The Emergency Medical Services Authority has illustrated changes to the original text in the following manner:

- Additions to the original text from 45-day comment period are shown underlined
- Deletions to the original text from 45-day comment period are shown in ~~strikeout~~

The Emergency Medical Services Authority has illustrated changes to the modified text from the 15-day comment period in the following manner:

- Additions to the modified text are shown in double underline.
- Deletions to the modified text are shown in ~~double strikeout~~.

The Emergency Medical Services Authority has illustrated changes to the modified text from the 2nd 15-day comment period in the following manner:

- Additions to the modified text are shown in highlighted *italics double underline*.
- Deletions to the modified text are shown in highlighted ~~*italics double strikeout*~~.

California Code of Regulations
Title 22. Social Security
Division 9. Prehospital Emergency Medical Services
Chapter 7.2 Stroke Critical Care System

ARTICLE 1. DEFINITIONS

§ 100270.200. Acute Stroke Ready Hospital

"Acute stroke-ready hospitals" or "Satellite stroke centers" means a hospital able to provide the minimum level of critical care services for stroke patients in the emergency department, and are paired with one or more hospitals with a higher level of stroke services.

Note: Authority cited: Sections ~~*1797.94,*~~ ~~*1797.103,*~~ 1797.107, and 1798.150, Health and Safety Code. Reference: Sections *1797.94,* 1797.103 and 1797.176, Health and Safety Code.

§ 100270.201. Board-certified

"Board-certified" means a physician who has fulfilled all the Accreditation Council for Graduate Medical Education (ACGME) requirements in a specialty field of practice, and has been awarded a certification by an American Board of Medical Specialties (ABMS) approved program.

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

§ 100270.202. Board-eligible

"Board-eligible" means a physician who has applied to a specialty board examination and has completed the requirements and ~~received permission~~ is approved to take the examination by ABMS. Board certification must be obtained within the allowed time by ABMS from the first appointment.

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

§ 100270.203. Comprehensive Stroke Center

"Comprehensive stroke center" means a hospital with specific abilities to receive, diagnose and treat ~~the most complex~~ all stroke cases and provide the highest level of care for stroke patients.

Note: Authority cited: Sections ~~*1797.94,* *1797.103,*~~ 1797.107, and 1798.150, Health and Safety Code. Reference: Sections *1797.94,* 1797.103 and 1797.176, Health and Safety Code.

§ 100270.204. Clinical Stroke Team

"Clinical stroke team" means a team of healthcare professionals who provide care for the stroke patient and may include, but is not limited to, neurologists, neuro-interventionalists, neurosurgeons, anesthesiologists, emergency medicine physicians, registered nurses, advanced practice nurses, physician assistants, pharmacists, and technologists.

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

§ 100270.205. Emergency Medical Services Authority

"Emergency ~~*m*~~*M*edical ~~*s*~~*S*ervices ~~*a*~~*A*uthority" or "EMS Authority" means the department in California that is responsible for the coordination and the integration of all state activities concerning emergency medical services (EMS).

Note: Authority cited: Section~~*s*~~ 1797.107~~ *and 1797.54*~~, Health and Safety Code. Reference: Sections *1797.54,* 1797.100, and 1797.103, Health and Safety Code.

§ 100270.206. Local Emergency Medical Services Agency

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

Note: Authority cited: Sections ~~*1797.94,*~~ 1797.107, 1797.176, ~~*and 1797.200,*~~ Health and

Safety Code. Reference: Section*s* 1797.94 *and 1797.200*, Health and Safety Code.

§ 100270.207. Primary Stroke Center

"Primary stroke center" means a hospital that ~~stabilizes and~~ treats acute stroke patients, ~~providing initial acute care,~~ and identif*~~y~~ies* patients who may benefit from transfer to ~~one or more~~ a higher level of care~~. Centers~~ when clinically warranted.

Note: Authority cited: Sections ~~*1797.94, 1797.103,*~~ 1797.107, and 1798.150, Health and Safety Code. Reference: Sections *1797.94,* 1797.103 and 1797.176, Health and Safety Code.

§ 100270.208. Protocol

"Protocol" means a predetermined, written medical care guideline, which may include standing orders.

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

§ 100270.209. Quality Improvement

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

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

§ 100270.210. Stroke

"Stroke" means a condition of impaired blood flow to a patient's brain resulting in brain dysfunction, most commonly through vascular occlusion or hemorrhage.

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

§ 100270.211. Stroke Call Roster

"Stroke call roster" means a schedule of licensed health professionals available twenty-four (24) hours a day, seven (7) days a week for the care of stroke patients.

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

§ 100270.212. Stroke Care

"Stroke care" means emergency transport, triage, diagnostic *evaluation*, acute

intervention and other acute care services for stroke patients that potentially require immediate medical or surgical intervention treatment, and may include education, primary prevention, acute intervention, acute and subacute management, prevention of complications, secondary stroke prevention, and rehabilitative services.

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

100270.213. Stroke Critical Care System

"Stroke critical care system" means a subspecialty care component of the EMS system developed by a local EMS agency. This critical care system links prehospital and hospital care to deliver optimal treatment to the population of stroke patients ~~who potentially require immediate medical or surgical intervention~~.

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

§ 100270.214. Stroke Medical Director

"Stroke medical director" means a board-certified physician ~~designated by the hospital who is~~ in neurology or neurosurgery or another board with sufficient experience and expertise dealing with cerebrovascular disease as determined by the hospital credentialing committee ~~and~~ that is responsible for the stroke service, performance improvement, and patient safety programs related to a stroke critical care system.

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

§ 100270.215. Stroke Program Manager~~/Coordinator~~

"Stroke program manager~~/coordinator~~" means a registered nurse or qualified individual designated by the hospital with the responsibility for monitoring and evaluating the care of stroke patients and the coordination of performance improvement and patient safety programs for the stroke center in conjunction with the stroke medical director**.**

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

§ 100270.216. Stroke Program

"Stroke program" means an organizational component of the hospital specializing in the care of stroke patients.

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

Code.

§ 100270.217. Stroke Team

"Stroke team" means the ~~*clinical*~~ ~~stroke team~~personnel, support personnel, and administrative staff that function together as part of the hospital's stroke *program*~~*team*~~.

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

§ 100270.218. Telehealth

"Telehealth" means 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.

Note: Authority cited: Sections 1797.107, 1797.176, and 1798.150, Health and Safety Code. Reference: Sections 1797.103, 1797.176, and 1797.220, Health and Safety Code. California Business and Professions Code Sec. 2290.5

§ 100270.219. Thrombectomy-Capable Stroke Center

"Thrombectomy-capable stroke center" means a primary stroke center with the ability to perform mechanical thrombectomy for the ischemic stroke patient when clinically warranted.

Note: Authority cited: Sections 1797.107, and 1798.150, Health and Safety Code. Reference: Sections 1797.94, 1797.103, and 1797.176, Health and Safety Code.

ARTICLE 2. LOCAL EMS AGENCY STROKE CRITICAL CARE SYSTEM REQUIREMENTS

§ 100270.220. Stroke Critical Care System Plan ~~Approval.~~

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

(b) The local EMS agency implementing a~~A~~ ~~s~~*Stroke* ~~c~~*Critical* ~~c~~*Care* ~~s~~*System Plan* ~~that starts after the effective date of these regulations~~ *stroke critical care system* shall have ~~the~~ a ~~S~~*stroke* ~~C~~*critical C*~~c~~*are* ~~S~~*system* ~~Plan~~ *Stroke Critical Care System Plan* approved by the EMS Authority prior to implementation.

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

(1) The names and titles of the local EMS agency personnel who have a role in a

stroke critical care system.

(2) ~~Verification of agreements with hospitals for designation~~The list of stroke designated facilities with ~~a list of stroke hospital contracts~~ the agreements~~ with~~ expiration dates.

(3) A description or a copy of the local EMS agency's stroke patient identification and destination policies.

(4) A description or a copy of the method of field communication to the receiving hospital-specific to stroke patients, designed to expedite time-sensitive treatment on arrival.

(5) A description or a copy of the policy that facilitates the inter-facility transfer of stroke patients.

(6) A description of the method of data collection from the EMS providers and designated stroke hospitals to the local EMS agency and the EMS Authority.

(7) A ~~copy~~ policy or description of ~~all written agreements for coordination of stroke transport across LEMSA lines, with neighboring local EMS agencies to provide stroke care~~how the L*ocal* EMS ~~A~~*agency* integrates a receiving center in a neighboring jurisdiction.

(8) A description of the integration of stroke into an existing quality improvement committee or a description of any stroke-specific quality improvement committee.

(9) A description of programs to conduct or promote public education specific to stroke.

(d) The EMS Authority shall, within 30 days of receiving a request for approval, notify the requesting local EMS agency in writing of approval or disapproval of its Stroke Critical Care System Plan. If the Stroke Critical Care System Plan is disapproved, the response shall include the reason(s) for the disapproval and any required corrective action items.

(e) The local EMS agency shall provide an amended plan to the EMS Authority within 60 days of receipt of the disapproval letter.

(f) The local EMS agency currently operating a stroke critical care system implemented before the effective date of these regulations, shall submit to the EMS Authority a Stroke Critical Care System Plan as an addendum to its next annual EMS plan update, or within 180 days of the effective date of these regulations, whichever comes first.

(g) Any stroke center designated by the local EMS agency before implementation

of these regulations may continue to operate. Before re-designation by the local EMS agency at the next regular interval, stroke centers shall be re-evaluated to meet the criteria established in these regulations.

(h) No health care facility shall advertise in any manner or otherwise hold itself out to be affiliated with a stroke critical care system or a stroke center unless they have been designated by the local EMS agency, in accordance with this ~~C~~chapter.

Note: Authority cited: Sections ~~1797.103,~~ 1797.105, 1797.107, ~~1797.173,~~ 1797.176, ~~1797.220, 1797.250,~~ and 1798.150, ~~1798.170, and 1798.172,~~ Health and Safety Code. Reference: Sections 1797.103, 1797.105, 1797.173, 1797.176, ~~and~~ 1797.220, 1797.250, 1798.170, and 1798.172, Health and Safety Code.

§ 100270.221. Stroke Critical Care System Plan Updates

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

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

(2) The status of the Stroke Critical Care System Plan goals and objectives.

(3) Stroke critical care system performance improvement activities.

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

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

ARTICLE 3. PREHOSPITAL STROKE CRITICAL CARE SYSTEM REQUIREMENTS

§ 100270.222. EMS Personnel and Early Recognition

(a) The local EMS agency shall ~~ensure that prehospital stroke assessment and treatment training is available~~ establish prehospital care protocols related to the early recognition, assessment, treatment, and transport of stroke patients for prehospital emergency medical care personnel as determined by the local EMS agency.

~~(b) The local EMS agency shall require the use of a validated prehospital stroke-~~

~~screening algorithm for early recognition and assessment.~~

(b) The local EMS agency shall require the use of a validated prehospital stroke-screening algorithm for early recognition and assessment.

~~(c)(b)~~(c) The local EMS agency's protocols for the use of online medical direction shall be used ~~in conjunction with transfer~~ to determine the most appropriate stroke center ~~utilized for suspicious~~ to transport a patient in cases of confusing or complex findings.

~~(d)(c)~~(d) The prehospital treatment policies for stroke-specific basic life support (BLS), advanced life support (ALS), and limited advanced life support (LALS) shall be developed according to the scope of practice and local accreditation.

~~(e)(d)~~(e) Notification of ~~P~~prehospital findings of suspected stroke patients~~, as defined by the local EMS agency,~~ ~~will~~ shall be communicated in advance of the arrival to ~~a hospital~~ the stroke centers ~~of care facility in advance of arrival,~~ according to the local EMS agency's Stroke Critical Care System Plan.

Note: Authority cited: Sections ~~*1797.92, 1797.103,*~~ 1797.107, 1797.176, ~~*1797.189(a) (2), 1797.206, 1797.214,*~~ and 1798.150, Health and Safety Code. Reference: Sections 1797.92, *1797.103,* 1797.176, *1797.189, 1797.206, 1797.214,* 1797.220, 1798.150, and 1798.170, Health and Safety Code.

ARTICLE 4. HOSPITAL STROKE CARE REQUIREMENTS AND EVALUATIONS

§ 100270.223. Comprehensive Stroke Care Centers

(a) Hospitals designated as a comprehensive stroke center by the local EMS agency shall meet the following minimum criteria:

(1) Satisfy all the requirements of a thrombectomy-capable and primary stroke center as provided in this chapter.

(2) Neuro-endovascular diagnostic and therapeutic procedures available twenty-four (24) hours a day, seven (7) days a week.

(3) Advanced imaging, available twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty-five (365) days per year, which shall include but not be limited to:

~~(A) Computed tomography (CT) angiography.~~

~~(B) Magnetic resonance imaging (MRI).~~

(A) All imaging requirements for thrombectomy-capable centers.

~~(C)~~~~(A)~~(B) Diffusion-weighted magnetic resonance imaging (MRI) and computed tomography (CT) perfusion imaging.

~~(B)~~(4) Transcranial Doppler (TCD) shall be available in a timeframe that is clinically appropriate.

~~(4)~~(5) Intensive care unit (ICU) beds with licensed independent practitioners with the expertise and experience to provide neuro-critical care twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty-five days (365) days per year.

~~(5) Written policies and procedures for comprehensive stroke services that are reviewed at least every two (2) years, revised as needed, and implemented.~~

~~(6)~~~~(5)~~(6) Data-driven, continuous quality improvement process~~,~~ including collection and monitoring of standardized ~~comprehensive stroke center~~ performance measures.

~~(7)~~~~(6)~~(7) A stroke patient research program.

~~(8)~~~~(7)~~(8) Satisfy all the following staff qualifications:

(A) A neurosurgical team capable of assessing and treating complex stroke and stroke- like syndromes.

~~(B) A neuro-radiologist with a current Certificate of Added Qualifications in Neuroradiology on staff.~~

~~(C) A physician with neuro-interventional angiographic training and skills on staff as deemed by the hospital's credentialing process.~~

~~(D)~~(B) A qualified neuro-radiologist, board-certified by the American Board of Radiology or the American Osteopathic Board of Radiology.

(E)~~*(C) A qualified vascular neurologist, board-certified by either the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry, or with appropriate education and experience as defined by the hospital credentials committee*~~.

(F)~~*(D)(C)* If teleradiology is used in image interpretation, all staffing and staff qualification requirements ~~provided~~ contained in this section shall remain in effect and shall be documented by the hospital.

~~*(E)*~~*(D)* Written call schedule for attending neurointerventionalist, neurologist, neurosurgeon providing availability twenty-four (24) hours a day seven (7) days a week.

~~(8)~~(9) Provide comprehensive rehabilitation services either on-site or by written

transfer agreement with another health care facility licensed to provide such services.

~~(9)~~(10) Written transfer agreements with primary stroke centers in the region to accept the transfer of patients with complex strokes when clinically warranted.

~~(10)~~(11) A comprehensive stroke center shall at a minimum, provide guidance and continuing stroke-specific medical education to hospitals designated as a primary stroke center with which they have transfer agreements.

(b) Additional requirements may be ~~required at the discretion of~~ stipulated by the local EMS agency medical director.

Note: Authority cited: Sections ~~*1797.103,*~~ 1797.107, 1797.176, ~~*1797.204, 1797.220, and*~~ 1798.150, ~~*and 1798.172,*~~ Health and Safety Code. Reference: Sections *1797.103,* 1797.204, 1797.220, ~~*and*~~1797.222, *and 1798.172,* Health and Safety Code.

§ 100270.224. Thrombectomy-Capable Stroke Centers

(a) Hospitals designated as a thrombectomy-capable stroke center by the local EMS agency shall meet the following minimum criteria:

(1) Satisfy all the requirements of a primary stroke center as provided in this chapter.

(2) The ability to perform mechanical thrombectomy for the treatment of ischemic stroke twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty-five (365) days per year.

(3) Dedicated neuro-intensive care unit beds to care for acute ischemic stroke patients twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty-five (365) days per year.

(4) Satisfy all the following staff qualifications:

~~(A) A neurosurgical team capable of assessing and treating complex stroke and stroke-like syndromes, if provide neurosurgical services.~~

~~(B) A neuro-radiologist with a current Certificate of Added Qualifications in Neuroradiology on staff.~~

~~(C)~~(A) A *qualified* physician*, board certified by the American Board of Radiology, American Osteopathic Board of Radiology, American Board of Psychiatry and Neurology, or the American Osteopathic Board of Neurology and Psychiatry,* with neuro-interventional angiographic training and skills on staff as deemed by the hospital's credentialing ~~*process*~~*committee*.

~~(D)~~(B) A qualified neuro-radiologist, board-certified by the American Board of Radiology or the American Osteopathic Board of Radiology.

~~(E)~~(C) A qualified vascular neurologist, board-certified by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry*, or with appropriate education and experience as defined by the hospital credentials committee*.

~~(F)~~(D) If teleradiology is used in image interpretation, all staffing and staff qualification requirements ~~provided~~ contained in this section shall remain in effect and shall be documented by the hospital.

(5) The ability to perform ~~expanded~~ advanced imaging twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty-five (365) days per year, which shall include, but not be limited to, the following:

(A) Computed tomography angiography (CTA).

~~(B) Magnetic resonance imaging (MRI).~~

~~(C)~~(B) Diffusion-weighted ~~magnetic resonance imaging~~ MRI ~~and /~~or CT Perfusion.

~~(D) Computed tomography (CT) of the head.~~

~~(E)~~(C) Catheter angiography.

~~(F)~~(D) Magnetic resonance angiography (MRA).

(E) And the following modalities available when clinically necessary:

~~(G)(E)~~(i) Carotid duplex ultrasound.

~~(H) Transcranial ultrasonography.~~

~~(I)(F)~~(ii) Transesophageal echocardiography (TEE).

~~(G)~~(iii) Transthoracic Echocardiography (TTE).

(6) A process to collect and review data regarding adverse patient outcomes following mechanical thrombectomy.

~~(7) The ability to submit data for thirteen standardized performance measures:~~

~~(A) Eight (8) stroke (STK) measures.~~

~~(B) Five comprehensive stroke (CSTK) measures for the ischemic stroke population.~~

~~(8)~~(7) Written transfer agreement with at least one comprehensive stroke center.

(b) Additional requirements may be ~~required at the discretion of~~ stipulated by the local EMS agency medical director.

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

§ 100270.225. Primary Stroke Centers

(a) Hospitals designated by the local EMS agency as a primary stroke center shall meet all the following minimum criteria:

(1) Adequate staff, equipment, and training to perform rapid evaluation, triage, and treatment for the stroke patient in the emergency department.

(2) Standardized stroke care protocol/order set.

(3) Stroke diagnosis and treatment capacity twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty-five (365) days per year.

(4) ~~A~~ Data-driven, continuous quality improvement ~~system,~~process including ~~data~~ collection and monitoring of standardized performance measures.

(5) Continuing education in stroke care provided for staff physicians, staff nurses, staff allied health personnel, and EMS personnel.

(6) Public education on stroke and illness prevention.

(7) A~~n acute~~clinical stroke team, available to see in person or via telehealth, a patient identified as a potential acute stroke patient within 15 minutes following the patient's arrival at the hospital's emergency department or within 15 minutes following a diagnosis of a patient's potential acute stroke.

(A) At a minimum, a~~n acute care~~clinical stroke team shall consist of:

~~1.~~ (i) A neurologist, neurosurgeon, interventional neuro-radiologist, or emergency physician who is board certified or board eligible in neurology, neurosurgery, endovascular neurosurgical radiology, or other board-certified physician with sufficient experience and expertise in managing patients with acute cerebral vascular disease

as determined by the hospital credentials committee.

~~2.~~ (ii) A registered nurse, physician assistant or nurse practitioner ~~who has demonstrated competency, as determined by the physician director described in above, in~~ capable of caring for acute stroke patients that has been designated by the hospital *who may serve* as a stroke program manager.

(8) Written policies and procedures for stroke services which shall include written protocols and standardized orders for the emergency care of stroke patients. These policies and procedures shall be reviewed at least every ~~two (2)~~ three (3) years, revised as needed, and implemented.

(9) Data-driven, continuous quality improvement process including collection and monitoring of standardized performance measures.

(10) Neuro-imaging services capability that is available twenty-four (24) hours a day, seven (7) days a week, three hundred sixty-five (365) days per year, such that imaging shall be initiated within twenty-five (25) minutes following emergency department arrival.

(11) CT scanning or equivalent neuro-imaging shall be initiated within twenty-five (25) minutes following emergency department arrival.

~~(11)~~(12) ~~Neuro-~~Other imaging ~~services~~ shall be available within ~~this~~ a clinically appropriate timeframe and shall, at a minimum, include:

~~(A) Computerized tomography (CT) scanning.~~

~~(B)~~(A) ~~Magnetic resonance imaging (~~MRI~~)~~.

~~(C)~~(B) ~~Computed tomography angiography (~~CTA~~)~~ and / or Magnetic resonance angiography (MRA).

~~(D)~~(C) TEE or ~~Transthoracic echocardiography (~~TTE~~).~~

~~(C)~~~~(E)~~(13) Interpretation of the imaging.

~~(12)~~(A) If teleradiology is used in image interpretation, all staffing and staff qualification requirements contained in this section shall remain in effect and shall be documented by the hospital.

~~(13)~~(B) Neuro-imaging studies shall be reviewed by a physician with appropriate expertise, such as a board-certified radiologist, board-certified neurologist, a board-certified neurosurgeon, or residents who interpret such studies as part of their training in ACGME-approved radiology, neurology, or neurosurgery training program within forty- five (45) minutes of emergency department arrival.

~~(A)~~(i) For the purpose of this subsection, a qualified radiologist shall be board certified by the American Board of Radiology or the American Osteopathic Board of Radiology.

~~(B)~~(ii) For the purpose of this subsection, a qualified neurologist shall be board certified by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

~~(C)~~(iii) For the purpose of this subsection, a qualified neurosurgeon shall be board certified by the American Board of Neurological Surgery.

(14) Laboratory services capability that is available twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty-five (365) days per year, such that services may be performed within forty-five (45) minutes following emergency department arrival.

(15) Neurosurgical services ~~that are~~ shall be available, including operating room availability, either directly or under an agreement with a thrombectomy-capable, comprehensive or other ~~*primary*~~ stroke center with neurosurgical services, within two (2) hours following the ~~admission~~ arrival of acute stroke patients to the primary stroke center.

(16) Acute care rehabilitation services.

(17) Transfer arrangements with one or more higher level of care centers when clinically warranted or for neurosurgical emergencies.

(18) There shall be a ~~physician~~ stroke medical director of a primary stroke center, who may also serve as a physician member of a stroke team, who is board-certified in neurology or neurosurgery or another board-certified physician with sufficient experience and expertise dealing with cerebral vascular disease as determined by the hospital credentials committee.

(b) Additional requirements may be stipulated by ~~required at the discretion of~~ the local EMS agency medical director.

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

§ 100270.226. Acute Stroke Ready Hospitals

(a) Hospitals designated by the local EMS agency as an acute stroke ready hospital shall meet all the following minimum criteria:

(1) A~~n acute~~ clinical stroke team available to see, in person or via telehealth, a patient identified as a potential acute stroke patient within ~~thirty (30)~~ twenty (20) minutes following the patient's arrival at the hospital's emergency department.

(2) Written policies and procedures for emergency department stroke services that are reviewed, revised as needed, and implemented at least every three (3) years.

(3) Emergency department policies and procedures shall include written protocols and standardized orders for the emergency care of stroke patients.

(4) Data-driven, continuous quality improvement process including collection and monitoring of standardized performance measures.

(5) Neuro-imaging services capability that is available twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty-five (365) days per year, such that imaging shall be performed and reviewed by a physician within ~~*sixty (60)*~~ *forty-five (45)* minutes following emergency department arrival.

(6) Neuro-imaging services shall, at a minimum, include~~:~~ CT or MRI, or both.

~~(A) Computerized tomography (CT).~~

~~(B) Magnetic resonance imaging (MRI).~~

~~(C)~~(7) Interpretation of the imaging.

~~(7)~~(A) If teleradiology is used in image interpretation, all staffing and staff qualification requirements contained in this ~~sub~~section shall remain in effect and shall be documented by the hospital.

~~(8)~~(B) Neuro-imaging studies shall be reviewed by a physician with appropriate expertise, such as a board-certified radiologist, board-certified neurologist, a board-certified neurosurgeon, or residents who interpret such studies as part of their training in ACGME-approved radiology, neurology, or neurosurgery training program within forty-five (45) minutes of emergency department arrival.

~~(A)~~(i) For the purpose of this subsection, a qualified radiologist shall be board-certified by the American Board of Radiology or the American Osteopathic Board of Radiology.

~~(B)~~(ii) For the purpose of this subsection, a qualified neurologist shall be board-certified by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

~~(C)~~(iii) For the purpose of this subsection, a qualified neurosurgeon shall be board-certified by the American Board of Neurological Surgery.

~~(b)~~(8) Laboratory services shall, at a minimum, include blood testing, electrocardiography and x-ray services, and be available twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty-five (365) days per year, and able to be completed and reviewed by physician within sixty (60) minutes following emergency department arrival.

~~(c)~~(9) Neurosurgical services ~~that are~~ shall be available, including operating room availability, either directly or under an agreement with a thrombecotomy-capable, primary or comprehensive stroke center, within three (3) hours following the ~~admission~~ arrival of acute stroke patients to an acute stroke-ready hospital.

~~(d)~~(10) Provide IV thrombolytic treatment and have ~~T~~transfer arrangements with one or more thrombectomy-capable, primary or comprehensive stroke center(s) that facilitate the transfer of patients with strokes to the stroke center(s) for care when clinically warranted.

~~(e)~~(11) There shall be a medical director of an acute stroke-ready hospital, who may also serve as a member of a stroke team, who is a physician or advanced practice nurse who maintains at least ~~six (6)~~ four (4) hours per year of educational time in cerebrovascular disease;

~~(f)~~(12) ~~Acute care~~ Clinical stroke team for an acute stroke-ready hospital at a minimum shall consist of a nurse and a physician with training and expertise in acute stroke care.

~~(g)~~(b) Additional requirements may be ~~included at the discretion of~~ stipulated by the local EMS agency medical director.

Note: Authority cited: Sections ~~*1797.103,*~~ 1797.107, 1797.176, *and* ~~*1797.204, 1797.220,*~~ 1798.150, ~~*and 1798.172,*~~ Health and Safety Code. Reference: Sections *1797.103,* 1797.204, 1797.220, ~~*and*~~ 1797.222, *and 1798.172,* Health and Safety Code.

§ 100270.227. EMS Receiving Hospitals (Non-designated for Stroke Critical Care Services)

(a) An EMS receiving hospital that is not designated for stroke critical care services shall do the following, at a minimum and in cooperation with stroke receiving centers and the local EMS agency in their jurisdictions:

(1) Participate in the local EMS agency's quality improvement system, including data submission as determined by the local EMS agency medical director.

(2) Participate in the inter-facility transfer agreements to ensure access to a stroke critical care system for a potential stroke patient.

Note: Authority cited: Sections ~~*1797.88, 1797.103,*~~ 1797.107, 1797.176, ~~*1797.220, 1798.100,*~~ *and* 1798.150, ~~*and 1798.172,*~~ Health and Safety Code. Reference: Sections *1797.88, 1797.103,* 1797.176, 1797.220, *1798.100,* ~~*and*~~1798.150, 1798.170, *and 1798.172,* Health and Safety Code.

ARTICLE 5. DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATION

§ 100270.228. Data Management Requirements

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

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

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

(d) The hospital stroke patient care elements shall be ~~compliant~~ consistent with the U.S. Centers for Disease Control and Prevention, Paul Coverdell National Acute Stroke Program Resource Guide, dated October 24, 2016*, which is hereby incorporated by reference*.

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

(f) ~~Stroke~~ The prehospital care record and the hospital data elements shall be collected and submitted by the local EMS agency, and subsequently to the EMS Authority, on no less than a quarterly basis.

Note: Authority cited: Sections. ~~*1797.102, 1797.103,*~~ 1797.107, 1797.176, ~~*1797.204, 1797.220, 1797.227,*~~ *and* 1798.150, ~~*and 1798.172.*~~ Health and Safety Code. Reference: Section *1797.102, 1797.103, 1797.204,* 1797.220, 1797.222, 1797.~~*204*~~*227, and 1798.172, Health and Safety Code*.

§ 100270.229. Quality Improvement and Evaluation Process

(a) Each stroke critical care system shall have a quality improvement process ~~to include structure, process, and outcome evaluations which focus on improvement efforts to identify root causes of problems, intervene to reduce or eliminate these causes, and take steps to correct the process. This process~~that shall include, at a minimum:

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

~~(1)~~(2) ~~A detailed a Audit~~ Review of ~~all S~~stroke-related deaths, major complications, and transfers.

~~(2)~~(3) A multidisciplinary Stroke Quality Improvement Committee, including both prehospital and hospital members.

~~(3)~~(4) Participation in the ~~P~~QI process by all designated ~~S~~stroke centers~~, other hospitals that treat stroke patients~~ and prehospital providers involved in the stroke critical care system.

~~(4)~~(5) Evaluation of ~~both local and~~ regional ~~components of the~~ integration of stroke ~~system~~patient movement.

~~(3)~~(5)(6) Participation in the stroke data management system.

~~(4)(6)~~(7) Compliance with the California Evidence Code, Section 1157.7 to ensure confidentiality, and a disclosure-protected review of selected stroke cases.

~~(b) The local EMS agency shall be responsible for the following:~~

~~(1) The on-going performance evaluation of a local or regional stroke critical care system.~~

~~(2) The development of a quality improvement process.~~

~~(3) Ensuring that designated stroke centers, other hospitals that treat stroke patients and prehospital providers involved in a Stroke critical care system participate in the quality improvement process.~~

~~(c)~~(b) The local EMS agency shall be responsible for on-going performance evaluation~~s of all levels of stroke centers~~ and quality improvement of the stroke critical care system.

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