

INITIAL STATEMENT OF REASONS

CHAPTER 7.1 ST-ELEVATION MYOCARDIAL INFARCTION (STEMI) CRITICAL CARE SYSTEM

PROBLEM STATEMENT

Heart disease is the leading cause of death and long-term disability nationwide¹. Every 43 seconds, someone in the United States has a heart attack.² According to American College of Cardiology, every year about 785,000 Americans have a first coronary attack, and about 470,000 who have already had one or more coronary attacks have another attack. In California, heart disease accounts for approximately 25% of deaths each year and the annual cost of coronary heart disease in California is approximately \$20 billion (California Center for Disease Control and Prevention, 2010 report).

One type of heart attack is called an ST elevation myocardial infarction (STEMI) which refers to the specific pattern that is observed on an electrocardiogram (ECG). In United States, STEMI comprises 25-40% of the 683,000 U.S. patients diagnosed with acute coronary syndrome (ACS) each year. The irreversible damage to the heart muscle cells is preventable if STEMI treatment strategies are applied within 90 minutes of the onset of the attack.³

Existing law authorizes the California Emergency Medical Services Authority (EMS Authority) to develop regulations to implement various Emergency Medical Services (EMS) components, including the assessment of hospitals and critical care centers. Local EMS agencies designate hospitals as STEMI facilities to provide care for STEMI patients based on differing standards. Furthermore, the designated hospitals operate under differing processes and procedures. The goal of the STEMI regulations is to improve patient care in the pre-hospital setting and to standardize the designation of hospitals receiving critical care patients.

¹ Deaths: Final Data for 2013 by Jiaquan Xu, M.D.; Sherry L. Murphy, B.S.; Kenneth D. Kochanek, M.A.; and Brigham A. Bastian, B.S., Division of Vital Statistics

² Mozaffarian D, Benjamin EJ, Go AS, et al. Heart Disease and Stroke Statistics—2015 update: A report from the American Heart Association. *Circulation*. 2015; 131(4):e29-322

³ O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX. & American Heart Association

BENEFITS

The implementation of a standardized Critical Care System for acute heart attack throughout the State of California will have a direct public benefit by improving the care of patients suffering from life-threatening acute heart attacks. Improving the system and standardization of STEMI care statewide will reduce the time interval between the emergency call, arrival at the hospital, and the onset of treatment.

PURPOSE

Section 100270.100 through 100270.124: These sections 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 fields.

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 these regulations.

PURPOSE

Section 100270.125(a): To allow local EMS agencies to develop and implement STEMI Critical Care Systems within their jurisdictions.

NECESSITY: This regulation is necessary to clarify implementation and operation of a STEMI Critical Care Systems within the local EMS agencies jurisdiction is voluntary.

PURPOSE

Section 100270.125(b): To specify that local EMS agencies operating a STEMI Critical Care System in their jurisdiction, or local EMS agencies that plan on implementing a STEMI Critical Care System, are required to submit a STEMI System Plan to the EMS Authority for approval.

NECESSITY: This regulation is necessary to establish the specific documentation that is required to be contained in the STEMI System Plan that will be reviewed for approval by the EMS Authority. The adoption of this section will ensure uniform, statewide standards for the implementation of STEMI Critical Care Systems in California.

PURPOSE

Section 100270.125(c, d): To clarify the responsibilities of local EMS agencies and the EMS Authority for time frames on plan submission, responses, process of approval/disapproval, and action corrections for local EMS agencies who currently do not have a STEMI Critical Care System in place.

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

PURPOSE

Section 100270.125(e): To specify the plan submission requirements for the local EMS agencies that already have a STEMI Critical Care System in place before this proposed regulation development.

NECESSITY: The proposed regulation requires local EMS agencies to adjust their STEMI Critical Care System according to the national and state standard.

PURPOSE

Section 100270.125(f): To specify that local EMS agencies must provide a report to EMS Authority with any changes in their STEMI Critical Care System on an annual basis.

NECESSITY: The EMS Authority will need to review local EMS agency's STEMI Critical Care System on an annual basis to ensure all changes and activities are based on the national standard of care.

PURPOSE

Section 100270.126(a): Has been prepared to require submittal of an organizational chart and contact information for the responsible parties who have a role in the STEMI Critical Care System for local EMS agencies.

NECESSITY: It is necessary that the EMS Authority has contact information regarding communication at the local EMS agency level.

PURPOSE

Section 100270.126(b, c, d, e, f, g): To clarify the responsibility of local EMS agencies to create the policy and procedure for implementation of the STEMI Critical Care System, and specify requirements of plan requirements submittal to the EMS Authority for review.

NECESSITY: It is the EMS Authority's statutory responsibility to review the policies and procedures for the requirements of STEMI Critical Care System for each local EMS agency to ensure they comply with this regulation.

PURPOSE

Section 100270.126(h): To specify that each local EMS agency should have a STEMI program specific Continuous Quality Improvement (CQI) committee.

NECESSITY: It is necessary for local EMS agencies to control the quality of their program and make improvements based on these regulations and the recommendations of the American Heart Association (AHA).

PURPOSE

Section 100270.126(i): To specify that each STEMI Critical Care System shall have a public education component.

NECESSITY: It is necessary for local EMS agencies to create a public education and awareness program for early symptom recognition of a heart attack by the public and use of the prehospital system to get help and prevent permanent damage to the heart.

PURPOSE

Section 100270.127(a, b, c, d): To clarify that every local EMS agency is required to report to the EMS Authority, the status of their system on an annual basis as part of the EMS Plan status report. Status includes any changes to the plan in that time period, the details of CQI activities, and list of improvements to their system.

NECESSITY: It is necessary that the EMS Authority review the status of each system of care in California to ensure STEMI Critical Care Systems are consistent with the requirements of regulations and national recommendations.

PURPOSE

Section 100270.128(a): To specify that every STEMI Critical Care System needs to use 12-lead Electrocardiogram (12-lead ECG) equipment as the most accurate assessment tools for STEMI patients.

NECESSITY: It is necessary that STEMI Critical Care Systems identify a suspected STEMI patient as early as possible. Based on the national recommendation, the most accurate way to recognize a STEMI patient is with a 12-lead ECG and the resulting findings and interpretation.

PURPOSE

Section 100270.128(b): To clarify the responsibility of local EMS agencies to define the ECG readings of the suspected STEMI patient and to ensure that these readings are communicated and reported to STEMI Centers for further action and continuation of care for the patient.

NECESSITY: It is necessary that local EMS agencies ensure the continuation of care for a suspected STEMI patient continues to the STEMI facility.

PURPOSE

Section 100270.129(a-n): To clarify that local EMS agencies have the authority to designate STEMI Receiving Centers (SRC) with specific criteria according to the AHA and national recommendations.

NECESSITY: It is the EMS Authority's statutory responsibility to ensure minimum requirements to receive designation as a SRC are met and are based on this regulation, AHA, and national recommendations to achieve the highest result of care for STEMI patients.

PURPOSE

Section 100270.129(o): To clarify that local EMS agencies have the authority to add specific requirements to the minimum criteria for the designation of a SRC in their jurisdiction based on the needs of its own LEMSA.

NECESSITY: It is necessary that local EMS agencies have the authority within their jurisdiction to add requirements for SRC designation as the needs vary among local EMS agencies due to geographic location, population, and size.

PURPOSE

Section 100270.130(a-f): To clarify that local EMS agencies have the authority to designate a STEMI Referral Hospital (SRH) with specific criteria according to the AHA and national recommendations.

NECESSITY: It is the EMS Authority's statutory responsibility to ensure minimum requirements to be an SRH are met and are based on this regulation, AHA, and national recommendations to achieve the highest result of care for STEMI patients.

PURPOSE

Section 100270.130(g): To clarify that local EMS agencies have the authority to add specific requirements to the minimum criteria for designation of an SRH in their jurisdiction based on the needs of its own local EMS agency.

NECESSITY: It is necessary that local EMS agencies have the authority within their jurisdiction to add requirements for SRH designation as the needs vary among local EMS agencies due to geographic location, population, and size.

PURPOSE

Section 100270.131(a, b): To clarify the roles and responsibilities of hospitals, local EMS agencies and the EMS Authority regarding STEMI patient data collection, analysis and reporting in a specific time frame.

NECESSITY: It is necessary to clarify the responsibilities of parties in collecting data and data usage to improve the quality of care and evaluate the STEMI Critical Care System based on the AHA and National recommendations.

PURPOSE

Section 100270.131(c): To specify the minimum data variables collected from prehospital and hospital for each STEMI patient.

NECESSITY: It is necessary to have these minimum variables to evaluate and measure the quality of care and improve STEMI patient's outcome in the STEMI Critical Care System.

PURPOSE

Section 100270.132(a): To require all STEMI related deaths be reviewed by subject matter experts.

NECESSITY: It is necessary to evaluate the cause of death in a STEMI patient in any STEMI Critical Care System for improvement efforts and reduction and/or elimination of such cause of death to improve the quality of care.

PURPOSE

Section 100270.132(b): To specify that the STEMI Critical Care System is required to have a group of experts review complicated STEMI cases and the cause of death in STEMI patients from all level of care providers (pre-hospital and hospital) to improve the quality of care according to national standards.

NECESSITY: It is necessary for an expert team to review complicated STEMI patient cases for educational purposes and to improve the quality of care in each STEMI Critical Care System.

PURPOSE

Section 100270.132(c): To establish the confidentiality of each case.

NECESSITY: It is necessary to protect the reviewer and individuals involved in review of STEMI death cases.

PURPOSE

Section 100270.133(a, b, c): To clarify that local EMS agencies are responsible for evaluating the STEMI Critical Care System within a specific time frame, based on the requirements in these regulations. Furthermore, the local EMS agency is to ensure the mandatory participation of the STEMI centers in this evaluation and the quality improvement in their jurisdiction.

NECESSITY: The STEMI Critical Care System needs evaluation and supervision by the local EMS agency to control the quality of care for STEMI patients in California.

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 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, that address eight specific components (H&SC §1797.103), assess each county EMS area or the system's service area (H&SC §1797.102), provide technical assistance to existing agencies, counties, and cities for the purpose of developing components of EMS systems (H&SC §1797.104), receive and approve

plans for the implementation of EMS and critical care systems including ST-Elevation Myocardial Infarction (STEMI) System from local EMS agencies (H&SC §1797.105), 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 H&SC Division 2.5 (Section 1797.107).

The EMS Authority is proposing to put these guidelines, policies, and procedures into regulations to provide statewide consistency, fairness, protect public health and safety, and increase 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 (H&SC §1797.200) to develop an EMS system, but if they do, they are required by law, among other things, to do the following:

1. Upon the request of a city or fire district that contracted for or provided prehospital EMS as of June 1, 1980, enter into an agreement with the city or fire district regarding the provision of prehospital EMS (H&SC §1797.201)
2. Have a full- or part- time licensed physician and surgeon as medical director to provide medical control and to assure medical accountability throughout the planning, implementation, and evaluation of the EMS system (H&SC §1797.202).
3. Plan, in accordance with eight specific components (H&SC §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 (H&SC §1797.204).
4. Be responsible for implementation of advanced life support systems and limited advanced life support systems (H&SC §1797.206).
5. 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 (H&SC §1797.220).
6. 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 including STEMI, Stroke, Trauma, or pediatric centers adopted by the local EMS agency.
7. Annually submit their STEMI Systems Plan as part of the EMS plan to the EMS Authority in accordance with guidelines established by the EMS Authority (H&SC §1797.254 and H&SC §1798.150.) for EMS Authority approval.
8. Consistent with their EMS plan, coordinate and otherwise facilitate arrangements necessary to develop their Critical Care EMS systems (H&SC §1797.252).

9. Through the governing board of a local EMS agency or a medical care committee, annually do the following: 1) review ambulance services operating within the county, emergency medical care offered within the county, and first aid practices in the county (H&SC §1797.274), and 2) annually report to the EMS Authority and to the county its observations and recommendations (H&SC §1797.276) regarding EMS activities.

The regulations being proposed by the EMS Authority implement, clarify, and make specific the rules and provisions for accomplishing the elements noted above. Counties have the ability under their own governing rules to assess fees to cover the costs of their STEMI system responsibilities. Currently, 28 out of 33 local EMS agencies in California have a STEMI Critical Care System and are complying, in varying degrees, with 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 public health and safety, increase transparency of local and state government, and achieve compliance with statute.

The EMS Authority is the state agency responsible for the development and coordination of EMS statewide (H&SC §1797.1). To carry out these responsibilities, the EMS Authority is charged with developing, planning and implementing guidelines for EMS as well as critical care systems which address specific topics (H&SC's §1797.103, and §1798.150.) and promulgating rules and regulations as may be reasonable and proper to carry out the purposes and intent of H&SC Division 2.5 (H&SC §1797.107). In accordance with H&SC's 1797.250 and 1797.254 the EMS Authority reviews local EMS plans, including the critical care section submitted by local EMS agencies, based on standards and guidelines. The EMS Authority is proposing to publish those standards and guidelines in regulations to provide consistency, fairness, protection of public health and safety, increase transparency in local and state government, and achieve compliance with statute.

The EMS Authority's responsibilities for reviewing and approving local EMS 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 (H&SC §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.