APPENDIX B

STATEMENT OF WORK
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Attachment A.1 – Intentionally Omitted

Attachment A.2 – Procedure for Non-Compliance with Data Collection Requirements
EXHIBIT A
STATEMENT OF WORK

1.0 SCOPE OF WORK

The Comprehensive Stroke System (CSS) will be comprised of Comprehensive Stroke Centers (CSCs) and Thrombectomy-Capable Stroke Centers (TSCs) to provide acute care for suspected stroke patients in Los Angeles County (County) who access the 9-1-1 system for emergency medical care. Implementation of the CSS will facilitate the Emergency Medical Services (EMS) Agency’s implementation of higher-level standards for the CSCs and TSCs to provide neurosurgery and/or thrombectomy procedures and improve outcomes for patients suffering the debilitating effects of stroke. These higher-level standards are designed to improve stroke patient care while enabling both the Hospitals and the County to better target and track the affected population and meet the guidelines developed by the American Heart Association/American Stroke Association.

2.0 DEFINITIONS

Throughout this Statement of Work (SOW), references are made to certain persons, groups, or departments/agencies. For convenience, specific terms and definitions can be found in the Agreement, Paragraph 2.0 Definitions.

3.0 ADDITION AND/OR CHANGES TO CSS(S), SPECIFIC TASKS AND/OR DATA REQUIREMENTS

3.1 The EMS Agency may elect to restructure the CSS as it deems necessary in accordance with Paragraphs 6.3 and 6.4 of this Exhibit A, SOW.

3.2 All changes must be made in accordance with Paragraph 8.0, Standard Terms and Conditions, Sub-paragraph 8.1, Amendments, of the Agreement.

4.0 RESPONSIBILITIES - HOSPITAL

4.1 Project Manager

4.1.1 Contractor shall provide a full-time Project Manager or designated alternate. County must have access to the Project Manager during all hours, 365 days per year. Contractor shall provide a telephone number where the Project Manager may be reached on a twenty-four (24) hour per day basis.

4.1.2 Project Manager shall act as a central point of contact with the County.

4.1.3 Project Manager/alternate shall have full authority to act for Hospital on all matters relating to the daily operation of the Agreement. Project Manager/alternate shall be able to effectively communicate, in English, both orally and in writing.

4.2 Personnel
4.2.1 Hospital shall assign a sufficient number of employees to perform the required work. **At least one employee on site shall be authorized to act for Contractor in every detail and must speak and understand English.**

4.2.2 Stroke Program Medical Director

Hospital shall designate a physician on Hospital staff to direct and coordinate the functions of the CSC or TSC (including without limitation, the quality improvement program for the services provided herein), and to ensure compliance with policies, procedures, and protocols established by the EMS Agency. This physician, who shall have the title of “Stroke Program Medical Director”, shall:

1) Be a licensed physician in the State of California.

2) Be Board Certified in Neurology or Neurosurgery by the American Board of Psychiatry and Neurology; or the American Board of Neurological Surgery by the American Board of Medical Specialties.

3) Be privileged by Hospital in interventional procedures according to their specialty.

4) Provide medical oversight and ongoing performance of stroke quality improvement (QI) programs and adherence to the requirements of this Agreement.

5) Participate in the Hospital Stroke Committee and other committees associated with stroke care.

6) Collaborate with the Stroke Program Manager to ensure adherence to the Stroke Receiving Center Standards and provisions set forth in the Los Angeles County Prehospital Care Manual.

7) Act as a liaison with hospital administration, Stroke Program Manager, Medical and Clinical Staff across stroke patient’s continuums of care.

8) Attend 100% of EMS Agency Stroke Center Advisory Committee. Fifty percent (50%) of meetings may be attended by an alternate physician, who is involved in Hospital’s stroke program.

9) Ensure continued certification as a CSC or TSC by a certifying body deemed acceptable by Los Angeles County EMS Agency.

4.2.3 Hospital Staff Physicians
FOR CSCs

1) Hospital shall have a dedicated on-call endovascular neurosurgeon, neurointensivist, neurologist, and interventional neuroradiologist. These physicians cannot be concurrently on-call at any other hospital or specialty service (e.g. trauma).

2) Hospital shall have a neurosurgeon with expertise in cerebrovascular/ endovascular surgery to perform on-site surgical interventions. Neurosurgery must be available within 30 minutes, 24 hours per day and 7 days per week. These physicians cannot be concurrently on-call at any other hospital or specialty service (e.g. trauma).

FOR TSCs

Hospital shall have a dedicated neurointensivist, neurologist, and interventional neuroradiologist. These physicians cannot be concurrently on-call at any other hospital or specialty service (e.g. trauma).

4.2.4 Stroke Program Manager

1) Hospital shall designate a Stroke Program Manager who shall:

   a) Be responsible for managing all CSC activities sponsored by Hospital to ensure compliance with this Agreement, and policies, procedures and protocols established by the EMS Agency.

   b) Be a licensed Registered Nurse (RN) in the State of California.

   c) Be knowledgeable in critical care and interventional stroke care procedures.

   d) Collaborate with the Stroke Program Medical Director to ensure development of stroke care policies, procedures, and protocols.

   e) Maintain up-to-date continuous stroke QI program and disseminating EMS Agency reports to pertinent program participants.

   f) Participate in Hospital Stroke Committee and other committees associated with stroke care.

   g) Ensure compliance with data collection requirements.
h) Attend 100% of EMS Agency Stroke Center Advisory Committee. Fifty percent (50%) of meetings may be attended by an alternate RN, who is involved in Hospital’s stroke program.

i) Collaborate with the emergency department to ensure processes are in place to capture patients transported to the Stroke Center by EMS providers or other acute care hospitals.

j) Develop relationships and collaborating with surrounding Primary Stroke Centers and Stroke Referral Facilities to facilitate interfacility transfers.

k) Assure stroke diversion is appropriate and processes are in place to minimize the need for diversion.

l) Collaborate with the Stroke Program Medical Director to ensure continued certification as a CSC or TSC by a certifying body deemed acceptable by Los Angeles County EMS Agency.

4.3 Materials and Equipment

The purchase of all materials/equipment to provide the needed services is the responsibility of the Hospital. Hospital shall use materials and equipment that are safe for the environment and safe for use by the employee.

4.4 General Requirements

4.4.1 Hospital shall comply with all the requirements specified in the Los Angeles County EMS Agency Stroke Standards.

4.4.2 Hospital shall publicly report outcomes related to interventional procedures, as determined by the Hospital.

4.4.3 Hospital shall participate in the ReddiNet® and VMED28 communication systems.

4.4.4 Hospital shall have a dedicated telephone line to facilitate direct communication with EMS personnel, paramedic base hospitals and the Medical Alert Center.

4.4.5 Hospital shall implement and monitor the policies and procedures of the EMS Agency related to the services performed by Hospital under this Agreement.

4.4.6 Hospital administration, medical staff and hospital staff shall meet the requirements under applicable State regulations and the EMS Agency’s policies and procedures for the provision of services under this Agreement.

4.5 Data Collection
4.5.1 Hospital shall collect and submit patient level data as specified in the most current version of the Prehospital Care Manual Reference No. 650, Stroke Center Data Dictionary.

4.5.2 Data collection shall be conducted through: 1) Los Angeles County Stroke Center Database or 2) Get With The Guidelines®-Stroke registry. Hospital shall only utilize one system and not a combination of both systems.

4.5.3 Hospital shall comply with all changes or modifications in the data collection process identified by the EMS Agency. All modifications or request for additional data identified by the EMS Agency must first be reviewed by the Stroke Center Advisory Committee.

4.5.4 Hospital shall submit stroke patient data within sixty (60) calendar days following patient discharge to hospital.

4.5.5 Hospital shall submit a monthly tally of newly diagnosed stroke patients to the EMS Agency by the end of the month for the previous month (For example: January tally is due February 28th).

4.5.6 Hospital must maintain a minimum 90% compliance for:

1) Capture of patients meeting the inclusion criteria for data collection

2) Data field completion

3) Data field accuracy

4) Timely data collection

5) Timely tally submission

4.5.7 Hospital shall collect stroke data on all patients who are initially identified in the prehospital setting by EMS or transported by EMS and identified in the emergency department as meeting one or more of the following:


2) Final hospital (if admitted) or emergency department (if not admitted) diagnosis of ischemic stroke, transient ischemic attack, intracerebral hemorrhage, intraventricular hemorrhage, or subarachnoid hemorrhage;

3) Transported to CSC or TSC for acute stroke care either primarily by 9-1-1 or interfacility transport; or
4) Transferred from another acute care facility to the CSC or TSC for acute stroke care.

4.5.8 Hospital shall seek assistance from County’s Project Manager or designee, whenever County’s Stroke Center Database application is not functioning correctly.

4.5.9 Hospital shall assign adequate data collection personnel, who will work collaboratively with Emergency Department personnel, to assure capture and entry of patient stroke data on an ongoing basis. Hospital shall identify qualified back-up personnel, excluding Stroke Program Manager, to collect data, as reasonably appropriate for Hospital to meet Hospital’s data collection responsibilities described herein. Furthermore, Hospital shall permit adequate time for complete training of such personnel. Arrangements for training of new or replacement Hospital personnel shall be the primary responsibility of Hospital.

4.5.10 Patient Outcome:

Hospital shall provide the EMS Agency patient outcome of ALL patients transported to the Hospital via the 9-1-1 system. Outcome data shall include all variables listed in the most current 9-1-1 Receiving Hospital Data Dictionary. Outcome data shall be provided utilizing the EMS Agency online data collection tool.

4.5.11 Non-Compliance with Data Collection Requirements:

Procedures for non-compliance of data collection requirements shall be in accordance with Attachment A.2 – Procedure for Non-Compliance with Data Collection Requirements.

4.6 Program Monitoring

4.6.1 Hospital extends to County the right to monitor Hospital’s programs and procedures with respect to this Agreement, and to inspect its facilities for contractual compliance with State and EMS Agency policies, procedures, protocols, and regulations.

4.6.2 Program Review

At minimum, program review shall be conducted by EMS Agency every three (3) years to ensure compliance with State and EMS Agency policies, procedures, protocols, and regulations. Hospital shall be given no less than ten (10) calendar days’ notice in advance of said review. Hospital’s director of utilization review and director of medical records shall be permitted to participate in the review and Hospital and its staff shall fully cooperate with EMS Agency representatives. In the conduct of such audit and review, Hospital shall allow such EMS Agency representatives access to all reports,
audio recordings, medical records, and other reports pertaining to this Agreement, and shall allow photocopies to be made of these documents, utilizing Hospital's photocopier.

4.6.3 Focus Reviews

Notwithstanding the above program reviews, County reserves the right to conduct focus reviews due to complaints, failure to meet data requirement, or other term of the Agreement by EMS Agency representatives during County's normal business hours and only after County has given Hospital at least three (3) working days prior written notice thereof. In computing the three (3) working days, a Saturday, Sunday, or legal holiday shall not be included. Said notice need not be given where County determines that the health and welfare of patients may be jeopardized by waiting the three-day period.

4.6.4 Exit Conference for Program Reviews and Focus Reviews

An exit conference shall be held following the performance of program reviews or focus reviews by EMS Agency representatives and results of the program review or focus review shall be discussed with Hospital's Administrator or his or her authorized designee prior to the generation of any final written report or action by Director, or designee, or other EMS Agency representatives based on such review. The exit conference shall be held on site prior to the departure of the reviewers and Hospital shall be provided with an oral or written list of preliminary findings at the exit conference. A written report of the program monitoring review shall be prepared and provided to Hospital. Hospital shall permit periodic unscheduled site visits by EMS Agency representatives for monitoring stroke diversion status, quality improvement and/or continuing education programs and stroke care meetings.

4.7 Written Transfer Agreements

4.7.1 Hospital shall have written transfer agreements with its Stroke Referral Facilities, including but not limited to Primary Stroke Centers. Written transfer agreements shall include, at a minimum, the following:

1) List the specific responsibilities of the CSC or TSC and the Stroke Referral Facility;

2) Notification procedures including communication between facilities at the physician and nursing level;

3) Patient care procedures prior to the transfer of the patient;

4) Process to provide copies of all medical records and imaging to the receiving facility;
5) Notification of transport agency, unit and transport team;

4.7.2 Hospital shall have a written transfer agreement with at least one other CSC that includes the following:

1) Contact names;
2) Contact phone numbers; and
3) Allows for timely transfer 24 hours a day, 7 days a week

4.8 Written Transportation Agreements

Hospital shall have written transportation agreements with transport agency/private ambulance companies licensed in Los Angeles County to ensure timely transport of patient occurs. Written agreements shall include provisions to ensure the type of transport vehicle (Ambulance) and appropriate level of transport medical personnel (advanced life support: e.g., paramedic, nurse, physician) is available at the Stroke Referral Facility within 60 minutes, 24 hours per day and 7 days per week. Utilization of the 9-1-1 system to conduct interfacility transports of stroke patients is not acceptable.

4.9 Telemedicine Capabilities

Hospital shall have telemedicine capabilities to deliver health care services and clinical information to Stroke Referral Facilities. This includes a wide array of clinical services using internet, wireless, satellite and telephone media.

4.10 Quality Improvement (QI)

4.10.1 Hospital shall have a current comprehensive stroke care QI plan approved by the EMS Agency and ensure participation in the EMS Agency's system-wide QI program by designating a representative for the meetings.

4.10.2 Hospital shall have a process developed, with input from the stroke center medical director, Hospital physician staff, stroke nurses, paramedics, and Hospital administration to:

1) Identify important aspects of stroke care issues.
2) Identify indicators for those important aspects.
3) Evaluate the stroke care and service, including trends, to identify opportunities for improvement.
4) Take action to improve care and service, or to solve problems, and evaluate the effectiveness of those actions.
4.10.3 Hospital shall also participate in the EMS Agency's QI Program, with records provided by Hospital in accordance with the terms of this Agreement.

4.10.4 Hospital shall develop a comprehensive-multidisciplinary QI Committee which shall include at minimum; EMS, emergency department, nursing, intensive care, neurology, neurosurgery and neuroradiology.

4.11 Stroke Certification

Hospital shall provide the EMS Agency results of the subsequent certification review(s) conducted by the certifying body, which shall include but not limited to, action plans to correct any identified issue(s) and final approval by the certifying body showing compliance with all requirements.

4.12 Ambulance Patient Offload Time

Hospital will be placed on diversion to stroke patients if three ambulance units from the same emergency medical services provider have been waiting to offload more than 30 minutes.

4.13 Community Education Programs

Hospital shall offer at least two annual programs to educate the public about stroke prevention, diagnosis and/or the availability of acute therapies. Community education programs are designed to be delivered through various means to address:

1) Risk factors, signs and symptoms for stroke or other cardiovascular diseases.

2) General prevention efforts that target smoking cessation, obesity and diabetes.

3) Management of hypertension, lipid levels, atrial fibrillation and medication adherence.

4) Other issues as identified by Hospital.

4.14 Contractor’s Office

Contractor shall maintain an office with a telephone in the company’s name where Contractor conducts business. The office shall be staffed during the hours of 8:00 a.m. to 5:00 p.m., Monday through Friday, by at least one employee who can respond to inquiries and complaints which may be received about the Contractor’s performance of the Agreement.

5.0 QUALITY CONTROL
The Contractor shall establish and utilize a comprehensive Quality Control Plan (Plan) to assure the County a consistently high level of service throughout the term of the Agreement. The Plan shall be submitted to the Facility Project Monitor for review and approval. The Plan shall include, but may not be limited to the following:

5.1 Method of monitoring to ensure that Agreement requirements are being met.

5.2 A record of all inspections conducted by the Contractor, any corrective action taken, the time a problem was first identified, a clear description of the problem, and the time elapsed between identification and completed corrective action, shall be provided to the County upon request.

6.0 RESPONSIBILITIES - COUNTY

6.1 Personnel

The County will administer the Agreement according to the Agreement, Paragraph 6.0, Administration of Agreement - County. Specific duties will include:

6.1.1 Monitoring Hospital’s performance in the daily operation of this Agreement.

6.1.2 Preparing Amendments in accordance with the Agreement, Paragraph 8.0, Standard Terms and Conditions, Sub-paragraph 8.1 Amendments.

6.2 Policies, Procedures, and Protocols

6.2.1 Maintain policies, procedures, and protocols consistent with State and County laws, regulations, and standards to assure adequate access and provision of stroke care.

6.2.2 Review and revise policies, at minimum, every three years; more frequently as needed.

6.2.3 Make available to Hospital a complete manual containing all policies, procedures, and protocols which the EMS Agency currently considers to be applicable to participants in the CSS.

6.3 Interim CSS Re-Configuration

County may, on an interim basis, re-configure the CSS as it deems necessary in those instances when a designated CSC or TSC gives notice that it is withdrawing from the CSS or when a designated CSC or TSC is suspended or terminated from the CSS. In the event that an interim re-configuration occurs, Hospital, if affected by the re-configuration, shall be given the immediate opportunity to provide written and oral statements to the Director, or designee and shall be provided with the "due process" procedures specified in Paragraph 9.1, Due Process of the Agreement. Nothing herein however,
is intended to prevent implementation by Director, or designee, on an emergency basis of such changes as he/she may find measurably necessary to preserve the integrity of the CSS and to protect the health and safety of County residents.

6.4 CSS Configuration

County shall notify Hospital of proposals for substantial operational or structural changes in the components of the CSS or in the overall operation or configuration of such system. This shall include, but not be limited to, decreasing the number of hospitals in the event that a re-configuration of the CSS is deemed necessary. In the event the number of hospitals is decreased, and unless otherwise agreed upon by the parties, written notice shall be given to Hospital at least sixty (60) calendar days prior to the effective date of any resulting substantial operational or structural changes to the CSS. If the need for Hospital to serve as a CSC or TSC can no longer be substantiated, Hospital, upon request, shall be provided with "due process" as specified in Paragraph 9.1, Due Process of the Agreement.

6.5 Data Management

6.5.1 County, after consultation with and advice from the Stroke Center Advisory Committee, and its bylaws, if duly constituted, shall continue maintenance of a Stroke Center Database.

County Stroke Center Database includes:

1) Stroke Center Data Dictionary

2) Los Angeles County online data collection software

3) Data use agreement with Get With The Guidelines®-Stroke to provide the EMS Agency Hospital-identified Limited Data Set via an online System Report/Downloader

6.6 Staff Designation

The EMS Agency shall assign staff to provide direction and review, monitor, communicate and coordinate matters affecting the CSS under the jurisdiction of the EMS Agency. EMS staff shall periodically attend Hospital's meetings related to the CSS and shall perform contract compliance reviews as specified in this Agreement.