Health Services
LOS ANGELES COUNTY

ADOPTED

BOARD OF SUPERVISORS
COUNTY OF LOS ANGELES

17 October 10, 2017

LORI GLASGOW
EXECUTIVE OFFICER

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To ensure access to high-quality, patient-centered, cost-effective health care to Los Angeles County residents through direct services at DHS facilities and through collaboration with community and university partners.

October 10, 2017

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

Dear Supervisors:

APPROVAL OF AN AMENDMENT TO THE SPONSORED PROGRAMS AGREEMENT WITH RANCHO RESEARCH INSTITUTE, INC. TO ADD PROGRAMS FROM ITS EXPIRING AGREEMENTS (SUPERVISORIAL DISTRICT 4) (3 VOTES)

SUBJECT

Request approval and delegated authority to: (i) execute an Amendment to the Sponsored Programs Agreement with Rancho Research Institute, Inc. to add in the remaining programs from its expiring Medical Research and Education Agreement and Orthotics Services Agreement; and (ii) take other contractual actions related to the Sponsored Programs Agreement.

IT IS RECOMMENDED THAT THE BOARD:

1. Delegate authority to the Director of Health Services (Director), or his designee, to execute Amendment No.1 to Sponsored Programs Agreement No. H-707147 with Rancho Research Institute, Inc. (RRI) serving Rancho Los Amigos National Rehabilitation Center (RLANRC), effective November 1, 2017 to add the following Sponsored Programs: medical research, education, and robotics rehabilitation with no money paid for RRI's services; patient transportation services program with County providing fuel and maintenance with an estimated annual value of $0.058 million for the vehicles used by this program; and orthotics services program at an estimated annual cost of $1.470 million.

2. Delegate authority to the Director, or his designee, as required by the Health Insurance Portability and Accountability Act of 1996 (HIPPA) Privacy

Rule to execute Data Use Agreements with research project managers for the use and disclosure of information of a limited data set for specified limited purposes in connection with research activities.

3. Delegate authority to the Director, or his designee, to execute Amendments to: (a) add Sponsored Programs, at no net County cost, with review and approval by County Counsel and notification to the Chief Executive Office (CEO) and the Board; and (b) delete Sponsored Programs that either no longer benefit RLANRC and the community at large or that RRI can no longer provide.

PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION

Background

RRI is a non-profit, reportable support group initially organized by physicians at RLANRC with a mission of engaging in research and education activities which contribute to the County's provision of healthcare services and benefit the medical community and public at large. RRI is distinct from the Rancho Foundation whose primary purpose is to fundraise for RLANRC. The Department of Health Services (DHS) and RRI have a longstanding partnership whereby RRI provides medical research, education programs, and patient services.

The Board approved a new agreement with RRI on November 1, 2016 for Sponsored Programs. A Sponsored Program is a program or category of programs defined in the Agreement that is for the benefit of RLANRC patients or RLANRC, the medical community, and/or the health and wellness of the community at large. The intent of the Sponsored Programs Agreement is to consolidate the array of programs which RRI currently manages and/or supports at RLANRC under its Medical Research and Education Agreement and Orthotic Services Agreement. The first program that was incorporated into the Sponsored Programs Agreement was the Wellness Center Program that coincided with the opening of the new Wellness Center. The remaining programs to be incorporated into the Sponsored Program Agreement are the research, education, robotics rehabilitation, patient transportation services, and orthotic services programs.

Research Program

RRI performs research that provides direct benefits to both County patients and the medical community at large. An example of a research project that is currently performed by RRI is the Spinal Cord Injury (SCI) Modal System: National SCI Database. RRI is one of 14 organizations in the country participating in the SCI Model System grant, a multi-center collaborative grant to establish best clinical practices and determine the outcome of rehabilitation and prevent secondary conditions in SCI. Another example is the Secondary Stroke Prevention by Uniting Community and Chronic Care Model Teams Early to End Disparities: the SUCCEED Trial. In this project, County stroke survivors are provided in-home intervention by care managers and/or community health workers to help them manage stroke risk factors to prevent future strokes.

Education Program

RRI arranges educational programs for RLANRC staff and community clinicians that benefit the delivery of care both at RLANRC and in the community. These educational programs range from inviting speakers for medical grand rounds, sponsoring registration and travel for specific medical meetings/conferences for physicians and therapists, to sponsoring conferences and lectures including the Women's Health Conference and the annual Dr. Thomas Beardmore Memorial Lecture

on Arthritis and Rheumatology.

Robotics Rehabilitation Program

The Tyler A. Dykes Robotics Center (Robotics Center) for Robotics Rehabilitation delivers robotics-based services to individuals seeking additional resources and interventions for health maintenance, wellness enhancement and functional benefits. The robotics services serve both pediatric and adult clients with diagnosis that include stroke, brain injury, cerebral palsy, hemispherectomy, spinal cord injury and other neurologic disorders. RLANRC therapists provide robotics services in the Robotics Center for its inpatients as a component of their rehabilitation program and has first priority for the use of the Robotics Center. However, when the Robotics Center is not in use by RLANRC, RRI provides low-cost community-based robotics services to enhance health and maintain or advance function for individuals with significant disability. The population served by this program either would not have access to such services, since very few organizations provide this technology or programing, or they would find the costs to be prohibitive as other programs in this region are for-profit entities with very high participation costs.

Patient Transportation Services Program

RRI, under its Paratransit Agreement with the Department of Public Works, provides free transportation for elderly persons and persons with disabilities who use the facilities, including the Wellness Center, at RLANRC. These patients reside in all parts of the County and generally have no other means of transportation to RLANRC. Historically this transportation program utilized County-owned vans and DHS paid for the fuel and maintenance of these vehicles. However, the County was able to work with RRI to obtain grants to obtain replacement transportation vans, which has saved the County money. DHS has continued to provide fuel and maintenance for the RRI-owned transportation vans to ensure the continuation of this essential service for RLANRC patients. The Sponsored Programs Agreement gives DHS the ability to terminate fueling and maintenance of the RRI transportation vans with thirty (30) days' notice, should DHS decide to utilize an alternate transportation program in the future.

Orthotic Services Program

RRI provides specialized expertise in fabrications and modifications of orthotic devices at RLANRC to address the special needs of patients. Because of the dynamic nature of neurologic and motor recovery (e.g. patients with progressive neurologic disorders or with chronic neurologic conditions who are undergoing recovery), certain patients require immediate and highly specialized evaluations in addition to the provision of specific orthotic devices. In concert with the research program, RRI has successfully developed many orthotic devices to meet patients' special needs. RRI has the requisite experience with chronic disabilities to meet the needs of RLANRC's patient population, which is essential for the success of the facility's rehabilitation program.

Recommendations

Approval of the first recommendation will allow the Director to execute Amendment No. 1 to Agreement No. H-707147, substantially similar to Exhibit I, with RRI to incorporate the remaining Sponsored Programs from the current Medical Research and Education and Orthotics Services Agreements that are scheduled to expire on October 31, 2017.

Approval of the second recommendation will ensure the confidentiality of protected health information of County patients participating directly or indirectly in research projects in accordance

with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and corresponding privacy regulations.

Approval of the third recommendation will allow for the addition of new Sponsored Programs for the benefit of RLANRC patients or RLANRC, the medical community, and/or the health and wellness of the community at large and the deletion of Sponsored Programs that no longer provide these benefits or that RRI is unable to continue to provide.

Implementation of Strategic Plan Goals

The recommended actions support Strategy II.2, "Support the Wellness of Our Communities" and III.3, "Pursue Operational Effectiveness, Fiscal Responsibility, and Accountability" of the County's Strategic Plan.

FISCAL IMPACT/FINANCING

Research Program

RRI shall reimburse DHS for research costs incurred by DHS that are related to administrative, clinical, ancillary services, and supplies which a patient would not have received absent their participating in a research project. DHS will charge the current Board-approved charge rates in effect at the time DHS provided the services or supplies to RRI.

Education Program and Robotics Rehabilitation Program

The net proceeds derived from income of operations of the programs shall be used solely for the benefit of such program from which it was derived.

Patient Transportation Services Program

The estimated annual cost of providing fuel and maintenance for the RRI-owned transportation vehicles is covered within RLANRC's existing resources.

Orthotic Services Program

Funding is included in the DHS Fiscal Year (FY) 2017-18 Adopted Budget and will be requested in subsequent fiscal years as necessary.

The County reimburses RRI for orthotics services provided to County-responsible patients at current rates listed on the Medi-Cal Schedule of Maximum Allowance (SMA). RRI bills third party payors (Medi-Cal, Medicare, private insurance, etc.) directly for reimbursement for all services/devices provided to County patients with those payor sources.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS

The Agreement includes all Board of Supervisors' required provisions, including the most recent provision – Compliance with County's Zero Tolerance Human Trafficking Policy.

The County has agreed to continue its medical malpractice indemnification of RRI for liability arising

from a research study conducted by RRI. However, this indemnification shall only apply when DHS, on behalf of the County, makes a written determination that the particular study is aligned with the priorities of the County and that indemnification by the County shall be in the public interest. For studies that do not receive this written determination, RRI will be required to provide its own malpractice insurance.

County Counsel has approved Exhibit I as to form.

CONTRACTING PROCESS

RRI is a reportable foundation/support group providing support through Sponsored Programs. A reportable foundation/support group provides support to County departments in the form of monetary or equipment donations, research, education, volunteer labor, etc., and its primary purpose is to directly and indirectly benefit the department and its mission or clients. This Agreement complies with the County Fiscal Manual (Chapter 16) which states that departments should establish Board-approved Agreements with their reportable foundations and support groups that specifically define the roles and responsibilities of each party and be approved as to form by County Counsel.

IMPACT ON CURRENT SERVICES (OR PROJECTS)

Approval of the recommendations will ensure the continuation of the research, education, robotics rehabilitation, patient transportation services, and orthotic services programs benefitting RLANRC and its current and former patients, the medical community, and the community at large.

Respectfully submitted,

Mitchell H. Katz, M.D.

Director

MHK:es

Enclosures

c: Chief Executive Office
County Counsel
Executive Office, Board of Supervisors

EXHIBIT I

Agreement No.: H-707147

SPONSORED PROGRAMS AGREEMENT

Amendment No. 1

THIS AMENDMENT is made and entered into this _____ day of _____, 2017,

By and between COUNTY OF LOS ANGELES (hereafter "County"),

And RANCHO RESEARCH INSTITUTE, INC. (hereafter "Contractor")

Business Address:
P.O. Box 3500
Los Amigos Station
Downey, CA 90242

WHEREAS, reference is made to that certain document entitled "Sponsored Programs Agreement," dated February 1, 2017, and further identified as Agreement No.: H-707147; and

WHEREAS, it is the intent of the parties hereto to amend the Agreement to incorporate Sponsored Programs from Contractor's previous Medical Research and Education Agreement No. H-202040 and Orthotic Services Agreement No. 702969 , and to provide for the other changes set forth herein; and

WHEREAS, Agreement provides that changes, in accordance to Paragraph 8.1, Amendments, may be made in the form of an Amendment which is formally approved and executed by the parties; and

WHEREAS, Contractor warrants that it possesses the competence, expertise and personnel necessary to provide services consistent with the requirements of this Agreement and consistent with the professional standard of care for these services.

NOW, THEREFORE, THE PARTIES HERETO AGREE AS FOLLOWS:

1. This Amendment shall commence and be effective November 1, 2017.

2. Agreement, Exhibit B, Program Specific Exhibits, is modified to add Exhibit B-2, Research Program, attached hereto and incorporated herein by reference.

3. Agreement, Exhibit B, Program Specific Exhibits, is modified to add Exhibit B-3, Education Program, attached hereto and incorporated herein by reference.

4. Agreement, Exhibit B, Program Specific Exhibits, is modified to add Exhibit B-4, Robotic Rehabilitation Program, attached hereto and incorporated herein by reference.

5. Agreement, Exhibit B, Program Specific Exhibits, is modified to add Exhibit B-5, Orthotics Services Program, attached hereto and incorporated herein by reference.

6. Agreement, Exhibit B, Program Specific Exhibits, is modified to add Exhibit B-6, Patient Transportation Services Program, attached hereto and incorporated herein by reference.

7. Agreement, Exhibit E, County's Administration, is deleted and replaced by Exhibit E(1) attached hereto and incorporated herein by reference. All references to Exhibit E in the Agreement shall hereafter be replaced by Exhibit E(1).

8. Except for the changes set forth hereinabove, Agreement shall not be changed in any respect by this Amendment.

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IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be executed by the County's Director of Health Services and Contractor has caused this Amendment to be executed on its behalf by its duly authorized officer, the day, month, and year first above written.

COUNTY OF LOS ANGELES

By:_____for
Mitchell H. Katz, M.D.
Director of Health Services

CONTRACTOR

RANCHO RESEARCH INSTITUTE, INC.

By:_____
Signature

_____
Printed Name

_____
Title

APPROVED AS TO FORM:
MARY C. WICKHAM
County Counsel

By_____
James A. Johnson, Deputy County Counsel

EXHIBIT B-2

PROGRAM SPECIFIC EXHIBIT: RESEARCH PROGRAM

1.0 DESCRIPTION OF SERVICES

1.1. Contractor conducts Research at Facility that involves direct contact with Facility patients, access to their personal health information, and/or utilization of Facility services and resources.

1.2. All Research shall align with Facility's mission to improve the County's health care delivery system, and prior to implementation, Research activities shall receive required County approvals as delineated in this Exhibit, and all Research shall comply with applicable governmental regulations.

1.3. Facility shall be compensated for any costs related to Research activities that are not part of standard care unless otherwise stated herein.

2.0 DEFINITIONS

2.1. **Ancillary Services and Supplies:** Ancillary services and supplies, other than room, board, medical and nursing services, includes services and supplies provided to Facility patient, which may include, but are not limited to, laboratory, radiology, pharmacy, and physical therapy.

2.2. **Business Associate:** Shall have the same meaning as the term "business associate" in 45 C.F.R. 160.103.

2.3. **CMS:** Centers for Medicare and Medicaid Services.

2.4. **Common Rule:** U.S. Department of Health and Human Services (HHS) Common Rule for the protection of human subjects in Research, codified in 45 CFR 46.101**.**

2.5. **Covered Entity:** Shall have the same meaning as the term "covered entity" in 45 C.F.R. 160.103.

2.6. **Data Use Agreement:** An agreement required by HIPAA's privacy rules between a covered entity and a person or entity that receives a limited data set. The Data Use Agreement must state at a minimum that the recipient will use or disclose the information in the limited data set only for specific limited purposes as set forth in DHS Policy No. 361.19 (De-identification of Protected Health Information/Limited Data Sets) and DHS Policy No. 361.27 (Use and Disclosure of Protected Health Information for Research Purposes) as in effect at any given time.

2.7. **DHS Research Committee, also known as the Research Oversight Board:** A committee or designee responsible for overseeing Facility's approved list of Research projects, with discussion and review of select project requests flagged by Facility or one of the committee members.

2.8. **Facility Bylaws and Policies:** Facility's medical staff bylaws, medical staff rules and regulations, and all policies and procedures adopted by Facility, as in effect and revised from time to time, to govern the provision of patient care, ethics, occupational health, fire safety, infection control, health information privacy and Research Program compliance.

2.9. **FDA:** U.S. Food and Drug Administration.

2.10. **Federalwide Assurance:** Assurance filed with the Office of Human Research Protections (OHRP) within HHS in compliance with 45 CRF part 46.

2.11. **Informed Consent:** Informed consent means the knowing consent of an individual (or of a legally authorized representative when a vulnerable or dependent person is to be involved) to his or her participation in a surgical or medical procedure without coercion or undue influence. Consent information, oral or written, shall be expressed with words and in a language which is understandable to the Research Program Subject or the representative. The text of the consent information shall not include any exculpatory language through with the Research Program Subject is made to waive, or to appear to waive, any legal rights, including release of Contractor or its agents from liability for negligence. All Research Program Subjects or their authorized representatives shall receive a copy of any consent document which has been completed by them.

2.12. **Institutional Review Board (IRB):** Institutional review board designated in Facility's Federalwide Assurance, including any other duly designated IRB.

2.13. **Medicare Coverage Analysis (MCA):** A detailed review required by Medicare of clinical research items, services, procedures, and Medicare billing rules to determine the appropriate payer/funding source for each item or service.

2.14. **Organized Health Care Arrangement:** Shall have the same meaning as the term "Organized Health Care Arrangement" in 45 C.F.R. 160.103.

2.15. **Principal Investigator (PI):** A person authorized by Contractor who takes direct responsibility for completion of a Research Program project, directing the Research project, and reporting directly to the funding agency.

2.16. **Research:** A systematic, intensive study, designed to increase knowledge or understanding of the subject studied, a systematic project specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

2.17. **Research Agreement:** An agreement between Contractor and third parties governing Research activities.

2.18. **Research Orders:** A template set of medical orders that will be developed by Facility, for each Research project, using a format that is mutually agreed upon by Facility and Contractor and that may change from time to time. Research Project Manager and Personnel must use Research Orders to request Facility services, Ancillary Services or Supplies during the conduct of a Research Project.

2.19. **Research Program Services:** Administrative and clinical services that Facility offers under this Research Program Statement of Work.

2.20. **Research Program Subject:** A living person participating in a Research project which obtains (a) data through intervention or interaction with the person, or (b) identifiable private information. A person may be a Research Program Subject when a Research project obtains data about the person from a third party or from the person directly. A Research Program Subject is a person recruited by the Contractor to participate in a Research project and may or may not be a patient who receives medical care at Facility.

2.21. **Research Project Manager:** Contractor's staff person, whom Contractor has designated to administer and oversee a Research project, which could include the PI, grant manager, or other persons deemed appropriate by Contractor. If any Research project involves Research Program Subjects, the Research Project Manager shall have appropriate licenses and certifications.

2.22. **The Joint Commission:** Formerly known as "The Joint Commission on Accreditation of Healthcare Organizations," is the accrediting body for healthcare facilities, or any successor organization.

3.0 PROGRAM SPECIFIC AGREEMENT PROVISIONS

The following Agreement provisions are applicable for the Research Program:

3.1. Contractor's Performance During Civil Unrest or Disaster

Contractor shall adhere to Agreement Sub-paragraph 8.24.2, Contractor Performance During Civil Unrest or Disaster.

3.2. HIPAA- Covered Entity

Contractor shall adhere to Agreement Sub-paragraph 8.26.1, Covered Entity.

3.3. Additional Indemnification

The following indemnification provision will apply in addition to the description in the Agreement Sub-paragraph 8.28, Indemnification:

3.3.1. Each Party shall indemnify, defend, and hold harmless the other Party and its elected and appointed officers, employees and agents from and

against any and all liability, including but not limited to demands, claims, actions, damages, fees, costs, and expenses (including attorney and expert witness fees), arising from or connected with the acts and/or omissions of the Party providing the indemnification arising from and/or relating to this Agreement. The Parties both acknowledge that the obligation to indemnify does not extend to any other person or entity except as described above.

The Contractor shall use reasonable efforts to obtain agreements from all project sponsors indemnifying and holding harmless County from any and all liability for damages arising out of the performance of projects sponsored by them.

3.3.2. Notwithstanding the foregoing, the County agrees to indemnify and hold harmless the Contractor, its officers, agents, and employees from and against any and all malpractice claims for damage, including defense costs and legal fees, arising from a research study conducted by the Contractor for which the County makes a written finding that such research study aligns with the priorities of the County. Such indemnification shall not exceed a maximum amount of $1.5 million per occurrence and $8.0 million in the aggregate each fiscal year (July 1 - June 30).

This indemnification for a particular study shall only apply if the Chief Medical Officer (CMO) or designee, on behalf of the County, makes a written determination that the particular study is aligned with the priorities of the County and that indemnification by the County shall be in the public interest. Absent such a written notification, the County shall not indemnify the Contractor for research. Further, this indemnification shall apply only to medical malpractice claims resulting from authorized research studies conducted hereunder by, through, or on behalf of the Contractor on Facility premises. Additionally, this indemnification shall apply only if the project from which the medical malpractice claim arises satisfies all other terms and conditions of this Agreement, including the written finding by the CEO that indemnification by the County for this particular study is appropriate, as described above.

3.4. Additional Insurance Coverage Requirements

The following insurance coverage is required in addition to the required coverages described in Agreement Sub-Paragraph 8.30, Insurance Coverage:

Professional Liability- Research Program

For claims solely related to the Research Program, which do not involve services that are typically provided absent a clinical trial, the Contractor shall provide Professional Liability Insurance covering liability arising from any error, omission, negligent or wrongful act of the Contractor, or its officers or employees with limits of not less than $1 Million per occurrence and $3 Million aggregate. Notwithstanding this requirement, the Contractor is not required to have Professional Liability Insurance covering those studies for which the County makes a written finding that such research study aligns with the priorities of the County.

4.0 RESPONSIBILITIES- CONTRACTOR

4.1. As applicable, Contractor shall provide Facility with a listing of the title, Contractor IRB number, and Research Project Manager of all Research Projects originated by Contractor and/or its Personnel and conducted at Facility at the time of execution of this Agreement and on a monthly basis thereafter. Contractor shall provide Facility, through CMO, with access to IRB or information relevant to the Research Program.

4.2. Contractor shall obtain the review and approval by CMO, or designee, and as applicable, DHS Research Committee, of all Contractor proposed Research projects that seek to use Facility facilities and/or resources prior to initiating such programs at Facility facilities or with Facility resources. Contractor shall notify CMO three weeks prior to when a Research project is planned to be submitted for review by Contractor's IRB that proposes to utilize Facility patients, their personal health information, or Facility resources. Contractor shall provide CMO access to IRB files for all such Research projects for purposes of review, as described in Sub-paragraphs 5.1 and 5.2. CMO will notify Contractor in writing when a Research project has received final clearance by Facility. Such final clearance shall be obtained from Facility prior to commencing Contractor's IRB review and approval of the proposed Research project.

4.3. Contractor shall allow CMO to send representative(s) to meetings of Contractor's IRB for purposes of gaining information on Research projects that are proposing to use Facility resources or Ancillary Services and Supplies. Contractor should be notified and given the opportunity to review and approve the appointment of any proposed representatives.

4.4. Contractor shall comply with the Common Rule, as applicable to all Research projects involving human subjects, as defined by Common Rule, for which Contractor is responsible, regardless of the source of funding or whether the Research project is funded. In the case of conflict between regulations of the funding or regulatory agency and HHS, the more restrictive shall prevail. Contractor is also obligated to adhere to the regulations of the FDA (21 CFR 50.1 and 56.101) governing Research projects involving investigational new

drugs [within the meaning of 21 U.S.C. sections 355(i)(j)], or investigational new devices [within the meaning of 21 U.S.C. section 360(g)].

4.5. Contractor shall ensure that all Research Personnel have the necessary licenses and certifications for Research related activity, and have appropriate and current credentials, reported to Contractor human resources department, to assure safe and competent Research projects.

4.6. **Requirements for Research Projects**

Contractor shall conduct Research at Facility and such Research projects shall be led by Contractor's Personnel.

4.6.1. The Research Project Manager shall have overall responsibility for the Research project, provided that subject to specific Research requirements, Contractor policy (e.g. conflicts of interest in research), and/or as applicable, the requirements of 21 CFR § 54, the Research Project Manager may be required to delegate some of his/her responsibilities to other qualified Personnel.

4.6.2. Research Project Managers who have obtained final clearance from Contractor IRB and have been given access to Facility approved Research Orders for a Research Project may refer Research Program Subjects to Facility for clinical services or request use of Facility's diagnostic, therapeutic, and Ancillary Services and Supplies. Facility retains sole discretion to prioritize access to its clinical, diagnostic, therapeutic, and Ancillary Services and Supplies.

4.6.3. Contractor shall notify Facility's Project Manager promptly of any change in a Research Project Manager.

4.6.4. As applicable, prior to initiation of a Research project at Facility, Contractor shall create and provide Facility with access to Contractor's Medicare Coverage Analysis (MCA) to allow Facility to develop its Research Orders for the Research project. In such MCA, Contractor shall make good faith efforts to correctly apply Medicare's rules regarding coverage and payment for services provided to Medicare beneficiaries who are participating in Research projects involving clinical trials, and shall designate in the MCA which services, if any, Contractor believes are covered by Medicare. Research Project Manager and other Personnel will be required to use the Research Order or other appropriate documentation as mutually agreed to and developed by both Parties to request Research Program Services and/or Ancillary Services and Supplies from Facility during the conduct of the Research project.

4.6.5. Facility is responsible for billing Medicare and other third party payers, consistently with the Research Orders. Facility will bill Contractor and Contractor will reimburse Facility for the cost of such non-routine care Research Program Services and/or Ancillary

Services and Supplies which the patient would not have received absent their participation in a Research project. Facility shall have sole responsibility, and any and all liability, for the accuracy of coding determinations and information included on claims submitted by Facility to Medicare and other third party payers. Facility will maintain and make available upon request by Contractor accurate and appropriate documentation to support all Research related claims submitted to Contractor.

4.6.6. Informed Consent. As applicable, the Research Project Manager will obtain Research Program Subject's Informed Consent that complies with requirements set forth in 45 CFR, Part 46, Subpart A (Section 46.116); and 21 CFR, Part 50 (Sections 50.20 and 50.25) and California Health and Safety Code Section 24172.

4.7. **Other Research Program Personnel**

Contractor shall ensure that adequate numbers of qualified Personnel are assigned to each Research project.

4.8. **Compliance**

The Research Project Manager and all Personnel shall comply with Contractor policies and regulations, Facility Bylaws and Policies, as applicable, related to Research activity at Facility. In addition, to the extent that federal or State law, or both, require additional approval(s) by federal or State agencies, or by others for the conduct of certain Research, Contractor shall assist Research Project Managers in assuring that such approval(s) shall be obtained. The Parties contemplate and intend that any Research project that receives such approval may be conducted by Research Project Manager and Personnel at Facility subject to the terms contained herein. Research projects that do not comply with all applicable Contractor, Facility, federal, and State policies and regulations will be considered as unauthorized Research projects. Unauthorized Research projects are unacceptable and shall result in immediate termination of Research Project Manager's ability to perform any Research at Facility until further analysis by CMO and as applicable, DHS Research Committee. Contractor shall be subject to suspension or termination of the Research project(s) at Facility.

4.9. **Access**

County shall grant Contractor and Research project Personnel access to Facility's:

4.9.1. Premises;

4.9.2. Staff, to the extent that access to Facility's staff is authorized;

4.9.3. Patients, medical records and other information required for Facility to provide Research Program Services for, as well as for Research

Personnel to conduct, in accordance with professional standards, Research projects; and

4.9.4. Other services, equipment, supplies and resources of Facility, as such items will be provided by County in accordance with the terms set forth in this Agreement.

The scope of the access granted under this Agreement shall be subject to compliance with applicable laws, rules and regulations and limited to the extent reasonably required by Contractor to perform Research activities, as further described hereunder. County does not authorize nor permit Personnel to add, delete, copy, transfer, or otherwise take possession or store in either a paper or electronic format any Facility patient's medical record without prior approval of Facility and unless the Research Project Manager(s) and Facility have entered into a Data Use Agreement. When needed, the Parties will enter into a mutually acceptable Data Use Agreement.

4.10. **Utilization of County Personnel**

Except as included in the cost of Research Program Services or Ancillary Services or Supplies requested through Research Orders, or with written approval by CMO and/or expressly authorized under the terms of this Agreement, County employees while on County time shall not be utilized by Contractor in the performance of non-standard patient care services hereunder.

4.11. **Research Program Performance**

4.11.1. Contractor shall, and will cause the Research Project Manager to, conduct the Research project in accordance with this Exhibit, Agreement, the applicable IRB-approved protocol (as amended from time to time), all IRB requirements, all reasonable written instructions of the sponsor (if any), and all applicable laws, regulations and standards; provided, however, the Research Project Manager may deviate from the protocol and such instructions to the extent that the safety, rights and welfare of Research Program Subjects so requires.

4.11.2. Research projects will commence at Facility only when the Research project has received approvals from the CMO, DHS Research Committee, when applicable, and Contractor's IRB.

4.12. **Records and Reporting**

4.12.1. <u>Research Program Records</u>

The Research Project Manager shall create and maintain records, including case report forms for all Research Program Subjects, in the manner and for the time period required by the Research project protocol or sponsor and all State and federal laws and regulations applicable to the Research project. For the studies utilizing Facility

facilities, the Research Project Manager shall make such records available to CMO as needed for compliance monitoring to the extent that such records do not contain confidential or proprietary information.

4.12.2. Medical Records

For Research projects that involve a clinical treatment or diagnostic intervention with Research Program Subjects, the Research Project Manager shall place the following in each Research Program Subject's clinical file in a manner that complies with the applicable requirements of Facility and The Joint Commission, licensing authorities, CMS, and other State and federal laws and regulatory standards:

- A copy of the Research Program Subject's signed Informed Consent form and HIPAA authorization, if required by the IRB (unless Informed Consent form is labeled "DO NOT PLACE IN MEDICAL RECORD");
- A medical record note of enrollment in named Research project;
- A list of any medication(s) administered as part of a Research project; and
- Notes needed for communication to primary provider care to assure continued safe clinical care, which required notes would be ordered on the Research Orders.

Inclusion of this information in the file does not necessarily imply inclusion in the legal health record or designated record set, which is determined by each institution's policies. The Parties will cooperate to ensure compliance with applicable law and guidance, including but not limited to HIPAA and its implementing regulations, with regard to restriction of Research Program Subjects' access to records during a Sponsored Program and disclosure of records.

4.12.3. Reports

The Research Project Manager shall do the following:

- Report adverse events as defined by Contractor's IRB adverse reporting procedures, in accordance with Facility Bylaws and Policies, and if applicable, to Facility's electronic reporting system for clinical errors or safety risk events; and
- Provide the names and medical record numbers of Research Program Subjects at intervals consistent with Hospital Bylaws and Policies.

4.13. **Acknowledgement and Attribution of Facility's Contribution**

4.13.1. To the extent feasible, investigators whose Research projects are performed within Facility in whole or in part shall acknowledge and provide appropriate attribution to Facility in all scientific presentations and publications.

4.13.2. To the extent feasible, Contractor and Facility will jointly prepare any media press release/advisory, media notification, or social media content that announces the findings of any Research project conducted at Facility in accordance with the Research Agreement.

4.13.3. Contractor and Research Project Managers reserve the sole right to publish scientific papers in connection with its Research projects to the extent authorized by federal and State law.

4.14. **Research Closeout**

For studies utilizing Research Program Services or Ancillary Services and Supplies, Contractor shall notify CMO, or if designated, the Chief Research Officer (CRO) at the time that a Research project is closed or completed.

4.15. **Research Contract Provisions**

Contractor acknowledges that Facility shall not be bound by provisions in Research Agreements to which it is not a party, unless County as an opportunity to review such provisions and agrees to them in writing.

4.16. **Debarment and Disqualification**

Contractor shall not knowingly allow any individual who appears on the FDA Debarment List, is disqualified or restricted as a clinical investigator by the FDA, or appears on the Public Health Service Administrative Actions List to provide services related to the Research Program. Contractor further represents and warrants that Contractor personnel have not been found by the FDA or any other state or federal government agency or enforcement body to have violated any federal, state, or local laws, rules, or regulations relating to the Research Program. If Contractor becomes aware of any relevant disbarment or restriction during the term of this Agreement, or comes under investigation for conduct related to any Research project, Contractor shall promptly notify Facility.

4.17. **Suspension of Research Project by CMO**

Notwithstanding any other suspension or termination provisions herein, in the event CMO finds that any activity conducted by Contractor's Personnel at Facility endangers the health or safety of county patients, County personnel, or others, Contractor shall request such Personnel to suspend such activity immediately upon Contractor's receipt of a written notice from CMO. In addition, Contractor shall agree that CMO may close or secure the premises where the activity has been conducted until such time as the activity is reasonably determined to be safe, or when hazardous, until such time that the premises

are reasonably determined to be non-hazardous to County patients, County workers, and others.

5.0 RESPONSIBILITIES- COUNTY

5.1. Institutional Approval of Research Applications

CMO, CRO and as applicable, DHS Research Committee, will review all Research proposals that seek to use Facility facilities in accordance with Facility's policies and procedures. Research involving a clinical trial will be considered approved for initiation at Facility when it has been approved by the Facility, has received full clearance from Contractor IRB, and when it has been given access to Facility approved Research Orders. At such time of approval, CMO will identify the category of research as described in Paragraph 2 of Exhibit B-2, Attachment I.

5.2. Review by CMO and as applicable, DHS Research Committee

As applicable, three weeks prior notification should be provided to CMO, or if designated by the CMO, the CRO, by Contractor that a new Research project requiring full IRB review is being proposed for conduct at Facility. Facility will notify Contractor within ten (10) business days, if a review of a Research project will be conducted by the DHS Research Committee. Facility will notify Contractor of the outcome of the review within ten (10) business days thereafter. Approval by DHS Research Committee will be required for final clearance of studies that were identified as subject to further review by DHS Research Committee.

5.3. Debarment and Disqualification

County will ensure that its personnel do not knowingly include any individual who appears on the FDA Debarment List, is disqualified or restricted as a clinical investigator by the FDA, or appears on the Public Health Service Administrative Actions List to provide services related to the Research project.

5.4. Collaborative Research Program Practice Development

Facility may include representatives of Contractor in all planning activities and standing committees that will involve Research projects conducted by Contractor's Personnel within Facility premises.

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Exhibit B-2
Attachment I

RESEARCH PROGRAM

BILLING AND REIMBURSEMENT

1.0 PAYMENT TO FACILITY

1.1. Contractor shall pay Facility for Research costs incurred by Facility that are related to Research Program Services and/or Ancillary Services and Supplies, which a patient would not have received absent their participating in a Research project. Contractor shall reimburse Facility for the costs of such Research Program Services and/or supplies at the charge rates approved by the Governing Board. Upon execution of this Agreement, Facility shall send Contractor an electronic copy or, if both Parties agree, a hard copy of its current Governing Board approved charge rates, including any modification of such rates as may be approved by the Governing Board from time to time. The terms of this Paragraph 1- Payment to Facility shall survive termination of this Agreement with respect to contracted services rendered during the term of this Agreement.

1.2. Facility will bill Contractor within thirty (30) days after the Research Program Services and/or Ancillary Services and Supplies were provided to the Research Program Subjects in accordance with DHS' Board-approved billing rates in effect at the time that such Research Program Services and/or Ancillary Services and Supplies were provided by Facility.

1.3. Payment by Contractor to Facility hereunder shall be made within thirty (30) days after receipt of an invoice and billing statement. Contractor shall be responsible for payment to Facility for all Research Program Services and/or Ancillary Services and Supplies that the Research Program Subjects receive that are not routine care and which such subjects would not have received absent their participation in a Research Project. Such Research Program Services and/or Ancillary Services and Supplies shall be ordered on a Facility approved Research Order or other appropriate documentation as mutually agreed to and developed by both Parties.

1.4. Contractor and Facility will jointly work to ensure appropriate reimbursement occurs in compliance with this Agreement and legal requirements, including Stark and Anti-Kickback. Contractor shall be responsible for payment to Hospital for non-routine Research Program Services and/or supplies provided by Hospital which the patient would not have received absent their participation in a Research project, whether or not Contractor has received funding or corresponding payment from the sponsor.

2.0 RESEARCH PROGRAM SUBJECT BILLING

Contractor is responsible to provide Facility with the Medicare Coverage Analysis (MCA) and Facility is responsible to ensure Research Program Subject's payer

source is not billed for any tests or procedures that are identified as payable by Research project's MCA.

3.0 COMPLIANCE WITH DEFICIT REDUCTION ACT OF 2005

Each Party represents that the compensation provided under this Agreement represents the fair market value of the Research Program Services performed by Facility, has been negotiated in an arm's-length transaction, and has not been determined in any manner with regard to the value or volume of any business or referrals generated.

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EXHBIT B-3

PROGRAM SPECIFIC EXHIBIT: EDUCATION PROGRAM

1.0 DESCRIPTION OF SERVICES

1.1. Contractor organizes educational opportunities for Facility clinical personnel and the medical community at large.

1.2. Educational programming shall align with Facility's mission to improve the County's health care delivery system.

2.0 PROGRAM SPECIFIC AGREEMENT PROVISIONS

The following Agreement provisions are applicable for the Education Program:

2.1. Force Majeure

Contractor shall adhere to Agreement Sub-paragraph 8.24.1, Force Majeure.

2.2. HIPAA- Inadvertent Access

Contractor shall adhere to Agreement Sub-paragraph 8.26.1, Inadvertent Access.

3.0 RESPONSIBILITIES- CONTRACTOR

3.1. Contractor shall assign a Contractor's Program Manager for the Education Program to collaborate with Facility's Project Manager to provide educational programming.

3.2. Contractor shall submit quarterly to Facility's Project Manager a listing of educational programming that Contractor has provided in the previous quarter including the type of program, topic, and number of participants including the number of County participants.

3.3. Contractor may collect attendance fees for educational programming.

3.4. In accordance with Agreement, Sub-paragraph 5.2, Expenditures of Funds, Contractor shall not utilize any income derived from attendance fees for any purpose other than to offset Contractor's Education Program operating costs and to provide services as described herein. If any income remains after providing for these expenditures, it shall be used for the sole benefit of the Education Program.

4.0 RESPONSIBILITIES- COUNTY

Upon reasonable request by Contractor, County may provide space and staff support on a case by case basis for educational programming.

EXHIBIT B-4

PROGRAM SPECIFIC EXHIBIT:
ROBOTIC REHABILITATION PROGRAM

1.0 DESCRIPTION OF SERVICES

A joint effort between County and Contractor for use of medical robots in the Tyler A. Dykes Robotics Center (Robotics Center) to provide patient treatment and health maintenance opportunities to current and former patients as well as members of the community.

2.0 PROGRAM SPECIFIC AGREEMENT PROVISIONS

The following Agreement provisions are applicable for the robotic rehabilitation program:

2.1. Force Majeure

Contractor shall adhere to Agreement Sub-paragraph 8.24.1, Force Majeure.

2.2. HIPAA- Inadvertent Access

Contractor shall adhere to Agreement Sub-paragraph 8.26.3, Inadvertent Access.

3.0 RESPONSIBILITIES- CONTRACTOR

3.1. Contractor shall administer the low cost community-based robotics program to enhance health and maintain or advance function in persons at high risk for inactivity related secondary conditions due to mobility impairments.

3.2. Contractor shall provide all the necessary personnel to provide community-based robotics services including robotics technicians, administrative, accounting, bookkeeping and managerial services at no cost to the County.

3.3. **Fees**

3.3.1. Contractor shall establish fees for the community-based robotics services. Such fees shall be at a level that aligns with the intent of providing access to individuals in the community who traditionally do not have the economic means to purchase comparable services from a for-profit entity.

3.3.2. In accordance with Agreement Sub-paragraph 5.2- Expenditure of Funds, Contractor shall not utilize any income derived from the fees collected for any purpose other than to offset Contractor's community-based robotics operating costs and to provide services as described herein. If any income remains after providing for these expenditures, it shall be used for the sole benefit of the Robotics Center.

3.4. **Service Requirements**

3.4.1. Contractor shall only provide services to participants who have received an assessment and individualized health maintenance program from a County physical therapist or occupational therapist, as described in Paragraph 3 below. If individuals have not received the County assessment, Contractor shall refer such individuals to the Facility's Project Manager or designee.

3.4.2. Contractor shall ensure that all participants sign a waiver, approved by County, as a condition to use the Robotics Center facility and services. County may from time to time require revisions to such waiver.

3.4.3. Contractor shall coordinate with Facility's Project Manager or designee, to schedule participants for services when the Robotics Center is not in use by Facility inpatients.

3.4.4. Contractor shall ensure that all robotics technicians providing services hereunder have been trained and evaluated by a County physical therapist or occupational therapist and have written documentation from County indicating such technician's competency to implement the health maintenance programs designed for the community-based robotics program participants. Such competency shall be evaluated on no less than an annual basis.

3.5. Contractor shall be responsible for maintenance of Contractor-owned robotics equipment. Maintenance of such equipment shall be in accordance with manufacturer guidelines, including servicing by certified technicians, if applicable.

4.0 RESPONSIBILITIES- COUNTY

4.1. County will administer the inpatient robotics program and maintain oversight of the community-based robotics program.

4.2. A licensed County physical or occupational therapist trained by the robotic equipment manufacturer will provide training to Contractor's robotics technicians on how to operate the robotics equipment and how to assist participants on such equipment. County shall evaluate the competency of such technicians on no less than an annual basis.

4.3. Upon either direct inquiry or referral from the Contractor, a licensed County physical or occupational therapist will provide an assessment to potential participants of the community-based robotics program. If County determines that it is safe and such individual can benefit from participation in the program, County will refer the participant to the Contractor and provide an individualized health maintenance program for Contractor's robotics technicians to implement.

4.4. County will provide Contractor with the non-exclusive use of the Robotics Center, including any County-owned equipment.

4.5. County will provide maintenance for all County-owned equipment in accordance with the manufacturer guidelines, including servicing by certified technicians, if applicable.

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EXHBIT B-5

PROGRAM SPECIFIC EXHIBIT: ORTHOTIC SERVICES PROGRAM

1.0 DESCRIPTION OF SERVICES

1.1. Contractor shall provide orthotic services to Facility patients, and provide orthotic consultant services, inclusive of; highly specialized expertise in evaluation, fabrication and modification of orthotic devices at Facility.

1.2. Contractor shall be compensated for orthotic services in accordance with Attachment I to this Exhibit B-5.

2.0 PROGRAM SPECIFIC AGREEMENT PROVISIONS

The following Agreement provisions are applicable for the Orthotic Services Program:

2.1 Contractor's Performance During Civil Unrest or Disaster

Contractor shall adhere to Agreement Sub-paragraph 8.24.2, Contractor Performance During Civil Unrest or Disaster.

2.2 HIPAA- Business Associate

Contractor shall adhere to Agreement Sub-paragraph 8.26.2, Business Associate.

2.3 Additional Insurance Coverage Requirements

The following insurance coverage is required in addition to the required coverages described in Agreement Sub-paragraph 8.30, Insurance Coverage.

Professional Liability/Errors and Omissions

Insurance covering the Contractor's liability arising from or related to this Agreement, with limits of not less than $1 million per claim and $3 million aggregate. Further, the Contractor understands and agrees it shall maintain such coverage for a period of not less than three (3) years following this Agreement's expiration, termination or cancellation.

3.0 SPECIFIC WORK REQUIREMENTS

3.1 Orthotic services shall be performed by Contractor in accordance with the following practices and procedures:

3.1.1. Measurement and Fitting: Measurement for an orthosis shall be made on the Facility premises, as identified by the Facility attending physician or therapists(s) working under the supervision of such attending physician.

3.1.2. Patient Visits: Contractor shall be required to provide adequate representation by a certified or Board eligible orthotist at all scheduled patient visits (on the Facility premises) for consultation, fittings, measurements, or for training of the patient in the use of the orthosis.

3.1.3 Delivery: Time of delivery is essential and must be strictly observed. The delivery date and time are to be agreed upon by the orthotist and Facility attending physician or designated therapist, issuing the order for the orthosis. If Contractor is unable to complete an order because Contractor cannot contact the patient to arrange measurement and fitting, Contractor shall notify in writing Facility Project Manager so that they may assist either in locating the patient or in arranging for cancellation of the order.

3.1.4. Orders: Each referral order of instruction for an orthosis shall be issued and signed by Facility attending physician or designated therapist.

3.2 Special Projects Committee

3.2.1 County Project Manager or designee may refer to Contractor and the Special Projects Committee for any analysis and resolution of orthotic services related problems, with respect to needs experience by patients within a specific disease entity or problems encountered due to limitations imposed by current orthotic technology. Such referrals shall be presented to the Special project Committee and shall specify in detail the precise nature of the problem(s). the Special Projects Committee shall approve the projects in writing before its commencement. The County Project Manager may discontinue a project at any time providing notice to the Special Project Committee. The Special Projects Committee may discontinue projects which are deemed to be unproductive.

3.2.2 The Special Project Committee shall be comprised of a representative of Facility administration, Contractor's Chief Orthotists, Contractor's Executive Director, representatives of Facility Occupational Therapy and Physical Therapy Department and a Rehabilitation Physician with a patient population that will benefit from the special projects. The Special Project Committee shall meet on a quarterly bases or more if necessary. The meeting will include a progress update of all special projects. Minutes of these meetings will be kept by Contractor and shall be made available to Facility upon request.

3.2.3 Contractor shall provide a quarterly report to the Special Committee. The information provided on the reports shall, at a minimum, include:

the name of each project, names of orthotists working on each project, and estimated date of project completion.

4.0 RESPONSIBILITIES - CONTRACTOR

4.1 The Contractor shall have available and shall provide upon request to authorized representatives of Facility's Project Director, a list of persons by name, title, professional degree, and experience providing services hereunder.

4.2 In-Kind Services

In-kind services shall be provided by the Contractor in exchange for the use of the County-provided space to perform orthotic services. For the purpose of this Sub-paragraph, in-kind services shall mean those services that County determines County would have purchased or rented for the Facility if the Contractor had not made these items available to the Facility. Contractor's orthotists shall provide three hundred twenty-six (326) hours per month or equivalent value, as applicable, toward the following activities:

4.2.1 Attend Clinics

Orthotic staff will be available to attend Facility's major clinics on a weekly basis. At least one orthotist shall be present at the Neuro-Medicine, Foot and Shoe, Ortho Rehab, Ortho-Diabetic Service Evaluation, Muscle Disease, Arthritis, Workers' Compensation, Post-Polio, and Amputee clinics. Services provided in the clinics include but shall not limited to:

- Consults with physicians and other rehabilitation team members.
- Development of treatment plans.
- Measurement and casts.

4.2.2 Consult with physicians and/or rehabilitation therapists on inpatients at the bedside or in therapy rooms.

4.2.3 Perform fittings as needed for inpatients.

4.2.4 Provide repairs and/or adjustments to unscheduled patients as needed.

4.2.5 Repair or replacement of trial orthoses used for patient evaluations, gait training, activities of daily living (ADL) training and as requested by Facility Project Manager.

4.2.6 Sewing of canvas waist belts (includes attaching buckles and fasteners as requested by Facility Project Manager).

4.2.7 Consults with physicians and patients in gait analysis sessions.

4.2.8 Quarterly lectures to orthopedic resident physicians.

4.2.9 Realignment and tightening of halo braces on mannequins as needed by Nursing Education Department.

4.2.10 Provide orthotic repair toolkits for use by Facility therapists.

4.3 Orthosis and Warranty

An orthosis is to conform to the prescription of Facility's attending physician and under no circumstance is the prescription to be altered by Contractor.

4.3.1 The attending physician or designated therapist working under the supervision of such physician shall have the right to reject on behalf of County any orthosis which is faulty in alignment or fit. The attending physician or designated therapist shall also approve on County's behalf any orthosis ordered hereunder. No orthosis will be accepted for an outpatient receiving the orthosis at a clinic appointment or an inpatient until such orthosis has been inspected by the attending physician or designated therapist. Facility shall have up to three months to reject any orthosis that is faulty in alignment or fit on behalf of outpatients who accepted the delivery of an orthosis outside of a Facility clinic. Before final rejection is made, reasonable opportunity will be given to Contractor to make any required correction of faults and adjustments.

4.3.2 Each orthosis is guaranteed by Contractor from defective workmanship or materials, or both, for a period of one year of acceptance by (County or Patient). If within the guarantee period an article furnished under this Agreement is found to be unsatisfactory due to defective workmanship or materials, the same will be corrected, adjusted, or replaced if necessary by Contractor upon being returned to Contractor. Any such corrections, adjustments, or replacement is to be made at no charge and returned within seven (7) days unless other delivery arrangements have been made with the attending physician or designated therapist who ordered the correction, adjustment, or replacement.

4.3.3 If a correction, adjustment or replacement cannot be made which meets the need of the patient, as determined by the County's attending physician or designated therapist, and if payment for the original order has been received, Contractor agrees that it will immediately refund the entire purchase price forthwith by cash payment or, at the discretion of the County Project Director, such purchase price may serve as a credit on future billings. This paragraph does not apply, however, to adjustment incidental to wearing of an orthosis, adjustments required by physical or pathological changes of the wearer, in cases where there is evidence of deliberate misuse, or in cases where there is evidence that the orthosis has been altered by anyone other than the Contractor.

5.0 RESPONSIBILITIES – COUNTY

5.1 County will provide the space designed in Paragraph 6.0, Program Specific Space Use, of this Exhibit B-5.

5.2 Notwithstanding the provisions of Agreement, Sub-paragraph 8.19, Damage to County Facilities, Buildings or Grounds, County will provide all routine structural maintenance and repair for the Orthotic Services locations to be provided to the Contractor.

5.3 Facility Project Manager shall verify that the in-kind services claimed by the Contractor as payment to the County for the use of Facility space have been satisfactorily provided to the Facility. In the event the Facility Project Manager determines that in-kind services claimed by the Contractor have not been satisfactorily provided to the Facility, Facility will invoice Contractor for the dollar value of such in-kind services at the orthotist/ orthotic fitter/administrative staff blended salary rate of $64.53 per hour.

6.0 PROGRAM SPECIFIC SPACE USE

6.1 Total Value of Space

Total Sq. Ft. Occupied	8,947 Sq. Ft.
Annual Value of Space	$252,305.40
Monthly Value of Space	$21,025.45

6.2 Allocation of Space and Associated Value

USE	LOCATION	SQ. FT.	FMV* Per SQ. FT.	Total FMV Monthly	Total FMV Annual
Orthotic Services		8,947	$2.35	$21,025.45	$252,305.40

*Orthotic Services Fair Market Value (FMV) is Full Service Gross and includes operating expenses including utilities, cleaning, property tax, hazard insurance, routine repair and maintenance etc.

ORTHOTIC SERVICES
BILLING AND PAYMENT

The Contractor shall bill the County for orthoses delivered by the Contractor and received by County-responsible patients subject to and in accordance with the provisions set forth in Exhibit B-5 and this attachment.

1.0 CONTRACTOR BILLING:

1.1 Contractor shall bill Medi-Cal and Medicare for eligible patients as shown in the Billing and Payment Chart (Chart) below at the Medi-Cal Maximum Reimbursement Rates. For services not covered by Medi-Cal, Contractor shall bill in accordance with the Contractor's Catalog.

1.2 Contractor shall bill private/commercial insurance as reflected in the Chart.

1.3 Contractor is responsible for collecting any monies owed by the patient, e.g., share of share of cost, deductible and co-insurance amounts, as reflected in the Chart.

1.4 Contractor shall bill Department of Health Services (DHS) for Orthotic services rendered to Medicare eligible inpatients, Medi-Cal inpatients, DHS assigned Medi-Cal HMO inpatients (HealthNet, etc.), County responsible indigent persons as determined by Director and patients whose Medi-Cal eligibility is pending with no other resources, Self-Pay inpatients, etc., as further defined in the Chart below.

Except as provided hereinbelow, patients receiving Contractor services who have the ability to pay, or have third-party payor coverage or other sources available, including secondary or tertiary coverage etc., shall not be billed to County. Contractor shall bill and obtain payment for its services directly from such patients, payor(s), or other sources. For the purposes of this provision, a patient falling within one or more of the following patient categories at the time of the orthosis delivery and acceptance thereof, shall be ineligible for County reimbursement, except as provided in Sub-paragraphs 2.6.a and 2.6.b, Nonpayment and Partial Payment by Third-Party Payors. Contractor is responsible for verifying the insurance status of patients prior to delivery of orthoses.

1.5 The Contractor shall prepare invoices within six (6) months of the date of orthosis delivery and acceptance of such orthosis, which shall include the charges owed to the Contractor by the County under the terms of this Agreement.

1.6 All billings must be accompanied by a copy of the initial prescription or order which includes: date and location ordered; patient's complete name and Medical Record Number ("MRN"); the prescriber's printed name, title, license number, and signature; and delivery certificate with patient's signature. Any discrepancy in the requested orthotic versus the accepted orthotic, delivery date, or authenticity of the required DHS staff signatures will delay payments or cause non-payment of same.

1.7 DHS shall be refunded by Contractor within thirty (30) days after the end of the month in which Contractor receives any overpayments. Contractor may credit DHS in its monthly billings.

1.8 Contractor shall retain any Medi-Cal payments for outpatients as full and complete payment for services, and all monies received from DHS for such services shall be returned to DHS.

2.0 DHS PAYMENT:

2.1 All payments made by DHS are subject to the acceptance of the individual orthoses. Payments will not be made for any orthoses deemed unacceptable, payment will be made when Contractor reworks and/or replaces such orthoses to DHS satisfaction.

2.2 DHS shall not pay Contractor a separate charge for adjustment, fitting, measuring, and delivery of orthoses, or for training of patients in the use of such orthoses.

2.3 County Project Manager and/or Hospital Administrator may deduct any amount paid to Contractor during the time Contractor is attempting to rework or replace any unacceptable orthoses. Upon acceptance of any orthoses for which a deduction was made or refund received, DHS agrees to review orthoses for acceptance within thirty (30) days from date of delivery and provide payment no later than thirty (30) days thereafter.

2.4 Prior to payment, all invoices submitted by Contractor must have the written approval of the County's Project Manager, or authorized designee.

2.5 Contractor shall note on its invoice any duplicate orthoses and the reason a duplicate orthoses was provided to the same patient within the ninety (90) day period.

2.6 Nonpayment by Third-party Payor:

a. County shall pay Contractor for orthotic services rendered to non-County responsible patients in the third-party payor categories of Medi-Cal, Medi-Cal PHP, Medicare, and CCS after the Contractor has made an unsuccessful full administrative appeal of the nonpayment, provided that full documentation of said appeal on behalf of the patient is provided with the Contractor's invoice submitted to County.

b. County shall not be liable to the Contractor for any nonpayment if such nonpayment was the result of the Contractor's failure to file an appropriate claim or documentation in a timely manner with the third-party payor. Further, no County payment shall be made to Contractor if the third-party payor's reasons for failing to pay the Contractor are based on the payor's finding that the patient has sufficient financial resources to pay or partially pay for the services.

C. BILLING AND PAYMENT CHART

PAYOR TYPE	OUTPATIENT	INPATIENT
Medi-Cal	Contractor obtains Medi-Cal authorization [Treatment Authorization Request (TAR)] and bills Medi-Cal using its own provider number utilizing DHS' supporting documentation including financial and diagnostic.	Contractor bills DHS. Facility will bill Medi-Cal via its all-inclusive billing methodology.
Medi-Cal with Share of Cost (SOC)	Contractor obtains Medi-Cal TAR and bills Medi-Cal using its own provider number. Contractor collects or makes payment arrangements of SOC directly from the patient.	Contractor bills DHS. Facility will bill Medi-Cal via its all-inclusive billing methodology.

PAYOR TYPE	OUTPATIENT	INPATIENT
Medi-Cal pending	Contractor bills DHS for services rendered to patients pending Medi-Cal clearance with no other resources to pay. Upon Medi-Cal approval, Contractor obtains Medi-Cal TAR and bills Medi-Cal using its own provider number. If applicable, Contractor collects or makes payment arrangements of SOC directly from the patient. If DHS has previously paid Contractor while patient was pending Medi-Cal, then DHS will credit the next Contractor's invoice for the amounts previously paid by DHS upon notification that the patient's pending Medi-Cal application has been approved.	Contractor bills DHS for services rendered to Patients pending Medi-Cal clearance with no other resources to pay. NOTE: Facility will bill Medi-Cal via its all-inclusive billing methodology upon Medi-Cal approval.
Medicare Part A (Inpatient)	N/A	Contractor bills DHS. (Facility's all-inclusive bill to Medicare includes Orthotics prescribed/ordered while an inpatient).
Medicare Part B (Outpatient)	Contractor bills Medicare using its own provider number and collects any deductible/co-insurance amounts from the patient based upon the Medicare approved charges.	N/A
Medicare/Medi-Cal (Inpatient)	N/A	Contractor bills DHS.
Medicare/Medi-Cal (Outpatient)	Contractor bills Medicare (using its own provider number) and bills the patients' Medicare co-insurance and deductible amounts to Medi-Cal (using its own provider number).	N/A
DHS assigned Medi-Cal HMO (HealthNet, LA CARE, IHSS)	Contractor seeks necessary prior authorization and bills assigned insurance carrier.	Contractor seeks necessary prior authorization and bills assigned insurance carrier.
Reduced Cost Programs (AKA: Indigent care patient, i.e., Ability-to-Pay, My Health Los Angeles, Pre-Payment)	Contractor bills DHS. If applicable, Contractor collects or makes payment arrangements of SOC directly from the patient.	Contractor bills DHS.

PAYOR TYPE	OUTPATIENT	INPATIENT
Self-Pay/Prepayment (no other third party coverage)	Contractor bills Self-Pay patient using the Contractor's standard collection policy. **EXCEPTION**: Contractor bills DHS for devices that are medically required to be provided before the patient leaves the Hospital.	Contractor bills DHS for devices provided during the patient's hospitalization.
Commercial Insurance	Contractor seeks prior authorization and bills 3rd party insurance carrier.	Contractor bills DHS for devices provided during the patient's hospitalization.
Other County Department (i.e. Sheriff, Probation, etc.)	Contractor to bill DHS only if patient is referred to Contractor by a DHS Facility.	Contractor to bill DHS only if patient is referred to Contractor by a DHS Facility.

If claims are denied by Medi-Cal or Medicare (other than for non-benefit of program(s), then Contractor shall make every attempt to resubmit and/or appeal the claim. DHS staff will provide any additional supporting documentation, so that Contractor can re-bill Medi-Cal or Medicare.

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EXHIBIT B-6

PROGRAM SPECIFIC EXHIBIT:
PATIENT TRANSPORTATION SERVICES PROGRAM

1.0 SCOPE

1.1. The Contractor shall provide free patient transportation services in accordance with its Paratransit Services Agreement No. T1009 with the County on behalf of its Department of Public Works (DPW) and any successor agreements.

1.2. Continuation of this Patient Transportation Services Program will be contingent on the Contractor's continued ability to receive funds through its DPW agreement or other similar funding mechanism. If the Contractor is no longer able to secure such funds, Contractor shall not be obligated to continue the Patient Transportation Services Program.

2.0 RESPONSIBILITIES- CONTRACTOR

2.1. The Contractor shall assign a Contractor's Program Manager for the Patient Transportation Services Program to act as the primary point of contact for the program.

2.2. The Contractor shall coordinate with Facility Project Manager to obtain fuel and maintenance for its transportation vehicles used under this program.

3.0 RESPONSIBILITIES- COUNTY

3.1. The County will provide fuel and maintenance to support the Patient Transportation Services Program.

3.2. Facility will follow established County policies and guidelines to provide such fuel and maintenance.

3.3. The County reserves the right to discontinue its provision of fuel and maintenance for the Patient Transportation Services Program. The County shall provide the Contractor with thirty (30) days' prior written notice of its intent to exercise its right to discontinue this support.

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COUNTY'S ADMINISTRATION

AGREEMENT NO. H-707147

FACILITY'S PROJECT DIRECTOR:

Name: Jorge Orozco

Title: Chief Executive Officer

Address: 7601 E. Imperial Highway, HB 105
Downey, CA 90242

Telephone: 562-385-7022 Facsimile: 562-803-0056

E-Mail Address: jorozco@dhs.lacounty.gov

WELLNESS CENTER OPERATIONS PROGRAM

FACILITY'S PROJECT MANAGER:

Name: Sonia Kiseljak-Dusenbury, PT, DPT, MBA

Title: Director of Health and Wellness Services

Address: 7601 E. Imperial Highway, HB 105
Downey, CA 90242

Telephone: 562-385-6611 Facsimile: 562-385-6190

E-Mail Address: skiseljak-dusenbury@dhs.lacounty.gov

FACILITY'S PROJECT MONITOR:

Name: Same as Project Manager

Title: _____

Address: _____

_____

Telephone: _____ Facsimile: _____

E-Mail Address: _____

RESEARCH PROGRAM

FACILITY'S PROJECT MANAGER:

Name: _____

Title: _____

Address: _____

_____

Telephone: _____ Facsimile:_____

E-Mail Address: _____

FACILITY'S PROJECT MONITOR:

Name: _____

Title: _____

Address: _____

_____

Telephone: _____ Facsimile:_____

E-Mail Address: _____

EDUCATION PROGRAM

FACILITY'S PROJECT MANAGER:

Name: _____

Title: _____

Address: _____

_____

Telephone: _____ Facsimile:_____

E-Mail Address: _____

FACILITY'S PROJECT MONITOR:

Name: _____

Title: _____

Address: _____

_____

Telephone: _____ Facsimile:_____

E-Mail Address: _____

ROBOTIC REHABILITATION PROGRAM

FACILITY'S PROJECT MANAGER:

Name: _____

Title: _____

Address: _____

_____

Telephone: _____ Facsimile:_____

E-Mail Address: _____

FACILITY'S PROJECT MONITOR:

Name: _____

Title: _____

Address: _____

_____

Telephone: _____ Facsimile:_____

E-Mail Address: _____

ORTHOTICS SERVICES PROGRAM

FACILITY'S PROJECT MANAGER:

Name: _____

Title: _____

Address: _____

_____

Telephone: _____ Facsimile:_____

E-Mail Address: _____

FACILITY'S PROJECT MONITOR:

Name: _____

Title: _____

Address: _____

_____

Telephone: _____ Facsimile:_____

E-Mail Address: _____