

California Code of Regulations
Title 22. Social Security
Division 9. Prehospital Emergency Medical Services
Chapter 7.1 ST-Elevation Myocardial Infarction Critical Care System

ARTICLE 1. DEFINITIONS

§ 100270.101. Cardiac Catheterization Laboratory

“Cardiac catheterization laboratory” or “Cath lab” means the setting within the hospital where diagnostic and therapeutic procedures are performed on patients with cardiovascular disease.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.102. Cardiac Catheterization Team

“Cardiac catheterization team” means the specially trained health care professionals that perform percutaneous coronary intervention. It may include, but is not limited to, an interventional cardiologist, mid-level practitioners, registered nurses, technicians, and other health care professionals.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.103. Clinical Staff

“Clinical staff” means individuals that have specific training and experience in the treatment and management of ST-Elevation Myocardial Infarction (STEMI) patients. This includes, but is not limited to, physicians, registered nurses, advanced practice nurses, physician assistants, pharmacists, and technologists.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.104. Emergency Medical Services Authority

“Emergency Medical Services Authority” or “EMS Authority” or “EMSA” means the department in California responsible for the coordination and integration of all state activities concerning EMS.

Note: Authority cited: Sections 1797.1, 1797.107 and 1797.54, Health and Safety Code.
Reference: Sections 1797.100, and 1797.103, Health and Safety Code.

§ 100270.105. Immediately Available

“Immediately available” means:

- (a) Unencumbered by conflicting duties or responsibilities.
- (b) Responding without delay upon receiving notification.
- (c) Being physically available to the specified area of the hospital when the patient is delivered in accordance with local EMS agency policies and procedures.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.106. Implementation

“Implementation,” “implemented” or “has implemented” means the development and activation of a STEMI Critical Care System Plan by the local EMS agency, including the prehospital and hospital care components in accordance with the plan.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.107. Interfacility Transfer

“Interfacility transfer” means the transfer of a STEMI patient from one acute general care facility to another acute general care facility.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103, 1797.176 and 1798.170, Health and Safety Code.

§ 100270.108. Local Emergency Medical Services Agency

“Local emergency medical services agency” or “local EMS agency” means the agency, department, or office having primary responsibility for administration of emergency medical services in a county or region and which is designated pursuant Health and Safety Code commencing with section 1797.200.

Note: Authority cited: Sections 1797.107, 1797.200 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.109. Percutaneous Coronary Intervention (PCI)

“Percutaneous coronary intervention” or “PCI” means a procedure used to open or widen a narrowed or blocked coronary artery to restore blood flow supplying the heart, usually done on an emergency basis for a STEMI patient.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.110. Quality Improvement

“Quality improvement” or “QI” means methods of evaluation that are composed of structure, process, and outcome evaluations that focus on improvement efforts to identify root causes of problems, intervene to reduce or eliminate these causes, and take steps to correct the process, and recognize excellence in performance and delivery of care.

Note: Authority cited: Sections 1797.103, 1797.107, 1797.174, 1797.176 and 1798.150 Health and Safety Code. Reference: Sections 1797.174, 1797.202, 1797.204, 1797.220 and 1798.175, Health and Safety Code.

§ 100270.111. ST-Elevation Myocardial Infarction (STEMI)

“ST-Elevation Myocardial Infarction” or “STEMI” means a clinical syndrome defined by symptoms of myocardial infarction in association with ST-segment elevation on Electrocardiogram (ECG).

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.112. STEMI Care

“STEMI care” means emergency cardiac care, for the purposes of these regulations.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.113. STEMI Medical Director

“STEMI medical director” means a qualified board-certified physician by the American Board of Medical Specialties (ABMS) as defined by the local EMS agency and designated by the hospital that is responsible for the STEMI program, performance improvement, and patient safety programs related to a STEMI critical care system.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.114. STEMI Patient

“STEMI patient” means a patient with symptoms of myocardial infarction in association with ST-Segment Elevation in an ECG.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103, 1797.176 and 1797.220, Health and Safety Code.

§ 100270.115. STEMI Program

“STEMI program” means an organizational component of the hospital specializing in the care of STEMI patients.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.116. STEMI Program Manager

“STEMI program manager” means a registered nurse or qualified individual as defined by the local EMS agency, and designated by the hospital responsible for monitoring, coordinating and evaluating the STEMI program.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.117. STEMI Receiving Center (SRC)

“STEMI receiving center” or “SRC” means a licensed general acute care facility that meets the minimum hospital STEMI care requirements pursuant to Section 100270.124 and is able to perform PCI.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103, 1797.176 and 1797.220, Health and Safety Code.

§ 100270.118. STEMI Referring Hospital (SRH)

“STEMI referring hospital” means a licensed general acute care facility that meets the minimum hospital STEMI care requirements pursuant to Section 100270.125.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103, 1797.176 and 1797.220, Health and Safety Code.

§ 100270.119. STEMI Critical Care System

“STEMI critical care system” means a critical care component of the EMS system developed by a local EMS agency that links prehospital and hospital care to deliver treatment to STEMI patients.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.120. STEMI Team

“STEMI team” means clinical personnel, support personnel, and administrative staff that function together as part of the hospital’s STEMI program.

Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

ARTICLE 2. LOCAL EMS AGENCY STEMI CRITICAL CARE SYSTEM REQUIREMENTS

§ 100270.121. STEMI Critical Care System Plan

(a) The local EMS agency may develop and implement a STEMI critical care system.

(b) The local EMS agency implementing a STEMI critical care system shall have a STEMI Critical Care System Plan approved by the EMS Authority prior to implementation.

(c) A STEMI Critical Care System Plan submitted to the EMS Authority shall include, at a minimum, all of the following components:

(1) The names and titles of the local EMS agency personnel who have a role in a STEMI critical care system.

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187 (2) The list of STEMI designated facilities with the agreement expiration dates.
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189 (3) A description or a copy of the local EMS agency's STEMI patient identification and
190 destination policies.
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192 (4) A description or a copy of the method of field communication to the receiving
193 hospital specific to STEMI patient, designed to expedite time-sensitive treatment on
194 arrival.
195
196 (5) A description or a copy of the policy that facilitates the inter-facility transfer of a
197 STEMI patient.
198
199 (6) A description of the method of data collection from the EMS providers and
200 designated STEMI hospitals to the local EMS agency and the EMS Authority.
201
202 (7) A policy or description of how the local EMS agency integrates a receiving center in
203 a neighboring jurisdiction.
204
205 (8) A description of the integration of STEMI into an existing quality improvement
206 committee or a description of any STEMI specific quality improvement committee.
207
208 (9) A description of programs to conduct or promote public education specific to cardiac
209 care.
210
211 (d) The EMS Authority shall, within 30-days of receiving a request for approval, notify
212 the requesting local EMS agency in writing of approval or disapproval of its STEMI
213 Critical Care System Plan. If the STEMI Critical Care System Plan is disapproved, the
214 response shall include the reason(s) for the disapproval and any required corrective
215 action items.
216
217 (e) The local EMS agency shall provide a corrected plan to the EMS Authority within 60
218 days of receipt of the disapproval letter.
219
220 (f) The local EMS agency currently operating a STEMI critical care system implemented
221 before the effective date of these regulations, shall submit to the EMS Authority a
222 STEMI Critical Care System Plan as an addendum to its next annual EMS plan update,
223 or within 180-days of the effective date of these regulations, whichever comes first.
224
225 (g) After approval of the STEMI Critical Care System Plan, the local EMS agency shall
226 submit an update to the plan as part of its annual EMS update, consistent with the
227 requirements in Section 100270.122.
228
229 (h) No health care facility shall advertise in any manner or otherwise hold itself out to be
230 affiliated with a STEMI critical care system or a STEMI center unless they have been so
231 designated by the local EMS agency, in accordance with this chapter.

Note: Authority cited: Sections 1797.107, 1797.103, 1797.105, 1797.250, 1797.254 and 1798.150, Health and Safety Code. Reference: Section 1797.176 and 1797.220, Health and Safety Code.

§100270.122. STEMI Critical Care System Plan Updates

(a) The local EMS agency shall submit an annual update of its STEMI Critical Care System Plan, as part of its annual EMS plan submittal, which shall include, at a minimum, all the following:

(1) Any changes in a STEMI critical care system since submission of the prior annual plan update or a STEMI Critical Care System Plan addendum.

(2) The status of a STEMI critical care system goals and objectives.

(3) The STEMI critical care system quality improvement activities.

(4) The progress on addressing action items and recommendations provided by the EMS Authority within the STEMI Critical Care System Plan or status report approval letter if applicable.

Note: Authority cited: Sections 1797.103, 1797.107, 1797.176, 1797.250, 1797.254, 1798.150, and 1798.172, Health and Safety Code. Reference: Section 1797.176, 1797.220, 1797.222, 1798.170, Health and Safety Code.

ARTICLE 3. PREHOSPITAL STEMI CRITICAL CARE SYSTEM REQUIREMENTS

§ 100270.123. EMS Personnel and Early Recognition

(a) The local EMS agency with an established STEMI critical care system shall have protocols for the identification and treatment of STEMI patients, including paramedic performance of a 12-lead ECG and determination of the patient destination.

(b) The findings of 12-lead ECG shall be assessed and interpreted through one or more of the following methods:

(1) Direct paramedic interpretation.

(2) Automated computer algorithm.

(3) Wireless transmission to facility followed by physician interpretation or confirmation.

(c) Notification of prehospital ECG findings of suspected STEMI patients, as defined by the local EMS agency, shall be communicated in advance of the arrival to the STEMI centers according to the local EMS agency's STEMI Critical Care System Plan.

Note: Authority cited: Sections 1797.103, 1797.107, 1797.114, 1797.176, 1797.206, 1797.214 and 1798.150, Health and Safety Code. Reference: Section 1797.176, 1797.220, 1798, 1798.150 and 1798.170, Health and Safety Code.

ARTICLE 4. STEMI CRITICAL CARE FACILITY REQUIREMENTS

§ 100270.124. STEMI Receiving Center Requirements

(a) The following minimum criteria shall be used by the local EMS agency for the designation of a STEMI receiving center:

(1) The hospital shall have established protocols for triage, diagnosis, and Cath lab activation following field notification.

(2) The hospital shall have a single call activation system to activate the Cardiac Catheterization Team directly.

(3) Written protocols shall be in place for the identification of STEMI patients.

(A) At a minimum, these written protocols shall be applicable in the intensive care unit/coronary care unit, Cath lab and the emergency department.

(4) The hospital shall be available for treatment of STEMI patients twenty-four (24) hours per day, seven (7) days per week, three hundred and sixty-five (365) days per year.

(5) The hospital shall have a process in place for the treatment and triage of simultaneously arriving STEMI patients.

(6) The hospital shall maintain STEMI team and Cardiac Catheterization Team call rosters.

(7) The Cardiac Catheterization Team, including appropriate staff determined by the local EMS agency, shall be immediately available.

(8) The hospital shall agree to accept all STEMI patients according to the local policy.

(9) STEMI receiving centers shall comply with the requirement for a minimum volume of procedures for designation required by the local EMS agency.

(10) The hospital shall have a STEMI program manager and a STEMI medical director.

(11) The hospital shall have job descriptions and organizational structure clarifying the relationship between the STEMI medical director, STEMI program manager, and the STEMI team.

(12) The hospital shall participate in the local EMS agency quality improvement processes related to a STEMI critical care system.

(13) A STEMI receiving center without cardiac surgery capability on-site shall have a written transfer plan and agreements for transfer to a facility with cardiovascular surgery capability.

(14) A STEMI receiving center shall have reviews by local EMS agency or other designated agency conducted every three years.

(b) A STEMI center designated by the local EMS agency prior to implementation of these regulations may continue to operate. Before re-designation by the local EMS agency at the next regular interval, STEMI centers shall be re-evaluated to meet the criteria established in these regulations.

(c) Additional requirements may be stipulated by the local EMS agency medical director.

Note: Authority cited: Sections 1797.103, 1797.107, 1797.176, 1797.220, and 1798.150 1798.167 and 1798.172, Health and Safety Code. Reference: Section 1797.176, 1797.220, 1798, 1798.150 and 1798.170 Health and Safety Code.

§ 100270.125. STEMI Referring Hospital Requirements

(a) The following minimum criteria shall be used by the local EMS agency for designation of a STEMI referring hospital:

(1) The hospital shall be committed to supporting the STEMI Program.

(2) The hospital shall be available to provide care for STEMI patients twenty-four (24) hours per day, seven (7) days per week, three hundred and sixty-five (365) days per year.

(3) Written protocols shall be in place to identify STEMI patients and provide an optimal reperfusion strategy, using fibrinolytic therapy .

(4) The emergency department shall maintain a standardized procedure for the treatment of STEMI patients.

(5) The hospital shall have a transfer process through interfacility transfer agreements, and have pre-arranged agreements with EMS ambulance providers for rapid transport of STEMI patients to an SRC.

(6) The hospital shall have a program to track and improve treatment of STEMI patients.

(7) The hospital must have a plan to work with a STEMI receiving center and the local EMS agency on quality improvement processes.

(8) A STEMI referring hospital designated by the local EMS agency shall have a review conducted every three years.

(b) A STEMI center designated by the local EMS agency prior to implementation of these regulations may continue to operate. Before re-designation by the local EMS agency at the next regular interval, STEMI centers shall be re-evaluated to meet the criteria established in these regulations.

(c) Additional requirements may be stipulated by the local EMS agency medical director.

Note: Authority cited: Sections 1797.103, 1797.107, 1797.176, 1797.220, and 1798.150 1798.167 and 1798.172, Health and Safety Code. Reference: Section 1797.176, 1797.220, 1798.150 and 1798.170 Health and Safety Code.

ARTICLE 5. DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATIONS

§ 100270.126. Data Management.

(a) The local EMS agency shall implement a standardized data collection and reporting process for a STEMI critical care system.

(b) The system shall include the collection of both prehospital and hospital patient care data, as determined by the local EMS agency.

(c) The prehospital STEMI patient care elements selected by the local EMS agency shall be compliant with the most current version of the California EMS Information Systems (CEMSIS) database, and the National EMS Information System (NEMSIS).

(d) All hospitals that receive STEMI patients via EMS shall participate in the local EMS agency data collection process in accordance with local EMS agency policies and procedures.

(e) The prehospital care record and the hospital data elements shall be collected and submitted to the local EMS agency, and subsequently to the EMS Authority, on no less than a quarterly basis and shall include, but not be limited to, the following:

(1) The STEMI patient data elements:

- (A) EMS ePCR Number.
- (B) Facility.
- (C) Name: Last, First.
- (D) Date of Birth.
- (E) Patient Age.

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- 418 (F) Patient Gender.
- 419 (G) Patient Race.
- 420 (H) Hospital Arrival Date.
- 421 (I) Hospital Arrival Time.
- 422 (J) Dispatch Date.
- 423 (K) Dispatch Time.
- 424 (L) Field ECG Performed.
- 425 (M) 1st ECG Date.
- 426 (N) 1st ECG Time.
- 427 (O) Did the patient suffer out-of-hospital cardiac arrest.
- 428 (P) CATH LAB Activated.
- 429 (Q) CATH LAB Activation Date.
- 430 (R) CATH LAB Activation Time.
- 431 (S) Did the patient go to the CATH LAB.
- 432 (T) CATH LAB Arrival Date.
- 433 (U) CATH LAB Arrival Time.
- 434 (V) PCI Performed.
- 435 (W) PCI Date.
- 436 (X) PCI Time.
- 437 (Y) Fibrinolytic Infusion.
- 438 (Z) Fibrinolytic Infusion Date.
- 439 (AA) Fibrinolytic Infusion Time.
- 440 (BB) Transfer.
- 441 (CC) SRH ED Arrival Date.
- 442 (DD) SRH ED Arrival Time.
- 443 (EE) SRH ED Departure Date.
- 444 (FF) SRH ED Departure Time.
- 445 (GG) Hospital Discharge Date.
- 446 (HH) Patient Outcome.
- 447 (II) Primary and Secondary Discharge Diagnosis.
- 448
- 449 (2) The STEMI System data elements:
- 450
- 451 (A) Number of STEMIs treated.
- 452 (B) Number of STEMI patients transferred.
- 453 (C) Number and percent of emergency department STEMI patients arriving by
454 private transport (non-EMS).
- 455 (D) The false positive rate of EMS diagnosis of STEMI, defined as the percentage of
456 STEMI alerts by EMS which did not show STEMI on ECG reading by the
457 emergency physician.
- 458
- 459 Note: Authority cited: Sections 1791.102, 1797.103, 1797.107, 1797.176, 1797.204,
460 1797.220, 1798.150, and 1798.172, Health and Safety Code. Reference: Section
461 1797.220, 1797.222, 1797.204, Health and Safety Code.
- 462
- 463 **§ 100270.127. Quality Improvement and Evaluation Process**

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(a) Each STEMI critical care system shall have a quality improvement process that shall include, at a minimum:

(1) Evaluation of program structure, process, and outcome.

(2) Review of STEMI-related deaths, major complications, and transfers.

(3) A multidisciplinary STEMI Quality Improvement Committee, including both prehospital and hospital members.

(4) Participation in the QI process by all designated STEMI centers and prehospital providers involved in the STEMI critical care system.

(5) Evaluation of regional integration of STEMI patient movement.

(6) Compliance with the California Evidence Code, Section 1157.7 to ensure confidentiality, and a disclosure-protected review of selected STEMI cases.

(b) The local EMS agency shall be responsible for on-going performance evaluation and quality improvement of the STEMI critical care system.

Note: Authority cited: Sections 1797.102, 1797.103, 1797.107, 1797.176, 1797.204, 1797.220, 1797.250, 1797.254, 1798.150, and 1798.172, Health and Safety Code.
Reference: Section 1797.104, 1797.176, 1797.204, 1797.220, 1797.222, 1798.170, Health and Safety Code.