



EMS Stakeholder Engagement Process

CVEMSA Policy Development Process –Stakeholder Engaged Rulemaking; LEMSA Accountability

As the local regulatory entities charged with system planning, coordination and ongoing evaluation, Local EMS Agencies (LEMAs) must develop and maintain a body of policy to fulfill that mission.

Establishment of such policies are required by the California Health and Safety Code in section 1797.220, which states in part: *“The local EMS agency, using state minimum standards, shall establish policies and procedures approved by the medical director of the local EMS agency to assure medical control of the EMS system...”* Although HSC places the creation of standards at the state level with California EMS Authority, it specifies in section 1798 that the LEMSA is the entity responsible for establishing and maintaining medical control (see attachment A for LEMSA understanding of Medical Control) in compliance with those standards as follows:

[“1798.](#)

(a) The medical direction and management of an emergency medical services system shall be under the medical control of the medical director of the local EMS agency. This medical control shall be maintained in accordance with standards for medical control established by the authority.

(b) Medical control shall be within an EMS system which complies with the minimum standards adopted by the authority, and which is established and implemented by the local EMS agency...”

The California EMS Authority establishes the requirements for EMS System policy in a number of places within the California Code of Regulations (CCR) Title 22 sections it is responsible for maintaining; one example is CCR Section 100148 *“responsibility of the LEMSA”* which states in part:

“...The LEMSA that authorizes an ALS program shall establish policies and procedures approved by the medical director of the LEMSA that shall include:

(a) Approval, denial, revocation of approval, suspension, and monitoring of training programs, base hospitals or alternative base stations, and paramedic service providers.

(b) Assurance of compliance with provisions of this Chapter by the paramedic program and the EMS system.

(c) Submission to the Authority, as changes occur, of the following information on the approved paramedic training programs:

(1) Name of program director and/or program contact;

(2) Address, phone number, and facsimile number;

(3) Date of approval, date classes will initially begin, and date of expiration.

(d) Development or approval, implementation and enforcement of policies for medical control, medical accountability, and an EMSQIP of the paramedic services, including:

(1) Treatment and triage protocols.

- (2) Patient care record and reporting requirements.
- (3) Medical care audit system.
- (4) Role and responsibility of the base hospital and paramedic service provider.
- (e) System data collection and evaluation..."

Coastal Valleys EMS Agency (CVEMSA) promulgates local regulations in the form of administrative policies and treatment guidelines addressing the various areas it regulates or coordinates in compliance with state standards and guidelines. Administrative policies address the structural components of the EMS system including system organization and management, personnel, communications, response and transportation, facilities, data collection and quality improvement. Each of these areas are integral to the delivery of patient care, and each have each corresponding sections within the EMS Plan that describes the EMS System.

Treatment guidelines (sometimes generically referred to as "protocols" or "standing orders") are the specific patient care orders that direct the care delivered by EMS providers to individual patients. The treatment guidelines include the patient assessment and treatment modalities to be employed in the care of those patients served by the EMS system. Treatment guidelines range from general care principles to specific procedures as well as defining assessment-driven treatment.

Implementation of administrative policy and treatment guidelines represent the establishment of medical control within the Sonoma County EMS system. Provision of medical care cannot happen without the provider agencies, training programs, facilities and communications centers that form the structure of the system, and the input and engagement with those partners is critical to the successful implementation of policy that promotes the provision of quality care within the system.

To facilitate that engagement, the EMS Agency has a process for policy development and revision that is intended to allow stakeholders from across the spectrum of providers as well as the public to participate in the governance of the EMS system.

Because the delivery of medical care is a constantly changing area, EMS system policy is open for review and potential change as needed; there are no arbitrary restrictions on what can or cannot be considered. The EMS Agency feels decision-making should consider input from stakeholders, scientific research and best practices from other EMS systems.

Policy change suggestions can come from a number of different sources such as Medical Advisory Committee (MAC) or Emergency Medical Care Council (EMCC) meetings, stakeholder groups such as Sonoma County Fire Chiefs Association or the Continuous Quality Improvement (CQI) Committee. Suggestions also come from field providers attending EMS Agency ALS or BLS Update trainings, EMS System Provider agencies and individual paramedics or EMTs. There is no barrier to suggesting a change or requirement that a requestor have an organizational affiliation to be heard.

Suggested changes or additions follow the process outlined in Administrative Policy 1005 "Policy Development Process" last revised January 1, 2016, which states: *"1005.1 Purpose ... to provide a mechanism for policy development including medical and administrative policies and procedures as well as EMS system standards and guidelines."*

Policy 1005 applies to all EMS System policies, procedures, standards and guidelines and provides that mechanism for the review and input of internal staff, impacted external groups and EMCC members be included in all policy development.

Typically, when the need for a change or new policy is suggested, an EMS Agency staff person with responsibility for the area under review will be assigned to lead the work and provide staff support for

the Medical Director. In many cases, the lead staff person will convene a workgroup with internal staff and external partners having subject matter expertise relevant to the subject of the policy under revision. The Medical Director may lead the group at this point depending upon the nature of the policy under development or revision.

When a draft version is deemed ready for internal deliberative review by the author, it is sent to the EMS Agency Medical Director and Administrator as well as EMS Agency staff for comment. Staff may suggest edits for clarity, request regulatory clarification from the author or express concerns significant enough to require additional staff discussion. Any staff person may request a project meeting to address such concerns.

After internal review, the author may make changes as suggested and revisiting a previously convened workgroup as needed for additional discussion, or doing additional research in response to staff questions. The internal review process may repeat cyclically until any issues are solved to staff best understanding. At the point of completion, the policy goes to external or “public” comment.

The external comment period is a minimum sixty-day term during which the policy is sent to the CVEMSA- maintained EMCC and MAC (*please see Attachment B, “Stakeholder Groups” for a description of these groups*) email distribution lists¹ and is posted on the EMS Agency website (www.cvemsa.org). Comment received during that timeframe is collected by the author and considered by the Medical Director and project team as part of the final development process. During external comment period, EMS Agency staff report on the policy development process during meetings with stakeholders as well as regularly calendared EMCC and MAC meetings.

After external comment has closed, the policy author in consultation with the project team will address any issues raised. If significant changes are proposed or objections raised during external comment, the EMS Agency may convene an external workgroup to discuss the issues and/or make changes subject to an additional public comment period.

When final changes and version are approved by EMS Agency Administrator and Medical Director the policy is released with a notice to stakeholders via CVEMSA lists as well as website posting. A standard thirty-day implementation period is the norm although both immediate optional implementation and phased implementation strategies have been utilized in the past and will continue to be considered as appropriate in the future.

Some situations require a quicker response and more expeditious implementation; examples are changes in availability of specific medications, safety concerns around a medical device or other patient safety concerns. In such cases the EMS Agency Medical Director is authorized to issue interim direction via an EMS Special Memo pending a policy development process including implementation as soon as is needed to protect public and responder health and safety.

Some policy revisions are in response to state and/or federal statutory or regulatory changes and are therefore not open for editing to the extent LEMSA-derived policy is able to be changed. CVEMSA remains committed to provide appropriate flexibility for the system to meet the needs of patients to the extent it is allowable by law and in the interest of quality patient care.

During the course of the EMS Ordinance revision process, some stakeholders expressed concerns about the ability of the EMCC to consider and discuss proposed EMS System policy changes. The EMCC meets quarterly, so a 60-day external comment phase could miss an EMCC meeting entirely. EMS Agency staff feel exceptions have been made to the timeframe for comment periods to include EMCC meetings.

¹ Any interested individual may request to be added to the EMCC or MAC distribution by contacting EMS Agency staff at 707-565-6501 or via email at coastalvalleysemsagency.org

CVEMSA would like to add a provision to the Policy Development Process that automatically sets a closing date for external comment after the next EMCC meeting should the timeframe of an external comment period close before the EMCC has had an opportunity to publicly review the proposed changes.

During the course of the EMS Ordinance revision process, some stakeholders expressed concern regarding the final approval authority of the EMS Agency Medical Director in policy decision-making. The concerned stakeholders have asked for a limitation on the authority of the Medical Director in terms of scope of regulated area, that all policies be ultimately approved by the Sonoma County Board of Supervisors and/or the implementation of an appeal process for all decisions with the Sonoma County Board of Supervisors that could overrule the medical director with a final judgement on disputed issues.

CVEMSA takes the position that the EMS Agency may not regulate areas outside of those that are the responsibility of the agency as defined in HSC or by CCR as authorized by HSC. Within those areas, the authority to establish and maintain medical control must remain with the physician qualified to make decisions and whom is responsible for the medical management of the patients cared for by the system. CVEMSA also feels all system participants are accountable for the performance of duties within the system. EMS Agency staff, including the Medical Director are no exception. Decisions made by the Medical Director should be open for review and subject to protest if stakeholders believe the defined process was not followed, or if the outcome was grossly unfair in some manner. CVEMSA believes medical decision-making that is safe, appropriate and in the best interests of the patients, should be explainable and defensible to a third party.

In response to stakeholder's request for a formal policy appeal process, the EMS Agency proposes adding a step to the Policy Development Process that consists of a formal protest after the final version of any policy change and implementation date is published. A protest would result in the selection of a three-physician panel qualified by appropriate board certification in the subject area (Cardiology, Pediatrics) and/or Emergency Medicine to hear the protest and render a finding to the EMS Agency Medical Director for consideration. The panel should have in addition to physician peers, advisory experts for operational EMS system components (Fire, ambulance, communications center are examples) affected by the decision under review. Although California law cannot require or permit the EMS Agency Medical Director to abdicate responsibility for decision-making, proceeding against the stated recommendations of a qualified panel of peers informed by expert opinions and stakeholder concerns represents a deterrent to capricious rulemaking.

A similar process is in place today with a limited scope. All disciplinary actions against an individual EMT certificate issued by CVEMSA fall under the final decision-making authority of the EMS Medical Director, but appeals are available to disciplined EMTs via the Office of Administrative Hearings. A finding from the OAH Administrative Law Judge in favor of an appellant, while not binding on the Medical Director, represents a significant factor in final outcome decisions as a liability if disregarded. In some cases, medical expertise may inform the Medical Director's decision in opposition to the ALJ ruling, but the stakes are high should there be a lawsuit, and the risk to health and safety should be explainable to the ALJ as an experienced arbiter.

The EMS Agency suggests protests to a policy development process initiate with a public governing entity or EMS Service Provider organization. Special Districts with EMS services, Fire and Community Services Districts as well as healthcare districts would have agency in this regard as would authorized providers of EMS and hospital partners. Cities and the Sonoma County Board of Supervisors would represent any individuals or groups not included in another manner. The form of the protest should take the form of a written communication clearly identifying the entity requesting the appeal. Chief executive officers of public or private agencies may have delegated authority for protests provided by the entity they represent with the following exception; any protest to an EMS Agency policy based on an infringement of rights granted to a City or Fire District as described in HSC 1797.201 shall originate with the governing body of the City or Special District concerned. The EMS Agency would request a 10-day notification prior to the hearing or board meeting containing the agenda item that includes the request for protest.

The EMS Agency feels the addition of a protest/review process builds upon the engagement in place currently and expanding it to ensure those not engaged in initial phases have a final opportunity for consideration while allowing for additional discussion on the issues most important to our system partners.

The EMS Agency is open to suggestions on the proposed process and any additional ideas on how it can foster transparency and accountability while staying compliant with its HSC –derived responsibilities.