INITIAL STATEMENT OF REASONS
CHAPTER 7.1 ST-ELEVATION MYOCARDIAL INFARCTION (STEMI) CRITICAL CARE SYSTEM

PROBLEM STATEMENT
Health and Safety Code (HSC) sections 1797.103, 1797.176 and 1798.150 charge the Emergency Medical Services Authority (EMSA) with establishing guidelines for critical care facilities, develop planning and implementation guidelines for EMS systems and set minimum standards for the policies and procedures necessary for medical control of the EMS system. However, these sections do not clarify or adequately define standardized best practices for the development and implementation of specialty care facilities.

Therefore, in compliance with HSC section 1797.107, EMSA has prepared the proposed regulations to clarify and make specific the requirements for a local EMS agency (LEMSA) to develop and implement an ST-Elevation Myocardial Infarction (STEMI) Critical Care System.

There are currently 145 designated STEMI centers in California serving ninety-eight (98) percent of the population. However, because there are no standardized statewide requirements for the development and implementation of a STEMI critical care system, the LEMSA’s designate hospitals as STEMI facilities based on differing standards. The proposed regulations will set criteria for review and approval of local EMS plans and protect the health and safety of the public by providing statewide uniform standards and requirements.

The proposed regulations are designed to clarify and make specific the requirements for a LEMSA to develop and implement a STEMI critical care system including the submission of STEMI critical care system plans and plan updates to EMSA. The regulations also specify requirements for a hospital to become a designated STEMI critical care facility, a process for data collection, STEMI system evaluations, and the quality improvement process. These regulations protect the health and safety of the public by establishing consistent and uniform standards for a STEMI critical care system in the state.

PURPOSE
The purpose of these regulations is to protect the health and safety of the public by defining and specifying the procedures that enable a LEMSA to develop and implement a STEMI critical care system. These regulations will protect the health and safety of the public by establishing minimum requirements for the development and implementation of a STEMI critical care system plan, plan update requirements, the process for hospital designation, and data collection. The regulations authorize EMSA to annually review and approve STEMI critical care system plans and plan updates submitted by a LEMSA.
The broad objective of the regulation is to improve the care of patients suffering from a life-threatening acute heart attack. The specific benefit from the regulation is to protect the health and safety of the public by providing standardized statewide requirements to develop and implement a STEMI critical care system, which will lead to the consistent statewide application of the requirements. Irreversible damage to the heart muscle cells is preventable if STEMI treatment strategies are applied within 90 minutes of the onset of the attack. Improving the system through standardization of STEMI care statewide will enhance patient care in the prehospital setting and designated hospitals receiving critical care patients.

**PURPOSE AND NECESSITY**

**ARTICLE 1. DEFINITIONS**

Sections 100270.101 through 100270.123.

These definitions are necessary to ensure that the terms used in the regulations are clear to readers, including the public, LEMSAs, and others impacted by these regulations adopted by EMSA and found in Title 22 of the California Code of Regulations (CCR).

**ARTICLE 2. LOCAL EMS AGENCY STEMI CRITICAL CARE SYSTEM REQUIREMENTS**

The provisions in this article provide the minimum standards to be met and procedures to be followed if a LEMSA chooses to develop and implement a STEMI critical care system. The provisions specify the requirements for plan approval and plan updates and provide timelines.

Section 100270.124. STEMI critical care system Plan Approval

**SPECIFIC PURPOSE**

The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.103, 1797.105, 1797.176, 1797.257 and 1798.150 regarding STEMI critical care system plan approval to ensure that only a qualified STEMI critical care system meeting the minimum standards are implemented.

**NECESSITY**

EMSA is authorized by statute to review and approve EMS plans submitted by a LEMSA. EMSA is also authorized to establish the minimum standards necessary for medical control of the EMS System.

A LEMSA may, but is not mandated to develop and implement a STEMI critical care system within their jurisdictions. To ensure that all STEMI system plans conform to a uniform, statewide standard it is necessary that a LEMSA wishing to develop and implement a STEMI critical care system have their system plan approved by EMSA before implementation of the system.
EMSA has established minimum requirements to be included in the plan. These requirements will ensure statewide consistency, thereby protecting the health and safety of the public. The minimum requirements clarify the responsibility of the local EMS agencies to create policies and procedures for implementation of the STEMI system, convene a quality improvement (QI) committee, compile agreements between all parties in the system, provide an organizational chart and contact information for the parties who have a role in the STEMI critical care system and submit them to EMSA for review and approval.

The proposed regulations establish the timelines for plan submission, response, approval/disapproval, and corrective actions for EMSA and LEMSA. This is necessary for accountability and timeliness and is consistent with other chapters of regulations promulgated by EMSA concerning timelines for approval of a program.

To ensure statewide consistency, a LEMSA currently operating a STEMI critical care system implemented before these regulations must submit their stroke system plan to EMSA as an addendum to its next annual EMSA plan update or within 180 days of the effective date of these regulations, whichever comes first.

Section 100270.125 STEMI critical care system Plan Updates.
SPECIFIC PURPOSE
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.103, 1797.105, 1797.176, 1797.258 and 1798.150 regarding the submission of the annual update of a STEMI critical care system plan to EMSA.

NECESSITY
EMSA is authorized by statute to review and approve EMS plans submitted by a LEMSA. EMSA is also authorized to establish the minimum standards necessary for medical control of the EMS system.

Each LEMSA is required to report to EMSA the status of their system after implementation on an annual basis as part of their EMS Plan Status Report. The status report includes any changes that occurred within the time period, the details of quality improvement activities, and improvement activities. It is necessary that EMSA annually review each STEMI critical care system in California to ensure all the changes and operations are based on the state’s standard of care and requirements. This will ensure statewide consistency, thereby protecting the health and safety of the public.

ARTICLE 3. PREHOSPITAL STEMI CRITICAL CARE SYSTEM REQUIREMENTS.
The provisions in this article provide the requirements to be met and the policies and procedures to be drafted and utilized by a LEMSA for prehospital personnel.

Section 100270.126 EMS Personnel and Early Recognition
SPECIFIC PURPOSE
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.103, 1797.176, 1797.204 and 1798.150 regarding the development of protocols by a LEMSA for the treatment of STEMI patients by prehospital EMS
personnel.

NECESSITY
An ST-Elevation Myocardial Infarction (STEMI) is commonly known as an acute heart attack caused by clotting in one or more arteries. A STEMI usually requires aggressive treatment promptly to prevent permanent heart damage. The most accurate assessment tool to determine if a person has had a myocardial infarction is through electrocardiograms (ECGs) that trace the electrical signals in the heart.

The section is necessary as it specifies that a LEMSA with a STEMI critical care system must establish protocols for prehospital EMS personnel treatment of STEMI patients. Because the most accurate assessment tool for STEMI patients is the use and resulting findings of a 12-lead ECG, the protocols are necessary to ensure the ability of a paramedic to use 12-lead Electrocardiogram (12-lead ECG) equipment and the ability to assess and interpret those findings through various methods. The protocols also need to address an advance notification process to communicate the information to the STEMI facility, center or hospital.

The section is necessary to comply with HSC 1797.204 requiring a LEMSA to plan, implement, and evaluate an EMS system consisting of an organized pattern of readiness and response services based on public and private agreements and operational procedures.

This section is necessary to ensure that prehospital personnel is able to identify a suspected STEMI patient as early as possible through an ECG and communicate the ECG findings to STEMI facilities, centers or hospitals for further action and continuation of care for the patient promptly to prevent permanent heart damage.

ARTICLE 4. STEMI CRITICAL CARE FACILITY REQUIREMENTS
The provisions of this article provide the criteria and requirements for STEMI receiving centers and STEMI Referring Hospitals.

§ 100270.127. STEMI Receiving Renters Requirements
SPECIFIC PURPOSE
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.103, 1797.176 and 1798.150 regarding minimum criteria requirements to be designated a STEMI receiving centers by a LEMSA including those centers implemented before these regulations.

NECESSITY
STEMI receiving centers are medical centers that specialize in receiving STEMI cases. Working in coordination with emergency medical responders, the physicians and staff at STEMI receiving centers expedite the diagnosis and treatment of cardiac episodes. A LEMSA designates specific hospitals as STEMI receiving centers to handle such cardiac emergencies.
EMSA has established minimum requirements to be a designated STEMI receiving center. To accomplish this task, EMSA convened a workgroup of subject matter experts, stakeholders and interested parties that provided information and subject matter expertise from operational, educational, administrative and medical perspectives. The workgroup provided specific and detailed components for a STEMI receiving center to ensure the highest quality of care for STEMI patients.

The requirements are based upon standards and best practices contained in the documents specified in the section below titled “Technical, Theoretical, and/or Empirical Study, Reports, or Documents.”

Section 100270.128. STEMI Referring Hospital Requirements.

SPECIFIC PURPOSE
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.103, 1797.176 and 1798.150 regarding minimum criteria requirements to be designated a STEMI referring hospital by a LEMSA including those hospitals implemented before these regulations.

NECESSITY:
STEMI referring hospitals are a vital link in the lifeline for heart attack patients. STEMI referring hospitals are facilities with established programs that may improve outcomes for the non-ST-Elevation acute coronary syndrome and STEMI patients by developing protocols for the rapid transfer of heart attack patients to the most appropriate hospital.

EMSA has established minimum requirements to be a designated STEMI receiving center. To accomplish this task, EMSA convened a workgroup of subject matter experts, stakeholders and interested parties that provided information and subject matter expertise from operational, educational, administrative and medical perspectives. The workgroup provided specific and detailed components for a STEMI receiving center to ensure the highest quality of care for STEMI patients.

The requirements are based upon standards and best practices contained in the documents specified in the section below titled “Technical, Theoretical, and/or Empirical Study, Reports, or Documents.”

ARTICLE 5. DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATIONS.
The provisions in this article provide requirements related to data management, quality improvement processes, and the evaluations of a STEMI critical care system.

Section 100270.129. Data Management.

SPECIFIC PURPOSE
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.102, 1797.103, 1797.176, and 1798.150 regarding the roles and responsibilities of hospitals, local EMS agencies and EMSA of STEMI patient data
collection, analysis, and reporting.

**NECESSITY**

This section is necessary to establish the roles and responsibilities for the data collection process for all hospitals that receive STEMI patients. The minimum data elements to be collected and submitted to the LEMSA by the hospitals, and subsequently to EMSA, is necessary to ensure the patient care elements are compliant with the California EMS Information System (CEMSIS) database, the National EMS Information System (NEMSIS) database and the National Cardiovascular Data Registry (NCDR). The collection of this data for each STEMI patient is necessary to evaluate and measure the quality of care and improve, as necessary, STEMI patient outcomes in the STEMI critical care system.

Health facilities already collect and provide data that is based on the national standards for certification and accreditation by the Joint Commission. The regulations will align our data collection requirements with existing requirements which are listed in the proposed regulations.

EMSA is required in statute (Health and Safety Code Section 1797.102) to “assess each EMS area or the system’s service area for the purpose of determining the need for additional emergency medical services, coordination of emergency medical series, and the effectiveness of emergency medical services.” The collection of this data will enable EMSA to evaluate and measure the EMS system allowing us to see where and how the quality of patient care can be improved.

These regulations will standardize what data is submitted to the LEMSAs and allow EMSA to adequately assess the statewide system as required in Health and Safety Code Section 1797.102.

**Section 100270.130 Quality Improvement and Evaluation Process.**

**SPECIFIC PURPOSE**

The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.103, 1797.176 and 1798.150 regarding quality improvement requirements of a STEMI critical care system.

**NECESSITY**

This section is necessary as any STEMI related death must be reviewed by a group of experts to learn from any potential mistakes and improve the quality of care in each STEMI critical care system. Requiring a STEMI critical care system to participate in the quality improvement process is necessary to monitor and enhance the quality of care in the STEMI system thereby protecting the health and safety of the public.

The section is also necessary to clarify that the LEMSA is responsible for ensuring STEMI centers in their jurisdiction participate in the evaluation and quality improvement process. The on-going evaluation of the STEMI critical care system is necessary to control the quality of care for STEMI patients ensuring the health and safety of the
“TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, or DOCUMENTS.”

EMSA relied on input from a working group comprised of various subject matter experts, stakeholders and interested parties that provided information and subject matter expertise from operations, education, administrative and medical perspectives.

The groups and organizations that participated in the workgroup include:
Local EMS agencies LEMSA), Emergency Medical Services Administrators’ Association of California (EMSAAC), Emergency Medical Services Medical Directors Association of California (EMDAC), Emergency Nurses Association (ENA), Kaiser Foundation Hospital, California Department of Public Health (CDPH), Orange County Fire Authority, Stanford University, American Heart Association (AHA), California Hospital Association (CHA), and Advanced Practice Group.

The documents relied upon include:
- Recommendations for the Early Management of Adults with ST-Elevation Myocardial Infarction (STEMI).
- National Cardiology Data Registry, Data Collection Form Premier 2.4.2, date April 10, 2017.

ECONOMIC IMPACT ASSESSMENT/ANALYSIS

The Creation or Elimination of Jobs within the State of California
The proposed regulations are designed to clarify and make specific the requirements for a LEMSA to develop and implement a STEMI critical care system including the submission of STEMI critical care system plans and plan updates to EMSA. The proposed regulations also specify requirements for a hospital to become a designated STEMI critical care system, a process for data collection, system evaluations and the quality improvement process. These proposed regulations protect the health and safety of the public by establishing consistent and uniform standards for a STEMI critical care system in the state. The regulations continue existing practices and do not mandate any business to develop and implement a STEMI critical care system. Therefore, EMSA has determined that it’s unlikely jobs in California will be created or eliminated.

The Creation of New Businesses or the Elimination of Existing Businesses Within the State of California
The proposed regulations are designed to clarify and make specific the requirements for a LEMSA to develop and implement a STEMI critical care system including the submission of STEMI critical care system plans and plan updates to EMSA. The proposed regulations also specify requirements for a hospital to become a designated STEMI critical care system, a process for data collection, system evaluations, and the quality improvement process. These proposed regulations protect the health and safety of the public by establishing consistent and uniform standards for a STEMI critical care system in the state.
system in the state. The regulations continue existing practices and do not mandate any business to develop and implement an EMSC program. Therefore, EMSA has determined that it’s unlikely that any new or existing businesses in California will be created or eliminated.

The Expansion of Businesses Currently Doing Business Within the State of California

The proposed regulations are designed to clarify and make specific the requirements for a LEMSA to develop and implement a STEMI critical care system including the submission of STEMI critical care system plans and plan updates to EMSA. The proposed regulations also specify requirements for a hospital to become a designated STEMI critical care system, a process for data collection, system evaluations, and the quality improvement process. These proposed regulations protect the health and safety of the public by establishing consistent and uniform standards for a STEMI critical care system in the state. EMSA has determined the regulations may result in the expansion of businesses (hospitals) within the state because hospitals may choose to expand their EMS with the implementation a STEMI critical care system.

Benefits of the Regulations to the Health and Welfare of California Residents, Worker Safety, and the State’s Environment

The proposed regulations will benefit California residents and worker safety by allowing a person suffering from an acute heart attack to receive potentially lifesaving medical care from EMS responders and designated hospitals. The proposed regulations increase public safety through consistent statewide standards and requirements to be met to become a designated STEMI critical care system. The proposed regulations are not anticipated to benefit or negatively impact the state’s environment.

Results of the Economic Impact Analysis/Assessment

The EMSA concludes that it is (1) unlikely that the proposal will eliminate any jobs (2) unlikely the proposal will create any new jobs (3) unlikely the proposal will create any new businesses (4) unlikely the proposal will eliminate any existing businesses, and (5) the regulations may result in the expansion of businesses (hospitals) currently doing business within the state.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESS.

EMSA has not identified any alternatives that would lessen any adverse impact on small businesses.

EVIDENCE SUPPORTING FINDING OF ADVERSE ECONOMIC IMPACT ON ANY BUSINESS

EMSA has determined that these regulations are not likely to result in an adverse economic impact on any business due to the voluntary nature of these regulations which establish uniform standards across the state. These regulations do not mandate that a LEMSA, individual or business develop and implement a STEMI critical care
EMSA has determined that this proposed regulation is not inconsistent or incompatible with existing regulations.

FOR FURTHER INFORMATION
Contact Corrine Fishman, Emergency Medical Services Authority, 10901 Gold Center Drive, Suite 400, Rancho Cordova, California 95670, (916) 431-3727 or corrine.fishman@emsa.ca.gov