CA

100091.03 Paramedic Trial Studies

A paramedic may perform any prehospital emergency medical care treatment procedures(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.

(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 the 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.

(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 the 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.

(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 send a copy of the proposed trial study plan at least forty-five (45) days prior to the proposed initiation of the study to the Director of the Authority for approval in accordance with the provisions of section 1797.172 of the Health & Safety Code. The Authority shall inform the Commission on EMS (Commission) of studies being initiated.

(d)

The Authority shall notify, within fourteen (14) days of receiving the request, the medical director of the LEMSA submitting its request for approval of a trial study that the request has been received, and shall specify what information, if any, is

missing.

(e)

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

(f)

The medical director of the LEMSA within eighteen (18) months of initiation of the procedure(s) or medication(s), shall submit a written report to the Commission 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 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 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 paramedic basic or local optional scope of practice.

(1)

Recommend termination of the study if there are adverse effects or 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 paramedic basic or local

optional scope of practice.

(h)

If option (g)(2) is selected, the Commission 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 with the same format as described in (f) above.

(j)

The Commission 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) Recommend the procedure or medication be added to the paramedic basic or local optional scope of practice.

(1)

Recommend termination or further extension of the study.

(2)

Recommend the procedure or medication be added to the paramedic basic or local optional scope of practice.

(k)

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