100066.05 EMT Trial Studies

An EMT may perform any prehospital emergency medical care treatment procedure(s) or administer any medication(s) on a trial basis when approved by the medical director of the LEMSA and the director of the Authority. The medical director of the LEMSA shall review the medical literature on the procedure or medication and determine in his/her professional judgement whether a trial study is needed.

(a)

The medical director of the LEMSA shall review a trial study plan which, at a minimum, shall include the following: (1) A description of the procedure(s) or medication(s) proposed, the medical conditions for which they can be utilized, and the patient population that will benefit. (2) A compendium of relevant studies and material from the medical literature. (3) A description of the proposed study design, including the scope of study and method of evaluating the effectiveness of the procedure(s) or medication(s), and expected outcome. (4) Recommended policies and procedures to be instituted by the LEMSA regarding the use and medical control of the procedure(s) or medication(s) used in the study. (5) A description of the training and competency testing required to implement the study. Training on subject matter shall be consistent with the related topic(s) and skill(s) specified in Section 100093.03, Chapter 3.3 (Paramedic regulations), Division 9, Title 22, California Code of Regulations.

(1)

A description of the procedure(s) or medication(s) proposed, the medical conditions for which they can be utilized, and the patient population that will benefit.

(2)

A compendium of relevant studies and material from the medical literature.

(3)

A description of the proposed study design, including the scope of study and method of evaluating the effectiveness of the procedure(s) or medication(s), and expected outcome.

(4)

Recommended policies and procedures to be instituted by the LEMSA regarding the use and medical control of the procedure(s) or medication(s) used in the study.

(5)

A description of the training and competency testing required to implement the study. Training on subject matter shall be consistent with the related topic(s) and skill(s) specified in Section 100093.03, Chapter 3.3 (Paramedic regulations), Division 9, Title 22, California Code of Regulations.

(b)

The medical director of the LEMSA shall appoint a local medical advisory committee to assist with the evaluation and approval of trial studies. The membership of the committee shall be determined by the medical director of the LEMSA, but shall include individuals with knowledge and experience in research and the effect of the proposed study on the EMS system.

(c)

The medical director of the LEMSA shall submit the proposed study and a copy of the proposed trial study plan at least forty-five (45) calendar days prior to the

proposed initiation of the study to the director of the Authority for approval in accordance with the provisions of Section 1797.221 of the Health and Safety Code. The Authority shall inform the Commission on EMS of studies being initiated.

(d)

The Authority shall notify the medical director of the LEMSA submitting its request for approval of a trial study within fourteen (14) working days of receiving the request that the request has been received.

(e)

The Director of the Authority shall render the decision to approve or disapprove the trial study within forty-five (45) calendar days of receipt of all materials specified in subsections (a) and (b) of this section.

(f)

Within eighteen (18) months of the initiation of the procedure(s) or medication(s), the medical director of the LEMSA shall submit to the Commission on EMS a written report which includes at a minimum the progress of the study, number of patients studied, beneficial effects, adverse reactions or complications, appropriate statistical evaluation, and general conclusion.

(g)

The Commission on EMS shall review the above report within two (2) meetings and advise the Authority to do one of the following: (1) Recommend termination of the study if there are adverse effects or if no benefit from the study is shown. (2) Recommend continuation of the study for a maximum of eighteen (18) additional months if potential but inconclusive benefit is shown. (3) Recommend the procedure or medication be added to the EMT scope of practice.

(1)

Recommend termination of the study if there are adverse effects or if no benefit from the study is shown.

(2)

Recommend continuation of the study for a maximum of eighteen (18) additional months if potential but inconclusive benefit is shown.

(3)

Recommend the procedure or medication be added to the EMT scope of practice.

(h)

If option (g)(2) is selected, the Commission on EMS may advise continuation of the study as structured or alteration of the study to increase the validity of the results.

(i)

At the end of the additional eighteen (18) month period, a final report shall be submitted to the Commission on EMS with the same format as described in (f) above.

(j)

The Commission on EMS shall review the final report and advise the Authority to do one of the following: (1) Recommend termination or further extension of the study. (2) Accept the study recommendations. (3) Recommend the procedure or medication be added to the EMT scope of practice.

(1)

Recommend termination or further extension of the study.

(2)

Accept the study recommendations.

(3)

Recommend the procedure or medication be added to the EMT scope of practice.

(k)

The Authority may require a trial study(ies) to cease after thirty-six (36) months.