Memorandum

OSHPD

State of California

"Access to Safe, Quality Healthcare Environments that Meet California's Diverse and Dynamic Needs"

To: Robert P. David
Director

Date: October 13, 2014

Via: Stephanie Clendenin
Chief Deputy Director

From: Lupe Alonzo-Diaz
Deputy Director
Healthcare Workforce Development Division

Subject: Recommendation Regarding Health Workforce Pilot Project (HWPP) #173 Community Paramedicine Proposal

On December 28, 2013, the California Emergency Medical Services Authority (EMSA) submitted an application for the HWPP Program's consideration for status as a pilot project. EMSA proposes a pilot project regarding the practice of Community Paramedicine (CP) in the following areas:

- Transport patients with specified conditions to alternate locations other than an acute care emergency department,
- Address the needs of frequent 9-1-1 callers or frequent visitors to emergency departments,
- Provide short-term home follow-up care for persons recently discharged from a hospital and at increased risk of a return visit to the emergency department or readmission to the hospital, and
- Provide short-term home support for persons with diabetes, asthma, congestive heart failure, or multiple chronic conditions.

The HWPP Program has completed a review process for application HWPP #173 in accordance with California Health and Safety Code Section 128175. This included:

- A review of the application to ensure that it met statutory and regulatory criteria,
- Seeking input from relevant healing arts licensing boards and professional organizations,
- Posting the application for public comment before and during the public meeting and public hearing,
- Holding a public meeting on April 9, 2014 to permit the HWPP #173 sponsor to present and receive public input on the application, and
- Holding a public hearing on July 30, 2014 by a disinterested state government official as is required for projects sponsored by a state agency.

I recommend approval of the HWPP #173 application for pilot project status with the following modifications and provisions. This recommendation is based on the HWPP

Program's review and consideration of the information presented via the review process.

The required modifications and provisions are as follows:

Patient Safety

- The sponsor shall work with the HWPP Program and HWPP #173 project evaluator to determine the scope and timeline for data submission and reports during the initial six months of the Phase III: Intervention Period.
- The sponsor shall require all sites to include in their patient eligibility protocols and consent forms that patients who cannot consent due to inebriation, mental incapacity, legal incapacity, or no responsiveness will be treated in accordance with current regulations and local protocols governing EMT-Paramedics. These patients would not be included in the pilot project unless consent is lawfully given.
- The sponsor shall provide triage protocols for each site to the HWPP Program and HWPP Program Advisory Committee for review and feedback, and strengthen those protocols if requested by the HWPP Program.

Representation

- The sponsor shall include a paramedic and a member of the general public who is not a licensed healthcare provider on each site's Community Paramedic Steering Committee.

Consent Forms

- The sponsor shall require all sites to incorporate the following heading on all consent forms "Informed Consent" as identified in the program regulations.
- The sponsor shall require all sites to develop an Informed Consent form specific to languages of the population proposed to be served.

Training

- The sponsor shall ensure that core standards for training address multiple disciplinary team coordination.
- The sponsor shall require additional training for project participants, where warranted (i.e., if after the review and expansion of additional data collection elements, the HWPP Program deems additional training necessary to ensure patient safety).

Pilot Project Evaluation

- The sponsor shall conduct an overall evaluation of the pilot project and an evaluation at the site level.

Data Collection and Analysis

- The sponsor shall work with the HWPP Program to more explicitly define "patient safety" as it relates to the submission of data during the Phase III: Intervention Period.

- The sponsor shall work with the HWPP Program in collaboration with the HWPP Advisory Committee to identify and expand the data elements collected during the Phase III: Intervention Period to include patient outcomes. The expansion of patient outcomes will be specific to each site and may include items such as:
    - When was the patient discharged?
    - Where was the patient discharged (i.e. home or hospitalized)?
    - Did the patient need additional treatment?
- The sponsor shall collaborate with the HWPP Program in determining the frequency of data submission to HWPP.

HWPP Program Monitoring
If the project is approved, the HWPP Program will:

- Monitor the approved project through reporting and site visit evaluations as well as collaborate with the HWPP Program Advisory Committee,
- Request the sponsor's oversight advisory committee assist the HWPP Program with monitoring and development of guidelines to tighten protocols pursuant to any findings, and
- Request the sponsor to submit a copy of each site's Institutional Review Board (IRB) approved report for each site seeking IRB approval. The IRB approval should be obtained prior to the implementation of the employment/utilization phase.

Any findings related to an endangerment to participating patients will be addressed as follows:

- Sponsor shall provide immediate notification to the HWPP Program regarding any and all patient safety concerns and adverse consequences, and
- Sponsor shall advise the HWPP Program of any resolution or proposed resolution to the safety concerns and adverse consequences.

Notwithstanding any proposed resolutions to safety concerns and adverse consequences, the HWPP Program will:

- Consider any proposed solution brought by the sponsor, the site's Community Paramedicine Steering Committee, and the HWPP Advisory Committee,
- Consider the degree of endangerment by reviewing all data collected, reports written and any other relevant information which may provide insight into the activity,
- Review program regulations and project protocols to determine if the project was operating in compliance with the stated guidelines,
- Consider suspending project activities at the specified site and the trainee(s) involved,
- Consider the termination of that portion of the pilot project if it deems there has been no satisfactory resolution,

- Consider the termination of the pilot project if there were system-wide concerns relating to any endangerment activity without resolution, and
- Make available its findings to the general public.