

OSHDP Office of Statewide Health Planning and Development

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November 14, 2014

Howard Backer, MD, MPH
Director
Emergency Medical Services Authority
10901 Gold Center Drive, Suite 400
Rancho Cordova, CA 95670

RE: Health Workforce Pilot Project (HWPP) #173 – Community Paramedicine Approval with Modifications

Dear Dr. Backer:

I am pleased to announce the approval of the Emergency Medical Services Authority (EMSA) application, HWPP #173 Community Paramedicine with modifications. This project will test, demonstrate, and evaluate the practice of Community Paramedicine 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 Emergency Medical Services Authority, as the project sponsor, is approved to proceed with all of the concepts and pilot sites proposed in its application for HWPP #173 provided that all of the modifications specified in the OSHPD staff recommendation memorandum dated October 13, 2014 (attached for reference) are implemented. Those recommendations 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.

Additionally, all of the following five provisions must be met:

- In addition to the requirements specified in the OSHPD staff recommendation memorandum dated October 13, 2014, the sponsor shall ensure that all project sites modify the Informed Consent form to read as follows:

"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. An exception to this requirement will be allowed for study sites where the main objective is to evaluate alternative destinations for

patients with mental health issues that potentially prevent them from having adequate capacity to consent, and where paramedics participating in the Behavioral Health Pilot Project have completed a specified Psychiatric Emergency Response Team Training Course in Behavioral Health issues in addition to the completion of the Community Paramedicine Core Training. In these cases, efforts should still be made to obtain informed patient consent for the study, but inability for psychiatric reasons will not prevent the patient from participating. Patients in these mental health projects with other reasons for incapacity, such as unresponsiveness, and patients in all other projects cannot be included in the pilot projects unless consent is lawfully given."

- The sponsor shall work with the project sites to develop further consistency with the medical criteria, protocols and training for similar concepts that are being tested.
- The sponsor shall ensure that all alternate destination concepts (CP 001, CP 003, CP 009 and CP 012) send additional personnel to both the statewide and local training.
- The sponsor shall require all sites to pursue local Institutional Review Board (IRB) approval.
- OSHPD will ensure that data safety monitoring is included in the responsibility of the HWPP #173 Advisory Committee, through site visits and data submission reports.

As was stated in the staff recommendation, 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 Program 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,

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- 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.

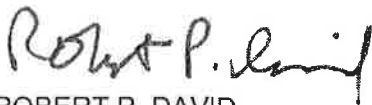
We appreciate your willingness to modify aspects of your project as a result of the review and comment phase of the application process. This approval is granted pursuant to Health and Safety Code Section 128125 of the governing administration of the HWPP Program.

This approval is effective immediately and will expire on November 14, 2015. You will be asked to submit reports and data that describe the progress in meeting objectives. If an extension of time is needed, you will be required to provide this Office with information to justify the request by September 15, 2015.

OSHPD will monitor HWPP #173 through written reports and site visit evaluations. In addition, we expect the Advisory Committee to assist the Office with the monitoring and development of guidelines to strengthen protocols, if possible, pursuant to their findings.

Ms. Kristen M. Widdifield will serve as the Program Administrator and you may contact her with any questions at (916) 326-3718 or Kristen.Widdifield@oshpd.ca.gov.

Very truly yours,



ROBERT P. DAVID
Director

cc: Lupe Alonzo-Diaz, Deputy Director, Healthcare Workforce Development Division