

**Third 15-Day Public Comment Period - Third Modified Text**  
January 23, 2019, through February 7, 2019

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

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

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

- 8  
9 • Additions to the modified text are shown in double underline.
- 10 • Deletions to the modified text are shown in ~~double-strikeout~~.

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

- 14  
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16 • Additions to the modified text are shown in **highlighted *italics double underline***.
- 17  
18 • Deletions to the modified text are shown in **highlighted ~~*italics double-strikeout*~~**.

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20  
21 **California Code of Regulations**  
22 **Title 22. Social Security**  
23 **Division 9. Prehospital Emergency Medical Services**  
24 **Chapter 7.2 Stroke Critical Care System**  
25

26  
27 **ARTICLE 1. DEFINITIONS**

28  
29 **§ 100270.200. Acute Stroke Ready Hospital**

30 “Acute stroke-ready hospitals” or “Satellite stroke centers” means a hospital able to  
31 provide the minimum level of critical care services for stroke patients in the emergency  
32 department, and are paired with one or more hospitals with a higher level of stroke  
33 services.  
34

35 Note: Authority cited: Sections ~~1797.94, 1797.103~~, 1797.107, and 1798.150, Health and  
36 Safety Code. Reference: Sections 1797.94, 1797.103 and 1797.176, Health and  
37 Safety Code.  
38

39 **§ 100270.201. Board-certified**

40 “Board-certified” means a physician who has fulfilled all the Accreditation Council for  
41 Graduate Medical Education (ACGME) requirements in a specialty field of practice, and  
42 has been awarded a certification by an American Board of Medical Specialties (ABMS)  
43 approved program.  
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45 Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.  
46 Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

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**§ 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~~Medical ~~s~~Services ~~a~~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: Sections 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

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

95  
96 **§ 100270.207. Primary Stroke Center**

97 “Primary stroke center” means a hospital that ~~stabilizes and treats~~ acute stroke patients,  
98 ~~providing initial acute care, and~~ identifies patients who may benefit from transfer to one  
99 ~~or more a~~ higher level of care. ~~Centers~~ when clinically warranted.

100

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

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105 **§ 100270.208. Protocol**

106 “Protocol” means a predetermined, written medical care guideline, which may include  
107 standing orders.

108

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

112

113 **§ 100270.209. Quality Improvement**

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

119

120 Note: Authority cited: Sections 1797.103, 1797.107, 1797.174, 1797.176 and 1798.150  
121 Health and Safety Code. Reference: Sections 1797.103, 1797.174, 1797.202, 1797.204,  
122 1797.220 and 1798.175, Health and Safety Code.

123

124 **§ 100270.210. Stroke**

125 “Stroke” means a condition of impaired blood flow to a patient’s brain resulting in brain  
126 dysfunction, most commonly through vascular occlusion or hemorrhage.

127

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

130

131 **§ 100270.211. Stroke Call Roster**

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

134

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

137

138 **§ 100270.212. Stroke Care**

139 “Stroke care” means emergency transport, triage, diagnostic evaluation, acute

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

144  
145 Note: Authority cited: Sections 1797.107, 1797.176, and 1798.150, Health and Safety  
146 Code. Reference: Sections 1797.103, 1797.176, and 1797.220, Health and Safety  
147 Code.

148  
149 **100270.213. Stroke Critical Care System**

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

154  
155 Note: Authority cited: Sections 1797.107, 1797.176, and 1798.150, Health and Safety  
156 Code. Reference: Sections 1797.103, 1797.176, and 1797.220, Health and Safety  
157 Code.

158  
159 **§ 100270.214. Stroke Medical Director**

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

165  
166 Note: Authority cited: Sections 1797.107, 1797.176, and 1798.150, Health and Safety  
167 Code. Reference: Sections 1797.103, 1797.176, and 1797.220, Health and Safety  
168 Code.

169  
170 **§ 100270.215. Stroke Program Manager/Coordinator**

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

175  
176 Note: Authority cited: Sections 1797.107, 1797.176, and 1798.150, Health and Safety  
177 Code. Reference: Sections 1797.103, 1797.176, and 1797.220, Health and Safety  
178 Code.

179  
180 **§ 100270.216. Stroke Program**

181 “Stroke program” means an organizational component of the hospital specializing in  
182 the care of stroke patients.

183  
184 Note: Authority cited: Sections 1797.107, 1797.176, and 1798.150, Health and Safety  
185 Code. Reference: Sections 1797.103, 1797.176, and 1797.220, Health and Safety

186 Code.

187

188 **§ 100270.217. Stroke Team**

189 “Stroke team” means the clinical stroke team personnel, support personnel, and  
190 administrative staff that function together as part of the hospital’s stroke  
191 program team.

192

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

196

197 **§ 100270.218. Telehealth**

198 “Telehealth” means the mode of delivering health care services and public health via  
199 information and communication technologies to facilitate the diagnosis, consultation,  
200 treatment, education, care management, and self-management of a patient’s health  
201 care while the patient is at the originating site and the health care provider is at a  
202 distant site.

203

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

207

208 **§ 100270.219. Thrombectomy-Capable Stroke Center**

209 “Thrombectomy-capable stroke center” means a primary stroke center with the ability  
210 to perform mechanical thrombectomy for the ischemic stroke patient when clinically  
211 warranted.

212

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

216

217 **ARTICLE 2. LOCAL EMS AGENCY STROKE CRITICAL CARE SYSTEM**  
218 **REQUIREMENTS**

219

220 **§ 100270.220. Stroke Critical Care System Plan ~~Approval~~**

221

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

223

224 (b) The local EMS agency implementing a ~~Stroke Critical Care System Plan~~  
225 that starts after the effective date of these regulations ~~stroke critical care system~~ shall  
226 have the a ~~Stroke Critical Care System Plan~~ Stroke Critical Care System Plan  
227 approved by the EMS Authority prior to implementation.

228

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

231

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

- 233 stroke critical care system.
- 234
- 235 (2) ~~Verification of agreements with hospitals for designation~~The list of stroke  
236 designated facilities with a list of stroke hospital contracts the agreements with  
237 expiration dates.
- 238
- 239 (3) A description or a copy of the local EMS agency's stroke patient identification  
240 and destination policies.
- 241
- 242 (4) A description or a copy of the method of field communication to the receiving  
243 hospital-specific to stroke patients, designed to expedite time-sensitive treatment on  
244 arrival.
- 245
- 246 (5) A description or a copy of the policy that facilitates the inter-facility transfer of  
247 stroke patients.
- 248
- 249 (6) A description of the method of data collection from the EMS providers  
250 and designated stroke hospitals to the local EMS agency and the EMS  
251 Authority.
- 252
- 253 (7) ~~A copy policy or description of all written agreements for coordination of stroke~~  
254 ~~transport across LEMSA lines, with neighboring local EMS agencies to provide~~  
255 ~~stroke care~~how the Local EMS Agency integrates a receiving center in a  
256 neighboring jurisdiction.
- 257
- 258 (8) A description of the integration of stroke into an existing quality improvement  
259 committee or a description of any stroke-specific quality improvement committee.
- 260
- 261 (9) A description of programs to conduct or promote public education specific to stroke.
- 262
- 263 (d) The EMS Authority shall, within 30 days of receiving a request for approval,  
264 notify the requesting local EMS agency in writing of approval or disapproval of its  
265 Stroke Critical Care System Plan. If the Stroke Critical Care System Plan is  
266 disapproved, the response shall include the reason(s) for the disapproval and any  
267 required corrective action items.
- 268
- 269 (e) The local EMS agency shall provide an amended plan to the EMS Authority  
270 within 60 days of receipt of the disapproval letter.
- 271
- 272 (f) The local EMS agency currently operating a stroke critical care system  
273 implemented before the effective date of these regulations, shall submit to the EMS  
274 Authority a Stroke Critical Care System Plan as an addendum to its next annual EMS  
275 plan update, or within 180 days of the effective date of these regulations, whichever  
276 comes first.
- 277
- 278 (g) Any stroke center designated by the local EMS agency before implementation

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

282  
283 (h) No health care facility shall advertise in any manner or otherwise hold itself out to  
284 be affiliated with a stroke critical care system or a stroke center unless they have been  
285 designated by the local EMS agency, in accordance with this ~~C~~chapter.

286  
287 Note: Authority cited: Sections ~~1797.103,~~ 1797.105, 1797.107, ~~1797.173,~~ 1797.176,  
288 ~~1797.220, 1797.250, and~~ 1798.150, ~~1798.170, and 1798.172,~~ Health and Safety Code.  
289 Reference: Sections 1797.103, 1797.105, 1797.173, 1797.176, ~~and~~ 1797.220,  
290 1797.250, 1798.170, and 1798.172, Health and Safety Code.

291  
292 **§ 100270.221. Stroke Critical Care System Plan Updates**

293  
294 (a) The local EMS agency shall submit an annual update of its Stroke Critical  
295 Care System Plan, as part of its annual EMS plan submittal, which shall include,  
296 at a minimum, all the following:

- 297  
298 (1) Any changes in a stroke critical care system since submission of the prior  
299 annual plan update or the Stroke Critical Care System Plan addendum.  
300  
301 (2) The status of the Stroke Critical Care System Plan goals and objectives.  
302  
303 (3) Stroke critical care system performance improvement activities.  
304  
305 (4) The progress on addressing action items and recommendations provided by the  
306 EMS Authority within the Stroke Critical Care System Plan or status report approval  
307 letter, if applicable.

308  
309 Note: Authority cited: Sections ~~1797.103,~~ 1797.107, 1797.176, ~~1797.250,~~ 1797.254,  
310 ~~and~~ 1798.150, ~~and 1798.172,~~ Health and Safety Code. Reference: Sections  
311 1797.103, 1797.176, 1797.220, 1797.222, ~~1797.250, and~~ 1798.170, and 1798.172,  
312 Health and Safety Code.

313  
314 **ARTICLE 3. PREHOSPITAL STROKE CRITICAL CARE SYSTEM REQUIREMENTS**

315  
316 **§ 100270.222. EMS Personnel and Early Recognition**

317  
318 (a) The local EMS agency shall ensure that ~~prehospital stroke assessment and~~  
319 ~~treatment training is available~~ establish prehospital care protocols related to the  
320 early recognition, assessment, treatment, and transport of stroke patients for  
321 prehospital emergency medical care personnel as determined by the local EMS  
322 agency.

323  
324 (b) ~~The local EMS agency shall require the use of a validated prehospital stroke-~~

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

326

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

329

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

334

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

338

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

343

344 Note: Authority cited: Sections 1797.92, 1797.103, 1797.107, 1797.176, 1797.189(a)  
345 (2), 1797.206, 1797.214, and 1798.150, Health and Safety Code. Reference: Sections  
346 1797.92, 1797.103, 1797.176, 1797.189, 1797.206, 1797.214, 1797.220, 1798.150, and  
347 1798.170, Health and Safety Code.

348

349 **ARTICLE 4. HOSPITAL STROKE CARE REQUIREMENTS AND EVALUATIONS**

350

351 **§ 100270.223. Comprehensive Stroke Care Centers**

352

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

355

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

358

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

361

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

365

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

367

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

369

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

371

372 ~~(C)(A)(B)~~ Diffusion-weighted magnetic resonance imaging (MRI) and computed  
373 tomography (CT) perfusion imaging.  
374  
375 ~~(B)(4)~~ Transcranial Doppler (TCD) shall be available in a timeframe that is clinically  
376 appropriate.  
377  
378 ~~(4)(5)~~ Intensive care unit (ICU) beds with licensed independent practitioners with  
379 the expertise and experience to provide neuro-critical care twenty-four (24) hours a  
380 day, seven (7) days a week, three hundred and sixty-five days (365) days per  
381 year.  
382  
383 ~~(5)~~ Written policies and procedures for comprehensive stroke services that are  
384 reviewed at least every two (2) years, revised as needed, and implemented.  
385  
386 ~~(6)(5)(6)~~ Data-driven, continuous quality improvement process, including collection and  
387 monitoring of standardized comprehensive stroke center performance measures.  
388  
389 ~~(7)(6)(7)~~ A stroke patient research program.  
390  
391 ~~(8)(7)(8)~~ Satisfy all the following staff qualifications:  
392  
393 (A) A neurosurgical team capable of assessing and treating complex stroke and  
394 stroke- like syndromes.  
395  
396 ~~(B)~~ A neuro-radiologist with a current Certificate of Added Qualifications  
397 in Neuroradiology on staff.  
398  
399 ~~(C)~~ A physician with neuro-interventional angiographic training and skills on staff  
400 as deemed by the hospital's credentialing process.  
401  
402 ~~(D)(B)~~ A qualified neuro-radiologist, board-certified by the American Board of  
403 Radiology or the American Osteopathic Board of Radiology.  
404  
405 ~~(E)(C)~~ A qualified vascular neurologist, board certified by either the American Board of  
406 Psychiatry and Neurology or the American Osteopathic Board of Neurology and  
407 Psychiatry, or with appropriate education and experience as defined by the hospital  
408 credentials committee.  
409  
410 ~~(F)(D)(C)~~ If teleradiology is used in image interpretation, all staffing and staff  
411 qualification requirements provided contained in this section shall remain in effect and  
412 shall be documented by the hospital.  
413  
414 ~~(E)(D)~~ Written call schedule for attending neurointerventionalist, neurologist,  
415 neurosurgeon providing availability twenty-four (24) hours a day seven (7) days a  
416 week.  
417  
418 ~~(8)(9)~~ Provide comprehensive rehabilitation services either on-site or by written

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

421  
422 ~~(9)~~(10) Written transfer agreements with primary stroke centers in the region to  
423 accept the transfer of patients with complex strokes when clinically warranted.

424  
425 ~~(10)~~(11) A comprehensive stroke center shall at a minimum, provide guidance and  
426 continuing stroke-specific medical education to hospitals designated as a primary  
427 stroke center with which they have transfer agreements.

428  
429 (b) Additional requirements may be ~~required at the discretion of~~ stipulated by the  
430 local EMS agency medical director.

431  
432 Note: Authority cited: Sections 1797.103, 1797.107, 1797.176, 1797.204, ~~1797.220~~,  
433 and 1798.150, ~~and 1798.172~~, Health and Safety Code. Reference: Sections  
434 1797.103, 1797.204, 1797.220, ~~and~~ 1797.222, and 1798.172, Health and Safety  
435 Code.

436  
437 **§ 100270.224. Thrombectomy-Capable Stroke Centers**

438  
439 (a) Hospitals designated as a thrombectomy-capable stroke center by the local  
440 EMS agency shall meet the following minimum criteria:

441  
442 (1) Satisfy all the requirements of a primary stroke center as provided in this chapter.

443  
444 (2) The ability to perform mechanical thrombectomy for the treatment of ischemic  
445 stroke twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty-  
446 five (365) days per year.

447  
448 (3) Dedicated neuro-intensive care unit beds to care for acute ischemic stroke patients  
449 twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty-five (365)  
450 days per year.

451  
452 (4) Satisfy all the following staff qualifications:

453  
454 ~~(A) A neurosurgical team capable of assessing and treating complex stroke and~~  
455 ~~stroke-like syndromes, if provide neurosurgical services.~~

456  
457 ~~(B) A neuro-radiologist with a current Certificate of Added Qualifications~~  
458 ~~in Neuroradiology on staff.~~

459  
460 ~~(C)~~(A) A qualified physician, board certified by the American Board of Radiology,  
461 American Osteopathic Board of Radiology, American Board of Psychiatry and  
462 Neurology, or the American Osteopathic Board of Neurology and Psychiatry, with  
463 neuro-interventional angiographic training and skills on staff as deemed by the  
464 hospital's credentialing ~~process~~ committee.

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~~(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:

- 508  
509 ~~(A) Eight (8) stroke (STK) measures.~~  
510  
511 ~~(B) Five comprehensive stroke (CSTK) measures for the ischemic stroke population.~~  
512  
513 ~~(8)(7)~~ Written transfer agreement with at least one comprehensive stroke center.  
514  
515 (b) Additional requirements may be ~~required at the discretion of~~ stipulated by the  
516 local EMS agency medical director.

517  
518 Note: Authority cited: Sections 1797.107, 1797.176, and 1798.150, Health and Safety  
519 Code. Reference: Sections 1797.103, 1797.204, 1797.220, 1797.222, and 1798.172,  
520 Health and Safety Code.

521  
522 **§ 100270.225. Primary Stroke Centers**

- 523  
524 (a) Hospitals designated by the local EMS agency as a primary stroke center shall  
525 meet all the following minimum criteria:  
526  
527 (1) Adequate staff, equipment, and training to perform rapid evaluation, triage,  
528 and treatment for the stroke patient in the emergency department.  
529  
530 (2) Standardized stroke care protocol/order set.  
531  
532 (3) Stroke diagnosis and treatment capacity twenty-four (24) hours a day, seven  
533 (7) days a week, three hundred and sixty-five (365) days per year.  
534  
535 (4) ~~A~~ Data-driven, continuous quality improvement system process including ~~data~~  
536 collection and monitoring of standardized performance measures.  
537  
538 (5) Continuing education in stroke care provided for staff physicians, staff nurses,  
539 staff allied health personnel, and EMS personnel.  
540  
541 (6) Public education on stroke and illness prevention.  
542  
543 (7) ~~An acute~~ clinical stroke team, available to see in person or via telehealth, a patient  
544 identified as a potential acute stroke patient within 15 minutes following the patient's  
545 arrival at the hospital's emergency department or within 15 minutes following a  
546 diagnosis of a patient's potential acute stroke.  
547  
548 (A) At a minimum, ~~an acute care~~ clinical stroke team shall consist of:  
549  
550 ~~4~~ (i) A neurologist, neurosurgeon, interventional neuro-radiologist, or emergency  
551 physician who is board certified or board eligible in neurology, neurosurgery,  
552 endovascular neurosurgical radiology, or other board-certified physician with sufficient  
553 experience and expertise in managing patients with acute cerebral vascular disease

554 as determined by the hospital credentials committee.

555

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

560

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

565

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

568

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

573

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

576

577 ~~(11)(12) Neuro-Other imaging services shall be available within this a clinically~~  
578 appropriate timeframe and shall, at a minimum, include:

579

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

581

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

583

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

586

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

588

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

590

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

594

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

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~~(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:

- 646 (1) ~~An acute-clinical~~ stroke team available to see, in person or via telehealth, a patient  
647 identified as a potential acute stroke patient within ~~thirty (30)~~ twenty (20) minutes  
648 following the patient's arrival at the hospital's emergency department.
- 649
- 650 (2) Written policies and procedures for emergency department stroke services that  
651 are reviewed, revised as needed, and implemented at least every three (3) years.
- 652
- 653 (3) Emergency department policies and procedures shall include written protocols  
654 and standardized orders for the emergency care of stroke patients.
- 655
- 656 (4) Data-driven, continuous quality improvement process including collection  
657 and monitoring of standardized performance measures.
- 658
- 659 (5) Neuro-imaging services capability that is available twenty-four (24) hours a  
660 day, seven (7) days a week, three hundred and sixty-five (365) days per year,  
661 such that imaging shall be performed and reviewed by a physician within ~~sixty (60)~~  
662 forty-five (45) minutes following emergency department arrival.
- 663
- 664 (6) Neuro-imaging services shall, at a minimum, include: CT or MRI, or both.
- 665
- 666 ~~(A) Computerized tomography (CT).~~
- 667
- 668 ~~(B) Magnetic resonance imaging (MRI).~~
- 669
- 670 ~~(C)(7)~~ Interpretation of the imaging.
- 671
- 672 ~~(7)(A)~~ If teleradiology is used in image interpretation, all staffing and staff  
673 qualification requirements contained in this subsection shall remain in effect and  
674 shall be documented by the hospital.
- 675
- 676 ~~(8)(B)~~ Neuro-imaging studies shall be reviewed by a physician with appropriate  
677 expertise, such as a board-certified radiologist, board-certified neurologist, a board-  
678 certified neurosurgeon, or residents who interpret such studies as part of their  
679 training in ACGME-approved radiology, neurology, or neurosurgery training program,  
680 within forty-five (45) minutes of emergency department arrival.
- 681
- 682 ~~(A)(i)~~ For the purpose of this subsection, a qualified radiologist shall be board-certified  
683 by the American Board of Radiology or the American Osteopathic Board of  
684 Radiology.
- 685
- 686 ~~(B)(ii)~~ For the purpose of this subsection, a qualified neurologist shall be board-certified  
687 by the American Board of Psychiatry and Neurology or the American Osteopathic  
688 Board of Neurology and Psychiatry.
- 689
- 690 ~~(C)(iii)~~ For the purpose of this subsection, a qualified neurosurgeon shall be board-  
691 certified by the American Board of Neurological Surgery.

692  
693 ~~(b)(8)~~ Laboratory services shall, at a minimum, include blood testing,  
694 electrocardiography and x-ray services, and be available twenty-four (24) hours a day,  
695 seven (7) days a week, three hundred and sixty-five (365) days per year, and able to  
696 be completed and reviewed by physician within sixty (60) minutes following emergency  
697 department arrival.

698  
699 ~~(e)(9)~~ Neurosurgical services ~~that are~~ shall be available, including operating room  
700 availability, either directly or under an agreement with a thrombectomy-capable,  
701 primary or comprehensive stroke center, within three (3) hours following the ~~admission~~  
702 arrival of acute stroke patients to an acute stroke-ready hospital.

703  
704 ~~(d)(10)~~ Provide IV thrombolytic treatment and have Transfer arrangements with one  
705 or more thrombectomy-capable, primary or comprehensive stroke center(s) that  
706 facilitate the transfer of patients with strokes to the stroke center(s) for care when  
707 clinically warranted.

708  
709 ~~(e)(11)~~ There shall be a medical director of an acute stroke-ready hospital, who may  
710 also serve as a member of a stroke team, who is a physician or advanced practice  
711 nurse who maintains at least ~~six (6)~~ four (4) hours per year of educational time in  
712 cerebrovascular disease;

713  
714 ~~(f)(12)~~ ~~Acute care~~ Clinical stroke team for an acute stroke-ready hospital at a minimum  
715 shall consist of a nurse and a physician with training and expertise in acute stroke  
716 care.

717  
718 ~~(g)(b)~~ Additional requirements may be ~~included at the discretion of~~ stipulated by the  
719 local EMS agency medical director.

720  
721 Note: Authority cited: Sections ~~1797.103,~~ 1797.107, 1797.176, ~~and 1797.204,~~  
722 ~~1797.220,~~ 1798.150, ~~and 1798.172,~~ Health and Safety Code. Reference: Sections  
723 ~~1797.103,~~ 1797.204, 1797.220, ~~and~~ 1797.222, ~~and 1798.172,~~ Health and Safety Code.

724  
725 **§ 100270.227. EMS Receiving Hospitals (Non-designated for Stroke Critical Care**  
726 **Services)**

727  
728 (a) An EMS receiving hospital that is not designated for stroke critical care  
729 services shall do the following, at a minimum and in cooperation with stroke  
730 receiving centers and the local EMS agency in their jurisdictions:

731  
732 (1) Participate in the local EMS agency's quality improvement system, including  
733 data submission as determined by the local EMS agency medical director.

734  
735 (2) Participate in the inter-facility transfer agreements to ensure access to a  
736 stroke critical care system for a potential stroke patient.

737

738 Note: Authority cited: Sections ~~1797.88, 1797.103,~~ 1797.107, 1797.176, ~~1797.220,~~  
739 ~~1798.100, and~~ 1798.150, ~~and 1798.172,~~ Health and Safety Code. Reference:  
740 Sections ~~1797.88, 1797.103,~~ 1797.176, 1797.220, ~~1798.100, and~~ 1798.150,  
741 1798.170, ~~and 1798.172,~~ Health and Safety Code.

## 742 **ARTICLE 5. DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATION**

### 743 **§ 100270.228. Data Management Requirements**

- 744
- 745 (a) The local EMS agency shall implement a standardized data collection and  
746 reporting process for stroke critical care systems.
- 747 (b) The system shall include the collection of both prehospital and hospital patient  
748 care data, as determined by the local EMS agency.
- 749
- 750 (c) The prehospital stroke patient care elements shall be compliant with the most  
751 current version of the California EMS Information Systems (CEMSIS) database and  
752 the National EMS Information System (NEMSIS) database.
- 753 (d) The hospital stroke patient care elements shall be ~~compliant~~ consistent with the  
754 U.S. Centers for Disease Control and Prevention, Paul Coverdell National Acute Stroke  
755 Program Resource Guide, dated October 24, 2016, which is hereby incorporated by  
756 reference.
- 757 (e) All hospitals that receive stroke patients via EMS shall participate in the local  
758 EMS agency data collection process in accordance with local EMS agency policies  
759 and procedures.
- 760 (f) ~~Stroke~~ The prehospital care record and the hospital data elements shall be  
761 collected and submitted by the local EMS agency, and subsequently to the EMS  
762 Authority, on no less than a quarterly basis.

763

764 Note: Authority cited: Sections. ~~1797.102, 1797.103,~~ 1797.107, 1797.176, ~~1797.204,~~  
765 ~~1797.220, 1797.227, and~~ 1798.150, ~~and 1798.172,~~ Health and Safety Code. Reference:  
766 Section ~~1797.102, 1797.103, 1797.204,~~ 1797.220, 1797.222, 1797. ~~204227, and~~  
767 ~~1798.172.~~ Health and Safety Code.

### 768 **§ 100270.229. Quality Improvement and Evaluation Process**

- 769
- 770 (a) Each stroke critical care system shall have a quality improvement process to  
771 ~~include structure, process, and outcome evaluations which focus on improvement~~  
772 ~~efforts to identify root causes of problems, intervene to reduce or eliminate these~~  
773 ~~causes, and take steps to correct the process. This process that~~ shall include, at a  
774 minimum:  
775
- 776 (1) Evaluation of program structure, process, and outcome.

784  
785 ~~(1)(2)~~ A detailed Audit Review of all Stroke-related deaths, major complications, and  
786 transfers.

787  
788 ~~(2)(3)~~ A multidisciplinary Stroke Quality Improvement Committee, including both  
789 prehospital and hospital members.

790  
791 ~~(3)(4)~~ Participation in the PQI process by all designated Stroke centers, other  
792 hospitals that treat stroke patients and prehospital providers involved in the  
793 stroke critical care system.

794  
795 ~~(4)(5)~~ Evaluation of both local and regional components of the integration of  
796 stroke system patient movement.

797  
798 ~~(3)(5)(6)~~ Participation in the stroke data management system.

799  
800 ~~(4)(6)(7)~~ Compliance with the California Evidence Code, Section 1157.7 to  
801 ensure confidentiality, and a disclosure-protected review of selected stroke  
802 cases.

803  
804 ~~(b)~~ The local EMS agency shall be responsible for the following:

805  
806 ~~(1)~~ The on-going performance evaluation of a local or regional stroke critical care  
807 system.

808  
809 ~~(2)~~ The development of a quality improvement process.

810  
811 ~~(3)~~ Ensuring that designated stroke centers, other hospitals that treat stroke patients  
812 and prehospital providers involved in a Stroke critical care system participate in the  
813 quality improvement process.

814  
815 ~~(c)(b)~~ The local EMS agency shall be responsible for on-going performance evaluations  
816 of all levels of stroke centers and quality improvement of the stroke critical care system.

817  
818 Note: Authority cited: Sections 1797.102, 1797.103, 1797.107, 1797.176, 1797.204,  
819 1797.220, 1797.250, 1797.254, and 1798.150, and 1798.172, Health and Safety Code.  
820 Reference: Section 1797.102, 1797.103, 1797.104, 1797.176, 1797.204, 1797.220,  
821 1797.222, 1797.250, 1798.170, and 1798.172, Health and Safety Code.