Emergency Medical Services

STEMI/Cardiac Arrest Receiving Center

Agreement

County of Alameda

And

Stanford Health Care Tri-Valley

Effective Date: January 1, 2023

DEFINITIONS AND ACRONYMS

AED	Automated External Defibrillator
AICD	Automated Implantable Cardiovertor-Defibrillator
ALCO	Alameda County
BHDE	Bidirectional Healthcare Data Exchange
CABG	Coronary Artery Bypass Graph
CARC	Cardiac Arrest Receiving Center: A comprehensive cardiac care center that is able to offer needed basic and advanced life support: Cardiopulmonary Resuscitation and Post Resuscitation Care: Therapeutic Hypothermia, Emergent Primary Coronary Interventions (PCI), Metabolic Support and Rehabilitation to patients suffering from Cardiopulmonary arrest.
CARES	Cardiac Arrest Registry to Enhance Survival
Cardiac Catheterization Laboratory	"Cardiac catheterization laboratory" or "Cath lab" means the setting within the hospital where diagnostic and therapeutic procedures are performed on patients with cardiovascular disease. 22 CCR § 100270.101. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code
Cardiac Catheterization Team	"Cardiac catheterization team" means the specially trained health care professionals that perform percutaneous coronary intervention. It may include, but is not limited to, an interventional cardiologist, mid-level practitioners, registered nurses, technicians, and other health care professionals. 22 CCR § 100270.102. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and

	1797.176, Health and Safety Code.
CCU	Coronary Care Unit
CCT	Critical Care Transport
Clinical Staff	"Clinical staff" means individuals that have specific training and experience in the treatment and management of ST-Elevation Myocardial Infarction (STEMI) patients. This includes, but is not limited to, physicians, registered nurses, advanced practice nurses, physician assistants, pharmacists, and technologists. 22 CCR § 100270.103. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.
CPC	Cerebral Performance Category
ECMO	Extracorporeal Membrane Oxygenation
ECG	Electrocardiogram
EEG	Electroencephalogram
ED	Emergency Department
Emergency Medical Services Authority	"Emergency Medical Services Authority" or "EMS Authority" or "EMSA" means the department in California responsible for the coordination and integration of all state activities concerning EMS. 22 CCR § 100270.104. Note: Authority cited: Sections 1797.1, 1797.107 and 1797.54, Health and Safety Code. Reference: Sections 1797.100, and 1797.103, Health and Safety Code.
GWTG-CAD	Get With The Guidelines Coronary Artery Disease is a registry offered by the American Heart Association to capture data regarding STEMI patients

HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health Act
ICD	Implantable Cardiac Defibrillator
ICU	Intensive Care Unit
Immediately Available	"Immediately available" means: (a) Unencumbered by conflicting duties or responsibilities. (b) Responding without delay upon receiving notification. (c) Being physically available to the specified area of the hospital when the patient is delivered in accordance with local EMS agency policies and procedures. 22 CCR § 100270.105. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.
Implementation	"Implementation," "implemented," or "has implemented" means the development and activation of a STEMI Critical Care System Plan by the local EMS agency, including the prehospital and hospital care components in accordance with the plan. 22 CCR § 100270.106. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.
Interfacility Transfer (IFT)	"Interfacility transfer" means the transfer of a STEMI patient from one acute general care facility to another acute general care facility. 22 CCR § 100270.107. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103, 1797.176 and 1798.170, Health and Safety Code
IRB	Internal Review Board
Local Emergency Medical Services	"Local emergency medical services agency" or "local EMS agency" means the agency, department, or office having primary responsibility

Agency (LEMSA)	for administration of emergency medical services in a county or region and which is designated pursuant Health and Safety Code commencing with section 1797.200. 22 CCR § 100270.108. Note: Authority cited: Sections 1797.107, 1797.200 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.
MOU	Memorandum of Understanding
NCDR	National Cardiovascular Data Registry
Percutaneous Coronary Intervention (PCI)	"Percutaneous coronary intervention" or "PCI" means a procedure used to open or widen a narrowed or blocked coronary artery to restore blood flow supplying the heart, usually done on an emergency basis for a STEMI patient. 22 CCR § 100270.109. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.
PHI	Protected Health Information
Quality Improvement (QI)	"Quality improvement" or "QI" means methods of evaluation that are composed of structure, process, and outcome evaluations that focus on improvement efforts to identify root causes of problems, intervene to reduce or eliminate these causes, and take steps to correct the process, and recognize excellence in performance and delivery of care. 22 CCR § 100270.110. Note: Authority cited: Sections 1797.103, 1797.107, 1797.174, 1797.176 and 1798.150 Health and Safety Code. Reference: Sections 1797.174, 1797.202, 1797.204, 1797.220 and 1798.175, Health and Safety Code.
RH	Referring Hospital
RN	Registered Nurse

ROSC	Return of Spontaneous Circulation
SCA	Sudden Cardiac Arrest
ST-Elevation Myocardial Infarction (STEMI)	"ST-Elevation Myocardial Infarction" or "STEMI" means a clinical syndrome defined by symptoms of myocardial infarction in association with ST-segment elevation on Electrocardiogram (ECG). 22 CCR § 100270.111. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.
STEMI Care	"STEMI care" means emergency cardiac care, for the purposes of these regulations. 22 CCR § 100270.112. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.
STEMI Medical Director	"STEMI medical director" means a qualified board-certified physician by the American Board of Medical Specialties (ABMS) as defined by the local EMS agency and designated by the hospital that is responsible for the STEMI program, performance improvement, and patient safety programs related to a STEMI critical care system. 22 CCR § 100270.113. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.
STEMI Patient	"STEMI patient" means a patient with symptoms of myocardial infarction in association with ST-Segment Elevation in an ECG. 22 CCR § 100270.114. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103, 1797.176 and 1797.220, Health and Safety Code.
STEMI Program	"STEMI program" means an organizational component of the hospital specializing in the care of STEMI patients. 22 CCR § 100270.115. Note: Authority cited: Sections 1797.107 and

	1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.
STEMI Program Manager	"STEMI program manager" means a registered nurse or qualified individual as defined by the local EMS agency, and designated by the hospital responsible for monitoring, coordinating and evaluating the STEMI program. 22 CCR § 100270.116. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.
STEMI Receiving Center (SRC)	"STEMI receiving center" or "SRC" means a licensed general acute care facility that meets the minimum hospital STEMI care requirements pursuant to Section 100270.124 and is able to perform PCI. 22 CCR § 100270.117. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103, 1797.176 and 1797.220, Health and Safety Code.
STEMI Referring Hospital (SRH)	"STEMI referring hospital" or "SRH" means a licensed general acute care facility that meets the minimum hospital STEMI care requirements pursuant to Section 100270.125. 22 CCR § 100270.118. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103, 1797.176 and 1797.220, Health and Safety Code.
STEMI Critical Care System	"STEMI critical care system" means a critical care component of the EMS system developed by a local EMS agency that links prehospital and hospital care to deliver treatment to STEMI patients. 22 CCR § 100270.119. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.
STEMI Team	"STEMI team" means clinical personnel, support personnel, and administrative staff that function together as part of the hospital's STEMI program.

	22 CCR § 100270.120. Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.
TTM	Targeted Temperature Management (FKA: Therapeutic Hypothermia)
V/F	Ventricular Fibrillation: life threatening cardiac rhythm
V/T	Ventricular Tachycardia: life threatening cardiac rhythm

Section 1 - Introduction

1.1 Alameda County EMS is the Local Emergency Medical Service Agency (LEMSA) as defined in the California Health and Safety Code Division 2.5, Section 1797.94: responsible for establishing policies and procedures within Alameda County. The LEMSA also has primary responsibility for administration of emergency medical services in a county or region, which is designated under Health and Safety Code commencing with section 1797.200.

1.2 This Agreement, dated as of the first day of January 2023, and in accordance with California Code of Regulations Title 22. Social Security; Division 9. Prehospital Emergency Medical Services; Chapter 7.1 ST-Elevation Myocardial Infarction Critical Care System (22 CCR §100270.119.), is by and between the COUNTY OF ALAMEDA, hereinafter referred to as the "COUNTY," and The Hospital Committee for the Livermore-Pleasanton Areas dba Stanford Health Care Tri-Valley, hereinafter referred to as the "Contractor."

1.3 Whereas, CONTRACTOR, in consideration of the COUNTY'S designation of CONTRACTOR as a STEMI (S-T Elevation Myocardial Infarction) Receiving Center (22 CCR § 100270.117) and Cardiac Arrest Receiving Center (SRC/CARC) as described in this document shall perform the services identified in this agreement without interruption, 24 hours per day, 7 days per week, 52 weeks per year for the full term of this Contract, as set forth in Exhibit A. Exceptions would include the lack of technology (equipment) available to perform the procedure: catastrophic plant failure or pre-planned scheduled maintenance, or an extraordinary circumstance that is beyond Contractor's reasonable control, including, without limitation, acts of war or terrorism, civil or military disturbances, nuclear or natural catastrophes, or acts of God. Contractor shall (a) provide written notice to COUNTY of the nature and extent of any such cause; and (b) use reasonable efforts to remove any

such causes and resume performance under this Agreement as soon as reasonably practicable.

1.4 Whereas, Contractor is professionally qualified to provide such services and is willing to provide the same to COUNTY.

Now, therefore it is agreed that COUNTY does hereby designate Contractor to provide STEMI and Cardiac Arrest Resuscitation and Post-Resuscitation Services, and Contractor accepts such designation as specified in this Agreement, and the following described exhibits, all of which are incorporated into this Agreement by this reference:

Exhibit A – Scope of Services

Exhibit B – Data Elements

Exhibit C – Application

Exhibit D – California Regulations: ST-Elevation Myocardial Infarction Critical Care System

1.5 The parties hereby execute the single agreement that will constitute formal designation of Contractor as a STEMI Receiving Center/Cardiac Arrest Receiving Center within the Alameda County EMS system under Health & Safety Code Sections 1797.67, 1798.170 et seq., 1797.107 and 1798.150,

Section 2 - Term

2.1 The term of this Agreement shall be from January 1, 2023, through December 31, 2025.

2.2 The current designation term expires December 31, 2022, at which time contractor shall submit a new SRC/CARC application and provide supporting documentation that reflects compliance with the requirements under 22 CCR § 100270.124. This Agreement is subject to the review and approval of the application by ALCO EMS. There will be NO interruption of service during the COUNTY EMS review/approval process for existing SRC/CARCs that are in good standing with an expired MOU.

2.3 SRC designation term will be for up to three-years with re-designation reviews by local EMS agency or other designated agency conducted at least every three years: (Exhibit D, 22 CCR § 100270.124(a)(14).

2.4 Before SRC re-designation by the local EMS agency at the next regular interval, the SRC shall be re-evaluated to meet the criteria established in these regulations: (Exhibit D, 22 CCR § 100270.124(b).)

2.5 Upon fifteen (15) days prior written notice to CONTRACTOR, the local EMS agency medical director may stipulate additional requirements: (Exhibit D, 22 CCR § 100270.124(c).)

2.6 LEMSA may suspend or revoke the SRC designation for lack of compliance with this Agreement, local EMS agency requirements or applicable laws and regulations. LEMSA may terminate this Agreement as provided under Section 5.5, Termination, below.

2.7 During the term of this agreement, it is strongly recommended that the CONTRACTOR obtain "Heart Attack" or "Cardiac" center certification by the American Heart Association/ The Joint Commission (AHA/TJC), or by another EMS approved certifying organization. This certification will be required by the second year (2027) of the following three-year contract cycle. CONTRACTOR shall obtain the appropriate level of certification that accurately reflects the patient volume and level of service they currently provide. Such certification will be required to maintain STEMI/Cardiac Arrest Receiving Center (SRC/CARC) designation by EMS.

Section 3 - Services

3.1 Contractor shall provide hospital, equipment, resources and personnel services as described in Exhibits A and D; data collection and reporting requirements as described in Exhibits A, B and D; quality improvement requirements as described in Exhibits A and D. Contractor shall participate in an annual review and adhere to compliance standards as described in Exhibits A and D. For initial EMS approval, Contractor shall complete and submit a SRC/CARC Application as described in Exhibit C. Contractor shall comply with ALL criteria in accordance with 22 CCR § 100270.124. STEMI Receiving Center Requirements as described in Exhibit D.
(ALCO EMS Policies and protocols for the ALCO SRC/CARC programs will be reviewed and revised as needed).

3.2 COUNTY shall perform all its obligations as described in this Agreement including in Exhibit A.

Section 4 - Required Reports

4.1 To the extent required by Contractor's GWTG-CAD Super User Agreement or local EMS Agency requirements, and permitted by applicable laws or regulations, Contractor shall provide data specified in Exhibits B and D for individual EMS transported patients (identified) with suspected STEMI. Contractor shall complete data pursuant to Exhibit B (b-B2) entry into GWTG-CAD registry regarding all EMS patients no later than 30 calendar days following the prior month's end. This will allow for timely access by ALCO EMS via established GWTG-CAD "Super User" agreement and must include ALL: EMS transported patients with a diagnosis of STEMI.

4.2 Contractor shall provide identified performance and clinical outcome data specified in 22CCR Section 100270.126, Exhibits B (B3-4) and D regarding individual patients transported by EMS with Cardiac Arrest and Post Cardiac Arrest. Patient specific EMS Cardiac Arrest, post-cardiac arrest and IFT follow-up data must be available to ALCO EMS and CARES as soon as possible or within 30 calendar days of receipt, request or prior month's end, and must include:

- EMS transported STEMI patients
- EMS transferred patients from SRH for STEMI and or Post-Cardiac Arrest care
- EMS Cardiac Arrest and Post Cardiac Arrest patients

4.3 Contractor shall submit aggregate data reports regarding performance and clinical outcomes in the format and timeline established by the EMS Agency in Exhibit B (B1-2)

4.4 Contractor shall submit an annual aggregate performance and clinical outcome data report in the format and timeline established by the LEMSA in Exhibit B (B1-2). Said report shall be submitted on LEMSA request for prior year respectively and present said data at requested ALCO EMS SRC/CARC Meeting.

4.5 Any data elements specified in Exhibits B and D are subject to modification/change at any time upon fifteen (15) days prior notice and review by the LEMSA and Contractor as consistent with Section 4.1 above or otherwise mandated by the State.

Section 5 – Miscellaneous / Signatory

5.1 **CONFLICTS OF INTEREST.** Contractor acknowledges that ambulances shall be directed by EMS Agency policies and procedures. Contractor and COUNTY shall comply with all applicable federal, state, and local conflict of interest laws and regulations.

5.2 Confidentiality and Privacy. Each party agrees to comply with applicable state and federal privacy laws and regulations.

5.3 **DISPUTE RESOLUTION**

5.3.1 Contractor shall identify specific individuals and provide their contact information for those who are authorized to assist the EMS Agency with dispute resolution under this Agreement.

5.3.2 Contractor is encouraged to resolve normal day-to-day operational concerns directly with involved parties, such as other EMS System providers and hospitals. If a dispute is not resolved at this level, the Contractor may refer the dispute to the Director of the EMS Agency or his or her designee for further review and action.

5.4 **TERMINATION**

5.4.1 Termination for Convenience. Either party may terminate this Agreement, either in whole or in part, for convenience at any time without penalty or liability by giving 90 days prior written notice specifying the effective date and scope of such termination.

5.4.2. Termination for Cause. In the event that the COUNTY reasonably determines that the cause for termination poses a danger to health or safety, the COUNTY may, in its sole and absolute discretion, to immediately terminate this Agreement without penalty upon issuing written notice to HOSPITAL.

5.5 ENTIRE AGREEMENT

This Agreement contains the entire agreement between the parties relating to the rights granted and the obligations assumed by the parties with respect to the subject matter hereof. This Agreement supersedes all prior and contemporaneous agreements, either oral or in writing, with respect to the subject matter hereof.

5.6 **NO THIRD PARTY RIGHTS**

No provision in this Agreement shall be construed to confer any rights to any third person or entity.

5.7 **INDEPENDENT PROVIDER STATUS**

This Agreement is not intended, and shall not be construed, to create the relationship of agent, servant, employee, partnership, joint venture, or association, between either party to this Agreement. Contractor understands and agrees that all Contractor employees rendering services under this Agreement are, for purposes of Workers' Compensation liability, employees solely of the Contractor and not of COUNTY.

5.8 **SEVERABILITY**

Should any part of this Agreement be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect the validity of the remainder of the contract which shall continue in full force and effect, provided that such remainder can, absent the excised portion, be reasonably interpreted to give the effect to the intentions of the parties.

5.9 **GOVERNING LAW; VENUE**

This Agreement has been executed and delivered in, and shall be construed and enforced in accordance with, the laws of the State of California. Subject to California law, adjudication of any and all legal claims regarding breach or performance of this Agreement shall be heard in a court of competent jurisdiction in the County of Alameda, California (and, to the extent applicable, the appellate courts with jurisdiction over such courts).

5.10 **WAIVER**

No delay or failure to require performance of any provision of this Agreement shall constitute a waiver of that provision as to that or any other instance. Any waiver granted by a party must be in writing and shall apply to the specific instance expressly stated.

5.11 **NOTICES**

Any and all notices required, permitted, or desired to be given hereunder by one party to the other shall be in writing and shall be delivered to the other party personally or by

United States mail, certified or registered, postage prepaid, return receipt requested, to the parties at the following addresses and to the attention of the person named.

Notices to COUNTY shall be addressed as follows:
EMS Agency Director or Designee:
Specialty Systems of Care Coordinator
Alameda County Emergency Medical Services
1000 San Leandro Blvd, Suite 200
San Leandro, Ca. 94577

Notices to Contractor shall be addressed as follows:
Stanford Health Care Tri-Valley
5575 W. Las Positas Blvd, #300
Pleasanton, CA 94588
Attention: Chief Executive Officer
With a copy to:
Stanford University
Office of the General Counsel
Main Quad, Building 170
Stanford, CA 94305
Attn: Stanford Health Care Tri-Valley Counsel

5.12 **COUNTERPARTS**

This Agreement may be executed in one or more counterparts, each of which shall be considered an original, but all of which together shall constitute one and the same instrument.

5.13 **SIGNATORY**

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

COUNTY OF ALAMEDA

DocuSigned by:
William McClurg
AF0BFE397A6C49D...

By: _____
Signature

Name: William McClurg
(Printed)

Title: Deputy EMS Director

Approved as to Form:
DocuSigned by:
K. Joon Oh
EFDCE3E661894A0...

By: _____
K. Joon Oh, Deputy County Counsel

CONTRACTOR

_____
Hospital Name

Tracey Lewis Taylor
Tracey Lewis Taylor (Jan 22, 2023 13:10 PST)

By: _____
Signature

Name: Tracey Lewis Taylor
(Printed)

Title: COO

Date: ~~Jan 22, 2023~~

By signing above, signatory warrants and represents that he/she executed this Agreement in his/her authorized capacity and that by his/her signature on this Agreement, he/she or the entity upon behalf of which he/she acted, executed this Agreement.

EXHIBIT A – SCOPE OF SERVICES

1. SCOPE OF SERVICES: STEMI Receiving Center (SRC)
(Exhibit D22 CCR § 100270.117.)

Contractor shall:

1.1 Provide services as a SRC. "STEMI receiving center" or "SRC" means a licensed general acute care facility that meets the minimum hospital STEMI care requirements pursuant to 22 CCR § 100270.124 and is able to perform PCI. SRC must be able to provide all services, equipment, and personnel including maintenance of adequate staffing levels, equipment, and facilities according to STEMI/Cardiac Arrest Receiving Center designation criteria which is described in Exhibits A and D.

1.2 Accept all Alameda County EMS patients triaged as having a suspected STEMI and or suffer from Cardiac Arrest and transported to Contractor's facility. Provide appropriate medical management for said patients without regard to the race, color, national origin, religious affiliation, age, sex, or ability to pay.

1.3 Contractor shall participate in an annual review regarding modifications of any and compliance with ALL sections as described in Exhibit A and a review for Exhibit D at least once every three years.

2. HOSPITAL SERVICES: 22 CCR § 100270.124. STEMI Receiving Center Requirements, in addition, Cardiac Arrest Receiving Center Requirements:

(a) The following minimum criteria shall be used by the local EMS agency for the designation of a STEMI receiving center:

(1) The hospital shall have established protocols for triage, diagnosis, and Cath lab activation following field notification.

(2) The hospital shall have a single call activation system to activate the Cardiac Catheterization Team directly.

(3) Written protocols shall be in place for the identification of STEMI patients.

(A) At a minimum, these written protocols shall be applicable in the intensive care unit/coronary care unit, Cath lab and the emergency department.

(4) The hospital shall be available for treatment of STEMI patients twenty-four (24) hours per day, seven (7) days per week, three hundred and sixty-five (365) days per year.

(5) The hospital shall have a process in place for the treatment and triage of simultaneously arriving STEMI patients.

(6) The hospital shall maintain STEMI team and Cardiac Catheterization Team call rosters.

(7) The Cardiac Catheterization Team, including appropriate staff determined by the local EMS agency, shall be immediately available.

(8) The hospital shall agree to accept all STEMI patients according to the local policy.

(9) STEMI receiving centers shall comply with the requirement for a minimum volume of procedures for designation required by the local EMS agency: 36 PPCI/Year (including EMS transports and walk-ins)

(10) The hospital shall have a STEMI program manager and a STEMI medical director.

(11) The hospital shall have job descriptions and organizational structure clarifying the relationship between the STEMI medical director, STEMI program manager, and the STEMI team.

(12) The hospital shall participate in the local EMS agency quality improvement processes related to a STEMI critical care system.

(13) A STEMI receiving center without cardiac surgery capability on-site shall have a written transfer plan and agreements for transfer to a facility with cardiovascular surgery capability.

(14) A STEMI receiving center shall have reviews by local EMS agency or other designated agency conducted every three years.

(b) A STEMI center designated by the local EMS agency prior to implementation of these regulations may continue to operate. Before re-designation by the local EMS agency at the next regular interval, STEMI centers shall be re-evaluated to meet the criteria established in these regulations.

(c) Additional requirements may be stipulated by the local EMS agency medical director.

In addition to abiding by the requirements above, Contractor shall keep in effect the following:

2.1 Licensure under California Health and Safety Code Section 1250 et seq.

2.2 Permit for Basic or Comprehensive Emergency Medical Services pursuant to the provisions of Title 22, Division 5, of the California Code of Regulations,

2.3 Cardiac Catheterization Laboratory as a supplemental service pursuant to the provisions of Title 22, Division 5, of the California Code of Regulations,

2.4 Intra-aortic balloon pump capability with necessary staffing available,

2.5 Electronic ability (computer and software) to receive diagnostic quality 12-lead ECG's transmitted by prehospital personnel prior to suspected STEMI patient arrival at that SRC/CARC (not to be used for consult, unless SRC/CARC is an approved EMS Base Station),

2.6 Designated priority telephone line to be used by prehospital personnel to contact the SRC/CARC regarding patients with suspected STEMI that are being transported to that facility for potential intervention,

2.7 Cardiovascular Surgery availability.

- 2.7.1 California permit for cardiovascular surgery; or,
- 2.7.2 A plan for emergency transport to a facility with cardiovascular surgery available that describes steps for timely transfer (within 1 hour).

2.8 Equipment and staffing to provide:

- 2.8.1 Resuscitation for cardiopulmonary arrest including mechanical options.
- 2.8.2 Targeted Temperature Management (TTM) in ED and ICU 24/7.
- 2.8.3 Emergent PCI 24/7.
- 2.8.4 Post-resuscitation care for cardiac arrest (uniform approach).
- 2.8.5 Ventilator support/strategies.
- 2.8.6 EEG monitoring.
- 2.8.7 Cardiac arrest consultation service (to be determined).
- 2.8.8 Neurology Consultation (automatic/uniform).
- 2.8.9 Neurosurgical Consultation (automatic/uniform).
- 2.8.10 Organ Procurement Consultation (uniform approach);
- 2.8.12 Electrophysiology Consultation (automatic/uniform).
- 2.8.13 Social Work Consultation (automatic/uniform).
- 2.8.14 Inpatient physical and or occupational therapy (automatic/uniform).
- 2.8.15 Outpatient physical and or occupational therapy (patient specific).
- 2.8.16 Outpatient neurological rehabilitation.
- 2.8.17 Outpatient psychological services
- 2.8.18 CPR training: Professional, community and patient's family on discharge.

3. HOSPITAL PERSONNEL: 22 CCR § 100270.120. STEMI Team

Contractor shall provide program oversight staff and shall have available all staff necessary to perform optimal care for patients with STEMIs, including the following:

3.1 SRC Program Medical Director (Exhibit D, 22 CCR § 100270.113.)

3.1.1. **Qualifications**:

- Board Certified in Cardiology or Cardiothoracic Surgery,
- Board Certified in Interventional Cardiology (desired),
- Credentialed member of medical staff with privileges for primary percutaneous coronary intervention (PCI).

3.1.2. **Responsibilities**:

- Oversight of STEMI program patient care,
- Coordination of staff and services,
- Authority and accountability for quality and performance improvement,
- Participation in protocol development,
- Establish and monitor quality control, including Mortality and Morbidity, and,
- Participation in County STEMI system QI Committee meeting .

3.2 SRC Program Manager (Exhibit D, 22 CCR § 100270.116.)

3.2.1. **Qualifications**:

- STEMI patient / program experience (ED, ICU, CCU, Cath. Lab.).

3.2.2. **Responsibilities**:

- Supports SRC Medical Director Functions
- Acts as EMS-STEMI Program Liaison
- Assures EMS-Facility STEMI data sharing
- Manages EMS-Facility STEMI QI activities
- Authority and accountability for QI/PI

3.3 CARC Program Medical Director

3.3.1 **Qualifications**:

- Board Certified in Emergency Medicine; or,
- Board Certified in Cardiology; or,
- Board Certified in Intensive Care / Critical Care, or Pulmonology.

3.3.2 **Responsibilities**:

- Oversight of CARC program patient care,
- Coordination of staff and services,
- Authority and accountability for quality and performance improvement,
- Participation in protocol development,
- Establish and monitor quality control, including Mortality and Morbidity, and,
- Participate in County SRC/CARC QI meetings.

3.4 **CARC Program Manager**

3.4.1 **Qualifications**:

- Cardiac Arrest and Post Cardiac Arrest patient experience (ED, ICU, CCU).

3.4.2 **Responsibilities**:

- Supports CARC Medical Director Functions
- Acts as EMS-CARC Program Liaison
- Assures EMS-Facility CARC data sharing
- Manages EMS-Facility CARC QI activities
- Authority and accountability for QI/PI

3.5 **Physician Consultants** - Hospital shall maintain a daily on-call roster of:

3.5.1 Cardiologist(s) with PCI privileges and evidence of training/experience in PCI including primary PCI.

3.5.2 Cardiovascular Surgeon(s) if cardiovascular surgery is a service provided by Hospital.

3.5.3 Intensivist(s) / Critical Care

3.5.4 Neurologist(s)

3.5.5 Neurosurgeon (s) if Neurosurgery is a service provided by Hospital.

3.6 **Additional personnel**:

3.6.1 Intra-aortic balloon pump technician(s) / staff,

3.6.2 Cardiac catheterization lab manager/coordinator

3.6.3 Appropriate cardiac catheterization nursing and support personnel.

4. PERFORMANCE STANDARDS

4.1 Contractor shall strive to meet the following goals and current evidence-based recommendations regarding in caring for patients who present to Hospital with identified STEMI:

- Fibrinolysis within 30 minutes of ED arrival if administered.
- PCI "Door-to-Intervention" time ≤90 minutes of ED arrival at primary SRC.
- Patients that cannot get to the Cath-lab within 30 minutes of arrival at the primary SRC or receive intervention ≤90 minutes require emergent interfacility transfer (IFT) to the next closest SRC. This should preferably be facilitated by 911 or Critical Care Transport (CCT) if immediately available and warranted for transport.
- STEMI patients that present at a non-SRC require emergent interfacility transfer (IFT) to the closest SRC. This should preferably be facilitated by 911 or Critical Care Transport (CCT) if immediately available and warranted for transport. Time from patient ED arrival at SRH to PCI at SRC should be ≤120 minutes.

- SRC establishing written agreements with geographically surrounding non-STEMI hospitals: STEMI Referring Hospital (SRH) in attempt to improve continuity of care and expedite emergent transfer of the STEMI patient.

4.2 Contractor shall strive to meet the current evidence-based recommendations in caring for patients who present to Hospital with Cardiac Arrest or Post-Cardiac Arrest:

a) Resuscitation for cardiopulmonary arrest.

b) Post-resuscitation TTM.

c) Emergent cardiac catheterization for persistent/recurrent cardiac arrest and post cardiac arrest.

d) Hemodynamic/metabolic support and monitoring post cardiac arrest.

e) Prognostication post cardiac arrest interventions. This should include EEG monitoring for comatose patients.

f) Electrophysiology testing and AICD placement as appropriate.

g) Organ procurement/donation.

h) Rehabilitation: cardiac, physical, speech, occupational and others needed.

i) CPR training: Professional, community and hospital discharge (patient's family).

5. HOSPITAL POLICIES AND PROCEDURES (Exhibit D, 22 CCR § 100270.124.)

Contractor shall develop and implement policies and procedures designed to assure that patients presenting to their facility with possible STEMI and or Cardiac Arrest / Post cardiac Arrest receive appropriate care in a timely manner. Such internal policies shall include but are not limited to:

5.1 Definition of patients with defined inclusion criteria that shall receive emergent angiography and patients who shall receive emergent fibrinolysis, based on physician decision for individual patients.

5.2 Processes by which fibrinolytic therapy or PCI (including prompt activation of personnel) can be delivered rapidly to meet Performance Standards identified in this Contract.

5.3 For hospitals without cardiovascular surgery services, written arrangements with a tertiary institution that provides for rapid transfer of patients for any required additional care, including elective or emergency cardiac surgery or PCI.

5.4 Standardized written agreements with referral hospitals by which the expeditious transfer and acceptance of STEMI and or Post-Cardiac Arrest patients can occur.

5.5 Standardized written guidelines / protocol regarding TTM with inclusion criteria for patient selection.

5.6 Standardized written guidelines / protocol regarding emergent PCI with inclusion criteria for post cardiac arrest patients.

5.7 Standardized written order set / protocol for ED and ICU care regarding post ROSC patients.

5.8 Standardized written guidelines / protocol regarding an appropriate process and timing for neurologic prognostication of post cardiac arrest patients.

5.9 Standardized written guidelines / protocol regarding the appropriate use of electrophysiology testing and placement of AICD for post cardiac arrest patients.

5.10 Sharing of EMS patient specific cardiac arrest outcome data with the Alameda County EMS Agency by participating in CARES.

5.11 Required availability of at least ONE mechanical CPR device (preferably LUCAS device with radiolucent back plate for the use in Cath-lab if needed).

5.12 Standardized written guidelines / protocol regarding a comprehensive cardiac arrest consultation service (for patient and family).

5.13 During the term of this contract, the Contractor shall establish a written agreement with at least one Bay Area hospital that agrees to accept and provide ECMO services for warranted patients. These patients may include but are not limited to cardiogenic shock as well as refractory cardiac arrest. If the receiving ECMO facility does not have a formal ECMO-TO-GO program, the contractor may establish a written agreement with a third-party service that can provide timely response, treatment and transfer for patients that require this higher level of specialty critical care. This requirement shall terminate at such time that the Contractor independently provides said service.

6. DATA MANAGEMENT AND REPORTING (Exhibit D, 22 CCR § 100270.126.)

(a) The local EMS agency shall implement a standardized data collection and reporting process for a STEMI critical care system.

(b) The system shall include the collection of both prehospital and hospital patient care data, as determined by the local EMS agency.

(c) The prehospital STEMI patient care elements selected by the local EMS agency shall be compliant with the most current version of the California EMS Information Systems (CEMSIS) database, and the National EMS Information System (NEMSIS).

(d) All hospitals that receive STEMI patients via EMS shall participate in the local EMS agency data collection process in accordance with local EMS agency policies and procedures.

(e) The prehospital care record and the hospital data elements shall be collected and submitted to the local EMS agency, and subsequently to the EMS Authority, on no less than

a quarterly basis and shall include, but not be limited to, the following:

(1) The STEMI patient data elements:
- (A) EMS ePCR Number.
- (B) Facility.
- (C) Name: Last, First.
- (D) Date of Birth.
- (E) Patient Age.
- (F) Patient Gender.
- (G) Patient Race.
- (H) Hospital Arrival Date.
- (I) Hospital Arrival Time.
- (J) Dispatch Date.
- (K) Dispatch Time.
- (L) Field ECG Performed.
- (M) 1st ECG Date.
- (N) 1st ECG Time.
- (O) Did the patient suffer out-of-hospital cardiac arrest.
- (P) CATH LAB Activated.
- (Q) CATH LAB Activation Date.
- (R) CATH LAB Activation Time.
- (S) Did the patient go to the CATH LAB.
- (T) CATH LAB Arrival Date.
- (U) CATH LAB Arrival Time.
- (V) PCI Performed.
- (W) PCI Date.
- (X) PCI Time.
- (Y) Fibrinolytic Infusion.
- (Z) Fibrinolytic Infusion Date.
- (AA) Fibrinolytic Infusion Time.
- (BB) Transfer.
- (CC) SRH ED Arrival Date.
- (DD) SRH ED Arrival Time.
- (EE) SRH ED Departure Date.
- (FF) SRH ED Departure Time.
- (GG) Hospital Discharge Date.
- (HH) Patient Outcome.
- (II) Primary and Secondary Discharge Diagnosis.

(2) The STEMI System data elements:
- (A) Number of STEMIs treated.
- (B) Number of STEMI patients transferred.
- (C) Number and percent of emergency department STEMI patients arriving by private transport (non-EMS).
- (D) The false positive rate of EMS diagnosis of STEMI, defined as the

percentage of STEMI alerts by EMS which did not show STEMI on ECG reading by the emergency physician.

6.1 As further specified in Exhibit B, Contractor shall collect on-going aggregate data (de-identified) for patients below, submit and present to Alameda County Emergency Medical Services for annual review:

a) Number of patients identified with possible STEMI transported from the field by EMS for intervention.

b) Number of above patients who received primary PCI.

c) Number of patients identified with possible STEMI, transferred (IFT) by EMS from another acute care hospital ED (RH) to SRC for intervention.

d) Number of above patients who received primary PCI (IFT)

e) Number of SRC walk-in patients identified in ED with possible STEMI.

f) Number of above patients (walk-in) who received primary PCI.

g) For ALL STEMI patients door-to-infusion time (median) for fibrinolysis; and, door-to-intervention time (median) for primary PCI. (EMS, IFT by EMS, SRC walk-in)

h) Contractor shall collect and provide data to the National Cardiovascular Data Registry (NCDR) using CathPCI and or American Heart Association (AHA) Get With The Guidelines Coronary Artery Disease (GWTG CAD) database. Use of GWTG-CAD and ALCO EMS "Super User" "Read-only" access to contractor's GWTG-CAD data is mandatory for CA State EMSA data reporting.

i) Provide ALCO EMS non-specific, de-identified, aggregate NCDR rolling quarterly data via **Executive Summary** report on request.

j) PCI volumes (number)/year by Cardiologist (de-identified).

6.2 Support and facilitate the implementation of future data elements related to STEMI and Cardiac Arrest Resuscitation and Post-Resuscitation system performance and quality improvement strategies.

6.3 Provide data for individual EMS transported patients with suspected STEMI and or Cardiac Arrest. Patient specific Follow-Up data must be available to ALCO EMS as soon as possible after patient encounter or within 30 calendar days of previous months end, and must include ALL data elements required by § 100270.126:

- EMS transported STEMI patients (GWTG-CAD)

- EMS transferred patients from RH for STEMI (GWTG-CAD) and or Post-Cardiac Arrest (CARES).
- EMS Cardiac Arrest and Post Cardiac Arrest patients (CARES)

6.4 As further specified in Exhibit B and in accordance with Contractor's CARES agreement, Contractor shall collect and provide CARES with the following cardiac arrest hospital outcome data that includes but not limited to current CARES hospital specific data elements:

a) Emergency Department outcome

b) Was hypothermia care initiated/continued in the hospital?

c) Hospital outcome

d) Discharge from the hospital

e) Neurological outcome at discharge from hospital

f) Was final diagnosis acute myocardial infarction?

g) Coronary Angiography performed?

h) Was a cardiac stent placed?

i) CABG performed?

j) Was an ICD placed and/or scheduled?

6.5 The data further specified in Exhibits B1-4 shall be provided to the EMS Agency in the timeline and manner defined, until a Bidirectional Healthcare Data Exchange (BHDE) network is established between County EMS and the SRC/CARC Contractor.

6.6 The Contractor and County EMS are both fully committed to establishing a Bidirectional Healthcare Data Exchange (BHDE) during the Term of this Agreement.

6.7.1 The Contractor and County EMS will collaborate and agree in the design, and implementation of the BHDE on an agreed upon timeframe.

6.7.2 The development of the BHDE shall address the Contractor's information security standards.

6.7.3 The cost to establish the BHDE network between County EMS and the Contractor shall be fairly shared by apportionment as agreed upon by both parties.

6.7.4 When BHDE details are finalized, Agreement will be amended to add agreed terms as an appendix to this Agreement.

6.7 The BHDE network established between County EMS and the Contractor must be interoperable with other data systems, including the functionality to exchange electronic patient health information in real-time with other entities in an HL7 format.

6.8 The BHDE network is expected to address the following components (with details to be agreed by the parties):

6.9.1 Search a patient's health record for problems, medications, allergies, and end of life decisions to enhance clinical decision-making;

6.9.2 Alert the receiving hospital regarding the patient's status directly onto a dashboard in the emergency department to provide decision support;

6.9.3 File the EMS Patient Care Report data directly into the patient's electronic health record for timely and longitudinal patient care documentation;

6.9.4 Reconcile the electronic health record information including diagnoses and disposition back into the EMS patient care report for use in ensuring timely provider feedback and enhanced quality improvement strategies for the County EMS system.

6.9 Any access to, or exchange of, individually identifiable health information or protected health information shall comply with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HiTECH).

7. QUALITY IMPROVEMENT AND EVALUATION PROCESS (Exhibit D, 22 CCR § 100270.127.)

(a) Each STEMI critical care system shall have a quality improvement process that shall include, at a minimum:

(1) Evaluation of program structure, process, and outcome.

(2) Review of STEMI-related deaths, major complications, and transfers.

(3) A multidisciplinary STEMI Quality Improvement Committee, including both prehospital and hospital members.

(4) Participation in the QI process by all designated STEMI centers and prehospital providers involved in the STEMI critical care system.

(5) Evaluation of regional integration of STEMI patient movement.

(6) Compliance with the California Evidence Code, Section 1157.7 to ensure confidentiality, and a disclosure-protected review of selected STEMI cases.

(b) The local EMS agency shall be responsible for on-going performance evaluation and quality improvement of the STEMI critical care system.

7.1 STEMI/Cardiac Arrest Receiving Center Program staff shall participate in Alameda County EMS quarterly SRC/CARC QI Committee meetings, with a minimum attendance requirement of two / year. Each SRC/CARC shall provide at minimum, multi-disciplinary representation including one decision-making representative from Emergency Medicine, Cardiology and Critical Care at every meeting attended.

7.2 Hospital shall maintain a written internal quality improvement plan for STEMI, Cardiac Arrest and Post Cardiac Arrest patients that includes, but is not limited to the determination and evaluation of:

a) Death rate
b) Complications
c) Sentinel events
d) System issues
e) Organizational issues and resolution processes

7.3 Hospital shall support EMS Agency QI activities including educational activities for prehospital personnel.

7.4 CONTRACTOR shall provide a minimum of one hour of annual EMS education/training (virtual or in person). EMS education should focus on the recognition, treatment, and transport of Acute Coronary Syndromes (ACS): including but not limited to ST-Elevation Myocardial Infarction (STEMI), Non-ST-Elevation ACS (NSTE-ACS) and ACS mimics.

7.5 STEMI/Cardiac Arrest Receiving Center Program staff shall actively participate in system wide consortium meetings of Alameda County Cardiac Arrest Receiving Centers. This consortium will have the mission and intention to standardize clinical strategies and protocols regarding the care of post-OHCA patients. Each SRC/CARC shall provide at minimum, one decision-making representative from the ED, Cardiology and the ICU at every meeting.

8. COMPLIANCE

8.1 Contractor shall provide ongoing and consistent Oversight for ALL sections pertaining to Services and quality of care as described in Exhibit A and for Exhibit D.

8.2 Contractor shall advise ALCO EMS immediately regarding any changes that would result in material non-compliance with any section pertaining to Services or quality of care in Exhibit A.

8.3 Contractor shall participate in an annual review regarding modifications of any and compliance with ALL sections as described in Exhibit A and a three-year review for Exhibit D.

8.4 Material failure by Contractor to comply with any section(s) as described in Exhibit A, B and D may result in the loss of EMS STEMI and or Cardiac Arrest/Post-Cardiac Arrest patients transported to contractor's SRC/CARC for potential intervention

until compliance issue(s) is resolved.

9. PREHOSPITAL STEMI CRITICAL CARE SYSTEM REQUIREMENTS (Exhibit D, Article 3. § 100270.123. EMS Personnel and Early Recognition)

(a) The local EMS agency with an established STEMI critical care system shall have protocols for the identification and treatment of STEMI patients, including paramedic performance of a 12-lead ECG and determination of the patient destination.

(b) The findings of 12-lead ECG shall be assessed and interpreted through one or more of the following methods:

(1) Direct paramedic interpretation.

(2) Automated computer algorithm.

(3) Wireless transmission to facility followed by physician interpretation or confirmation.

(c) Notification of prehospital ECG findings of suspected STEMI patients, as defined by the local EMS agency, shall be communicated in advance of the arrival to the STEMI centers according to the local EMS agency's STEMI Critical Care System Plan.

County shall also keep in effect the following:

9.1 Make electronic prehospital patient care records available to Contractor via computer for all STEMI and/or Cardiac Arrest patients taken by 911 ambulance to Contractor's facilities.

9.2 Maintain the confidentiality of all patient information and data (includes de-identified data) provided by Contractor and use such information solely for the local EMS Agency's internal quality improvement, peer review and oversight functions as mandated/authorized by law or regulation. County also agrees to not identify Contractor by name in any aggregate report of the data or release any reports or data showing individual hospital performance unless agreed to by contractor or required by law. Notwithstanding anything in this Agreement to the contrary, the parties acknowledge and agree that Contractor shall not be required to disclose any patient information or other data to the COUNTY to the extent not otherwise permitted or required by applicable laws or regulations.

9.3 Provide to Contractor and/or the STEMI/CARC Quality Improvement Committee prehospital system data, including patient destination data, related to STEMI and Cardiac Arrest/Post- Cardiac Arrest care.

9.4 Meet and consult with Contractor prior to the adoption of any policy or procedure that concerns the administration of the STEMI and Cardiac Arrest/Post-Cardiac Arrest Care System, STEMI/Cardiac Arrest public education efforts or the triage, transport and treatment of STEMI/Cardiac Arrest/Post-Cardiac Arrest patients.

9.5 In order to improve quality of care, direct 911 ambulance transport providers to inform hospital of identification of patients determined to have STEMI and/or have experienced Cardiac Arrest prior to the patient's arrival at hospital.

9.6 Transport suspected STEMI, Cardiac Arrest and Post-Cardiac Arrest patients to Contractor in accordance with County EMS field assessment, treatment and transport protocols.

10. OBLIGATIONS of County

10.1 County shall comply with all County obligations set forth herein.

10.2 County shall provide or cause to be provided to Contractor system data related to prehospital care that County determines shall contribute to continuous quality improvement, provided, however, that this subsection shall not confer any right to Contractor to receive or demand system data from County.

10.3 County shall develop and promulgate medical control policies and EMS System procedures consistent with applicable federal and state statutes and regulations, and County ordinances.

10.4 County shall administer and coordinate the EMS System consistent with the Emergency Medical Services System and the Prehospital Emergency Medical Care Personnel Act, codified in California Health and Safety Code Division 2.5.

10.5 County shall use its best efforts to procure funding to maintain the EMS System, including actively seeking grant funding at the federal, state, and local levels.

10.6 County shall provide Contractor with standardized EMS System policies and/or protocols as contained in the Alameda County policies as amended from time to time. Whenever reasonably possible, County shall provide Contractor with adequate time to plan, budget and train personnel affected by changes in EMS policies, procedures, clinical protocols or other EMS plans.

EXHIBIT B – DATA ELEMENTS

As set forth in Section 4 of this Agreement and in Section 6 of Exhibit A to the Agreement, Contractor shall provide the specified data elements in the formats established by the ALCO EMS Agency and included in this Exhibit B: (B-1, B-2, B-3, etc.)

B-1

Contractor shall collect continuous aggregate (de-identified) performance measures using data elements below, submit and present to ALCO EMS on an annual basis at ALCO SRC/CARC meeting: (6.1.1-6.1.7)

B1

Alameda County EMS SRC Annual Performance Data

1. # of patients identified by EMS STEMI ALERT and transported to SRC?

1a. # of patients identified by EMS STEMI ALERT and transported to SRC who went for emergency angiography?

1b. # of patients identified by EMS STEMI ALERT and transported to SRC who received primary PCI?

1c. Median time to PCI for patients identified by EMS STEMI ALERT and transported to SRC who received primary PCI?

2. # of patients identified by from another acute care hospital ED with possible STEMI and transferred (IFT) to SRC?

2a. # of patients identified by from another acute care hospital ED with possible STEMI and transferred (IFT) to SRC who received primary PCI?

2b. Median time to PCI for patients identified by from another acute care hospital ED with possible STEMI and transferred (IFT) to SRC who received primary PCI?

3. # of walk-in SRC patients identified in ED with possible STEMI?

3a. # of walk-in SRC patients identified in ED with possible STEMI who received primary PCI?

3b. Median time to PCI for walk-in SRC patients identified in ED with possible STEMI who received primary PCI?B-2Contractor shall collect continuous aggregate (de-identified) performance measures using NCDR data elements from either CathPCI and submit to ALCO EMS for review on request via NCDR CathPCI "EXECUTIVE SUMMARY": (6.1.8-6.1.9)

B-2

Contractor shall provide SRC performance and clinical outcome data for individual EMS patients transported with suspected STEMI. Patient specific Follow-Up data shall include data elements required by22 CCR § 100270.126.) and shall be entered into GWTG-CAD registry for timely ALCO EMS "read-only" access via "Super User" agreement. EMS patients shall be identified by a unique

incident number provided by EMS and entered by SRC (6).

B2

STEMI Activation / IFT Follow-up

(1) The STEMI patient data elements:

(A) EMS ePCR Number.
(B) Facility.
(C) Name: Last, First.
(D) Date of Birth.
(E) Patient Age.
(F) Patient Gender.
(G) Patient Race.
(H) Hospital Arrival Date.
(I) Hospital Arrival Time.
(J) Dispatch Date.
(K) Dispatch Time.
(L) Field ECG Performed.
(M) 1st ECG Date.
(N) 1st ECG Time.
(O) Did the patient suffer out-of-hospital cardiac arrest.
(P) CATH LAB Activated.
(Q) CATH LAB Activation Date.
(R) CATH LAB Activation Time.
(S) Did the patient go to the CATH LAB.
(T) CATH LAB Arrival Date.
(U) CATH LAB Arrival Time.
(V) PCI Performed.
(W) PCI Date.
(X) PCI Time.
(Y) Fibrinolytic Infusion.
(Z) Fibrinolytic Infusion Date.
(AA) Fibrinolytic Infusion Time.
(BB) Transfer.
(CC) SRH ED Arrival Date.
(DD) SRH ED Arrival Time.
(EE) SRH ED Departure Date.
(FF) SRH ED Departure Time.
(GG) Hospital Discharge Date.
(HH) Patient Outcome.
(II) Primary and Secondary Discharge Diagnosis.

Exceptions for delay to PCI:

(V-Fib/D-Fib, Cardiac arrest/CPR, Intubation, CT r/o head bleed, TEE r/o aortic dissection)

EMS Patient Inclusion Criteria (STEMI Activation / ITF follow-up)

All patients who:

have a prehospital ECG interpreted by EMS as suspected STEMI/equivalent and transported to a PCI capable hospital (SRC) for potential intervention; **OR,**

are in the ED of an acute care hospital without PCI capability (RH), have an ECG interpreted as STEMI/equivalent and are transferred by EMS to a PCI-capable hospital (SRC) for potential intervention; **OR,**

have experienced witnessed out-of-hospital sudden cardiac arrest (SCA) of suspected cardiac etiology, or with an initial EMS ECG rhythm of V/F or V/T, or were shocked by AED prior to EMS arrival, or have return of spontaneous circulation with an ECG interpreted as STEMI/equivalent following SCA and transported to a PCI capable hospital (SRC) for potential intervention.

B-3

Contractor shall provide clinical outcome data for individual EMS patients transported with suspected Cardiac Arrest and or Post Cardiac Arrest. Patient specific Follow-Up data shall include but not be limited to data elements listed below and shall be collected and sent to CARES via designated SECURE website as soon as possible following patient encounter or within 30 calendar days of receipt of patient follow-up list sent by CARES. (6.5)

CARES HOSPITAL DATASET FOR CARDIAC ARREST / POST CARDIAC ARREST

EMERGENCY Department OUTCOME

Description

- The final disposition of the patient from the emergency department.
- This variable will be used to quantify the outcome of the patient from emergency department specifically. It will be used to differentiate the outcome in the field (EMS resuscitation) and the outcome from the hospital (hospital survival) from the outcome in the emergency department.

Instructions for Coding

- This variable should not be left blank. All the information from the EMS trip sheet and patient medical record should be used to complete this data field.
- If "Transferred to another acute care facility from the emergency department" (Code 4) is selected,

the destination hospital should be documented using the corresponding drop-down menu. If a transfer hospital is not selected, CARES will prompt the user to choose one from the drop-down menu or to type the name of the facility (if not listed) in the comments box.

- Codes for hospitals receiving transfers are established through the CARES registry for each particular EMS Agency. Contact the CARES Coordinator if the correct hospital is not located on the drop-down menu.

Field Values:

Code	Definition
1	Resuscitation terminated in ED
2	Admitted to hospital
3	Transferred to another acute care facility from the emergency department

Examples:

Example	Appropriate Code/Value
Patient was received in the ED after successful resuscitation in the field by EMS personnel. Patient blood pressure was labile upon receiving in the ED and continued to deteriorate…..Patient was pronounced dead in the ED 20 minutes after arrival.	1 – Resuscitation terminated in ED
Patient was received in the ED after successful resuscitation in the field by EMS personnel. Patient blood pressure was adequate upon receiving in the ED and continued to improve after the addition of Dopamine…Patient was transported to the CCU.	2 – Admitted to hospital
Patient was received in the ED with ongoing resuscitation by EMS personnel. Patient was stabilized in the ED after the addition of Dopamine…..Patient was transported to Pine Valley Tertiary Care Hospital for further intervention.	3 – Transferred to another acute care facility from the emergency department

WAS HYPOTHERMIA CARE INITIATED/CONTINUED IN THE HOSPITAL

Description

- Hypothermia care is provided in the hospital if measures were taken to reduce the patient's body temperature by either non-invasive means (administration of cold intravenous saline, external cold pack application to armpits and groin, use of a cooling blanket, torso vest or leg wrap devices) or by invasive means (use of a cooling catheter inserted in the femoral vein).

Instructions for Coding

- Indicate "Yes" or "No"
- Indicate whether hypothermia procedures (e.g. external cooling-ice packs or cooling blankets/pads and internal cooling – cold IV fusion or invasive catheter lines for internal cooling) were performed in ED.
- If the patient is admitted or transferred, then this field is required.
- This field should not be left blank, even if a facility is not providing hypothermia. If hypothermia is
  not being provided, then "No" should be selected.
- In the case of a transfer, this field should be completed by the original destination hospital.

Field Values:

Code	Definition
1	Yes
2	No

HOSPITAL OUTCOME

Description

- The final disposition of the patient from the hospital.
- This variable will be used to quantify the outcome of the patient from the hospital.

Instructions for Coding

- This variable should not be left blank. All the information from patient medical record and discharge summary should be used to complete this data field.
- If "Transferred to another acute care facility" (Code 4) is selected, the destination hospital should be documented using the corresponding drop-down menu. If a transfer

hospital is not selected, CARES will prompt the user to choose one from the drop-down menu or to type the name of the facility (if not listed) in the comments box.

- If "Patient has not been disposed" (Code 8) is selected, the patient will remain in the hospital's inbox until the patient has been discharged and a final outcome has been selected.
- Codes for hospitals receiving transfers are established through the CARES registry for each particular EMS Agency. Contact the CARES Coordinator if the correct hospital is not located on the drop-down menu.

Field Values:

Code	Definition
1	Died in the Hospital
2	Discharged Alive
3	Patient made DNR
	If yes, choose one of the following:
1	o Died in the hospital
2	o Discharged alive
3	o Transferred to another acute care hospital
4	o Not yet determined
4	Transferred to another acute care hospital
8	Not yet determined

Examples:

Example	Appropriate Code/Value
Patient was admitted to CCU after successful resuscitation from sudden cardiac arrest. Patient became unstable after 2 days in the CCU. Blood pressure could not be maintained after pharmacological support. Patient arrested at 04:30 after being admitted to the CCU Resuscitation attempts	1 – Died in the Hospital

were unsuccessful and patient was pronounced dead at 6:00.	
Patient was received in the ED after successful resuscitation in the field by EMS personnel. Patient blood pressure was adequate upon receiving in the ED and continued to improve after the addition of Dopamine…..Patient was transported to the CCU……Patient remained stable and Dopamine was weaned off in 12 hours. Patient was transferred to the floor and discharged home after one week in the hospital.	2 – Discharged Alive
Patient was admitted to CCU after successful resuscitation from sudden cardiac arrest. Patient is still in the CCU and has not yet been discharged from the hospital.	8 – Patient has not been disposed

DISCHARGE FROM THE HOSPITAL

Description

- This variable will be used to determine the type of destination and the frequency of each destination type for discharged patients.

Instructions for Coding

- If the field "Hospital Outcome" has a value of "Discharged Alive," this variable should not be left blank. All the information from patient medical record and discharge summary should be used to complete this data field.
- Rehabilitation facility is defined as an establishment for "treatment or treatments designed to facilitate the process of recovery from injury, illness, or disease to as normal a condition as possible."
- Skilled nursing facility is defined as "an establishment that houses chronically ill, usually elderly patients, and provides long-term nursing care, rehabilitation, and other services. Also called *long-term care facility*, *nursing home.* Hospice facility is defined as a providing special care for people who are near the end of their life. Note: If a patient is discharged home with hospice care, this should be coded as "Home/residence."

Field Values:

Code	Definition
1	Home/residence

2	Rehabilitation facility
3	Skilled nursing facility/Hospice

Examples:

Example	**Appropriate Code/Value**
After two weeks in the CCU following sudden cardiac arrest, and a week on the floor, the patient was discharged home with follow up orders.	1 – Home/residence
After 3 weeks in the CCU and 5 weeks on the floor patient was transported to Sunshine Rehabilitation Hospital for further treatment.	2 – Rehabilitation facility
After an extensive stay at Memorial Hospital, the patient was discharged home with severe cerebral disability in hospice care.	3 – Skilled nursing facility/Hospice

NEUROLOGICAL OUTCOME AT DISCHARGE FROM HOSPITAL

Description

- Survival without higher neurological outcome is suboptimal; therefore it is important to attempt to assess neurological outcome at discharge.
- This variable will be used to determine the frequency of neurological outcome in resuscitation survivors at the time of discharge.

Instructions for Coding

- The level of cerebral performance of the patient at the time of discharge from the hospital. The following simple, validated neurological score is referred to as the Cerebral Performance Category, CPC.
- 1 = Good Cerebral Performance – Conscious, alert, able to work and lead a normal life.
- 2 = Moderate Cerebral Disability – Conscious and able to function independently (dress, travel, prepare food), but may have hemiplegia, seizures, or permanent memory or mental changes.
- 3 = Severe Cerebral Disability – Conscious, dependent on others for daily support, functions only in an institution or at home with exceptional family effort.
- 4 = Coma, vegetative state.
- If the field "Hospital Outcome" has a value of "Discharged Alive," this variable should not be left blank. All the information from patient medical record and discharge summary should be used to complete this data field.

- If a record is coded as discharged to a 'Rehabilitation Facility' or 'Skilled Nursing Facility/Hospice' with 'Good Cerebral Performance' at time of discharge, CARES will prompt the use to clarify in the comments box.
- If a record is coded as discharged to 'Home/residence' with 'Severe Cerebral Performance' or 'Coma, vegetative state' at time of discharge, CARES will prompt the user to clarify in the comments box.

Field Values:

Code	Definition
1	Good Cerebral Performance; CPC 1
2	Moderate Cerebral Disability; CPC 2
3	Severe Cerebral Disability; CPC 3
4	Coma, vegetative state; CPC 4

Examples:

Example	Appropriate Code/Value
At discharge, patient was conscious, alert, and able to work and lead a normal life.	1 – Good Cerebral Performance
At discharge, patient was conscious and able to function independently but had some permanent memory changes.	2 – Moderate Cerebral Disability
At discharge, patient was unable to function independently with severe cognitive disability,	3 - Severe Cerebral Disability
Patient was in a vegetative state at time of discharge.	4 - Coma, vegetative state

WAS FINAL DIAGNOSIS ACUTE MYOCARDIAL INFARCTION?

Description

- Determine the number of cardiac arrests that were eventually confirmed as a myocardial infarction.

Instructions for Coding

- Indicate "Yes" or "No"
- In the case of a transfer, this field should be completed by the destination hospital.

Field Values:

Code	Definition
1	Yes
2	No

CORONARY ANGIOGRAPHY PERFORMED?

Definition:

- Coronary Angiography is a therapeutic procedure used to treat the stenotic (narrowed) coronary arteries of the heart.
- Indicate whether emergency coronary angiography was performed after patient has ROSC

Coding Instruction:

- If yes, please provide date and time of the coronary angiography

Code	Options
1	Yes
2	No
3	Unknown
	If yes, provide date and time

Examples:

Example	Appropriate Code/Value
Coronary Angiography was performed on the patient.	1 – Yes; provide date and time

Coronary Angiography was not performed on the patient.	2 – No

WAS A CARDIAC STENT PLACED?

Definition:

- A cardiac stent is a small mesh tube that is introduced into the coronary artery and is used to prop it open during a PCI procedure

Coding Instruction:

Code	Options
1	Yes
2	No
3	Unknown

Examples:

Example	Appropriate Code/Value
A cardiac stent was placed.	1 – Yes
A cardiac stent was not placed.	2 – No

CABG PERFORMED?

Definition:

- CABG is defined as a coronary artery bypass graft

Coding Instruction:

- Indicate whether CABG was performed after patient has ROSC.

Code	Options
1	Yes
2	No
3	Unknown

Examples:

Example	Appropriate Code/Value
CABG was performed on the patient.	1 – Yes
CABG was not performed on the patient.	2 – No

WAS AN ICD PLACED AND/OR SCHEDULED?

Definition:

- ICD - An implantable cardioverter-defibrillator (ICD) is a small battery powered electrical impulse generator which is implanted in patients who are at risk of sudden cardiac death due to vfib and vtach.

Coding Instructions:

- Indicate "yes" if ICD was placed and/or scheduled.

Code	Options
1	Yes
2	No
3	Unknown

Examples:

Example	Appropriate Code/Value
ICD was placed.	1 – Yes
ICD was not placed.	2 – No

EXHIBIT C – SRC/CARC APPLICATION

HOSPITALS_____January 1, 2020

STEMI/CARDIAC ARREST RECEIVING CENTER (SRC/CARC) APPLICATION (# 5501)

Hospital Name: **Date:** __/__/__

Dedicated phone number for paramedic call-ins: (_____) ____ - _____

Does your hospital have a special permit for cardiac catheterization? ☐ Yes ☐ No

Number of percutaneous coronary interventions (PCI)[1] per year:

Does your hospital have a special permit for cardiovascular surgery? ☐ Yes ☐ No

Name of proposed SRC program Medical Director:

Meets the requirements for SRC Medical Director in section 3.1? ☐ Yes ☐ No

Name of proposed SRC Program Manager:

Meets the requirements for SRC Program Manager in section 3.2? ☐ Yes ☐ No

Catheterization lab contact: Name: Phone: (_____) ____ - _____

Name of proposed CARC program Medical Director:

Meets the requirements for CARC Medical Director in section 3.3? ☐ Yes ☐ No

Name of proposed CARC Program Manager:

Meets the requirements for CARC Program Manager in section 3.4? ☐ Yes ☐ No

CARDIOLOGISTS PROPOSED FOR ON-CALL LIST	
Name:	**Number of PCIs per year[2]:**

Does your hospital participate in the ACC/NCDR and or AHA GWTG-CAD? ☐ Yes ☐ No,
if yes, ☐ CathPCI ☐ GWTG-CAD

Does your hospital have a cardiovascular surgical on-call staff available 24/7? ☐ Yes ☐ No

Does your hospital have the capability to place an intra-aortic balloon pump? ☐ Yes ☐ No

Does your hospital have Intra-aortic balloon pump staff on-call 24/7? ☐ Yes ☐ No

Does your hospital have a policy on the treatment of ST-elevation myocardial infarction that emphasizes rapid treatment and meets the requirements of sections 4 and 5? ☐ Yes ☐ No

Does your hospital collect data and have quality improvement policies that meet the requirements of sections 6 and 7? ☐ Yes ☐ No

Does your hospital have a data system that identifies the time the cath lab team was notified and time of first device deployment? ☐ Yes ☐ No

Does your hospital have the electronic capability to receive diagnostic quality ECG's transmitted by prehospital personnel? ☐ Yes ☐ No

Does your hospital have a designated priority phone line for use by prehospital personnel to contact your facility regarding suspected STEMI patients prior to arrival? ☐ Yes ☐ No

(_____)_____-_____

CARDIAC ARREST AND POST CARDIAC ARREST CARE:

Does your hospital have the capability to provide resuscitation for cardiopulmonary arrest with an ALCO EMS approved radiolucent mechanical CPR device? ☐ Yes ☐ No

Does your hospital have the capability to provide ECMO?
☐ Yes ☐ NO

If no, does your hospital have a written agreement with another facility to provide

ECMO services? ☐ Yes ☐ NO

Does your hospital have the capability and standardized protocol to provide Targeted Temperature Management in ED and ICU 24/7?	☐ Yes	☐ No
Does your hospital have the capability to provide emergent PCI 24/7?	☐ Yes	☐ No
Does your hospital have the capability to provide post-resuscitation care for cardiac arrest?	☐ Yes	☐ No
Does your hospital have the capability to provide ventilator support?	☐ Yes	☐ No
Does your hospital have the capability to provide EEG monitoring?	☐ Yes	☐ No
Does your hospital have the capability to provide cardiac arrest consult service?	☐ Yes	☐ No
Does your hospital have the capability to provide Neurology Consultation?	☐ Yes	☐ No
Does your hospital have the capability to provide Neurosurgical Consultation?	☐ Yes	☐ No
Does your hospital have the capability to provide Organ Bank consultation?	☐ Yes	☐ No
Does your hospital have the capability to provide Electrophysiology Consultation?	☐ Yes	☐ No
Does your hospital have the capability to provide Social Work Consultation?	☐ Yes	☐ No
Does your hospital have the capability to provide Inpatient physical and or occupational therapy?	☐ Yes	☐ No
Does your hospital have the capability to provide Outpatient physical and or occupational therapy?	☐ Yes	☐ No
Does your hospital have the capability to provide Outpatient neurological rehabilitation?	☐ Yes	☐ No
Does your hospital have the capability to provide Outpatient psychological services?	☐ Yes	☐ No
Does your hospital have the capability to provide CPR training: Professional, community and patient's family on discharge?	☐ Yes	☐ No
Is your hospital currently participating in the Cardiac Arrest Registry to Enhance Survival (CARES)?	☐ Yes	☐ No
Does your hospital have the capability to provide ECMO?	☐ Yes	☐ No

If not, does your hospital have an agreement with one that does? ☐ Yes ☐ No

[1] PCI is defined as a therapeutic coronary intervention such as angioplasty, stent placement etc.

[2] Total personally performed PCIs per year at all institutions, not just this center.

This would include any PCI as defined above and not restricted to acute myocardial infarction.

STEMI RECEIVING CENTER (SRC/CARC) APPLICATION (# 5501)

EXHIBIT D – CALIFORNIA REGULATIONS: STEMI SYSYTEM OF CARE

California Code of Regulations
Title 22. Social Security
Division 9. Prehospital Emergency Medical Services
Chapter 7.1 ST-Elevation Myocardial Infarction Critical Care System
ARTICLE 1. DEFINITIONS

§ 100270.101. Cardiac Catheterization Laboratory
"Cardiac catheterization laboratory" or "Cath lab" means the setting within the hospital where diagnostic and therapeutic procedures are performed on patients with cardiovascular disease.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.102. Cardiac Catheterization Team
"Cardiac catheterization team" means the specially trained health care professionals that perform percutaneous coronary intervention. It may include, but is not limited to, an interventional cardiologist, mid-level practitioners, registered nurses, technicians, and other health care professionals.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.103. Clinical Staff
"Clinical staff" means individuals that have specific training and experience in the treatment and management of ST-Elevation Myocardial Infarction (STEMI) patients. This includes, but is not limited to, physicians, registered nurses, advanced practice nurses, physician assistants, pharmacists, and technologists.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.104. Emergency Medical Services Authority
"Emergency Medical Services Authority" or "EMS Authority" or "EMSA" means the department in California responsible for the coordination and integration of all state activities concerning EMS.
Note: Authority cited: Sections 1797.1, 1797.107 and 1797.54, Health and Safety Code.
Reference: Sections 1797.100, and 1797.103, Health and Safety Code.

§ 100270.105. Immediately Available
"Immediately available" means:
(a) Unencumbered by conflicting duties or responsibilities.
(b) Responding without delay upon receiving notification.
(c) Being physically available to the specified area of the hospital when the patient is delivered in accordance with local EMS agency policies and procedures.

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

§ 100270.106. Implementation
"Implementation," "implemented," or "has implemented" means the development and activation of a STEMI Critical Care System Plan by the local EMS agency, including the prehospital and hospital care components in accordance with the plan.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.107. Interfacility Transfer
"Interfacility transfer" means the transfer of a STEMI patient from one acute general care facility to another acute general care facility.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103, 1797.176 and 1798.170, Health and Safety Code.

§ 100270.108. 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 or region and which is designated pursuant Health and Safety Code commencing with section 1797.200.
Note: Authority cited: Sections 1797.107, 1797.200 and 1798.150, Health and Safety Code.
Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.109. Percutaneous Coronary Intervention (PCI)
"Percutaneous coronary intervention" or "PCI" means a procedure used to open or widen a narrowed or blocked coronary artery to restore blood flow supplying the heart, usually done on an emergency basis for a STEMI patient.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.110. Quality Improvement
"Quality improvement" or "QI" means methods of evaluation that are composed of structure, process, and outcome evaluations that focus on improvement efforts to identify root causes of problems, intervene to reduce or eliminate these causes, and take steps to correct the process, and recognize excellence in performance and delivery of care.
Note: Authority cited: Sections 1797.103, 1797.107, 1797.174, 1797.176 and 1798.150 Health and Safety Code. Reference: Sections 1797.174, 1797.202, 1797.204, 1797.220 and 1798.175, Health and Safety Code.

§ 100270.111. ST-Elevation Myocardial Infarction (STEMI)
"ST-Elevation Myocardial Infarction" or "STEMI" means a clinical syndrome defined by symptoms of myocardial infarction in association with ST-segment elevation on Electrocardiogram (ECG).
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.112. STEMI Care
"STEMI care" means emergency cardiac care, for the purposes of these regulations.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.113. STEMI Medical Director
"STEMI medical director" means a qualified board-certified physician by the American Board of Medical Specialties (ABMS) as defined by the local EMS agency and designated by the hospital that is responsible for the STEMI program, performance improvement, and patient safety programs related to a STEMI critical care system.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.114. STEMI Patient
"STEMI patient" means a patient with symptoms of myocardial infarction in association with ST-Segment Elevation in an ECG.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103, 1797.176 and 1797.220, Health and Safety Code.

§ 100270.115. STEMI Program
"STEMI program" means an organizational component of the hospital specializing in the care of STEMI patients.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.116. STEMI Program Manager
"STEMI program manager" means a registered nurse or qualified individual as defined by the local EMS agency, and designated by the hospital responsible for monitoring, coordinating and evaluating the STEMI program.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.117. STEMI Receiving Center (SRC)

"STEMI receiving center" or "SRC" means a licensed general acute care facility that meets the minimum hospital STEMI care requirements pursuant to Section 100270.124 and is able to perform PCI.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103, 1797.176 and 1797.220, Health and Safety Code.

§ 100270.118. STEMI Referring Hospital (SRH)
"STEMI referring hospital" or "SRH" means a licensed general acute care facility that meets the minimum hospital STEMI care requirements pursuant to Section 100270.125.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103, 1797.176 and 1797.220, Health and Safety Code.

§ 100270.119. STEMI Critical Care System
"STEMI critical care system" means a critical care component of the EMS system developed by a local EMS agency that links prehospital and hospital care to deliver treatment to STEMI patients.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

§ 100270.120. STEMI Team
"STEMI team" means clinical personnel, support personnel, and administrative staff that function together as part of the hospital's STEMI program.
Note: Authority cited: Sections 1797.107 and 1798.150, Health and Safety Code. Reference: Sections 1797.103 and 1797.176, Health and Safety Code.

ARTICLE 2. LOCAL EMS AGENCY STEMI CRITICAL CARE SYSTEM REQUIREMENTS

§ 100270.121. STEMI Critical Care System Plan
(a) The local EMS agency may develop and implement a STEMI critical care system.

(b) The local EMS agency implementing a STEMI critical care system shall have a STEMI Critical Care System Plan approved by the EMS Authority prior to implementation.

(c) A STEMI Critical Care System Plan submitted to the EMS Authority shall include, at a minimum, all of the following components:

(1) The names and titles of the local EMS agency personnel who have a role in a STEMI critical care system.

(2) The list of STEMI designated facilities with the agreement expiration dates.

(3) A description or a copy of the local EMS agency's STEMI patient identification and destination policies.

(4) A description or a copy of the method of field communication to the receiving hospital specific to STEMI patient, designed to expedite time-sensitive treatment on arrival.

(5) A description or a copy of the policy that facilitates the inter-facility transfer of a STEMI patient.

(6) A description of the method of data collection from the EMS providers and designated STEMI hospitals to the local EMS agency and the EMS Authority.

(7) A policy or description of how the local EMS agency integrates a receiving center in a neighboring jurisdiction.

(8) A description of the integration of STEMI into an existing quality improvement committee or a description of any STEMI specific quality improvement committee.

(9) A description of programs to conduct or promote public education specific to cardiac care.

(d) The EMS Authority shall, within 30-days of receiving a request for approval, notify the requesting local EMS agency in writing of approval or disapproval of its STEMI Critical Care System Plan. If the STEMI Critical Care System Plan is disapproved, the response shall include the reason(s) for the disapproval and any required corrective action items.

(e) The local EMS agency shall provide a corrected plan to the EMS Authority within 60 days of receipt of the disapproval letter.

(f) The local EMS agency currently operating a STEMI critical care system implemented before the effective date of these regulations, shall submit to the EMS Authority a STEMI Critical Care System Plan as an addendum to its next annual EMS plan update, or within 180-days of the effective date of these regulations, whichever comes first.

(g) After approval of the STEMI Critical Care System Plan, the local EMS agency shall submit an update to the plan as part of its annual EMS update, consistent with the requirements in Section 100270.122.

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

Note: Authority cited: Sections 1797.107, 1797.103, 1797.105, 1797.250, 1797.254 and

1798.150, Health and Safety Code. Reference: Section 1797.176 and 1797.220, Health and Safety Code.

§100270.122. STEMI Critical Care System Plan Updates
(a) The local EMS agency shall submit an annual update of its STEMI Critical Care System Plan, as part of its annual EMS plan submittal, which shall include, at a minimum, all the following:

(1) Any changes in a STEMI critical care system since submission of the prior annual plan update or a STEMI Critical Care System Plan addendum.

(2) The status of a STEMI critical care system goals and objectives.

(3) The STEMI critical care system quality improvement activities.

(4) The progress on addressing action items and recommendations provided by the EMS Authority within the STEMI Critical Care System Plan or status report approval letter if applicable.

Note: Authority cited: Sections 1797.103, 1797.107, 1797.176, 1797.250, 1797.254, 1798.150, and 1798.172, Health and Safety Code. Reference: Section 1797.176, 1797.220, 1797.222, 1798.170, Health and Safety Code.

ARTICLE 3. PREHOSPITAL STEMI CRITICAL CARE SYSTEM REQUIREMENTS

§ 100270.123. EMS Personnel and Early Recognition
(a) The local EMS agency with an established STEMI critical care system shall have protocols for the identification and treatment of STEMI patients, including paramedic performance of a 12-lead ECG and determination of the patient destination.

(b) The findings of 12-lead ECG shall be assessed and interpreted through one or more of the following methods:

(1) Direct paramedic interpretation.

(2) Automated computer algorithm.

(3) Wireless transmission to facility followed by physician interpretation or confirmation.

(c) Notification of prehospital ECG findings of suspected STEMI patients, as defined by the local EMS agency, shall be communicated in advance of the arrival to the STEMI centers according to the local EMS agency's STEMI Critical Care System Plan.

Note: Authority cited: Sections 1797.103, 1797.107, 1797.114, 1797.176, 1797.206, 1797.214 and 1798.150, Health and Safety Code. Reference: Section 1797.176,

1797.220, 1798, 1798.150 and 1798.170, Health and Safety Code.

ARTICLE 4. STEMI CRITICAL CARE FACILITY REQUIREMENTS

§ 100270.124. STEMI Receiving Center Requirements

(a) The following minimum criteria shall be used by the local EMS agency for the designation of a STEMI receiving center:

(1) The hospital shall have established protocols for triage, diagnosis, and Cath lab activation following field notification.

(2) The hospital shall have a single call activation system to activate the Cardiac Catheterization Team directly.

(3) Written protocols shall be in place for the identification of STEMI patients.

(A) At a minimum, these written protocols shall be applicable in the intensive care unit/coronary care unit, Cath lab and the emergency department.

(4) The hospital shall be available for treatment of STEMI patients twenty-four (24) hours per day, seven (7) days per week, three hundred and sixty-five (365) days per year.

(5) The hospital shall have a process in place for the treatment and triage of simultaneously arriving STEMI patients.

(6) The hospital shall maintain STEMI team and Cardiac Catheterization Team call rosters.

(7) The Cardiac Catheterization Team, including appropriate staff determined by the local EMS agency, shall be immediately available.

(8) The hospital shall agree to accept all STEMI patients according to the local policy.

(9) STEMI receiving centers shall comply with the requirement for a minimum volume of procedures for designation required by the local EMS agency.

(10) The hospital shall have a STEMI program manager and a STEMI medical director.

(11) The hospital shall have job descriptions and organizational structure clarifying the relationship between the STEMI medical director, STEMI program manager, and the STEMI team.

(12) The hospital shall participate in the local EMS agency quality improvement processes related to a STEMI critical care system.

(13) A STEMI receiving center without cardiac surgery capability on-site shall have a written transfer plan and agreements for transfer to a facility with cardiovascular surgery capability.

(14) A STEMI receiving center shall have reviews by local EMS agency or other designated agency conducted every three years.

(b) A STEMI center designated by the local EMS agency prior to implementation of these regulations may continue to operate. Before re-designation by the local EMS agency at the next regular interval, STEMI centers shall be re-evaluated to meet the criteria established in these regulations.

(c) Additional requirements may be stipulated by the local EMS agency medical director.

Note: Authority cited: Sections 1797.103, 1797.107, 1797.176, 1797.220, and 1798.150 1798.167 and 1798.172, Health and Safety Code. Reference: Section 1797.176, 1797.220, 1798, 1798.150 and 1798.170 Health and Safety Code.

§ 100270.125. STEMI Referring Hospital Requirements
(a) The following minimum criteria shall be used by the local EMS agency for designation of a STEMI referring hospital:

(1) The hospital shall be committed to supporting the STEMI Program.

(2) The hospital shall be available to provide care for STEMI patients twenty-four (24) hours per day, seven (7) days per week, three hundred and sixty-five (365) days per year.

(3) Written protocols shall be in place to identify STEMI patients and provide an optimal reperfusion strategy, using fibrinolytic therapy .

(4) The emergency department shall maintain a standardized procedure for the treatment of STEMI patients.

(5) The hospital shall have a transfer process through interfacility transfer agreements, and have pre-arranged agreements with EMS ambulance providers for rapid transport of STEMI patients to a SRC.

(6) The hospital shall have a program to track and improve treatment of STEMI patients.

(7) The hospital must have a plan to work with a STEMI receiving center and the local EMS agency on quality improvement processes.

(8) A STEMI referring hospital designated by the local EMS agency shall have a review

conducted every three years.

(b) A STEMI center designated by the local EMS agency prior to implementation of these regulations may continue to operate. Before re-designation by the local EMS agency at the next regular interval, STEMI centers shall be re-evaluated to meet the criteria established in these regulations.

(c) Additional requirements may be stipulated by the local EMS agency medical director.

Note: Authority cited: Sections 1797.103, 1797.107, 1797.176, 1797.220, and 1798.150 1798.167 and 1798.172, Health and Safety Code. Reference: Section 1797.176, 1797.220, 1798.150 and 1798.170 Health and Safety Code.

ARTICLE 5. DATA MANAGEMENT, QUALITY IMPROVEMENT AND EVALUATIONS

§ 100270.126. Data Management.
(a) The local EMS agency shall implement a standardized data collection and reporting process for a STEMI critical care system.

(b) The system shall include the collection of both prehospital and hospital patient care data, as determined by the local EMS agency.

(c) The prehospital STEMI patient care elements selected by the local EMS agency shall be compliant with the most current version of the California EMS Information Systems (CEMSIS) database, and the National EMS Information System (NEMSIS).

(d) All hospitals that receive STEMI patients via EMS shall participate in the local EMS agency data collection process in accordance with local EMS agency policies and procedures.
(e) The prehospital care record and the hospital data elements shall be collected and submitted to the local EMS agency, and subsequently to the EMS Authority, on no less than a quarterly basis and shall include, but not be limited to, the following:

(1) The STEMI patient data elements:
(A) EMS ePCR Number.
(B) Facility.
(C) Name: Last, First.
(D) Date of Birth.
(E) Patient Age.
(F) Patient Gender.
(G) Patient Race.
(H) Hospital Arrival Date.
(I) Hospital Arrival Time.

(J) Dispatch Date.
(K) Dispatch Time.
(L) Field ECG Performed.
(M) 1st ECG Date.
(N) 1st ECG Time.
(O) Did the patient suffer out-of-hospital cardiac arrest.
(P) CATH LAB Activated.
(Q) CATH LAB Activation Date.
(R) CATH LAB Activation Time.
(S) Did the patient go to the CATH LAB.
(T) CATH LAB Arrival Date.
(U) CATH LAB Arrival Time.
(V) PCI Performed.
(W) PCI Date.
(X) PCI Time.
(Y) Fibrinolytic Infusion.
(Z) Fibrinolytic Infusion Date.
(AA) Fibrinolytic Infusion Time.
(BB) Transfer.
(CC) SRH ED Arrival Date.
(DD) SRH ED Arrival Time.
(EE) SRH ED Departure Date.
(FF) SRH ED Departure Time.
(GG) Hospital Discharge Date.
(HH) Patient Outcome.
(II) Primary and Secondary Discharge Diagnosis.
(2) The STEMI System data elements:
(A) Number of STEMIs treated.
(B) Number of STEMI patients transferred.
(C) Number and percent of emergency department STEMI patients arriving by private transport (non-EMS).
(D) The false positive rate of EMS diagnosis of STEMI, defined as the percentage of STEMI alerts by EMS which did not show STEMI on ECG reading by the emergency physician.
Note: Authority cited: Sections 1791.102, 1797.103, 1797.107, 1797.176, 1797.204, 1797.220, 1798.150, and 1798.172, Health and Safety Code. Reference: Section 1797.220, 1797.222, 1797.204, Health and Safety Code.

§ 100270.127. Quality Improvement and Evaluation Process
(a) Each STEMI critical care system shall have a quality improvement process that shall include, at a minimum:

(1) Evaluation of program structure, process, and outcome.

(2) Review of STEMI-related deaths, major complications, and transfers.

(3) A multidisciplinary STEMI Quality Improvement Committee, including both prehospital and hospital members.

(4) Participation in the QI process by all designated STEMI centers and prehospital providers involved in the STEMI critical care system.

(5) Evaluation of regional integration of STEMI patient movement.

(6) Compliance with the California Evidence Code, Section 1157.7 to ensure confidentiality, and a disclosure-protected review of selected STEMI cases.

(b) The local EMS agency shall be responsible for on-going performance evaluation and quality improvement of the STEMI critical care system.
Note: Authority cited: Sections 1797.102, 1797.103, 1797.107, 1797.176, 1797.204, 1797.220, 1797.250, 1797.254, 1798.150, and 1798.172, Health and Safety Code.
Reference: Section 1797.104, 1797.176, 1797.204, 1797.220, 1797.222, 1798.170,

Health and Safety Code.