INITIAL STATEMENT OF REASONS

CHAPTER 7.2 STROKE CRITICAL CARE SYSTEM

PROBLEM STATEMENT

Stroke is the third leading cause of death in California and the leading cause of long-term disability. A stroke occurs when blood flow to a part of the brain is interrupted because a blood vessel in the brain is blocked or bursts open. Recent advances in stroke care, including the introduction of time-sensitive therapies, have emphasized the critical need for optimal stroke treatment pathways.

By law, (Division 2.5 of the California Health and Safety Code) Critical Care Systems, including hospital designations, shall be regulated by the Emergency Medical Services Authority (EMS Authority). California Health and Safety Code sections 1797.107 and 1798.150 authorize the EMS Authority to adopt regulations and establish guidelines for critical care statewide in California. Since this legislation has not adequately defined and provided statewide standardized best practice details for all Local Emergency Medical Services agencies (local EMS agencies), the EMS Authority created this regulatory language for EMS and prehospital care to develop and implement specialty systems of care in California. The goal of stroke regulations is to improve patient care in the prehospital setting and to standardize the processes for hospital designation.

BENEFITS

Establishment of an acute Stroke Critical Care System throughout the State of California and regulations created by the EMS Authority will have a direct public benefit by improving the care of patients suffering from life threatening acute strokes. Improving the system and standardization of stroke care statewide will reduce the time interval between the emergency call and arrival at the hospital, and reduce the time between arrival at the hospital and treatment of a stroke patient.

PURPOSE AND NECESSITY OF ADOPTION OF REGULATIONS

PURPOSE

Sections 100270.200 through 100270.216 have been prepared to define the terms used in this Article. Terms defined are consistent throughout all Articles and documents in the Rulemaking File. Definitions of these terms are also consistent with those used within the medical, healthcare, and EMS industries.

NECESSITY: These definitions are necessary to ensure that the terms used in the regulations are clear and specific to readers, including the general public, local EMS agencies, and others impacted by the proposed regulations.

PURPOSE
Section 100270.217 (a) has been prepared to specify that local EMS agencies are allowed, but not required, to develop and implement a Stroke Critical Care System within their jurisdictions.

NECESSITY: This regulation is necessary to clarify that local EMS agencies may, but are not required to implement a Stroke Critical Care system within their jurisdiction.

PURPOSE
Section 100270.217 (b) has been prepared to specify that local EMS agencies operating a Stroke Critical Care System in their jurisdiction, or local EMS agencies that plan on implementing a Stroke Critical Care System, are required to provide a Stroke System Plan to the EMS Authority for approval.

NECESSITY: This regulation is necessary to establish the requirements of specific documentation to be included in the Stroke System Plans submitted for approval by the EMS Authority. The adoption of this section will ensure uniform, statewide standards for the implementation of Stroke Systems of Care in California.

PURPOSE
Section 100270.217 (c, d) has been prepared to establish the timelines for plan submission, response, approval/disapproval, and corrective actions for the EMS Authority and for local EMS agencies who do not have a Stroke Critical Care System already in place.

NECESSITY: This regulation is necessary to clarify the compliance timeline for both local EMS agencies and the EMS Authority.

PURPOSE
Section 100270.217 (e) has been prepared to specify the plan submission requirements for local EMS agencies with an existing Stroke Critical Care System in place prior to the development of these regulations to the EMS Authority.

NECESSITY: This section specifies that local EMS agencies with an existing Stroke Critical Care System before this stroke regulation is in place, must submit their Stroke System Plan to the EMS Authority. The EMS Authority has the responsibility to ensure the system is operating according to the national and state standard requirements.

PURPOSE
Section 100270.217 (f) has been prepared to require local EMS agencies to inform the EMS Authority of any changes in their Stroke Critical Care System on an annual basis.

NECESSITY: It is necessary that EMS Authority review the local EMS agency's Stroke System Plan on an annual basis to ensure all the changes and activities are based on the national standard of care and state requirements.

PURPOSE
Section 100270.218 (a) has been prepared to require submission of an organizational chart and contact information for the responsible parties who have a role in the Stroke Critical Care System for local EMS agencies.

NECESSITY: It is necessary that the EMS Authority has contact information of parties who have a role in the Stroke System Plan for any communication with the local EMS agency.

PURPOSE
Section 100270.218 (b, c, d, e, f, g) has been prepared to clarify the responsibility of the local EMS agencies to create the policy and procedure for implementation of the stroke system, compile the agreements between all parties in the system, and submit them to the EMS Authority for review.

NECESSITY: It is the EMS Authority's statutory responsibility to review the policy and procedure to ensure requirements for Stroke Critical Care System comply with these regulations and national standards.

PURPOSE
Section 100270.218 (h) has been prepared to specify that each local EMS agency should have a Quality Improvement (QI) committee specifically for the Stroke Critical Care System.

NECESSITY: It is necessary for local EMS agencies to control the quality of their program and make improvements based on the proposed regulations and the national recommendations for stroke care of the American Heart Association/American Stroke Association (AHA/ASA).

PURPOSE
Section 100270.218 (i) has been prepared to specify that each Stroke Critical Care System should have a public education component regarding the causes, treatments, and rehabilitation of stroke disease.

NECESSITY: It is necessary for local EMS agencies to develop public education and awareness programs to educate the public on how to prevent permanent damage caused by stroke and follow the national goal of being a healthy nation.

PURPOSE
Section 100270.219 (a, b, c, d) has been prepared to require each local EMS agency to report to the EMS Authority the status of their system after implementation on an annual basis as part of the EMS Plan Status Report. The status report should include any changes that occurred within the time period, the details of QI activities, and improvement activities.

NECESSITY: It is necessary that the EMS Authority review the status of each Stroke Critical Care System in California to ensure consistency with the requirements of regulations and national recommendations.

PURPOSE
Section 100270.220(a) has been prepared to require every local EMS agency with a Stroke Critical Care System in place needs to provide training for pre-hospital EMS personnel on Stroke patient assessment and treatment.

NECESSITY: It is necessary that the local EMS agency provide special training and updates for pre-hospital responders and ensure that they follow the latest protocol and guidelines of AHA/ASA for treatment and assessment of stroke patients.

PURPOSE
Section 100270.220(b) has been prepared to specify that every local EMS agency with a Stroke Critical Care System needs to have a validated stroke-screening tool for early recognition.

NECESSITY: It is necessary that pre-hospital responders in a Stroke Critical Care System use specific diagnostic tools for recognizing stroke symptoms in the patient as soon as possible to begin early treatment and prevent permanent brain damage.

PURPOSE
Section 100270.220(c) has been prepared to require local EMS agencies to have policy that states prehospital staff can take medical direction from subject matter experts when having difficulties assessing and diagnosing a stroke patient.

NECESSITY: It is necessary that pre-hospital responders have access to the medical stroke specialists to assist with uncertain situations or complex findings during prehospital assessment.

PURPOSE
Section 100270.220(d) has been prepared to clarify that local EMS agencies are to have a stroke specific policy for Basic Life Support (BLS) and Advanced Life Support (ALS) scope of practice.

NECESSITY: It is necessary that each local EMS agency clarify the scope of practice for ALS and BLS in its jurisdiction based on the national standard and AHA/ASA recommendations.

PURPOSE
Section 100270.220(e) has been prepared to establish the responsibility of local EMS agencies to report the prehospital findings for the suspected stroke patient and to ensure that these findings are communicated and reported to the Stroke Critical Care facilities for further action and continuation of care for the patient.

NECESSITY: It is necessary that the local EMS agencies ensure the continuation of care for the suspected stroke patient extends to Stroke Critical Care facilities.

PURPOSE
Section 100270.221 (a-d) has been prepared to clarify the definition of Primary Stroke Centers and minimum requirements according to the AHA/ASA and national recommendations.

NECESSITY: It is necessary that local EMS agencies oversee the criteria for designation of Primary Stroke Centers and to ensure those centers are based on regulations, national standards and AHA/ASA recommendations, to achieve the best care for stroke patients.

PURPOSE
Section 100270.222 (a-k) has been prepared to require local EMS agencies to evaluate the designated Primary Stroke Centers on a regular basis as part of their stroke system according to these regulations which are based on the national recommendation and the recommendation of AHA/ASA.

NECESSITY: It is necessary that local EMS agencies evaluate the requirements and needs of the Primary Stroke Centers according to the latest AHA/ASA recommendations so they can provide the highest quality of care for stroke patients in their jurisdiction.

PURPOSE
Section 100270.223 (a-j) has been prepared to clarify the definition, criteria, and requirements of Comprehensive Stroke Centers which provide a higher level of service for stroke patients compared to Primary Stroke Centers. It also clarifies that the designation of these centers is the responsibility of the local EMS agency.

NECESSITY: It is necessary that local EMS agencies designate Comprehensive Stroke Centers based on the requirements and criteria of the proposed regulations which are based on current national recommendations and the AHA/ASA best practices to achieve the highest quality of care for stroke patients.

PURPOSE
Section 100270.224 (a-k) has been prepared to clarify the definition, criteria, and requirements for the Acute Stroke Ready Hospital (Satellite Stroke Centers) and their role in the Stroke Critical Care System. Additionally, the proposed regulation establishes responsibility of the designation of these centers to the local EMS agency ensuring the assessment and criteria are carried out according to the proposed regulations.

NECESSITY: It is necessary that local EMS agencies designate the Acute Stroke Ready Hospital based on the requirements and criteria of these regulations which are adopted from current national recommendations and AHA/ASA best practices for the highest quality of care for stroke patients.

PURPOSE
Section 100270.225 (a, b) has been prepared to clarify that it is the responsibility of the local EMS agency to promote other emergency hospitals in their system without special stroke services, to be part of their Stroke Critical Care System by cooperating and participating in the interfacility transfer agreements with the Stroke Receiving Centers, participating in their QI system meetings, and providing data for the potential stroke patients.

NECESSITY: It is necessary that local EMS agencies have an active plan to recruit non Stroke Centers in their jurisdiction to provide appropriate and time-sensitive services recommended by the AHA/ASA in any geographic area without Stroke Centers.

PURPOSE
Section 100270.226 has been prepared to establish roles and responsibilities of Hospitals, local EMS agencies, and the EMS Authority for the needs of data collection, analysis, and reporting for each stroke patient.

NECESSITY: It is necessary to clarify the responsibilities of the parties regarding data collection and usage to improve the quality of care and to ensure the Stroke Critical Care System operates based on AHA/ASA and national recommendations.

PURPOSE
Section 100270.227 (a) has been prepared to clarify that any stroke related death must be reviewed by a group of experts.

NECESSITY: It is necessary to determine/review the cause of death of a stroke patient to resolve and prevent similar cases in the future. Further reviews will provide insight that contributes to improving the quality of care within the Stroke Critical Care System.

PURPOSE
Section 100270.227 (b) has been prepared to specify that each Stroke Critical Care System has to have a group of experts available to review all complicated stroke cases

and the cause of death in stroke patients from all levels of care providers (pre-hospital and Hospital) to improve the quality of care according to the national standard and AHA/ASA recommendations.

NECESSITY: It is necessary to review complicated stroke patient cases by an expert team to learn from any potential mistakes and improve the quality of care in each Stroke Critical Care System.

PURPOSE
Section 100270.227(c) has been prepared to require the QI group expert participate in the stroke data management system.

NECESSITY: It is necessary because the data management system is a powerful tool to improve the quality of care in the stroke system.

PURPOSE
Section 100270.227(d) has been prepared to ensure confidentiality will be maintained when reviewing any stroke related case.

NECESSITY: It is necessary to protect the reviewer and people involved in an audit of stroke death cases.

PURPOSE
Section 100270.228 (a,b,c) has been prepared to establish that it is the local EMS agencies' responsibility to evaluate the Stroke Critical Care System within a specific time frame, based on the specifications in these proposed regulations. Furthermore, the local EMS agency is to ensure the mandatory participation of the Stroke Centers in this evaluation and the QI process in their jurisdiction.

NECESSITY: The Stroke Critical Care System needs continuous evaluation and supervision by the local EMS agency to control the quality of care for stroke patients in California according to these regulations and based on the AHA/ASA recommendations.

ECONOMIC IMPACT ANALYSIS

In 1980, the Emergency Medical Services System and Prehospital Emergency Care Personnel Act were signed into law creating the Emergency Medical Services Authority (EMS Authority) and adding Division 2.5 Emergency Medical Services to the Health and Safety Code (Sections 1797-1799). This law required the EMS Authority to develop, among other things, planning and implementation guidelines for Emergency Medical Services (EMS) and Critical Care System programs, to include hospitals, that address eight specific components (HSC §1797.103), assess each county EMS area or the system's service area (HSC §1797.102), provide technical assistance to existing agencies, counties, and cities for the purpose of developing components of EMS

systems (HSC §1797.104), receive and approve plans for the implementation of EMS and critical care systems including the Stroke Program from local EMS agencies (HSC §1797.105 HSC §1797.250 and HSC §1797.254), and adopt, amend, or repeal, after approval by the Commission on EMS, rules and regulations as may be reasonable and proper to exercise the powers and perform the duties as specified in HSC Division 2.5 (Section 1797.107).

Local EMS agencies implementing a Stroke Critical Care System shall plan, implement, and evaluate their EMS system in accordance with the provisions of HSC §1797.204 and HSC §1798.150.

Historically, the procedures and provisions for carrying out the responsibilities noted above have been specified in state guidelines and local EMS agency policies and procedures. The EMS Authority is now proposing to put these guidelines, policies, and procedures into regulations to provide statewide consistency and fairness, protect the public health and safety, and increase openness and transparency of local and state government. These regulations merely continue existing practices and do not impose any new economic impacts on business and/or employees, small businesses, jobs or occupations, California competitiveness, individuals, nor do they impose any new reporting requirements or prescriptive instead of performance standards.

Counties are not required by law (HSC §1797.200) to develop a local EMS system and Stroke Critical Care System as part of their EMS. Further, if they implement a Stroke Critical Care system; they are required by law to do the following:

1. Have a full or part-time licensed physician or surgeon as medical director to provide medical control and to assure medical accountability throughout the planning, implementation, and evaluation of the EMS system (HSC §1797.202).
2. Plan, in accordance with eight specific components (HSC §1797.103), implement, and evaluate their EMS system consisting of an organized pattern or readiness and response services based on public and private agreements and operational procedures (HSC §1797.204).
3. Be responsible for implementation of advanced life support systems and limited advanced life support systems (HSC §1797.206).
4. Establish, using state minimum standards, policies and procedures approved by the medical director of the local EMS agency to assure medical control of the EMS system (HSC §1797.220).
5. May adopt ordinances governing the transport of a patient who is receiving care in the field from prehospital emergency medical personnel, when the patient meets specific criteria for critical care like Stroke, STEMI, Trauma, or Pediatric Centers adopted by the local EMS agency.

6. Annually submit their Stroke System Plan, after this regulation is in place, as part of the EMS plan to the EMS authority in accordance with guidelines established by the EMS Authority (HSC §1797.254 and HSC §1798.150) for EMS Authority approval.
7. Consistent with their EMS plan, coordinate and otherwise facilitate arrangements necessary to develop their Critical Care EMS Systems (HSC §1797.252).

The regulations being proposed by the EMS Authority implement, clarify, and make specific the rules and provisions for accomplishing the elements noted above. Local EMS agencies have the ability under their own governing rules to assess fees to cover the costs of their Stroke Critical Care responsibilities. Currently 16 out of 33 Local EMS agencies in California have a Stroke Critical Care System and are complying, in varying degrees, with the elements noted above pursuant to guidelines established by the EMS Authority and approved by the Commission on EMS. The regulations being proposed by the EMS Authority are intended to provide statewide consistency, provide fairness, protect the public health and safety, increase openness and transparency of local and state government, and achieve full compliance with statute.

The EMS Authority is the state agency responsible for the development and coordination of EMS statewide (HSC §1797.1). To carry out these responsibilities, the EMS Authority is charged with developing planning and implementation guidelines for EMS as well as critical care systems which address specific topics (HSC §1797.103 and HSC §1798.150.) and promulgating rules and regulations as reasonable and proper to carry out the purposes and intent of HSC Division 2.5 (HSC §1797.107). Since the 1980's, the EMS Authority has been reviewing and approving local EMS plans including the critical care section of that submitted by LEMSAs based on standards and guidelines as required in HSC §1797.250 and 1797.254. The EMS Authority is now proposing to publish those standards and guidelines in regulations to provide consistency, fairness, protection of the public health and safety, increase openness and transparency in local and state government, and achieve full compliance with statute. There will be no new costs to the EMS Authority in carrying out these ongoing responsibilities, which are currently funded by Preventive Health and Health Services Block Grant Funding.

The EMS Authority's responsibilities for reviewing and approving local EMS and Critical Care Systems plans submitted by local EMS agencies, in accordance with standards and guidelines developed by the EMS Authority, and for providing technical assistance to agencies, counties, and cities for the purpose of developing components of EMS systems (HSC §1797.104) are funded by Federal Block Grant Funds. The proposed regulations do not impose any new responsibilities on the EMS Authority and are intended to provide transparency in local and state government, as well as promote

consistency statewide among the 33 local EMS agencies (counties or region of counties). Therefore, the proposed regulations do not have any fiscal effect on the federal funding currently provided to the EMS Authority.

According to Government Code 14837(d)(1), small business is defined as "an independently owned and operated business that is not dominant in its field of operation, the principal office of which is located in California, the officers of which are domiciled in California, and which, together with affiliates, has 100 or fewer employees, and average annual gross receipts of ten million dollars ($10,000,000) or less over the previous three years, or is a manufacturer, as defined in subdivision (c), with 100 or fewer employees." The proposed regulation has no impact on businesses corresponding to this definition. Hospitals and Stroke Centers would not fit the category of small business defined in the aforementioned Government Code.

A 2014 survey of the local EMS agencies shows there are 15 Stroke Critical Care Systems implemented in California. The goal of stroke regulations is to improve patient care in the prehospital setting and to standardize the Stroke Critical Care System, having no negative impact on current or future Stroke Centers.