

**COMMENTS for DRAFT STEMI REGULATIONS**

**Comment Period: December 16, 2016 - January 30, 2017**

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
General	Sierra – Sacramento Valley EMS Agency	<p>Current chapter 7 trauma regulations (section 100253), (k) states “No health care facility shall advertise in any manner or otherwise hold themselves out to be a trauma center unless they have been so designated by the local EMS agency, in accordance with this Chapter.”</p> <p>Similar language should be added to the STEMI regulations ““No health care facility shall advertise in any manner or otherwise hold themselves out to be a STEMI center unless they have been so designated by the local EMS agency, in accordance with this Chapter.”</p>	<p>Comment acknowledged. Consistency of language of regulations will be confirmed.</p>
	Los Angeles County EMS Agency	Suggest adding wording to ensure participating hospital is licensed and accredited	<p>Comment acknowledged. Comment is unclear as to what area of draft regulations it is referencing.</p>
	Los Angeles County EMS Agency	Review Terms and Definitions to assure they are consistent across all of the different regulations ie Qualified Specialist, Immediately Available etc.	<p>Comment acknowledged. Definitions are consistent.</p>
§100270.101 Page 1, Lines 9-10	BJ Bartleson, CHA	Change the definition to match Title 22, §70438, “Cardiac Catheterization Laboratory” or “Cath Lab” means the setting in the hospital where laboratory procedures for obtaining physiologic, pathologic and angiographic data can be performed”.	<p>Comment acknowledged. Change made.</p>

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§100270.101 Page 1, Lines 9-10 Cardiac Catheterization	BJ Bartleson, CHA	Add a definition for “Cardiac Catheterization the performance of laboratory procedures for obtaining physiologic , pathologic and angiographic data on patients with cardiovascular disease” Title 22 §70438	Comment acknowledged. Change made..
ARTICLE 1. DEFINITIONS. §100270.2XX STEMI Center Addition	REMSA	Consider adding a definition for STEMI Receiving Center: “STEMI Center” or “designated stroke center” means a licensed hospital accredited by The Joint Commission, Healthcare Facilities Accreditation Program (HFAP), or Det Norske Veritas (DVN).	Comment acknowledged. We have SRC Definition. The designation of STEMI Centers falls under the LEMSAs’ authority and responsibility; we will not prescribe a specific certifying body in Regulations.
ARTICLE 1. DEFINITIONS. §100270.2XX STEMI Center Addition	Inland Counties Emergency Medical Agency (ICEMA)	Consider adding a definition for STEMI Receiving Center: “STEMI Center” or “designated stroke center” means a licensed hospital accredited by The Joint Commission, Healthcare Facilities Accreditation Program (HFAP), or Det Norske Veritas (DVN).	Comment acknowledged. We have SRC Definition. The designation of STEMI Centers falls under the LEMSAs’ authority and responsibility; we will not prescribe a specific certifying body in Regulations.

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Article 1 Definitions §100270.xxx	BJ Bartleson, CHA	<p>Add the following new definitions:            American Heart Association- (AHA) is the national non-profit health organization that sets standards of cardiac care delivery to foster appropriate cardiac care to reduce disability and deaths caused by Cardiovascular disease and stroke.            American Heart Association            Mission:Lifeline - A national initiative to advance the systems of care for patients with ST-segment elevation myocardial infarction (STEMI) and Out of Hospital Cardiac Arrest (OOHCA American Heart Association Get With The Guidelines, GWTG®- Heart Failure- an in-hospital program for improving cardiac care by promoting consistent adherence to the latest scientific treatment guidelines with metrics and performance improvement.            American Heart Association, STEMI Systems of Care - A proactive system of care that connects healthcare providers, prehospital providers and community stakeholders that saves and improves lives from symptom onset through cardiac rehabilitation.</p>	<p>Comment acknowledged.            No change. We will not be listing or defining entities involved in cardiac care unless they have specific reference or use in these regulations.</p>
100270.102 Page 1 Lines 14	Los Angeles County EMS Agency	<p>Delete: word "medical":            Change to: special trained healthcare staff that coordinate and performs PCI- Medical Staff is generally considered MD or mid-level practitioners. Team includes staff that act in a coordination role, not just those performing PCI.</p>	<p>Comment acknowledged.            No Change. Review completed and all the staff mentioned are medical staff.</p>

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
§100270.102 Page 1, line 14-17	BJ Bartleson, CHA	Change to: "Cardiac Catheterization Team means the specialty trained medical staff that performs and assists with cardiac catheterization. It may include, but is not limited to, an interventional cardiologist, mid-level practitioners, registered nurses, technicians and other health care professionals".	Comment acknowledged. Change made.
100270.104 & 100270.105 Page 2 Line 27-33	Mary Magocsy, RN, MBA San Francisco Emergency Medical Services Agency	100270.104 Door to Balloon Time and 100270.105 Door to Needle Time • San Francisco calls this the "Door to Intervention Time" to acknowledge that there may be other interventions done.	Comment acknowledged. No Change. The terms used in these regulations are consistent with national practice.
100270.102/ p.1/ L24	Patrick Powers Powers Mobile HealthCare INC.	Suggestion to add Paramedic and EMT to definition since both may work in acute care hospitals in California in specified circumstances.	Comment acknowledged. No Change. Language is permissive with "Not limited to" in this area.
Page 1/before 100270.104	Los Angeles County EMS Agency	Add: definition for first medical contact to balloon time.	Comment acknowledged. No change. This term is not used in the regulations.
100270.105 Page 2 Line 35	Los Angeles County EMS Agency	Add: "attempt to" between "to" and "open". To open-fibrinolytic therapy does not always unblock the artery.	Comment acknowledged. Change made for clarification.
100270.107 Page 2 Line 44	Los Angeles County EMS Agency	Comment: "Immediately Available" should be consistent across all of the different specialty regulations (stroke/trauma) Clarify if requirement refers to an on-call or in-house status	Comment acknowledged. The definition is consistent with other regulations.

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ARTICLE 1. DEFINITIONS. §100270.107 Immediately Available p.2 line 44-45	REMSA	Add in definition "within 15 minutes", to be consistent with Trauma Regulations.	Comment acknowledged. No change. Consistent with Stroke Regulations; the definitions are for the purpose of this specific specialty care systems.
ARTICLE 1. DEFINITIONS. §100270.107 Immediately Available p.2 line 44-45	Inland Counties Emergency Medical Agency (ICEMA)	Add in definition "within 15 minutes", to be consistent with Trauma Regulations.	Comment acknowledged. No change. Consistent with Stroke Regulations; the definitions are for the purpose of this specific specialty care systems.
§100270.107. Page 2, line 45-49	BJ Bartleson, CHA	Delete the definition of immediately available and utilize the AHA STEMI time standards	Comment acknowledged. No change. Consistent with Stroke Regulations; the definitions are for the purpose of this specific specialty care systems.
100270.110 Page 3 Line 63	Mary Magocsy, RN, MBA San Francisco Emergency Medical Services Agency	100270.110 Local Emergency Medical Services Agency • LEMSAs are already defined in the H&S Code Division 2.5 section 1797.94	Comment acknowledged. Change to be consistent with the H&S Code Division 2.5 section 1797.94.
§100270.111 Page 3, lines 74-76	BJ Bartleson, CHA	Change to: "Percutaneous Coronary Intervention" or PCI means a broad group of percutaneous techniques utilized in the dilation of coronary, heart or arterial obstructions to diagnose and treat patients with STEMI.	Comment acknowledged. No change. We will review for clarification.

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100270.111 Page 3 Line 76	Los Angeles County EMS Agency	Define "Primary PCI" separately or delete sentence.	Comment acknowledged. Change made.
Page 4/ Lines 79 – 84	Brian Henricksen Napa County EMS Agency	Pre-Arrival Instructions is defined in the regulations but the term is never used in the following regulations.	Comment acknowledged. Change made.
100270.112 Page 4 Line 82-83	Los Angeles County EMS Agency	Delete: "that provide necessary assistance and control of the situation"- Unnecessary, sentence is difficult to follow, meaning is clearer with this removed.	Comment acknowledged. Change made.
100270.113 Page 4 Line 88	Mary Magocsy, RN, MBA San Francisco Emergency Medical Services Agency	100270.113 Quality Improvement • Redundant – this mentioned elsewhere in the H&S Code Division 2.5	Comment acknowledged. Change made for consistency with H&S Code.
Section 100270.114 Page 4 Line 97	Santa Clara County STEMI Committee	Change definition to match ACC definition. Should also include STEMI equivalent definition.	Comment acknowledged. Change made for clarity.
100270.114 Page 4 Line 99-100	Los Angeles County EMS Agency	Delete "characteristic symptoms" and Change to: ...presence of myocardial infarction in association with ST-segment elevation on the ECG. Delete "and the subsequent release of biomarkers of myocardial necrosis"	Comment acknowledged. Change made.
Page 4/ Line 104	Brian Henricksen Napa County EMS Agency	This should include expanded cardiac life support, which may include PCI during cardiac arrest, implanted pump, or extracorporeal membrane oxygenation (ECMO)	Comment acknowledged. No change. All treatment plans are not explained in this definition.

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ARTICLE 1. DEFINITIONS. §100270.116 STEMI Medical Director p. 5 line 107-111	Inland Counties Emergency Medical Agency (ICEMA)	Consider adding "board-certified": "STEMI Medical Director" means a board- certified physician designated by the hospital who is responsible for the STEMI program, performance improvement, and patient safety programs related to the STEMI Critical Care System.	Comment acknowledged. No Change. This would eliminate board-eligible situations.
ARTICLE 1. DEFINITIONS. §100270.116 STEMI Medical Director p. 5 line 107-111	REMSA	Consider adding "board-certified": "STEMI Medical Director" means a board- certified physician designated by the hospital who is responsible for the STEMI program, performance improvement, and patient safety programs related to the STEMI Critical Care System.	Comment acknowledged. No Change. This would eliminate board-eligible situations.
Section 100270.117 Page 5 Line 114	Santa Clara County STEMI Committee	Above the age of 18	Comment acknowledged. No change. Age specifications are needed in this definition.
100270.117 Page 5 Line 115-116	Los Angeles County EMS Agency	Delete "characteristic symptoms" and Change to: ...with acute myocardial infarction in association with ST-segment elevation on the ECG.	Comment acknowledged. No change. Suggested wording would exclude certain patient populations.
Section 100270.119 Page 5 Line 124	Santa Clara County STEMI Committee	Should be dedicated to the program.	Comment acknowledged. No change. Staff may have different roles and responsibilities.
Section 100270.119 Page 5 Line 124	Santa Clara County STEMI Committee	Is there a requirement for the LEMSA to have a program manager?	Comment acknowledged. No Change. Refer to the STEMI Center requirement section for LEMSA requirements.

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100270.119 Page 5 Line 127-128	Los Angeles County EMS Agency	Delete: 'STEMI patients, performance improvement, and patient safety programs related to the STEMI Critical Care System' Change to:...evaluating the STEMI program.	Comment acknowledged. No change. Language consistent with other regulations.
§100270.121 STEMI Referring Hospital (SRH) Page 6 Lines, 138-139	BJ Bartleson, CHA	Change to, "a licensed acute care facility that meets the minimum hospital STEMI care requirements pursuant to section 100270.130.	Comment acknowledged. Change made.
§100270.123 STEMI Critical Care System Page 6 Lines149-152	BJ Bartleson, CHA	Change to: "A critical care system developed by the local EMS agency that meets all the criteria for the AHA STEMI Systems of Care.	Comment acknowledged. No change. The designation is the LEMSA's responsibility; minimum criteria set at the state level.
100270.123 Page 6 Line 150-152	Los Angeles County EMS Agency	Delete: the period and 'This system of care'. Add: "that" links prehospital and hospital care to deliver treatment to STEMI patients. Delete: within the timeframes recommended by the AHA. While the goal is to guidelines, a STEMI care system may exist for that goal but not meet them; therefore should not be included in the definition. Move to QI	Comment acknowledged. No change. The purpose is to use a national standard of measure.



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§100270.124 STEMI Team Page 6 Lines 156-157	BJ Bartleson, CHA	Change to “STEMI Team” refers to all personnel in the PCI, Non-PCI, and EMS components of the STEMI system of care, that perform STEMI related functions according to the AHA STEMI Systems of Care Criteria	Comment acknowledged. No change. Language refers to all staff indicated and allows for variances.
100270.124 Page 6 Line 156	Los Angeles County EMS Agency	Change word “component” –refers to personnel or staff, change language	Comment acknowledged. Change made.
Article 2, 100270.125, (e) Line175-177	North Coast EMS	Allowing a LEMSA that is currently operating a STEMI system prior to the effective date of these regulations to submit “a STEMI System Plan as an addendum to the next EMS Plan update” is spot on and the Stroke and EMSC regulations should have the same wording. Please note that the draft Stroke regulations are different and require a plan addendum to be submitted with 180 days of adoption of the regulation, which creates extra work and cost to the LEMSA and EMSA. Thank you!	Comment acknowledged. Change made for clarity and consistency with other regulations.
Article 2. Local EMS Agency STEMI Critical Care System Requirements §100270.126 STEMI Critical Care System Plan Requirements, Page 7-8 Line 187	BJ Bartleson, CHA	Add, “Adherence to all criteria in AHA’s STEMI Systems of Care” as the initial requirement in addition to (a) through (f).	Comment acknowledged. No change. Listing one single entity’s standard, given multiple options available, is not something we want to put in these regulations.

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Page 8/ Line 189	Brian Henricksen Napa County EMS Agency	Affirmation that agreements exist should be sufficient. Agreements between LEMSA and facility are a matter of local control. LEMSA should not be required to submit copies of agreements.	Comment acknowledged. Change made with stipulation that agreements are readily available upon request.
100270.126 Page 8 Line 189	Los Angeles County EMS Agency	Please clarify if you want a copy of all individual SRC agreements or the template agreement and the names of all approved SRCs?	Comment acknowledged. Change made with stipulation that agreements are readily available upon request.
ARTICLE 2. LOCAL EMS AGENCY STEMI CRITICAL CARE SYSTEM § 100270.126 State Stroke System Plan Requirements(b) p.8 line 189	REMSA	Consider changing "copies of agreements to:  A copy of the model agreement with hospitals for designation of STEMI facilities with a list of STEMI hospital contracts with expiration and terms dates.  Currently, some LEMSAs have over 10 STEMI facilities. Providing a copy of each agreement would be labor intensive.	Comment acknowledged. Change made with stipulation that agreements are readily available upon request.
ARTICLE 2. LOCAL EMS AGENCY STEMI CRITICAL CARE SYSTEM § 100270.126 State Stroke System Plan Requirements(b) p.8 line 189	Inland Counties Emergency Medical Agency (ICEMA)	Consider changing "copies of agreements to:  A copy of the model agreement with hospitals for designation of STEMI facilities with a list of STEMI hospital contracts with expiration and terms dates.  Currently, some LEMSAs have over 10 STEMI facilities. Providing a copy of each agreement would be labor intensive.	Comment acknowledged. Change made with stipulation that agreements are readily available upon request.

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100270.126 Page 8 Line 194	Dan Burch San Joaquin County EMS Agency	Recommend eliminating item e) from STEMI plan submission. This information is not relevant to the state's oversight of STEMI services.	Comment acknowledged. No change. Inter-facility transfer is part of the process in the patient care plan for STEMI patients.
Page 8/ Line 197-198	Brian Henricksen Napa County EMS Agency	What is the purpose of the written agreements with neighboring local EMS agencies? Is it for data sharing and QI purposes? Even without written agreements patients should be and are generally transported to the closest, most appropriate STEMI Receiving Center.	Comment acknowledged. The purpose is to not have any conflict with the in the areas that fall between LEMSAs.
100270.126 Page 8 Line 198	Los Angeles County EMS Agency	Add: if applicable or clarify	Comment acknowledged. No change. Each LEMSA has a neighboring LEMSA so this is applicable statewide.

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§100270.126 Page 8 Lines 197-198	Contra Costa County	<p>What is the purpose of the submission of copies of the hospital written agreements to the EMSA?</p> <p>Regardless of a written agreement and county lines, patients should be transported to the closest, most appropriate SRC. LEMSAs as part of normal operations typically coordinate oversight with neighboring out of county LEMSAs as part of a quality process and it is NOT necessary to duplicate designation efforts.</p> <p>Remove item B and G and replace with LEMSA verification of written agreements and letter of agreement to cooperate between jurisdictions when indicated. No reason to add to workflow activities which will simply add cost with no value in the management of STEMI systems. Copies of contracts are unnecessary as contractual requirements are clearly the responsibility of the LEMSA local control. EMSA reporting should be limited to information on system design, partners and processes data supporting oversight.</p>	<p>Comment acknowledged.            Change made with stipulation that agreements are readily available upon request.</p>
100270.126 Page8 Line197	Kern	<p>What will the state do with copies of the agreements with hospitals? Seems like a lot of unnecessary paperwork. Remove requirement</p>	<p>Comment acknowledged.            Change made with stipulation that agreements are readily available upon request.</p>

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100270.127 STEMI System Plan Updates Page 8 Line 206	Contra Costa County	Remove all references to "STEMI Critical Care System". This language in this section relating to prehospital care suggests expanded scope BEYOND paramedic and evidenced based practice associated with STEMI System planning. This language creates confusion and does not serve any purpose. Simplify and replace with STEMI System Plan.	Comment acknowledged. No change. A STEMI Critical Care System is different than a STEMI System Plan.
100270.127 Pge8 Line 206	Kern	There has to be a better way to compile this information. Please include these requirements for any specialty programs in the form of a template for the LEMSA to complete.	Comment acknowledged. No change. This regulation discusses content and not format of the information to be submitted.
100270.127, Line 206-217	"North Coast EMS	Excellent – concise, consistent with current EMS Plan update requirements and this section should be the template for the draft Stroke and EMSC regulations.	Comment acknowledged.
100270.127 STEMI System Plan Updates Line b 211	Contra Costa County	Verification of agreements is sufficient with information on entities and dates. Submitting copies of agreements is unnecessary and is the responsibility of the LEMSA as part of their local control.	Comment acknowledged. Change made with stipulation that agreements are readily available upon request.
Article 3. Prehospital STEMI Critical Care Requirements §100270.128 Page 9, lines 219- 230	BJ Bartleson, CHA	Change lines 220-222 to read, "A local EMS agency with an established STEMI Critical Care System shall perform all protocols outlined in AHA's Mission Lifeline Criteria for STEMI Systems of Care, EMS. Remove lines 223-230.	Comment acknowledged. No change. Minimum requirements in these regulations are set at the state level; the rest is the responsibility of the LEMSA.

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100270.128 Page9 Line219-230	Judith A. Scott, MHA RN PHN FAEN One Baldwin Ave #901 San Mateo, CA 94401 M 760 644-0102 CA ENA	Time frame for care – From recognition of possible STEMI to Cath Lab – 90 minutes (60 would be better)	Comment acknowledged. No change. Subject of the comment was not found in the addressed section of the draft.
100270.128 Page 9 Line 222	Los Angeles County EMS Agency	Delete: 'use of', 'equipment', and of Change to: ...capability to perform a 12-lead ECG to determine patient destination.	Comment acknowledged. Change made.
100270.128 EMS Personnel and Early Recognition Page 9 Line 223-224	Contra Costa County	227(3) Should be changed to "Physician interpretation or confirmation via a technologic modality approved by system stakeholders. Typo found on line 224 though should be "through"	Comment acknowledged. Change made.
100270.128 Page 9 Line 223	Los Angeles County EMS Agency	Delete: 'equipment is used those findings shall be assessed and'... Change to : When a 12-lead ECG is acquired it shall be interpreted ...	Comment acknowledged. Change made.
100270.128 Page9 Line 219-230	Judith A. Scott, MHA RN PHN FAEN One Baldwin Ave #901 San Mateo, CA 94401 M 760 644-0102 CA ENA	When training additional positions to do EKGs, these positions must learn to recognize a problem. We are not saying make a diagnosis but to be able to say – this is not normal. That way a problem EKG will receive attention.	Comment acknowledged. No change. Not EMSA preview.
Article 3 Page 9 Line 224	Heather Ellis EMS Coordinator Ventura City Fire Department	Interpreted through (sp) two or more of the following methods.  Rationale: Automated computer algorithms have been deemed unreliable through research (AHA); therefore, paramedic interpretation and/ or wireless transmission should be added to prevent missing a STEMI patient	Comment acknowledged. No change. The false negative by the machine can still be assessed by the physician.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
Page 9/ Line 224	Brian Henricksen Napa County EMS Agency	Typo – though should be through	Comment acknowledged. Change made.
Article 4. STEMI Critical Care Facility Requirements, Page 9, lines 236-266	BJ Bartleson, CHA	Change lines 236-237 to say: "AHA Primary PCI Hospital STEMI Receiving Center criteria shall be used by the local EMS agency for the designation of SRC." Remove lines 238-241 Remove lines 244-248 Remove lines 252-253 Remove lines 252-262 Change line 266 to: "Additional requirements may be included at the discretion of the local EMS agency medical director with the concurrence of the local EMS STEMI Systems of Care providers."	Comment acknowledged No change. It is the LEMSA's responsibility to establish designations. EMSA sets the minimum criteria at the state level.
100270.129 Page 9 Line 236-237	Los Angeles County EMS Agency	Add: licensed facility, accredited by CMS approved accrediting body to the minimum criteria	Comment acknowledged. Change made.
4 Page 9 Line 236	Kula Koenig & Mick Smith- American Heart Association/American Stroke Association	In addition to hospitals designated by local EMS agency, EMSA shall recognize those STEMI hospitals designated by nationally accrediting bodies without these hospitals having to go through a separate accrediting process by the local EMS agency.	Comment acknowledged. It is LEMSA's responsibility to designate the hospital consistent with these regulations.



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4/ Pge9 Line 236	Kula Koenig & Mick Smith- American Heart Association/American Stroke Association	EMSA shall recognize any hospital as a STEMI Receiving Center if that hospital has been accredited as a Mission: Lifeline STEMI Receiving Center by the American Heart Association (AHA) accreditation process or another department approved nationally recognized organization that provides STEMI Receiving Center accreditation.	Comment acknowledged. No change. It is LEMSA's responsibility to designate the hospital consistent with these regulations.
ARTICLE 4. STEMI CRITICAL CARE FACILITY REQUIREMENTS § 100270.129 STEMI Receiving Center (a) - (o) p. 9 lines 236-267 Addition	Inland Counties Emergency Medical Agency (ICEMA)	Consider adding: <ul style="list-style-type: none"> <li>No provider of prehospital care 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.</li> </ul> <p>This can allow hospitals to bypass LEMSA designation and advertise their services directly to EMS providers and undermine any LEMSA destination policy.</p>	Comment acknowledged. Change made to be consistent with other regulations (on Facilities for STEMI Care not for prehospital providers though) and also not to bypass LEMSA's destination policy.
100270.129 STEMI Receiving Center Page 9 Line 235	Contra Costa County	This information should suffice instead or the requirements for copies of written agreements. Recommend this be collected as part of checklist submitted to EMSA. No need for EMSA to duplicate local control processes for oversight. That is the sole domain of the LEMSA	Comment acknowledged. Change made with stipulation that agreements are readily available upon request.
100270.129 Page 9 Line 238-239	Los Angeles County EMS Agency	How is this measured?; provide criteria or clarification	Comment acknowledged. Change made.



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ARTICLE 4. STEMI CRITICAL CARE FACILITY REQUIREMENTS § 100270.129 STEMI Receiving Center (a) - (o) p. 9 lines 236-267 Addition	REMSA	<p>Consider adding:</p> <ul style="list-style-type: none"> <li>No provider of prehospital care 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.</li> </ul> <p>This can allow hospitals to bypass LEMSA designation and advertise their services directly to EMS providers and undermine any LEMSA destination policy.</p>	<p>Comment acknowledged. Change made to be consistent with other regulations and also not to bypass LEMSA's destination policy.</p>
100270.129 Line 245-246	Coleman MD Coastal Valley EMS	This sounds like EMS is telling a hospital how to run their STEMI program.	<p>Comment acknowledged. No change. The STEMI System of care designed at the state level with setting minimal requirements and implement by Local EMS Agencies.</p>
100270.127 Pge 10 Line 254	Kern	Please add a requirement that the Physician shall not be available on-call for more than 1 facility at any given time.	<p>Comment acknowledged. No change. Not under EMSA's preview.</p>
100270.129 Page 10 Line 254	Los Angeles County EMS Agency	Delete: Too complicated. EMTALA rules, capacity issues, etc.	<p>Comment acknowledged. Modify sentence to clarify.</p>

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100270.129 Line 255	Coleman MD Coastal Valley EMS	Volume requirements should not be set by the local EMS agency but by Title 22 requirements.	Comment acknowledged. No change. This is a local control issue for quality improvement that might vary by the geographic locations.
Line255	Brian Wilson R.N Dignity Health	No Minimum volume requirement, this will force some institutions out and increase intervention times	Comment acknowledged. No change. This is a local control issue for quality improvement that might vary by the geographic locations.
100270.129 Page 10 Line 263	Los Angeles County EMS Agency	Delete: 'Local EMS Agency shall ensure' - redundant as above Change: 'Facilities' to 'Centers'	Comment acknowledged. Change made. This is a local control issue for quality improvement that might vary by the geographic locations.
100270.129 Page 10 Line 255- Line 256	Los Angeles County EMS Agency	Delete: This is a credentialing issue. Numbers should be evaluated by accrediting bodies and by the hospital for credentialing individual physicians-not the responsibility of the EMS Agency. The final part of the sentence is redundant-entire section is a list of criteria for designation by EMS Agency.	Comment acknowledged. No change. This is a local control issue for quality improvement that might vary by the geographic locations.
4/ page10 line/267	Kula Koenig & Mick Smith- American Heart Association/American Stroke Association	Included in the written policy should be on-site accreditation reviews to be conducted every three years for the STEMI Receiving Center.	Comment acknowledged. Change made.

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100270.130 Page 11 Line 272-288	Los Angeles County EMS Agency	Add; if applicable. Is it a requirement for all systems to designate SRHs? Instead, it should be the default for all non-SRC 911 receiving hospitals - all hospitals should do this. Hospitals will avoid designation to avoid the requirements for transfer agreements, data submission, etc. More emphasis should be placed on integration of the SRH with the SRC.	Comment acknowledged. No change.
100270.130 Page 11 Line 272 - 288	San Joaquin County EMS Agency	Recommend eliminating entire section on STEMI Referring Hospitals (SRHs). There are limited incentives to justify the cost of planning, designating, and continually evaluating SRHs.	Comment acknowledged. No change. If the hospital request designation, it is the LEMSA's responsibility for the designation and any cost involved.
§100270.130 STEMI Referring Hospital (SRH), Page 11, lines 272-288	BJ Bartleson, CHA	Change Lines 272-273 to:"AHA Non-PCI Hospital STEMI Receiving Center criteria shall be used by the local EMS agency for designation of an SRH. Remove lines 274-281 Remove lines 285-286  Change 287-288 to," Additional requirements may be included at the discretion of the local EMS agency medical director with the concurrence of the local EMS STEMI Systems of Care providers."	Comment acknowledged. No change. It is the LEMSA's responsibility and the Medical Directors.

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4/ page11 line272	Kula Koenig & Mick Smith- American Heart Association/American Stroke Association	EMSA shall recognize any hospital as a STEMI Referring Center if that hospital has been accredited as a Mission: Lifeline STEMI Referring Center by the American Heart Association accreditation process or another department approved nationally recognized organization that provides STEMI Referring Center accreditation.	Comment acknowledged. No change. This is the LEMSA's responsibility.
100270.130 Page 11 Line 282	Los Angeles County EMS Agency	Change: 'system' to 'process'	Comment acknowledged. Change made.
4/ page11 line/288	Kula Koenig & Mick Smith- American Heart Association/American Stroke Association	Included in the written policy should be on-site accreditation reviews to be conducted every three years for the STEMI Referring Center.	Comment acknowledged. Change made.

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<p>Article 5. Data Management, Quality Improvement and Evaluations Page 11 Lines 294-307</p>	<p>BJ Bartleson, CHA</p>	<p>Change lines 294-295 to, "The local EMS agency shall implement a standardized data collection and reporting process for STEMI Critical Care Systems based on AHA's Mission Lifeline required data elements and Get With The Guidelines GWTG® or equivalent data registry" Remove lines 296-297 Change lines 303-304 to, "STEMI data shall be integrated into the local EMS agency and the EMS Authority data management system through data submission or data acquisition, on no less than a quarterly basis. Change lines 305-307 to: all hospitals that receive STEMI patients shall participate in the local EMS agency data collection process in accordance with local EMS, and AHA Criteria for STEMI Systems of Care policies and procedures.</p>	<p>Comment acknowledged. Change made for clarity.</p>
<p>Page 11/ Line 296 - 301</p>	<p>Brian Henricksen Napa County EMS Agency</p>	<p>Do not specify versions of CEMSIS or NEMSIS in the regulations as versions change over time. Perhaps "the most current version of CEMSIS/NEMSIS" would work to allow for changes.</p>	<p>Comment acknowledged. Change made.</p>
<p>Article 5, 100270.131, (1), Line 296-297</p>	<p>North Coast EMS "</p>	<p>"As determined by the LEMSA" is spot on.</p>	<p>Comment acknowledged.</p>

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100270.131 Data Management Line 298-301	Contra Costa County	Do not specify versions in the regulations as CEMSIS or NEMSIS versions as these will change over time and become obsolete. Recommend stating the most current version of NEMSIS or other statement	Comment acknowledged. Change made.
ARTICLE 5 DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATION § 100270.131 Management P.11-12 line 298-302.	Inland Counties Emergency Medical Agency (ICEMA)	Consider removing date.  Consider adding: "...most current version as stated by EMSA."  Versions may change more quickly than the regulations.	Comment acknowledged. Change made.
ARTICLE 5 DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATION § 100270.131 Management P.11-12 line 298-302.	REMSA	Consider removing date.  Consider adding: "...most current version as stated by EMSA."  Versions may change more quickly than the regulations.	Comment acknowledged. Change made.
100270.131 Page 12 Line 301-302	Los Angeles County EMS Agency	Delete: version 2.4 dated March 2014.	Comment acknowledged. Change made.
100270.131 Page 12 Line 301-302	San Joaquin County EMS Agency	There is a more current version for the National Cardiovascular Data Registry, Action Registry = version 2.4.2 Dated 12/16/2015. Recommend deleting CEMSIS from requirements.	Comment acknowledged. Change made.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
5/ page12 line/301	Kula Koenig & Mick Smith- American Heart Association/American Stroke Association	Recommend wording for Action Registry to be "Action-Registry GWTG."	Comment acknowledged. Change made.
5/ Page 12 line/302	Kula Koenig & Mick Smith- American Heart Association/American Stroke Association	Instead of version dated March 2014 should be most available and updated version.	Comment acknowledged. Change made.
§ 100270.131 – Data Management – Line 303 – 304	Contra Costa County	What EMS Authority data management system? Has this been developed? Recommend not putting language in regulation reference to state data systems that have not been fully developed. Change to "Data will be submitted to EMS Authority on no less than a quarterly basis" Clarify language regarding what "integrated into local EMS agency" means. Integrated as part of the QI process? That is already addressed elsewhere in the regulations.	Comment acknowledged. Change made.
100270.131 Page12 Line 303	Kern	EMSA is already getting all PCR information and should be able to pull this data from their end. Hospitals are already reporting each of these data elements to Mission Lifeline and Action Registry, which is the ACC and AHA Standard. This is redundant. Remove quarterly data submission requirement.	Comment acknowledged. No change. EMSA is not receiving all PCR information statewide and not all hospitals report.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
100270.131 (3), Line 303-304	North Coast EMS "	<p>While we support the concept of pre-hospital and hospital data system integration, and HIE, this requirement is currently premature and should not be required in a state regulation. We recommend dropping it or adding wording that qualifies that this will be required "after pre-hospital and hospital data system integration has been achieved." Until EMSA required CEMSIS and NEMSIS pre-hospital e-PCR programs are successfully integrated at the state level with the "National Cardiovascular Data Registry, Action Registry, version 2.4 dated March 2014" referenced within these regulations, or other hospital utilized STEMI data systems, this requirement is not feasible. This is particularly true for smaller LEMSAs that do not have the staff size, expertise or funding to establish integrated data systems that could potentially utilize numerous different vendors and platforms, and could involve substantial LEMSA and hospital costs. Until data integration is successfully accomplished and cost effective, quarterly reporting is not possible. Also, this requirement could discourage hospital and LEMSA participation in STEMI System development or maintenance. Perhaps this could become a requirement within one or two years after the regulations are adopted to give EMSA and LEMSAs time to develop, test and implement pre-hospital and hospital integrated data systems. That written, we are very supportive of this objective when feasible.</p>	<p>Comment acknowledged. Change made.</p>



Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
ARTICLE 5 DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATION § 100270.131 Management P.12 line 308-345.	REMSA	Remove specific data elements names or provide definitions to the data elements. When referring to EMS times, is EMSA asking for first responder or transport responders times?	Comment acknowledged. Change made for clarity.
100270.131 Page12 &13 Lines 308-345	Laura Wallin, RN Monterey County EMS Agency	Specific data elements should not be included in regulation, but could be mandated via Qi plan or other EMSA mandates. Please delete these lines.	Comment acknowledged. Change made for clarity.
100270.131 Page 12&13 Line 308-345	Laura Wallin, RN Monterey County EMS Agency	If the specific data elements are included, each data element needs to be specifically defined (eg., is "Hospital Arrival Time" the time the ambulance CAD says the patient arrived at the hospital, or the time that the patient is first documented as arriving in the ER?)	Comment acknowledged. Change made for clarity.
100270.131 Page 12 Line 313-314	Los Angeles County EMS Agency	Delete: Name and Date of Birth from data requirements. Difficult to obtain-We do not provide for other systems such as trauma.	Comment acknowledged. No change. These items are used initially for matching of patients.
100270.131 Page 12 &13 Lines 308-345	Laura Wallin Monterey County EMS Agency	If the specific data elements are included, each data element needs to be specifically defined (eg., is "Hospital Arrival Time" the time the ambulance CAD says the patient arrived at the hospital, or the time that the patient is first documented as arriving in the ER?)	Comment acknowledged. Change made for clarity.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
§ 100270.131 P.12 line 308-345.	Inland Counties Emergency Medical Agency (ICEMA)	Remove specific data elements names or provide definitions to the data elements.  When referring to EMS times, is EMSA asking for first responder or transport responder's times?	Comment acknowledged. Change made for clarity.
100270.131 Page 12 &13 Lines 308-345	Laura Wallin Monterey County EMS Agency	Specific Data Elements should not be included in a regulation, but could be mandated via QI plans or other EMSA mandates. Please Delete these lines.	Comment acknowledged. Change made for clarity. However data elements will still exist.
Article 5, 100270.131, Section b, page 12, Line 309	Judith A. Scott, MHA RN PHN FAEN One Baldwin Ave #901 San Mateo, CA 94401 M 760 644-0102 CA ENA	"collected and submitted to the local EMS agency by the hospital" s/b revised to read "collected by hospitals, LEMSA's and Prehospital Agencies". There are data requirements that the hospital would be unable to collect and submit.	Comment acknowledged. Change made for clarity.
Article 5, 100270.131, Section b, page 12, Line 313	Judith A. Scott, MHA RN PHN FAEN One Baldwin Ave #901 San Mateo, CA 94401 M 760 644-0102 CA ENA	Remove Name: Last, First from minimum data element requirement. There is no need for name identifier in databases.	Comment acknowledged. No Change. It is the patient identifier used for matching patient records.
Article 5, 100270.131, Section b, page 12, Line 317	Judith A. Scott, MHA RN PHN FAEN One Baldwin Ave #901 San Mateo, CA 94401 M 760 644-0102 CA ENA	Add Ethnicity to data element Race	Comment acknowledged. No change.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
5/ page12 line/318	Kula Koenig & Mick Smith- American Heart Association/American Stroke Association	Recommend adding "First Medical Contact (FMC)" as a minimum data element in order to effectively track compliance with current ACC/AHA guideline recommendations found in the 2013 ACCF/AHA Guideline for Management of ST-Elevation Myocardial Infarction.	Comment acknowledged. No Change. The specific elements listed were based on recommendations from the subject matter experts who assisted with drafting of these regulations.
100270.131 ((b), 1, 10,11, 12, 13. 311, 320,321, 322, 323.	"North Coast EMS	Not all STEMI patients are transported by EMS and arrive by other means. Therefore, collecting pre-hospital data is not possible on these patients and should not be required. Recommend: change wording in (b) to "The following minimum pre-hospital data elements shall be collected and submitted to the LEMSA by the designated SRC or SRH on all EMS transported STEMI patients...": then list only the pre-hospital specific elements that are currently #s 1, 10,11, 12, 13. And, add (c) The following hospital data elements...shall be collected and submitted...on all STEMI patients...by SRC...". Then add the hospital data elements. Also, add (d) and specify only the data specific to a SRH – that is, drop CATH LAB references and PCI references. Otherwise, it will not be possible for hospitals to provide the required pre-hospital data elements for those STEMI patients that do not arrive by EMS, and SRH will not be able to provide required CATH LAB and PCI data on STEMI patients because they do not have a CATH LAB by definition.	Comment acknowledged. Change made for clarity. However, all patients who enter the STEMI system should be tracked even though their arrival is not via EMS.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
100270.131 Page 13 Line 339-342	Los Angeles County EMS Agency	Change: 'SRF' to 'SRH' consistent with prior language	Comment acknowledged. Change made.
100270.131 Page 13 Lines 339-342	Laura Wallin, RN Monterey County EMS Agency	What is an SRF	Comment acknowledged. Change to SRH.
100270.131 Page 13 Lines 339-342	Laura Wallin Monterey County EMS Agency	What is an SRF?	Comment acknowledged. Change to SRH.
100270.131 Lines 339, 340, 342	Mary Magocsy, RN, MBA San Francisco Emergency Medical Services Agency	100270.131 Data Management Lines 339, 340, 342 mention "SRF" but the abbreviation in lines 131 and 137 is "SRC" and "SRH."	Comment acknowledged. Change to SRH.
Section 100270.132 Page 13 Line 349	Santa Clara County STEMI Committee	The committee does not feel peer-review case discussion is appropriate.	Comment acknowledged. No change. This is part of the QI process.
100270.132/100270.132 Page 13-14 Line 349-371	Los Angeles County EMS Agency	Merge the two sections into one Quality Improvement Process then breakdown into: <input type="checkbox"/> LEMSA Requirements <input type="checkbox"/> Hospital/SRC Requirements	Comment acknowledged. No change.
100270.132 Page 13 Line 350	Los Angeles County EMS Agency	Delete: 'STEMI Critical Care System' Change to: 'STEMI Receiving Center' Currently it is unclear what is the hospital-level responsibility. Clarify that hospital-level responsibilities are listed in this section vs LEMSA responsibilities that follow. See below	Comment acknowledged. No change. This is a combination of Hospital and LEMSA responsibilities. Will review for clarity.
§100270.132 Quality Improvement Process Page 13, lines 350-	BJ Bartleson, CHA	Change lines 350-353 to read:" STEMI Critical Care System shall have a quality improvement process based on AHA's Criteria for STEMI Systems of Care, Mission Lifeline guidelines. In addition, the process shall include: Remove lines 355-356	Comment acknowledged. No change. These items are subject to LEMSA control.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
ARTICLE 5 DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATION § 100270.132 Management P.13 line 350-359.	Inland Counties Emergency Medical Agency (ICEMA)	Consider adding: A local EMS agency may specify additional requirements in this Chapter.	Comment acknowledged. No change. Current language includes consideration for LEMSA to have additional requirements.
ARTICLE 5 DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATION § 100270.132 Management P.13 line 350-359.	REMSA	Consider adding: A local EMS agency may specify additional requirements in this Chapter.	Comment acknowledged. No change. Current language includes consideration for LEMSA to have additional requirements.
100270.132 Page 13 Line 354	San Joaquin County EMS Agency	Recommend limiting to: "an audit of all STEMI-related deaths occurring at a STEMI center"	Comment acknowledged. No change. That would eliminate system STEMI-related deaths that do not just occur at the center.
100270.132 Page 13 Line 354	Laura Wallin, RN Monterey County EMS Agency	How is a STEMI-related death determined? By whom?	Comment acknowledged. No change. This is would be determined by the local EMS agency.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
Page 13/ Line 354(a)	Brian Henricksen Napa County EMS Agency	STEMI Receiving Centers, as required by CMS and Joint Commission, to review all STEMI related deaths. Perhaps the LEMSA should focus on deaths that may be associated with pre-hospital care, such as the undertriaged patient versus a review that duplicates what the hospitals are doing.	Comment acknowledged. The LEMSA should be a part of the committee of reviewing any STEMI-related deaths.
Article 5, 100270.132, Section a, Line 354	Judith A. Scott, MHA RN PHN FAEN One Baldwin Ave #901 San Mateo, CA 94401 M 760 644-0102 CA ENA	Define STEMI-related deaths. "Audit" implies selection not ALL revise to make consistent. Hospitals have internal QIP that review all STEMI-related deaths there is not a need to repeat same process in multi-disciplinary STEMI QI committee.	Comment acknowledged. The LEMSA should be a part of the committee of reviewing any STEMI-related death.
§100270.132 Line 354(a)	Contra Costa County	STEMI related death audits are the domain of the STEMI hospital QI morbidity and mortality internal QI review process. Revise to an audit of all STEMI related deaths received from EMS. , LEMSA QI should focus on review cases that may be associated with pre-hospital care. Regulation is duplicative as hospital processes that are well established in hospital policy, procedure , CMS and Joint Commission requirements for all SRCs	Comment acknowledged. The LEMSA should be a part of the committee of reviewing any STEMI-related death.
§ 100270.132 and §100270.133 Page 13 &14	Contra Costa County	Recommend that these be combined to form and title changed to "STEMI System Oversight".	Comment acknowledged. No change. Existing language is appropriate.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
§ 100270.133 Page 14 Line 368-369	San Joaquin County EMS Agency	Recommend eliminating “and other hospitals.” It is unclear how a LEMSA would hold a non STEMI Center responsible. Any hospital, including non-EMS system hospitals, may receive a walk-in STEMI patient or have an existing admitted patient experience a STEMI. A hospital’s ability to refuse to participate is likely option.	Comment acknowledged. No change. Local EMS agencies should engage system participants to ensure adequate reporting of STEMI cases from all emergency departments in their area.
§100270.133 STEMI Critical Care System Evaluation, Page 14, lines 368-371	BJ Bartleson, CHA	Lines 368-371 to read: “The local EMS agency shall be responsible for ensuring the standards set forth by the AHA STEMI Systems of Care Criteria for all aspects of care, as these recommendations may evolve over time.”	Comment acknowledged. No change. This is a local EMS agency control item but not to be consistent with any one specific standard.
	North Coast EMS	For patients not transported by EMS or by EMS providers with 12-lead capability (if such still exists), add: 1st ED ECG Date and 1st ED ECG Time to both SRC and SRHs.	Comment acknowledged. No change. This is difficult to track in the hospital and not all systems are designed to capture it.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
	<p>Peter Pelikan, MD, FACC, FSCAI Medical Director, Cardiac Catheterization Lab and Structural Heart Program Pacific Heart Institute and Providence Saint Johns Health Center</p>	<p>It has come to my attention that patients are being transported from STEMI Referring Hospitals (SRH) to STEMI Receiving Centers (SC), over great distances, through traffic, based solely on hospital ownership, and not to the closest available hospital. This is clearly not in keeping with all the data showing that "time is muscle," i.e., the faster the coronary intervention occurs, the lower the morbidity and mortality for the STEMI patient. I propose that any SRH transporting patient for acute STEMI cath lab intervention send the patient to the closest available hospital. With the advent of Waze and Google Maps, this can be determined in a matter of seconds, and fully account for the heavy traffic in Los Angeles. SRHs should have pre-arranged relationships with several of their closest hospitals, and choose based on lowest transport time.</p>	<p>Comment acknowledged. No change. This is the LEMSA's responsibility to address this kind of issue in the STEMI patient transfer policy.</p>