ARTICLE 1. DEFINITIONS

§ 100270.101. Cardiac Catheterization Laboratory
“Cardiac Catheterization Laboratory” or “Cath Lab” means the setting within the hospital where laboratory procedures for obtaining physiologic, pathologic, and angiographic data can be performed on patients with cardiovascular disease, the percutaneous coronary intervention (PCI) is done.

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 medical staff that performs 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 an individual that has 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. Door-to-Balloon Time (Also known as Door-to-Device Time)

“Door-to-Balloon Time” or “D2B Time” means the amount of time between a STEMI patient’s arrival at the hospital to the time he/she receives percutaneous coronary intervention, such as angioplasty.

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

§ 100270.105. Door-to-Needle Time

“Door-to-Needle Time” means the time interval between the arrival of a STEMI patient at a hospital to the time fibrinolytic therapy is administered to open a blocked artery.

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. Emergency Medical Services Authority

“Emergency Medical Services Authority” or “EMS Authority” 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.

§ 100270.107. Immediately Available

“Immediately Available” means

(a) unencumbered by conflicting duties or responsibilities,
(b) responding without delay upon receiving notification, and
(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.
§ 100270.108. 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 pre-hospital 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.

§ 100270.109. Interfacility Transfer

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

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

§ 100270.110. Local Emergency Medical Services Agency

"Local Emergency Medical Services Agency" or "local EMS agency" means a county health department, an agency established and operated by the county, or an entity with which the county contracts for the purposes of local emergency medical services administration, or a joint powers agency created for the administration of emergency medical services by agreement between counties or cities and which is designated pursuant to Chapter 4 of the California Health and Safety Code, Division 2.5, Section 1797.200.


§ 100270.111. 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. A primary PCI is generally 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.
§ 100270.112. Pre-Arrival Instructions

“Pre-Arrival Instructions” means the medically approved scripted instructions used in time-critical situations where evaluation, verification, and advice is given by trained emergency medical dispatchers to callers that provide necessary assistance and control of the situation prior to arrival of emergency medical services personnel according to the local EMS agency policy.


§ 100270.112. 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.


§ 100270.113. ST-Elevation Myocardial Infarction (STEMI)

“ST-Elevation Myocardial Infarction” or “STEMI” means a clinical syndrome defined by characteristic symptoms of myocardial infarction in association with ST-segment elevation in ECG, and the subsequent release of biomarkers of myocardial necrosis.


§ 100270.114. STEMI Care

“STEMI Care” means emergency cardiac care, for the purposes of these regulations.
§ 100270.115. STEMI Medical Director

“STEMI Medical Director” means a qualified physician 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 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.

§ 100270.116. STEMI Patient

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

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

§ 100270.117. 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.

§ 100270.118. 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 and evaluating STEMI patients, performance improvement, and patient safety programs related to the 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.
§ 100270.119. STEMI Receiving Center (SRC)

“STEMI Receiving Center” or “SRC” means a licensed general acute care facility hospital that meets the minimum hospital STEMI care requirements pursuant to Section 100270.128 and is able to perform primary PCI.

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

§ 100270.120. STEMI Referring Hospital (SRH)

“STEMI Referring Hospital” means a licensed general acute care facility hospital that meets the minimum hospital STEMI care requirements pursuant to Section 100270.129.

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

§ 100270.121. STEMI Technical Advisory Committee

“STEMI Technical Advisory Committee” means a multidisciplinary committee as appointed by the EMS Authority. The STEMI Technical Advisory Committee serves as an advisory committee to the EMS Authority on STEMI related issues.


§ 100270.122. STEMI Critical Care System

“STEMI Critical Care System” means a critical care component of the EMS system developed by a local EMS agency. This system of care links pre-hospital and hospital care to deliver treatment to STEMI patients within the timeframes recommended by the American Heart Association (AHA).

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

§ 100270.123. STEMI Team

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


ARTICLE 2. LOCAL EMS AGENCY STEMI CRITICAL CARE SYSTEM REQUIREMENTS

§ 100270.124. General Requirements and Timeframes

(a) The local EMS agency may develop and implement a STEMI Critical Care System.

(b) A local EMS agency implementing a STEMI Critical Care System shall submit to the EMS Authority a STEMI System Plan in accordance with the requirements in Section 100270.125.

(c) A new STEMI Critical Care System that starts after the effective date of these regulations shall have a STEMI System Plan approved by the EMS Authority prior to implementation. The EMS Authority shall notify the local EMS agency of approval or disapproval of its STEMI System Plan within 30 days from receipt of the Plan. If the EMS Authority disapproves a plan, it shall provide written notification including the reason(s) for the disapproval and the corrective action items required.

(d) The local EMS agency shall provide a corrected plan to the EMS Authority within 60 days of receipt of the disapproval letter.

(e) A local EMS agency currently operating a STEMI Critical Care System implemented prior to the effective date of these regulations, shall submit to the EMS Authority a STEMI System Plan as an addendum to its next annual EMS Plan update, or within 180 days of the effective date of these regulations whichever comes first.

(f) After approval of the Plan, the local EMS agency shall submit an update to its STEMI System Plan as part of its annual EMS update, consistent with the requirements in Section 100270.125.

(g) No health care facility shall advertise in any manner or otherwise hold itself out to be affiliated with the STEMI Critical Care System or a STEMI center unless they have been so designated by the local EMS agency, in accordance with this Chapter.
§ 100270.125. STEMI Critical Care System Plan Requirements

The STEMI System Plan submitted to the EMS Authority shall include, at a minimum, the following components:

(a) the names and titles of the local EMS agency personnel who have a role in the STEMI Critical Care System,

(b) copies verification of agreements with hospitals for designation of STEMI facilities with the list of stroke hospital contracts and contract expiration dates,

(c) description or copy of the local EMS agency’s STEMI patient identification and destination policies,

(d) description or copy of the method of field communication to the receiving hospital specific to STEMI patient, designed to expedite time-sensitive treatment on arrival

(e) description or copy of policy that facilitates inter-facility transfer of a STEMI patient,

(f) description of the method of data collection from the EMS providers and designated STEMI hospitals to the local EMS agency and the EMS Authority,

(g) a copy of all written agreements with neighboring local EMS agencies that provide STEMI care,

(h) description of the integration of STEMI into an existing QI Committee or description of any STEMI specific QI committee, and

(i) description of programs to conduct or promote public education specific to cardiac care.


§100270.126. STEMI System Plan Updates

The local EMS agency shall submit a STEMI System Plan update as part of its annual EMS Plan submittal. The update shall include at a minimum, the following:
(a) any changes in the STEMI Critical Care System since submission of the prior annual plan update or the STEMI System Plan addendum,
(b) status of STEMI Critical Care System goals and objectives,
(c) STEMI Critical Care System QI activities, and
(d) progress on addressing action items and recommendations provided by the EMS Authority within the STEMI System Plan or Status Report approval letter if applicable.


ARTICLE 3. PRE-HOSPITAL STEMI CRITICAL CARE SYSTEM REQUIREMENTS

§ 100270.127. EMS Personnel and Early Recognition
A local EMS agency with an established STEMI Critical Care System shall have protocols for the treatment of STEMI patients, including paramedic capability to perform use of a 12-lead ECG equipment, and determination of to determine patient destination.

(a) When 12-lead ECG equipment is used, those findings shall be assessed and interpreted through one or more of the following methods:

(1) direct paramedic interpretation,
(2) automated computer algorithm, or
(3) wireless transmission to facility followed by physician interpretation or confirmation.

(b) Advance notification of pre-hospital ECG findings of suspected STEMI patients, as defined by the local EMS agency, will be communicated to the STEMI facilities, centers or hospitals according to the local EMS agency STEMI System Plan.


ARTICLE 4. STEMI CRITICAL CARE FACILITY REQUIREMENTS
Any STEMI center designated by the local EMS agency prior to implementation of these regulations may continue to operate. Upon redesignation by the local EMS agency at
the next regular interval, STEMI centers shall be reevaluated to meet the criteria established in these regulations.

§ 100270. STEMI Receiving Center

The following minimum criteria shall be used by the local EMS agency for the designation of SRC:

(a) The hospital shall have leadership committed to supporting and sustaining the STEMI Critical Care System.

(b) The hospital shall have established protocols for triage, diagnosis, and Cath Lab activation from field notification.

(c) Written protocols and standing orders shall be in place for the identification of STEMI patients. At a minimum, these protocols shall be available in the intensive care unit/coronary care unit and the emergency department (ED).

(d) The hospital shall be available for treatment of STEMI patients 24 hours per day/7 days per week/365 days per year.

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

(f) The hospital shall maintain a STEMI team call roster.

(g) The Cath Lab team, including appropriate staff determined by the local EMS agency, shall be immediately available.

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

(i) SRCs shall comply with the requirement for a minimum volume of procedures for designation by the local EMS agency.

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

(k) The hospital shall have job descriptions and organizational charts depicting the relationship between the STEMI medical director, STEMI program manager, and the STEMI team.

(l) The hospital shall participate in the local EMS agency QI processes related to the STEMI Critical Care System.
Local EMS agencies shall ensure STEMI receiving Centers facilities without cardiac surgery capability on-site shall have a written transfer plan and agreements for transfer to a facility with cardiovascular surgery capability.

SRCs shall have on-site accreditation reviews conducted every three years.

Additional requirements may be included at the discretion of the local EMS agency medical director.

§ 100270.129. STEMI Referring Hospital (SRH)

The following minimum criteria shall be used by the local EMS agency for designation of an SRH:

(a) The hospital shall be committed to supporting and sustaining the STEMI Program.

(b) The hospital shall be available to provide care for STEMI patients 24 hours per day/7 days per week/365 days per year.

(c) Written protocols and standing orders shall be in place for the identification of STEMI patients. At a minimum, these protocols shall be available in the intensive care unit/coronary care unit and the emergency department (ED).

(d) The ED shall maintain a standardized procedure for the treatment of STEMI patients.

(e) The hospital shall have a transfer system process through interfacility transfer agreements, and have pre-arranged agreements with EMS providers for a higher level of care and rapid transport of STEMI patients to an SRC when considering ground or air transport.

(f) The hospital shall have a program to track and improve treatment.

(g) The hospital must have a plan to work with SRCS and the local EMS agency on QI processes.

(h) SRH shall have on-site accreditation reviews conducted every three years.

(i) Additional requirements may be included at the discretion of the local EMS agency medical director.


ARTICLE 5. DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATIONS

§ 100270.130. Data Management

(a) The local EMS agency shall implement a standardized data collection and reporting process for STEMI Critical Care Systems.

(1) The system shall include the collection of both pre-hospital and hospital patient care data, as determined by the local EMS agency.
(2) The prehospital and hospital 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, the National EMS Information System (NEMSIS) and the National Cardiovascular Data Registry, Action Registry, version 2.4 dated March 2014.

(2) 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).

(3) STEMI data shall be integrated into the local EMS agency and the EMS Authority data management system through data submission on no less than a quarterly basis.

(3) The hospital STEMI patient care elements shall be compliant with the most current version of National Cardiovascular Data Registry, Action Registry.

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

(b) The following minimum elements shall be collected and submitted to the local EMS agency by the hospital and subsequently to the EMS Authority on no less than a quarterly basis to be used to determine pre-hospital and hospital system performance:

(1) EMS ePCR Number
(2) Facility
(3) Name: Last, First
(4) Date of Birth
(5) Patient Age
(6) Patient Gender
(7) Patient Race
(8) Hospital Arrival Date
(9) Hospital Arrival Time
(10) Dispatch Date
(11) Dispatch Time
(12) Field ECG Performed
(13) 1st Field ECG Date

§ 100270.131. Quality Improvement Process

STEMI Critical Care Systems shall have a quality improvement process to include structure, process, and outcome evaluations that focus on improvement efforts to identify root causes of problems, reduce or eliminate such causes, and take steps to correct the process. This process shall include, at a minimum:

(a) an audit of all STEMI-related deaths.
(b) a multidisciplinary STEMI QI Committee, including both pre-hospital and hospital members.

(c) compliance with the California Evidence Code, Section 1157.7 to ensure confidentiality, and

(d) a disclosure-protected review of selected STEMI cases.


§ 100270.132. STEMI Critical Care System Evaluation

(a) The local EMS agency is responsible for on-going performance evaluation of the local or regional STEMI Critical Care System.

(b) The local EMS agency shall be responsible for the development of a QI process pursuant to Section 100270.131.

(c) The local EMS agency shall be responsible for ensuring that designated STEMI centers and other hospitals that treat STEMI patients participate in the QI process contained in Section 100270.131, as well as pre-hospital providers involved in the STEMI Critical Care System.