COMMENTS for DRAFT STROKE REGULATIONS
Comment Period: December 9, 2016 - January 23, 2017

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
General Comment	California ENA	Thank you for developing the Stroke Regulations. We look forward to working with EMSA as these progress	Comment acknowledged.
General	Vince Pierucci San Luis Obispo County EMS Agency	No reference to Joint Commission certification standards	Comment acknowledged. There will not be any CA Joint Commission reference within these Regulations.
General	Mills-Pen San Mateo, Stroke Committee	It is unclear what the purpose of these regs are. Regs merely defining different types of hospitals is less important than determining how those hospitals should be integrated, which should probably be at a local level anyway. Rather than focus on facilities, should more concentrate on capabilities.	Comment acknowledged. The proposed Stroke Regulations are to provide statewide consistency with oversight and standards for stroke systems.
General	Sierra – Sacramento Valley EMS Agency	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." Similar language should be added to the stroke regulations "No health care facility shall advertise in any manner or otherwise hold themselves out to be a stroke center unless they have been so designated by the local EMS agency, in accordance with this Chapter."	Comment acknowledged. Ammendments made to be consistent with specialty care regulations.

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ARTICLE 1. DEFINITIONS. §100270.2XX Stroke Center Addition	Chris Yoshida McMath Inland Counties Emergency Medical Agency	Consider adding a definition for Stroke Receiving Center: "Stroke 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. Modifications will be made regarding Stroke Centers. However, no reference will be made to the Joint Commission.
ARTICLE 1. DEFINITIONS. §100270.2XX Stroke Center Addition	Shanna Kissel, MSN, RN REMSA	Consider adding a definition for Stroke Receiving Center: "Stroke 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. Modifications will be made regarding TSCs. However, no reference will be made to the Joint Commission.
Article 1. Definitions	BJ Bartleson, CHA	Add two additional terms to the Definitions section: 1. AHA/ASA Stroke Certification-American Heart Association, American Stroke Association – nationally recognized stroke certification body 2. Get With The Guidelines®-Stroke(GWTG-Stroke)-AHA's national database that adheres to the latest scientific AHA/ASA sanctioned guidelines	Comment acknowledged. Additions will not be made. EMSA cannot authorize one specific organization for certification.
§100270.200 Board-Certified, page 1 lines 7-9	BJ Bartleson, CHA	Change the definition to : "Board Certified is defined as Certification by the American Board of Medical Specialties (ABMS) which demonstrates a physician's exceptional expertise in a particular specialty and/or subspecialty of medical practice"-Board certification occurs under the authority of the ABMS. ACGME approves residency Programs	Comment acknowledged. Modifications made to the language. ACGME will be the standard training and ABMS for the certification and examination.

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Article 1 definitions: Board certification line 7-9	Tong (Mills-Pen) San Mateo, Stroke Committee	Clarify that board certification does not require recertification. There is substantial controversy within medicine as to the need for board recertification. While initial certification (or certification at some time) is appropriate it should not require recertification or active certification.	Comment acknowledged. Modifications made to the language. ACGME will be the standard training and ABMS for the certification and examination.
100270.200 Page 1 Line 9,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Delete "diploma by an ACGME approved program" and replace with "certification by a specialty board of the American Board of Medical Specialties (ABMS)."	Comment acknowledged. Modifications made to the language. ACGME will be the standard training and ABMS for the certification and examination.
Article 1. 100270.200	Bryn Mumma, MD, MAS Assistant Professor of Emergency Medicine University of California, Davis	This definition of "board-certified" seems incorrect. ACGME is the governing body for residency programs; it does not provide board certification. Board certification is usually provided through one of the 24 Member Boards of the American Board of Medical Specialties (ABMS). Successfully completing an ACGME- or RCPSC-certified residency program is one requirement for being "board-eligible."	Comment acknowledged. Modifications made to the language. ACGME will be the standard training and ABMS for the certification and examination.
100270.201 Page 1 Line 13-14	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Delete "received a ruling that he or she" and add after "take the examination"- "Board certification must be obtained within the ABMS board eligibility time period for their specialty."	Comment acknowledged. Modifications made to the language. ACGME will be the standard training and ABMS for the certification and examination.
§100270.201 Board Eligible, page1 lines 14-15	BJ Bartleson, CHA	Change the second sentence to: "Board certification must be obtained within the specified time allotted for the respective medical board, between 3-7 years" – ABMS	Comment acknowledged. Ammendments made to the language.
Article 1 definitions line 27-30	DCT (Mills-Pen) San Mateo, Stroke Committee	What is meant by "highest level of CME approved"? Vague. CME is CME.	Comment acknowledged. "Highlest level" has been removed.

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§100270.203 Continuing Medical Education, page 2, 28-30	BJ Bartleson, CHA	Change the definition to: "Educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, thepublic, or the profession," ACGME	Comment acknowledged. Ammendments have been made to §100270.203.
ARTICLE 1. DEFINITIONS. §100270.205 Immediately Available page2 line 39	Chris Yoshida McMath Inland Counties Emergency Medical Agency	Add in definition "within 15 minutes", to be consistent with Trauma Regulations.	Comment acknowledged. Definitions are specific to these regulations. Rule making procedures require defenitions be specific to each set of proposed regulations.
ARTICLE 1. DEFINITIONS. §100270.205 Immediately Available Page 2 line 39	Shanna Kissel, MSN, RN REMSA	Add in definition "within 15 minutes", to be consistent with Trauma Regulations.	Comment acknowledged. Definitions are specific to these regulations. Rule making procedures require defenitions be specific to each set of proposed regulations.
§100270.205 Immediately Available, page 2, lines 41-44	BJ Bartleson, CHA	Change the definition to "physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure .CMS. CMS does not include specifics about the proximity of the person providing supervision in terms of time or distance (e.g. the person providing supervision must be able to reach the patient within X minutes or must be located within X distance). The 2011 requirements have been revised to remove any reference to physical boundaries.	Comment acknowledged. EMSA will delete the definition for lack of use.

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§100270.207 Protocol, page 3, lines 58-59	BJ Bartleson, CHA	Change this definition as medical care guidelines and protocols are two different entities-add medical guidelines definition and change protocol definition to: "Protocol describes a method to be used in a clinical trial (e.g. of a drug or medical treatment) or a medical research study". Add Medical Guidelines definition:"written document that includes a treatment plan, summarized consensus statements and addresses practical issues.	Comment acknowledged. Definitions are specific to these regulations. Rule making procedures require defenitions be specific to each set of proposed regulations.
Line 63-65	Mills-Pen San Mateo, Stroke Committee	Seems to imply ischemic stroke, not as clear this refers to hemorrhage. Should clarify	Comment acknowledged. The definition specifies any kind of impaired blood flow to a patients brain resulting in brain dysfunction.
§100270.208 Stroke, page 3, lines64-65	BJ Bartleson, CHA	Change definition to : Stroke means a condition where there is sudden death of brain cells due to lack of oxygen, caused by blockage of blood flow or rupture of an artery to the brain. Specifies types of impaired blood flow.	Comment acknowledged. EMSA must keep definitions clear and consice.
Page 3 Line 64-65	Brian Henricksen Napa County EMS Agency	Define Stroke: "means a condition of impaired blood flow to a patient's brain resulting in brain dysfunction, most commonly through vascular occlusion or hemorrhage.	Comment acknowledged. The definition specifies any kind of impaired blood flow to a patients brain resulting in brain dysfunction.
ARTICLE 1. DEFINITIONS. §100270.211Stroke Medical Director page. 4 line 83	Chris Yoshida McMath Inland Counties Emergency Medical Agency	Consider adding: "Stroke Medical Director" means a board-certified physician designated by the hospital who is responsible for the stroke service, performance improvement, and patient safety programs related to the Stroke Critical Care System.	Comment acknowledged. Ammendments made to reflect Medical Director requirement of being Board-Certified.

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ARTICLE 1. DEFINITIONS. §100270.211Stroke Medical Director page 4 line 83	Shanna Kissel, MSN, RN REMSA	Consider adding: "Stroke Medical Director" means a board-certified physician designated by the hospital who is responsible for the stroke service, performance improvement, and patient safety programs related to the Stroke Critical Care System.	Comment acknowledged. Ammendments made to reflect Medical Director requirement of being Board-Certified.
Page 5 Line 103	Brian Henricksen Napa County EMS Agency	Stroke System of Care is the term generally used by EMS. Change "Stroke Critical Care System" to Stroke System of Care. Replace critical care system with system of care.	Comment acknowledged. The definition is based off of Statute, 1798.150 which states "critical care".
Page 5 Line 106-107	Brian Henricksen Napa County EMS Agency	Replace the word "immediate" with the word "timely".	Comment acknowledged. Definitions are specific to these regulations. Stroke is a critical emergency matter.

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Sec. 100270.216 Page 5 Line 117	Mei Wa Kwong, JD Christine Calouro Center for Connected Health Policy 1331 Garden Highway, Sacramento, CA 95833 Phone: (916) 285-1868	California Business and Professions Code Sec. 2290.5 currently provides a definition for telehealth, which replaced the term "telemedicine" in CA statute in 2011. It defines "telehealth" as follows: "the mode of delivering health care services and public health via information and communication technologies to facilitate the diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care while the patient is at the originating site and the health care provider is at a distant site. Telehealthfacilitates patient self management and caregiver support for patients and includes synchronous interactions and asynchronous store and forward transfers."	Comment acknowledged. Ammendments have been made to reflect "Telehealth".
100270.216 Page 5 Line 120,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Delete sentence: "A neurology specialist will assist the physician in the center in rendering a diagnosis"	Comment acknowledged. Ammendments have been made to reflect "Telehealth".
Line 120	Mills-Pen San Mateo, Stroke Committee	Should be any appropriately trained physician, not just neurologist	Comment acknowledged. Ammendments have been made to reflect "Telehealth".
§100270.216 Telemedicine, page5, lines, 120-122	BJ Bartleson, CHA	Delete the second sentence involving a neurologist , irrelevant to the basic definition of telemedicine	Comment acknowledged. Ammendments have been made to reflect "Telehealth".
100270.216	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	The plan should require the LEMSA to identify the type/level of Stroke Centers for the system	Comment acknowledged. Stroke Centers are LEMSA designated.

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ARTICLE 2. § 100270.217 General Requirements and Timeframes (a) - (f) page 5-6 lines129-147 Addition	Chris Yoshida McMath Inland Counties Emergency Medical Agency	Consider adding: • No provider of prehospital care shall advertise in any manner or otherwise hold itself out to be affiliated with the Stroke Critical Care System or a stroke center unless they have been so designated by the local EMS agency, in accordance with this Chapter. This can allow hospitals to bypass LEMSA designation and advertise their services directly to EMS providers and undermine any LEMSA destination policy.	Comment acknowledged. Modifications will be made for consistency.
General	Reza Vaezazizi, MD ICEMA Medical Director	In my first review of proposed stroke regulations, I did not see any reference to LEMSAs as the only authority for designating Stroke centers when developing a Stroke system of care. I compared this to trauma regulations and found the following reference there: Title 22; 100253 (K) 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. I did not find a similar reference in the proposed stroke regulations and I am wondering if a similar statement may be need to be included there as well?	Comment acknowledged. Modifications will be made for consistency.

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ARTICLE 2. LOCAL EMS AGENCY STROKE CRITICAL CARE SYSTEM § 100270.217 General Requirements and Timeframes (a) - (f) page 5-6 lines129-147 Addition	Shanna Kissel, MSN, RN REMSA	Consider adding: • No provider of prehospital care shall advertise in any manner or otherwise hold itself out to be affiliated with the Stroke Critical Care System or a stroke center unless they have been so designated by the local EMS agency, in accordance with this Chapter. This can allow hospitals to bypass LEMSA designation and advertise their services directly to EMS providers and undermine any LEMSA destination policy.	Comment acknowledged. Modifications will be made for consistency.
ARTICLE 2. LOCAL EMS AGENCY STROKE CRITICAL CARE SYSTEM § 100270.217 General Requirements and Timeframes (a) - (f) page 5-6 lines129-147 Addition	Shanna Kissel, MSN, RN REMSA	Consider adding: • A local EMS agency may specify additional requirements in addition to those specified in this Chapter.	Comment acknowledged. This section pertains to the LEMSA requirements of plan submittal to EMSA. LEMSAs have authority to add any extra requirements for the designation of a stroke center.

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Article 2. 100270.217 Line 139	Contra Costa County EMS Agency	60 day timeline may be unrealistic depending on identified issues or gap. Regulations should not be prescriptive in the timelines given the multistakeholder efforts required to support Stroke System development. Regardless of the regulations stroke systems have been successfully developed and sustained without prescriptive requirements in regulation to support optimal patient care through voluntary cooperation. Regulations should support not restrict LEMSAs from facilitating developing and sustaining systems of care. Whether EMSA approves the plan or not stroke system workflows facilitate appropriate stroke patient care. The most important aspect is to have the regulations support LEMSA coordination and oversight.	Comment acknowledged. The proposed Stroke Regulations are to provide statewide consistency with oversight and standards for stroke systems.
Page 6 Line 142	Brian Henricksen Napa County EMS Agency	This section should be worded same for Stroke Regulations as it is for STEMI. LEMSA "shall submit, to the authority, a Stroke System Plan as an addendum to its annual EMS Plan update." The update should be allowed during the next annual EMS plan submission, not requiring an update within 180 days.	Comment acknowledged. Modifications will be made to the language to provide clarity.
Article 2. 100270.217 Line 143-144	Contra Costa County EMS Agency	Please make the same as the Stroke regs, suggestion "shall submit to the EMS Authority a Stroke System plan as an addendum to its next annual EMS Plan update"	Comment acknowledged. Modifications will be made to the language to provide clarity.

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100270.217, Page 6, Lines 141 -144	Larry Karsteadt North Coast EMS	Recommend requiring a LEMSA with a currently operating Stroke Critical Care System implemented before the effective date of the regulation to "submit an update to its Stroke System Plan as part of its annual EMS Plan update…" LEMSAs that have EMSA approved annual EMS Plan updates will already have submitted annual Specialty Care System updates on the Stroke System and should only be required to continue to report annually rather than submitting yet another redundant plan update within 180 days. Recommend dropping (e) to reduce redundancy and save time and costs for both the EMSA and LEMSAs.	Comment acknowledged. No change. The proposed Stroke Regulations are to provide statewide consistency with oversight and standards for stroke systems. As such, a LEMSA currently operating a Stroke Critical Care System would need to submit a Stroke System Plan to EMSA for review. EMS Systems Standards and guidelines are currently under review to address manner in which these programs are reported.
ARTICLE 2. LOCAL EMS AGENCY STROKE CRITICAL CARE SYSTEM § 100270.218 State Stroke System Plan Requirements(b) Page 6 line 156	Chris Yoshida McMath Inland Counties Emergency Medical Agency	Consider changing "copies of agreements to: A copy of the model agreement with hospitals for designation of stroke facilities with a list of stroke hospital contracts with expiration and terms dates. Currently, some LEMSAs have over 10 stroke facilities. Providing a copy of each agreement would be labor intensive.	Comment acknowledged. EMSA has made modifications to the proposed regulations requesting copies be "readily available upon request". EMSA has statutory responsibility.
Page 6 Line 156	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. EMSA has made modifications to the proposed regulations requesting copies be "readily available upon request". EMSA has statutory responsibility.

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ARTICLE 2. LOCAL EMS AGENCY STROKE CRITICAL CARE SYSTEM § 100270.218 State Stroke System Plan Requirements(b) page6 line 156	Shanna Kissel, MSN, RN REMSA	Consider changing "copies of agreements to: A copy of the model agreement with hospitals for designation of stroke facilities with a list of stroke hospital contracts with expiration and terms dates. Currently, some LEMSAs have over 10 stroke facilities. Providing a copy of each agreement would be labor intensive.	Comment acknowledged. EMSA has made modifications to the proposed regulations requesting copies be "readily available upon request". EMSA has statutory responsibility.
100270.218 Page 6 Line 156,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Delete entire line 156- (b). This reads as if you are requiring a copy of agreements with every hospital. This is unwieldy. It is unclear why this would be necessary. We do not do this for other regional systems.	Comment acknowledged. EMSA has made modifications to the proposed regulations requesting copies be "readily available upon request". EMSA has statutory responsibility.
Article 2. 100270.218. Line 156	Contra Costa County EMS Agency	Remove requirement to have the LEMSA submit copies of agreements with hospitals for designation of stroke facilities. Verification of agreements by the LEMSA is sufficient with information on entities and agreement terms. Submitting copies of agreements to the state is unnecessary.	Comment acknowledged. EMSA has made modifications to the proposed regulations requesting copies be "readily available upon request". EMSA has statutory responsibility.
100270.218 d	Kaiser San Mateo, Stroke Committee	…specific to stroke patients**, designed to expedite time-sensitive treatment on arrival.** Rationale: although not asking specifically for PHI, this language reinforces the important of PHI prior to arrival in the ED, which would help identify POLST status, prior neurological exam and status, use of anticoagulants, family contact information, etc	Comment acknowledged. Mdifications have been made to the language.

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100270.218 e	Kaiser San Mateo, Stroke Committee	…facilitates the inter-facility transfer of stroke patients, **including the role of EMS in these transfers** Rationale: requires that EMS define its role, whether participating or not, in these transfers for clarity	Comment acknowledged. No amendments will be made. Roles would be defined within LEMSA Transfer Agreements.
100270.218 pg.6/ Line 156	Kimberly Tollison Kern County EMS	Copies of contracts removed, instead a list of local stroke facilities.	Comment acknowledged. EMSA has made modifications to the proposed regulations requesting copies be "readily available upon request". EMSA has statutory responsibility.
100270.218, Page 6, Section 218	Larry Karsteadt North Coast EMS	As written, this section is out of compliance with the current EMS Plan requirements for Specialty Care Systems, and until those two sets of standards are integrated, LEMSAs will face two different reporting requirements. We recommend that the EMS System Standards and Guideline requirements that conflict with this wording be simultaneously discontinued by the EMSA and Commission for established Stroke Care Systems to avoid duplicate reporting for LEMSAs.	Comment Aknowledged. The proposed regulations will supersede guidelines. Subsequent to these regulations, EMSA will allign guidelines.
100270.218 Page 7 Line 159-160,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Suggest deleting (d) This seems too granular? C is sufficient and this may be included.	Comment acknowledged. No modifications will be made.

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State Stroke System Plan Requirements 100270.218(d) Page 7 Lines 159-160	Jay Goldman, MD, FACEP Director of EMS and Ambulance Kaiser Permanente NCAL Lynn Parkinson, Strategic Leader for Accreditation, Regulation and Licensing, Kaiser Foundation Hospitals, Northern California	Please add the statement highlighted in bold lettering "…specific to stroke patients, **designed to expedite time sensitive treatment on arrival."** Rationale: having the patient's identification prior to arrival allows the ED to find a medical record on many patients to determine POLST status, prior neurological exam and status, use of anticoagulants, family contact information, etc., all allowing faster decision-making regarding care paths such as administration of tPA Identifying the patient is an important contribution to reducing door-to-tPA times and thus toward improving stroke outcomes.	Comment acknowledged. Modifications will be made to the language to provide clarity.
State Stroke System Plan Requirements 100270.218(e) Page 7 Lines 161-162	Jay Goldman, MD, FACEP Director of EMS and Ambulance Kaiser Permanente NCAL Lynn Parkinson, Strategic Leader for Accreditation, Regulation and Licensing, Kaiser Foundation Hospitals, Northern California	Please add the statement highlighted in bold lettering "…facilitates the interfacility transfer of stroke patients, **including the role of EMS in these transfers."** Rationale: requires that EMS define its role for clarity and transparency, whether participating or not, in these transfers.	Comment acknowledged. No amendments will be made. Roles would be defined within LEMSA Transfer Agreements.
100270.218 Page 7 Line 165-166,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Change 'all' to 'any'. Clarify that only required if exist. Do these exist between any counties?	Comment acknowledged. Based on the standardization statewide, EMSAn is ensuring neighboring LEMSA's have agreements for treatment of stroke patients within their jurisdiction.
100270.218, Page 7, Lines 169 - 170	Larry Karsteadt North Coast EMS	Change to: description of collaborative programs to conduct or promote…"	Comment acknowledged. No amendments will be made.

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100270.218 Page 7 Line 170,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS	Remove "and Cardiac"	Comment acknowledged. Modifications have been made to the language.
2 page7 line174	Kula Koenig- American Heart Association/American Stroke Association	All EMS agencies across the state shall establish pre-hospital care protocols related to the assessment, treatment, and transport of stroke patients by licensed emergency medical services providers in California.	Comment acknowledged.
100270.219, Page 7,	Larry Karsteadt North Coast EMS	As written, this section is out of compliance with the current EMS Plan requirements for Specialty Care Systems, and until those two sets of standards are integrated, LEMSAs will face two different reporting requirements. We recommend that the EMS System Standards and Guideline requirements that conflict with this wording be simultaneously discontinued for established Stroke Care Systems to avoid duplicate reporting for LEMSAs.	Comment Aknowledged. The proposed regulations will supersede guidelines. Subsequent to these regulations, EMSA will allign guidelines.
100270.219, Page 7, Line 179	Larry Karsteadt North Coast EMS	Current EMS Plan Specialty Care requirements do not include "goals and objectives", nor does Section 218. Sections 218 and 219 should be better integrated. Also, the "goals and objectives" of any Specialty Care System are generally to enhance the care of that specialty patient and reduce mortality and morbidity, etc. It seems that this generic requirement that the EMS system is already dedicated to does not add value to an annual plan specialty care plan update and we recommend dropping it.	Comment acknowledged. Stroke Critical Care Systems should have objectives for reaching the goals which are enhancing the care for stroke patients. Reporting on the status of Stroke System Plan goals and objectives provides EMSA with valuable statewide quality improvement information.

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100270.219 Page 7 Line 180	Laura Wallin, RN Monterey County EMS Agency	Are "Performance improvement activities" the same as QI activities?	Comment acknowledged. Yes, performance improvement activities may be considered QI..
100270.219, Page 8, Lines 190 – 192	Larry Karsteadt North Coast EMS	Change to: "The LEMSA shall ensure that pre-hospital stroke assessment and treatment training is provided for pre-hospital emergency medical care personnel as determined by the LEMSA." Drop "as part of accreditation" as only paramedics are accredited.	Comment acknowledged. Ammendments will be made to the language.
Article 3. Prehospital Stroke Critical Care System Requirements §100270.220 EMS Personnel and Early Recognition, Page 8 ,lines 191,192	BJ Bartleson, CHA	Recommend in line 191 changing available to" provided" to assure adequate pre-hospital stroke assessment training Use of the term "accreditation" in lines 191,192 is unclear- who is accrediting what?	Comment acknowledged. Ammendments will be made to the language.
EMS Personnel and Early Recognition 100270.220(c) Page 8 Lines 195 - 196	Jay Goldman, MD, FACEP Director of EMS and Ambulance Kaiser Permanente NCAL Lynn Parkinson, Strategic Leader for Accreditation, Regulation and Licensing, Kaiser Foundation Hospitals, Northern California	Please add the statement highlighted in bold lettering "…online medical direction shall **include suggested actions for patients with ambiguous** or complex findings." Rationale: clearer clarification.	Comment acknowledged. Modification will not be made. EMSA cannot use ambiguous words in Regulations.
100270.220 c Page 8	Kaiser San Mateo, Stroke Committee	…online medical direction shall **include suggested actions** for **patients with ambiguous** or complex findings Rationale: clarification	Comment acknowledged. Modification will not be made. EMSA cannot use ambiguous words in Regulations.

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100270.220 e Page 8 Line 200	Kaiser San Mateo, Stroke Committee	…defined by the local EMS agency**, as well as the suspected stroke patient's identity,** will be communicated… Rationale: see comments to 100270.218d above. There have been several legal opinions that sharing information, provided by phone or EMS radio, is not in conflict with either HIPAA nor with CA confidentiality law	Comment acknowledged. Responsibility will be with the LEMSA Medical Director.
100270.220, Page 8, Line 193-194	Larry Karsteadt North Coast EMS	Does a standardized "validated pre-hospital stroke-screening algorithm" exist and if so, shouldn't it be specifically referenced here? If not, each LEMSA will not be able to develop a "validated" algorithm and we could end up with 31 different ones.	Comment acknowledged. Yes, there are various Pre-Hospital Stroke Screening Scales, like Cincinnati Stroke Scale. It will be the responsibility of theLEMSA Medical Director to determine the appropriate screening scale.
100270.220, Page 8	Larry Karsteadt North Coast EMS	This entire section seems overly detailed for a regulation and could be simplified.	Comment acknowledged. EMSA beleives the details are needed. A recommended simplified version may be submitted to EMSA during any public comment period.
Article 4, Pages 8 - 14	Larry Karsteadt North Coast EMS	It seems that Primary Stroke Centers, Comprehensive Stroke Centers, and Acute Stroke Centers should be required to have Joint Commission or other national or state certification instead of hospitals and LEMSAs having to go through an additional, redundant and expensive designation process. The LEMSA need only verify such certification and evaluate other criteria that exceeds that certification.	Comment acknowledged. There will not be any CA Joint Commission reference within these Regulations. All Centers are LEMSA designated.

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Article 4. Page 8 Line 208	Laura Wallin, RN Monterey County EMS Agency	Delete the comma after the word "redesignation"	Comment acknowledged. Ammendments will be made.
4/ page8/ line210	Kula Koenig- American Heart Association/American Stroke Association	In addition to hospitals designated by local EMS agency, EMSA shall recognize those hospitals designated by nationally certifying bodies without these hospitals having to go through a separate certification process by the local EMS agency. EMSA shall recognize as many accredited acute care hospitals as Comprehensive Stroke Centers, Primary Stroke Centers, and Acute Stroke Ready Hospitals as apply and are certified as a Comprehensive Stroke Center, Primary Stroke Centers, and Acute Stroke Ready Hospitals as certified by a national certifying body (such as the American Heart Association, the Joint Commission or another department approved nationally recognized guidelines based organization that provides Comprehensive Stroke Center, Primary Stroke Center and Acute Stroke Ready Hospitals certification for stroke care), provided that each applicant continues to maintain its certification.	Comment acknowledged. There will not be any CA Joint Commission reference within these Regulations. Centers shall be LEMSA designated.

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ARTICLE 4. HOSPITAL STROKE CARE REQUIREMENTS § 100270.221. Primary Stroke Centers page 8-9 line 211-220 Addition And ARTICLE 4. HOSPITAL STROKE CARE REQUIREMENTS § 100270.221. Comprehensive Stroke Centers page 11 line 285 Addition	Chris Yoshida McMath Inland Counties Emergency Medical Agency	Consider adding: • The Joint Commission (TJC), Healthcare Facilities Accreditation Program (HFAP) Det Norske Veritas (DVN), or recognized accrediting body as a Primary Stroke Center. • The Joint Commission (TJC), Healthcare Facilities Accreditation Program (HFAP) Det Norske Veritas (DVN), or recognized accrediting body as a Comprehensive Stroke Center.	Comment acknowledged. There will not be any CA Joint Commission reference within these Regulations. Centers shall be LEMSA designated.
Article 4. Hospital Stroke Requirements 100270.221 Line 212	Contra Costa County EMS Agency	Primary Stroke Center is a designation term (which may be trademarked) used by The Joint Commission. If hospitals are not designated by TJC or some other credentialing entity, suggest they be called Stroke Receiving Centers	Comment acknowledged. Stroke Receiving Center is a general term for all levels of care centers including Primary, Comprehensive, and Aute.

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ARTICLE 4. HOSPITAL STROKE CARE REQUIREMENTS § 100270.221. Primary Stroke Centers page 8-9 line 211-220 Addition And ARTICLE 4. HOSPITAL STROKE CARE REQUIREMENTS § 100270.221. Comprehensive Stroke Centers page 11 line 285 Addition	Shanna Kissel, MSN, RN REMSA	Consider adding: • The Joint Commission (TJC), Healthcare Facilities Accreditation Program (HFAP) Det Norske Veritas (DVN), or recognized accrediting body as a Primary Stroke Center. • The Joint Commission (TJC), Healthcare Facilities Accreditation Program (HFAP) Det Norske Veritas (DVN), or recognized accrediting body as a Primary Stroke Center.	Comment acknowledged. There will not be any CA Joint Commission reference within these Regulations. Centers shall be LEMSA designated.
Article 4. Hospital Stroke Center Requirements, §100270..221, Page 8 lines 212- 214	BJ Bartleson, CHA	Have minimum standards be based on the most current AHA/ASA certification standards- "Hospitals to be designated by the local EMS agency as a Primary Stroke Center shall meet the most current AHA/ASA certification standards to provide care for stroke patients in the emergency department and those patients that are admitted.	Comment acknowledged. Mininmum requirements have been established.

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Page 9 lines, 215- 220	BJ Bartleson, CHA	Remove Lines 215-220 , as these are all qualification s of a certified primary stroke center	Comment acknowledged. Minmum requirements have been established.
Pg 9 Line 225	Vince Pierucci San Luis Obispo County EMS Agency	Does terminology correspond with Joint Commission Certification – If so then if the hospital is certified as a Primary Stroke center they can be assumed to meet these requirements?	Comment acknowledged. It is the LEMSA's responsibility to evaluate the centers and ensure that they comply with the requirements.
100270.222 Page 9 Line 225,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Move these specifications below to include within the minimum requirements for Primary Stroke Centers. The statement 'The local EMS Agency **Shall** ensure evaluation of the Primary Stroke Center as part of their Stroke Critical Care System' should remain and stand alone. This also allows for consistency with the CSC structure below.	Comment acknowledged. Amemendments will be made.
100270.222 Page 9 Line 225-248	Judith A. Scott, MHA RN PHN FAEN One Baldwin Ave #901 San Mateo, CA 94401 M 760 644-0102 CA ENA	It gets confusing with all the different time regulations. Think about - 1. time recognized to reading or 2. door to reading – 45 minutes	Comment acknowledged. No modifications will be made.
4/ page9 line229	Kula Koenig- American Heart Association/American Stroke Association	An acute stroke team that is available 24/7, at bedside within 15 minutes. The stroke team should have at least 8 hours of stroke education annually.	Comment acknowledged. No modifications will be made.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
ARTICLE 4. HOSPITAL STROKE CARE REQUIREMENTS § 100270.221. Primary Stroke Centers Page9-10 line 229, line 239, line 245, line 260 § 100270.221Acute Stroke Ready Hospitals and overall	Chris Yoshida McMath Inland Counties Emergency Medical Agency	Consider removing the time frames and replace with "Immediately available." Best practice times may change.	Comment acknowledged. No modifications will be made.
ARTICLE 4. HOSPITAL STROKE CARE REQUIREMENTS § 100270.221. Primary Stroke Centers Page 9-10 line 229, line 239, line 245, line 260 § 100270.221Acute Stroke Ready Hospitals and overall	Shanna Kissel, MSN, RN REMSA	Consider removing the time frames and replace with "Immediately available." Best practice times may change.	Comment acknowledged. No modifications will be made.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
100270.222 introduction	Kaiser San Mateo, Stroke Committee	…including assessment of the following **minimal criteria: Rationale:** explicitly permits LEMSA to require additional functions, including, for example Joint Commission requirements	Comment acknowledged. "Minimal criteria" will be added to the sentence.
100270.222 Page 9	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Rename and restate this section to be requirements for Primary Stroke Center	Comment acknowledged. It is not just the requirement for PSC. LEMSA's have responsibility in this section for the evaluation of the centers and to ensure compliance with the requirements..
100270.222 Page 9 Line 228,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Needs clarification, what does it mean for a hospital to be 'committed to supporting the Stroke System'? This is not specific and measurable.	Comment acknowledged. Agree to remove 222.(a) as it is not measurable.
100270.222 Page 9 line 229	Pat Smith (Sequoia) San Mateo, Stroke Committee	What is their definition of "potential acute stroke patient"?	Comment acknowledged. Any patients with signs and/or symptoms of stroke before actual diagnosis confirmation.
4/ page9 line 233	Kula Koenig- American Heart Association/American Stroke Association	There should be emergency medical services collaboration with PSC and PSC has access to protocols used by EMS. Facility must have stroke unit or designated beds for the acute care of stroke patients. Initial assessment of patients much be done by emergency department physician.	Comment acknowledged. This is criteria a LEMSA can use to evaluate a Primary Stroke Center and it is a mutual effort by both parties.
L 230-36, L 240-241 L 258-59	Mills-Pen San Mateo, Stroke Committee	Specific time intervals may vary depending on guidelines over time. Rather than specifying times, might be better to say in accordance with local or established guidelines for response	Comment acknowledged. Without specific time intervals there will be no statewide standard.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
4/ page9 Line 234	Kula Koenig- American Heart Association/American Stroke Association	Included in the written policy should be on-site certification reviews – one reviewer for one day. PSC must adhere to recommendations from Brain Attack Coalition for Primary Stroke Centers.	Comment acknowledged. No specific certifying body can recommend or mandate in regulations. No change will be made.
4/ page9 line/236	Kula Koenig- American Heart Association/American Stroke Association	Primary stroke centers (PSC) shall have the following treatment capabilities: IV thrombolytics; May have the ability to perform the following: Neurovascular interventions for aneurysms, Stenting of carotid arteries, Carotid endarterectomy, and Endovascular therapy.	Comment acknowledged. Agree to add IV Thrombolytic as another bullet.
4/ Page 9 line 238	Kula Koenig- American Heart Association/American Stroke Association	Clinical performance measures shall include evaluation of 8 core stroke measures: 1. VTE Prophylaxis 2. Discharged on Antithrombotic Therapy 3. Patients with Atrial Fibrillation Receiving Anticoagulation Therapy 4. Thrombolytic Therapy Administered 5. Antithrombotic Therapy By End of Hospital Day Two 6. Discharged on Statin Medication 7. Stroke Education 8. Assessed for Rehabilitation	Comment acknowledged. EMSA will not add the elements as we mentioned the "Standardized performance measures". No change will be made.
4 Page 9 Line 239	Kula Koenig- American Heart Association/American Stroke Association	Diagnostic testing capability by CT, MRI, labs, CTA, MRA 24/7, and cardiac imaging when necessary.	Comment acknowledged. No change will be made. Please reference § 100270.222. (e) (1)

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
Line239 - 245	San Mateo, Stroke Committee	Many neuro fellowships are not acgme approved. This should be removed as requirement if appropriately trained non acgme trainees are managing patients. Fellows should also be added as appropriate trainees. Other physicians: Ed physicians, for example may also be appropriate to review imaging if appropriately trained	Comment acknowledged. Ammendments will be made.
§100270.222 Evaluation of Primary Stroke Center, lines 228	BJ Bartleson, CHA	Add a new (a), "The hospital will be AHA/ASA certified as a Primary Stroke Center/, (b) the hospital shall be committed to supporting the agency Stroke Critical Care System. Remove lines 229-238 as all required in PSC certification Delete Lines 239-251 Delete Lines 269-271	Comment acknowledged. LEMSAs are responsible for the designation.
Lines 273-279	BJ Bartleson, CHA	Change the sentence to read, " a neurologist, neurosurgeon, interventional neuroradiologist, who is board certified or board eligible in neurology, neurosurgery, endovascular neurosurgical radiology, with experience and expertise dealing with cerebral vascular disease, or emergency physician with experience and expertise dealing with cerebral vascular disease	Comment acknowledged.
100270.222 Page 9 line 240-241	Pat Smith (Sequoia) San Mateo, Stroke Committee	When they say "shall be performed" what does this mean? i.e. When the CT is begun? When the CT is complete? What constitutes begun and complete?	Comment acknowledged. We may modify the language.
100270.222 pg.9 Line 240-241	Kimberly Tollison Kern County EMS	Change wording to Arrival to CT instead of "order entry".	Comment acknowledged. No change will be made.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
100270.222 Page 10 line 244-245	Pat Smith (Sequoia) San Mateo, Stroke Committee	What is their definition of "study completion"?	Comment acknowledged. We may modify the language.
4/ page10 line/245	Kula Koenig- American Heart Association/American Stroke Association	Neurologist accessibility 24/7 via in-person nor telemedicine. Neurosurgical services within 2 hours or available 24/7 in primary stroke centers providing neurosurgical services.	Comment acknowledged.
100270.222 Page 10 Line 252,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Include ABMS in your definition for board certification and use the term 'board certified' instead of 'qualified'	Comment acknowledged. Agree to add ABMS to definition.Change the language to board certified and board qualified….
252-258	Mills-Pen San Mateo, Stroke Committee	All physicians are already monitored and accredited by their respective hospitals so this section is unnecessary and redundant.	Comment acknowledged. No change will be made. The evaluation is LEMSA's responsibility.
100270.222 Page 10 Line 256,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Include ABMS in your definition for board certification and use the term 'board certified' instead of 'qualified'	Comment acknowledged. Agree to add ABMS to definition Change the language to board certified and board qualified….
100270.222 Page 10 Line 257-258	Laura Wallin, RN Monterey County EMS Agency	Why is a Neurosurgeon required for Primary Stroke Center?	Comment acknowledged. It is not required; it will be one of the possibilities of reading the study if they have available in their hospital. We also can delete this since we cover that in (e) Line 239-245. Will review.
100270.222 Page 10 Line 258,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Include ABMS in your definition for board certification and use the term 'board certified' instead of 'qualified'	Comment acknowledged. Agree to add ABMS to definition and change the language to board certified and board qualified.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
259-260	Mills-Pen San Mateo, Stroke Committee	Laboratory time is not necessary with 45' in most cases, especially thrombolysis where it unlikely to chg mgt. Again specifying this in the regs is unnecessary and should simply say it should follow current guidelines rather than being fixed.	Comment acknowledged
262-265	Mills-Pen San Mateo, Stroke Committee	Where does 2h come from? Not evidence based. Again should be based on local practice and availability	Comment acknowledged

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
Lines 262-265	R Cook Director of Clinical Quality Twin Cities Community Hospital	Lines 262-265 are a little concerning, the rest looks appropriate. The goal of a primary stroke centers is to assure patients receive tPA and other primary measures as close to the event as possible, then expedite them for intervention if indicated. Having primary stroke centers in rural communities assures patients can receive this life saving treatment quickly. However, some rural hospitals are going to be more than 2 hours away form a facility that can perform neurosurgery or other interventions. Patient would be harmed if they had to be transported further to receive primary interventions like tPA, just so they would be closer to surgical intervention. 262- 265 (g) Neurosurgical services that are available, including operating room availability, either directly or under agreement with a comprehensive or another primary stroke center, within two (2) hours following admission of acute stroke patients to the primary stroke center – please clarify expectations.	Comment acknowledged
100270.222/ pg.10 Line 264	Kimberly Tollison Kern County EMS	Change the wording to arrival, instead of admission	Comment acknowledged. No change will be made.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
100270.222 page 10 line 266	Joanne Chapman, RN Trauma/Clinical Coordinator Coastal Valleys EMS Agency	Need to define "acute care rehabilitation services". Is this referring to in house services, transfer agreements with facilities that do have rehabilitation services in house or just assessed for acute rehabilitation (STK-10 Joint Commission Core Measure for PSC). Suggest mirroring The Joint Commissions requirements.	Comment acknowledged
4 page10 line/267	Kula Koenig- American Heart Association/American Stroke Association	PSC shall have transfer protocol plans for neurosurgical emergencies	Comment acknowledged
269	Mills-Pen San Mateo, Stroke Committee	More than just neuro. What about ed or gen'l medical? Depends more on experience and training	Comment acknowledged. We might need to add ER Physician as they can be the medical director for the stroke program. Will review.
§ 100270.222, Page 10, Line 269	Sierra – Sacramento Valley EMS Agency	An emergency physician should be qualified to serve as the physician director of a primary stroke center.	Comment acknowledged. Agree to add. ER Doctor can be a Medical Director.
100270.222. Evaluation of Primary Stroke Centers, page 10, line 269-71	Gary Duckwiler, MD Professor, Director UCLA Division of Interventional Neuroradiology	Please add "board certified in Radiology with Interventional Neuroradiology specialization" to the physicians that can be stroke director. Interventionalists are one of the cornerstones of acute stroke management and should be able to be a stroke director along with other stroke subspecialists	Comment acknowledged. Amendments will be made.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
100270.222 Page 10, line 269-271	Debbie Becker, RN, BSN Central California Stroke Coordinator Committee	Do not require board-certification in neurology or neurosurgery for the stroke program physician medical director. The Joint Commission does not require the physician director of a stroke program to be board certified or require that the director be a neurologist or neurosurgeon. The majority of the primary stroke centers in Central California are accredited by the Joint Commission.	Comment acknowledged. Agree to add. ER Doctor can be a Medical Director.
100270.222 Page 10 Lines 269-271	Mary Barrnes San Joaquin County EMS Agency	Many of the existing Primary Stroke Centers (PSC) do not have neurologists available to serve as their physician director as this is not a requirement for Joint Commission accreditation. Adopting this higher standard may limit the number of hospitals eligible for LEMSA designation as a PSC creating confusion between LEMSA and Joint Commission standards. Recommend changing the regulations to adopt the Joint Commission standard for physician PSC director.	Comment acknowledged. Agree to add. ER Doctor can be a Medical Director

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
Page 10 Line 271	Brian Henricksen Napa County EMS Agency	Physician Director could also be a physician board certified in "emergency medicine". Would also need to define board certified in emergency medicine above this section: "For the purpose of this subsection, a qualified emergency medicine physician shall be board certified by the American Board of Emergency Medicine or American Osteopathic Board of Emergency Medicine."	Comment acknowledged. Agree to add. ER Doctor can be a Medical Director
100270.222 Page 10, line 272	Debbie Becker, RN, BSN Central California Stroke Coordinator Committee	Change (k) to read: At a minimum an acute care stroke team may include but not limited to: This would be the same verbiage as 100270.202. Not all primary stroke centers have endovascular neurosurgery radiology and not required by the Joint Commission.	Comment acknowledged. Amendments will be made to be consistent with definitions.
100270.222 Page10 Line269-271	Syung M Jung, MD, FACP San Joaquin General Hospital	The role of physician director of a primary stroke center should not be limited only to board-certified neurologists or neurosurgeons. Primary stroke centers, in particular that have tele-neurology service, can be run under the directorship of a physician who is board certified in internal medicine and/or emergency medicine.	Comment acknowledged. Agree to add. ER Doctor can be a Medical Director
Line 269 Pg. 10	California ENA	Allow a board-certified ED physician to be the champion of the stroke program	Comment acknowledged. Agree to add. ER Doctor can be a Medical Director

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
100270.222 Page 10 Line 271,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Suggest including emergency medicine and neuroradiology for PSC.	Comment acknowledged Agree to add, ER Doctor can be a Medical Director
100270.222 page10 line272-274	Syung M Jung, MD, FACP San Joaquin General Hospital	1) This statement needs clarification. Does this statement mean that an acute care stroke team has to have all three: neurologist AND neurosurgeon AND interventional neuroradiologist? 2) 24/7 tele-neurology coverage by board certified neurologists should fulfill the role of a neurologist within the acute care stroke team. 3) An interventional neuroradiologist should not be required for a primary stroke program's acute care stroke team. This role is typically required for comprehensive stroke centers.	Comment acknowledged. Amendments will be made to provide clarity.
100270.222 Page 10 Lines 272-276	Mary Barrnes San Joaquin County EMS Agency	Recommend including physicians board certified in Internal Medicine to the list of qualifying stroke team members.	Comment acknowledged Agree to add. ER Doctor can be a Medical Director.
Line 272 - 276	Byron Merritt Stroke Coordinator Byron.merritt@chomp.org	Most (if not all) Primary Stroke Centers do not have "Endovascular Neurosurgical Radiology. " Perhaps simply saying that PSCs shall "have access" to endovascular therapy via transfer agreements.	Comment acknowledged
§ 100270.222, Page 10, Line 273	Sierra – Sacramento Valley EMS Agency	The emergency physician should also be board certified in their own specialty (emergency medicine).	Comment acknowledged We will modify the language for clarity.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
100270.222 k.1 Page 10 Line 273	Kaiser Hospitals San Mateo, Stroke Committee	…endovascular neurosurgical radiology**,** **or emergency medicine**, with experience… Rationale: since EM physician listed as part of acute care stroke team, same level of documented competency should be required as for all other specialties	Comment acknowledged Agree to add. ER Doctor can be a Medical Director.
Article 4. 100270.222	Contra Costa County EMS Agency	This section has numerous errors and is out of date and not based on current stroke system data/time parameters. Times are calculated from presentation of patient, not order entry. Recommend to not include data/time parameters in regs as these evolve and change based on current research, evidence based medicine. Imaging technologies may also change and would recommend not to specify type of imaging.	Comment acknowledged. Please provide specifics.
Article 4. 100270.223	Contra Costa County EMS Agency	Comprehensive Stroke Center is a designation by performed by The Joint Commission. LEMSAs "recognize" that designation as meeting criteria for qualifying to be a Stroke Receiving Center. Regulations should not mandate hospitals to have designations through a specific accrediting body.	Comment acknowledged. It is a LEMSA's responsibility to designate and evaluate the hospital for designation as a stroke center. They can choose any certifying body as a reference but need to adhere to the criteria outlined in this Regulation.
Page 11 Line 275	Brian Henricksen Napa County EMS Agency	Qualification of board certification should include "emergency medicine".	Comment acknowledged Agree to add. ER Doctor can be a Medical Director.
Line 278 Page 11	California ENA	Nurse qualifications should be approved by the hospitals appropriate governing board with input from the Director of the Stroke Committee	Comment acknowledged. No modifications will be made.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
4/ page11 line 279	Kula Koenig- American Heart Association/American Stroke Association	PSC response team shall have training a minimum of twice a year and provide educational opportunities to prehospital personnel; Provide at least 2 stroke education activities per year to public	Comment acknowledged.
Page 11 Line 284	Mills-Pen San Mateo, Stroke Committee	It is unclear why regs based on equipment rather than expertise. Better to base on what types of patients rather than vague guidelines on equipment	Comment acknowledged.
§100270.223, Comprehensive Stroke Centers, page 11 Lines 285- 287 Lines 298-299 Lines 314-316		Utilize and add AHA/ASA standards – add, after the word shall in line 285, meet the most current AHA/ASA certification standards and" Delete lines 288-299 as all required by certification Delete lines 314-316	Comment acknowledged. LEMSA designations
4/ page11 line290	Kula Koenig- American Heart Association/American Stroke Association	Comprehensive Stoke Center (CSC) should have diagnostic testing capability available including CT, MRI, labs, CTA, MRA, other cranial and carotid duplex ultrasound, TEE, TTE, catheter angiography 24/7 and cardiac imaging when necessary	Comment acknowledged. No change will be made. Minimum criteria not limited.
4/ page11 line/292	Kula Koenig- American Heart Association/American Stroke Association	Neurologist is accessible and meets concurrently emergent needs of multiple complex stroke patients; Written call schedule for attending physicians providing availability 24/7; 24/7 availability for Neurointerventionalist; Neuroradiologist; Neurologist; Neurosurgeon.	Comment acknowledged.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
4/ page11 line/296	Kula Koenig- American Heart Association/American Stroke Association	There should be on-site certification reviews – two reviewers for two days. CSC must adhere to recommendations from Brain Attack Coalition for CSC in the written policies. Initial assessment of patient by emergency department physician in policies.	Comment acknowledged. It is the LEMSA's responsibility to evaluate and review the designation certification.
100270.223 Page 11 Line 296-297	Christine Clare, RN, MN, BC-NE Los Angeles County EMS	Can this be left to the regulatory bodies and not be an EMS Agency requirement?	Comment acknowledged. The designation and evaluation of a Stroke Center is the LEMSA's responsibility.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
4/ page11 line/298	Kula Koenig- American Heart Association/American Stroke Association	Clinical performance measures shall include 8 core stroke measures and 8 comprehensive stroke measures: **Core Measures:** 1. VTE Prophylaxis 2. Discharged on Antithrombotic Therapy 3. Patients with Atrial Fibrillation Receiving Anticoagulation Therapy 4. Thrombolytic Therapy Administered 5. Antithrombotic Therapy By End of Hospital Day Two 6. Discharged on Statin Medication 7. Stroke Education 8. Assessed for Rehabilitation **Compressive stroke measures:** 1.National Institutes of Health Stroke Scale (NIHSS Score Performed for Ischemic Stroke Patients) 2.Modified Rankin Score (mRS at 90 Days) 3.Severity Measurement Performed for SAH and ICH Patients (Overall Rate) 4.Procoagulant Reversal Agent Initiation for Intracerebral Hemorrhage (ICH) 5.Hemorrhagic Transformation (Overall Rate) H 6.Nimodipine Treatment Administered 7.Thrombolysis in Cerebral Infarction (TICI Post-Treatment Reperfusion Grade) 8.Arrival Time to Skin Puncture	Comment acknowledged. We will not add the elements as we mentioned the "Standardized performance measures". No change will be made.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
4/ page11 line298	Kula Koenig- American Heart Association/American Stroke Association	CSC shall have the following treatment capabilities: IV thrombolytics; Microsurgical neurovascular clipping of aneurysms; Neuroendovascular coiling of aneurysms; Stenting of extracranial carotid arteries; Carotid endarterectomy; Endovascular therapy	Comment acknowledged. Comment does not match with the line number. Details of a treatment plan for the Stroke patient would not be appropriate within a rule making package.
4/ page11 line/299	Kula Koenig- American Heart Association/American Stroke Association	CSC must participate in patient-centered research that is approved by the IRB.	Comment acknowledged. Will review.
4/ page11 line/300	Kula Koenig- American Heart Association/American Stroke Association	Program medical director must have extensive expertise and be available 24/7 with 8 hours of stroke education annually. Acute stroke team must be available 24/7, at bedside within 15 minutes and at least 8 hours of stroke education annually.	Comment acknowledged. This is mentioned in the Primary Stroke Center Requirements. The comprehensive stroke center criteria are in addition to those Primary Stroke Center.
Article 4. 100270.224 Page 12	Contra Costa County EMS Agency	Acute Stroke Ready is a designation performed by The Joint Commission and should not be used in regulation. LEMSAs "recognize" that designation as meeting criteria for qualifying as a Stroke Ready Center. Times to imaging, treatment, transfer should not be included as these change based on current research and evidence based medicine.	Comment acknowledged No change will be made. Acute Stroke Ready is another level of care in the California Stroke Critical Care System.
4/ page12 line/314	Kula Koenig- American Heart Association/American Stroke Association	Telemedicine is available is necessary.	Comment acknowledged.
4/ page12 line/319	Kula Koenig- American Heart Association/American Stroke Association	CSC has access to protocols used by EMS, routing plans; records from transfer.	Comment acknowledged.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
4/ page12 line/320	Kula Koenig- American Heart Association/American Stroke Association	Transfer protocol plans in writing including receiving transfers and circumstances for not accepting transferred patients	Comment acknowledged. These are all details of the transfer protocol; no change will be made.
4/ page12 line/321	Kula Koenig- American Heart Association/American Stroke Association	Education requirement for CSC: Nurses and other ED response team 2 hours annually, stroke nurses 8 hours annually. CSC sponsors at least 2 public educational opportunities annually; LIPs and staff present 2 or more educational courses annually for internal staff or individuals external to the comprehensive stroke center (e.g., referring hospitals)	Comment acknowledged. The hours of CE is not specified within these regulations.
§100270.224 Acute Stroke Ready Hospitals (Satellite Stroke Centers) Page 12, lines 328- 330. Lines330-332 Line 334 Lines 336-357 Lines 365-381	BJ Bartleson, CHA	Change the sentence to : Acute Stroke Ready Hospitals (Satellite Stroke Centers) provide the minimum level of care for stroke patients in the emergency department , are AHA/ASA certified and paired with one or more hospitals with higher level of services. Delete," In these hospitals the necessary emergency department neurological expertise may be provided in person or through telemedicine". Delete "of the following structural components" and insert "AHA/ASA certification Delete Delete	Comment acknowledged. Not specified within these regulations.
100270.223 Page 12 Line 307-308,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Delete, covered under #6 line 311 Or clarify further how this is different.	Comment acknowledged.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
100270.223 Page 12 Line 321-323,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS	May be too onerous for hospitals. CME is very prescriptive. Suggest 'guidance and feedback...'	Comment acknowledged. No change will be made.
P12 line 327	Vince Pierucci San Luis Obispo County EMS Agency	Minimize confusion re: Hospital categorizations – call them either "Acute Stroke Ready Hospital" or Satellite Stroke Centers - the verbiage is use the terms back a forth in this section – prefer you pick one	Comment acknowledged.
100270.224 Page 13 Line 333,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	We do not recognize Acute Stroke Ready Hospitals in our system. We feel this is detrimental to our system, where PSCs are readily available with short transport times. This seems to require ASRH as part of the system. Suggest changing to 'responsible for evaluation of ASRH IF they are part of the Stroke Critical Care System'. Further, this language is inconsistent with that used under PSCs and language regarding evaluation of CSCs does not exist, it is incorporated into 'minimum criteria' suggest the same here. 'IF ASRH is part of the Stroke System the following are the minimum criteria':	Comment acknowledged. TOM MIGHTWANT TO ADDRESS THIS
4/ page13 line/336	Kula Koenig- American Heart Association/American Stroke Association	In Acute Stroke Ready Hospital (ASRH) Acute Stroke Team is available 24/7, at bedside within 15 minutes and has at least 4 hours of stroke education annually	Comment acknowledged. Language modified to provide clarity.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
Page 13 Line 336 – 351	Brian Henricksen Napa County EMS Agency	Timeline from patient arrival at facility and study review is too long. A patient received at an Acute Stroke Ready Hospital could potentially not receive intervention for more than 2 hours and 15 minutes. As stroke care is changing rapidly, consider removal all time requirements from 100207.221, 100207.223, and 100207.224 and instead add a statement that hospitals meet current Joint Commission guidelines.	Comment acknowledged. The times are based on the National requirement.
4 page13 line/339	Kula Koenig- American Heart Association/American Stroke Association	Include in written policies that initial assessment of patients to be done by emergency department physician, nurse practitioner, or physician assistant.	Comment acknowledged. That is a hospital policy and it will decided by the Stroke Medical Director of the hospital.
100270.224 Page 13 & 14 Line 337, 346, 367	Laura Wallin, RN Monterey County EMS Agency	Why are Stroke Ready Hospital not held to the same time standards as Primary and Comprehensive Stroke Centers, since we are talking about the same population of patients?	Comment acknowledged.
100270.224 Page 13 Lines 339-340,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Review length cycle is different than PSC and CSC is this intentional or should it also be 2 years?	Comment acknowledged. It is intentional, as committee decided for the higher level of care/shorter time period of review is necessary to be current with the national standards.
4/ page13 line340	Kula Koenig- American Heart Association/American Stroke Association	ASRH has access to protocols used by EMS	Comment acknowledged.
4/ page13 line340	Kula Koenig- American Heart Association/American Stroke Association	ASRH has following treatment capabilities: IV thrombolytics; Anticipate transfer of patients who have received IV thrombolytics	Comment acknowledged.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
4/ page13 line 340	Kula Koenig- American Heart Association/American Stroke Association	Included in the written policy should be on-site certification reviews – one reviewer for one day. ASRH must adhere to recommendations from Brain Attack Coalition for Primary Stroke Centers.	Comment acknowledged. These types of details are with LEMSA's responsibilities.
Page 13 line 340	Kimberley Roderick EMS Chief Palo Alto Fire Department	It mentions the Satellite Stroke receiving reviews policy every 3 years but the other receiving hospitals review and revise every 2 years. Should these be the same?	Comment acknowledged. No Change needed. The committee decided the higher level of care/shorter time period of review is necessary to be current with the national standard. The Satellite Stroke Centers are the lowest care in the system. Three years review is sufficient.
4/ page13/ line344	Kula Koenig- American Heart Association/American Stroke Association	ASRH to choose 4 measures of performance, at least 2 are clinical measures related to clinical practice guidelines.	Comment acknowledged.
4/ page13 line 351	Kula Koenig- American Heart Association/American Stroke Association	Neurologist is accessible 24/7 in person or via telemedicine; Neurosurgical Services are available within 3 hours (provided through transferring the patient)	Comment acknowledged.
4/ page13 line352	Kula Koenig- American Heart Association/American Stroke Association	ARSH should have CT, MRI, labs available 24/7 for diagnostic testing	Comment acknowledged.
4/ page13/ line355	Kula Koenig- American Heart Association/American Stroke Association	Telemedicine is available within 20 minutes of it being necessary	Comment acknowledged.
100270.224 Page 13 Line 359,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Remove the use of 'qualified', include ABMS in definition of 'board-certified', use 'board-certified' throughout in place of 'qualified'	Comment acknowledged. Agree to modify the sentence and add ABMS.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
Line 351-375 Pg. 13	California ENA	Current language is confusing. Suggest identification of "door to read" time of 45 minutes.	Comment acknowledged. The term used in these regs is the more common national standard terminology.
100270.224 Page 13 Line 362,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Remove the use of 'qualified' and include ABMS in definition of 'board-certified', use 'board-certified' throughout in place of 'qualified'	Comment acknowledged. Agree to change to ABMS.
4/ page14 line/375	Kula Koenig- American Heart Association/American Stroke Association	Director should have sufficient knowledge of cerebrovascular disease	Comment acknowledged. Six hours CME is required per year.
100270.224 Page 14 Line 364,	Christine Clare, RN, MN, BC-NE Los Angeles County EMS Agency	Remove the use of 'qualified' and include ABMS in definition of 'board- certified', use 'board-certified' throughout in place of 'qualified'	Comment acknowledged. Agree to change to ABMS.
4/ page14 line379	Kula Koenig- American Heart Association/American Stroke Association	Education requirement for ASRH response team: ED response team a minimum of twice a year. ASRH Provides educational opportunities to prehospital personnel	Comment acknowledged. The citation is about the Acute Care Stroke Team.
§ 100270.224, Page 14, Line 380	Sierra – Sacramento Valley EMS Agency	"Additional requirements may be included at the discretion of the local EMS agency medical director" language is only listed under 'Acute Stroke Ready Hospitals' section. Similar language should be added for 'Primary Stoke Centers' and 'Comprehensive Stroke Centers'	Comment acknowledged. Amendments will be made to be consistent with other level of care language.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
Article 4 100270.225 Line 387	Contra Costa County EMS Agency	Hospital participation in the System of Care is voluntary. Regulations cannot force Hospitals to participate in the System that are not designated. Change Shall to MAY in cooperation with Stroke Receiving Centers and the local EMS agency in their jurisdictions.	Comment acknowledged. The system is voluntary but if they choose to be in the system, the requirement is mandatory. No change
§100270.225 EMS Receiving Hospitals, page 14 Lines 389-390	BJ Bartleson, CHA	Insert ," EMS receiving hospitals" and the local EMS agency medical director	Comment acknowledged.
100270.225 Page 14 Line 389, 390	Laura Wallin, RN Monterey County EMS Agency	This line should be added to the Primary, Comprehensive, and Stroke Ready hospitals. Realizing that this is addressed later in the document in 100270.226, lines 411/412, it was thought to be important enough to add to the EMS Receiving Hospitals, so it belongs in all the referenced levels of stroke centers.	Comment acknowledged. Amendments will be made to be consistent with all the levels of care.
§100270.226. Data Management Page15 Line 402 Line 404	BJ Bartleson, CHA	Add, "and participating hospitals" after local EMS agency. Insert after the word of, "AHA/ASA Get With The Guidelines, or equivalent stroke database,	Comment acknowledged. Do not agree. In the first comment: It will be repetitive. We will modify the language in Data Management section for clarity.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
Article 5. Data Management 100270.226 Lines 403 – 408	Contra Costa County EMS Agency	Remove date reference for Paul Coverdell. Suggestion: Keep as generic as possible as data elements change based on current research and best practice. Any reference to data elements should recommend data elements consistent with national stroke system of care benchmarks or remove all references to specify the data elements. Limit language to LEMSA to collect data for stroke system of care performance and evaluation.	Comment acknowledged. Agree with the most current version.
ARTICLE 5 DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATION § 100270.226 Management Page15 line 408	Shanna Kissel, MSN, RN REMSA	Consider removing date. Consider adding: "…most current version as stated by EMSA." Versions may change more quickly than the regulations.	Comment acknowledged. Agree with the most current version.
ARTICLE 5 DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATION § 100270.226 Management Page15 line 408	Chris Yoshida McMath Inland Counties Emergency Medical Agency	Consider removing date. Consider adding: "…most current version as stated by EMSA." Versions may change more quickly than the regulations.	Comment acknowledged. Agree with the most current version.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
100270.226, Page 15 Lines 411 - 412	Larry Karsteadt North Coast EMS	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 the 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 Acute Stroke Program Resource Guide" referenced within these regulations, or other hospital utilized stroke 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. Finally, until data integration is this is successfully accomplished and cost effective, this requirement could discourage hospital and LEMSA participation in Stroke System development or maintenance. That written, we are very supportive of this objective when feasible.	Comment acknowledged. We will modify the language in Data Management section for clarity.
ARTICLE 5 § 100270.227 page15-16 line 417-426	Chris Yoshida McMath Inland Counties Emergency Medical Agency	Consider adding: • A local EMS agency may specify additional requirements in addition to those specified in this Chapter.	Comment acknowledged. It is LEMSA's authority to have additional requirements.

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
Article 5. Quality Improvement Process. 100270.227 Line 421	Contra Costa County EMS Agency	Stroke related death audits are the domain of the Stroke hospital QI morbidity and mortality internal QI review process. Revise to an audit of all Stroke related deaths received via 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 Primary Stroke Center requirements.	Comment acknowledged. EMSA will not separate the QI of prehospital from hospital, and LEMSA should be included in both review of Pre-hospital and hospital cases. No change will be made.
Notice of Rulemaking, Page 2, Bullet #4	Larry Karsteadt North Coast EMS	The Data Management requirement on Page 15, lines 409, 410 that "stroke data shall be integrated into the LEMSA and EMSA data management system" may likely have costs, potentially substantial, to EMSA and LEMSAs to develop NEMSIS and the National Acute Stroke Program data system integration. If so, some LEMSAs may not be able to accomplish this worthy goal without new revenue sources. Also, additional new reporting requirements for LEMSAs (see next comment) will add new work and costs. Potential new state, regional and local government costs should be stated in the DISCLOSURES section.	Comment acknowledged. EMSA will modify the language in Data Management section for clarity.
Add section	Christine Clare, RN, MN, BC-NE Los Angeles County EMS	Add language to allow LEMSA to charge designation and system management fees for both Primary and Comprehensive Stroke Centers.	Comment acknowledged. It is the LEMSA's Authority. No change will be made

Section/Page/Line	Commenter's Name	Comments/ Suggested Revisions	Response
Data elements	Vince Pierucci San Luis Obispo County EMS Agency	Minimum described by Joint Commission – should you include a minimum set	Comment acknowledged. Modifications will be made in the Data Management section for clarity.
Community Education	Vince Pierucci San Luis Obispo County EMS Agency	Missing from Primary and Comprehensive	Comment acknowledged. Pleaseprovide specifics.