INITIAL STATEMENT OF REASONS
CHAPTER 14. EMERGENCY MEDICAL SERVICES FOR CHILDREN (EMSC)

PROBLEM STATEMENT
The Legislature added Chapter 12, (Chapter 197, Statutes of 1996) The California Emergency Medical Services for Children Act of 1996, commencing with Section 1799.202 of Division 2.5 of the Health and Safety Code (HSC). The intent of the Legislature was to ensure that children receive adequate and appropriate EMS necessary to prevent loss of life and human potential, thus creating the Emergency Medical Services Systems for Children (EMSC) program.

HSC Sections 1797.102, 1797.103, 1797.107, 1797.176 and 1798.150 authorize the Emergency Medical Services Authority to adopt regulations relating to emergency medical care and establish guidelines for prehospital and critical care facilities. Also, HSC Sections 1799.202 – 1799.207 charge EMSA with overseeing the development and implementation of an EMSC program by local EMS agencies (LEMSA). Currently, 21 of the 33 LEMSAs have developed and implemented an EMSC program. However, no specific requirements or standards for local EMSC programs exist.

Therefore, in compliance with the statute, EMSA proposes regulations to clarify and make specific the requirements for a LEMSA to develop and implement EMSC programs into their EMS plans.

The proposed EMSC regulations create quality improvement (QI) assurance models as well as specified requirements for pediatric facility designation. Necessary resources are outlined to ensure pre-hospital providers and hospital emergency departments are adequately prepared to provide medical services for pediatric patients, from neonates to adolescents.

PURPOSE
The purpose of these regulations is to protect the welfare, health, and safety of pediatric patients. The regulations provide consistent, equitable, and standardized criteria statewide, and would ensure adequate resources necessary to prepare prehospital providers and hospital emergency departments to serve pediatric patients. Additionally, this carries out our statutory mandate and provides direction to local EMS agencies for implementation of EMSC programs into their EMS plans.

The proposed EMSC regulations establish specific requirements and standards for implementing and operating an EMSC program and create quality improvement assurance models as well as specified requirements for pediatric facility designation. Necessary resources are outlined to ensure prehospital providers and hospital emergency departments are adequately prepared to provide medical care for pediatric patients, from neonates to adolescents.

BENEFIT
The benefits of the proposed regulations are to provide standards for establishing statewide consistency in policy and program elements, support coordination of limited resource of pediatric specialty centers, and improve pediatric patient care within California EMSC Programs. Children requiring emergency care have unique needs, especially during emergencies or life-threatening situations. EMS providers deliver prehospital medical care to children, and hospital emergency departments provide medical care upon arrival at the hospital. It is vital that EMS providers and hospital emergency departments have the appropriate resources and staff to provide coordinated, collaborative, and effective medical care for pediatric patients.

PURPOSE AND NECESSITY

ARTICLE 1. DEFINITIONS
The provisions in this article provide definitions for terms used in the regulations.

§ 100450.200 - § 100450.218
PURPOSE:
The specific purpose of these provisions is to define specific terms used throughout the regulations to provide clarity and guidance to local EMS agencies and the public.

NECESSITY:
These definitions are necessary to ensure that the terms used within the regulations will have clear and unambiguous meaning, be clear to readers, including the public, and particularly to the persons and organizations affected by these regulations.

ARTICLE 2. LOCAL EMS AGENCY EMSC PROGRAM 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 an EMSC Program. The provisions specify the requirements for plan approval, notification, and updates.

§ 100450.219 EMSC Program Approval
PURPOSE:
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.107, 1798.150 and 1799.202-1799.207 with regard to EMSC Program approval to ensure that only qualified EMSC Programs meeting the minimum standards are implemented.

NECESSITY:
EMSA has a statutory responsibility to oversee the implementation and status of each EMSC program in California. As such, EMSA has established minimum requirements to be included in the EMSC plan. These requirements are necessary to ensure statewide consistency, thereby protecting the health and safety of the public. The minimum requirements clarify the responsibility of the local EMS agency in developing and implementing an EMSC program. This includes policies and procedures for inter-facility transfer, copies of agreements, a quality improvement process, and providing contact information for the parties who have a role in the EMSC Program. Additionally, the
proposed regulations establish timelines for plan submission, response, approval/disapproval, and corrective actions for EMSA and LEMSA. This is consistent with other chapters of regulations promulgated by EMSA concerning timelines for approval of a program. Requiring specific timeframes and requirements is necessary to ensure notification between EMSA and a LEMSA is done promptly.

It is necessary that a LEMSA wishing to develop and implement an EMSC Program have their system plan approved by EMSA before implementation of the system. This will ensure that all EMSC program plans conform to a uniform, statewide standard. A LEMSA may, but is not mandated to develop and implement an EMSC program within their jurisdiction.

A LEMSA currently operating an EMSC program implemented before these regulations must submit their EMSC program 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. This is necessary to ensure statewide consistency with EMSC programs thereby protecting the health and safety of the public.

§ 100450.220 Annual EMSC Program Update
PURPOSE:
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.105, 1797.107, 1798.150 and 1799.202-1799.207 related to the submission of the LEMSA annual EMSC program update.

NECESSITY:
EMSA has a statutory responsibility to oversee the implementation and status of each EMSC program in California. Each LEMSA is required to report to EMSA the status of their program after implementation on an annual basis as part of the EMS Plan Status Report.

This section is necessary to specify the requirements of a local EMS agency’s submission of an annual update to its EMSC program to EMSA. The update includes any changes in the program, the status of the goals and objectives of the program, a summary of improvement activities and progress on any action items recommended previously. This will ensure all EMSC programs are continually reviewing their individual goals and objectives while also ensuring that consistent statewide standards are being met.

ARTICLE 3. PEDIATRIC RECEIVING CENTERS (PedRC)
The provisions in this article provide local EMS agencies with specific requirements related to the designation, staffing, and equipment for all levels of PedRC.

§100450.221 Level I PedRC Requirements
PURPOSE:
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.107, 1798.150 and 1799.202-1799.207 related to the requirements for a
hospital to be designated as a Level I PedRC.

NECESSITY:
A level I PedRC is a California Children’s Services (CCS) approved tertiary hospital with specialized in-patient intensive care, diagnostic, operative, therapeutic services and equipment, and with in-house and/or promptly available physician specialists in pediatric subspecialties. A level I pediatric community hospital may be designated as a PedRC by the local EMS agency if the hospital has full, provisional, or CCS approval readily available.

This section is necessary to establish minimum requirements for a local EMS agency’s designation of a level I PedRC to achieve the highest level of care for pediatric patients. Facility designation allows local jurisdictions to coordinate resources consistently to create regional systems that protect specialty center resources. These provisions will ensure all PedRCs, and their staff, are held to uniform standards, qualifications, and requirements.

EMSA has established minimum requirements for a hospital to be designated a level I PedRC. 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 level I PedRC to ensure the highest quality of care for pediatric patients.

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

§100450.222 Level II PedRC Requirements
PURPOSE:
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.107, 1798.150 and 1799.202-1799.207 related to the requirements for a hospital to be designated as a Level II PedRC.

NECESSITY:
A Level II PedRC is a CCS-approved pediatric community hospital. A level II pediatric community hospital may be designated as a PedRC by the local EMS agency if the hospital has full, provisional, or CCS approval readily available.

This section is necessary to establish minimum requirements for a local EMS agency’s designation of a level II PedRC to achieve the highest level of care for pediatric patients. Facility designation allows local jurisdictions to coordinate resources consistently to create regional systems that protect specialty center resources. These provisions will ensure all PedRCs, and their staff, are held to uniform standards, qualifications, and requirements.

EMSA has established minimum requirements for a hospital to be designated a level II
PedRC. 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 level II PedRC to ensure the highest quality of care for pediatric patients.

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

§100450.223 Level III PedRC Requirements
PURPOSE:
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.107, 1798.150 and 1799.202-1799.207 related to the requirements for a hospital to be designated as a Level III PedRC.

NECESSITY:
A level III PedRC is a hospital with necessary emergency services, staffed 24 hours a day, seven (7) days a week, three hundred and sixty-five (365) days per year, but which may have limited inpatient services. The Level III PedRC is a general community hospital that has adult inpatient specialty care with no dedicated inpatient pediatric services. Diagnostic, operative, therapeutic services and equipment must be available, and selected physician specialists must be available for consultation. A level III pediatric community hospital may be designated as a PedRC by the local EMS agency if the hospital has full, provisional, or CCS approval readily available.

This section is necessary to establish minimum requirements for a local EMS agency’s designation of a level III PedRC to achieve the highest level of care for pediatric patients. Facility designation allows local jurisdictions to coordinate resources consistently to create regional systems that protect specialty center resources. These provisions will ensure all PedRCs, and their staff, are held to uniform standards, qualifications, and requirements.

EMSA has established minimum requirements for a hospital to be designated a level III PedRC. 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 level III PedRC to ensure the highest quality of care for pediatric patients.

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

§100450.224. Level IV PedRC Requirements
PURPOSE:
The specific purpose of this section is to clarify, interpret and make specific HSC
sections 1797.107, 1798.150 and 1799.202-1799.207 related to the requirements for a hospital to be designated as a Level IV PedRC.

**NECESSITY:**
A level IV PedRC is a small and rural hospital, with a basic emergency department permit with limited or no inpatient care capability and limited physician specialists available for consultation. Emergency department services may include physician staffing 24 hours a day, seven (7) days a week or a physician available for consultation. A level IV pediatric community hospital may be designated as a PedRC by the local EMS agency if the hospital has full, provisional, or CCS approval readily available.

This section is necessary to establish minimum requirements for a local EMS agency’s designation of a level IV PedRC to achieve the highest level of care for pediatric patients. Facility designation allows local jurisdictions to coordinate resources consistently to create regional systems that protect specialty center resources. These provisions will ensure all PedRCs, and their staff, are held to uniform standards, qualifications, and requirements.

EMSA has established minimum requirements for a hospital to be designated a level IV PedRC. 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 level IV PedRC to ensure the highest quality of care for pediatric patients.

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

**§ 100450.225. Pediatric Receiving Center Personnel Requirements**

**PURPOSE:**
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.107, 1798.150 and 1799.202-1799.207 related to the minimum qualifications and training policies to be used by all PedRC personnel.

**NECESSITY:**
This section is necessary to ensure all PedRCs, and their staff, are held to uniform standards, qualifications, and requirements to ensure the highest quality of care for pediatric patients.

**§ 100450.226. Pediatric Equipment, Supplies, and Medication Requirements**

**PURPOSE:**
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.107, 1798.150 and 1799.202-1799.207 related to the minimum equipment, supplies and medication(s) required of all PedRC to ensure the highest quality of care for pediatric patients.
NECESSITY:
It is necessary to define requirements for specific equipment and supplies necessary for treatment of pediatric patients in PedRC to ensure proper equipment, supplies and medication(s) are available for optimum treatment of pediatric patients in PedRCs.

ARTICLE 4. DATA MANAGEMENT, QUALITY IMPROVEMENT, AND EVALUATIONS
The provisions in this article will provide local EMS agencies with data reporting requirements and a quality improvement and evaluation process for PedRC.

§ 100450.227. Data Management Requirements
PURPOSE:
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.102, 1797.107, 1798.150 and 1799.202-1799.207 related to establishing data reporting requirements for local EMS agencies.

NECESSITY:
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.

Establishing data reporting requirements is necessary to ensure uniform reporting of pediatric medical data throughout the State of California. Uniform data reporting is essential to properly evaluate a statewide system to establish benchmarks and compare regions.

This section is necessary to identify the categories of data local EMS agencies must collect and report to EMSA. This section also specifies the frequency with which local EMS agencies shall communicate this information, methods of submission, and sets forth uniformity requirements to EMSA and local EMS agencies. In addition to benefiting the health and safety of pediatric patients, the specific data elements and data values provided within this provision will ensure uniformity and consistency in the data reported.

§ 100450.228. Quality Improvement and Evaluation Process
PURPOSE:
The specific purpose of this section is to clarify, interpret and make specific HSC sections 1797.107, 1798.150 and 1799.202-1799.207 related to establishing quality improvement requirements and ongoing performance evaluations of the local or regional EMSC Programs.

NECESSITY:
This section is necessary for compliance with California Evidence Code §1157.7
requiring a quality improvement process and to define the LEMAs responsibility for evaluation of their EMSC Program. This includes structure, process and outcome evaluations that focus on improvement efforts. This information will help identify causes of problems, which is necessary to reduce or eliminate these causes, and take steps to correct the process. Evaluation of all EMSC Programs facilitates continuous improvement of the quality of care provided to California pediatric patients. “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: Harbor-UCLA Medical Center, Emergency Medicine Associates, Pediatric & Emergency Medicine, Rady Children’s Hospital San Diego, Department of Health Care Services, Public members, local EMS Agencies.

The documents relied upon include:

*Development and Implementation of EMS-C: A step by Step Approach*

**ECONOMIC IMPACT ASSESSMENT/ANALYSIS**

**The Creation or Elimination of Jobs within the State of California**

The regulations are designed to clarify and make specific the requirements for a LEMSA to develop and implement an EMSC Program including the submission of EMSC program plans and plan updates to EMSA. The regulations also specify requirements for a hospital to implement an EMSC Program, a process for data collection, program evaluations, and the quality improvement process. These regulations protect the health and safety of the public by establishing consistent and uniform standards for an EMSC program 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 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 regulations are designed to clarify and make specific the requirements for a LEMSA to develop and implement an EMSC Program including the submission of EMSC program plans and plan updates to EMSA. The regulations also specify requirements for a hospital to implement an EMSC Program, a process for data collection, program evaluations, and the quality improvement process. These regulations protect the health and safety of the public by establishing consistent and uniform standards for an EMSC program 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 regulations are designed to clarify and make specific the requirements for a LEMSA to develop and implement an EMSC Program including the submission of EMSC program plans and plan updates to EMSA. The regulations also specify requirements for a hospital to implement an EMSC program, a process for data collection, program evaluations, and the quality improvement process. These regulations protect the health and safety of the public by establishing consistent and uniform standards for an EMSC program 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 an EMSC program.

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 protecting the welfare, health, and safety of pediatric patients. The regulations provide consistent, equitable, and standardized criteria statewide, and would ensure adequate resources necessary to prepare prehospital providers and hospital emergency departments to serve pediatric patients. Additionally, these regulations provide direction to local EMS agencies for implementation of EMSC programs into their EMS plans. 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 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 an EMSC PedRC. EMSA has determined that this proposed regulation is not inconsistent or incompatible with existing regulations.

FOR FURTHER INFORMATION
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