile Stroke Unit Program"
- (§ 100137.07) "Stroke Certification Entity"
- (§ 100138.07) "Pediatric Readiness"
- (§ 100138.09) "Pediatric Recognition Program"
- (§ 100138.10) "Patient Care"
- (§ 100137.07)" Stroke Certification Entity"
- (§ 100138.02) "National Pediatric Readiness Project"

Terms renamed for clarity and alignment with national standards:

- (§ 100135.05) "Trauma Receiving Hospital"
- (§ 100135.06) "Residency Program."
- (§ 100135.03) "Pre-hospital Triage Criteria."
- (§ 100136.07) "STEMI Critical Care"
- (§ 100136.04) "Critical or Specialty Care Transfer"
- (§ 100138.05) "Pediatric Intensivist"

Definitions updated for clarity and alignment with national standards:

- (§ 100136.02) "Cardiac Catheterization Team"
- (§ 100135.10) "Trauma Center"
- (§ 100136.12) "STEMI Program Manager"
- (§ 100136.13) "STEMI Receiving Center"
- (§ 100137.06) "Stroke Center"
- (§ 100137.11) "Stroke Program Manager"
- (§ 100137.08) "Stroke Critical Care"
- (§ 100137.13) "Stroke Team"
- (§ 100138.03) "Pediatric Emergency Care Coordinator (PECC)"
- (§ 100138.12) "Qualified Pediatric Specialist"
- (§ 100137.01) "Board-certified"
- (§ 100137.02) "Board-eligible"
- (§ 100136.14) "STEMI Referring Hospital (SRH)
- (§ 100136.13) "STEMI Receiving Center
- (§ 100156.04) "Clinical Stroke Team"
- (§ 100137.04) "Mobile Stroke Unit Program"
- (§ 100138.06) "Pediatric Patient"

Terms renumbers for organizational consistency:

- (§ 100135.02) "Implementation"
- (§ 100135.04) "Qualified Specialist"
- (§ 100135.08) "Service Area"
- (§ 100135.09) "Trauma Care System"
- (§ 100135.15) "Trauma Service"
- (§ 100135.16) "Trauma Team"
- (§ 100136.01) "Cardiac Catheterization Laboratory"
- (§ 100136.05) "Percutaneous Coronary Intervention (PCI)"
- (§ 100136.06) "ST-Elevation Myocardial Infarction (STEMI)"
- (§ 100136.15) "STEMI Team"
- (§ 100136.13) "STEMI Critical Care System"
- (§ 100136.14) "STEMI Medical Director"
- (§ 100136.16) "STEMI Program"
- (§100137.05) "Stroke Call Roster"
- (§100137.14) "Telehealth"
- (§100138.01) "Emergency Medical Services for Children (EMSC) Program"
- (§100138.08) "Pediatric Receiving Center (PedRC)"
- (§100138.11) "Qualified Emergency Specialist"
- (§100138.12) "Qualified Pediatric Specialist"

Chapter 6.2 Trama Care Systems Updates

Definition Expansion and Clarification:

- § 100141.02 Trauma System Criteria (a)(1): Expanded language to specify "timely access to definitive trauma care for adults and children" and emphasize a coordinated approach to patient care.
- § 100141.03(d): Clarified that Trauma System goals and objectives must be included in the Trauma Plan.
- § 100141.03(g): Clarified language distinguishing "trauma pre-hospital" triage criteria.
- § 100141.05 Data Collection (a): Specified that data collection must comply with the California EMS Information System (CEMSIS).
- § 100141.05 Data Collection (i): Expanded to provide specific data elements for patient matching and Quality Improvement; deleted "total hospital charges" as irrelevant.
- § 100141.06 Level IV Trauma Center (h): Added requirement for trauma team activation criteria.

<u>Updates for Modern Standards:</u>

- § 100141.02 Trauma System Criteria (f): Deleted as trauma center early notification policies are now LEMSA policies.
- § 100141.02 Trauma System Criteria (e): Deleted as the telecommunication requirement is obsolete.
- § 100141.03 Trauma Plan and Policy Development: Updated to provide detailed requirements for "Trauma System Plan Update," including specific components (a)(1)-(17) and (b).
- § 100141.05 Data Collection (f)-(g): Added sections requiring monthly hospital data submissions and LEMSAs to share hospital trauma data for Quality Improvement.
- § 100141.05 Data Collection (c): Added requirement for trauma care data elements to align with the American College of Surgeons 2022 Standards.
- § 100141.06 (Level IV Trauma Center): Subsections (d)-(q) added or edited to specify requirements for trauma care performance, data collection, credentialing, peer review, and disaster preparedness in accordance with modern expectations.

<u>Renamed for Clarity:</u>

- § 100141.03 Policy Development: Renamed to "Trauma Plan and Policy Development" to better describe section contents.
- § 100141.03(h)(1): Updated "destination criteria" to "pre-hospital triage criteria."
- § 100141.03(h)(2): Changed to "Critical care capacity."
- § 100141.03(h)(3): Changed to "Transportation Plan Quality Improvement and Data Sharing Enhancements."
- § 100141.05 Data Collection (g): Added bi-directional data sharing between LEMSAs and hospitals.

- § 100141.06 Trauma System Evaluation (b): Expanded to include trauma system policies, quality improvement data, performance measures, and trauma team activation criteria.
- § 100142.01: Renamed to apply to "Level I-III Adult Trauma Centers" with 2022 ACS standards.
- § 100142.02: Renamed to "Pediatric Trauma Centers" to reflect ACS 2022 standards.

Deleted as Redundant/Outdated:

- § 100141.02 Trauma System Criteria (e): Deleted obsolete telecommunication requirement.
- § 100141.05 Data Collection (e): Deleted as criteria for trauma centers exist elsewhere.
- §100137.02: Deleted; Pediatric Trauma requirements moved to § 100142.02.
- § 100137.02: Deleted; Additional Level I Pediatric Trauma criteria moved to § 100142.02.
- § 100137.05: Deleted; Level III Trauma Center requirements moved to § 100142.01.

Changes Reflecting Exemptions and Documentation Requirements:
100141.02 (a)(1)(B)(2)-(11): Expanded from 4 to 10 documentation requirements to justify exemptions for population criteria in trauma center designations.

Adopted 2022 ACS Standards (Incorporated by Reference):

- § 100142.01 (Level I-III Adult Trauma Centers): Updated to adopt 2022 ACS standards in place of 2014 standards, per unanimous State Trauma Advisory Committee recommendation.
- § 100142.02 (Pediatric Trauma Centers): Requirements now align with ACS 2022 standards.
- Resources for Optimal Care of the Injured Patient | ACS

Quality Improvement and Data Sharing Enhancements

- § 100141.02 (f): Added monthly data submission requirement.
- § 100141.02 (g): Introduced inter-LEMSA data sharing for quality improvement.
- § 100142.03 (Level IV Trauma Center): Emphasis on data sharing, disaster preparedness, and performance metrics for Quality Improvement.
- § 100142.03(b): Expanded to require bi-directional information sharing through trauma committees.

Chapter 6.3 ST. Elevation Myocardial Infraction Critical Care System

Renumbered for Organizational Consistency

- § 100145.01: Renamed to "STEMI Critical Care System and Advisory Committee."
- § 100145.02: Renamed to "Initial STEMI Critical Care System Plan."
- § 100145.03: Renamed to "STEMI Critical Care System Plan Updates."
- § 100146.01: Renamed to "EMS Personnel and Early Recognition."
- § 100147.01: Renamed to "STEMI Receiving Center."
- § 100147.02: Renamed to "STEMI Referring Hospital."
- § 100148.01: Renamed to "Data Management."
- § 100148.02: Renamed to "Quality Improvement and Evaluation Process."

Definition Expansion and Clarification

- § 100145.01: Requires the formation of a STEMI Advisory Committee for any STEMI program, per national guidelines.
- § 100145.02: Clarified "Initial" to distinguish from annual updates to STEMI system plans.
- § 100146.01 (d): Added requirement to capture critical prehospital data into CEMSIS for data consistency.
- § 100148.01 (d): Added requirement for STEMI hospital data to be uploaded to CEMSIS and shared with EMS provider agencies for quality improvement.
- § 100148.01 (f): Ensures data sharing between hospitals and EMS agencies for quality improvement and education.
- § 100148.01 (g): Edited data nomenclature to match national dataset elements.
- § 100147.01 (d): Added requirement for trauma care performance and Patient Safety Program for Level IV Trauma Centers.
- § 100147.01 (i): Added requirement for Level IV Trauma Centers to have a multidisciplinary trauma peer review committee.
- § 100147.02 (k): Added requirement for Level IV Trauma Centers to participate in local and regional disaster management committees.
- Updates for Modern Standards
- § 100145.02: Edited content to reflect current pre-hospital and hospital components of STEMI systems.
- § 100145.03: Edited content for clarity to reflect the annual updates to the STEMI Critical Care System Plan.
- § 100146.01 (d): Added to capture critical prehospital data into CEMSIS.
- § 100147.01 (d)-(q): Added or edited subsections to reflect modern expectations for Level IV Trauma Centers, including data collection, performance metrics, credentialing, peer review, and disaster preparedness.

Renamed for Clarity

- § 100145.01: Renamed to "STEMI Critical Care System and Advisory Committee" for clearer understanding of committee's role.

- § 100145.02: Renamed to "Initial STEMI Critical Care System Plan" for specificity.
- § 100145.03: Renamed to "STEMI Critical Care System Plan Updates" to reflect its purpose.
- § 100146.01: Renamed to "EMS Personnel and Early Recognition" to clarify focus on EMS roles in early recognition of STEMI.
- § 100147.01: Renamed to "STEMI Receiving Center" to streamline and clarify the title.
- § 100147.02: Renamed to "STEMI Referring Hospital" for clarity.
- § 100148.01: Renamed to "Data Management" to reflect data management focus.
- § 100148.02: Renamed to "Quality Improvement and Evaluation Process" for clarity.

Chapter 6.4 Stroke Critical Care System

Renumbered for Organizational Consistency

- § 100149.01: Renamed to "Stroke Critical Care System and Advisory Committee."
- § 100149.03: Renamed to "Stroke Critical Care System Plan Updates."
- § 100150.01: Renamed to "EMS Personnel and Early Recognition."
- § 100151.02: Renamed to "Acute Stroke Ready Hospitals."
- § 100151.03: Renamed to "Primary Stroke Centers."
- § 100151.04: Renamed to "Thrombectomy-Capable Stroke Centers."
- § 100151.05: Renamed to "Comprehensive Stroke Center" to reflect currently accepted terminology.
- § 100152.01: Renamed to "Data Management Requirements."
- § 100152.02: Renamed to "Stroke Quality Improvement and Evaluation Process."

Definition Expansion and Clarification

- § 100149.01: Requires the formation of a Stroke Advisory Committee for any Stroke program, consistent with national guidelines.
- § 100149.02: Clarified the "Initial Stroke Critical Care System Plan" with a focus on both pre-hospital and hospital components of Stroke systems.
- § 100149.03: Edited the content of the "Stroke Critical Care System Plan Updates" to reflect both pre-hospital and hospital components of Stroke systems.
- § 100151.01: Added section to clarify requirements and responsibilities of EMS receiving hospitals that are not designated as stroke receiving facilities.
- § 100152.01 (d): Added requirement to upload Stroke hospital data to CEMSIS.

- § 100152.01 (f): Ensures Stroke hospital data is shared with EMS provider agencies for quality improvement.
- § 100152.01 (g): Edited data nomenclature to align with current national dataset elements.

Updates for Modern Standards

- § 100149.02: Updated and edited to reflect current pre-hospital and hospital components of Stroke systems.
- § 100149.03: Updated to reflect current standards for annual updates to the Stroke Critical Care System Plan.
- § 100150.01: Language edited for clarity and brevity in addressing EMS Personnel and Early Recognition.
- § 100151.02: Updated to reflect the current understanding of Acute Stroke Ready Hospitals.
- § 100151.03: Edited to reflect the current components of Primary Stroke Centers.
- § 100151.04: Updated to reflect modern standards for Thrombectomy-Capable Stroke Centers.
- § 100151.05: Updated to align with current terminology for Comprehensive Stroke Centers.
- § 100152.01: Edited language to ensure compliance with current standards and national data collection requirements.
- § 100152.02: Updated to reflect the Quality Improvement and Evaluation Process for Stroke systems.

Renamed for Clarity

- § 100149.01: Renamed to "Stroke Critical Care System and Advisory Committee" for clarity on committee's role.
- § 100149.03: Renamed to "Stroke Critical Care System Plan Updates" to clarify purpose of annual updates.
- § 100151.05: Renamed to "Comprehensive Stroke Center" to reflect current terminology in stroke care.
- § 100152.01: Renamed to "Data Management Requirements" for consistency and clarity in reporting requirements.
- § 100152.02: Renamed to "Stroke Quality Improvement and Evaluation Process" for clarity.

Chapter 6.5 Emergency Medical Services for Children

Renumbered for Organizational Consistency

- § 100153.01: Renamed to "EMSC Program Approval." Language edited for clarity and brevity.
- § 100162.02: Deleted, as the content was moved to 100155.02 in another article.

- § 100156.01: Renamed to "All PedRC Requirements."
- § 100156.02: Renamed to "Basic PedRC Requirements."
- § 100156.03: Renamed to "General PedRC Requirements."
- § 100156.04: Renamed to "Advanced PedRC Requirements."
- § 100156.05: Renamed to "Comprehensive PedRC Requirements."
- § 100157.01: Renamed to "Data Management Requirements."
- § 100157.02: Renamed to "EMSC Quality Improvement and Evaluation."

Definition Expansion and Clarification

- § 100153.01 (c): Added requirement for LEMSAs to have an EMSC advisory committee if they have an EMSC program.
- § 100153.01 (d): Added requirement for EMSC programs to have a "pediatric recognition program" as defined in the section.
- § 100155.01: Added language to better describe EMSC Plan requirements.
- § 100155.02: Added language to better describe EMSC Plan Update requirements.
- § 100157.01 (b): Edited to remove specific data reporting requirements and encourage collaboration of data sharing between hospitals and LEMSAs.
- Updates for Modern Standards
- § 100153.01: Edited throughout for clarity and brevity, incorporating national guidelines for EMSC programs.
- § 100155.01: Edited to improve clarity on EMSC Plan approval and updated to reflect current standards.
- § 100155.02: Updated to better describe the requirements for annual EMSC Plan updates.
- § 100157.01: Edited for clarity in relation to data sharing between hospitals and LEMSAs.

Renamed for Clarity

- § 100153.01: Renamed to "EMSC Program Approval" to clarify the content of the section.
- § 100156.01: Renamed to "All PedRC Requirements" for clarity in Pediatric Receiving Center standards.
- § 100156.02: Renamed to "Basic PedRC Requirements" for clarity.
- § 100156.03: Renamed to "General PedRC Requirements" for clarity.
- § 100156.04: Renamed to "Advanced PedRC Requirements" for clarity.
- §100156.05: Renamed to "Comprehensive PedRC Requirements" to reflect the current standard for Pediatric Receiving Centers.

OTHER REQUIRED SHOWINGS – GOVERNMENT CODE §11346.2(b)(2)-(5)

Studies, Reports, or Documents Relied Upon – Gov. Code §11346.2(b)(3):

None.

Items Incorporated by Reference:
Resources for Optimal Care of the Injured Patient (2022 Standards, Revised 12/2023)
- https://www.facs.org/quality-programs/trauma/quality/verification-review-and-consultation-program/standards/

National Trauma Data Bank
- https://www.facs.org/quality-programs/trauma/quality/national-trauma-data-bank/

Reasonable Alternatives That Would Lessen the Impact on Small Business – Government Code §11346.2(b)(4)(B): None.

Reasonable Alternatives That Would Be Less Burdensome and Equally Effective – Government Code §11346.2(b)(4)(A): None.

Evidence Relied Upon to Support the Initial Determination That the Regulation Will Not Have a Significant Adverse Economic Impact on Business – Government Code §11346.2(b)(5): None.

ECONOMIC IMPACT STATEMENT – GOVERNMENT CODE § 11346.3(b)(1)(A)-(D)
(A) Creation or elimination of jobs within the state: None.
(B) Creation of new businesses or elimination of existing businesses within the state: None.
(C) Expansion of businesses currently doing business within the state: None.
(D) Benefits of regulation to health and welfare of California residents, worker safety, and the state's environment.]: As described above in more detail, the proposed regulations will benefit the overall health and welfare of California residents because these regulations are essential to address operation and clinical gaps, ensuring California's EMS system aligns with national care standards and meets the evolving needs of healthcare. It is not anticipated to directly benefit worker safety or the state's environment.