

1 DRAFT – December, 2016

2 California Code of Regulations

3 TITLE 22. SOCIAL SECURITY

4 DIVISION 9. PREHOSPITAL EMERGENCY MEDICAL SERVICES

5 CHAPTER 7.1 ST ELEVATION MYOCARDIAL INFARCTION (STEMI) CRITICAL  
6 CARE SYSTEM

7 **ARTICLE 1. DEFINITIONS**

8 **§ 100270.101. Cardiac Catheterization Laboratory**

9 “Cardiac Catheterization Laboratory” or “Cath Lab” means the setting within the hospital  
10 where the percutaneous coronary intervention (PCI) is done.

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

12 Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

13 **§ 100270.102. Cardiac Catheterization Team**

14 “Cardiac Catheterization Team” means the specially trained medical staff that performs  
15 percutaneous coronary intervention. It may include, but is not limited to, an  
16 interventional cardiologist, mid-level practitioners, nurses, technicians and other health  
17 care professionals.

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

19 Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

20 **§ 100270.103. Clinical Staff**

21 “Clinical Staff” means an individual that has specific training and experience in the  
22 treatment and management of ST-Elevation Myocardial Infarction (STEMI) patients.  
23 This includes, but is not limited to, physicians, registered nurses, advanced practice  
24 nurses, physician assistants, pharmacists, and technologists.

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

26 Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

27 **§ 100270.104. Door-to-Balloon Time (Also known as Door-to-Device Time)**  
28 “Door-to-Balloon Time” “D2B Time” means the amount of time between a STEMI  
29 patient’s arrival at the hospital to the time he/she receives percutaneous coronary  
30 intervention, such as angioplasty.

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

33 **§ 100270.105. Door-to-Needle Time**

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

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

38 **§ 100270.106. Emergency Medical Services Authority**

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

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

44 **§ 100270.107. Immediately Available**

45 “Immediately Available” means  
46 (a) unencumbered by conflicting duties or responsibilities,  
47 (b) responding without delay upon receiving notification, and  
48 (c) being physically available to the specified area of the hospital when the patient is  
49 delivered in accordance with local EMS agency policies and procedures.

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

52 **§ 100270.108. Implementation**

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

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

57 Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

58 **§ 100270.109. Interfacility Transfer**

59 “Interfacility Transfer” means the transfer of a STEMI patient from one acute care  
60 hospital to another.

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

62 Reference: Sections 1797.103, 1797.176 and 1798.170, Health and Safety Code.

63 **§ 100270.110. Local Emergency Medical Services Agency**

64 “Local Emergency Medical Services Agency” or “local EMS agency” means a county  
65 health department, an agency established and operated by the county, or an entity with  
66 which the county contracts for the purposes of local emergency medical services  
67 administration, or a joint powers agency created for the administration of emergency  
68 medical services by agreement between counties or cities and which is designated  
69 pursuant to Chapter 4 of the California Health and Safety Code, Division 2.5, Section  
70 1797.200.

71 Note: Authority cited: Sections 1797.107, 1797.200 and 1798.150, Health and Safety

72 Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

73 **§ 100270.111. Percutaneous Coronary Intervention (PCI)**

74 “Percutaneous Coronary Intervention” or “PCI” means a procedure used to open or  
75 widen a narrowed or blocked coronary artery to restore blood flow supplying the heart.  
76 A primary PCI is generally done on an emergency basis for a STEMI patient.

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

78 Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

79 **§ 100270.112. Pre-Arrival Instructions**

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

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

88 **§ 100270.113. Quality Improvement**

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

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

97 **§ 100270.114. ST-Elevation Myocardial Infarction (STEMI)**

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

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

103 **§ 100270.115. STEMI Care**

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

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

107 **§ 100270.116. STEMI Medical Director**

108 “STEMI Medical Director” means a qualified physician as defined by the local EMS  
109 agency and designated by the hospital that is responsible for the STEMI program,  
110 performance improvement, and patient safety programs related to STEMI Critical Care  
111 System.

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

113 Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

114 **§ 100270.117. STEMI Patient**

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

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

118 Reference: Sections 1797.103, 1797.176 and 1797.220, Health and Safety Code.

119 **§ 100270.118. STEMI Program**

120 “STEMI Program” means an organizational component of the hospital specializing in the  
121 care of STEMI patients.

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

123 Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

124 **§ 100270.119. STEMI Program Manager**

125 “STEMI Program Manager” means a registered nurse or qualified individual as defined  
126 by the local EMS agency, and designated by the hospital responsible for monitoring and  
127 evaluating STEMI patients, performance improvement, and patient safety programs  
128 related to the STEMI Critical Care System.

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

130 Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

131 **§ 100270.120. STEMI Receiving Center (SRC)**

132 “STEMI Receiving Center” or “SRC” means a hospital that meets the minimum hospital  
133 STEMI care requirements pursuant to Section 100270.129 and is able to perform  
134 primary PCI.

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

136 Reference: Sections 1797.103, 1797.176 and 1797.220, Health and Safety Code.

137 **§ 100270.121. STEMI Referring Hospital (SRH)**

138 “STEMI Referring Hospital” means a hospital that meets the minimum hospital STEMI  
139 care requirements pursuant to Section 100270.130.

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

141 Reference: Sections 1797.103, 1797.176 and 1797.220, Health and Safety Code.

142 **§ 100270.122. STEMI Technical Advisory Committee**

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

146 Note: Authority cited: Sections 1797.107, 1797.133 and 1798.150, Health and Safety

147 Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

148 **§ 100270.123. STEMI Critical Care System**

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

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

154 Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

155 **§ 100270.124. STEMI Team**

156 “STEMI Team” means a component of the hospital’s STEMI Program consisting of a  
157 clinical team, support personnel, and administrative staff.

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

160 **ARTICLE 2. LOCAL EMS AGENCY STEMI CRITICAL CARE SYSTEM**  
161 **REQUIREMENTS**

162 **§ 100270.125. General Requirements and Timeframes**

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

164 (b) A local EMS agency implementing a STEMI Critical Care System shall submit to  
165 the EMS Authority a STEMI System Plan in accordance with the requirements in  
166 Section 100270.126.

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

173 (d) The local EMS agency shall provide a corrected plan to the EMS Authority within  
174 60 days of receipt of the disapproval letter.

175 (e) A local EMS agency currently operating a STEMI Critical Care System  
176 implemented prior to the effective date of these regulations, shall submit to the EMS  
177 Authority a STEMI System Plan as an addendum to its next annual EMS Plan update.

178 (f) After approval of the Plan, the local EMS agency shall submit an update to its  
179 STEMI System Plan as part of its annual EMS update, consistent with the requirements  
180 in Section 100270.127.

181 Note: Authority cited: Sections 1797.107, 1797.103, 1797.105, 1797.250, 1797.254 and  
182 1798.150, Health and Safety Code. Reference: Section 1797.176 and 1797.220, Health  
183 and Safety Code.

184 **§ 100270.126. STEMI Critical Care System Plan Requirements**

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

- 187 (a) the names and titles of the local EMS agency personnel who have a role in the  
188 STEMI Critical Care System,
- 189 (b) copies of agreements with hospitals for designation of STEMI facilities,
- 190 (c) description or copy of the local EMS agency's STEMI patient identification and  
191 destination policies,
- 192 (d) description or copy of the method of field communication to the receiving hospital  
193 specific to STEMI patient,
- 194 (e) description or copy of policy that facilitates interfacility transfer of a STEMI patient,
- 195 (f) description of the method of data collection from the EMS providers and  
196 designated STEMI hospitals to the local EMS agency and the EMS Authority,
- 197 (g) a copy of all written agreements with neighboring local EMS agencies that provide  
198 STEMI care,
- 199 (h) description of the integration of STEMI into an existing QI Committee or description  
200 of any STEMI specific QI committee, and
- 201 (i) description of programs to conduct or promote public education specific to cardiac  
202 care.

203 Note: Authority cited: Sections 1797.103, 1797.107, 1797.114, 1797.204, 1797.220,  
204 1798.150, 1798.170 and 1798.172, Health and Safety Code. Reference: Section  
205 1797.176, 1797.220, 1797.222, Health and Safety Code.

206 **§100270.127. STEMI System Plan Updates**

207 The local EMS agency shall submit a STEMI System Plan update as part of its annual  
208 EMS Plan submittal. The update shall include at a minimum, the following:

- 209 (a) any changes in the STEMI Critical Care System since submission of the prior  
210 annual plan update or the STEMI System Plan addendum,
- 211 (b) status of STEMI Critical Care System goals and objectives,
- 212 (c) STEMI Critical Care System QI activities, and
- 213 (d) progress on addressing action items and recommendations provided by the EMS  
214 Authority within the STEMI System Plan or Status Report approval letter if applicable.



215 Note: Authority cited: Sections 1797.103, 1797.107, 1797.176, 1797.250, 1797.254,  
216 1798.150, and 1798.172, Health and Safety Code. Reference: Section 1797.176,  
217 1797.220, 1797.222, 1798.170, Health and Safety Code.

### 218 **ARTICLE 3. PREHOSPITAL STEMI CRITICAL CARE SYSTEM REQUIREMENTS**

#### 219 **§ 100270.128. EMS Personnel and Early Recognition**

220 A local EMS agency with an established STEMI Critical Care System shall have  
221 protocols for the treatment of STEMI patients, including paramedic capability to perform  
222 use of 12-lead ECG equipment, and determination of patient destination.

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

225 (1) direct paramedic interpretation,

226 (2) automated computer algorithm, or

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

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

231 Note: Authority cited: Sections 1797.103, 1797.107, 1797.114, 1797.176, 1797.206,  
232 1797.214 and 1798.150, Health and Safety Code. Reference: Section 1797.176,  
233 1797.220, 1798, 1798.150 and 1798.170, Health and Safety Code.

### 234 **ARTICLE 4. STEMI CRITICAL CARE FACILITY REQUIREMENTS**

#### 235 **§ 100270.129. STEMI Receiving Center**

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

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

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

242 (c) The hospital shall have a single call activation system to activate the Cath Lab  
243 team directly.

- 244 (d) Written protocols and standing orders shall be in place for the identification of  
245 STEMI patients. At a minimum, these protocols shall be available in the intensive care  
246 unit/coronary care unit and the emergency department (ED).
- 247 (e) The hospital shall be available for treatment of STEMI patients 24 hours per day/7  
248 days per week/365 days per year.
- 249 (f) The hospital shall have a process in place for the treatment and triage of  
250 simultaneously arriving STEMI patients.
- 251 (g) The hospital shall maintain a STEMI team call roster.
- 252 (h) The Cath Lab team, including appropriate staff determined by the local EMS  
253 agency, shall be immediately available.
- 254 (i) The hospital shall agree to accept all STEMI patients.
- 255 (j) SRCs shall comply with the requirement for a minimum volume of procedures for  
256 designation by the local EMS agency.
- 257 (k) The hospital shall have a STEMI program manager and a STEMI medical director.
- 258 (l) The hospital shall have job descriptions and organizational charts depicting the  
259 relationship between the STEMI medical director, STEMI program manager, and the  
260 STEMI team.
- 261 (m) The hospital shall participate in the local EMS agency QI processes related to the  
262 STEMI Critical Care System.
- 263 (n) Local EMS agencies shall ensure STEMI receiving facilities without cardiac  
264 surgery capability on-site have a written transfer plan and agreements for transfer to a  
265 facility with cardiovascular surgery capability.
- 266 (o) Additional requirements may be included at the discretion of the local EMS agency  
267 medical director.

268 Note: Authority cited: Sections 1797.103, 1797.107, 1797.176, 1797.220, and 1798.150  
269 1798.167 and 1798.172, Health and Safety Code. Reference: Section 1797.176,  
270 1797.220, 1798, 1798.150 and 1798.170 Health and Safety Code.

271 **§ 100270.130. STEMI Referring Hospital (SRH)**

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

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

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

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

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

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

285 (f) The hospital shall have a program to track and improve treatment. The hospital  
286 must have a plan to work with SRCs and the local EMS agency on QI processes.

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

289 Note: Authority cited: Sections 1797.103, 1797.107, 1797.176, 1797.220, and 1798.150  
290 1798.167 and 1798.172, Health and Safety Code. Reference: Section 1797.176,  
291 1797.220, 1798.150 and 1798.170 Health and Safety Code.

292 **ARTICLE 5. DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATIONS**

293 **§ 100270.131. Data Management**

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

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

298 (2) The prehospital and hospital STEMI patient care elements selected by the local  
299 EMS agency shall be compliant with the most current version of the California EMS  
300 Information Systems (CEMSIS) database, the National EMS Information System

301 (NEMESIS) and the National Cardiovascular Data Registry, Action Registry, version 2.4  
302 dated March 2014.

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

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

308 (b) The following minimum elements shall be collected and submitted to the local  
309 EMS agency by the hospital and utilized to determine prehospital and hospital system  
310 performance:

- 311 1. EMS ePCR Number
- 312 2. Facility
- 313 3. Name: Last, First
- 314 4. Date of Birth
- 315 5. Patient Age
- 316 6. Patient Gender
- 317 7. Patient Race
- 318 8. Hospital Arrival Date
- 319 9. Hospital Arrival Time
- 320 10. Dispatch Date
- 321 11. Dispatch Time
- 322 12. Field ECG Performed
- 323 13. 1st Field ECG Date
- 324 14. 1st Field ECG Time
- 325 15. Did the patient suffer out-of-hospital cardiac arrest
- 326 16. CATH LAB Activated
- 327 17. CATH LAB Activation Date
- 328 18. CATH LAB Activation Time
- 329 19. Did the patient go to the CATH LAB
- 330 20. CATH LAB Arrival Date
- 331 21. CATH LAB Arrival Time
- 332 22. PCI Performed

- 333 23. PCI Date
- 334 24. PCI Time
- 335 25. Fibrinolytic Infusion
- 336 26. Fibrinolytic Infusion Date
- 337 27. Fibrinolytic Infusion Time
- 338 28. Transfer
- 339 29. SRF ED Arrival Date
- 340 30. SRF ED Arrival Time
- 341 31. SRF ED Departure Date
- 342 32. SRF ED Departure Time
- 343 33. Hospital Discharge Date
- 344 34. Patient Outcome
- 345 35. Discharge Diagnosis

346 Note: Authority cited: Sections 1791.102, 1797.103, 1797.107, 1797.176, 1797.204,  
347 1797.220, 1798.150, and 1798.172, Health and Safety Code. Reference: Section  
348 1797.220, 1797.222, 1797.204, Health and Safety Code.

349 **§ 100270.132. Quality Improvement Process**

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

- 354 (a) an audit of all STEMI-related deaths;
- 355 (b) a multidisciplinary STEMI QI Committee, including both pre-hospital and hospital  
356 members;
- 357 (c) compliance with the California Evidence Code, Section 1157.7 to ensure  
358 confidentiality; and
- 359 (d) a disclosure-protected review of selected STEMI cases.

360 Note: Authority cited: Sections 1797.103, 1797.107, 1797.176, 1797.204, 1797.220,  
361 1798.150, Health and Safety Code. Reference: Section 1797.176, 1798.204, 1797.220,  
362 1798.150, Health and Safety Code.

363 **§ 100270.133. STEMI Critical Care System Evaluation**

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

366 (b) The local EMS agency shall be responsible for the development of a QI process  
367 pursuant to Section 100270.132.

368 (c) The local EMS agency shall be responsible for ensuring that designated STEMI  
369 centers and other hospitals that treat STEMI patients participate in the QI process  
370 contained in Section 100270.132, as well as prehospital providers involved in the  
371 STEMI Critical Care System.

372 Note: Authority cited: Sections 1797.102, 1797.103, 1797.107, 1797.176, 1797.204,  
373 1797.220, 1797.250, 1797.254, 1798.150, and 1798.172, Health and Safety Code.

374 Reference: Section 1797.104, 1797.176, 1797.204, 1797.220, 1797.222, 1798.170,  
375 Health and Safety Code.