

**Emergency Medical Services
Primary Stroke Receiving Center
Agreement**

County of Alameda

and

Washington Hospital Healthcare System

Effective Date: January 1, 2023

Alameda County Primary Stroke Receiving Center Agreement

Contract No. _____

DEFINITIONS AND ACRONYMS

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. 22 CCR § 100270.200. 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.
AHS	Acute Hemorrhagic Stroke
AIS	Acute Ischemic Stroke
ALCO	Alameda County
BHDE	Bidirectional Healthcare Data Exchange
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. 22 CCR § 100270.201. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.
Board-eligible	“Board-eligible” means a physician who has applied to a specialty board examination and has completed the requirements and is approved to take the examination by ABMS. Board certification must be obtained within the allowed time by ABMS from the first appointment. 22 CCR § 100270.202. 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.
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 interventionists, neurosurgeons, anesthesiologists, emergency medicine physicians, registered nurses, advanced practice nurses, physician assistants, pharmacists, and technologists. 22 CCR § 100270.204. 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.

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Comprehensive Stroke Center	“Comprehensive stroke center” means a hospital with specific abilities to receive, diagnose and treat all stroke cases and provide the highest level of care for stroke patients. 22 CCR § 100270.203. 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.
CT	Computed Tomography
Dx	Diagnosis
ED	Emergency Department
EMS	Emergency Medical Services
Emergency Medical Services Authority (EMSA)	“Emergency Medical Services Authority” 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). 22 CCR § 100270.205. Note: Authority cited: Section 1797.107 Health and Safety Code. Reference: Sections 1797.54, 1797.100, and 1797.103, Health and Safety Code.
Local Emergency Medical Services Agency (LEMSA)	“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. 22 CCR § 100270.206. Note: Authority cited: Sections 1797.107, 1797.176, Health and Safety Code. Reference: Sections 1797.94 and 1797.200, Health and Safety Code.
GWTG-Stroke	Get With The Guidelines Stroke is a registry offered by the American Heart Association to capture data regarding Stroke patients
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health Act
IA	Intra-arterial
IFT	“Interfacility transfer” means the transfer of a Stroke patient from one acute general care facility to another acute general care facility.

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IR	Interventional Radiology
JC	The Joint Commission
MRI	Magnetic Resonance Imaging
Primary Stroke Center	“Primary stroke center” means a hospital that treats acute stroke patients, and identifies patients who may benefit from transfer to a higher level of care when clinically warranted. 22 CCR § 100270.207. 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.
Protocol	“Protocol” means a predetermined, written medical care guideline, which may include standing orders. 22 CCR § 100270.208. 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.
PSRC or Primary Stroke Receiving Center	Designation by Alameda County of a hospital as a primary stroke center, thrombectomy-capable stroke center, and/or comprehensive stroke center where patients with suspected possible Stroke who may benefit by rapid assessment and timely treatment with fibrinolytic if warranted are to be transported to via the 9-1-1 system.
Quality Improvement (QI)	“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. 22 CCR § 100270.209. Note: Authority cited: Sections 1797.107, 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.
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. 22 CCR § 100270.210. 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.
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. 22 CCR § 100270.211. Note: Authority cited: Sections 1797.107, 1797.176, and 1798.150, Health and Safety Code. Reference: Sections

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	1797.103 and 1797.220, Health and Safety Code.
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. 22 CCR § 100270.212. 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.
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. 22 CCR § 100270.213. 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.
Stroke Medical Director	“Stroke medical director” means a board-certified physician in neurology or neurosurgery or another board with sufficient experience and expertise dealing with cerebrovascular disease as determined by the hospital credentialing committee that is responsible for the stroke service, performance improvement, and patient safety programs related to a stroke critical care system. 22 CCR § 100270.214. 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.
Stroke Program Manager	“Stroke program manager” 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. 22 CCR § 100270.215. 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.
Stroke Program	“Stroke program” means an organizational component of the hospital specializing in the care of stroke patients. 22 CCR § 100270.216. 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.

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Stroke Team	“Stroke team” means the personnel, support personnel, and administrative staff that function together as part of the hospital’s stroke program. 22 CCR § 100270.217. 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.
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. 22 CCR § 100270.218. 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
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. 22 CCR § 100270.219. 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.
TIA	Transient Ischemic Accident
tpA	Tissue Plasminogen Activator

Section 1 – Introduction

- 1.1 Alameda County is designated as the Local Emergency Medical Service Agency (LEMSA) as defined in the California Health and Safety Code Division 2.5, Sections 1797.94, 1797.67, 1798, and 1798.170, responsible for establishing policies and procedures within its jurisdiction. The LEMSAs also has primary responsibility for administration of emergency medical services in a county or region, which is designated pursuant Health and Safety Code commencing with section 1797.200.
- 1.2 This Agreement, dated as of the first day of January 2023, and in accordance with California Code of Regulations Title 22. Social Security; Division 9. Prehospital Emergency Medical Services; Chapter 7.2 Stroke Critical Care System (§ 100270.213.), is by and between the COUNTY OF ALAMEDA, hereinafter referred to as the “COUNTY”, and Washington Hospital Healthcare System, hereinafter referred to as the “Contractor”.
- 1.3 Whereas, COUNTY, in consideration of the County’s PSRC designation of Contractor as a primary stroke center (22 CCR § 100270.207.) as described in ALCO EMS field assessment, treatment and transport protocol. Contractor shall perform the services identified in this agreement without interruption, 24 hours per day, 7 days per week, 52 weeks per year for the full term of this Contract, as set forth in Exhibit A. Exceptions would include, the lack of technology (equipment) available to perform appropriate diagnostics: catastrophic plant or equipment failure (CT and or MRI) or pre-planned scheduled maintenance.
- 1.4 Whereas, Contractor is professionally qualified to provide such services and is willing to provide the same to COUNTY.
- 1.5 Now, therefore it is agreed that COUNTY does hereby designate Contractor to provide Primary Stroke Services, and Contractor accepts such designation as specified in this Agreement, and the following described exhibits, all of which are incorporated into this Agreement by this reference:
- Exhibit A – Scope of Services
- Exhibit B – Data Elements
- Exhibit C – Application
- Exhibit D – California Regulations: Stroke Critical Care System

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Exhibit E – Paul Coverdell National Acute Stroke Program Resource Guide, dated October 24, 2016: <https://emsa.ca.gov/wp-content/uploads/sites/71/2019/02/USCDP-Paul-Coverdell-Nation-Acute-Stroke-Prog-Resource-Guide-10-24-16.pdf>

- 1.6 The parties hereby execute this single agreement that will constitute formal designation of Contractor as a Primary Stroke Receiving Center within the Alameda County EMS system under Health & Safety Code Sections 1797.67 and 1798.170 et seq.

Section 2 – Term

- 2.1 The term of this Agreement shall be from January 1, 2023, through December 31, 2025.
- 2.2 The current designation term expires December 31, 2022, at which time Contractor shall submit a new PSRC application and provide supporting documentation demonstrating compliance with the requirements under 22 CCR§ 100270.225. This Agreement is subject to the review and approval of the application by ALCO EMS. There will be NO interruption of service during the COUNTY EMS review/approval process for existing PSRCs that are in good standing with an expired MOU.
- 2.3 The term for the PSRC designation will be for up to three-years, with re-designation reviews by LEMSA conducted at least every three years.
- 2.4 At minimum, Contractor shall maintain JC Certification as a Primary Stroke Center to continue designation as a PSRC, even if thrombectomy capable.
- 2.5 Current PSRCs that offer IR services for thromectomy shall obtain Thromectomy-Capable Stroke Center status by JC during the term of this Agreement.
- 2.6 Before PRSC re-designation by the LEMSA at the next regular interval, the Contractor shall be re-evaluated to meet the criteria established in these regulations: Exhibit D, Article 4. (22 CCR § 100270.225.)
- 2.7 The LEMSA medical director may stipulate additional requirements: Exhibit D, Article 4. (§ 100270.225.–18b)
- 2.8 LEMSA may suspend or revoke the PSRC designation for lack of compliance with this Agreement or applicable laws and regulations.

Section 3 – Services

- 3.1 Contractor shall provide hospital, equipment, resources and personnel services as described in Exhibits A and D; data collection and reporting requirements as described in Exhibits A, B, D and E; quality improvement requirements as described in Exhibits A and D. Contractor shall participate in an annual review and adhere to compliance standards as described in Exhibits A and D. For initial EMS approval, Contractor shall complete and submit a PSRC Application as described in Exhibit C. Contractor shall comply with ALL criteria in accordance with ARTICLE 4. § 100270.225. Primary Stroke Center Requirements as described in Exhibit D. Currently designated ALCO EMS PSRCs' that offer IR services for thrombectomy, shall at minimum, comply with ALL criteria in accordance with ARTICLE 4. § 100270.224. Thrombectomy-Capable Stroke Centers. (ALCO EMS Policies and protocols for the ALCO PSRC program will be reviewed and revised as needed).

Section 4 – Required Reports

- 4.1 Contractor shall provide data specified in Exhibits B, D, and E for individual EMS transported patients (identified) with suspected Stroke. Contractor shall complete data (b-2) entry into GWTG-Stroke registry regarding all EMS patients no later than 30 calendar days following the prior month's end. This will allow for timely access by ALCO EMS via established GWTG-Stroke "Super User" agreement and must include ALL: EMS transported patients with a diagnosis of stroke (AHS, AIS, TIA).
- 4.2 Contractor shall submit an annual aggregate performance data report in the format established by the LEMSA in Exhibit B (B-1). Said report shall be submitted on LEMSA request for prior year respectively and present said data at requested ALCO EMS PSRC Meeting.
- 4.3 Any and all data elements specified in Exhibits B, D and E are subject to modification/change at any time as agreed upon by the LEMSA and Contractor or otherwise mandated by the State.

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Section 5 – Signatory

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

COUNTY OF ALAMEDA

DocuSigned by:
William McClurg
By: _____
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Signature

Name: William McClurg

(Printed)

Title: Deputy EMS Director

Approved as to Form:

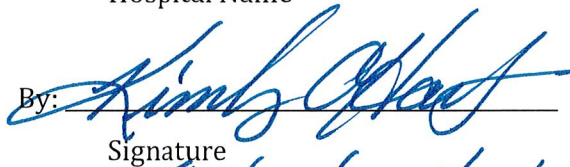
K. Joon Oh
By: _____
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K. Joon Oh, Deputy County Counsel

CONTRACTOR

Washington Hospital

Hospital Name

By: 
Signature

Name: Kimberly Harte

(Printed)

Title: CEO

Date: 12/6/2022

By signing above, signatory warrants and represents that he/she executed this Agreement in his/her authorized capacity and that by his/her signature on this Agreement, he/she or the entity upon behalf of which he/she acted, executed this Agreement.

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EXHIBIT A – SCOPE OF SERVICES

1. SCOPE OF SERVICES: Primary Stroke Center (Exhibit D, Article 1. § 100270.207.)

Contractor shall:

1.1 Meet and maintain minimum requirements as a Primary Stroke Center defined in § 100270.225 and maintain current JC certification as a Primary Stroke Center to be designated by ALCO EMS as a Primary Stroke Receiving Center (PSRC) for EMS transported patients with suspected stroke. This means a licensed general acute care facility that meets the minimum hospital Stroke Care requirements pursuant to and defined in 22 CCR § 100270.212. Patients with suspected “Stroke” means a condition of impaired blood flow to a patient’s brain resulting in brain dysfunction, most commonly through vascular occlusion or hemorrhage § 100270.210. In addition, Contractor is able to provide all services, equipment, and personnel including maintenance of adequate staffing levels, equipment, and facilities according to PSRC designation criteria described in Exhibits A and D.

At minimum, be currently certified as a Primary Stroke Center and without interruption provide all services according to Joint Commission (JC) requirements for Disease-Specific Care (DSC) Advanced Certification Program for Primary Stroke Center (PSC), and if applicable, Thrombectomy-Capable Stroke Center (TSC) or Comprehensive Stroke Center (CSC).

1.2 Accept all Alameda County EMS patients triaged as having suspected Stroke, transported to Contractor’s facility, and provide appropriate medical management for said patients without regard to race, color, national origin, religious affiliation, age, sex, or ability to pay.

2. HOSPITAL SERVICES: 22 CCR § 100270.225. Primary Stroke Centers (Exhibit D, Article 4. HOSPITAL STROKE CARE REQUIREMENTS AND EVALUATIONS)

(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.

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- (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) Data-driven, continuous quality improvement process including 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 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 clinical stroke team shall consist of:

- (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.
- (ii) A registered nurse, physician assistant or nurse practitioner 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 that shall include written protocols and standardized orders for the emergency care of stroke patients. These policies and procedures shall be reviewed at least every 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.

(12) Other imaging shall be available within a clinically appropriate timeframe and shall, at a minimum, include:

(A) MRI.

(B) CTA and / or Magnetic resonance angiography (MRA).

(C) TEE or TTE.

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(13) Interpretation of the imaging.

(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.

(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.

(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.

(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.

(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 shall be available, including operating room availability, either directly or under an agreement with a thrombectomy-capable, comprehensive or other stroke center with neurosurgical services, within two (2) hours following the 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 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) Hospitals designated by the local EMS agency as a primary stroke center shall meet additional requirements that may be stipulated by the LEMSA medical director, including the following:

Contractor shall keep in effect the following:

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- a) Licensure under California Health and Safety Code Section 1250 et seq.
- b) Permit for Basic or Comprehensive Emergency Medical Services pursuant to the provisions of Title 22, Division 5, of the California Code of Regulations,
- c) Designated priority telephone line to be used by prehospital personnel to contact the PSRC regarding patients with suspected Stroke that are being transported to that facility for potential intervention,
- d) Neurovascular intervention and Neurosurgical availability.
 - i. Neurovascular intervention and or neurosurgery; or,
 - ii. A plan for emergency transport to a facility with neurovascular intervention and or Neurosurgery availability that describes steps for timely transfer.

3. 22 CCR § 100270.224. Thrombectomy-Capable Stroke Centers

(Exhibit D, Article 4. HOSPITAL STROKE CARE REQUIREMENTS AND EVALUATIONS)

(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 § 100270.225.
- (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 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 committee.
 - (B) A qualified neuro-radiologist, board-certified by the American Board of Radiology or the American Osteopathic Board of Radiology.
 - (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.

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(D) 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.

(5) The ability to perform 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) Diffusion-weighted MRI or CT Perfusion.

(C) Catheter angiography.

(D) Magnetic resonance angiography (MRA).

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

(i) Carotid duplex ultrasound.

(ii) Transesophageal echocardiography (TEE).

(iii) Transthoracic Echocardiography (TTE).

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

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

(b) Hospitals designated as a thrombectomy-capable stroke center by the local EMS agency shall meet additional requirements may be stipulated by the local EMS agency medical director.

4. HOSPITAL PERSONNEL

Contractor shall provide program oversight staff and shall have available all staff necessary to perform optimal care for patients with Stroke, including the following:

4.1 PSRC Program Medical Director: (Exhibit D, 22 CCR § 100270.214.)

4.1.1 Qualifications:

- Board Certified in either Internal Medicine, Cardiology, or Neurology and have preferred knowledge and expertise in the diagnosis and treatment of cardiovascular disease and stroke.

4.1.2 Responsibilities:

- Oversight of PSRC program patient care,
- Coordination of staff and services,
- Authority and accountability for quality and performance improvement,
- Participation in protocol development,

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- Establishes and monitors quality control, including Mortality and Morbidity, and,
- Participation in County PSRC QI Committee.

4.2 PSRC Program Manager: (Exhibit D, 22 CCR § 100270.215.)

4.2.1 Qualifications:

- Experience with monitoring and evaluating the care of stroke patients and/or the coordination of performance improvement and patient safety programs (ED, ICU, CCU).

4.2.2 Responsibilities:

- Supports PSRC Medical Director Functions
- Acts as EMS-PSRC Program Liaison
- Assures EMS-PSRC data sharing
- Manages EMS-PSRC QI activities
- Authority and accountability for quality oversight and performance improvement.

4.3 Physician-Consultants - Hospital shall maintain a daily on-call schedule for: Neurologist(s) (on-site or remote); Radiologist(s) (on-site or remote); and Interventional Neurologist(s), Neurosurgeon(s) if these services are provided by Hospital.

4.4 Stroke Team / Additional personnel: (Exhibit D, 22 CCR § 100270.217.)

- a) Emergency department (ED)
- b) Interventional radiology (IR)
- c) Neurosurgery
- d) Nursing
- e) Computed tomography (CT)
- f) Laboratory
- g) Pharmacy
- h) Rehabilitation
- i) Inpatient units

5. PERFORMANCE STANDARDS

Contractor shall follow current science/evidence based recommendations regarding the assessment and treatment of acute ischemic stroke as well as acute hemorrhagic (American Heart Association /American Stroke Association); and strive to meet the following recommended timelines in caring for patients who present to hospital with identified acute ischemic stroke and meet inclusion criteria for treatment:

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- 5.1 Systemic Fibrinolytic within 4.5 hours of symptom onset if administered.
- 5.2 Systemic Fibrinolytic within 60 minutes of ED arrival if administered.
- 5.3 Timely IFT to a thrombectomy-capable center if necessary.

6. HOSPITAL POLICIES AND PROCEDURES

Contractor shall:

6.1 Develop and implement policies and procedures designed to ensure that patients presenting to hospital with possible Stroke receive appropriate care in a timely manner. Such internal policies shall include Program Management (DSPR), Delivering or Facilitating Clinical Care (DSDF), Supporting Self-Management (DSSE), Clinical Information Management (DSCT), and Performance Measurement (DSPM) as defined and specified by The Joint Commission requirements for Disease-Specific Care (DSC) Advanced Certification Program for Primary Stroke Center Certification Manual (Current standards for PSRC JC Certification cycle).

7. DATA MANAGEMENT AND REPORTING: (Exhibit D, 22 CCR § 100270.228.)

Data 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 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 (Exhibit-E).
- (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) 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.

Contractor in addition shall provide:

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- 7.1 As further specified in Exhibit B, Contractor shall collect on-going aggregate data (de-identified) for patients below and forward to ALCO EMS review: annual or on ALCO EMS request:
- a) Number of EMS "Stroke Alerts".
 - b) Number of above patients (a) with diagnosis of Non-Stroke.
 - c) Number of above patients (a) with diagnosis of AHS.
 - d) Number of above patients (a) with diagnosis of TIA.
 - e) Number of above patients (a) with diagnosis of AIS.
 - f) Number of above AIS patients (e) treated with systemic (IV) TPA.
 - g) % of above AIS patients (f) treated with TPA ≤60 minutes of arrival.
 - h) Median "Door-to-Drug" time of above AIS patients (f) treated with TPA.
 - i) Number of AIS patients (e) that received an acute IR Approach.
 - j) Number of AIS patients (f) treated with systemic (IV) TPA and transferred to an IR capable facility for further diagnostics and treatment.
 - k) Number of Non-EMS patients diagnosed in ED with AIS diagnosis (Dx).
 - l) Number of above Non-EMS patients (k) treated with systemic (IV) TPA.
 - m) % of above Non-EMS patients (l) treated with TPA ≤60 minutes of Dx.
 - n) Median "Door-to-Drug" time of above AIS patients (l) treated with TPA.
 - o) Number of AIS patients (k) that received an acute IR Approach.
 - p) Number of AIS patients (l) treated with systemic (IV) TPA and transferred to an IR capable facility for further diagnostics and treatment.
- 7.2 Provide data for ALL EMS transported patients (identified) with suspected possible Stroke. Patient specific Follow-Up data must be accessible to ALCO EMS via GWTG Super-User account as soon as possible or within 30 calendar days of previous months end or date of request received.
- 7.3 At minimum, participate by providing data to a National Stroke Registry using American Heart Association Get with the Guidelines Stroke (GWTG) database and be willing to participate in other data sharing strategies that may include but are not limited to the California Stroke Registry and or the Coverdell National Acute Stroke Registry on request by County (ALCO EMS). Facilitate implementation of future data elements related to Stroke system performance and quality improvement.
- 7.4 Contractor shall allow the use of provided data for IRB approved clinical research without hospital identifiers.
- 7.5 The data further specified in Exhibits B and D shall be provided to the EMS Agency in the timeline and manner defined, until a real time Bidirectional Healthcare Data Exchange (BHDE) network is established between County EMS and the PSRC Contractor.
- 7.6 At some point in time (to be determined at the discretion of EMS) during the term of this MOU, the contractor will establish a Bidirectional Healthcare Data Exchange (BHDE) network with County EMS.

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- 7.7 The cost to establish the BHDE network between County EMS and the Contractor shall be fairly shared by apportionment as agreed upon by both parties.
- 7.8 The BHDE network established between County EMS and the Contractor must be interoperable with other data systems, including the functionality to exchange electronic patient health information in real-time with other entities in an HL7 format.
- 7.9 The minimum requirements and capability of the BHDE network established between County EMS and the Contractor shall include but are not limited to:
- 7.10 Search a patient's health record for problems, medications, allergies, and end of life decisions to enhance clinical decision-making;
 - 7.10.1 Alert the receiving hospital regarding the patient's status directly onto a dashboard in the emergency department to provide decision support;
 - 7.10.2 File the EMS Patient Care Report data directly into the patient's electronic health record for timely and longitudinal patient care documentation;
 - 7.10.3 Reconcile the electronic health record information including diagnoses and disposition back into the EMS patient care report for use in ensuring timely provider feedback and enhanced quality improvement strategies for the County EMS system.
 - 7.10.4 Any access to, or exchange of, individually identifiable health information or protected health information shall comply with the requirements of HIPAA and HITECH.

8. QUALITY IMPROVEMENT AND EVALUATION PROCESS: (Exhibit D, 22 C 100270.229.)

(a) Each stroke critical care system shall have a quality improvement process that shall include a minimum:

- (1) Evaluation of program structure, process, and outcome.
- (2) Review of stroke-related deaths, major complications, and transfers.
- (3) A multidisciplinary Stroke Quality Improvement Committee, including both prehospital and hospital members.
- (4) Participation in the QI process by all designated stroke centers and prehospital providers involved in the stroke critical care system.
- (5) Evaluation of regional integration of stroke patient movement.
- (6) Participation in the stroke data management system.

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(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 on-going performance evaluation and quality improvement of the stroke critical care system.

Contractor shall provide the following:

- 8.1 PSRC Program staff shall participate in Alameda County EMS PSRC QI Committee meetings, with a minimum requirement of two / year. Each PSRC shall provide at minimum, multi-disciplinary representation including one decision-making representative from Emergency Medicine and Neurology at every meeting attended.
- 8.2 PSRC shall maintain a written internal quality improvement plan for Stroke patients that includes, but is not limited to the determination and evaluation of:
 - a) Death rate
 - b) Complications
 - c) Sentinel events
 - d) System issues
 - e) Organizational issues and resolution processes
- 8.3 PSRC shall support EMS Agency QI activities including educational activities for prehospital personnel.

9. COMPLIANCE

- 9.1 Contractor shall provide continuous Oversight for compliance with ALL sections in Exhibit A.
- 9.2 Contractor shall advise ACLO EMS immediately regarding any changes that would result in non-compliance with any section in Exhibit A.
- 9.3 Contractor shall participate in an annual review (on request by ALCO EMS) regarding modifications of any and compliance with ALL sections as described in Exhibit A and D.
- 9.4 Failure by Contractor to comply with any section(s) as described in this Agreement, including in Exhibits A or B, may result in the loss of EMS Stroke patients transported to Contractor's hospital for potential intervention until compliance issue(s) is resolved.

10. PREHOSPITAL STROKE CRITICAL CARE SYSTEM REQUIREMENTS

(Exhibit D, Article 3. § 100270.222. EMS Personnel and Early Recognition)

(a) The local EMS agency shall establish prehospital care protocols related to the early recognition, assessment, treatment, and transport of stroke patients for

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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.

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

(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) Notification of prehospital findings of suspected stroke patients shall be communicated in advance of the arrival to the stroke centers according to the local EMS agency's Stroke Critical Care System Plan.

County shall also keep in effect the following:

- 10.1 Make electronic prehospital patient care records available to Contractor via computer for all Stroke patients taken by 911 ambulance to Contractor's facilities.
- 10.2 Maintain the confidentiality of all patient information and data (includes de-identified data) provided by Contractor and use such information solely for the local EMS Agency's internal quality improvement, peer review and oversight functions as mandated/authorized by law or regulation. County also agrees to not identify Contractor by name in any aggregate report of the data or release any reports or data showing individual hospital performance unless agreed to by Contractor or required by law or regulation. Notwithstanding anything in this Agreement to the contrary, the parties acknowledge and agree that Contractor shall not be required to disclose any patient information or other data to the COUNTY to the extent not otherwise permitted or required by applicable laws or regulations.
- 10.3 Provide to Contractor and/or the PSRC Quality Improvement Committee prehospital system data, including patient destination data, related to Stroke care.
- 10.4 Meet and consult with Contractor prior to the adoption of any policy or procedure that concerns the administration of the Stroke Critical Care System, Stroke public education efforts or the triage, transport and treatment of Stroke patients.
- 10.5 In order to improve quality of care, direct 911 ambulance transport providers to inform hospital of identification of patients determined to have suspected Stroke prior to the patient's arrival at hospital.
- 10.6 Transport suspected Stroke patients to Contractor in accordance with County EMS field assessment, treatment and transport protocols. .

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EXHIBIT B – DATA ELEMENTS

As defined in Section 6 of Exhibit A and as further specified in this Exhibit B, Contractor shall provide the specified data elements required by the State of California and in the reporting formats established by the Alameda County EMS Agency.

B-1

Contractor shall collect continuous aggregate (de-identified) performance measures using data elements below, submitted on ALCO EMS request and presented to Alameda County Emergency Medical Services on an annual basis at ALCO PSRC meeting. (Ex. A, Sec. 7.1)

Alameda County EMS PSRC Annual Performance Data

1. Number of EMS “Stroke Alerts”.
 - 1a. Number of above patients (1) with diagnosis of Non-Stroke.
 - 1b. Number of above patients (1) with diagnosis of AHS.
 - 1c. Number of above patients (1) with diagnosis of TIA.
 - 1d. Number of above patients (1) with diagnosis of AIS.
2. Number of above AIS patients (1d) treated with systemic (IV) TPA.
 - 2a. % of above AIS patients (2) treated with TPA ≤60 minutes of arrival.
 - 2b. Median “Door-to-Drug” time of above AIS patients (2) treated with TPA.
 - 2c. Number of AIS patients (1d) that received an acute IR Approach.
 - 2d. Number of AIS patients (2) treated with systemic (IV) TPA and transferred to an IR capable facility for further diagnostics and treatment.
3. Number of Non-EMS patients diagnosed in ED with AIS diagnosis (Dx).
 - 3a. Number of above Non-EMS patients (3) treated with systemic (IV) TPA.
 - 3b. % of above Non-EMS patients (3a) treated with TPA ≤60 minutes of Dx.
 - 3c. Median “Door-to-Drug” time of above AIS patients (3a) treated with TPA.
 - 3d. Number of AIS patients (3) that received an acute IR Approach.
 - 3e. Number of AIS patients (3a) treated with systemic (IV) TPA and transferred to an IR capable facility for further diagnostics and treatment

B-2

Contractor shall provide PSRC performance and clinical outcome data for individual EMS patients transported with suspected Stroke via GWTG-Stroke Registry and allow “Super User” access by ALCO EMS through a signed Data Use Agreement. Patient specific follow-up data shall include but not be limited to data elements below and shall be accessible to

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ALCO EMS as soon as possible or within 30 calendar days following the prior month's end or on receipt of request by ALCO EMS.

EMS Patient Inclusion Criteria (Stroke Alert follow-up)

All patients who:

Have **one or more** positive finding(s): signs/symptoms are present when assessed with the Cincinnati Prehospital Stroke Scale (CPSS), has a normal blood glucose level when obtained and CPSS signs/symptoms were initially observed within **4 hours** of contact by a valid historian.

Please note: ask when the patient was last seen at normal baseline **and** when the onset of new stroke signs and symptoms appeared, and interpreted by EMS as suspected Stroke and transported to a PSRC for potential intervention. **(Data collection tool B2: GWTG-Stroke)**

Data collection tool B2 captured in GWTG-Stroke:

EMS STROKE ALERT /IFT FOLLOW-UP

- Was the patient a "Stroke Alert" by EMS?
- Stroke confirmed at hospital: if yes, (ischemic, hemorrhagic or TIA)
- Was patient transported by EMS to your PSRC, NOT "Stroke Alert" and diagnosed with Stroke?
- Did EMS record "TIME patient last known normal or at base-line"?
- Was a Systemic (IV) fibrinolytic (tpA) administered at PSRC?
- If yes, was the systemic (IV) fibrinolytic (tpA) administered within 4.5 hours of symptom onset?
- Was the (IV) systemic fibrinolytic (tpA) administered within 60 minutes of EMS ED arrival?
- If a systemic fibrinolytic (tpA) was NOT administered (reason)?
- Did the patient receive an Acute IR approach (if PSRC capable)?
- Was the patient transferred from your PSRC to another hospital for further IR diagnostics and or treatment?
- Diagnoses ?

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EXHIBIT C – PSRC APPLICATION

Alameda County EMS Primary Stroke Receiving Center (PSRC) Designation

(To complete this form electronically tab through the fields and then save it.)

Objective: To assess the interest and capabilities of Alameda County hospitals for designation as an Alameda County EMS Primary Stroke Receiving Center ("PSRC").

Definition: A PSRC is a hospital that receives suspected stroke patients pre-screened by Alameda County EMS and is certified as a Primary Stroke Center, Thrombectomy-Capable Stroke Center, or Comprehensive Stroke Center by the Joint Commission.

In the future, ALCO EMS may further designate PSRCs to include "enhanced" capabilities for the treatment of stroke patients. These interventions include but are not restricted to Invasive Radiologic Approaches: intra-arterial fibrinolytics, mechanical thrombectomy or other invasive surgical procedures.

Facility Name: _____

Phone ext _____

Address:

_____ street

_____ city

_____ zip

Name of the person completing the form: _____

Title: _____

email: _____

Phone: ext: _____

Is your facility currently certified as a primary stroke center (PSC), Thrombectomy-Capable Stroke Center (TSC), or Comprehensive Stroke Center (CSC) by Joint Commission (JC)? ☐ Yes ☐ No

If yes, what level of JC certification?

☐ PSC ☐ TSC ☐ CSC

If **yes**, what is the date of certification expiration? ____/____/____

If **no**, are you in the process of applying?

☐ Yes ☐ No

(Note: Joint Commission certification visit on "ENTER DATE", Evidence of Standards Compliance submission pending).

If **yes**, when do you anticipate certification? ____/____/____

If **no**, please keep EMS informed if you change your mind in the future. You do not need to complete the remainder of this form – thank you.

If your facility is currently JC Certified as a PSC or in process, please fill out below:

Name of stroke center Medical Director? _____

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email: _____ Phone: ext: _____

Name of stroke center Nurse Coordinator?

email: _____ Phone: ext: _____

Name of stroke center Administrative Liaison?

email: _____ Phone: ext: _____

Name of Liaison for data collection, analysis, and reporting?

Phone: ext: _____

email: _____ Phone: ext: _____

What is the dedicated phone number for EMS stroke patient notification?

Phone: ext: _____

Does your facility participate in the American Heart Association (AHA) Get With The Guidelines (GWTG) Stroke registry?

☐ Yes ☐ No

If your facility participates in any additional stroke registries, please list:

If your facility is certified by Joint Commission as a Primary Stroke Center and you wish to be designated as a PSRC by ACLO EMS, or your facility is renewing its status with ALCO EMS, please complete this form and, save it and email as an attachment, or print and mail or fax to:

Dr. Zita Konik or, Michael Jacobs, Paramedic

1000 San Leandro Blvd. San Leandro, CA 94577

Zita.konik@acgov.org or, michael.jacobs@acgov.org

(510) 618.2086 fax: (510) 618-2099

We will contact you to schedule a site visit. Thank you for your interest and support!

EXHIBIT D – CALIFORNIA STATE STROKE REGULATIONS

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 1797.107, 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 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 all stroke cases and provide the highest level of care for stroke patients.

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.

§ 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.

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§ 100270.205. Emergency Medical Services Authority

"Emergency Medical Services Authority" 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 1797.107 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 1797.107, 1797.176, Health and Safety Code. Reference: Sections 1797.94 and 1797.200, Health and Safety Code.

§ 100270.207. Primary Stroke Center

"Primary stroke center" means a hospital that treats acute stroke patients, and identifies patients who may benefit from transfer to a higher level of care 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.

§ 100270.208. Protocol

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

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.

§ 100270.209. 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 1797.107, 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.

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§ 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.

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 in neurology or neurosurgery or another board with sufficient experience and expertise dealing with cerebrovascular disease as determined by the hospital credentialing committee 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

“Stroke program manager” 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.

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§ 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 personnel, support personnel, and administrative staff that function together as part of the hospital's stroke program.

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.

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ARTICLE 2. LOCAL EMS AGENCY STROKE CRITICAL CARE SYSTEM REQUIREMENTS

§ 100270.220. Stroke Critical Care System Plan

- (a) The local EMS agency may develop and implement a stroke critical care system.
- (b) The local EMS agency implementing a stroke critical care system shall have a 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) The list of stroke designated facilities with the agreement 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 policy or description of how the Local EMS 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

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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 chapter.

Note: Authority cited: Sections 1797.105, 1797.107, 1797.176, and 1798.150, Health and Safety Code. Reference: Sections 1797.103, 1797.105, 1797.173, 1797.176, 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 1797.107, 1797.176, 1797.254, and 1798.150, Health and Safety Code. Reference: Sections 1797.103, 1797.176, 1797.220, 1797.222, 1797.250, 1798.170, and 1798.172, Health and Safety Code.

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ARTICLE 3. PREHOSPITAL STROKE CRITICAL CARE SYSTEM REQUIREMENTS

§ 100270.222. EMS Personnel and Early Recognition

(a) The local EMS agency shall 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.

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

(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) Notification of prehospital findings of suspected stroke patients shall be communicated in advance of the arrival to the stroke centers according to the local EMS agency's Stroke Critical Care System Plan.

Note: Authority cited: Sections 1797.107, 1797.176, 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) All imaging requirements for thrombectomy-capable centers.

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

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

(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.

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

(7) A stroke patient research program.

(8) Satisfy all the following staff qualifications:

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

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

(C) 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.

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

(9) Provide comprehensive rehabilitation services either on-site or by written transfer agreement with another health care facility licensed to provide such services.

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

(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 stipulated by the local EMS agency medical director.

Note: Authority cited: Sections 1797.107, 1797.176, and 1798.150, Health and Safety

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Code. Reference: Sections 1797.103, 1797.204, 1797.220, 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 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 committee.

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

(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.

(D) 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.

(5) The ability to perform 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) Diffusion-weighted MRI or CT Perfusion.

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(C) Catheter angiography.

(D) Magnetic resonance angiography (MRA).

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

(i) Carotid duplex ultrasound.

(ii) Transesophageal echocardiography (TEE).

(iii) Transthoracic Echocardiography (TTE).

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

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

(b) Additional requirements may be 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) Data-driven, continuous quality improvement process including 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.

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(7) A 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 clinical stroke team shall consist of:

(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.

(ii) A registered nurse, physician assistant or nurse practitioner 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 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.

(12) Other imaging shall be available within a clinically appropriate timeframe and shall, at a minimum, include:

(A) MRI.

(B) CTA and / or Magnetic resonance angiography (MRA).

(C) TEE or TTE.

(13) Interpretation of the imaging.

(A) If teleradiology is used in image interpretation, all staffing and staff qualification

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requirements contained in this section shall remain in effect and shall be documented by the hospital.

(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.

(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.

(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.

(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 shall be available, including operating room availability, either directly or under an agreement with a thrombectomy-capable, comprehensive or other stroke center with neurosurgical services, within two (2) hours following the 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 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 the local EMS agency medical director.

Note: Authority cited: Sections 1797.107, 1797.176, 1797.254, and 1798.150, 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.

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§ 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 clinical stroke team available to see, in person or via telehealth, a patient identified as a potential acute stroke patient within 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 forty-five (45) minutes following emergency department arrival.

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

(7) Interpretation of the imaging.

(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.

(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.

(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.

(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.

(iii) For the purpose of this subsection, a qualified neurosurgeon shall be board-

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certified by the American Board of Neurological Surgery.

(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.

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

(10) Provide IV thrombolytic treatment and have 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.

(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 four (4) hours per year of educational time in cerebrovascular disease;

(12) 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.

(b) Additional requirements may be 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.

§ 100270.227. 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 1797.107, 1797.176, and 1798.150, Health and Safety Code.
Reference: Sections 1797.88, 1797.103, 1797.176, 1797.220, 1798.100, 1798.150, 1798.170, and 1798.172, Health and Safety Code.

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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 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) 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. 1797.107, 1797.176, and 1798.150, Health and Safety Code.
Reference: Section 1797.102, 1797.103, 1797.204, 1797.220, 1797.222, 1797.227, 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 that shall include, at a minimum:

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

(2) Review of stroke-related deaths, major complications, and transfers.

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

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(4) Participation in the QI process by all designated stroke centers and prehospital providers involved in the stroke critical care system.

(5) Evaluation of regional integration of stroke patient movement.

(6) Participation in the stroke data management system.

(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 on-going performance evaluation and quality improvement of the stroke critical care system.

Note: Authority cited: Sections 1797.107, 1797.176, 1797.254, and 1798.150, 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.
